ABHI

ABHI Patient Safety System Foundations: A Call for Action

FOREWORDS

Professor Henrietta Hughes OBE,
Patient Safety Commissioner for England

Safe, effective and compassionate healthcare is what patients should expect and receive. Yet too often, we still see avoidable harm and missed opportunities to learn and improve. The Patient Safety Principles set out how, by making decisions which involve the patient's perspective, we can get better outcomes. The HealthTech industry can lead in this area by creating a culture of safety in healthcare for all patients.

This paper from the ABHI Patient Safety Group sets out a blueprint for exactly how this can happen, aligned to the three shifts in the 10 Year Health Plan. It describes how collaboration between manufacturers, clinicians and patients hardwires safety into every stage of design, regulation, and delivery. It reflects the huge difference that listening to patients and families makes, so their voices shape safer systems and more equitable outcomes. It also shows how vital it is to create psychological safety for staff to speak up.

By adopting the principles of Safety Management Systems, using data and information and committing to transparency and accountability, we can move from reacting to incidents to designing for safety. I welcome this call to action and commend ABHI's leadership in uniting industry around a shared goal: reducing avoidable harm and creating a healthcare system that is grounded in the needs of patients and safer by design.

David Lawson
Director of Medical Technology & Innovation, Department of Health and Social Care

Delivering safer care is the foundation on which quality, efficiency, and trust are built. Across the NHS, we have made significant progress through the National Patient Safety Strategy and the establishment of Safety Management Systems. But achieving lasting improvement depends on partnership, particularly with industry.

The HealthTech sector provides the tools, data, and innovation that enable staff to work safely and patients to receive the best outcomes. This report from the ABHI Patient Safety Group demonstrates how industry can embed safety science within its own organisations, while working alongside the NHS to share learning, strengthen culture, and measure improvement.

I am encouraged to see alignment with England's 10 Year Health Plan and the emphasis on just culture, professionalisation, and patient engagement. By working together, grounded in safety as a core value, we can reduce harm, protect staff, and deliver safer, more sustainable care for all.

EXECUTIVE SUMMARY

This white paper has been produced by the Association of British HealthTech Industries (ABHI) Patient Safety Group. The group works to establish the HealthTech industry as a trusted partner for leading improvements in patient safety and healthcare worker safety. Working closely across the healthcare community, the group aims to ensure that innovation and technology, which improve the individual experience of care, are identified and accessible.

Patient safety should be at the core of our approach to health and care. The ABHI Patient Safety Group believes that industry can, and must, play a key role in ensuring this. To support, we have worked with the charity Patient Safety Learning to develop this white paper.

The paper sets out the scale of avoidable unintended harm in health care and detail how the stubborn persistence of this coincides with a time when the health system faces a perfect storm of challenges. We also share a selection of case studies to illustrate how the HealthTech industry currently helps to improve both patient safety and healthcare worker safety.

Subsequently, utilising Patient Safety Learning's framework for 'What Good Looks Like' in patient safety, we consider what we believe this might mean from the perspective of six different healthcare stakeholder groups:

- Patients
- Healthcare providers
- Integrated Care Boards
- System leaders
- Industry
- Regulators

However, the focus of this white paper is to set a call for action by ABHI members, and the wider HealthTech industry, to work with the healthcare community to ensure that patient safety and healthcare worker safety remains front and centre.

Recommendations For a Call To Action

Our approach to Equity, Diversity, and Inclusion is a key part of ABHI's culture. We are committed to ensuring that every voice, regardless of background or identity, is actively sought out, heard and respected.

We will strive, constantly, to create an industry where everybody feels able to bring their whole self to work.

We will promote understanding and awareness of how important it is to embrace inclusivity of all in our industry and the patients we serve. Including fully diverse perspectives drives creativity, innovation and our ability to transform healthcare.

We will steadfastly challenge behaviours, wherever they occur, that detract from the integrity of our sector.

Professionalising Patient Safety

Use human factors:
Integrate ergonomics expertise.

Adopt standards:
Build safety into a company culture.

Patient & Family Engagement

Listen actively:
Engage patients & families directly.

Educate better:
Provide clear, inclusive resources.

Data

Share expertise:
Help interpret safety data.

Be transparent:
Share both positive and negative outcomes.

Delivering Safer Care, Including Healthcare Worker Safety

Support staff safety:
Link worker wellbeing to patient safety.

Track performance:
Partner on post-market device follow-up.

Research & Innovation

Expand insights:
Use feedback to inform wider system needs.

Support value-based care:
Partner for safer, more efficient services.

Equity & Sustainability

Promote equity:
Support fair access and inclusive design.

Champion diversity:
Reflect it in studies and standards.

Share resources:
Help smaller firms on equity and sustainability.

The recently published 10 Year Health Plan for England identifies many of the key underlying causes of avoidable harm. Its ambitions for the future of the health service present an opportunity for a generational shift that ensures tackling avoidable harm and improving patient safety is fundamental across all health settings.

If this is to be achieved, ABHI members, and the wider HealthTech industry, must be ready to match and engage in this challenge. We believe that the actions set out in this white paper present an important framework for how we can begin to take practical steps to realise this ambition.

INTRODUCTION

Patient harm as a result of unsafe care is a major global health challenge.

The World Health Organization (WHO) estimates that 1 in every 10 patients is harmed while receiving hospital care, and 50% of that harm is preventable.

In 2019, NHS England stated in its Patient Safety Strategy that there were around **11,000** avoidable deaths annually due to safety concerns.

The persistence of this level of harm is not acceptable.

This white paper has been produced by the ABHI Patient Safety Group. We believe that tackling avoidable harm and improving patient safety should be fundamental to care and treatment across all health settings. We need everyone, politicians, policymakers, patients, communities, clinicians, industry, managers, system and professional regulators, and health system leaders involved in this effort. We know that industry can play a key role in supporting this, and in doing so help to secure the 10 Year Health Plan for England's aim of building a health service fit for the future.

ABHI supports the HealthTech community to provide products and services that help people live healthier lives. As the voice of the industry, we show the value of health technology and overcome barriers to people benefitting from it now and in the future. Members include leading multinationals through to small and medium sized enterprises. We represent the HealthTech industry to key stakeholders, such as governments, health systems and regulators.

Investment in safety enhancing technologies, and ensuring these are effectively adopted and implemented, will be key to achieving this. This should be coupled with a renewed focus on the symbiotic relationship between patient safety and healthcare worker safety. Combined, we believe these can help us achieve safety improvements that:

- Reduce avoidable harm and the number of lives being lost to the biggest diseases.
- Improve the effectiveness and efficiency of the health system, freeing up resources to be reinvested in frontline care and treatment.
- Help to create a sustainable NHS for the long term.

To drive forward this change, in our view this requires support from a systems and standards-based approach to patient safety. To this end, in developing our thinking in this white paper, we have been working with Patient Safety Learning and their framework for assessing 'What Good Looks Like' in patient safety.[1]

In this white paper we set out our ambitions for how the HealthTech industry can work with the wider healthcare community to ensure that patient safety and healthcare worker safety is at the heart of everything that we do.

AVOIDABLE HARM IN HEALTHCARE

Patient safety, simply put, is concerned with avoiding unintended harm to people during their care and treatment. The WHO Global Patient Safety Action Plan defines this as:

"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 errors less likely and reduce the impact of harm when it does occur."[2]

Patient safety, as a discipline, has emerged as modern health has become increasingly complex, resulting in many different ways in which unintended harm can occur during care and treatment. The scale of this harm is a serious global health challenge. The WHO estimates that 1 in every 10 patients is harmed while receiving hospital care, and 50% of that harm is preventable.[3] Avoidable patient harm is also accompanied by a huge financial footprint.

The Cost of Unsafe Care in Healthcare

As a result of the increasingly complexity of healthcare there are a range of different causes and types of issues that can result in avoidable harm, including:

- Diagnostic errors.
- Medication errors.
- Healthcare associated infections.
- Surgical incidents (e.g. wrong site surgery, retained foreign objects, surgical fires etc).
- Communication and information errors (can occur both between healthcare professionals, and between patients and healthcare professionals).
- Staff workload and workforce related issues.

Common to all of the above is the behaviour of people working within the health system and the need to understand all the factors that influence this behaviour.

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.**

Excluding safety lapses that may not be preventable, this figure is **8.7% of health expenditure.**

NHS Resolution estimates 'annual cost of harm' for incidents in 2024/25 for the main clinical scheme, Clinical Negligence Scheme for Trusts, was **£4.6 billion.**

CURRENT STATE OF THE HEALTH SERVICE

The stubborn persistence of avoidable harm coincides with a time when the health system faces a perfect storm of challenges. The scale of the current challenge faced by the health service was starkly illustrated by Lord Darzi's review of its overall performance in September 2024.

This stated that:

"… the NHS is in critical condition. It continues to struggle with the aftershocks of the pandemic. Its managerial capacity and capability have been degraded by disastrous management reforms, and the trust and goodwill of many frontline staff has been lost. The service has been chronically weakened by a lack of capital investment which has lagged other similar countries by tens of billions of pounds. All of this has occurred while the demands placed upon the health service have grown as the nation's health has deteriorated."[4]

Responding to the findings of Lord Darzi's review, this year the UK Government has published a new 10 Year Health Plan for England.[5] This reimagines the NHS through three radical shifts:

- **Hospital to community** - initiating a historic expansion of provision in people's neighbourhoods. By bringing more integrated services into local communities, patients will have more power to tailor care to their individual needs and more convenient access.
- **Analogue to digital** - transforming the NHS from being a bricks and mortar service to a digitally led one, where patients can access care online and offline 24 hours a day, 365 days a year.
- **Sickness to prevention** - with a goal to halve the gap in healthy life expectancy between the richest and poorest regions, while increasing it for everyone, and to raise the healthiest generation of children ever.

The creation of this new plan provides an opportunity for a generational shift in our approach to health and care. The ABHI Patient Safety Group believes tackling avoidable harm and improving patient safety will be key to achieving this. In this white paper we seek to explore this in further detail, highlighting the areas that ABHI, and the HealthTech industry more broadly, can help to deliver this.

HEALTHTECH AND PATIENT SAFETY

HealthTech supplies a wide range of products and services that save and enhance lives. ABHI members, including both multinationals and small and medium sized enterprises, supply products from syringes and wound dressings to surgical robots, diagnostics and digitally enhanced technologies. These products, used correctly, can significantly improve people's health and the safety of their care. All technologies have risks and the appetite of ABHI members is to know and mitigate any patient safety and staff safety risks.

The following examples are a selection of four case studies which illustrate how the HealthTech industry is currently working as a key partner to improve both patient safety, tackling the persistence of avoidable harm. These are the foundations we are seeking to build when discussing later in this white paper how we can expand our work with key stakeholders in this respect.

ICNET

Healthcare associated infections are a key cause of avoidable patient harm. 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, urinary tract infections and surgical site infections.

ICNET is a clinical surveillance system designed to support infection prevention and control (IPC) teams by providing data, actionable insights, and streamlined workflows. It helps to utilise data analytics to identify trends and patterns in infection control; by analysing multiple data sets, it can pinpoint areas of concern, such as high rates of infection or specific risk factors associated with patient harm, enabling healthcare organisations to make informed decisions and implement targeted interventions.

The software is in use in more than 40 per cent of NHS Trusts and health boards in the UK and more than 1,200 facilities globally.

It has helped to deliver patient safety benefits including:

- 79% reduction in healthcare-associated Surgical Site infections rates (Royal Wolverhampton NHS Trust).
- 41% reduction in time spent on common daily Infection Prevention Control tasks (Chesterfield Royal Hospital).
- 90% reduction in time taken to identify patients on Anti-Microbial Stewardship (AMS) rounds.[6]
- 43% reduction in use of broad-spectrum antibiotics.[7]

This approach enables a significant improvement in patient safety using a data and evidenced based approach. This systemic approach secures safer and more effective care for patients and releases resources for staff to deploy on other priority activities.

PLASMA+

Benign prostate enlargement (BPE) is the medical term to describe an enlarged prostate, a condition that can affect how you urinate. It affects around half of men aged 60–70 and up to 90% of men over 80 in the UK. Non-muscle invasive Bladder Cancer (NMIBC) is an early-stage bladder cancer where tumours are confined to the bladder's inner wall, requiring careful treatment to stop the disease from progressing.

PLASMA+ is an electrical system that utilises bipolar energy that can be used to treat both BPE and NMIBC. It can be used in procedures such as Transurethral Resection of the Prostate and Transurethral Resection of Bladder Tumours.

This technology offers several significant safety advantages over traditional monopolar methods:

- Unlike in monopolar electrosurgery, PLASMA+ does not require a patient return electrode (PRE), as both the active and return electrodes are located within the surgical instrument. This provides a significant patient safety benefit by eliminating the risk of burns at the electrode site, for example if the PRE is not applied with full skin contact or if the PRE circuit is interrupted.
- PLASMA+ uses saline rather than glycine as an irrigation fluid. During transurethral resection (TUR) procedures there is a rare but serious risk that glycine absorbed in significant amounts can result in a complication known as TUR syndrome. By the use of saline, this risk is removed, greatly reducing the risk of TUR syndrome.

For BPE specifically, PLASMA+ is also a National Institute for Health and Care Excellence (NICE) recommended technology. It also has the benefits for treating BPE including a reduced need for blood transfusions and shorter hospital stays. For NMIBC, evidence suggests that bipolar technology reduces muscle spasms (obturator reflex) during surgery, which may lower the risk of accidental bladder injuries[8]

Olympus, working with Cheltenham General Hospital (part of the Gloucestershire Hospitals NHS Foundation Trust) and NHS Supply Chain, ran a pilot to show how PLASMA+ as a part of a day-case pathway affects day-case rates, readmissions, and hospital stays.[9] Between November 2021 and October 2022, the urology unit at Cheltenham General Hospital performed 313 procedures to treat enlarged prostates and 320 procedures to treat NMIBC, all using PLASMA+. Following its implementation, Cheltenham General Hospital found the following benefits:

- Delivery of care moved from inpatient to day case, reducing pressure on inpatient beds.
- Improved surgical waiting times by treating more patients per list; the hospital now routinely performs 8-9 PLASMA+ (prostate) cases during a dedicated Saturday list.
- Increased theatre efficiency, by treating more patients per list.
- Maximised the use of day case pathways, aligning with a key aim of Getting it Right First Time (GIRFT) and the British Association of Day Surgery (BADS).
- Harmonisation of electrosurgical generators across theatres, reducing cost through technology investment and standardising procedures and usability across departments.

Better catheter care: Tackling avoidable infections

Catheter-associated urinary tract infections (CAUTIs) are a significant cause of avoidable infection. CAUTIs often result in prolonged hospital stays, increasing the need for antibiotics, and driving unnecessary costs to the health system.

Despite national guidance and longstanding awareness of the risks around this, CAUTIs remain stubbornly persistent across many care settings. Results from Freedom of Information data requests from all acute NHS Trusts in England indicate that these are on a significant upward trajectory, with the average number of CAUTI patients per Trust rising year-on-year (having grown by almost 70% since 2021-22).[10] As the UK's population is gaining, the problem is likely to become worse.

The PureWick Female External Catheter a non-invasive urine-management device designed for adult female patients. Rather than inserting a catheter inside the urethra, this device uses a soft, flexible wick placed externally between the labia and buttocks. By avoiding the need for insertion into the bladder/urethra, it helps to lower the risk of CAUTIs.

An observational study in UK care homes compared PureWick with incontinency pads and Foley catheters, with 25 female patients over the age of 76. Foley catheters are invasive medical devices where a flexible tube that is inserted through the urethra into the bladder to drain urine[11].

Reported benefits noted from users of PureWick were improved independence, dignity, and quality of life over other continence products, with meaningful improvements in patient experience and care efficiency. The use of PureWick in the trial also reduced night-time interventions by 65%, significantly improving both patient rest and staff workflow.

Key patient experience outcomes also included:

- 89% reduction in sleep disturbance.
- 88% stayed dry all/most of the time.
- 56% reported not worrying about odour (compared with 16% with pads/traditional catheters).

In a separate case study at Thomas Jefferson University Hospital, use of PureWick over a three-year period for adult female patients saw a 55% reduction in CAUTI rates, significantly attributable to this external catheter intervention[12].

Sage structured oral care systems for ventilated patients

Oral care in the critical care setting is a well-established aspect of patient management. Critically ill patients, particularly those who are intubated, are at heighted risk of oral plaque forming and travelling. This can harbour respiratory pathogens, particularly around endotracheal tubing, leading to ventilated associated pneumonia (VAPs). VAP is a serious complication, with mortality rates reported up to 25%[13] and is also associated with prolonged stays in intensive care units.

The Sage oral care system is designed to aid the removal of dental plaque, debris and oral secretions while helping healthcare professionals comply with their oral care protocol. In 2023, this oral care system was introduced to patient care within a single-centre critical care unit at East Kent Hospitals University, NHS Foundation Trust. The system was embedded into routine practice, with data collection to monitor VAP rates pre and post implementation.

The implementation of the system between 2023 and 2024 was associated with significant improvements in patient care among invasively ventilated patients. Key outcomes included:

- 56% relative reduction in VAP rates.
- 45-60% reduction in ventilated days to diagnosis.
- 52% decrease in total ventilated days.
- 31-40% reduction in critical care length of stay.

The above changes translated into a 25% reduction in mortality. This approach has decreased costs and improvement in antibiotic stewardship and patient safety, resulting in nearly 50% savings in antibiotic costs clinical staff also reflected favourable on the interventions feasibility and acceptability. The system's simple process of have mouth care packs numbered and hanging next to the bedside, acted as a visual prompt to staff to undertake mouth care and thus resulting in improved outcomes.

‘WHAT GOOD LOOKS LIKE’ IN PATIENT SAFETY

Improving patient safety and reducing avoidable harm should be fundamental to care and treatment across all healthcare settings. We know that industry can play a key role in supporting this, and in doing so, can help to secure the aim of the forthcoming 10 Year Health Plan of building a health service fit for the future.

To drive forward this change, the ABHI Patient Safety Group believes in and requires support from a systems and standards-based approach to patient safety. Therefore, in the development of this white paper we have been working with the charity Patient Safety Learning and their framework for assessing ‘What Good Looks Like’ in patient safety.

Since Patient Safety Learning was founded in 2018, they have been engaging with organisations looking to improve patient safety. A consistent theme from their work has been the need for Trusts, ICBs, Independent Care Providers and individual hospitals to have access to expert advice to help them become true learning entities within a reliable Safety Management System (SMS).

SMSs are an organised approach to managing safety, which are used widely in different industries. The purpose of an SMS is to ensure that an industry achieves its business and operational objectives in a safe way and complies with the safety obligations that apply to it.[14] An SMS has formal risk management processes for identifying hazards, mitigating and managing residual risk with safety policy and objectives, safety risk management, safety assurance and safety promotion.

To support this, Patient Safety Learning have developed a unique set of patient safety standards, with detailed evidence-based outputs, outcomes, behaviours and actions necessary for successful delivery.[15] They have been developed from 20 years of research, plus inputs from NHS England’s Patient Safety Strategy, as well as learning from inquiries, policy and good practice within UK and international healthcare. Their development has been in partnership with specialists and practitioners and is quality assured with ‘real world’ practicality.

Within the context of this framework, in the next section of this white paper we consider what good looks like for patient safety. This is the ABHI Patient Safety Group’s ambitions of patient safety, divided into different key stakeholder groups.

‘WHAT GOOD LOOKS LIKE’ FOR HEALTHCARE STAKEHOLDERS

Considering what good looks like in patient safety, in this section of the white paper we focus on the perspective of six different stakeholder groups, each of whom have key role to play in improving patient and healthcare worker safety and reducing avoidable harm. For each group we have selected a small number of ‘key ambitions’ that we consider as particularly important.

1. Patients

When thinking about the key stakeholders in healthcare, the experiences of patients, families and carers and outcomes of their care and treatment should be at the forefront of our mind. The ABHI Patient Safety Group believes that it is vital that patients are actively involved in decisions over their care and treatment. When they report incidents of avoidable harm or patient safety risks, they should have confidence that they will be listened to and that their concerns will be acted on. This links to one of the major themes identified in the 10 Year Health Plan for England, empowering patients to take as much control of their care as possible.

Patients and patient safety – key ambitions

1. **Prevention of avoidable harm** – patients should receive safe care with a reduced likelihood of avoidable harm.

2. **Safety is put at the core of HealthTech** – patients should be assured that patient safety is hardwired into every stage of the development of medical technology. This should also be hardwired into care pathway management.

Considering what good looks like in patient safety from the perspective of patients, we believe they should also be able to expect:

- Medical devices that recognise that is not a one-size-fits-all approach to patent safety.
- Information about medical devices and patient safety should be clear, understandable, accessible and readily available.
- To feel like they are a real peer in their interactions in all part of their care and treatment. It is important to recognise this cannot simply be a ‘bolt on’, patients should be seen as part of the multidisciplinary team.
- Safe care is the norm, and they will receive the best possible healthcare experience.
- To have a clear understanding of their rights and expectations, with their insights and experiences captured and actioned for improvement.

Considering factors that may influence the ability to achieve these aspirations, key issues we have identified include:

- How can HealthTech companies support patients to engage and be involved in patient safety? This includes providing them with clear, informed information for choices when it comes to situations where they may need to make decisions on their care and treatment and understanding benefit and risk of having or not having an intervention.
- When things go wrong in healthcare, too often many of cases safety issues have been identified with recommendations for change suggested do not lead to meaningful improvement. This is different from other areas of life where the public would expect improvement or be able to turn to an alternative provider.
- How can patients be better empowered to ask for information in relation to their care and treatment? There is often a significant power imbalance between healthcare professionals and members of the public that can make this difficult. Other factors, including a person’s social background or ethnic background can also impact this.

2. Healthcare providers

There are many different types of healthcare providers involved in different aspects of the health system, ranging from primary care organisations such as GP's offices to large acute care hospitals.

Healthcare providers and patient safety – key ambitions

1. **Organisations should demonstrate that patient safety is core priority** – it should run throughout organisation's delivery plans and always be on the Board agenda. Significant changes and decisions should include an assessment of their safety implications, with patient safety at the core of system and process design and redesign.

2. **Organisations should create and maintain a safety culture** – organisations must understand the barriers that negative organisational cultures have on patient and healthcare worker safety prioritisation, fostering safe cultures where staff feel able to speak up. This needs to be matched by active listening and action to address the safety concerns.

We would also expect organisations to place a strong focus on eliminating 'Never Events'. These are defined by the NHS as serious incidents that are wholly preventable because guidance or strategy recommendations provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.[16] What incidents are classed as Never Events is expected to change over time as the NHS has recently begun to explore and test alternatives to the existing Never Events framework.[17]

Considering factors that may influence the ability to achieve these aspirations, key issues we would identify include:

- Organisations need to have a patient safety strategy accompanied with a plan on how to implement this. Many healthcare organisations do not have a written commitment, and there is currently no requirement to publish such documents in the public domain. Often organisational action and responses to patient safety are reactive in relation to new NHS initiatives rather than informed by safety risk assessments against standards and 'what good looks like' framework.
- Most organisations do not have a patient safety director, but instead a member of the board who holds patient safety in their portfolio. There may be a role for Patient Safety Specialists to assist with increasing the visibility of patient safety at a Board level, although early analysis of these new roles suggests they are not always getting the access that this would require.[18]
- For organisations to prioritise patient safety they need to have access to the relevant data and reports to identify, learn from and act on patient safety issues. The new national Learn from Patient Safety Events (LfPSE) service allows organisations to access their own data, but does not currently share this with others to enable wider learning and easy comparison with other organisations. Having access to the LfPSE national database would allow organisations to spot trends and identify other organisations with similar issues, to enable networking for better understanding causal factors and develop solutions for wide and consistent application.

3. Integrated Care Boards

Integrated Care Boards are statutory NHS organisations 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.[19] They operate within 42 Integrated Care Systems (ICSs) across England, partnerships that that bring together NHS organisations, local authorities and others to plan and deliver healthcare services in a geographical area.

ICBs and patient safety – key ambitions

1. **Providing patient safety leadership** – ICB's should set high and consistent standards for patient safety behaviours and actions in their local areas. While they may not have direct input on organisational decisions, they should be leading the patient safety agenda, pushing provider organisations to prioritise patient safety, collaborate across the safety system and scrutinising their performance.

2. **Prioritise quality** – ICBs should support organisations to make procurement and purchasing decisions that priority quality and safety. Cutting costs in the short term can resulting in higher costs as a result of unsafe care in the long run, something ABHI members see time and time again.

In driving forward efficiency measures intended to ensure the NHS is fit for the future, ICBs have been tasked with streamlining their services to avoid duplication of functions elsewhere in the NHS. With this comes a renewed focus on their role on commissioning, where ICBs can play a major role in reducing avoidable harm if they ground their decisions in patient safety. Though patient safety has not been set as an explicit priority for these ICBs and ICSs, the delivery of safe care runs implicitly through each of their main aims. In their 2023 report, *The elephant in the room: Patient safety and Integrated Care Systems,* Patient Safety Learning set out in more detail what steps could be taken to ensure ICSs and their ICBs help to embed and improve patient safety.[20]

4. System leaders

At a system level, the key organisation leading healthcare England is the Department of Health and Social Care, now that change is now underway to move NHS England back within the Department.

There are also organisations who while not having a responsibility for delivering healthcare services have an important function here too, such the Patient Safety Commissioner for England and Patient Safety Commissioner for Scotland. Our ambitions set out here then apply to system leaders in general. This current environment is currently undergoing a process of re-organisation and consolidation following the publication of recommendations of the Dr Penny Dash's review of the patient safety landscape.[21]

System leaders and patient safety – key ambitions

1. **Should work in partnership with industry** – HealthTech should be able to work in partnership with system leaders to achieve patient safety aims and reduce avoidable harm.

2. **Develop a safety management system (SMS) approach to healthcare** – system leaders should look at how we can develop an organised approach to managing safety used widely in other safety critical industries. We welcome the leadership and reports already taken by the Health Services Safety Investigations Body (HSSIB) in this area.[22]

Looking at what good looks like in patient safety from the perspective of these system leaders we see the following areas as particularly important:

- Ensuring learning from safety incidents and safer recommendations are shared widely and actions for improvements are implemented throughout the system.
- Taking a proactive approach to patient safety issues, rather than a reactive one.
- The importance of system leaders not simply focusing on the scale of physical and psychological patient harm and the costs of implementing patient safety improvements, but also the costs of inaction. This can range from staff wellbeing and morale to the additional financial costs of responding to additional care and treatment, costs of clinical negligence and wider societal costs of supporting people and families with long term disability and ill health.

To achieve these aims, the ABHI Patient Safety Group strongly believes in the importance of system leaders looking at how a SMS approach to help to improve patient safety and reduce avoidable harm in healthcare. The purpose of an SMS is to ensure that an industry achieves its business and operational objectives in a safe way and complies with the safety obligations that apply to it. An SMS has formal risk management processes for identifying hazards, mitigating and managing residual risk with safety policy and objectives, safety risk management, safety assurance and safety promotion. HSSIB has set out previously what this could look like in their report, *Safety management systems: an introduction for healthcare.*[23]

Considering factors that may influence the ability to achieve these aspirations, key issues we would identify include:

- System leaders should have a strong focus on data and analysis of patient safety incidents and avoidable harm, with a focus on measurable reductions in these and systems failures.
- There is a need for more joined-up/coordinated thinking and leadership at a national level, too much work currently remains siloed in specific organisations.

5. Industry

The HealthTech industry is comprised of companies, such as members of ABHI and other private providers of healthcare products and technologies. They provide a wider range of products and services that save and enhance lives, and we believe can play a key role in taking forward three of the major themes identified by the Darzi Review for the forthcoming 10 Year Health Plan:

- Simplify and innovate care delivery for a neighbourhood NHS.
- Drive productivity in hospitals.
- Tilt towards technology.

Industry and patient safety – key ambitions

1. **Develop a thought leader role** – industry should develop and utilise its patient safety expertise, sharing knowledge widely across the healthcare system for the reduction of avoidable harm.

2. **Focus on quality and value and not just cost** – improving patient safety and patient outcomes should be at the heart of the development of new products and services.

3. **Work collaboratively together** – the sector should come together on patient safety issues, providing 'one voice' for safety from companies.

The ABHI Patient Safety Group wants to see industry as trusted partners, peers in patient and healthcare worker safety alongside other stakeholders, working together as a whole system focused on safety. HealthTech companies should take a proactive role in patient safety, both enabling and supporting improvements and role modelling positive behaviours. This includes working with healthcare providers to ensure the full implementation of medical devices to realise their value, delivering better clinical outcomes, patient safety and better value for money.

6. Regulators

At a system level, the Care Quality Commission (CQC) is the independent regulator of health and social care in England, with the Medicines and Healthcare products Regulatory Agency (MHRA) the regulator of medicines, medical devices and blood components in the UK. As with all system leaders, this existing structural environment may undergo significant change in the near future in terms of how these bodies and their functions are organised.

There are also a number of other regulators who have significant patient safety aspects to their role, such as bodies governing the conduct of different healthcare professionals as well as regulators from outside of healthcare such as the Health and Safety Executive (HSE).

Regulators and patient safety – key ambitions

1. **Regulators should be responsive to patient safety concerns** – they must be swift to respond and have clear processes and investigations in response to reported incidences of avoidable harm.

2. **Role model transparency** – regulators should be transparent in their actions and behaviours and clear on what patient safety issues and avoidable harm they are responding to.

Looking at what good looks like in patient safety from a regulatory perspective, we see the following areas as particularly important:

- Regulators should have a focus on improving communications around patent safety incidents and risks and explicitly saying how HealthTech can support safety.
- Patient safety should be their key priority, with this being the primary driver of regulators and they should have explicit strategies on how they will support patient safety including responding to recommendations from inquiries, parliamentary committees and the Patient Safety Commissioner.

Regulators need to take a more proactive and rigorous approach to patient safety and post-market surveillance. They should ensure that regulation allows for progress and innovation, requiring an organic framework of safety standards that can grow and evolve as technologies emerge and develop.

Considering factors that may influence the ability to achieve these aspirations, key issues we would identify include:

- Importance of acknowledging the products do sometimes fail. We need to have a system which gathers data from multiple sources (clinicians, patients, manufacturers, safety managers etc) when this occurs and responds and shares learning for future improvement.
- Challenges of standards of regulation and standards for regulation. How can the current system be improved?

HOW THE UK IS SEEN ON THE INTERNATIONAL STAGE

As well as considering these six stakeholder groups, we also consider 'What Good Looks Like' in patient safety from the perspective of how the UK is seen on the international stage, from which we identified two ambitions.

How the UK is seen on the international stage – key ambitions

1. **A flagship for patient safety good practice** – we want the UK to be seen as a global patient safety exemplar..

2. **Focused on sharing learning** – we should lead the way in sharing insights and learning from patient safety, to and from international partners.

It is important we collaborate at an international level, both sharing our learning with other countries and looking at how we can learn from them.

HOW THE HEALTHTECH INDUSTRY CAN CONTRIBUTE TO PATIENT SAFETY AND STAFF SAFETY

The ABHI Patient Safety Group believes that the HealthTech industry can, and must, be a key partner in working to improve both patient safety and healthcare worker safety, tackling the persistence of avoidable harm.

We believe that successful implementation and utilisation of healthcare technologies, products and devices will be key to enabling the three strategic shifts set out in the 10 Year Health Plan for Plan: hospital to community; sickness to prevention; analogue to digital. They can help to both unlock efficiencies and savings and when well implemented deliver better patient experiences and outcomes.

In this section of the white paper we set out how we think ABHI members, and the HealthTech industry more broadly, can contribute to patient safety and healthcare worker safety in each of these areas. We have considered this against a series of system safety foundations and highlighted a set of specific patient safety actions for the HealthTech industry.

Leadership and governance

To improve patient safety, we require a model for leadership and governance for patient safety in health and social care that set and require high and consistent standards and behaviours of our leaders. This is essential to support a system-wide approach to patient safety, so that all organisations are clear on their collective and individual roles and responsibilities.

We believe that the HealthTech industry has in place some strong foundations that can help to support this:

- **Collaborative working for patient safety.** Evidenced by the growth of initiatives where companies coming together to discuss how to improve patient safety, through forums such as the ABHI Patient Safety Group.
- **A mission driven approach.** HealthTech companies are normally guided by strong mission statements, which inform organisational culture and behaviours. When infused with a focus on patient safety, these can support more effective leadership and governance in this respect.

In supporting other stakeholders in improving their approach to leadership and governance for patient safety, HealthTech companies may also be a source of learning and insights that could benefit healthcare providers. In particular, our approach to leadership training, compliance and reputational risk could be of value to healthcare providers. In the case of the latter, in industry this can often be seen as a potentially positive tool, informing a focus on safety and encouraging sharing and improvements to guard against reputational risk. This contrasts with how we often see this mentioned when it comes to patient safety and healthcare, where this can take a negative edge, associated with the suppression and cover up of safety concerns.

Leadership and Governance - Actions for the HealthTech industry

1. **Being less risk averse in raising concerns** – industry should positively challenge the performance on the healthcare system on patient safety issues and make the case for improvement. Healthcare organisations should embrace this opportunity, be open to these perspectives and embrace the opportunity to learn from third parties.

2. **Working with healthcare organisations to ensure they get the best value from healthcare products following their purchase** – in many cases the full benefits to both patient safety and improved patient outcomes are not always realised.

3. **Greater proactive engagement with system leaders and organisations** – in areas where the HealthTech industry can work with others to add value and improve patient safety.

Just culture

An organisational culture that seeks to assign blame when things go wrong makes patient harm more likely to happen again. In their report, *A Blueprint for Action,* Patient Safety Learning identify a just culture as one of the six foundations of safer care to improve patient safety.[24] A just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution.

Considering culture and patient safety, strengths of HealthTech industry in this area include:

- **Culture that informs product development.** In many cases a company's culture plays an important role in shaping product development and rollout. Creating the conditions where a safety culture can flourish in healthcare organisations is a key component to improving patient safety.
- **A focus on ethics.** Many HealthTech companies place a strong emphasis on the importance of ethics in the workplace. To support this, they provide specific avenues and support for employees to raise concerns and issues, such as ethics hotlines.

Just Culture - Actions for the HealthTech industry

1. **Proactively work with healthcare providers to encourage and support speaking up and listening up initiatives.**

2. **Providing support, advice and expertise to help develop culture programmes in healthcare** – creating and nurturing a safety culture is not an overnight task and healthcare leaders and organisations require greater support if they are to achieve this.

Sharing learning

This area is another one of Patient Safety Learning's six core foundations of safer care include in *A Blueprint for Action.*[25] Healthcare is systematically poor at learning from harm. If patients are to be safer, we need people and organisations to share learning when they respond to incidents of avoidable harm, and when they develop good practice for making care safer. It is vital that patients, clinicians, managers, and health and social care system leaders share learning about safety practice and performance to make care safer.

We believe that the HealthTech industry has in place some strong foundations that can help to support this:

- **Sharing learning with peers.** Through forums such as the ABHI Patient Safety Group, HealthTech companies will informally share patient safety insights and learning.
- **Promoting the patient voice.** There is increasing focus to include patient experiences and stories in case reports about products and services.
- **Dedicated safety teams.** Larger HealthTech companies are able to employ staff with patient safety specific remits, focused on sharing and promoting good practice.

Sharing learning – Actions for the HealthTech industry

1. **Improving how we communicate, to both healthcare professionals and patients, information about benefit/risk decisions related to products** – importance of using plain English language descriptions and information.

2. **Explore how we can support smaller HealthTech companies to share patient safety learning.**

3. **Overcoming competition barriers that may deter some companies from sharing information with each other** – working through groups such as ABHI to share patient safety insights and learning.

Professionalising patient safety

To improve patient safety and reduce avoidable harm in healthcare, we need an approach that sets and embeds consistent standards for patient safety performance. This should be supported by a skilled workforce, including specialists in patient safety and human factors to deliver of this.

Considering professionalising patient safety, strengths the HealthTech industry can bring to this include:

- **Research and development expertise.** HealthTech companies often have connections and in-house knowledge and experience in these areas.
- **Communication and promotion.** Industry partners can leverage their influence to help support and promote the professionalise of patient safety and upskilling of the health workforce.
- **Dedicated safety teams.** Larger HealthTech companies are able to employ staff with patient safety specific remits, focused on sharing and promoting good practice.

Professionalising patient safety – Action for the HealthTech industry

1. **Encourage and support the embedding of human factors and ergonomics expertise into healthcare** – with the potential to working towards a cross-industry message on this.

2. **Encourage the development and adoption of patient safety standards in HealthTech companies** – to achieve their patient safety goals.

Patient and family engagement

Patients play a pivotal role in maintaining and improving patient safety. This is identified in the WHO Global Patient Safety Action Plan, which states that:

"Patients, families and other informal caregivers bring insights from their experiences of care that cannot be substituted or replicated by clinicians, managers or researchers. This is especially so for those who have suffered harm. Patients, families and caregivers can serve as vigilant observers of a patient's condition and can alert health care professionals when new needs arise. Given proper information, the patient and family can help to be the eyes and ears of the system."[26]

This is also identified as a core foundation of safer care in Patient Safety Learning's *A Blueprint for Action.*[27] They make the case that patients should be 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. Working with patients and their families to improve patient safety is also an area where the ABHI Patient Safety Group believe the HealthTech industry could potentially take a much bigger role.

Currently much of our engagement with patients often relates to case studies and examples of products and devices in use. However, direct patient engagement is not something that is hardwired into the way the HealthTech industry works. Developing these relationships can also be complicated by the fact that healthcare providers are positioned between the supply of these products and their use by patients, meaning this is not always a straightforward connection.

Patient and family engagement – Actions for the HealthTech industry

1. **Developing more mechanisms to engage directly with patients and their families** – enabling us to listen to their experiences and champion their voices.

2. **Increase the availability of patient education and information resources and materials** – these can be used by healthcare providers to help to engage patients further in their care and treatment.

Data

Having access to the right data is crucial in setting effective goals and objectives for tackling systemic causes of avoidable harm in healthcare. This needs to be accompanied by transparent reporting to measure progress and hold organisations to account for their performance.

Considering the importance of data in improving patient safety, strengths we believe the HealthTech industry can bring to this include:

- **Use of data platforms.** Companies within the HealthTech industry are familiar and experienced with using a wide variety of systems to measure data and report on performance.
- **Working in partnership to look at data.** HealthTech companies often work closely with healthcare providers to look at and analyse existing data sets.

Data - Actions for the HealthTech industry

1. **Explore means of working directly with healthcare providers, and lend our expertise, to interpret and analyse insights from patient safety data.**

2. **Increase transparency to the sharing of data by industry** – not just information about positive patient outcomes but also negative ones to alert regulators and others on safety risks that need to be addressed.

We also have identified the following areas where we believe the HealthTech industry could improve its approach to support the data and patient safety:

- Greater time and resources could be invested into more sophisticated means of trend analysis to inform patient safety improvement.
- More could be done to share data and insight between different companies, addressing competition that can often be a barrier to this.
- Data registries can be a key tool in patient safety insight, but there are open questions about how these are driven forwards and funded that need to be resolved.

Delivering safer care, including healthcare worker safety

To ensure patients are kept safe from avoidable harm, healthcare needs to be focused on ensuring services are delivered safely. This requires patient safety to be embedded in organisational approaches to human resources and organisational and system approaches to workforce planning. This includes both ensuring that staff have the resources and systems to enable to deliver safe care and ensuring that organisations have the right numbers of staff "with the right skills, in the right place, at the right time".[28]

Many HealthTech companies have a keen focus on looking at how products and devices are used across different care and treatment pathways, and work closely with healthcare providers to see how they can complement the implementation of new technologies. However, this is a complex area and one where we believe there is more that needs to be done in this area through a greater focus on what is needed in terms of Post-Market Clinical Follow-up (PMCF) activities and how industry can actively support this.

Delivering safer care, including healthcare worker safety – Actions for the HealthTech industry

1. **Encourage and support healthcare worker safety initiatives** – recognising the symbiotic relationship of staff safety and patient safety, working towards a cross-industry message on this.

2. **Increase industry support for Post-Market Clinical Follow-up activities** – actively partnering with healthcare stakeholders to develop new ways to continuously assess the performance, safety and benefits of medical devices in use.

Research and innovation

To deliver safer care and find new ways to reduce the risk of avoidable harm, we believe the role of research and innovation needs to be embraced as part of this. We see the HealthTech industry as being able to bring a number of strong foundations to support this:

- **Large evidence base.** Across a range of different companies there exists a strong pipeline of different medical devices and products that are in use and improve safety to learn from.
- **Human factors expertise.** Within the HealthTech industry there is significant experience of carrying out human factors-based research and development.
- **Procurement.** HealthTech companies have extensive experience of working in partnership with healthcare providers in the NHS in value-based procurement processes.

We note, however, that the role of industry in research and development can sometimes be viewed as negative. Even when funding independent research, direct involvement by industry can be seen as potentially tainting the outcome of this. Work is needed to address this so HealthTech companies are able to support research as a trusted partner. At the same time, we think more work is needed for the HealthTech industry to fully understand what is needed and desired from patient safety research and innovation by those on the frontline of healthcare.

Research and Innovation – Actions for the HealthTech industry

1. **Drawing out broader implications of research –** exploring how existing processes, such as clinical feedback groups, can be developed to provide not just device specific feedback, but also help to provide insights on wider system needs and demands that can be shared with other healthcare stakeholders.

2. **Seek to support the expansion of value-based procurement in the health system** – working in partnership with key stakeholders, against a backdrop of finite financial resources, to help deliver both safe services and productivity gains.

Equity and sustainability

As discussed earlier in this white paper, equity in medical devices and products, ensuring they do not embed existing societal biases, is an increasingly live topic when considering HealthTech and patient safety. Sustainability is also an increasing area of focus, looking at how we can improve this in healthcare in way that also supports quality improvement and patient safety.

Considering professionalising patient safety, strengths the HealthTech industry can bring to this include:

- **Equality and diversity.** Many HealthTech companies have well developed and extensive internal approaches to equality, diversity and inclusion, coupled with a strong focus on staff welfare.
- **Focus on sustainability.** Industry is increasingly looking at its impact on the environment and ways to improve sustainability for both ethical and cost-effectiveness reasons and looking more closely at the life cycle of products.

Equity and sustainability – Actions for the HealthTech industry

1. **Equity in medical devices** – to support the implementation of the recommendations included in the recent independent review of equity in medical devices.[29]

2. **Embrace diversity in clinical and non-clinical studies** – as well as design and practice standards.

3. **Looking at how larger companies with greater resources can support smaller companies** – on both issues of equity and sustainability.

CONCLUSION

Our healthcare system is currently confronted by an array of difficulties and emerging challenges. Coupled with rising demand and an ageing population, we face significant treatment backlogs and increasing workload pressures across the board.

At the same time, preventable avoidable harm continues to persist at unacceptably high levels, exacerbated by these conditions. Every avoidable injury and death is a tragedy for patients, their loved ones and healthcare professionals. It is also accompanied by an eye watering financial footprint, estimated as accounting for 8.7% of all health expenditure in a high-income country such as the UK.

The 10 Health Year Plan for England presents an opportunity to meet these challenges head on strengthening and making more consistent the often excellent and safe care that is widely provided. We also believe this it gives us a chance to make a generational shift in our approach to health and care and patient safety. A shift that ensures tackling avoidable harm and improving patient safety is a fundamental necessity across all health and social care settings.

In this white paper, we have considered what we think this shift could look like from the perspective of six different key stakeholder groups. For each group we have identified a number of key ambitions that we consider to be particularly important. These range from patients being assured that patient safety is hardwired into every stage of the development of medical technology, to the imperative for system leaders to develop a safety management system approach to healthcare. We also outline our ambition for the UK to be a global patient safety exemplar. Our health system should aspire to lead the way in sharing insights and learning from patient safety, with international partners.

The effective implementation of new technology products and devices can play a key role in meeting these ambitions. This will also be central to delivering the forthcoming 10 Year Heath Plan and unlocking efficiencies and savings that help to deliver better patient experiences and outcomes.

We set out in this white paper how we think that ABHI members, and the HealthTech industry more broadly, can contribute to this across a range of system safety foundations:

- Leadership and governance
- Just culture
- Sharing learning
- Professionalising patient safety
- Patient and family engagement
- Data
- Delivering safer care including healthcare worker safety
- Research and innovation
- Equity and sustainability

Across these foundations we have identified several specific patient safety actions for the HealthTech industry. In some cases, these involve how we work with each other, such as overcoming competition barriers that can deter companies from sharing patient safety insights and learning. There are also actions that relate to how we engage with others, for example developing more mechanisms to engage directly with patients and their families.

In other areas we identify challenges to ourselves as an industry and how we work. We point to a need to positively challenge the performance on the healthcare system on patient safety issues and make the case for improvement. A need to increase transparency of data sharing by the industry – not just information about positive patient outcomes but also negative ones to alert regulators and others on safety risks that need to be addressed. An ambition to encourage the development and adoption of patient safety standards in HealthTech companies to achieve their patient safety goals.

The ABHI Patient Safety Group believes that the HealthTech industry can, and must, be a key partner in working to improve both patient safety and healthcare worker safety, tackling the persistence of avoidable harm. We see the actions set out in this white paper as a means of framing how we can take practical steps to realise this ambition.

Tackling avoidable harm and improving patient safety should be fundamental to care and treatment across all health settings. We need everyone, politicians, policymakers, patients, communities, clinicians, industry, managers, system and professional regulators, and health system leaders involved in this effort. We commend this white paper to all our partners and look forward to collaborating on our shared journey to improve the safety, efficiency and equity of healthcare.

FURTHER READING

ABHI Patient Safety Group

The ABHI Patient Safety Group works to establish the HealthTech industry as a trusted partner for leading improvements in patient safety and healthcare worker safety. We provide key insights to stakeholders and support the implementation of the NHS Patient Safety Strategy. Working closely across the healthcare community, the group aims to ensure that innovation and technology, which improve the individual experience of care, are identified and accessible.

Patient Safety Learning

The ABHI Patient Safety Group has been supported in creating this white paper by Patient Safety Learning, a charity and independent voice for improving patient safety.

They harness the knowledge, enthusiasm and commitment of healthcare organisations, professionals and patients for system-wide change and the reduction of harm. Patient Safety Learning believes that patient safety is not just another priority; it is a core purpose of health and social care. Patient safety should not be negotiable.

Through their work they support safety improvement through policy, influencing and campaigning, and the development of 'how to' resources such as the hub, their free award-winning platform to share learning for patient safety, and their unique Patient Safety Standards and support tools.

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