PATIENT SAFETY 2030
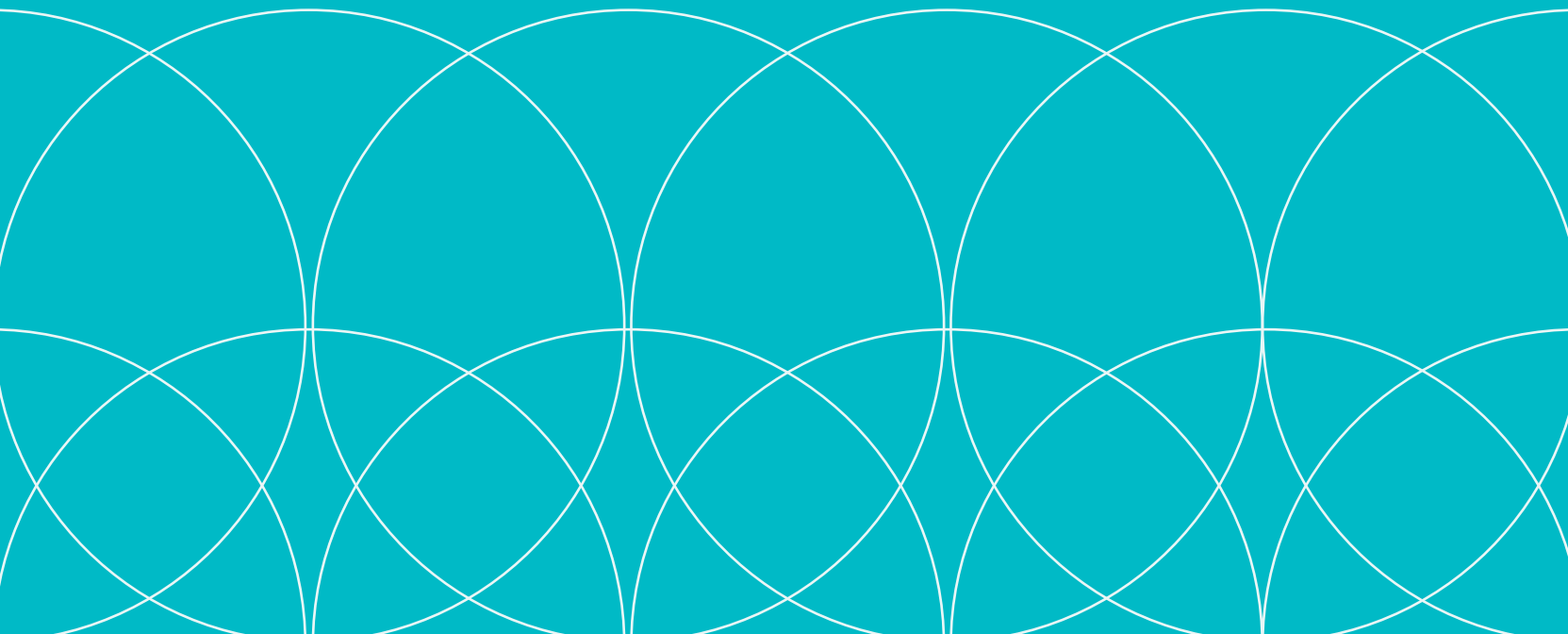
NIHR Patient Safety Translational Research Centre at Imperial College London and Imperial College Healthcare NHS Trust

NHS
National Institute for
Health Research

NIHR IMPERIAL PATIENT SAFETY TRANSLATIONAL RESEARCH CENTRE

The NIHR Imperial Patient Safety Translational Research Centre (PSTRC) is part of the National Institute for Health Research and is a collaboration between Imperial College London and Imperial College Healthcare NHS Trust.

The NIHR Imperial PSTRC undertakes research to drive forward improvements in patient safety within the NHS and internationally. We use our funding to deliver sustainable long-term, high impact programmes of translational research in patient safety. Our research has the potential to translate into real benefits for patients, such as reducing prescription errors, improving diagnosis and reducing accidents during surgery.

Our strategy is to develop patient safety through engagement with patients, carers, the public, clinical partners, healthcare organisations, social care, industry and government. We do this by carrying out research in our unique areas of academic strength in safety information, design and technology, patient engagement, teamwork, economics and policy.

www.imperial.ac.uk/patient-safety-translational-research-centre

PATIENT SAFETY 2030

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ACKNOWLEDGEMENTS

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FOREWORD

Dear Secretary of State for Health, Ministers and distinguished experts,

In the decade and a half since *To Err is Human*, safety has become embedded in the lexicon of policymakers, healthcare professionals and the media in most developed countries. We've untangled some of the root causes of error and have implemented specific interventions which have shown immense promise in reducing patient harm. On the other hand, research and intervention continue to be concentrated in particular settings of care and as serious policy priorities, safety and quality have received far less attention in developing nations than is deserved.

With this report we have reached a watershed. If we are to save more lives and significantly reduce patient harm we need to adopt a holistic, systematic approach that extends across professional, cultural, technological and procedural boundaries. It is my hope that we emerge collectively with greater clarity on the tools available to reduce harm and the principles underpinning their deployment to catalyse and sustain a truly global movement on patient safety.

As we shift our attention to the next 15 years of patient safety, let us remind ourselves why we are here. For too long the mindset has been that patient harm is inevitable, about which nothing can be done. But keeping patients safe is a fundamental part of care. This is a call to action on many fronts and for many actors. As we embark on the next decade and a half, we must focus on the following:

- **A system-based approach.** Expanding research and implementation efforts to all settings of care and the transitions between them; engaging all levels of political and health systems to take coordinated action.

- **International collaborations.** Building systems of accountability so that patients in all health systems are able to access safe, effective, timely, efficient and equitable care; diffusing learning to the four corners of a global network.

It is time. Let us reflect on our collective insights from the past 15 years and let us charge forth wiser, committed and readied to shape truly safer systems in the journey to 2030.

Yours sincerely,

Ara Darzi
Professor the Lord Darzi of Denham

EXECUTIVE SUMMARY

"First do no harm." This principle remains central to the provision of high-quality healthcare. The mission to make care safer unites professionals and patients alike, and safety is a key component of any quality initiative. Yet there are still too many avoidable errors.

The global patient safety movement was first spurred by the Institute of Medicine's landmark report, *To Err is Human*.[1] Nearly two decades later, while progress has been made, harm to patients remains an everyday reality in health systems all over the world.[2–4]

While longstanding issues remain unresolved, new formidable threats to the provision of safe care are also emerging. Patients are getting older, have more complex needs, and are often affected by multiple chronic conditions. New treatments and care practices to address this patient population have tremendous potential, yet also present novel challenges. The increased complexity of care creates new risks of error and harm to patients.

In addition to an increasingly complex patient population, wider trends in healthcare complicate the delivery of safe care. In recent years, healthcare budgets have tightened across OECD countries, a necessity to ensure sustainability while facing reduced economic growth. However, this limits expenditure on resources that are crucial for patient safety, such as staffing levels and investment in appropriate facilities and equipment. At the same time, the growing prevalence of antimicrobial resistance may dramatically increase the risk of acquiring infections while receiving care.

When facing these challenges, health system leaders and policymakers should find comfort in the fact that there are already many tools available to improve patient safety. Appropriate deployment of governance and regulation, improved use of data and information, stronger leadership, and enhanced education and training all promote safer care. Moreover, emerging approaches – including behavioural insights and digital health – will add new options to the patient safety toolkit.

However, there is no simple solution to improve safety, and no single intervention implemented in isolation will fully address the issue. This report highlights four pillars of a safety strategy:

1. **A systems approach.** The approach to reduce harm must be integrated and implemented at the system level.

2. **Culture counts.** Health systems and organisations must truly prioritise quality and safety through an inspiring vision and positive reinforcement, not through blame and punishment.

3. **Patients as true partners.** Healthcare organisations must involve patients and staff in safety as part of the solution, not simply as victims or culprits.

4. **Bias towards action.** Interventions should be based on robust evidence. However, when evidence is lacking or still emerging, providers should proceed with cautious, reasoned decision-making rather than inaction.

For safety to triumph, we must make a global commitment to improve the safety of the care we provide. Patient safety is a shared goal of health systems all over the world. However, there is significant untapped potential in this global movement. To capture this potential, three ingredients are necessary:

1. **Global:** the movement should be truly global and include low- and middle-income countries that have so far been at its margins.

2. **Focused:** while safety is a common goal across countries, some issues are more dependent on the local context and require tailored solutions. International collaboration should focus on identifying high-level trends and raising awareness of common issues, including measurement of a core set of high-level indicators.

3. **Coordinated:** to maximise their impact and avoid duplication of efforts, the patient safety movement should be coordinated across all stakeholders.

This paper and the Summit it informs are only small steps toward the goal of continuously reducing harm; the hope is that they spark increased energy to catalyse true change and provide an accessible summary of the challenges and most promising solutions in patient safety.

INTRODUCTION

At its core, patient safety is the prevention of errors associated with healthcare[5] and the mitigation of their effects. It is both the processes used to reduce harm, and the state that arises from the actions taken to secure patients from harm.[6] Throughout this report both meanings will be used interchangeably.

Patient safety is also a right, guaranteeing patients a state of freedom from accidental or preventable injuries in medical care.[7,8] Protecting this freedom requires establishing systems that minimise the likelihood of errors while maximising the likelihood of intercepting them.[9] Although error is unlikely to be completely eliminated, harm and impact to patients can be minimised.

Simplistic interpretations of safety consider harm to be the result of incompetence or negligence. However, during the 1990s a paradigm shift in the patient safety movement led to a better understanding of the many factors underlying adverse events.[1] It became clear – especially after the publication of the landmark report from the Institute of Medicine, *To Err is Human* – that avoidable patient harm was far more common in health systems than previously identified, and that errors occurring at point of care were caused by more than just human lapses. Rather, the improper establishment of operations and processes, and the resultant environment in which care is delivered, play a much more significant role in causing harm.[1]

Patient safety is an important aspect of quality across, and between, all settings of care. However, much of the evidence on this topic centres around acute hospital care. This report uses the available evidence and examples to establish the priorities for the next 15 years of patient safety – a direction that will apply to all settings of care – while also recognising the need to continue to develop evidence for settings outside of acute care.

The case for patient safety

The case for patient safety should be obvious: no one would argue in favour of harming patients. However, in a complex healthcare setting with many competing priorities, it is useful to outline the quality, economic, and political reasons why safety should be at the top of the agenda for decision-makers in health systems (Exhibit 1).

Ensuring a safe care environment with minimal harm to patients is an indispensable component of high-quality care. Together with the provision of a

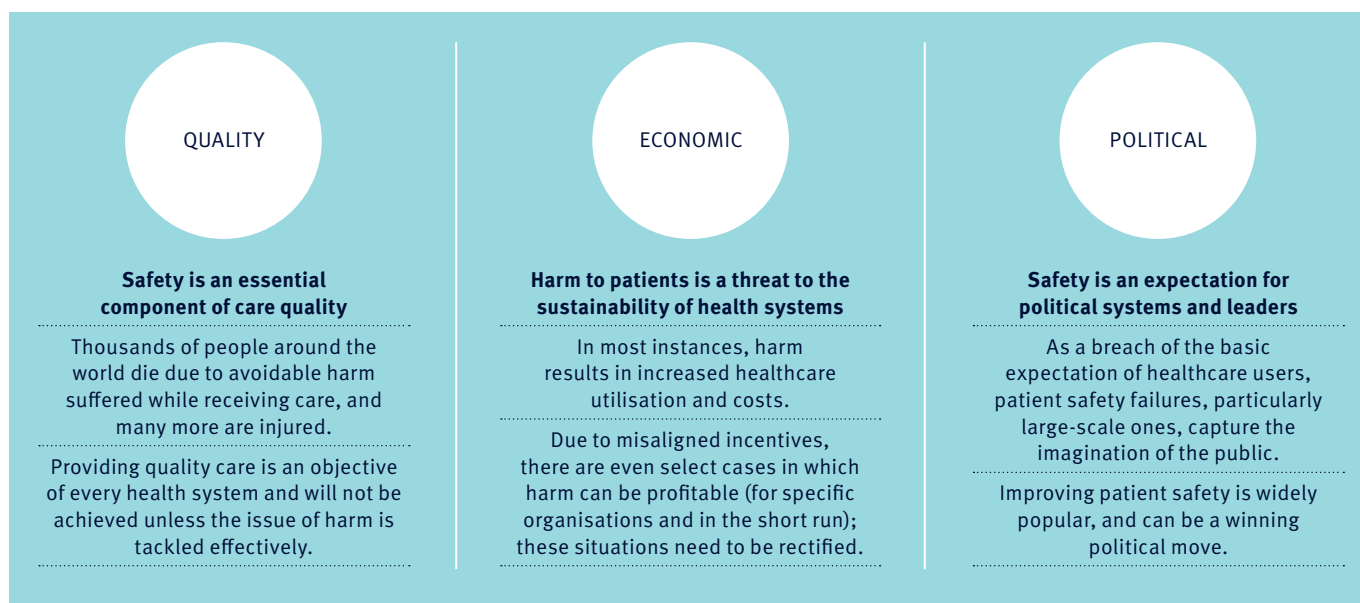| QUALITY	ECONOMIC	POLITICAL
Safety is an essential component of care quality	**Harm to patients is a threat to the sustainability of health systems**	**Safety is an expectation for political systems and leaders**
Thousands of people around the world die due to avoidable harm suffered while receiving care, and many more are injured.	In most instances, harm results in increased healthcare utilisation and costs.	As a breach of the basic expectation of healthcare users, patient safety failures, particularly large-scale ones, capture the imagination of the public.
Providing quality care is an objective of every health system and will not be achieved unless the issue of harm is tackled effectively.	Due to misaligned incentives, there are even select cases in which harm can be profitable (for specific organisations and in the short run); these situations need to be rectified.	Improving patient safety is widely popular, and can be a winning political move.

EXHIBIT 1: The case for patient safety

positive patient experience and the delivery of effective care, ensuring patient safety is one of the three domains healthcare quality.[10]

However, avoidable patient harm continues to be a burden on healthcare systems across the globe. The most striking indicator is the number of deaths that can be attributed to preventable harm. In England, researchers attribute at least 3.6% of deaths in acute hospitals to avoidable problems in care.[11] If this proportion was the same in other OECD countries, the total number of avoidable deaths would be 175,000, of which 70,000 would be considered "highly preventable".[12] These figures are only a tool for discussion and have not been properly validated.

Beyond an impact on overall care quality, adverse events attributable to poor care have important economic implications. The Health Foundation's *Continuous Improvement* report rightly synthesised the business case for building safer health systems: unreliable systems are unproductive. Unsafe care is expensive. Safer care can reduce costs.[13] Economic implications are mainly derived from unnecessarily high resource use[14,15] and litigation costs.[16] In the United States, estimates of the economic impact of adverse events in the acute care setting range from US$1,500 per surgical foreign body detected to more than US$4 million per transfusion-related incident. In the UK, the cost of excess hospital bed days attributable to patient injuries alone amount to over £1 billion.[17] Further, these figures are likely to underestimate the problem, as they are mostly limited to specific adverse events in the acute care setting[18] and vary greatly in scope and quality.[19] They also use a narrow definition of costs. For example, they do not consider indirect and intangible costs to the economy, such as loss of productivity attributed to the occurrence of harm or costs associated with loss of trust in the health system and long-term emotional damage due to harm.

Tuberculosis deaths in the US — y-axis: No. of deaths/100,000 (0, 80, 160, 240); x-axis: 1900, 1910, 1920, 1930, 1940, 1950, 1960

Highway vehicle fatalities in the US — y-axis: Fatalities per 100 million vehicle miles travelled (0, 1, 2, 3, 4, 5, 6, 7); x-axis: 1950, 1955, 1960, 1965, 1970, 1975, 1980, 1985, 1990, 1995, 2000, 2005, 2010
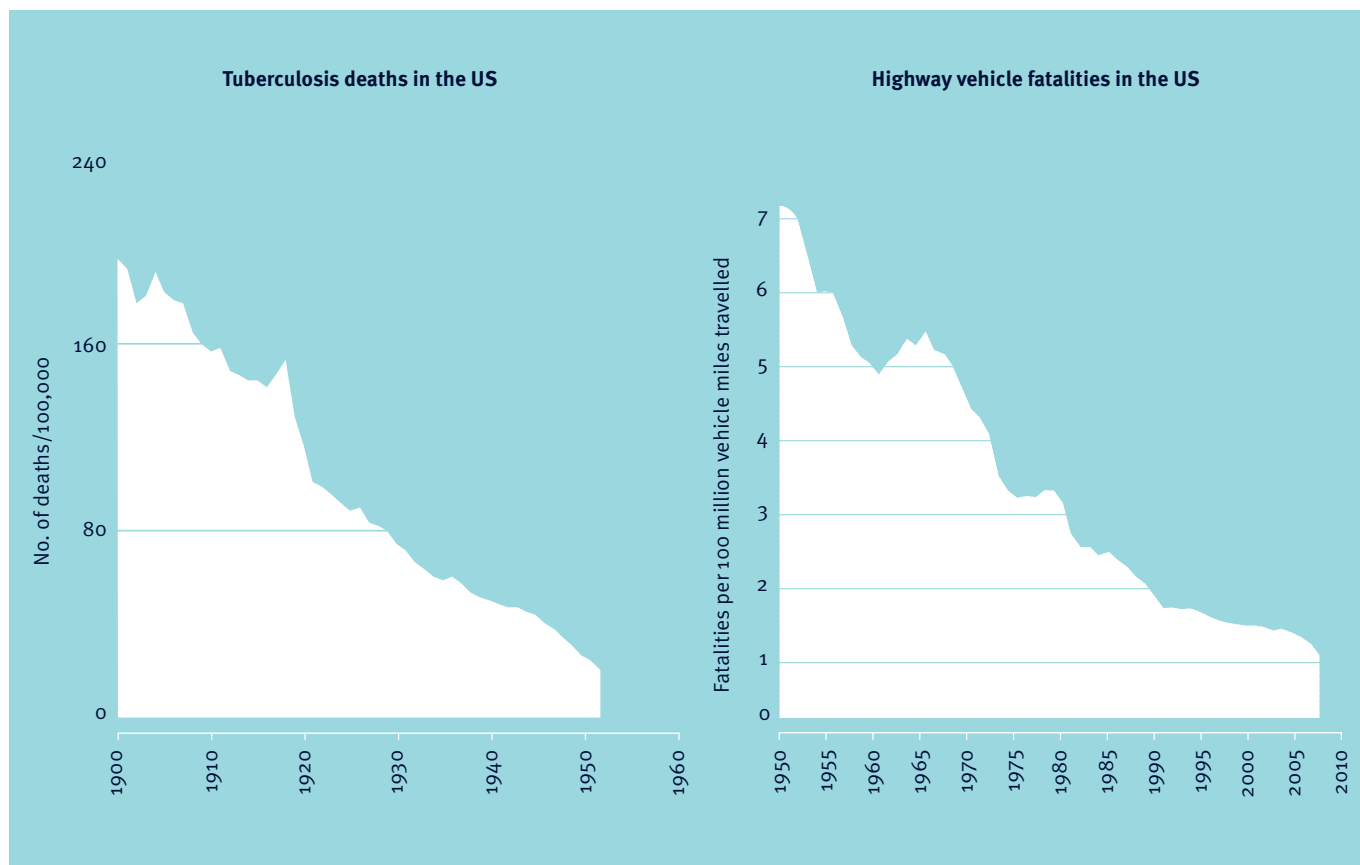
EXHIBIT 2: Unthinkable achievements[22]

The political benefits of addressing patient safety are rarely discussed in the literature –perhaps due to the strength of the quality and economic rationales. However, in healthcare the competition for attention from policymakers and investment is fierce. Therefore, the pragmatic reasons for politicians and policymakers prioritising patient safety should be highlighted. Few issues are more upsetting to members of the public than the idea that they could be harmed while under the care of a healthcare provider. In many countries, failures in this area are the only instances in which healthcare is discussed on the front pages of newspapers or on television. Committing to improving patient safety, and achieving this goal, can be a winning political proposition for politicians.

The next horizon

Over the past 15 years, there have been commendable achievements in patient safety. For example, in the United States, estimates show that 50,000 fewer patients died in hospitals and approximately $12 billion in healthcare costs were saved between 2010 and 2013 due to reductions in hospital-acquired conditions.[20]

However, a step change is required to move beyond the successes we have achieved thus far.[21] While this effort will require significant time and investment, healthcare has managed seemingly impossible feats in the past, including the eradication of several lethal diseases. In 1900, tuberculosis was the top cause of death in the United States. By 2012, the death rate for tuberculosis was effectively zero. Similarly, the fatality rate due to road traffic accidents has been greatly reduced thanks to strong safety interventions (Exhibit 2).

About this report

This report aims to inform policymakers and health system leaders about the existing and emerging threats to patient safety, and to provide specific recommendations on how to tackle these threats. It also builds on existing recommendations to integrate patient safety within each level of healthcare systems, each setting of care, and across each juncture of the patient pathway.[21] Finally, it highlights the important role that international collaboration can play in the quest to minimise avoidable harm.

The National Institute for Health Research Imperial Patient Safety Translational Research Centre developed the report in partnership with Imperial's Centre for Health Policy, in addition to collaboration with, and input from, some of the world's most respected experts on patient safety.

The report will:

- Outline the emerging trends that threaten patient safety over the next 15 years.

- Argue for the need to reduce harm by employing an integrated, system-wide approach, which involves: creating a culture of safety, putting patients and staff at the centre of all interventions and implementing evidence-based policies.

- Introduce the tools available to improve patient safety – including those that have been available, but have remain underutilised, as well as more innovative ones that promise newer ways to reduce harm.

- Highlight the potential of international collaboration for improving safety.

- Synthesise the key recommendations to health system leaders and policymakers.

CHAPTER ONE

EMERGING THREATS TO PATIENT SAFETY

Increasingly complex cases

The demographic shift towards an older population and the increase in multimorbidity add complexity to care delivery and new potential for error and harm.

Increasingly complex care

Advances in the tools available to healthcare are extremely promising, but are also bound to increase the complexity of care and potentially cause information overload for staff. Their introduction must be properly managed – adhering to the principles of interoperability, security and accountability.

Budget constraints

As complexity in care increases, budgets are stagnant or decreasing. Organisations and staff are likely to experience a reduction or limitation in the resources available for quality improvement.

Antimicrobial resistance

Among broader healthcare trends, the rise of antimicrobial resistance is particularly relevant for patient safety; it increases the risk that infections once considered under control could re-emerge, thereby further complicating efforts to limit patient harm.

Many existing issues at the root of patient harm have yet to be solved. Unfortunately, trends in healthcare are likely to increase the risks to safety. This report will focus on four emerging threats: increasingly complex patients; increasingly complex care; budget constraints; and antimicrobial resistance.

The burden that these factors impose on healthcare staff is significant. For example, increasingly complex cases and treatment options will mean that clinicians will face greater cognitive and physical demands, which may compromise performance and decision-making, leading to errors, adverse events, and eventually harm to patients.[23,24]

Increasingly complex cases

The great advances achieved in medicine and healthcare have significantly improved life expectancy, particularly in high-income countries. As a consequence, the size of the elderly, often frail, population has increased. This effect, together with the impact of a number of risk
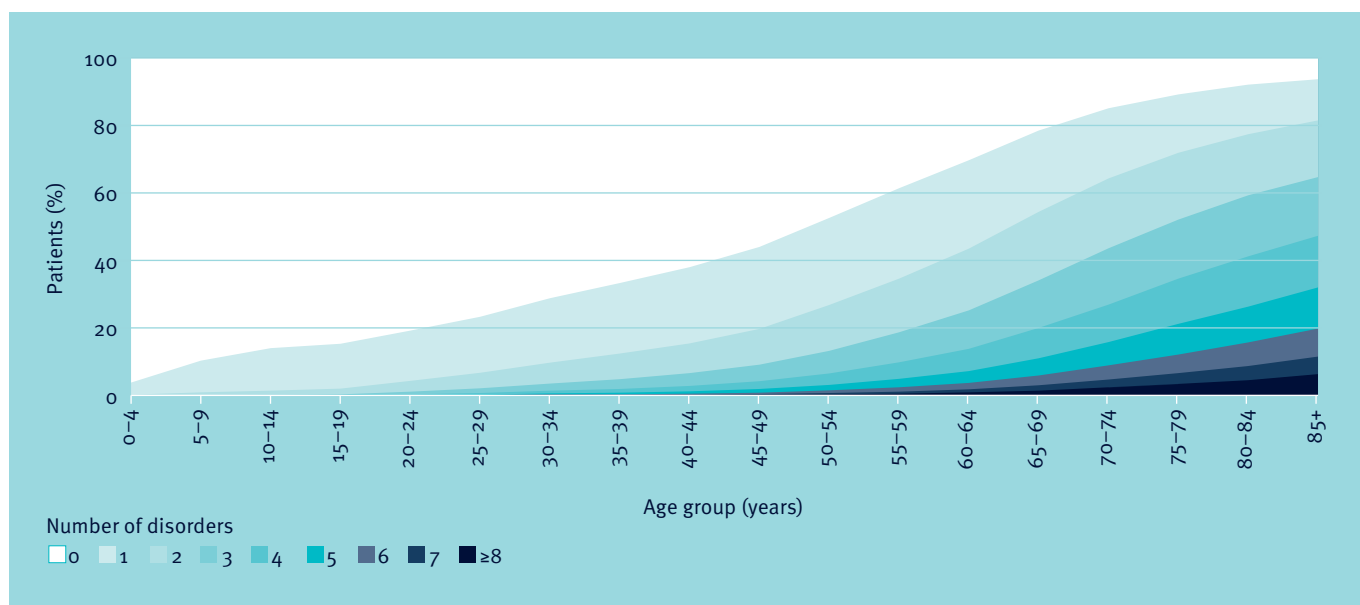

EXHIBIT 3: Patterns of multimorbidity by age group[25] – Image provided by Professor Bruce Guthrie
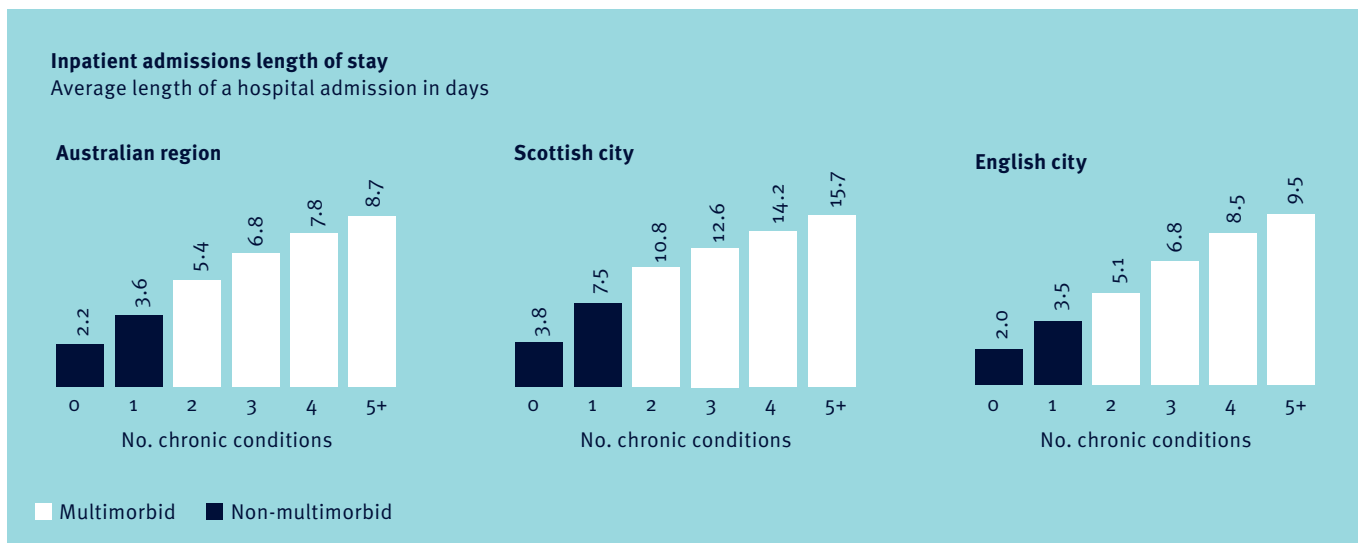
Inpatient admissions length of stay
Average length of a hospital admission in days

Australian region

8.7
7.8
6.8
5.4
3.6
2.2

0   1   2   3   4   5+
No. chronic conditions

Scottish city

15.7
14.2
12.6
10.8
7.5
3.8

0   1   2   3   4   5+
No. chronic conditions

English city

9.5
8.5
6.8
5.1
3.5
2.0

0   1   2   3   4   5+
No. chronic conditions

□ Multimorbid   ■ Non-multimorbid

EXHIBIT 4: Increased length of stay in patients with multiple chronic conditions[29]

■ BOX 1: **Diagnostic error**[34]

Diagnosing a patient's health problem is a complex, yet critical aspect of the care delivery pathway. The goal of the diagnostic process is to reduce uncertainty and work towards precise treatment of the patient's problem without any harm to the patient. A proper diagnosis involves a patient-centric approach: in addition to correctly interpreting a patient's condition, it also consists of accurate, timely communication to the patient to ensure both the patient and the healthcare professionals are involved in the care pathway.

A diagnostic error occurs when there is a failure to establish an accurate and timely explanation of the patient's health problem or communicate that explanation to the patient. Patient harm can occur if a diagnostic error prevents or delays treatment, or leads to wrong or excess treatment to the patient, thereby generating clinical, psychological and financial repercussions to both the patient and the health system.[34]

Diagnostic errors are estimated to occur at high rates within all settings of care. In the US, a conservative estimate of the incidence of diagnostic errors is estimated at 5% within outpatient settings alone.[35] Diagnostic errors are also the most common cause of litigation for General Practitioners in most developed countries. As diagnosis in these settings relies largely on individual clinical decision-making,[36,37] addressing this issue requires careful consideration of how best to support individuals' cognitive tasks.[38,39]

However, given the growing complexity of patients and care delivery, diagnostic errors pose an even greater challenge.

With rising multimorbidity, it will be increasingly difficult to correctly diagnose patients presenting with complex, multiple symptoms, where 'overshadowing', the attribution of important new symptoms to an existing problem, may occur. Poor interoperability of IT systems and weak diagnostic support for healthcare professionals, including a lack of good evidence and integration of diagnostic decision support with electronic health record systems, in the face of complex patient cases add to the challenge.

Measurement of diagnostic error is critical to developing and implementing methods to improve diagnosis. Work on linking health record data across care settings has led to the development of a framework for potential error, but predictive values are low and more research is needed.[41] Not all diagnostic errors lead to patient harm, and many 'missed' diagnoses are simply 'delayed'. However, to truly realise patient safety, near misses must also be prevented. Interventions to improve diagnoses so as to prevent the likelihood of both diagnostic errors and near misses should focus on strengthening all components of the diagnostic process – from the individual clinician, the workforce team, IT systems, organisation, physical environment, tasks and external environment across all care settings. This involves improving the evidence base for diagnosis, understanding the precise cognitive causes of misdiagnosis and combating them with education and training for health professionals, as well as proper design, implementation and efficient use of technology.

factors, such as obesity and physical inactivity, has multiplied the number of patients living with two or more chronic morbidities (Exhibit 3).[23,25]

These patients require more care: studies have found that elderly individuals with multimorbidity require over three times as many primary care and specialist consultations per year compared with elderly individuals without multimorbidity, and are nearly six times more likely to be admitted to hospital.[26–28] If hospitalised, patients with multimorbidity stay in hospital longer due to the complexity of their care, increasing the risk of being subject to an adverse event (Exhibit 4).

Furthermore, the treatment of each condition is complicated by the presence of the others. The complexity of the requisite care causes a greater risk of error. Patients with multiple conditions are at risk of interactions of drugs or other therapies, duplication of tests, potentially confusing self-management and treatment guidelines, and medication or treatment errors.[30]

In particular, polypharmacy – the use of multiple prescription medications – is an important safety challenge for patients with multimorbidities. Due to the presence of multiple conditions, multimorbid patients are often prescribed a wide range of medications.[31] Even when guidelines are followed for each individual disease, there is a chance that the combination of drugs will lead to interactions and adverse reactions, particularly given that guidelines are mostly focused on individual diseases.[32] Complex medicine regimens are

also associated with non-adherence in patients,[33] which could exacerbate other threats to patient safety, for example antimicrobial resistance.

Increasingly complex care

As cases become more complex, the solutions available to address them will become more sophisticated. Medicine will continue to move towards personalisation; genomics will allow a much more accurate understanding of patients' conditions, and the quantity of data and information available will increase exponentially. While these are promising developments, they pose risks and will increase the complexity of care. Compounded by other factors such as antimicrobial resistance, new opportunities for error will emerge.

One area where the challenges are already apparent is IT. The increasing reliance on IT in healthcare can threaten patient safety in various ways.

IT systems are often built in a siloed fashion, designed to meet the needs of a particular setting or practice. Given the complex interactions of patients across multiple care settings, this poses a challenge for interoperability. A lack of cohesiveness and integration across systems can cause breakdowns in care delivery and increase the risk of patient harm. It is therefore essential to ensure that IT systems align with user needs and can communicate with each other.[41]

IT systems can also become a burden for healthcare staff. For example, if routine yet crucial tasks in the

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■ BOX 2: **Breakdowns in care continuity**

The increasing complexity of care, both in terms of cases and delivery, means that patients are exposed to different settings of care and different healthcare professionals during the course of treatment. Lapses in communication between caregivers during patient transitions can cause harm by increasing the risk of medical error during treatment. This can occur during patient handover between caregivers in a single care setting or different settings of care in the health system.[42]

Transition from inpatient to outpatient settings during patient discharge has been identified as an area of risk for breakdowns in communication and potential patient harm. Providers may not clearly communicate medication side effects, when to resume normal activities, or provide adequate plans for discharge or

follow-up.[43] In a five-country study of patients' perceptions of their care, the most commonly reported problems concerned continuity and transition, including provision of information about the purpose of medicines and their side effects, information about danger signals to watch for at home, and advice about resumption of normal activities.[44]

Effective communication between clinicians and patients is critical to avoid breakdowns in care continuity. A meta-analysis showed positive associations between the quality of clinician–patient communications and adherence to medical treatment in 125 of 127 studies analysed and showed the odds of patient adherence was 1.62 times higher where physicians had communication training.[45]

EXHIBIT 5: Slowing growth in healthcare expenditure in OECD countries[48]

care delivery pathway, such as patient data entry, become more complicated, the risk of error increases. The transition to the new technology can also require a significant amount of resources, potentially detracting from care delivery.

Furthermore, as IT systems and electronic health records capture increasing amounts of patient data, new, non-physical types of harm (for example, breaches of patient privacy) will become more prevalent. Before systems are integrated and start collecting patient information on a large scale, their security needs to be assessed and guaranteed.

Budget constraints

The global economic crisis has put considerable pressure on health budgets worldwide with potential detrimental consequences for patient safety and care quality. After years of continuous growth and an increasing share of GDP allocated to healthcare, health expenditures have stagnated, or even decreased, in most OECD countries since 2010 (the average growth rate in the OECD was close to zero in 2010, while it was around 5% in the years preceding the crisis) (Exhibit 5).[46] Some countries experienced drastic reductions in growth rate between the pre- and post-crisis periods and 15 OECD countries actually spent less on healthcare in real terms following the crisis.[46,47]

At the same time, the demand for health and social care worldwide is increasing, driven by economic, demographic and technological changes. This sustained

spending pressure coupled with tighter budgets will likely generate large gaps between healthcare needs and resources available. In the UK, for instance, it is estimated that a 4% annual increase in demand and the stagnation of expenditure growth under current policies will lead to a £30bn funding gap by 2020/21.[49]

Sustained spending pressure coupled with tighter budgets will likely generate large gaps between healthcare needs and available resources; this gap could have large consequences for patient safety

A response to constrained budgets is to try to do 'more with less'. However, this type of approach, if not carefully devised, could have an impact on patient safety in at least three ways: staffing of healthcare professionals; the state of facilities; and other cuts in resourcing.[50]

In a sector as labour-intensive as healthcare, productivity gains typically imply the need to achieve the same levels of outcomes with fewer staff.[51] The result could be increased workload for healthcare personnel and lower staff to patient ratios, with potential consequences for patient safety. There is a relatively robust evidence pool that demonstrates higher nursing workload is associated with higher rates of non-fatal adverse outcomes and higher incidence of medication errors.[43] Longer working hours and fatigue are likely to have an impact on care quality and patient satisfaction.[23,52,53]

Constrained budgets can also impact the structural features of the healthcare system. For instance, reduction in care capacity may reduce access. Insufficient investments in physical maintenance may also have implications for patient safety.

Lastly, a widespread measure to address fiscal pressures is to increase user charges and change eligibility for some treatments to limit access, which may disrupt care continuity. Cuts may also involve taking resource away from activities such as infection prevention and control that are not considered high priority, which may have an impact on infection rates.[54]

More broadly, fewer resources for healthcare could result in fewer resources for quality improvement. This is particularly problematic for patient safety, where

investment is badly needed – as discussed, maintaining the status quo is not acceptable.

Antimicrobial resistance

Hospital-acquired infections present a significant challenge in patient safety, and rising rates of antimicrobial resistance further complicate the issue. Antimicrobial resistance is the ability of infectious organisms, including bacteria, to survive the agents designed to kill them. It is a natural process arising from selective pressure in the environment among bacterial species. Randomly arising genetic mutations or exchange of genetic material can also allow a bacterium to acquire resistance to an antibiotic and render treatment ineffective.[55]

In recent years, the challenge of antimicrobial resistance for the healthcare system has reached a rate that puts patient safety at risk by making infection control more difficult.

The number of deaths due to antimicrobial resistance has nearly reached half a million per year worldwide, with a majority occurring in the developing world.[55]

The US Center for Disease Control and Prevention estimates at least 23,000 deaths from resistant infections occur each year in the US.[56] Meanwhile, in 2007, 25,000 deaths were attributed to antimicrobial infection in Europe.[57] The numbers are expected to be much higher in developing regions where data is scarce and the use of antibiotics is largely unregulated. If current trends continue, the *Review on Antimicrobial Resistance* estimated that ten extra million deaths will be due to antimicrobial resistance by 2050 – higher than any other single major cause of disease, including cancer and diabetes. By the same year, antimicrobial resistance is also estimated to cumulatively cost US$100 trillion globally.[58]

The emergence of antimicrobial resistance is rooted in the overuse of antibiotics in humans and animals, the slow progression in the development of new antibiotic agents, and the increasingly mobile global population.

Health systems are overusing, misusing, and inappropriately prescribing antibiotics (Exhibit 6). In humans, research shows that one additional daily dose of an
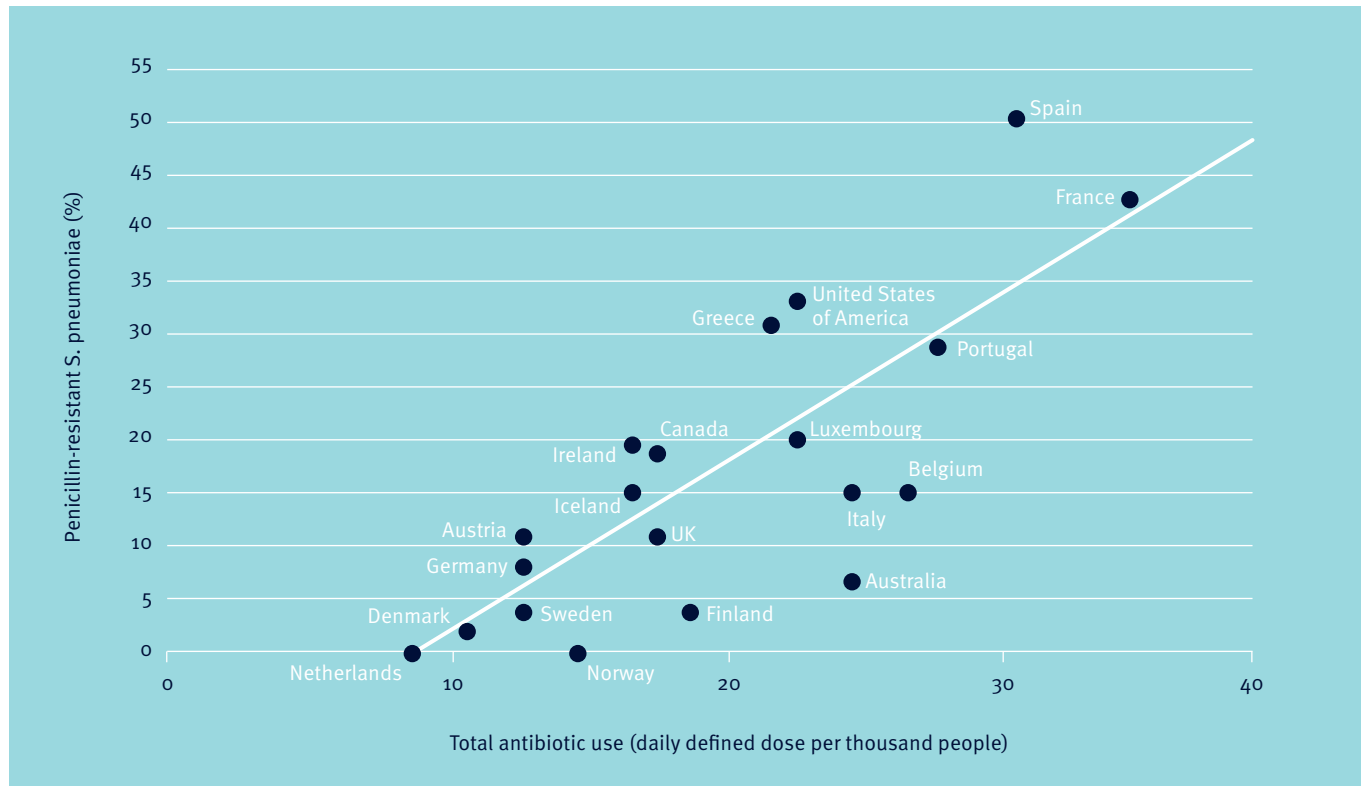
EXHIBIT 6: Correlation between antibiotic use and resistance[55]

antibiotic per thousand people increases the prevalence of resistance by nearly 1.5%.[59] Worryingly, the problem is pervasive: it has been reported in various healthcare settings, from primary care to surgery,[60] and in both developed and developing countries.[61,62] In animals and in the US alone, it is estimated that more than 70% of medically imported antimicrobials are used in livestock; globally, the amount consumed is estimated to at least match that of human consumption. The overuse of antibiotics in farming increases the risk of exposure to drug-resistant strains through direct human contact, the food chain and animal excretions.[58]

Health systems' ability to combat increasingly resistant strains of bacteria is limited by the state of pharmacological pipelines for antibiotic development. Progress in the development of new antibiotics has declined over the past 25 years, and nearly 80% of pharmaceutical companies that were previously involved in research and development of new antibiotics have halted their efforts.[55] Underlying reasons for halted research efforts reside with the commercial uncertainty of developing a new antibiotic, which is unlikely to become a first-line therapy until the end of its patent, thereby severely limiting its commercial attractiveness.[58]

Lastly, the increase in international travel has resulted in an increasingly borderless world. Resistance that develops in one region of the world can quickly spread globally (Exhibit 7).

Policymakers need to take decisive actions to tackle antimicrobial resistance. The Forum on Antimicrobial Resistance of the World Innovation Summit for Health has identified 15 priorities in five critical areas: awareness; antibiotic conservation; sanitation, hygiene, infection prevention and control; surveillance and monitoring; and research and development (Exhibit 8).

Innovation and regulation in antibiotic prescribing, new antimicrobial agents and care delivery processes are key to tackling the threat from resistance. There is an urgent need to establish and regulate measures of prescribing in the global population. A delicate balance is required here however, as antimicrobials are life-saving drugs with important effects on public health, especially in developing countries, where access is often limited.[58] As such, the global policy community must look to ways in which access for those who require it is maximised while excess or inappropriate use is minimised in other contexts. This will require first and foremost, an increased awareness of the threats of antimicrobial resistance, followed by stewardship and commitment across all actors, including veterinary medicine and agricultural sectors. Within a healthcare setting, antimicrobial stewardship should involve infection control, monitoring therapeutic drug use, and establishing protocols for best practices, among other measures.[63] With infection control and the lives of patients under threat, health facilities will also have

KLEBSIELLA PNEUMONIA CARBAPENEMASE	2000	2003	2005	After 2005
	Resistence first found in North Carolina	Spreads rapidly through New York	Found widespread in Israel	Spreads to Italy, Colombia, Sweden

NEW-DELHI METALLOBETA-LACTAMASE	Before 2008		2009	After 2010
	Resistence first found in India		Discovered in Sweden	Discovered in the UK and Canada
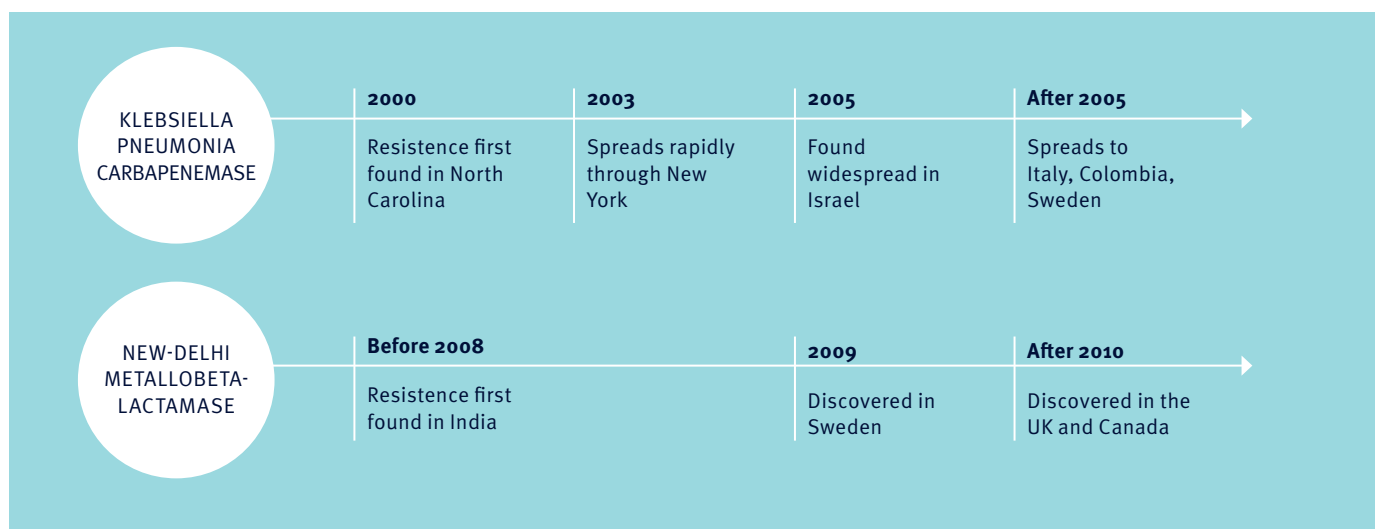
EXHIBIT 7: Spread of resistance across countries[55]

1. Raise awareness among politicians, scientists, hospital administrators, healthcare professionals, agricultural producers and the community

12. Increase the price
13. Extend intellectual property or patent protection
14. Decouple sales from R&D
15. Guarantee income to innovators

9. Standardise guidelines for data gathering
10. Coordinate national and regional interpretation and sharing of sales and usage data
11. Develop a coordinated global monitoring programme

RESEARCH AND DEVELOPMENT

ANTIBIOTIC CONSERVATION

AWARENESS

SURVEILLANCE & MONITORING

SANITATION, HYGIENE, INFECTION PREVENTION & CONTROL

2. Stronger regulation and mechanisms to enforce conservation
3. Diagnostics and treatment protocols to enforce appropriate use
4. Awareness-raising for professionals, patients and consumers

5. Establish infection control protocols and tracking mechanisms at the healthcare level
6. Develop and enforce sanitary regulation for the food industry
7. Educate the community
8. Map progress on implementation of international prevention programme

EXHIBIT 8: Five fronts of action to combat antimicrobial resistance[55]

to implement stringent infection prevention measures, particularly to screen patients for resistant infections and isolate them in due time. Lastly, new commercial models will be required which reduce the commercial uncertainty associated with new antibiotic entities and encourage increased and earlier investment.[58]

INTEGRATED APPROACH TO PATIENT SAFETY

Systems-based

The approach to improve patient safety should aim to transform the whole system of care delivery, using the systems engineering approach as a model.

Focused on culture

Transforming the culture of an organisation, while difficult, is a necessary condition for lasting improvements in patient safety. Leaders need to balance the goals of avoiding blame and negativity with ensuring accountability.

Patient- and staff-centred

Patients and staff should be actively involved in designing solutions to the problem of harm, rather than providing surface-level or superficial input.

Evidence-based

As much as possible, interventions to improve patient safety should be tested and validated. However, the evidence in this area is still evolving. Health systems are tasked with building this evidence base while also improving safety, even where evidence on how to do so is sparse.

The threats to patient safety are increasing, but they can be halted or their impact lessened by proactive initiatives. Recognising their importance is a first step in the efforts to improve safety. Too often responses have been piecemeal, focusing on one issue and deploying an isolated solution.[21] Health systems need to avoid repeating this mistake and instead employ an approach that is systems-based, focused on culture, patient- and staff-centred and evidence-based.

Systems-based

A system is an operating mechanism where the sub-parts work jointly towards achieving an outcome, and the success of the system is dependent upon this collaboration. In patient safety, these sub-parts include provider organisations across different care settings, regulators, policy-makers, and patients.[64]

The view that addressing systems, rather than individuals, will improve patient safety is first mentioned in the Institute of Medicine's *To Err is Human*[1] and reinforced 15 years later in the National Patient Safety Foundation's *Free from Harm*.[21] Successful examples from other complex industries suggest that to reduce harm, healthcare will need a large-scale change programme, integrating multiple factors.[64] The systems engineering approach can be a valuable blueprint, and its application in healthcare will require the following elements:[64]

- Consistent commitment by the leadership.

- Clear goals and definitions of success.

- Data to prove that change is needed and to measure progress and improvement.

- Incentives for meaningful participation and success.

- Shared accountability and openness, focusing on system problems rather than individual mistakes, and learning rather than blame.

- Well-defined processes for change (often including patient safety alerting systems).

- Education about goals and approaches to change.

- Multidisciplinary teams, including stakeholders in addition to the primary caregiver, with a focus on frontline staff and patients.

- Focus on communication and collaboration.

- Sustainability plans.

Considering patient safety as a system problem also means that action will be required at all levels: local, national, and global. The local level is responsible for the execution of interventions, ensuring that they are locally relevant and effective. The national level should focus on the operational design and development of health system attributes and policies that support safer care. This is not only the introduction of regulation, but also the coordination of all health policies to ensure that they support patient safety and mediate the impact of any new threats. Finally, the global level should focus

on coordinating actions and sharing knowledge across national and local organisations.

A systems-based approach to patient safety will require action at all levels: local, national, global. System 'integrators' will be essential in linking all sub-systems of the safety solution

Addressing the roles of sub-systems is only a first step; large-scale disruptive change requires 'integrators' for each element of patient safety (for example clinical, legal, regulatory and technical systems) to create an overall integrated system.[64] An example of successful system integration from outside the healthcare industry is in defence, where the idea was first derived in World War II. At the beginning of the war, naval ships were particularly vulnerable to attack from aircraft because weapons on board needed to be fired in close proximity to attacking planes. New weapons capable of protecting ships from aerial attacks required extensive time and manpower to operate. To address this issue, scientists, engineers, technicians and users developed the 'proximity fuse' – a device that detonates explosives automatically and vastly reduces the time and effort required to operate weapons. This example demonstrates how technology is only one piece of the puzzle. Working with users and considering the constraints of the environment is key to developing effective solutions.

Focused on culture

Effective organisational culture is essential to the success of new patient safety initiatives. In healthcare, the term 'culture' is often used to capture what it feels like to work in, or receive care from, a particular organisation. Specifically, safety culture can be defined as the individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management.[68]

Embedding the goal of providing safe care in the culture of the organisation is a prerequisite to achieving lasting improvement. However, transforming culture is a complex endeavour. In trying to do so, health system leaders should address two issues:

- Clearly defining and measuring culture.

- Balancing a positive culture with the need for accountability.

Culture is often seen as a nebulous and non-quantifiable concept even though it can be defined — and thus measured and improved. Historically it has been under-researched and slow to emerge as a root cause of adverse events.[69] This lack of attention to culture is problematic, given the role it plays in fostering safety. To improve culture, however, we need to understand what a good patient safety culture looks like and how to assess and monitor it.

BOX 3: **Life science partnerships between government and industry**

At the 2016 Word Economic Forum in Davos, 85 life science companies from 18 countries issued a joint Declaration on Combating Antimicrobial Resistance.[65] It called on governments to work in concert with industry to develop new antibiotics and diagnostic solutions to curtail the spread of antimicrobial resistance. The declaration echoes recommendations in the 2013 WISH Antimicrobial Resistance report,[55] the strategic objectives of the 2015 World Health Organization Global Action Plan,[66] the G7 Berlin Declaration on antimicrobial resistance[67] and emerging findings from the review of antimicrobial resistance by economist Jim O'Neill, commissioned by the UK's prime minister.[58] All of these efforts highlight the need to address the market failure observed in antibiotic development through the creation of new incentives and structures to encourage collaboration between the public and life sciences sectors.

There are several examples of successful cross-sectoral partnerships, such as the £10 million Longitude Prize – open to members of all sectors for the development of novel diagnostic tools for antimicrobial resistance – or the UK-China Business Forum joint fund of £9 million to support basic research on antimicrobial resistance. Both the O'Neill review and Davos declaration propose larger-scale public-private partnerships, akin to those seen in other areas of biomedicine. Successful examples include the EU's Innovative Medicines Initiative joint programme with industry on antimicrobial resistance, New Drugs for Bad Bugs, the US Medicines for Malaria Venture, and the Global Alliance for Vaccines and Immunization (GAVI) to accelerate vaccine production.[55]

Effective organisational culture is essential to the success of new patient safety initiatives. Embedding the goal of providing safe care in the culture of the organisation is a prerequisite to lasting impact

Validated tools to measure safety culture are available and capture a wide range of indicators regarding how staff members feel about their organisation. Examples include the Safety Attitudes Questionnaire and the Hospital Survey on Patient Safety.[70] Expanding the use of these tools is essential to ensuring a culture of safety and, thereby, the success of patient safety interventions. In the future, it will be important to extend these tools to patients as well, to enable them to contribute their opinions on safety culture in a structured way.

Organisations should foster a positive patient safety culture, encouraging honest disclosure of information and demonstrating a sincere interest in rectifying the problems that had led to harm.[71] Other key features of a positive safety culture include non-punitive responses to error, effective teamwork, both within and across teams, and a transparent communication style. This entails not only reporting when things go wrong, but also feedback and openness around error, and providing sufficient information about patients' conditions across team members to ensure safe handovers and coordinated care.[72]

Despite broad support for positive approaches, safety cultures that rely on fear and blame are well documented across health systems.[73] Staff perceive blame from their peers, managers, even themselves, and this has been associated with apprehension of reporting harm and potential problems, ultimately stifling improvement.[71] As the National Advisory Group on the Safety of Patients in England concluded "in the vast majority of cases it is the systems, procedures, conditions, environment and constraints they [staff] face that lead to patient safety problems",[74] with reference to the tragedies of the UK Mid Staffordshire events.

While avoiding punitive responses in cases of error, a positive safety culture should ensure accountability, particularly in cases of wilfully negligent behaviour.[75] This is a difficult trade-off to navigate. One potential approach is the introduction of 'Must Do' lists to pre-empt error and easily identify if staff have been dismissive of basic best practice.[76] Two key items on these lists, for example, are adherence to hand hygiene standards and mandatory influenza vaccinations. These

LEVELS OF ENGAGEMENT

EDUCATION

COMMUNITY HEALTH

Engagement of the public before they access the healthcare system (for example, "developing household capacities to stay healthy, make healthy decisions and respond to emergencies," and making informed decisions about when to seek healthcare from professional(s) or after access, when they are no longer under the direct care of a healthcare worker.

Relationship between healthcare professionals, patients and families in the context of individual care for a health condition (for example, shared decision-making, self-management of chronic conditions).

DIRECT CARE

ORGANISATIONAL DESIGN AND GOVERNANCE

The involvement of patients and families in influencing the way the organisation provides care (for example, patient and family advisory councils, patient and family partners for process improvement).

The involvement of patients and families in influencing public agencies' activities related to health or healthcare (for example, patient and family involvement in programme development, setting funding priorities).
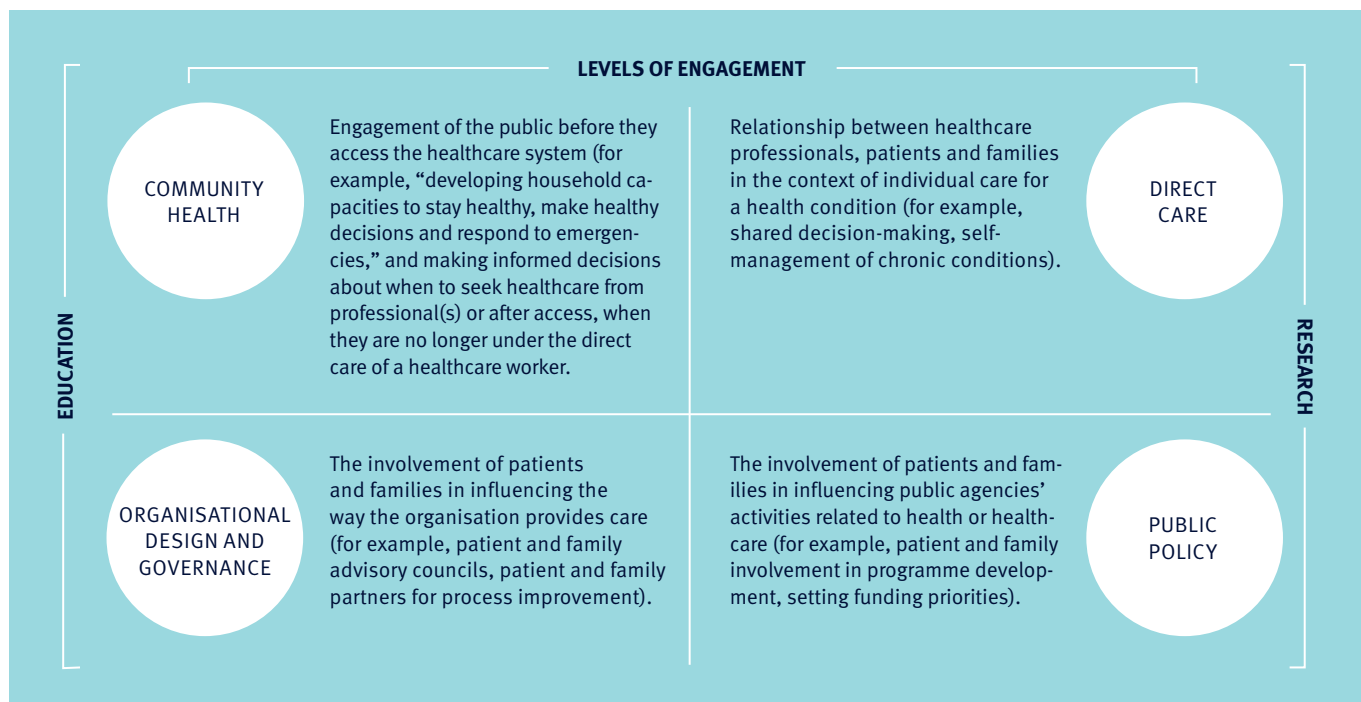
PUBLIC POLICY

RESEARCH

EXHIBIT 9: Levels of patient and carer engagement and underlying enablers[81]

procedures would eliminate vast amounts of harm to patients and would do so without placing blame, but rather by putting the onus on hospitals to ensure staff are accountable for these simple, high-impact infection control interventions.[76]

Patient- and staff-centred

With regard to patient safety, too often patients and staff are simply seen as either victims or causes of the problem. A shift in mindset is necessary to reposition both groups as part of the solution. Person-centred care refers to a style of health service delivery that places the needs and values of patients, carers and staff at the forefront and uses feedback from these groups to drive quality improvement. All of these stakeholders can be victims of patient safety incidents and feel the acute consequences of harm. Their eyewitness accounts should be considered and acted upon to mediate the impact of harm and prevent harm in the future. Despite gaining acceptance, this mindset is still not taken as seriously as it should be.

An increasing body of evidence demonstrates positive associations between patient experience and safety.[77] This primarily relates to involving patients, at all levels of care, in order to promote mutual attention to safety (Exhibit 9). Therefore, providing a better experience to patients is likely to improve treatment adherence and reduce costs caused by unnecessary admission to hospital[78] and malpractice claims.[79,80]

Evidence-based

When the stakes are high and resources are scarce, as is the case in healthcare improvement, making decisions based on reliable evidence is crucial. However, the scope and robustness of the evidence available in patient safety is limited.

Healthcare quality improvement, as a field of study, is newer than other biomedical fields. Moreover, the efficacy of interventions in this area is not as easily tested at the patient level when compared to other therapeutic measures.[82] For instance, many aspects of safety are not suitable to randomisation on the basis of practical and ethical considerations, thus preventing the use of randomised trials.[83]

Research should be seen as the R&D engine of the patient safety movement. It will provide the ideas for the next frontier of solutions

The implications for policymakers and health system leaders are clear. Firstly, they must strike the right balance between evidence and action. Implementing only initiatives that are tested and validated is unlikely to achieve the desired pace of improvement. Seeking the advice of experts in the field and reviewing the impact of similar interventions can help mitigate risks of interventions which lack strong evidence.

Secondly, a culture of learning is needed. This process will be iterative, consisting of a cycle of evaluation, feedback, learning and revision of the interventions.

Finally, there is a need to generate more robust evidence to fill the gaps. Existing sources of information, such as incident reporting systems, should be leveraged more effectively to generate learning. Root Cause Analysis (RCA) and Failure Modes and Effects Analysis (FMEA) are two methods in wide use for this purpose. RCA retrospectively identifies what went wrong during an adverse event and seeks consensus on the underlying determinants of the incident. FMEA aims to prospectively prevent patient harm by predicting potential failures. Systems are then re-engineered to reduce the likelihood of harm, involving a broad analysis of each aspect of the system, including its functioning and procedures, and components and their interactions.

More original research is also needed. For example, despite more than a decade of policy attention, there is a lack of evidence on the cost effectiveness of patient safety interventions.[84] Healthcare providers and governments have implemented strategies to improve patient safety despite considerable uncertainty about the relative economic value of alternative options.

More broadly, research should be seen as the research and development engine of the patient safety movement. It will provide the ideas for the next frontier of solutions. For this reason, a global effort to define the key future priorities should be undertaken.

THE PATIENT SAFETY TOOLBOX FOR THE NEXT 15 YEARS

Regulation and governance

Regulation, while necessary and effective, must be balanced in its application. Over-regulation can stifle innovation and impose additional costs. Effective governance structures will be critical to ensure accountability.

Leadership

For an entire health system to become safer, everyone must be empowered to take a leading role against harm. Leadership in improvement efforts should come from all levels of an organisation as well as from patients.

Education and training

In patient safety, education and training remain largely superficial. The strength of curricula and delivery methods are important factors, but health systems should also consider issues of training availability, access to training opportunities, and the ability to translate learning from classroom to practice.

Data and information

We cannot improve safety if we cannot measure harm accurately. Traditional tools like incident reporting should be strengthened and their outputs used more effectively for learning. The proliferation of healthcare data will create new opportunities to understand harm and support the development of preventative solutions. However, it is critical that data is distilled into an understandable and useful format, rather than becoming a source of increased cognitive burden.

Digital health

Given their potential to improve the effectiveness of existing interventions, emerging digital solutions should become a core component of the patient safety toolbox. However, their effectiveness and potential associated challenges should be carefully evaluated.

Behavioural insights and design

Improving safety is about changing behaviour. Applying lessons from behavioural insights and design can help to bridge the gap between intention and actual practice, thereby rendering other interventions in the toolbox more effective.

Health system leaders have a broad range of options to influence patient safety. This chapter highlights six areas that show great potential to reduce patient harm. The list is by no means exhaustive, but includes tools which have a strong evidence base demonstrating their effectiveness as well as some promising innovations in the field.

Regulation and governance

Regulation and governance help to institutionalise patient safety as a priority, establish minimum standards, hold providers accountable, and enable enforcement actions, if necessary.

While effective regulation for quality and patient safety varies across settings, some common characteristics include:[85]

- Proportionality: regulators should intervene formally only when necessary.

- Consistency: the enforcement of regulation should be fair and standardised across all scenarios.

- Focus: interventions should aim to resolve the root causes of the issue at hand.

- Transparency: regulators and the regulatory process should be clear to all relevant parties.

- Accountability: regulators must be able to justify decisions.

- Agility: regulation should anticipate future change, rather than prevent repetitive failures.

The effectiveness of patient safety regulation and governance is maximised when it is integrated, horizontally and vertically, with other regulatory frameworks. Horizontal integration refers to incorporating the mandate for safety under the accountability frameworks

for all regulatory bodies. For example, bodies overseeing the approval of pharmaceuticals, medical devices and providers should absorb the safety agenda in their own right. Vertical integration refers to linking the health system's safety objectives with organisational accountability. For example, making hospital boards accountable for patient safety outcomes has been found to be effective in reducing patient harm.[86]

Regulation and governance help to institutionalise patient safety as a priority, establish minimum standards, hold providers accountable and enforce actions if necessary. However punitive measures are more often destructive rather than effective

While punitive measures are an option to promote safer care, they are more often destructive than effective. Moreover, alternative levers exist, such as reimbursement schemes linking provider income to organisational performance.[87] However, the lack of availability of robust, evidence-based safety indicators that can be tied to reimbursement and are suitable for use in all health system contexts is a concern.[88]

Regulation and governance should also be deployed carefully, as in some cases they may hinder innovation. Stringent and uncertain regulatory environments can increase the cost of compliance, deter firms from innovating, and increase the probability of failure.[89] While regulation holds great potential to safeguard quality of care, regulatory measures instituted in the wake of high-profile failures have in many cases failed to address the root causes of patient harm[90] and actually weaken the culture of safety, which depends crucially on openness and transparency.

Lastly, government and regulatory institutions are not infallible; governing bodies and processes can fail and have done so in the past. Therefore, the type of regulation, as well as governing processes, should be carefully considered prior to implementation.

Leadership

The traditional top-down conception of leadership is important in the effort to reduce patient harm: without commitment from policymakers and senior executives,

meaningful and sustained change is unlikely. On the other hand, the elimination of harm also requires collective leadership by all individuals in the health system, including patients (Exhibit 10).

Political and health system leadership is vital to ensure the political and fiscal commitment of a health system to patient safety, determine the system's goals and culture, and establish reliable regulatory and governance frameworks.

Further to political leadership, **organisational leadership** helps to achieve system-level objectives by translating them into the values and goals of a health service organisation. Hospital board practices, for example, have shown to improve institutional care quality.[91–94]

As clinical staff are responsible for care delivery, **clinical leadership** is an essential component of the strategy to reduce patient harm. Further, evidence suggests an association between clinical leadership and positive organisational performance.[95–97] Encouraging clinical leadership requires engaging junior clinicians and dismantling embedded clinical hierarchies. Such hierarchies discourage clinical staff, particularly junior clinicians, from speaking up to prevent or report adverse events.[98–100]

A comprehensive model of leadership should also include **patients and their carers**. While their involvement

POLITICAL/ HEALTH SYSTEM LEADERSHIP

ORGANISATIONAL LEADERSHIP

CLINICAL LEADERSHIP

PATIENT LEADERSHIP

EXHIBIT 10: Four levels of leadership for patient safety

Executive and Board Leadership

1. Placing high organisational priority on quality and safety, and setting strategic goals which reflect this.
2. Removing blame and encouraging a culture which seeks to identify and prevent errors.
3. Supporting the use of measurement and the use of this information to realign strategic goals.
4. Reconfiguring internal structures and processes to increase board and executive oversight of quality and safety outcomes.

Clinical Leadership

1. Demonstrating personal qualities such as self-awareness and acting with integrity.
2. Working effectively with others, e.g. the ability to work in and lead teams and build and maintain relationships.
3. Efficiently managing people, resources and performance.
4. Improving services, particularly quality improvement.
5. Setting direction by critically evaluating the available evidence and evaluating impact of decisions and policies.

EXHIBIT 11: Attributes of effective leadership for patient safety[86,101]

is not always feasible or appropriate, there are many ways in which engaged service users can contribute to improving care quality. Health systems should take a variety of steps to ensure that patients and carers are able to act as stewards in the effort to reduce harm. This requires, first and foremost, a paradigm shift in how the health service approaches patient and carer engagement. Instead of aiming to achieve lay compliance with clinical guidance, the objective should be to build skills to support co-decision and co-delivery through effective educational interventions targeted at patients and carers. This will require, at all levels of the organisation, openness to feedback from patients and carers about their experience in care.

Education and training

As standards of care evolve and care delivery becomes more complex, education and training can equip staff and health service users with the knowledge, skills, attitudes, and behaviours needed to make care safer. Effective education and training for patient safety require attention to four factors:

1. Appropriate training is continuously **available** for a wide range of participants.

2. Participants have the time and capacity to **access** and internalise training.

3. Training curricula are **high-quality**, locally and clinically relevant, and delivered effectively.

4. Participants, having received training, are able to **translate** learning into practice.

While there has been momentum to increase the **availability** of education and training for patient safety since *To Err is Human,*[102] the provision of formal, high-quality education and training is still inconsistent across health systems and clinical professions.[103]

Although training programmes are usually available to health service providers, other participants could also benefit from training.[102] This includes patients and carers, and also non-clinical staff. For example, hospital catering staff can monitor patients' adherence to medicine regimens during meal service.[103]

Training interventions should also be made available at appropriate times.[103] For clinical and support staff, this means patient safety education should start early and continue throughout their careers. For patients and carers, continuity will parallel their healthcare journey: prior to, during, and following care.[103]

However, training programmes are of little use if intended recipients cannot **access** them. Clinical participants often forgo formal training due to workload and because time is not formally allotted for training courses.[103] These conditions may also disrupt informal learning. During service delivery, for example, clinical mentors and students may be unlikely to realise opportunities for teaching and learning.[103]

Logistical barriers can also contribute to staff foregoing training. Clinical staff having to travel far distances to attend training are less enthusiastic about attending.[103] To address this issue, many health systems are exploring the use of e-learning. Although promising, these solutions create a risk of programmes becoming 'tick-box' exercises and of reducing important team-based interactions.[103] For patients and carers, accessible training means that the information is delivered in a way that is easily understood by lay people.[103]

Training programmes need to be of high **quality** to be impactful. The quality of education and training programmes depends on three dimensions: content, delivery method and feedback. The WHO Patient Safety Curriculum is the current gold standard for patient safety education.[102] Although the evidence is still limited, simulations which realistically replicate clinical scenarios, and team-based training appear to be effective delivery methods.[104–111] A survey of clinical staff who have received training suggests a similar preference for simulations and discussion-based team training

(Exhibit 12).[103] Given the restricted pool of evidence, the collection, analysis and sharing of data in this area will be important to guide the design and implementation of future interventions.

Ultimately, training will be of limited value if participants are unable to **translate** lessons into practice. In this regard, several barriers related to the lack of an improvement-focused culture exist: entrenched hierarchies, the existence of a culture of blame, and fear of speaking out. In these contexts, individuals feel powerless to speak up against unsafe practices, despite the effectiveness of the training they received.[103] These considerations reinforce the importance of education and training as part of a systematic approach to patient safety.

Data and information

Data and information are critical for patient safety; what cannot be measured cannot be improved. However, measurement in patient safety is not straightforward, it requires sophistication in interpreting results. To this day, most health systems do not know exactly how much
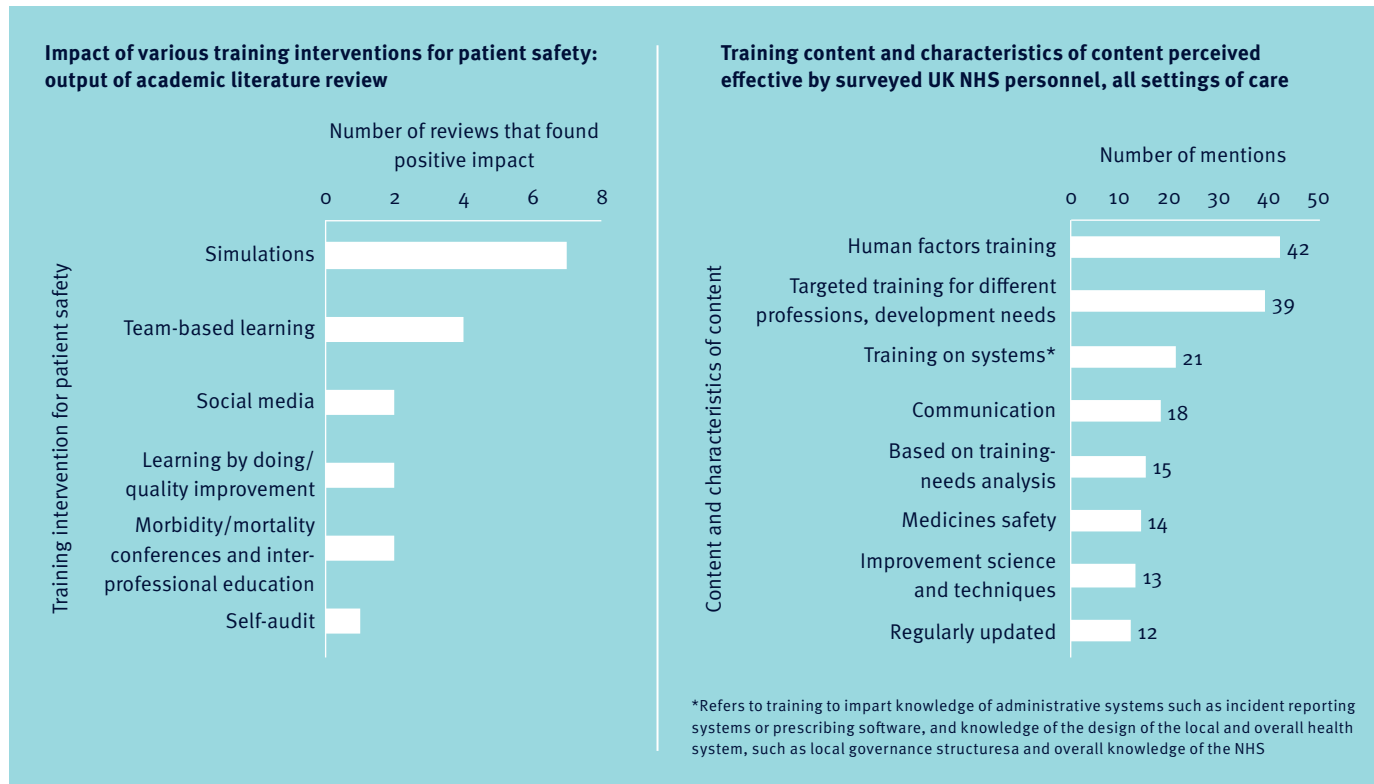
Impact of various training interventions for patient safety: output of academic literature review

Number of reviews that found positive impact

Training content and characteristics of content perceived effective by surveyed UK NHS personnel, all settings of care

Number of mentions

Content and characteristics of content	Number of mentions
Human factors training	42
Targeted training for different professions, development needs	39
Training on systems*	21
Communication	18
Based on training-needs analysis	15
Medicines safety	14
Improvement science and techniques	13
Regularly updated	12

*Refers to training to impart knowledge of administrative systems such as incident reporting systems or prescribing software, and knowledge of the design of the local and overall health system, such as local governance structuresa and overall knowledge of the NHS

EXHIBIT 12: Effective training interventions – evidence and perceptions[103]

I
DO NOT
REPORT
BECAUSE
…

Cause of incident is already clear

Incident was not preventable

Reporting process is too complicated

Not a priority

Fear of negative response by co-workers

Fear of viewed as incompetent by colleagues

Unaware of whose responsibility it is to report

Lack of belief that reporting system will lead to a change

Additional administrative task

Interrupts work process

Lack of anonymity and confidentiality

Incident unlikely to happen again

No major patient consequences

Fear of punishment

Incident has already happened before and has already been reported

Lack of clear definition of what to report

Too time-consuming

Fear of disciplinary action

Workload

Lack of feedback

I
REPORT
BECAUSE
…

I value the importance of patient safety incident reporting

I do not fear being punished

I am rewarded for reporting

I know what and how to report incidents

I work in an organisation that has a blame-free culture

I value the feedback received

I learn from reporting

There are clear guidelines and policies for reporting

The process of reporting an incident is simple

The patients have been seriously harmed

The system is anonymous and confidential

There is a clear policy in place to reporting incidents

I feel it is my duty to do so

The system is accessible

EXHIBIT 13: Barriers and facilitators to reporting[114]

harm they cause patients. Many of the most widely used data sources and measures rely on voluntary (incident reporting) or subjective (mortality due to poor care) inputs. Further, health systems that invest in improving patient safety should expect to see an increase in the number of recorded adverse events in the short term. This should not necessarily be interpreted as a deterioration in quality of care. It could be simply the result of improved awareness and transparency in the system.

One of the most widely used forms of measurement is incident reporting, which is designed to capture accounts of adverse events from frontline staff. In principle this unique perspective can help to promote accountability, improve patient safety culture and contribute to collective learning.[112,1] However, incident reporting is only useful if data is consistently entered into the system and learning is continuously derived. Unfortunately, as little as 5% of patient safety incidents, even in well-established systems, are actually reported.[113] The barriers and facilitators of reporting have been studied extensively (Exhibit 13). Though such systems produce data that can be used for improvement, lessons derived from these systems are often limited. For incident reporting systems to be useful, other cultural factors need to be in place to effectively analyse it, learn from it, and take informed action.

Health systems also employ additional measurement approaches, including patient or staff surveys, chart/record reviews, complaints analysis and direct observation.[115] In particular, user complaints should be acknowledged and taken seriously, as they are often the only reporting channel available to patients and carers.

Analyses of avoidable mortality, or mortality due to poor care are also widely used to assess harm caused to patients. Case note review at the provider level is typically used to score deaths on a preventability scale, but there is no global consensus around the proper approach. Case note reviews might therefore be more useful in learning how to improve care, rather than producing a robust indicator.

It is crucial that measurement is not only retrospective, assessing what occurred in the past, but also prospective, evaluating risk, preventing error where possible, and enabling learning. For instance, implementing risk assessments around operational processes can identify potential threats and help prioritise actions to prevent harm from occurring.[115,116]

■ Box 4: **Attributes of effective incident reporting**

Incident reporting has the potential to be a useful, person-centric means of gathering frontline, and possibly patient, feedback. In order to optimise its effectiveness, it will be important to ensure that systems are built with four considerations in mind:

1. Having the proper resources and organisational readiness to implement an incident reporting system.

2. Inviting uptake and usage through clear instructions, collaborative development and user-centred platforms.

3. Capturing high quality data via sensible and straightforward questions and taxonomies.

4. Generating information for improvement through feedback loops and presentation of the data in accessible ways.

More valuable information on patient safety is likely to become available due to increasing volumes of data from sources such as digital patient records, financial systems and registries, and from advances in analytical techniques. The fields of big data and analytics are rapidly evolving and are expected to deliver great benefits to healthcare.[117,118]

In patient safety, big data can be used to identify the cause of patient safety events, for example by analysing drug interactions from electronic health records. Health systems can use administrative data to benchmark performance and identify potential best practices. Providers can also use big data to uncover inherent safety risks in a specific patient population and tailor interventions accordingly. With the threat of antimicrobial resistance on the horizon, these surveillance mechanisms may allow timely identification and action towards infection control. Lastly, effective use of data can also generate a continuous feedback loop that enhances learning, also known as a 'learning health system'.[119,120]

However, to realise these benefits, the vast amount of available data needs to be translated into usable information. Health systems need to take into account four attributes of data: volume, velocity, variety, and veracity.[117] The first two are concerned with the sheer quantity of data created by a health system on a daily basis, including the infrastructure and resources required to store and process it in real time. Variety refers to the diverse formats in which

datasets are stored, including unstructured data such as free text (commonly found in non-digitalised doctors' notes). Finally, veracity, or data assurance, is crucial when making important decisions based on big data. In addition to accurate analytical methods, veracity depends on data capture and coding quality. Better use of clinical informatics approaches such as domain-specific ontologies, restricted code sets and closer ties between informatics specialists and clinicians are essential.[121]

■ Box 5: **Accelerating the use of big data in healthcare**

Devices like smartphones and computers have the potential both to enhance safety and to collect incredible amounts of data. Health systems can use data collected through these devices to monitor public health issues, predict care needs and conduct interventions in novel ways and at non-traditional points along the care pathway.

The opportunity is not limited to high-income countries; a programme called Data for Development uses mobile phone data to analyse population mobility. This helped understand HIV/AIDS patterns, and has the potential to help monitor the spread of other communicable diseases.[124]

To do this in a quick and secure way, regulation and analytical techniques need to develop in a coordinated way. The World Innovation Summit for Health's forum on Big Data in Healthcare recommended partnerships between private companies, institutes of excellence and clinicians to foster collaboration, training and knowledge sharing in big data science. Furthermore, it emphasised the importance of regulators permitting open access to non-sensitive data and developing secure portals for sensitive data that, if analysed and used carefully, would be helpful to patients.[64]

Finally, to capture the value of big data in healthcare, health systems need to ensure that researchers and healthcare professionals have access to data. Unfortunately the availability of large healthcare datasets, especially those linked across different care settings or providers, is still limited.[122,123] Policymakers should consider the variety of levers at their disposal to advance access to healthcare data,[122] while ensuring that the public's privacy concerns are taken into account and addressed.

Digital health

Smartphones have become ubiquitous across all aspects of daily life; more than 65% of the population and 90%

of doctors and nurses own a smartphone.[125–127] This fact, coupled with the thousands of available health apps, has led to huge excitement about the potential of digital health to transform healthcare. While the benefits for healthcare as a whole seem clear, the effects of digital health on patient safety are less certain.

Digital health solutions have the potential to support safer healthcare delivery by improving the uptake and effectiveness of existing processes and by enabling novel approaches. The benefits could be realised both at the point of care, where technology can support decisions, combat medication error and help deliver patient-centred care, and at the organisational level, where it can, for example, enhance reporting and learning from adverse events (Exhibit 14). It should be noted however, the proliferation of digital solutions also has the potential to generate new risks. For instance, the introduction of electronic prescribing has generally improved safety, but has also resulted in new forms of prescribing harm.[128]

Digital health solutions are also challenging traditional models of communication, a major cause of adverse events, and changing how clinicians make decisions at the point of care. For example, clinicians and researchers from Imperial College London, have developed an
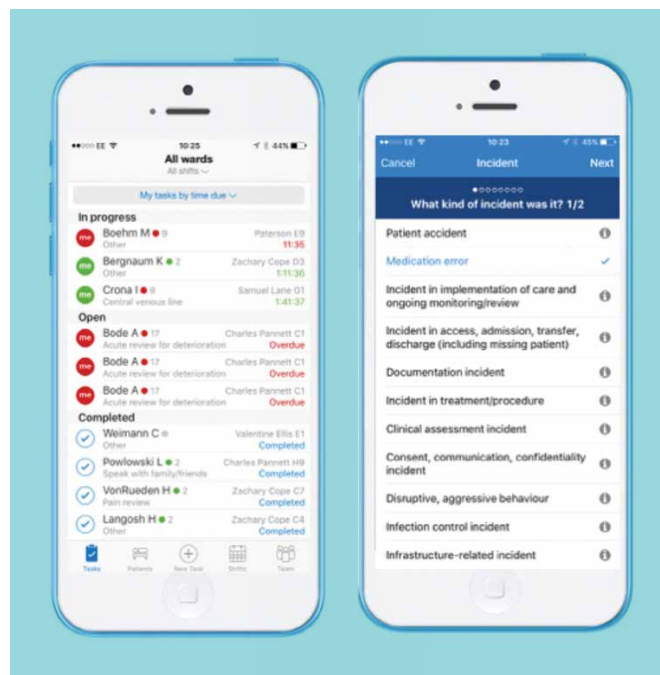

EXHIBIT 14: Examples of digital solutions for task management and incident reporting[130]

app-based communication system called Hark to facilitate and improve interpersonal communication and clinical task management. In pilot studies with NHS staff, Hark has been found to improve both the quality of information transfer and teamwork.[129] Apps can also deliver protocols and clinical decision support to nurses and doctors. The *British National Formulary* is now available through an app that enables easy access to the most up-to-date prescribing information. The National Institute of Health and Clinical Excellence (NICE) also delivers management protocols to clinicians on their smartphones.

Similarly, digital health platforms are reshaping how patients and carers interact with the healthcare system. These solutions fall into broad categories, which include solutions providing tailored health information, action-able reviews of health services, mobile health tracking, and telemedicine support. Wearable technology and other monitoring devices that collect day-to-day health data can provide more granular information to inform personalised care. Digital health platforms also provide patients with knowledge of 'what should happen' following a health service visit, helping to empower and involve them in their care.

Digital health solutions provide exciting new opportunities for making health systems safer but also raise concerns about quality, reliability, privacy, security and equity. Many of these concerns, however, can be resolved through updated digital health strategies and better engagement with healthcare professionals and patients. Systematically deploying digital solutions will require adherence to interoperability and security standards. In response, health systems could provide app endorsement and commissioning frameworks to incentivise inventors. If these issues can be resolved, there exists an opportunity to reshape and improve the safety of healthcare delivery.

Behavioural insights and design

Behavioural research examines the factors underlying the differences between intended and manifested behaviours, as there is often a disconnect between human intentions and behaviour. In the case of patient safety, health professionals rarely intend to cause harm, but often their behaviour contributes to adverse events. Patient safety could be improved by helping patients and staff realise their good intentions through an enhanced understanding of the underlying principles of behavioural insights and the implementation of behavioural design interventions.

Behavioural insights

Behavioural insights use research from behavioural economics, psychology and neuroscience to understand how humans behave and make decisions in everyday life. By better understanding people's behaviour, policymakers can design and implement more effective policies. Behavioural insights suggest simple techniques to change behaviours that may underpin many of the common adverse safety events.

For example, a major cause of hospital-acquired infections is poor hand hygiene. The median compliance rate for health professionals with recommended hand-washing guidelines is 40%.[131] Numerous strategies which rely on educating healthcare staff and service users have been implemented, but results have been mixed.[132] However, interventions designed based on be-havioural insights, particularly the provision of feedback on recorded handwashing rates, have had a dramatic impact, increasing rates from less than 10% to over 80%, sustained over 91 weeks.[133] Other interventions have used screensavers to deliver behavioural messages. Benefit-focused (known as 'grain-framed') and rotating messages (such as "By performing appropriate hand disinfection, you maintain good health for the infants you are caring for") were an effective way to increase hand hygiene rates.[134]

> **Health professionals rarely intend to cause harm. An enhanced understanding of the underlying principles of behaviour and behavioural design interventions could help to bridge the gap between intention and behaviour**

The traditional policy tools used for behaviour change include regulation, incentives and information provision. Recently, interest has been shown in 'nudge' type policies. Nudging uses the idea that people can be per-suaded to make better decisions by simple, non-coercive and small changes in the 'choice architecture'.[135] Policy

entities utilising this approach have demonstrated success across a range of areas including pension and tax policy, organ donation, and recycling.[136]

One of the strengths of behavioural insights is its experimental approach to service design, and there are a number of well-designed trials that show the benefits of nudge approaches in other areas of patient safety. Successful behaviour change has been seen in vaccination decisions, medication adherence programmes, and with the use of checklists in promoting safer surgery.[137–139] As with any behavioural intervention ethical questions, such as whether it is appropriate to target automatic processes to change behaviours, need to be considered.

Behavioural design

There has been recent interest in translating research findings from the behavioural sciences into the design of products, services, and places, to encourage behaviour change.[140] 'Behavioural design' describes the process of transforming our better understanding of human behaviour into innovative practical solutions that promote social benefit. Design-led interventions can make selecting better choices easier or make certain actions more difficult.

In everyday life there are numerous examples of how the environment can be designed to make desired behaviours physically easier. In petrol stations, nozzles are designed to prevent drivers with diesel cars from putting petrol in their engines, and ATM machines do not dispense cash until the card, which is usually forgotten, has been collected.[141] Similar thinking could be applied to reduce adverse safety incidents.

For example, the Imperial Drug Chart and Evaluation Study (IDEAS) demonstrated how prescribing behaviour could be improved by making design changes to NHS inpatient prescription charts.[140] Funded by The Behavioural Insights Team the project sought to reduce errors that affect more than one in 15 of all medications prescribed in UK hospitals. Efforts to improve prescribing among hospital doctors have tended to focus on education and training initiatives. However, these have often failed to demonstrate significant improvements in prescribing. The IDEAS project focused instead on the charts used to dispense prescriptions to investigate whether changes in the choice architecture (the design and content) of prescription charts could improve prescribing decisions. In the evaluation there were striking improvements in prescribing using the IDEAS compared to the existing chart, without the need for education or training. Prescribers were significantly more likely to include correct dose entries as well as prescriber details.[142]

GLOBAL COLLABORATION FOR PATIENT SAFETY

As discussed throughout this report, a global movement for patient safety already exists, and there are several organisations which facilitate international collaboration in this area: WHO Patient Safety serves to generate and disseminate effective patient safety policies across the globe; the Institute for Healthcare Improvement collates and supports evidence-based improvement ideas and programmes with the goal of improving care delivery; the International Society for Quality in Healthcare is a global network of professionals, policymakers, and academics dedicated to improving healthcare; the Leading Health Systems Network at Imperial College brings together regional health systems to compare performance and share best practices; a number of EU-focused entities, which bring together EU member states and stakeholders to enhance collaborations; and there exist a number of annual conferences that convene stakeholders around the topic of patient safety.

The emerging challenges to safety are relevant across all countries. Some, like antimicrobial resistance, require a global effort and have already been a key focus for the WHO. Similarly, health systems from all over the world face similar issues in trying to employ the tools available to combat harm. The scope and importance of collaboration and best practice will only increase. The global network of health systems and organisations active in this area should be a tool to achieve the goal of eradicating harm, and the collective energy of this movement should be harnessed to maximise its impact.

The patient safety community needs to include low- and middle-income countries. Many of the reductions in harm over the next 15 years are likely to come from these areas

As recently highlighted by the Institute of Medicine, to be truly global, the patient safety community needs to include low- and middle-income countries.[143] Many of the reductions in harm over the next 15 years are likely to come from these areas. Moreover, some tools that

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■ Box 6: **The Global Tracheostomy Collaborative, collaborating to improve care everywhere**

Tracheostomy refers to an incision made into a patient's windpipe at the front of the neck. The procedure is classically performed by surgeons for airway obstruction and a tracheostomy tube can be inserted to keep the airway open. However, the majority of tracheostomies are now performed in critically ill patients who are dependent on external devices to support their breathing. Tracheostomy problems can occur at initial placement or during subsequent use. Because patients are dependent on these simple tubes as their artificial airway, if problems occur, significant harm may rapidly develop, especially in the critically ill. There is a growing body of evidence which highlights continuing safety concerns related to tracheostomies,[145,146] many of which are associated with avoidable mortality.

An underlying challenge to improving the quality and safety tracheostomy care lies in the fact that tracheostomy care requires input from many clinical disciplines – for example, the team performing the procedure may well be different to the team responsible for subsequent management.[147] Furthermore, patients often need care in specialised settings that are not always adequately trained and supported in delivering safe tracheostomy care. Lastly, few institutions collect data on tracheostomy outcomes which can make identifying the scale and nature of problems difficult.

The Global Tracheostomy Collaborative (GTC) is the first quality improvement collaborative focused on tracheostomy care. It consists of "a multidisciplinary team of physicians, nurses, allied health professionals and patients working together to disseminate best-practices" from member institutions around the globe.[148] Member institutes collect patient-level data, which allows the tracking of process and successes, identifying areas of improvement and to benchmarking with other sites. The collaborative also provides and signposts to resources and support sites.

Echoing the ethos of the GTC, the Implementing the Global Tracheostomy Collaborative Quality Improvement Project, supported by the Health Foundation, an independent charity committed to bringing about better health and healthcare for people in the UK, introduced a number of best-practice quality improvement measures from the GTC in South Manchester, UK. The project saw significant reductions in the nature, frequency, and severity of harm that occurred as a result of patient safety incidents. Moreover, a significant reduction in total hospital length of stay was also observed due to better coordination of care, contributing to significant cost savings.[149] Building on the momentum of the South Manchester project, the initiative is set to expand further in the UK, with the aim of perform a detailed economic analysis.

have been applied successfully in high-income countries are still not fully deployed in lower income countries. These countries can also be extremely fertile ground for innovation. As shown in other industries, they are able to 'leapfrog' more developed health systems by jumping directly to the latest generation of solutions, particularly employing digital and mobile technology.[144] They have the potential to devise new approaches that deliver high value for money and can be translated to other, richer countries through a process of reverse innovation.

The global patient safety community should prioritise issues that are less affected by local context and will benefit most from international alignment. For example, measurement and benchmarking are essential tools for collaboration. They provide organisations with a sense of how they are performing, where they can improve, and from whom they can learn. However, international comparisons are bound to encounter resistance and scepticism if not employed correctly. They should not be used for ranking, but rather to understand contextual contributors of harm, highlight disparities in outcomes and processes, challenge the status quo, and identify key improvement areas. Further, not all measures are suitable for international comparisons. Some will be more of a reflection of the structure of a health system rather than of a difference in performance or outcomes. The global movement for patient safety is in need of an agreed set of indicators that are suitable for international comparison and that can form the basis local measurement systems.

Research is another area in which priorities are similar across countries and collaboration would be beneficial. Research findings need to be disseminated on a global scale and translated into policy recommendations. International research programmes would also be valuable. Finally, international standards and guidelines should be set on issues of global significance. This might include, for example, standards for medical device interoperability.[64]

The range of contributions by organisations from all over the world is what makes the safety community so vibrant. However, the efforts of these institutions, particularly those operating with an international remit, would be more impactful if more closely coordinated and aligned. This could be achieved by formalising the movement. For example, the patient safety report of the 2015 World Innovation Summit for Health called for "a global patient safety declaration … a unifying commitment that serves as a beacon for all those who have a role in patient safety."[64] A coordinating body with representation from the main stakeholders and a simple online solution to share best practices and learning could also be helpful.

■ Box 7: **Voluntary peer reviews in the nuclear industry**

The World Association of Nuclear Operators (WANO) is a membership-based organisation that includes all nuclear plants in the world. It was established in 1989 in the aftermath of the Chernobyl disaster to improve safety in nuclear plants. Today, it represents more than 130 members who operate more than 430 civil nuclear power reactors around the world.

Its organisational mission is "To maximise the safety and reliability of nuclear power plants worldwide by working together to assess, benchmark and improve performance through mutual support, exchange of information and emulation of best practices."

Peer reviews are one of WANO'S main programmes. They help members compare themselves against standards of excellence through an in-depth, objective review of their operations by an independent team from outside their organisation. The result is a frank report that highlights strengths and areas for improvement in nuclear safety and plant reliability.

Through peer reviews, members learn and share worldwide insights on safe and reliable plant operation and thereby improve their own performance. The same principles extend to companies, as well as stations, in the form of the corporate peer review.

Post-Fukushima, WANO has moved towards a four-year frequency for peer reviews, with a follow-up at the two-year point. Since 1992, WANO has conducted more than 500 operating station peer reviews in 31 countries/areas, including at least one at every WANO member station.

SUMMARY OF RECOMMENDATIONS

This report set out to provide healthcare leaders and policymakers with a clear overview of the main challenges to patient safety and of the most effective approaches to address them. Exhibit 15 summarises the main recommendations for the global movement for patient safety, for healthcare leaders and policymakers at the national and local level, and for researchers.

	SHORT TERM	**LONGER TERM**
GLOBAL MOVEMENT	• Launch a global declaration on patient safety setting clear shared goals • Enhance coordination, best practice sharing and mutual learning in the global patient safety community • Define key questions that researchers should explore	• Develop international standards and guidelines in areas of common concern • Expand the movement to include low- and middle-income countries • Develop an agreed set of validated, comparable patient safety indicators
HEALTH SYSTEM LEADERS AND POLICYMAKERS	• Review the effectiveness of current patient safety activities • Test novel solutions in areas like digital health, behavioural insights and design • Involve all healthcare actors in the development of an integrated, system-based patient safety strategy	• Work collaboratively with all healthcare actors, including industry, to implement the integrated patient safety strategy • Ensure that new initiatives are constantly evaluated
RESEARCHERS	• Develop a research agenda to address the priority questions of the global movement • Strengthen international links between researchers • Translate research findings into accessible policy recommendations	• Address gaps in evidence, for example in cost-effectiveness of interventions • Work in partnership with health systems and organisation to enhance impact of research • Develop and validate novel patient safety interventions

EXHIBIT 15: Summary of recommendations

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