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The economics of patient safety: From analysis to action

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The Economics of Patient Safety

From Analysis to Action

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JEL classification: I19, H51, I10, I18

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General acronyms and abbreviations

AHRQ	Agency for Healthcare Research and Quality
DALY	Disability Adjusted Life Year
CDC	Centers for Disease Control and Prevention (US)
FDA	Food and Drug Administration (US)
EU	European Union
HAC	Hospital-Acquired Condition
ICER	Incremental Cost-Effectiveness Ratio
IMF	International Monetary Fund
ICT	Information Communication Technology
IT	Information Technology
GBP	Great Britain Pound
GDP	Gross Domestic Product
GWP	Gross World Product (Global GDP)
NHS	National Health Service (United Kingdom)
OECD	Organisation for Economic Co-operation and Development
P4P	Pay for Performance
QALY	Quality-Adjusted Life Year
QoL	Quality of Life
ROI	Return on Investment
UK	United Kingdom
US	United States
USD	United States Dollar
WHO	World Health Organization
WTP	Willingness to Pay

Clinical acronyms and abbreviations

AE	Adverse Event
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CAUTI	Catheter-Associated Urinary Tract Infection (see also HAUTI)
CDS	Clinical Decision Support
CLABSI	Central-Line Associated Blood Stream Infection
COPD	Chronic Obstructive Pulmonary Disease
CPOE	Computerised Provider Order Entry
CQR	Clinical Quality Registry
DVT	Deep Vein Thrombosis
EHR	Electronic Health Record
EMR	Electronic Medical Record
HAI	Healthcare-Associated Infection / Hospital-Acquired Infection
HAP	Healthcare-Associated Pneumonia
HAUTI	Healthcare-Associated Urinary Tract Infection (see also CAUTI)
PE	Pulmonary Embolism
PI	Pressure Injury
PMS	Patient Monitoring Systems
PU	Pressure Ulcer
RNS	Result Notification Systems
SSI	Surgical Site Infection
UTI	Urinary Tract Infection
VAP	Ventilator-Associated Pneumonia
VTE	Venous Thromboembolism

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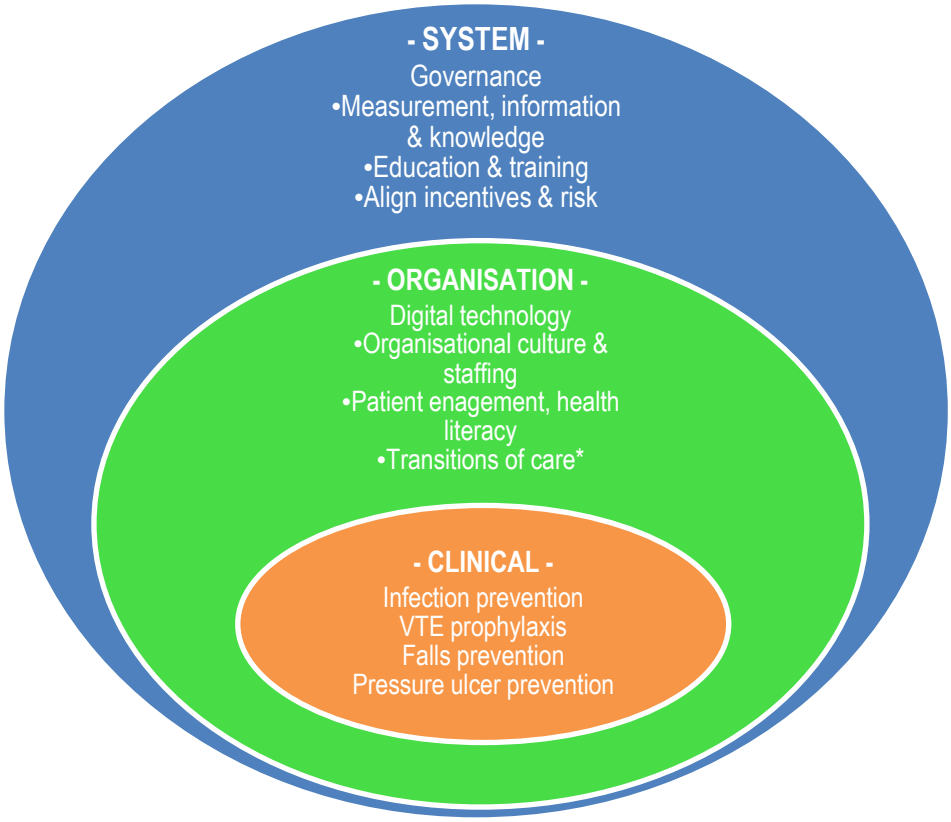
Abstract and key points

- Over 1 in 10 patients continue to be harmed from safety lapses during their care. Globally, unsafe care results in well over 3 million deaths each year. The health burden of harm is estimated at 64 million Disability-Adjusted Life Years (DALYs) a year, similar to that of HIV/AIDS.
- Most of this burden is felt in low- to middle-income countries (LMICs). Recent estimates suggest that as many as 4 in 100 people die from unsafe care in the developing world.
- The SARS-cov-2 pandemic has highlighted the risk of patient harm, with the estimated proportion of healthcare-acquired infections ranging from 12.5% to 65%. Evidence suggests that the incidence of other harms has increased during the pandemic as health system capacity has become challenged.
- Unsafe care also has high financial and economic costs. In developed countries, the direct cost of treating patients who have been harmed during their care approaches 13% of health spending. Excluding safety lapses that may not be preventable puts this figure at 8.7% of health expenditure. This amounts to USD 606 Billion a year, just over 1% of OECD countries' combined economic output.
- The indirect economic and social burden of unsafe care is even greater, exerting a far from negligible brake on productivity and growth. Based on willingness to pay, the social cost can be valued at USD 1 to 2 trillion a year. A human capital approach suggests that eliminating patient harm could boost global economic growth by over 0.7% a year. This seemingly small number would have compounded to approximately USD 118 trillion between 2000 and 2020.
- Governments, health systems and care providers have a duty to protect patients and the public from harm. Moving from analysis to action requires sober and rational decisions on how safety strategies, programmes and interventions can be implemented in a context of limited resources to generate the best value and return on investment (ROI) across a system.
- Improving safety requires a whole of system approach, with the value created by implementing and investing in mutually re-enforcing interventions within a policy framework encompassing all health system strata (Figure 1.1). The importance co-ordinating efforts has been recently highlighted by the responses to the covid-19 pandemic where, in many countries, agencies within and outside health systems have harmonised efforts quickly and effectively to manage risk and minimise harm from the outbreak.

Figure 1.1 Clinical – organisational- and system-level strategies can deliver ROI and value when implemented in concert



Source: Authors

- The foundations for system resilience and a capacity to minimise harm are found in strong safety governance, a 21st century information infrastructure, and sufficient staffing with a workforce skilled in handling safety risks in complex, dynamic environments, working in a supportive and just safety culture that values continuous learning and improvement.
- A national agency with well-defined objectives can be a powerful institution to enhance patient safety through better governance, oversight, and support of all health system actors. It is a worthwhile investment in most contexts.
- Digital technologies can reduce harm improving information and communication. They represent a good return on investment (ROI) at the margin, and over the medium-term if implemented effectively and as part of an overarching national strategy.
- At the clinical level, the strongest evidence points to interventions that target infections, blood clots (VTE), pressure ulcers and falls. Reducing these harms represents the greatest value for money. For example, every dollar invested in proven strategies to prevent healthcare-associated infections delivers a 7-fold return. Better communication, especially at the points where patients transition between care settings, is also proven to reduce harm at relatively low cost
- Patient-centred care, better health literacy and enhanced personal risk awareness is an important part of any harm-minimisation strategy. It should attract investment at the organisational and the system level.

- Multi-modal, systemic approaches can be effective even in complex and fragmented health systems. The Medicare hospital-acquired complication (HAC) Reduction Programme in the United States, for example, is estimated to have saved 25 000 lives and 7.7 billion dollars over 3 years.
- Better alignment of clinical, corporate, and professional risk management across the system is necessary. Currently, the full impact and costs of harm are not factored into decisions on improving safety. Also, in complex, fragmented health systems, the professional and financial impact of a safety lapse is most of the time felt further along the patient journey and not where a safety lapse occurred. Improving safety will be more difficult without addressing this.
- Acting on patient safety requires leadership and communication, political will, and investment. Transparency across a health system is also integral to begin improving safety and reducing harm. This can only be achieved through investing in a modern information infrastructure, but also relies on sound governance, accountability and proactive leadership.
- The analysis is clear: unsafe care kills millions, and harms tens of millions of people each year. It also exerts a great economic cost on health systems and society, consuming valuable resources that could be put to productive uses elsewhere. Much of this can be prevented through concerted action and adequate investment. The time for action is now.

Résumé et faits saillants

- Plus d'un patient sur dix continue d'être victime de manquements à la sécurité lors de ses soins. Au niveau mondial, les soins non sécurisés entraînent plus de 3 millions de décès chaque année. Le fardeau sanitaire de ces préjudices est estimé à 64 millions d'années de vie corrigées de l'incapacité (AVCI) par an, soit un chiffre similaire à celui du VIH/sida.
- La majeure partie de cette charge est ressentie dans les pays à revenu faible ou intermédiaire (PRFM). Selon des estimations récentes, jusqu'à 4 personnes sur 100 meurent de soins non sécurisés dans le monde en développement.
- La pandémie de SRAS-cov-2 a mis en évidence le risque de préjudice pour les patients, la proportion estimée d'infections liées aux soins de santé allant de 12,5 % à 65 %. Il semble que l'incidence d'autres préjudices ait augmenté pendant la pandémie, les capacités du système de santé étant mises à mal.
- Les soins non sécurisés ont également un coût financier et économique élevé. Dans les pays développés, le coût direct de la prise en charge des patients qui ont subi un préjudice au cours de leurs soins avoisine 13 % des dépenses de santé. Si l'on exclut les manquements à la sécurité qui ne peuvent être évités, ce chiffre s'élève à 8,7 % des dépenses de santé. Cela représente 606 milliards de dollars par an, soit un peu plus de 1 % du produit économique combiné des pays de l'OCDE.
- La charge économique et sociale indirecte des soins non sécurisés est encore plus importante, exerçant un frein loin d'être négligeable sur la productivité et la croissance. Sur la base de la volonté de payer, le coût social peut être évalué à 1 à 2 trillions de dollars par an. Une approche fondée sur le capital humain suggère que l'élimination des préjudices subis par les patients pourrait stimuler la croissance économique mondiale de plus de 0,7 % par an. Ce chiffre apparemment modeste se serait élevé à environ 118 000 milliards USD entre 2000 et 2020.
- Les gouvernements, les systèmes de santé et les prestataires de soins ont le devoir de protéger les patients et le public contre les préjudices. Pour passer de l'analyse à l'action, il faut prendre des décisions sobres et rationnelles sur la manière dont les stratégies, programmes et interventions en matière de sécurité peuvent être mis en œuvre dans un contexte de ressources limitées afin de générer la meilleure valeur et le meilleur retour sur investissement (ROI) dans l'ensemble du système.
- L'amélioration de la sécurité nécessite une approche globale du système, la valeur étant créée par la mise en œuvre et l'investissement dans des interventions se renforçant mutuellement dans un cadre politique englobant toutes les strates du système de santé (Figure 1.1). L'importance de la coordination des efforts a été récemment mise en évidence par les réponses à la pandémie de covid-19 où, dans de nombreux pays, les agences au sein et en dehors des systèmes de santé ont harmonisé leurs efforts rapidement et efficacement pour gérer le risque et minimiser les dommages causés par l'épidémie.
- Les fondements de la résilience du système et de la capacité à minimiser les préjudices se trouvent dans une gouvernance solide de la sécurité, une infrastructure d'information du 21e

siècle et une dotation suffisante en personnel, avec une main-d'œuvre qualifiée pour gérer les risques liés à la sécurité dans des environnements complexes et dynamiques, travaillant dans une culture de la sécurité juste et solidaire qui valorise l'apprentissage et l'amélioration continue.

- Une agence nationale aux objectifs bien définis peut être une institution puissante pour améliorer la sécurité des patients grâce à une meilleure gouvernance, une meilleure supervision et un meilleur soutien de tous les acteurs du système de santé. C'est un investissement qui vaut la peine dans la plupart des contextes.
- Les technologies numériques peuvent réduire les dommages en améliorant l'information et la communication. Elles représentent un bon retour sur investissement (ROI) à la marge, et à moyen terme si elles sont mises en œuvre efficacement et dans le cadre d'une stratégie nationale globale.
- Au niveau clinique, les preuves les plus solides concernent les interventions visant les infections, les caillots sanguins (TEV), les escarres et les chutes. La réduction de ces préjudices représente le meilleur rapport qualité-prix. Par exemple, chaque dollar investi dans des stratégies éprouvées de prévention des infections associées aux soins de santé est sept fois plus rentable. Il est également prouvé qu'une meilleure communication, en particulier aux moments où les patients passent d'un établissement de soins à un autre, permet de réduire les dommages à un coût relativement faible.
- Les soins centrés sur le patient, l'amélioration des connaissances en matière de santé et la sensibilisation accrue aux risques personnels constituent un élément important de toute stratégie de réduction des dommages. Ils doivent attirer des investissements au niveau de l'organisation et du système.
- Les approches systémiques et multimodales peuvent être efficaces même dans les systèmes de santé complexes et fragmentés. On estime par exemple que le programme Medicare de réduction des complications nosocomiales (HAC) aux États-Unis a permis de sauver 25 000 vies et d'économiser 7,7 milliards de dollars en trois ans.
- Un meilleur alignement de la gestion des risques cliniques, corporatifs et professionnels dans l'ensemble du système est nécessaire. Actuellement, l'impact et les coûts totaux des préjudices ne sont pas pris en compte dans les décisions relatives à l'amélioration de la sécurité. De plus, dans les systèmes de santé complexes et fragmentés, l'impact professionnel et financier d'un manquement à la sécurité est la plupart du temps ressenti plus loin dans le parcours du patient et non pas là où le manquement à la sécurité s'est produit. Il sera plus difficile d'améliorer la sécurité si l'on ne s'attaque pas à ce problème.
- Agir sur la sécurité des patients nécessite un leadership et une communication, une volonté politique et des investissements. La transparence au sein d'un système de santé est également essentielle pour commencer à améliorer la sécurité et à réduire les dommages. Cet objectif ne peut être atteint qu'en investissant dans une infrastructure d'information moderne, mais il repose également sur une gouvernance saine, la responsabilisation et un leadership proactif.
- L'analyse est claire : les soins non sécurisés tuent des millions de personnes et en blessent des dizaines de millions chaque année. Ils ont également un coût économique important pour les systèmes de santé et la société, consommant des ressources précieuses qui pourraient être utilisées de manière productive ailleurs. Une grande partie de ces problèmes peut être évitée grâce à une action concertée et à des investissements adéquats. Le temps de l'action est venu.

1. Introduction

Unsafe care resulting in unnecessary patient harm[1] continues to inflict a considerable toll on individuals, health systems and economies. Based on previous OECD analyses and more recent evidence gathered for this paper, harm resulting from health care remains a long-standing and major global public health issue that. Unsafe care results in over 3 million global deaths each year and exerts a health burden similar to HIV/AIDS or road accidents. It also incurs major financial and economic costs. In developed countries, over 1 of every 10 dollars spent on health care is diverted to treating the effects of safety lapses. Patient harm reduces global economic output by trillions of dollars every year.

The awareness of patient safety and its importance has grown in recent years. Bodies such as the World Health Organization (WHO), European Union (EU) and the G20 have elevated the issue on the crowded public health agenda. While patient harm incurs a huge toll on individuals and societies, much of it can be prevented through changes in practice and behaviour, better policy, and considered investment. The potential for good economic returns and value creation is there. But the recent attention has not yet been translated to enough action to address the patient safety problem worldwide, and given the scale of the problem, intervention and investment are still relatively modest. This must change.

The SARS-cov-2 pandemic has presented another major global public health and economic challenge with the official death toll in exceeding 5 million at the end of 2021. It has also served to illustrate that it is possible to mobilise immense amounts of resources to protect the public through public health measures, vaccination and treatment. It has also highlighted the risks of healthcare-associated harm. In previous SARS and MERS pandemics, 33% and 56% of all diagnosed cases were nosocomial. Early studies of Covid-19 estimated that between 12% and 44% of Covid-19 cases were nosocomial – acquired in hospital by patients who were admitted for other reasons, with healthcare workers comprising a third of cases (Rickman et al., 2020[1]; Zhou et al., 2020[2]). Nosocomial Covid-19 infection rates of up to 65% have been reported (Ngandu et al., 2022[3]). However, evidence from the United States suggests that some aspects of patient safety have declined increased during the pandemic (Fleisher et al., 2022[4]).

[1] Key terms and definitions are provided in Box 1.

Box 1.1. Key definitions

Harm is defined by the WHO as "impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological".

A patient is a person receiving health care (a medical intervention, procedure or diagnostic test). The term can also encompass the person's family, carer(s) or other surrogates.

Patient harm is any unintended and unnecessary harm resulting from, or contributed to by, health care. This includes the absence of indicated medical treatment.

An adverse event is an incident during care that results in patient harm. Common types of adverse events referred to in this report include:

- Adverse drug events (ADEs) – the result of medication error
- Healthcare-associated infections (HAI) (sometimes also referred to as hospital-acquired or nosocomial infections)
- Patient falls
- Pressure ulcers (PU)
- Venous thromboembolism (VTE) – comprising deep vein thrombosis (DVT) or pulmonary embolism (PE)
- Diagnostic error (incorrect or delayed diagnosis)

An error is the failure to carry out a planned action as intended or application of an incorrect plan through either doing the wrong thing (commission) or failing to do the right thing (omission) at either the planning or execution phase of healthcare intervention. Errors may not necessarily cause harm.

Patient safety is the reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered and weighed against the risk of non-treatment or alternative treatment.

Source: (Slawomirski, Auraaen and Klazinga, 2017[5])

The economic impact of the Covid-19 crisis has also been recognised and reacted to swiftly. In many cases this will lead to some reflection on optimal investment in health systems. The pandemic has served to underscore the importance of timely and reliable data, and the institutional arrangements within a health system to assure safe care in periods of unexpected upscaling and downscaling. It has also emphasised the key role of political leadership in ensuring a successful response. Covid-19 has shown that governments, health systems and healthcare providers *can* act swiftly, decisively and in unison to protect the public. While some countries have done better than others, change *is* possible if the will and urgency are there. Responding to, and limiting the impact of, the outbreak is rightly seen as everybody's responsibility.

The contrast with action to improve patient safety over the past decades is stark. For example, the pandemic response appears to have achieved what hand hygiene proponents have been working towards for years -- and may yet have the corollary benefit of reducing healthcare-associated infections in the future. The challenge is to harness the momentum and create the urgency to address the problem of unsafe care. Governments, whose principal responsibility is to protect the public from harm, play a critical role as does every person and institution involved in health. Safety must be everybody's

responsibility. An essential part is to invest resources commensurate with the size of the problem and what it will take to address.

This paper attempts to guide policy makers along a path that can achieve the goal of reducing harm to an acceptable minimum. It first quantifies the global burden and the cost of patient harm. Such analyses are important to establish urgency and a call for action. They also inform policy makers about the *total* costs of harm, which needs to be accurate and timely to guide optimal levels of investment in prevention. Measurement, information and knowledge are a key part of improving patient safety. As such, they also require adequate investment.

The paper then moves from analysis to policy action. It presents the latest evidence on how the greatest returns can be derived from investing in patient safety. It seeks to assess a range of interventions and strategies -- implemented at the clinical, organisation and system levels – to reduce the burden of unsafe care across a health system. While previous papers began this discussion by presenting findings of a nominal survey of experts, this iteration tries to review and solidify the previous findings with empirical evidence.

Findings suggest that reducing patient harm is one of the best ways to drive value in health care. Safety provides a way to optimise both the numerator (outcomes) and denominator (costs) of the value function. Not many other investments in health care can lay claim to that.

But the task for policy makers is more complicated than to select a set of interventions based on their individual cost-effectiveness or return on investment (ROI). Firstly, the evidence still contains several gaps, and high-quality economic evaluation of different interventions are relatively sparse. Secondly, available research methods mean that finding causal links between interventions and outcomes favours those targeting specific types of harm in the clinical setting over broader, cross-cutting strategies applied across organisations and systems.

Improving safety is a complex, socio-technical undertaking requiring changes in practice and behaviour in all settings and levels – from patients and providers to payers, regulators and policy makers. Specific interventions work best if implemented in an enabling policy and organisational environment. Across an entire health system, reducing harm is best approached using a framework of governance, resilience, culture and transparency. It also relies on better alignment of clinical, corporate, and professional risk, and a serious evaluation of the structures and institutions that dictate incentives and behaviour across a health system.

The policy challenge is to apply the evidence to the local context to best deploy scarce resources across the range of available programs and interventions. Meanwhile, a degree of experimentation to find new ways of improving safety should be encouraged. In a world of finite resources, achieving these things requires inevitable trade-offs. A deliberative approach is needed, based on value, but cognisant of system complexity and validity of decisions and outcomes from a societal perspective.

2. Unsafe care continues to incur a substantial burden on individuals, health systems and societies

The incidence and the impact of patient harm have been established in numerous studies conducted over the past few decades. This section provides an update on the extent of harm, its health burden as well as its direct and indirect economic costs.

Previous OECD papers on the economics of safety focused on individual settings, providing disaggregated figures on the direct costs of harm (Slawomirski, Auraaen and Klazinga, 2017[5]; Auraaen, Klazinga and Slawomirski, 2018[6]; de Bienassis, Llena-Nozal and Klazinga, 2020[7]). A harmful safety lapse changes a patient's care journey. This paper attempts to estimate the direct financial costs of such lapses in their entirety, including inpatient/acute, primary/community, and long-term care. *Direct costs* are the health system resources needed to ameliorate the effects and consequences (sequelae) of patient harm. This includes additional diagnostic testing, acute, non-acute and other health system activity (including administrative actions) that would not otherwise have been needed had the patient not been harmed. Direct costs exclude financial assistance and compensation paid to harmed patients and/or their families as a result of harm.

Direct costs should be considered as dollars but also the alternative ways the resources could be deployed. Because budgets and resources are finite, providing additional treatment and attention to harmed patients requires diversion from other uses where benefits are generated: diagnostic equipment, pharmaceuticals, hospital beds and, of course, the time and attention of highly trained staff who provide direct care to patients and are considered the first and last line of defence against patient harm. The foregone benefits of these alternative resource deployment incur opportunity costs. Each time a harmed patient requires additional care, another patient misses out or must wait for care. Reducing safety-related harm reduces this cost, freeing up scarce capacity that can be used more effectively to achieve important ends.

Indirect costs cover all other downstream consequences of unsafe care on society. Based on a human capital approach, these costs comprise *inter alia* lost productivity (of patients as well as their families and informal carers), lost taxation revenue as well as higher welfare payments and perhaps also financial compensation.[2] Indirect costs can also include the lost wages and decreased productivity of health workers and professionals involved in patient harm, who are often described as the 'second victims' of unsafe care. Indirect costs can also be calculated using the willingness to pay (WTP) method, which relies on estimates of how much societies are willing to pay for additional health or the prevention

[2] The latter is better seen as an opportunity cost (the benefits of alternative allocation of these resources) as they technically do not result in money taken out of the economy, rather result in its redistribution. More detail is provided in section 2.4.

of illness and disability, measured by healthy life years (QALYs)[3] or disability-adjusted life years (DALYs).[4]

2.1 The high burden of unsafe care continues, but severity and preventability vary across specialties and settings

Studies in the 1980s and 90s consistently suggested that around 1 in 10 patients are harmed during health care, and that approximately half of the safety lapses that result in harm are preventable. Recent evidence appears to confirm these findings. However, a more nuanced understanding is emerging of differences in severity and preventability between specialties and settings.

Low-to-middle income countries continue to experience most of the human cost of patient harm

The human cost of patient harm is the most important concern. Patients in all parts of the world continue to die from safety lapses. The burden is felt most in low-to-middle income countries (LMICs) where it is estimated that safety lapses result in 134 million adverse events, causing 2.6 million deaths each year. This suggests that in LMICs approximately 1 in 4 hospitalisations result in harm and that 1 in 24 people die from unsafe hospital care.[5] Improving safety must therefore be a critical aspect of achieving the goal of universal health care.

The figure of 2.6 million deaths in fact likely underestimates the true extent of the problem as it is based only on six types of hospital-based harm. [6] The actual number is likely to exceed 3 million deaths per annum (Jha, 2018[8]; National Academies of Sciences Engineering and Medicine, 2018[9]). A considerable proportion of these deaths can be prevented with (financially) inexpensive interventions such as hand hygiene (see Section 3).

This is not to say that developed countries do not have a safety problem. It is estimated that in the United Kingdom, Canada, and the Netherlands around 5% of hospital deaths are due to *preventable* safety lapses (Hogan et al., 2015[10]). In England, this translates to about 11,000 lives per year (NHS, 2019[11]). The figure of 98 000 deaths per annum from the seminal IOM report in the United States (Institute of Medicine, 2001[12]) was subsequently re-estimated to be around double that figure (Andel et al., 2012[13]). AHRQ suggests that improvements in hospital safety have prevented over 20 000 deaths between 2014 and 2017 in the United States (AHRQ, 2019[14]). The progress is commendable, but the fact remains that deaths from unsafe care in patients over 65 is about 130 000 per year.

Over 1 in 10 patients continue to be harmed during care

A 2019 meta-analysis of the prevalence, severity and nature of patient harm drawing on 70 studies across all healthcare settings[7] found a 12% pooled prevalence of harm, with 9% to 15% of safety lapses resulting in severe morbidity or death. In aggregate, approximately 50% of lapses were considered preventable. However, harm was more prevalent, more preventable *and* more severe in the more specialised settings of intensive care and surgery (Panagioti et al., 2019[15]).

[3] QALY – Quality adjusted life year. The equivalent of a year live in full health, typically measured by a health-related quality-of-life instrument such as the EQ-5D questionnaire.
[4] DALY – Disability adjusted life year - can be thought of as one lost year of "healthy" life. The sum of DALYs across a population represent the burden of attributed to a disease or risk factor in question.
[5] Based on 2018 population numbers, the figure would be 1 in 22.
[6] ADEs, CAUTI, VTE, pressure ulcers, falls, ventilator-associated pneumonia
[7] But predominantly focused on hospital care: emergency, medical, surgical, intensive care and obstetrics.

Preventability of harm continues to be a fluid concept, subject to incremental change as well as paradigm shifts. Technological advances and innovations in health care have the potential to reduce harm previously considered unavoidable. For example, a baseline rate of catheter-associated bloodstream infections (CLABSI) was previously considered an acceptable part of hospital care. However, the development and implementation of prevention protocols (and cultural change among providers) proved that most if not all CLABSI could be avoided (Pronovost et al., 2006[16]). The paradigm shift has meant that near-zero CLABSI rates are now the accepted benchmark. Digital technology can also change our understanding of preventability. Interoperable electronic health records (where information follows the patient wherever they seek care) can reduce safety lapses such as adverse drug reactions, limiting them only to cases where a patient has never been exposed to the medication in question (see Section 3).

Delayed or wrong diagnosis is a main contributor to patient harm in the community setting. For example, every adult in the United States liable to experience such as lapse in safety at least once in their lifetime. Electronic health records and other digital technology can contribute to reducing these (while ensuring overdiagnosis is not an unintended consequence). As a result, some consider up to 80% of this type of harm to be preventable (Auraaen, Klazinga and Slawomirski, 2018[6]). Overall, the preventability needs a more nuanced approach to enable more accurate analysis of the impact of harm.

The uneven distribution of preventability and severity of harm across settings, and specialties within them, influences the way costs are estimated. In surgical and intensive care harm tends to be more severe than in other acute care types, with a higher proportion of it deemed preventable (Panagioti et al., 2019[15]). Surgical and intensive care admissions are also more expensive and account for a sizable part of hospital activity. The disproportionate harm and lower preventability should be reflected in estimates of additional direct cost of harm. A blanket 50% adjustment of aggregate costs in the acute sector may in fact underestimate the true financial and economic impact of unsafe care (see Section 2.3).

The Covid-19 pandemic has impacted on patient safety

Beyond nosocomial SARS-COV-2 infection, the Covid-19 pandemic appears to have had a negative impact on patient safety more generally. In the United Sates, for example, encouraging trends of recent years have reversed. CLABSI, which had decreased by 31% in the 5 years preceding the pandemic, were 28% higher in the second quarter of 2020 than in the second quarter of 2019 (Patel et al., 2021[17]). Another study found that pandemic surges were associated with significant increases in CLABSI as well as catheter-associated urinary tract infections (CAUTI) and methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia infections, while no significant association with *Clostridium difficile* infection (CDI) was found (Baker et al., 2021[18]). Evidence suggests that that pandemic has also increased other types of harm most notably through delayed diagnosis and treatment (Stocking et al., 2021[19]). French General Practitioners reported increases in safety incidents mainly related to delayed diagnosis, cancellations of appointments, resulting in hospitalisation or procedure in 17% of cases (Fournier et al., 2021[20]).

Potential reasons for the observed decline in patient safety are many. In many health systems, repeated inundation with very ill patients has stretched staff and supplies. Personnel have responded with extraordinary dedication, adapting with speed and developing and modifying protocols in a period of constant flux while battling workforce safety problems such as exhaustion and a dearth of personal protective equipment (de Bienassis, Slawomirski and Klazinga, 2021[21]). These strains have undoubtedly affected routine safety practices such as checklists. The near-immediate negative impact on patient safety suggests that healthcare systems may lack sufficiently resilient safety cultures and infrastructures (Fleisher et al., 2022[4]). The importance of these contextual components of efforts to improve patient safety are discussed in more detail in Section 3.

2.2 The global burden of unsafe care remains significant and can be compared to that of HIV/AIDS

Recent evidence confirms that certain types of harm account for the greatest health and financial costs. (Anand, Kranker and Chen, 2019[22]) estimated the costs of unsafe hospital care in the United States using inpatient data that capture 90% of discharges in 12 states. Focusing on 9 common adverse event types,[8] they calculated the cost of additional hospital treatment during admission as well as any subsequent admissions within 90 days.[9]

In aggregate, the 9 events generated an additional cost of USD 2.8 billion per year across the 12 states. The costliest lapses in aggregate were hospital-acquired urinary-tract infections (HAUTI) accounting for over USD 2 billion or 70% of the additional costs exerted by all 9 events, followed by VTE, accounting for USD 471 million, or 16% of the total cost. This was principally a function of the comparatively high incidence of these two events, as the additional length of stay and other costs they exerted were modest. These findings highlight that reducing aggregate cost of harm needs to focus on the 'mundane' but common lapses (Anand, Kranker and Chen, 2019[22]).

(Duckett and Jorm, 2018[23]) found that the aggregate cost of hospital complications including adverse events such as HAI and ADEs account for 13% of public hospital spending in Australia. Complication rates varied considerably between hospitals even when patient complexity (casemix) is accounted for. The authors estimated that if all hospitals in the sample reduced their complication rate to that of the 10th percentile, 250,000 patients could avoid harm per year. This would free up beds and resources worth AUD 1.5 billion and allow approximately another 300,000 patients to be treated each year.

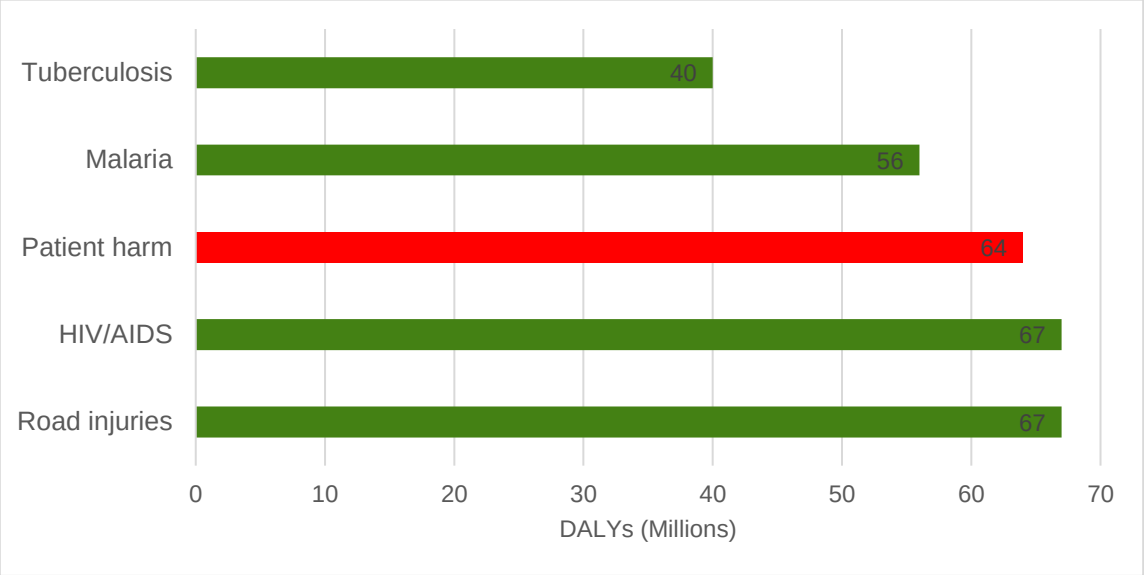
Medication errors and consequent adverse drug events (ADEs) continue to be frequent and costly. A study 2020 study estimates that over 237 million medication errors occur in England each year, with 66 million (27.8%) resulting in moderate or severe harm. Over 5% of all hospitalisations are the result of primary care ADEs. The annual cost of treating ADEs deemed 'definitely and probably avoidable' across all healthcare sectors in England is GBP 840 million (approx. USD 924 million) or 0.7% of healthcare expenditure (Elliott et al., 2020[24]).[10]

The disease burden and its impact on quality of life are considerable

Research is shifting towards measuring patient harm in terms of its impact on health-related quality-of-life (QoL). (Jha et al., 2013[25]) estimated that seven types of hospital-acquired harm[11] accounted about 23 million DALYs per annum globally, with over two thirds (15.4 million DALYs) felt in LMICs. The global burden of disease stemming from all types of harm was recently estimated at 64 million DALYs (Figure 2.1) putting the burden of unsafe care in the same league as traffic injuries or major infectious diseases (Jha, 2018[8]).

[8] HAUTI, CLABSI, falls, SSI, VTE, pressure ulcer, birth trauma and obstetric trauma (with and without instrument)
[9] The costs as a proportion of hospital or total healthcare expenditure were not provided.
[10] The authors estimate that 99 million medication errors occur in long-term care medication but these were not included in the cost estimates due to absence of robust data. The true figure is therefore likely to be higher.
[11] ADEs , CAUTI, CLABSI, Falls, pneumonia, pressure ulcer, VTE

Figure 2.1 The annual global disease burden of unsafe care compares to road injuries and HIV/AIDS (DALYs, millions per annum)



Source: Jha (2018)

Recent research has focused healthcare-associated infections (HAI). (Cassini et al., 2016[26]) found that six HAI types[12] occur 2.6 million times in European Union (EU) countries each year. This generates an annual disease burden of 2.5 million DALYs. The authors estimate that the cumulative (lifetime) disease burden of one year's HAIs is 501 DALYs per 100 000 population, which aggregates to 2.23 million DALYs based on the current EU population. Applying a 3.5% discount rate deflates this lifetime burden to just over 1.3 million DALYs.

More recently, the annual health burden of five types of HAI[13] was estimated to be 1.47 million DALYs across the EU. This exceeds the combined burden of 31 infectious diseases in Europe including influenza, tuberculosis and HIV/AIDS. The highest aggregate burden was also exerted by pneumonia, blood stream infections and urinary tract infections (Zacher et al., 2019[27]).

Antimicrobial-resistant HAI generate a disproportionate burden. (Cassini et al., 2019[28]) studied the burden of all resistant infections across Europe. They found that 426 277 a year (or 63.5%) of the resistant infections were healthcare-associated and that this subset was responsible for 72% of deaths, and 75% of DALYs of all infections, amounting to a total of 645 000 DALYs a year based on the 2015 EU population. This is roughly equivalent to the combined burden of influenza and tuberculosis in the relevant countries (Cassini et al., 2018[29]).

Interest is growing in the effects of adverse events on patients' subsequent quality of life (QoL). Researchers from Imperial College London are examining the effect of nine safety lapses during joint replacement surgery on patient-reported QoL.[14] Provisional analysis suggests that patients who experience one or more safety lapses during their admission report, on average, 0.07 lower improvement on the EQ-5D index compared to the average. This suggests that that the cost of these

[12] pneumonia, surgical site infection, blood stream infection, urinary tract infection, clostridium difficile infections, neonatal sepsis
[13] pneumonia, surgical site infection, blood stream infection, urinary tract infection, clostridium difficile infections
[14] 1 Retained Surgical Item or Unretrieved Device Fragment; 2 Central venous catheter-related blood stream infection; 3 Postoperative hip fracture; 4 Perioperative Hemorrhage or Hematoma; 5 Postoperative Acute Kidney Injury Requiring Dialysis; 6 Postoperative respiratory failure; 7 Perioperative VTE; 8 Postoperative Sepsis; 9 Unrecognized Abdominopelvic Accidental Puncture/Laceration.

lapses to patients is a 15-20% reduction in QoL (Kristensen, 2020[30]).[15] Extended over the remaining lifespan of a typical joint replacement patients, the incremental cost of these safety lapses is 1.4 QALYs each.[16]

Sepsis needs to be prevented and better managed

Sepsis, the body's inflammatory response to infection, is among the most common causes of in-hospital death and most expensive conditions to treat (Liu et al., 2014[31]; Torio and Moore, 2006[32]). Healthcare-associated infections (and other types of harm) can result in sepsis during acute care. But sepsis can also manifest after discharge.

While the management of sepsis has improved over the past two decades resulting in lower mortality, it remains a major public health concern. In addition, sepsis can be under-diagnosed and accurate data on its incidence, disease burden and costs have not been easy to obtain.

In the United States, the total cost of treating sepsis exceeds USD 60 billion each year. Approximately 60% of patients treated for septic shock die within 6 months, and hospital-acquired sepsis is associated with a greater mortality risk (Buchman et al., 2020[33]).

Globally, it is estimated that 49 million cases of sepsis and 11 million sepsis-related deaths occur each year. The latter represents about 20% of all deaths, with the highest burden experienced by LMICs. However, incidence and mortality rates have fallen by 37% and 53% respectively since 1990 (Rudd et al., 2020[34]).

(Rudd et al., 2020[34]) did not identify how what proportion of cases stem from iatrogenic causes. Previous research in the United States has, however, estimated that as much as 37% of sepsis cases are associated with health care (Page, Donnelly and Wang, 2015[35]) and that 1 in 4 surgical site infections are said to develop into sepsis (Haque et al., 2018[36]). This suggests that, globally, over 3 million sepsis-related deaths may originate from unsafe care each year.[17] Results of the studies discussed in this, and the previous section are summarised in Table 1.

[15] EQ-5D index using the United Kingdom valuation.
[16] Assuming an additional 20 life years, and constant QoL difference over that time (financial equivalent of this cost is provided in Section 2.4).
[17] The 37% figure was derived from a United States sample. It is possible but unlikely that the proportion is lower in other parts of the world.

Table 1 Summary of listed studies on the burden and cost of patient harm

STUDY	REGION	TYPE OF HARM	MEASURES	RESULTS
ANAND ET AL (2019)	United States (12 states)	In-hospital harm (9 types)	Direct costs	USD 2.8 billion across the 12 states; CAUTI and VTE most costly in aggregate
CASSINI ET AL (2016)	European Union	6 HAI types	DALYs	2.5M DALYs p.a.
CASSINI ET AL (2018)	European Union	HAI by resistant organisms	DALYs	645K DALYs p.a.
DUCKETT & JORM (2018)	Australia	In-hospital complications	Direct costs	13% of hospital expenditure
ELLIOTT ET AL (2020)	England	Medication error / Adverse Drug Events	Prevalence Direct costs	237 million errors p.a. 66 million ADEs GBP 840 million p.a.
JHA ET AL (2013)	Global	In-hospital harm (7 types)	DALYs	22.6M DALYs p.a. (68% in LMICs)
JHA (2018)	Global	All harm	DALYs	64M DALYs p.a.
NATIONAL ACADEMIES (2018)	LMICs	In-hospital harm (6 types)	AEs and deaths	134 000 AEs 2.6M deaths
RUDD ET AL (2020)	Global	Sepsis (all causes)	Mortality	11 M deaths globally p.a. 3-4M due to unsafe care[18]
KRISTENSEN (2020)	England	9 types of harm during hip/knee arthroplasty	QALYs	Harmed patients report 15-20% less improvement in QoL = 1.4QALYs
ZACHER (2019)	European Union	5 HAI types	DALYs	1.47M DALYs p.a.

2.3 Over 12% of national health expenditure is consumed by managing the clinical impact of unsafe care

The previous OECD papers exploring the economics of patient safety provided cost estimates for specific settings: acute/inpatient, primary/community/ambulatory and long-term care (LTC).

In acute care, the most harmful safety lapses were infections, VTE, adverse drug events, falls and pressure ulcers. The main sequelae were premature death and additional morbidity requiring prolonged admission, re-admission, and/or additional non-acute care. The headline finding was that, in a typical OECD country, approximately 15% of inpatient expenditure was consumed by treating the effects of hospital-acquired harm (Slawomirski, Auraaen and Klazinga, 2017[5]).

The 15% figure includes the additional care during the admission in which the safety lapse occurred. It excludes some unknown costs, such as:[19] (1) additional follow-up care required in the non-acute setting; (2) consequent hospital re-admissions, and (3) cases where the adverse event resulted in a new principal diagnosis and therefore 'new' admission (e.g. an inpatient fall resulting in a fracture).

In the community setting (primary / ambulatory care), most patient harm stems from adverse drug events, and wrong or delayed diagnosis and treatment. Harmed patients typically experience temporary morbidity requiring additional care or, in some cases, admission to hospital. Previous modelling

[18] Estimate of 30-35% based on literature

[19] These should be termed the 'known' unknown direct costs, as there may be other direct costs of harm that have not been conceived.

suggested that about 4% of inpatient expenditure could be attributed to unnecessary admissions for 5 conditions[20] that can be managed in the community setting. The literature suggests that adverse drug events may account for as much as 4% of inpatient capacity and 3.6% of hospital admissions (Auraaen, Klazinga and Slawomirski, 2018[6]).

The unknown direct costs of unsafe care the community setting include admissions resulting from safety lapses in addition to the five conditions examined previously, and the costs of additional non-acute care. In this setting, a considerable proportion of harm (up to 80%) can be prevented with existing knowledge and technology (Auraaen, Klazinga and Slawomirski, 2018[6]).

In LTC, the most common adverse events include pressure ulcers, falls, adverse drug events, malnutrition and infection. These can sometimes result in death (as seen with Covid-19 infections), but typically cause additional morbidity requiring extra care at the facility or a hospital admission. Admissions to hospital from LTC account for about 6.25% of inpatient expenditure in OECD countries, with 40% of these considered preventable. The cost of pressure ulcers is estimated at between 2 and 4% of total health expenditure (de Bienassis, Llena-Nozal and Klazinga, 2020[7]). The effects of malnutrition and the costs of harm borne at facility-level are not known, but these are likely to be modest compared to the costs of admissions.

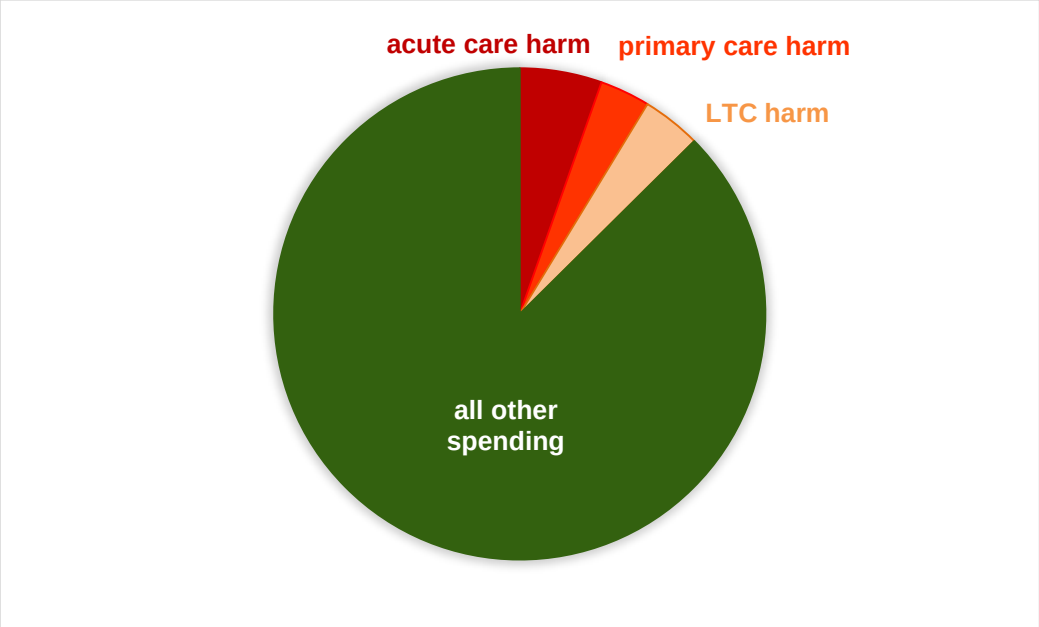
The previous three OECD papers used various denominators in estimating the direct costs of harm. Here, results have been re-calculated using a common denominator of all annual spending on health as reported to the OECD statistics database.

The direct cost of unsafe care in health systems of developed countries is estimated at 12.6% of health expenditure, comprising 5.4% in acute care, 3.3% in primary care and 3.9% in LTC (Figure 2.2 and Appendix 1). This amounts to approximately USD 878 Billion (2018 PPP) across OECD member countries each year, or about 1.4% of their combined GDP.[21,22] Excluding unknown harm reduces this to 10.5% of health expenditure (USD 732 Billion or 1.2% GDP).

Factoring in preventability reduces the direct cost to 8.7% of total health expenditure.[23] In other words, OECD countries spend about USD 606 Billion a year to treat patients harmed by *avoidable* safety lapses. This amounts to just over 1% of their combined economic output. It exceeds the annual health expenditure of Japan, and the entire GDP of Belgium. More importantly, it represents a considerable opportunity cost, as scarce resources are diverted from other important areas of health and social spending to manage a preventable problem.

[20] Heart failure, diabetes, asthma, COPD and hypertension.
[21] Health spending figures derived from http://www.oecd.org/els/health-systems/health-data.htm
[22] GDP figures are for 2018. Source: https://data.oecd.org/gdp/gross-domestic-product-gdp.htm
[23] Further detail, including explanation, assumptions and calculations, provided in Appendix 1.

Figure 2.2 Treating the effects of unsafe care occupies a sizable proportion of health spending in OECD countries



Source: Authors

2.4 The indirect costs of harm amount to trillions of dollars each year

Unsafe care exerts considerable unnecessary financial burden on health systems. It also incurs downstream economic and social costs. Just as any disease exerting a health burden (diabetes or cardiovascular disease, for example) patient harm lowers economic output and growth as well as social welfare. The two dominant methods to measure these indirect costs are willingness to pay (WTP) and the human capital approach (Jo, 2014[37]). While the following sub-sections provide estimates, further research is required (Box 2.1).

Box 2.1. The Social and economic cost of harm needs targeted research

A gap exists in estimating the impact of unsafe care on economic output, growth and social welfare. Cost of illness studies of patient harm have not been conducted. Using WTP and cost of illness studies from other diseases and conditions, as is done in this paper, provides approximations only.

A potential way to fill this gap would likely involve microsimulation modelling, drawing on retrospective clinical as well as economic, financial and census data. An econometric approach would compare two cohorts – one with and the other without iatrogenic harm - matched for other variables. This can be done prospectively or retrospectively, with the former more resource- and time-consuming. Both would require linking fiscal data such as taxation records with clinical and administrative data across healthcare settings. Another potential area of research is to elicit social preferences around the willingness to pay (WTP) to avoid harm and compare these to other health interventions.

The social cost of unsafe care is considerable, as is the willingness to invest in preventing certain types of harm

The WTP method examines the costs of a condition based on what societies would be willing to pay to ameliorate or avoid it. The approach is based on the amounts that a country or population typically pays for interventions with a known utility (i.e. its impact on health-related QoL). This cost-utility ratio[24] is really a measure of opportunity cost of health interventions – how much a society is willing to forego in order to generate a certain health benefit in an individual or population (Auraaen et al., 2016[38]).

Health systems explicitly or implicitly reveal their WTP for an additional or incremental QALY by how much they pay for various treatments, pharmaceuticals, and medical procedures. Yet the cost-utility ratio used in health technology assessment varies between, and even within, countries depending on factors such as the target disease, patient type and ability to pay (typically a function of GDP per capita).

For example, authorities in the United Kingdom apply a threshold of GBP 20 000 to 30 000 per QALY (USD 25 000 – 36 000) to decide whether a medical intervention should be provided by the National Health Service. However, the threshold can vary depending on the target disease, with more recent guidelines permitting up to GBP 50 000 (USD 62 000) in some cases (Paulden, 2017[39]).

In the United States a cost-utility threshold is not set explicitly, but has been calculated to range from USD 50 000 to USD 150 000 depending on location, payer and patient type (Smith, 2019[40]). Korea and the Slovak Republic apply a floating cost-utility threshold set at their GDP per capita, while Hungary and Poland set theirs at 3 times GDP per capita (Auraaen et al., 2016[38]). In developing countries the threshold is estimated to be 50% of GDP per capita or lower (Woods et al., 2016[41]).

If the extent to which patient harm increases patients' disability – or reduces their health-related QoL -- is known, a monetary value can be placed this based on what society would be willing to pay to prevent it. (Andel et al., 2012[13]) applied this method to estimate that the indirect cost of harm in the United States approaches USD 1 trillion per annum.

Section 2.2 described preliminary research from Imperial College London suggesting that patients who experience safety lapses during joint replacement surgery report QoL up to 20% lower compared to the average patient. This difference amounts to 1.4 QALYs over the patient's remaining lifespan. If a mere 1% of joint replacement patients in the United Kingdom experienced one of the harms investigated, each year's procedures would generate a loss of over 30 000 QALYs.[25] Using a WTP of USD 25 000

[24] In health technology assessment this is typically called the incremental cost-effectiveness ratio (ICER)
[25] Based on 2.2 million primary hip, and primary knee, replacements performed in the United Kingdom each year (NJR 2019).

per QALY means that a 1% harm rate in these procedures would create an incremental cost of USD 770 million per year (at the current number of annual procedures). Discounting at 3% reduces this to USD 585 million.

The WHO has been careful not to prescribe a cost-utility threshold, as this should ideally be based on the local context, preferences and priorities. However, it specifies that interventions with a cost-utility of less than the GDP/capita to be 'very cost-effective' and those with between 1- and 3-times GDP/capita as 'cost-effective'. Ratios above this are not considered cost-effective (Auraaen et al., 2016[38]).

Using a WTP of 2-times GDP per capita may provide a way to estimate the 'social cost' of harm more generally. One could presume that societies might be willing to pay to prevent harm based on how much they pay for interventions that ameliorate other causes of morbidity and mortality.

Applying this to the findings of (Cassini et al., 2016[26]) suggests that the social cost of the six types of healthcare-acquired infections in EU countries amounts to USD 230 Billion a year. [26] The five healthcare-acquired infections analysed by (Zacher et al., 2019[27]) incur a cost of USD 135 Billion a year in EU countries. [27]

Globally, the annual social cost of harm would near USD 1.4 Trillion based on the findings of (Jha, 2018[8]) using the 2-times global GDP per capita metric.[28] The annual social cost in high-income countries would be valued at USD 1.9 Trillion,[29] just over 2% of current annual gross world product (GWP) – a measure of global economic output.

These figures must be interpreted with caution as they do not consider preventability of harm and are based on WTP for medical interventions to *treat* morbidity and mortality, not prevent them. Societies and populations may place a lower or higher value on avoiding patient harm. In fact, some evidence suggests that avoiding certain types of iatrogenic harm attracts a much larger amount of resources per QALY/DALY than what is typically spent on medical interventions.

For example, the marginal cost of some screening tests of donated blood to reduce the risk of HIV and hepatitis B and C transmission during transfusion exceeds USD 50 million per QALY in some jurisdictions (Borkent-Raven et al., 2012[42]; Janssen et al., 2017[43]; Marshall et al., 2004[44]; Moatti, Loubière and Rotily, 2000[45]). This means that, societies place, at least implicitly, a very high value on preventing these adverse events.

Clearly the cost of unsafe care based on societies' WTP to avoid patient harm is considerable. It can be a useful way to present not only the size of the problem but also inform resource allocation decisions more explicitly. To advance this area, more research is needed on the QoL impact of unsafe care as well as societal preferences regarding the WTP to prevent patient harm.

Patient harm may reduce economic output by trillions each year

The human capital approach using cost-of-illness seeks to model the effect of morbidity and mortality on economic output. The main variable of interest would ideally be the change in economic productivity

[26] This assumes an interchangeability of the DALY and QALY, which should be done cautiously. When an intervention is aimed at preventing or treating a non-fatal disease, the relationship between QALYs gained and DALYs saved depends on age of onset and duration of the disease, as well as the quality of life / disability weights, while in case of a fatal disease, a larger number of factors may determine differences between outcomes assessed with the two metrics (Sassi, 2006[151]).

[27] Using an EU GDP per capita 2019 of USD 46 000 (Source: https://data.oecd.org/gdp/gross-domestic-product-gdp.htme)

[28] 2019 World GDP and population. Sources: http://statisticstimes.com/economy/gross-world-product.php and https://worldpopulationreview.com/

[29] HICs as defined by the World Bank; based on the 2018 GDP per capita of OECD countries: USD 46 173. Source: https://data.oecd.org/gdp/gross-domestic-product-gdp.htme

of the patient *and* their informal carers, who will need to reallocate some of their time and effort to caring for the harmed patient.[30] Lower taxation revenue and higher welfare payments are also calculated.

However, only the effects on patients (not on their informal carers) are typically included in this approach. This method is also biased towards people of working age, neglecting the fact that retired people are also economically active. Such activity is likely to be affected by prolonged morbidity due healthcare harm, more resources will be consumed in other areas and industries (health and social care).[31]

Studies have applied variations of the human capital approach to specific types of harm. (Gyllensten et al., 2014[46]) estimated the total social costs of adverse drug events (ADEs) in primary care using a random population sample in Sweden. That country's comprehensive system of clinical, cost and social insurance registries allowed both the direct and indirect costs such as sick leave and disability pensions to be calculated. The indirect costs (based only on productivity loss from sick leave and from income support/disability pension) were USD 3 405 per patient with at least one ADE, over double that of patients without ADE (who are also unwell and therefore experience a loss of productivity). The total marginal economic cost for people with ADEs in the sample was USD 3 794. Applying this figure across the entire population amounts to 0.75% of Sweden's GDP.[32]

Estimating the indirect cost of safety lapses can also be attempted by combining what is known about the disease burden of patient harm with cost of illness studies for other diseases. For example, (Schofield et al., 2016[47]) modelled the combined costs of productive life years lost (PLYLs) lost, welfare payments and lost tax revenue due to chronic diseases among Australians aged 45-64 years at 1.6% GDP in 2015. (Bommer et al., 2017[48]) estimated that the global economic cost of adult diabetes in 2015 was USD 1.31 Trillion or 1.8% of gross world product (GWP). Based on the human capital approach about 35% (USD 458 billion, or 0.63% of GWP) of these costs were indirect.[33] Diabetes accounts for approximately 57 million DALYs a year (Hay et al., 2017[49]), whereas the annual global burden of adverse events is estimated at 64 million DALYs (Jha, 2018[8]). Assuming a similar disease impact profile, patient harm may reduce on global economic output by as much as 0.71% each year.[34]

Based on this assumption, the potential cumulative effect of eliminating patient harm on GWP growth between 2000 and 2020 is illustrated in Figure 2.3. Eliminating harm during this timeframe would have resulted in: an average economic growth of 5.59% compared to 4.84%; 15% higher GWP in 2020 (USD 97.5 trillion versus 84.6 trillion); and an accumulated GWP gain of about USD 118 trillion over the two decades. While these figures should be interpreted with caution for several reasons (see Appendix 2), they underscore that unsafe care is a brake on inclusive growth.

[30] This comprises absence from work and 'presenteeism, where a worker is present but less productive due to their condition or disease.

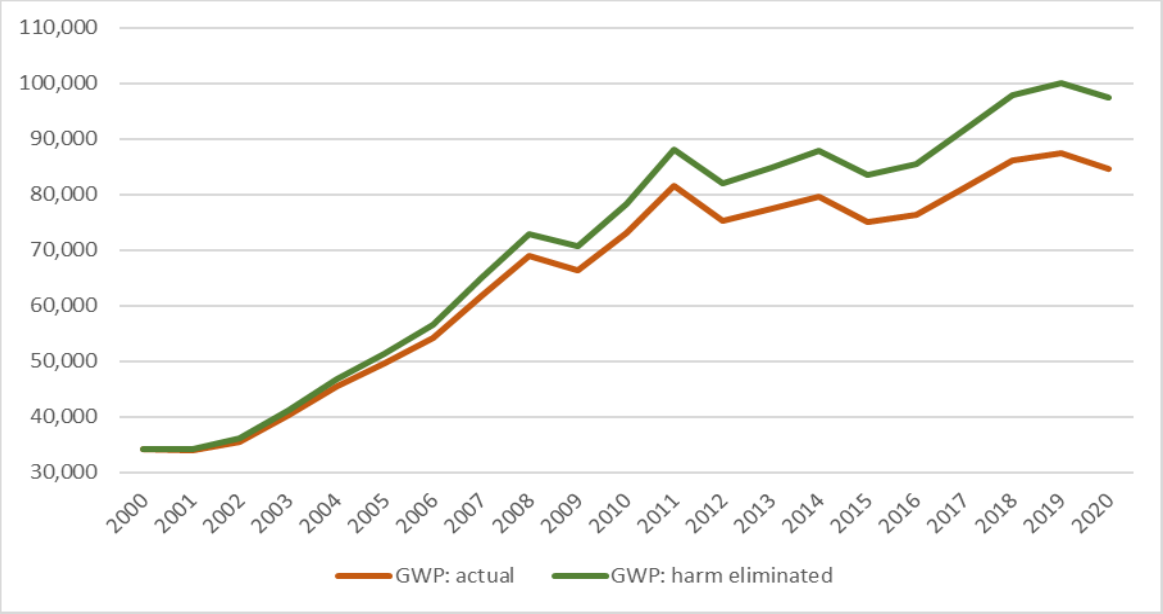
[31] This creates a circularity problem, where direct costs of harm also contribute to broader economic activity. Disentangling the net effect of this would require modelling beyond the scope of this report.

[32] This figure does not account for preventability of harm.

[33] The authors define indirect costs as "the economic burden caused by production losses due to premature mortality and morbidity (absenteeism, presenteeism, and labour-force dropout)".

[34] The mortality and morbidity profile of diabetes would differ to that of healthcare harm, but there are also some parallels. Both have a truly global impact -- perhaps more so than other diseases of similar aggregate burden such as malaria, tuberculosis and HIV/AIDS, which disproportionately affect poorer. In addition, the risk and effects of both are greater in older adults. See Appendix 2 for more detail.

Figure 2.3 GWP actual and with patient harm eliminated, 2000 – 2020 (USD billions, current prices)



Notes: Y-axis starts at USD 30 trillion
Source data: IMF *https://www.imf.org/en/Publications/WEO*

The complex problem of harm needs innovative solutions and investment

Considerable advances in medical technology have been made over the past 4 decades. Yet patients continue to be harmed at an unacceptable rate all over the world.

One possible explanation is that the growing complexity itself of health care inflates risk. (Reason, 2016[50]) warned that even the most advanced medical interventions are relatively simple compared to keeping all patients safe. To paraphrase Lewis Carrol, managing clinical risk needs to improve just to stay in the same place in terms of keeping patients safe in an ever-more complex system.

What can governments and policy makers do? First, they must see patient harm as a major public health and economic problem. Second, action and investment are needed to outpace the growing complexity of care, reduce the incidence of harm for all patients in all settings. The responses to the covid-19 pandemic and foreseen consequences for the world economy may prove to be fertile ground to re-emphasize focus on patient safety as an integral part of health system strengthening. Any state that wishes to protect its people from harm and promote inclusive growth is compelled to invest in reducing unsafe care, but to do so as efficiently as possible in the context of competing options and limited resources. This is the focus of the next section.

3. Investing in patient safety offers good returns

It is expected that by 2030 health expenditure in OECD countries will, on average, account for 11.3% of GDP, up from 8.8% in 2018. The main drivers of this increase are income growth (ability to pay), the low relative productivity and efficiency in health systems, and increasing complexity of medical care and technology (OECD, 2019[51]). Governments can constrain this growth by increasing revenues, re-allocating resources from other areas of spending, raising private financing of health care, or finding efficiency gains in health systems. Reducing unsafe care and improving safety presents an opportunity to prosecute the latter in managing expenditure growth. However, implementing and maintaining efforts to improve safety is not free. It also requires resources that need to be diverted from other uses.

Figures presented in Section 2.4 suggest that societies may be willing to pay considerable amounts to avoid certain serious adverse events. But this willingness to pay is not determined explicitly and is unlikely to apply to all adverse events. In the context of tightening health budgets and many competing funding demands, it is safe to assume that policy makers do not have *carte blanche* to begin funding all safety interventions in any manner they see fit.

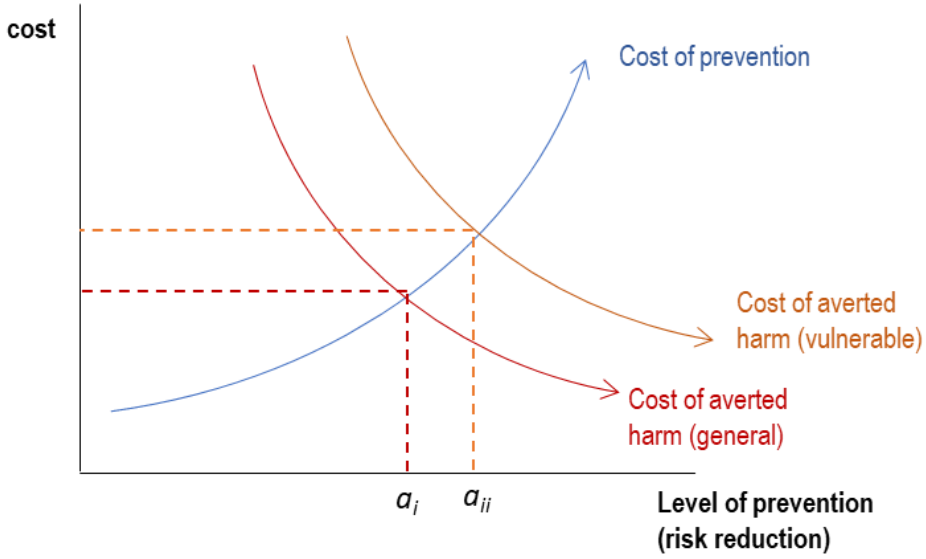
A useful way to approach this question is the concept of value for money. In its broadest conception, value is the ratio of the desired outcomes and cost of achieving them (Value = Outcome ÷ Cost). In the context of patient safety, the numerator (outcome) comprises (a) the extent of harm prevented or avoided and (b) the resources and other costs *saved* by preventing harm. The denominator comprises the costs of making care safer.

In a resource-constrained world, the question is which safety interventions, deployed either alone or in combination with one another, offer the best outcome at least cost? The main *economic* question is whether the benefits of investing in safer care outweigh those generated where the resources are taken from. This is the key for policy makers balancing prevention costs with the costs of safety failure. The challenge is to present the business case that safety strategies have a greater pay-off than alternatives.

Two important economic concepts increase the challenge for decision makers, especially at system level. First, to ensure optimal allocation of resources across all options in the health system (allocative efficiency) it is important to consider the incremental effects of investment (at the economic margin), as this will change depending on the amount that has already been invested. In any efforts aimed at reducing risk, the (opportunity) cost of preventing each additional quantum of harm will increase with the level of caution. Conversely, the marginal cost of safety lapses will diminish (Figure 3.1)

From a perspective of efficiency, investing in prevention is optimal up to the point where its marginal cost equals the marginal cost of harm. The optimal level is therefore at a_i, beyond which additional investment is likely to create more benefit elsewhere – the opportunity costs rise as one moves to the right of the curve. For example, (Begley, 1995[52]) analysed the cost-benefit of pharmacist visits to patients in their homes, finding that the net benefit of the fifth visit was 177 times less than that of the first visit. Sensible policy would limit visits and re-allocate the resources saved to another programme.

Figure 3.1 The cost of prevention increases and cost of harm avoided reduces at the economic margin



Source: Adapted from (Zsifkovits et al., 2016[53])

In some health systems, the marginal cost of certain medical interventions may indeed be at a point where re-allocation to other ends makes economic sense. For example, certain elective procedures appear to add little incremental benefit compared to their costs (Ferket et al., 2017[54]). Diverting any additional resources from these and other 'low-value' activities to make fiscal space for initiatives that reduce patient harm makes good economic sense. Given the level of variation and inappropriate care (Chew et al., 2016[55]; Buchan et al., 2016[56]; OECD, 2014[57]) and the hitherto nascent status of patient safety as an investment target, this is a likely scenario

It is important to acknowledge the inevitable trade-offs involved in making allocation decisions. For example, a tension exists between efficient versus equitable distribution of benefits (harm reduction) because the cost/benefit function will differ between, for example, geographic regions, patient types and healthcare settings. If equity is a policy objective, value judgements are needed to resolve this tension. This requires a more comprehensive conception of value, with more than simply health gain comprising the numerator of the value function.[35]

An intervention to reduce harm in a vulnerable patient population (e.g. in a remote location, for example) will be more costly. An equity consideration will move the curve to a new position in Figure 3.1, creating a new intersection point a_{ii} meaning that more investment is needed to achieve policy objectives.

Figure 3.1 also illustrates the rising cost/benefit of eradicating all harm and the need for policy makers to think in terms of an appropriate balance between the cost of prevention with the cost of harm. Health care is a complex, high-risk endeavour. Things will not go to plan 100% of the time. While health systems can certainly do better than the current 90% success rate, preventing *every* adverse event would effectively require shutting down health care altogether. This would incur a huge opportunity cost to health and the broader economy – adding up to much more than the cost of patient harm.

[35] If minimizing the aggregate health burden of unsafe care is the goal, the entire safety budget could potentially be invested in reducing HAI and VTE in surgical patients, at the expense of other specialties and settings. However, while potentially efficient, such allocation would not be palatable from an equity standpoint.

A useful analogy is civil aviation, another high-risk industry. Statistically, flying is extremely safe, but accidents are inevitable over time. The only way to prevent them altogether would be to ground all aircraft. But this would also forego all the benefits of air travel, which is obviously too high a price for eliminating *all* risk.[36]

A challenge is the lack of robust evidence for value and return on investment to guide decisions. High quality, full economic evaluations of safety interventions are rare, with many failing to include the cost of the interventions (Carter, 2021[58]). Most are effectively 'benefit' evaluations only. Another challenge is that results are expressed in a range of ways: savings-to-cost, cost-utility per QALY gained, cost per DALY avoided, and cost per adverse event prevented. This makes it difficult to directly compare the ROI of interventions across studies. (Carter, 2021[58]) found that approximately half of the literature identified addresses 3 patient safety outcomes: healthcare-associated infections, VTE and adverse drug events with only 17 high-quality randomised trials and economic evaluations. Twelve of these evaluated interventions aimed at preventing VTE, with most of these funded by industry.

Research is strongly skewed towards specific interventions, typically targeting one type of harm in a single setting. For example, an economic evaluation of decontaminating the digestive tract prior to elective gastrointestinal surgery - a highly specific, niche intervention – found a 92.1% probability of being cost-effective (Dijksman et al., 2013[59]). But in fact, the most savings and perhaps value may be in cross cutting, generic interventions. Zsifkovits et al., 2016[48] estimated savings of EUR 300 million through a programme to reduce healthcare-associated infections, about EUR 2 billion for pressure ulcers and about EUR 6 billion for implementing an electronic medication ordering system across EU member states.

The focus on specific interventions is unsurprising, given the methodological difficulties of gauging the effects of broad and cross-cutting interventions with research methods typically used to generate evidence for the efficacy and effectiveness of medical interventions. It is difficult to assess the impact of complex, multimodal interventions with powerful socio-technical determinants of success. As such, little evidence exists on such strategies as well as on the effectiveness of combining various interventions that cut across the levels of the health system.

This section attempts to provide evidence and information on where the best value and returns on investing in safety may be using a system perspective. Interventions are presented based on their level of implementation: 1. clinical, 2. organisational and 3. systemic. Despite the limitations of the evidence, a picture emerges. Safety should be at the heart of a value-based approach to health care. Some specific interventions targeting healthcare-associated infections, VTE and other types of events deliver a particularly high return. Evidence is also emerging for applying digital technologies and that improving information transfer can be very effective.

However, moving from analysis to action will require deeper behavioural change across entire health systems. This cannot be achieved with a piecemeal approach of deploying individual interventions and technologies. An overarching institutional and policy framework is needed as a vehicle to generate more benefit per dollar invested in safety. Such a framework includes governance, information and measurement as well as a consideration of the behavioural incentives, including financing and remuneration, that are embedded in all health systems.

[36] Notwithstanding other costs, such as environmental impact of air travel.

3.1 Targeting specific types of harm at clinical level is a worthwhile investment

Previous papers on the economics of patient safety identified patient safety interventions that can be considered to take place at the clinical level.37 Strategies targeting the most common adverse events (VTE, HAI, ADEs, surgical safety, pressure ulcers, falls and diagnostic errors) were ascribed the highest benefit to cost ratios. In this sub-section, recent evidence on the effectiveness and potential return on investment of clinical-level interventions is outlined.

Tackling healthcare-associated infections delivers excellent returns

Based on the available evidence, interventions aimed at preventing healthcare-associated infections (HAI) stand out as having the potential to deliver exceptional value in all countries. A systematic review of interventions targeting HAI found a median saving-to-cost ratio of 7:1 (a 7-fold ROI) across the 18 papers that met the inclusion criteria and reported both the costs and effects of the intervention (Arefian et al., 2016[60]).[38] This accords with a prior study that focused on interventions targeting hospital-acquired MRSA infections and found a median savings-to-costs ratio of just over 7:1 (Farbman et al., 2013[61]).

(Arefian et al., 2016[60]) also reported that the most common costs of implementing HAI interventions were practitioner time, antimicrobial and other pharmaceutical use, and administrative time. The reported ROI tended to be lower in multi-centre studies compared to single faculties perhaps due to higher implementation costs of changing behaviour across larger, disparate organisations. Higher ROIs were reported in studies of aimed at several types of HAI compared to preventing a specific type. Interventions in the surgical setting had higher ROI than other specialties.

Targeting HAI appears bear economic fruit irrespective of context or baseline levels. A systematic review and meta-analysis found that multifaceted interventions can deliver significant reduction in HAI rates irrespective of a country's income per capita (Schreiber et al., 2018[62]). (Nuckols et al., 2016[63]) reviewed the evidence for interventions to prevent bloodstream infections from central venous catheters (CLABSI) -- a frequent cause of hospital-acquired sepsis. The systematic review covered 113 hospitals found that the average impact was associated with 57% fewer infections and incremental net savings of USD 1.85 million per hospital over 3 years.

Moreover, each additional dollar invested generated a 3-fold return suggesting that larger initial investments may be associated with greater savings. Infections and costs declined even at hospitals already using checklists and/or with low baseline infection rates. Most interventions adopted protocols recommend by AHRQ, the United States' Agency for Healthcare Research and Quality (Nuckols et al., 2016[63]).

Overall, the evidence suggests that HAI reduction strategies across the relevant parts of a health system deliver an ROI of 3-1 to 4-1. Given the additional benefits of reduced harm and loss of life that stems from reducing HAIs, this figure would no doubt be an attractive value proposition for the policy maker compared to many alternatives, especially if these returns can be gained at the economic margin.

Minimising HAI with resistant organisms is critical in reducing patient harm as well as antimicrobial resistance. The majority of studies examined by (Bacon et al., 2020[64]) showed reduction in infections such as *C.Difficile* following a period of antimicrobial stewardship. Multi-modal interventions to prevent specific infection and spread of resistant organisms in are considered the most effective. The most

[37] Meaning they can theoretically be implemented at clinical or ward level without broader organisational or system involvement that would be required to implement, say, an electronic medical record.

[38] The average ROI was 11:1 but this figure was skewed by high ratios in two of the studies examined.

common components of these interventions are environmental cleaning, hand hygiene, patient isolation, and contact precaution, testing, and surveillance.

Interventions to address resistant HAI and indeed any type of harm have a strong socio-technical component. They require staffing, behaviour change technological resources, and provider buy-in. This is complex and costly but given the systemic and global risks of these infections, considerable marginal returns on investment are likely if the right culture and other institutional settings are created.

Hand hygiene, a fundamental aspect of reducing HAI, serves to illustrate the critical nature and cost of socio-technical change (Bacon et al., 2020[64]; GHP, 2020[65]). In terms of hardware and infrastructure, hand hygiene is an extremely cheap intervention. However, implementing behaviour and cultural change across an organisation can be challenging and therefore costly (Le et al., 2019[66]).

For example, compliance with the WHO '5 moments' protocol of hand hygiene practice even in medical and surgical intensive care units has been found to be as low as 42.6%. The main direct cost of improving hand hygiene is not soap, gel or dispensers, but staff time. The low compliance rate amounted to between 8.3 minutes and 11.1 minutes per patient per patient day. Full compliance would result in approximately an hour spent on hand hygiene per patient per day (Stahmeyer et al., 2017[67]).

A range of ways exist to promote hand hygiene in the healthcare setting. One study found that installing touchless dispensers in an intensive care unit resulted in an average 53% increase in usage across the unit. Usage of dispensers located next to patients almost doubled (Scheithauer et al., 2011[68]). However, the importance of organisational-level levers such as a safety culture in facilitating the necessary behavioural change must again be emphasised.

Turning to specific HAI types, CAUTI is a major source of additional costs but also are amenable to reduction through changed nursing practices such as *inter alia* more prudent use of catheters and better insertion protocols. Using chlorhexidine instead of saline solution cleaning prior to catheter insertion has been demonstrated to be a simple but effective method to reduce incidence by over 70% (Mitchell et al., 2019[69]). However, as with many interventions to reduce harm, this is more costly than usual practice. Not only is chlorhexidine approximately twice the price of saline solution, shifting to its use requires a change in established nursing practice that can often he hard to shift.

(Mitchell et al., 2019[69]) demonstrated that using the more expensive chlorhexidine solution can be deliver a good ROI. In an Australian hospital setting, it resulted in savings of AUD 387 909 per 100 000 catheterisations through shorter length of stay and treatment costs, freeing up 282 ward bed days per year. Across all Australian public hospitals (3.06 million overnight admissions) this would equate to AUD 2.9 million and 2 160 bed days each year. The intervention resulted in a gain of 1.43 QALYS per 100 000 catheterisations, suggesting a 75% probability of the intervention being cost-effective at a cost-utility ratio of AUD 28 000 (USD 19 000).

Evidence for preventing and managing sepsis is mixed (Bacon et al., 2020[64]). However, implementing a multi-faceted sepsis reduction programme across a large Australian public cancer hospital resulted in fewer ICU admissions, shorter length of stay and lower mortality. Post-implementation, the costs of admission were AUD 8 363 lower per non-surgical patient, a 30% reduction (Thursky et al., 2018[70]).

Unfortunately, implementation and maintenance costs of the programme were not compared to the savings, again underscoring the need for more research and greater rigour in economic analyses of safety interventions. However, the authors describe that implementation required "considerable effort" across all levels of the hospital. This included education and training of staff, nurse credentialling and changes in culture and practice. Such an undertaking would require considerable resourcing. Nevertheless, it would be surprising to expect the cost to approach 30% of patient admission revenues.

Patients who develop sepsis can deteriorate rapidly. Failure to detect and rescue deteriorating patients exerts considerable harm especially in the hospital setting. Implementing patient monitoring systems

(PMS) shows mixed and moderate evidence for a reduction in rescue events and on mortality, length of stay and ICU admissions. PMS with clinical monitoring seems to show little effect on mortality, while PMS with intermittent vital sign input has a moderate and inconsistent association with mortality (Bacon et al., 2020[64]). The evidence for rapid response teams is inconclusive, with moderate evidence that they can decrease cardiac arrest rates on normal wards (Bacon et al., 2020[64]). These interventions can be costly to implement and maintain. Better economic evaluations are needed to make an informed judgement on their value.

Pressure ulcers and falls must be reduced, especially in long-term care

Pressure ulcers and patient falls are more prevalent in the non-acute setting such as long-term care. While complete eradication of these adverse events is realistically impossible, significant reduction in their prevalence has been demonstrated.

Pressure ulcer incidence can be reduced with better protocols that include inspection, mobility, nutrition and hydration, and incontinence/moisture management. Falls risk can be managed with education and environmental risk reduction for falls. All require significant changes in behaviour, physical environment and organisation culture.

The economic value of preventing pressure ulcers among LTC patients is discussed in a recent OECD paper (de Bienassis, Llena-Nozal and Klazinga, 2020[7]). (Wood et al., 2019[71]) evaluated a collaborative approach to reduce pressure ulcers across provider organisations in the north-east of England. The programme was not costed but resulted in a reduction of pressure ulcer incidence of 36% in year 1 and 33% in year 2 of the study. The total estimated reduction in the number of marginal bed days lost was 220-352 across the region over two years.

(Barakat-Johnson et al., 2019[72]) studied the impact of healthcare-acquired pressure ulcer reduction programme in an Australian health region. A 51.4% reduction in incidence and a 71.6% reduction in prevalence were reported over 3 years. The authors estimate that the programme delivered net savings of AUD 837 387 (23% of relevant care costs). Implementation costs principally comprised changing staff behaviour through education and training.

In the inpatient setting, (Whitty et al., 2017[73]) estimated that a pressure ulcer prevention bundle in an Australian tertiary hospital produced a negative result. The bundle cost AUD 144.91 more per patient than standard care, with the largest contributor being clinical nurse time for repositioning and skin inspection. The cost per pressure ulcer avoided was estimated at AUD 3 296. The length of stay was unexpectedly higher in the care bundle group. The net monetary benefit for the care bundle was estimated at −AUD 2 320 per patient, suggesting the bundle was not an efficient use of resources in the tertiary hospital setting.

Investing in falls prevention can also deliver a good return in the LTC setting (de Bienassis, Llena-Nozal and Klazinga, 2020[7]). Evidence suggests that some inpatient groups should also be targeted. A patient-centered falls prevention programme in an Ontario (Canada) hospital's Transitional Care Unit resulted in an average net savings of CAD 5 848 per month. Implementing this intervention across all similar facilities in Ontario could potentially save almost CAD 8 million annually (Mendlowitz et al., 2020[74]).

(Haines et al., 2013[75]) studied the economics of a fall prevention programme in rehabilitation inpatients. The intervention comprised multimedia patient education with trained health professional follow-up. The cost per fall prevented was AUD 294 and AUD 526 to prevent a patient from becoming a 'faller'. With the average incremental cost of a fall being AUD 14 591, the interventions would appear to have a good ROI. The probability of the complete program being both more effective *and* less costly (from the health service perspective) compared to usual care was estimated to be 52%.

For VTE prophylaxis, aspirin can offer an efficient alternative

VTE exerts a large health and cost burden, and most cases can be prevented. The highest risk factor for developing VTE is a hospital admission, with surgical patients at particular risk. Without appropriate prophylaxis, rates of VTE among arthroplasty patients have been estimated to be as high as 60 percent (Stewart and Freshour 2013). Previous papers have highlighted the clinical and economic value of VTE risk assessment and prophylaxis. Checklists and protocols to improve safety and outcomes in surgical patients have been established in both developing and developed countries (Haynes et al. 2009; Ramsay et al. 2019; Seme et al. 2010; Shekelle et al. 2013; Slawomirski, Auraaen, and Klazinga 2017).

A series of economic evaluations have focused on novel anticoagulants that have recently entered the market. Many are of high quality but most are industry-sponsored (Carter, 2021[58]).[39] Recent research has focused on assessing the effectiveness of aspirin instead of other drugs with higher risk profile and/or cost. A systematic review by (Bacon et al., 2020[64]) found that, following major orthopaedic surgery, aspirin was generally found to be of similar effectiveness as other agents. Aspirin is significantly cheaper than newer alternatives. More prospective RCTs are needed to directly compare the effectiveness of aspirin to other prophylactic methods across patient risk levels but aspirin combined with mechanical prophylaxis should be considered, particularly among low-risk patients as an intervention with good ROI.

Evidence on reducing medication errors is mixed

Medication errors resulting in adverse drug events are a major source of avoidable patient harm. Several systematic reviews have found that medication reconciliation by pharmacists at hospital discharge significantly reduces the risk of medication discrepancies and subsequent harm. Pharmacist-led medication reconciliation prior to hospital discharge is cost-saving (in net terms) if it reduces the incidence of medication discrepancies by 11% or more (Shekelle et al., 2013[76]). Targeting of high-risk individuals would achieve a higher net benefit than a non-targeted intervention if the sensitivity and specificity of a screening tool were at least 90% and 70%, respectively (Najafzadeh et al., 2016[77]).

However, studies of domiciliary interventions by pharmacists to reduce medication error tell a different story. (Abbott et al., 2020[78]) reviewed randomised, controlled trials (RCTs) assessing the impact of pharmacist home visits for individuals at risk of adverse drug events. Their meta-analysis found no evidence of effect on hospital admission or mortality rates. No consistent evidence on quality of life, adherence and knowledge was found.

A RCT of pharmacist-led domiciliary medication review for older people in England found no evidence that this reduced hospital admissions. An economic evaluation of the results suggested an incremental cost per QALY gained by the intervention of GBP 54 454, finding only a 25% probability that home-based medication review is cost effective at a threshold of GBP 30 000 per QALY, with marginal cost per life year gained at GBP 33 541 (Pacini et al., 2007[79]).

(Avery et al., 2012[80]) conducted a RCT of a pharmacist-led IT intervention for medication errors called 'PINCER' for general practices in the United Kingdom. At 12 months after commencement, the mean incremental cost per medication error avoided was GBP 66.53. A follow up economic evaluation found that PINCER generated approximately 1 QALY per practice, at GBP 2 679 less compared with practices in the control group. Modelling suggests that PINCER had a 59% probability of being cost-effective at a GBP 20 000 per QALY threshold (Elliott et al., 2014[81]).

[39] All ten industry-sponsored studies of VTE prophylaxis produced a favourable result, with an average probability of cost-effectiveness of 88%. Two of the three publicly-sponsored studies had a favourable result, with an average probability of 52%.

Another study found that pharmacist-led medication reconciliation at the point of admission to hospital had a 60% probability of being cost-effective at GBP 10 000 per QALY (Karnon, Campbell and Czoski-Murray, 2009[82]).[40]

These findings suggest that pharmacist-led medication reconciliation may present the 'best buy' when applied during transition between care settings as opposed to home-based medication review. Cost appears to be the main factor. Pharmacists are typically already employed at a hospital, meaning that the marginal cost of their time will be lower than for home visits where they would need to be employed specifically for that purpose. In addition, a registered nurse may be equally equipped, especially when supported by ICT modalities, to conduct a medication review as part of a routine visit to the patient's home.

Better transitions of care are worth the investment

Stronger evidence can be found for the value of clinical handover. (Yao et al., 2012[83]) estimated the cost-effectiveness of a generic service delivery intervention to improve clinical handover in a large European hospital with 50,000 discharges each year. Harm attributable to handover errors was found to cost the organisation nearly EUR 3.5 million per annum. Modelling suggests that an intervention to improve handover would reduce these incidents by a third. The annual cost savings were estimated at EUR 771,602, which is considerable at the hospital level. Under the base case (21% effectiveness), 515 QALYs could be generated in one year, at EUR 214 per QALY – a highly cost-effective intervention.

More recently, (Bacon et al., 2020[64]) analysed 13 studies and 1 systematic review of interventions to improve transitions of care, including BOOST (Better Outcomes for Older Adults through Safe Transitions), CTI (Care Transition Intervention) and TCM (Transitional Care Model Model). The evidence suggests that these clinical handover programmes have been effective in reducing re-admission rates and are associated with significant reductions in healthcare costs which appear to offset the costs of their implementation and maintenance.[41]

But the value of clinical-level interventions is contingent broader factors

Clearly, a range of interventions to improve safety at the clinical level are a worth investing in. Infections, VTE, pressure ulcers and falls are a fruitful target, as are lapses in communication during care transitions. However, how much should be invested before the marginal returns begin to diminish? This will depend on the current level of investment, how results are tracked as well as how geared-up, or fertile, clinical microsystems are for implementation and improvement.

All safety interventions that are worthy of investment, based on the literature at least, require some underlying actions:

- change in behaviour and daily practice
- realigned responsibilities and accountability
- requisite knowledge, expertise and resilience
- adequate levels of staffing
- better communication and information transfer
- involvement and engagement of patients

[40] Digital technology offers more promise to reduce medication error and adverse drug events. Its potential and current evidence are discussed in Section 3.2.

[41] Costs *and* savings were analysed for CTI and TCM models only (Bacon et al 2020).

Their effectiveness is therefore highly likely to be enhanced (or diminished), and their implementation costs reduced (or inflated), by more fundamental factors spanning entire organisations and systems. This means investment in cross-cutting strategies, enabling technologies, processes and workflows as well as more intangible aspects of how complex systems function such as leadership, attitudes and organisational culture. These are addressed in the following section.

3.2 Cross-cutting organisational strategies are pivotal and require investment

Less empirical evidence on effectiveness and value exists for organisational-level interventions to improve safety. This is unsurprising given the difficulty of establishing causal links between cross-cutting strategies and reduction in harm compared to interventions aimed specifically at reducing specific types of adverse event. Nevertheless, interventions that build broader resilience and the institutional capacity to reduce harm are considered essential under a systems approach to safety (Braithwaite, Wears and Hollnagel, 2015[84]). These are typically implemented across an entire health service or organisation.

The evidence for digital technology and patient safety is growing

Functionality of digital technologies such as electronic health records (EHRs) and clinical decision support (CDS) has substantial potential to reduce the risk of adverse events. A 2015 review of reviews on health IT and patient safety found that the evidence for beneficial impact on safety is widespread, and that the number of studies showing positive effects (59%) substantially exceed the number of negative studies (8%) or studies with neutral or mixed effects (9% and 24%). The literature included a wide range of evaluations of both commercial and locally developed health IT systems (Banger and Graber, 2015[85]).

A systematic review and meta-analysis found that an “EHR system, when properly implemented, can improve the quality of healthcare, increasing time efficiency and guideline adherence and reducing medication errors and adverse drug events.” However, no association with patient mortality was determined (Campanella et al., 2016[86]).

(Hydari, Telang and Marella, 2019[87]) examined the incidence of adverse events reported from 231 Pennsylvania hospitals from 2005 to 2012, based on survey data from the Healthcare Information and Management Systems Society (HIMSS). After controlling for several confounding factors, the authors found that hospitals adopting advanced EHRs was associated with a 27% overall reduction in reported patient safety events, a 30% decline in medication errors and a 25% decline in procedure-related errors.

Computerised provider order entry (CPOE) appears to be very effective and cost-saving. Forrester et al. (2014) estimated the cost CPOE versus traditional paper-based prescribing in reducing medication errors and adverse drug events in the ambulatory setting of a mid-sized multidisciplinary medical group comprising 400 providers. Implementing CPOE cost USD 18 million less than paper prescribing and was associated with 1.5 million fewer medication errors and 14,500 fewer ADEs over five years.

(Encinosa and Bae, 2015[88]) studied adverse drug events in Florida hospitals, and whether use of health IT affected rates. Hospitals that had adopted all five of the core meaningful use measures saw medication error rates drop by a third.

Physician buy-in was found to be a dominant factor. Adverse drug events increased by 14% at hospitals reporting physician resistance to meaningful use versus a 52% ADE reduction at facilities where the health IT measures were better accepted.

The five core meaningful use measures regarding medication management included: 1. Using CPOE systems for medication orders; 2. Implementing decision support systems to check for drug–drug and drug–allergy interactions; 3. Having the capability to electronically exchange key clinical information

(such as medication lists, medication allergies, and test results) with other providers; 4. Maintaining an active medication list; and 5. Maintaining an active medication allergy list.

(Leung et al., 2013[89]) studied ADEs rates in five hospitals, correlated these rates with scoring on a tool that measures the functionality of CPOE. Both real and potential adverse drug events were highly correlated with scores on the CPOE instrument, with a 43% relative risk reduction for every 5% increase in CPOE score.

Diagnostic error has been earmarked for improvement through health IT for some time. By improving documentation, communication and coordination of care, EHR systems can help ensure that information is fully available at the point of care and that test results are seen and acted on (El-Kareh, Hasan and Schiff, 2013[90]; Schiff and Bates, 2010[91]; Singh et al., 2010[92]). For example, (Zuccotti et al., 2014[93]) studied 477 malpractice claims involving seven different hospitals in the United States, concluding that over half of these could have been effectively prevented through existing and available digital decision support tools that were not in use.

(Bacon et al., 2020[64]) found that digital tools to reduce diagnostic error, such as clinical decision support (CDS) and result notification systems (RNS) have improved diagnosis in exploratory and validation studies. Results varied by type of test result, setting, synchronous vs. asynchronous communication, and manual vs. automated alerting mechanisms.

However, most systems need to be fully implemented and tested in a clinical setting. Early evidence suggests that they are best used to complement not replace the clinician's decision-making process, but economic analyses are still lacking. Tackling diagnostic error must also incorporate education and training as well as patient engagement, which is discussed later.

High-quality economic evaluations of digital solutions for patient safety have not yet been conducted. (Zsifkovits et al., 2016[53]) suggest that implementing an electronic medication ordering system, comprising a CPOE system with a Clinical Decision Support System, across the EU can save EUR 6 billion a year.

However, implementing digital technology is notoriously expensive. Most implementation costs come from adapting workflows and changing daily practice as opposed to the acquisition of hardware, software and infrastructure. There is also the added risk that a high proportion of 'digital solutions' implemented at system or organisational level are not successful (OECD, 2019[94]).

Two considerations may make these costs more palatable. First, well designed and implemented digital platforms – especially EHRs - bestow a range of other advantages to a health organisation in addition to improving safety. These include better care co-ordination (if the platform spans or is interoperable across settings), patient engagement and easier administration. The costs can therefore be distributed across these other benefits (and means that the ROI of these technologies purely in terms of safety are difficult to estimate).

Second, while the initial cost of implementation is high, the marginal or incremental costs of maintenance can drop off significantly. Preventing the 1 000th medication error is much cheaper than preventing the first. Costs may not be so daunting if spread over several years, especially given the other potential benefits. However, IT solutions come with an important proviso that the systems or platforms must be able to exchange across silos, who must accept them as tools that makes their work of caring for patients easier, not harder. Many examples of the latter can be found (OECD, 2019[94]).

Three key messages on digital technology and safety can be distilled from the literature. First, more evidence comparing the implementation costs, health benefits and savings, and the success factors of these technologies is needed. Second, public policy plays a crucial role. Governance of personal health data - the lifeblood of these technologies and the knowledge created – is the responsibility of governments, especially in terms of assuring security of the data. Third, governments must also guide

the implementation of technical and operational standards for the introduction of digital technologies related to digitalization. Specifically to patient safety, policy can play a key role in explicitly guiding technical innovation as part of assuring public safety and health through a combination of governance, regulation and incentives (OECD, 2019[94]).

Optimal staffing levels need to be assured but depend on local requirements

Prior to the Covid-19 pandemic, the links between staffing levels, patient turnover rates and safety have been established, especially in the acute care setting. However, exact quotas or ratios are difficult to pinpoint (Keough, 2013[95]). This depends heavily on contextual factors such as patient complexity and casemix, other resourcing, staff experience, workflow as well as the physical environment, layout and organisation of care facilities.

Most studies of staffing use mortality, an important but rather blunt metric, as the outcome. Many studies compare different hospitals, but this may be flawed due to endogenous differences between facilities. Studies that examine staffing fluctuations within the same organisation are preferred, assuming independent factors such as HR policy and patient complexity remain consistent over the period studied. There is also a paucity of quality studies into optimal ratios in non-acute care.

(Needleman et al., 2019[96]) analysed 6 years of inpatient data from two tertiary and one community hospital in the United States, examining the association between patient mortality and registered nurse (RN) and nursing support staff (NSS) levels. Low RN staffing (compared to the ward average) across an entire admission increased the mortality risk by 2.3%, and 9.1% if the first and last days of the admission were excluded. For NSS, the figures were 3.0% and 3.2% respectively. Exposure to both low RN and NSS staffing levels was estimated to increase mortality risk by 2.5% for the entire episode and 13.6% if the first and last days were excluded.

(Griffiths et al., 2019[97]) examined the association between RN and NSS staffing levels in a large hospital in the United Kingdom. Using 3 years of admitted patient data, they found each day of RN staffing below the mean resulted in a 3% higher risk of death. The corresponding figure for NSS was 4%. Each additional RN hour per patient reduced patient mortality risk in a near-linear fashion (the more RNs, the lower the risk).[42]

NSS staffing levels below *and* above the ward mean appeared to increase patient mortality risk (i.e. U-shaped curve) (Griffiths et al., 2019[97]). This suggests that an optimal level of NSS may exist (with a mortality metric). This needs further exploration, with the authors suggesting that a greater number of NSS may create a division of labour resulting in RNs spending less time directly with patients. Another explanation may be that sicker patients (at a higher baseline risk of mortality) attract higher NSS levels, making the observed increase in mortality endogenous. Nevertheless, the finding suggests that increasing the number of lesser trained staff may not remedy the effects of nursing shortages in hospital care.

An older meta-analysis found a diminishing marginal effect of RNs in hospital care, with lower incremental benefit at higher staffing levels. However, the analysis drew on studies based in countries where average RN to patient ratios are typically higher than in the UK (Kane et al., 2007[98]).

The way staff are managed is also clearly important, with the role of the ward managers identified as critical to safety and other outcomes (NIHR, 2019[99]). This role is pivotal in staff engagement and well-being, which translates to productivity and culture within the clinical microsystem. Even though this role requires no formal patient interaction, it can greatly influence patient outcomes. Getting the right people with the requisite skills, attributes and experience into these roles is an important investment in safety.

[42] Although the curve presented in the paper does flatten slightly at the higher end of RN staffing levels.

An optimal staff ratio depends on several contextual factors and cannot be prescribed. A point clearly exists beyond which the cost of additional staffing adds too little value compared to alternative ways in which those resources can be deployed. The cost implications are considerable as the costs of permanent staff do not diminish greatly at the margin, and the costs of locum staff can be high. Nursing support staff are best seen as complementary not supplementary to registered nurses.

Policy makers should enable health services to determine the best staffing ratios based on local requirements. This can be enabled through flexible governance, including an infrastructure to measure harm accurately and to benchmark against peers. Beyond that, an adequate supply of trained personnel is needed to build resilience and capacity across a health system. This is a broader policy matter extending beyond individual organisations and is discussed in Section 3.3.

Evidence for the role of organisational culture is growing

Patient safety culture is a pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the process of care delivery (de Bienassis et al., 2020[100]). Culture is difficult to define and to study, especially in terms of finding direct causation of harm reduction in different contexts. However, enough evidence has now been generated to inform reviews on the subject. For example, an analysis of over 60 studies examining the relationship between organisational and workplace cultures, and patient outcomes, finding that over 70% of studies reported exclusively positive associations or a mixture of positive associations and no associations between culture and patient outcomes (Braithwaite et al., 2017[101]).

Other research on the effects of safety culture and patient outcomes has found mixed results. For example, a study of safety culture in NICUs did find that safety culture was significantly correlated with reduced hospital acquired infections, other quality metrics, such as antenatal corticosteroids, hypothermia, pneumothorax, chronic lung disease, growth velocity, and mortality were not correlated (Profit et al., 2018[102]).

Culture is notoriously difficult to change sustainably (Andres et al., 2019[103]) and a range of programmes and interventions can contribute towards a safety culture across an organisation. For example, Crew Resource Management (CRM) is a systematic approach to training leaders and staff and incorporating safety tools such as checklists into routine activities of a team, organisation or system. The aim is to foster permanent change in attitude and behaviour that permeates everything that is done. It was originally developed in aviation and subsequently translated to the healthcare industry (Moffatt-Bruce et al., 2017[104]). CRM can be effective with evidence suggesting that it results in greater knowledge, better confidence and increase use of teamwork skills, as well as improved clinical processes and improved patient outcomes (Bacon et al., 2020[64]).

(Moffatt-Bruce et al., 2017[104]) studied the implementation of a CRM programme at a large Academic Medical Centre in the United States, comprising 6 hospitals across two campuses, employing some 100 000 staff and caring for a population of over 1.5 million. The programme was implemented over 4 years at a cost of USD 3.6 million. Most of the costs were attributed to training and staff time. Compared to the baseline year, significant reductions in several types of hospital-acquired harm[43] were observed. A total 735 adverse events were estimated to have been avoided over the subsequent 3-year period at about USD 4 900 per adverse event avoided.[44] This is said to have generate between USD 12.6 million and USD 28 million in savings, translating to an ROI of 3.5 to 6.8 per dollar over four years.

[43] 1. falls 2. ventilator-associated pneumonia (VAP) 3. pressure ulcers 4. surgical site infection 5. *C. difficile* infection 6. adverse drug event 7. central line associated blood stream infection (CLABSI)

[44] A reduction in all adverse event types was observed with the exception of *C.difficile* infections, of which there were 192 more than expected over the follow-up period.

Despite its limitations (e.g. only one year of baseline data, no comparison or control hospital, omission of prominent AEs such as VTE), this study provides ground for optimism that investing in broad-based, systemic patient safety strategies, including those that aim to improve organisational culture, is worthwhile. Even the lower ROI estimate of 3.5 represents good value for money.

Importantly, about two-thirds (USD 2.44 million) of the estimated implementation costs were attributed to the initial roll-out of the CRMP. Ongoing expenses over the final year of the study were estimated to be USD 1.11 million – diminishing at the margin. This suggests that the ROI of this programme may be higher over a longer period if the reduction in harm can be maintained.

Evidence for interventions to improve teamwork such as Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS®), simulation and brief/debrief suggest mainly improvement in team member perception and confidence. Some reductions in adverse events such as HAI have been found, but no economic analyses are available (Bacon et al., 2020[64]).

Enhancing patient participation can bolster resilience

Discussion on the topic of safety has recently focused on building resilience within healthcare teams, organisations and systems to cope with complexity and prevent harm (see Section on governance below). Arguably the most important participant in the health care interaction and key member of the care team is, of course, the patient. It is therefore essential to also discuss how to make patients more resilient and engage them in care as part of any strategy to prevent harm and improve other outcomes.

A people-centred approach is a critical element in safe, high-quality care. Previous papers highlighted that patient and family engagement is strongly associated with better outcomes and less harm, and that such organisational interventions are very likely to represent good economic value (Slawomirski, Auraaen and Klazinga, 2017[5]; Auraaen, Klazinga and Slawomirski, 2018[6]).

Patient engagement, empowerment of patients and their informal carers, is not straightforward. Its implementation and practice depends on personal capacity, knowledge and relationships as well as personal values and priorities, especially when it encompasses family members and informal carers (Duhn and Medves, 2018[105]). Some studies show a statistically significant association with reduction in adverse events. But the approach depends on the clinical context and the quality of its implementation. Self-dialysis, for example, can empower patients and improve their experience while also reducing mortality and hospitalisation (Shinkman, 2018[106]).

A recent overview of the literature highlighted the importance of digital technology -- especially access to medical records, laboratory results and medication lists as well as portals that permit communication with providers – in reducing several types of harm (Sharma et al., 2018[107]). However, systematic reviews reveal a lack of understanding about the effects of engagement on patient safety among providers, patients, and families. Linking to educational interventions appears to result in positive perceptions and attitudes about patient engagement among healthcare providers (Bacon et al., 2020[64]).

Education of patients is critically important (Sharma et al., 2018[107]). Health literacy that changes the attitudes and behaviour of the patient is a powerful predictor of care outcomes. Fostering better health literacy among at-risk patient populations represents a good investment, as the benefits will follow the patient along their healthcare journey. This may be especially important for the growing population segments that are managing one or more chronic condition, who see multiple providers and access a range of services over time. Yet, recent evidence suggests that OECD countries are under-investing in, and underachieving satisfactory levels of health literacy (Moreira, 2018[108]).

Without leadership and positive role-modelling at all levels, a systemic pivot towards placing the patient and their informal carers at the centre of every action and activity will not be possible. It is difficult to

assign a precise financial value (or cost) to leadership, and perhaps it is better seen through a lens of political economy in health systems. It may be more about investing political capital by clinical, organisational and political leaders.

The value of education is in fostering the right attitudes, behaviours and skills

Education and training are important components of many clinical-level interventions including failure to rescue, antimicrobial stewardship and patient engagement. For practicing professionals, didactic or simulation training targeting clinical reasoning and diagnostic safety can be successfully delivered online. (Bacon et al., 2020[64]) found that studies of simulation-based education curricula for physicians and nurses report improvements in safety process and outcome measures. Cost savings were associated with reductions in central-line infections, overnight hospital days, or additional hospital days.

However, over the long-run education is also a fruitful investment that can have considerable return in patient safety as it fosters not just the right technical skills in health professionals and health workers more generally. Good undergraduate and post-graduate education pivotal in encouraging certain attitudes, behaviours and other transversal skills that are important in maximising patient safety.

Teaching only a simple, reductionist understanding of medical knowledge and practice may not prepare clinicians for real-world medical practice, where decisions incorporate more complicated kinds of information and require an element of tacit knowing, first formulated by Michael Polanyi in the mid-20th century (Henry, 2010[109]).

Training in metacognitive ability, complexity science and human factors has been shown to improve not only the 'soft skills' that foster better communication, teamwork and people-centred care, but also what was traditionally considered the 'hard', scientific and rational component of clinical practice such diagnostic accuracy - a major source of patient harm across settings. While important at both undergraduate and postgraduate levels, the effects are particularly evident as clinical experience increases (Bacon et al 2020).

The 'hidden curriculum' is also an important part of medical education. It includes the way they are socialised and role-modelling by teachers and supervisors, influencing what students learn in addition to what they are taught (Hafferty, 1998[110]). All of this determines the type of clinicians students eventually become and, as such, exerts a strong influence on organisational culture and the quality and safety of care (Slawomirski, Auraaen and Klazinga, 2017[5]).

In short, front-line clinical work does not take place in a vacuum. The cross-cutting strategies and interventions discussed in this section do not always affect service delivery immediately or directly, are nevertheless an important part of instituting (and institutionalising) safety practices across a health system. Similarly, health organisations do not operate in isolation from the broader health system, and there is a range of system-level policies and programmes that can foster a better environment to implement safer practices at organisational and clinical level. These are addressed in the next section.

3.3 System-level strategies are the foundation for safety

The survey informing the first OECD paper on the economics of patient safety asked a panel of experts to estimate the individual ROI of 42 safety interventions. It then asked respondents to select seven interventions that they would recommend implementing at the time of the survey in a 'typical' OECD health system. While the clinical-level interventions had the best individual cost-benefit ratios, introducing an system-level view and scarcity overwhelmingly favoured the systemic and organisational strategies such as professional education and training, clinical governance systems and frameworks, safety standards linked to accreditation and certification, EHR systems, and a national agency responsible for patient safety (Slawomirski, Auraaen and Klazinga, 2017[5]).

Compared to clinical-level interventions, these broad-based strategies take a considerable amount of time to establish and are challenging to implement and maintain. Given their scope and scale, it is difficult to measure their impact on specific safety outcomes using traditional methods. Such studies will always be observational and lacking in suitable controls, with the counterfactual always presenting room for doubt.

However, an absence of empirical evidence does not mean that systemic policy interventions are not an important or effective part of patient safety. Consensus is growing that broad-based strategies targeting entire systems not only add value in their own right, but provide the leverage and the framework for organisational- and clinical-level interventions to be more effective, especially given the multitude of different contexts these need to be implemented in across health systems.

National, whole-of-system programmes can be effective

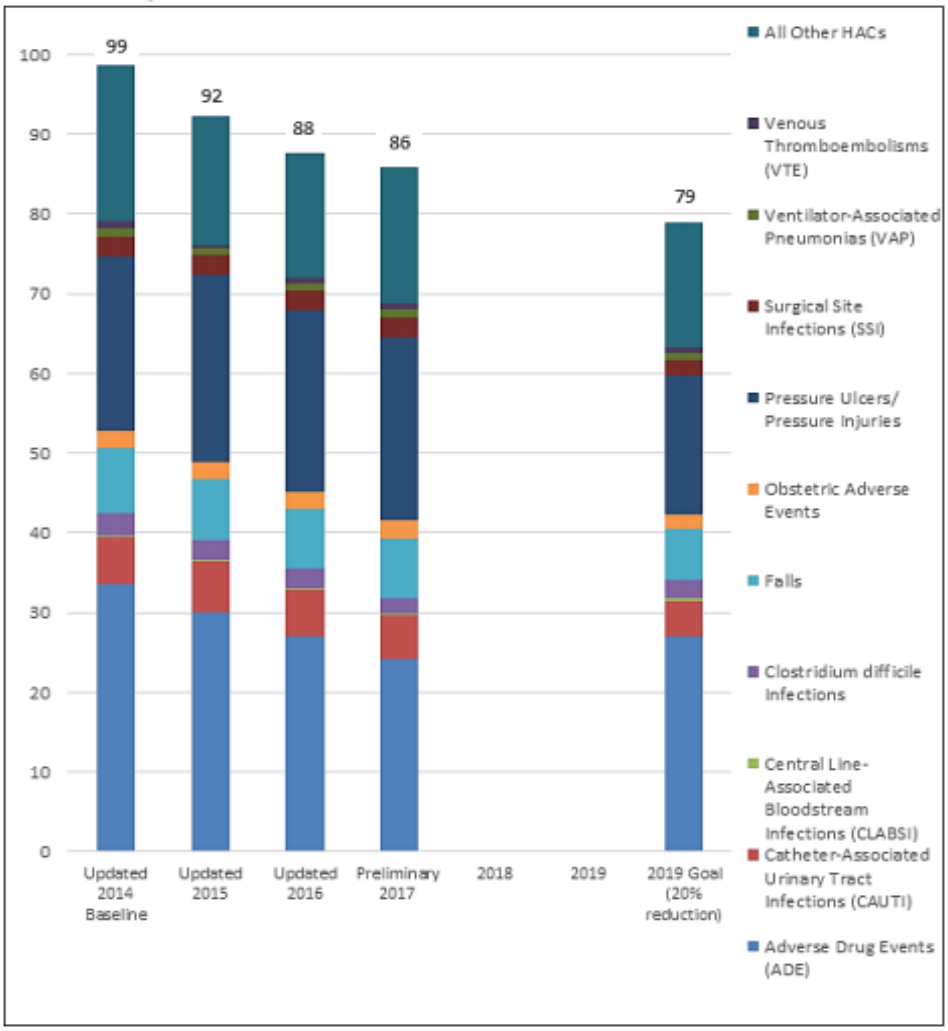
A pre-eminent example of an effective broad-based intervention to reduce harm across a complex and fragmented health system is the Hospital-Acquired Conditions (HAC) Reduction Program in the United States. The list of HACs comprises 28 patient safety events such as infection, VTE, adverse drug events, pressure ulcers and falls.[45] The programme applies to all acute care episodes across the country for patients covered by Medicare, which has over 100 million enrolees.

The latest estimates from the Agency for Healthcare Research and Quality (AHRQ) suggest a 13% reduction in the recorded HAC rate between 2014 and 2017 (Figure 3.2). This reduction translates 20 500 inpatient deaths averted, and USD 7.7 billion in costs saved over the 3-year period (AHRQ, 2019[14]). This equates to approximately 2.2 million DALYs and 1.1% of the annual Medicare budget saved.[46] A separate analysis suggests that healthcare–associated Clostridium difficile infection across the United States reportedly decreased by 36% between 2011 and 2017, whereas community-acquired infection rates remained unchanged (Guh et al., 2020[111]).

[45] For more detail see www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program

[46] Assuming 2.5 DALYs per event and based on the 2017 Medicare expenditure of USD 706 billion.

Figure 3.2 Updated 2014 data, with 2015, 2016, and preliminary 2017 national HAC rate data, and 2019 HAC goal



Source: AHRQ (2019)

The HAC Reduction Program is built on a pay-for-performance scheme with revenue adjustment of 1% based on hospitals' relative performance on the number and rate of HACs, degree of improvement on past performance, patient complexity and other factors. The adjustment itself is said to save Medicare approximately USD 350 Million per annum (NEJM Catalyst, 2018[112]).

It is unlikely that a 1% revenue adjustment is on its own enough incentive to drive change on that scale. The programme comprises several complementary initiatives of the *Value-Based Purchasing* scheme of the Centers for Medicare and Medicaid (CMS). These include public reporting, electronic health record implementation, initiatives targeted as specific types of harm as well as local quality improvement efforts, which ideally work in concert to achieve the objective of the programme.[47]

A well-orchestrated national program can therefore result improved safety outcomes and associated savings. The operational costs of the initiative are not known. But with combined savings of USD 8.7 billion over 3 years (350 annually plus 7.7 billion in reduced admission costs) the ROI is likely to be 3:1 even if annual operational and administrative costs across the system approach USD 1 Billion per

[47] The initiative may have some unintended consequences that have not been explored. These are outlined in the incentives and financing section below.

year.[48] At this price, the programme can be said to cost approximately USD 3.30 per prevented complication, USD 146 000 per death prevented and USD 1 363 per DALY averted – a very favourable cost-utility ratio in the United States context (see section 2.4).

Safety governance is essential but must be fit for purpose

Governance has been accepted as an essential mechanism to manage risk, minimise failure and maximise outcomes in any high-risk endeavour, including health care. Governance in the context of patient safety covers a range of steering and rulemaking related functions carried out by governments and decisions makers to improve patient safety. These functions flow across all levels of a healthcare systems.

Governance relies particularly on 1. clearly defined roles and responsibilities, 2. key accountabilities 3. established systems for measurement and monitoring, and 4. capacity and skills of the workforce (Auraaen, Saar and Klazinga, 2020[113]). While much can be learned from other industries, it is important to accept that health also differs in terms of its scope and complexity. This can be demonstrated be examining the risk model developed by (Pariès et al., 2019[114]) that places the activities of an industry on two axes: organisational control (the level of autonomy of front line operators) and predetermination (the management of uncertainty) (

Figure 3.3; see also Box 3.1).

Endeavours that exhibit low predetermination can be considered as more adaptive, allowing for more flexibility and innovation. Therefore, those in the top right corner are most suited to high-reliability principles. These focus on the capacity to operate high-risk processes by way of maintaining a tight control of existing risk. Activities in the bottom left corner may be most suited to the principles of another approach to safety: resilience, a model that allows efficient variability and acceptance of uncertainty as a key component of managing safety.

Figure 3.3 Governance model based on pre-determination and organisational control

	Low PRE-DETERMINATION	High
High ORGANIS-ATIONAL CONTROL Low	**Hierarchical – adaptive** • Fire brigades • Aircraft carriers • Submarines • Commando units • *Surgery* • *Long-term care*	**Hierarchical – normative** • Nuclear • Aerospace • Rail • Heavy industrial processes • *Radiotherapy* • *Blood transfusion*
	• Deep sea fishing • Road transport • *Emergency care* • *Primary care* • *Paramedics* **Autonomous – adaptive**	• Offshore drilling • ATM • *Intensive care* • *Anaesthesia* **Polycentric - normative**

Source: (Pariès et al., 2019[114])

[48] This figure would include costs borne by CMS as well as by the participating hospitals which need to comply with reporting requirements and, presumably, implement safety-enhancing interventions.

An example of the difference between the high-reliability approach and resilience engineering is illustrated in that of aviation (upper right) as compared to deep sea fishing (bottom left). Both activities entail significant exposure to risk, but the approach for managing risk varies significantly due to the inherent characteristics of these industries.

Aviation primarily handles risk by reducing risk exposure, and tightly regulating training, staffing, and operations. Organisations dealing with a constantly changing work environment, such as deep sea fishing or intensive care units, are less able to manage risk by using rules and procedures and may be more amenable to resilience engineering (Vincent and Amalberti, 2016[115]). Resilience engineering relies on the intelligence, adaptability and resilience of frontline operators, so, organisations focus on providing operators the support they need to address and confront the risks to which they are exposed

Health is unique in that its various settings and activities are spread across all four quadrants in Figure 3.1. This breadth of scope presents a challenge for designing a suitable governance model across an entire health system, which is not only very disaggregated but often also falls under various legal regimes and jurisdictions. For example, primary care providers in many countries operate as a small business, in contrast to hospitals. In Australia acute care and primary care are funded and overseen by a different level of government.

Health is so broad that it is better seen as comprising several industries in one. Different modes of governance may therefore be needed for different kinds of care. Some specialties may be candidates for ultra-safe care (such as radiotherapy) while others may benefit from high reliability (chronic care) or ultra-adaptive models (trauma) approaches, where the safety model gives more priority to flexibility and the ability to adapt to novel circumstances. These principles need to be applied to different parts of health care through targeted high reliability constructions and through fostering resilience among stakeholders, including the patients.

The long history of self-regulation also has an important effect on safety governance in health care. Regulation is often seen in a negative way, considered intrusive and distracting from conduct of clinical care (Oikonomou et al., 2019[116]). The regulatory landscape in healthcare is complex. It includes national laws, agencies, professional organisations and many other stakeholders. For considerable parts of health care, building capacity by following the principles of resilience engineering could be more appropriate than the comparison with high reliability organisations, which may be better suited for standardisation and top-down management.

Concerns have been raised about the applicability of controls and safety mechanisms from other sectors regarding regulation and top-down approaches. A study in the NHS of 42 risk controls concluded that the adoption of hierarchical approaches borrowed from other industries may not be highly relevant in health care settings in their ability to increase the reliability of outcomes—and that a more dynamic and flexible approach may be needed (Liberati, Peerally and Dixon-Woods, 2018[117]). The advantages and limitations of the conventional comparison with other high-risk industries such as aviation are discussed in Box 3.1.

An OECD paper on patient safety governance found that no ideal or optimal patient safety governance model exists. It is more important that patient safety governance (a) complements overall health system governance and financing, and (b) aligns its individual components and functions. However, patient safety governance should include all healthcare settings, and not neglect fragmented and ‘unwieldy’ sectors (Auraaen, Saar and Klazinga, 2020[113]). The focus must be the patient, whose perspective should be included in the design, implementation and execution of governance models.

Importantly, because many aspects of health care require resilience and adaptive thinking, governance should foster continuous learning from both harm and success, broadening the focus reacting to harm to risk assessment and management. A ‘just’ culture of transparency, openness and trust among all

stakeholders should be the aim. The importance of measurement means that data privacy/security policies and workforce preparedness must be incorporated (Auraaen, Saar and Klazinga, 2020[113]).

Finally, safety governance should encourage healthcare financing and investment that aligns clinical risk with corporate risk and consider the costs of prevention in the context of the costs of harm. The key elements of measurement and financing are addressed in later sections.

Box 3.1 Comparing safety governance in health to other high-risk industries

Parallels drawn between health and other industries can be useful but have limitations due to the inherent differences. For example, while professionalism is a common characteristic between aviation and health care, there are significant differences in terms of blame related to safety incidents, financial pressures, media coverage of mistakes, and concerns of safety for all levels of leadership and management (Kapur et al., 2016[118]).

In health, an adverse events most often affects one individual as opposed to large groups and the media coverage and pressure to adapt is not as high as in aviation. Reflection, investigation and learning are therefore not as rigorous. There is no such thing as a 'low level' incident in air travel. Any in-flight event that jeopardises the safety of passengers and crew is reported and thoroughly investigated—even near misses like engine failures appear in the media.

In health, low level harms such as CAUTI are often disregarded, at worst seen as an unfortunate but unavoidable part of hospital care. They fly 'under the radar' of consciousness and consequence. This is a big challenge.

Optimal safety management is also different because of the higher predictability of airplanes compared to patients. Faulty aircraft do not fly, period. In health the patient, by definition, presents with a standing level of risk.

The literature suggests systemic barriers to making health care delivery ultra-safe, including "the need to limit the discretion of workers, the need to reduce worker autonomy, the need to make the transition from a craftsmanship mind-set to that of equivalent actors, the need for system level (senior leadership) arbitration to optimize safety strategies, and the need for simplification" in ultra-safe systems (Amalberti et al., 2005[119]). Such arguments note that healthcare cannot be compared to high-reliability organisations due to variation in risk among medical specialties, insufficient definitions of medical error, and other structural constraints.

There are other differences that relate to the broader structures and institutions of other industries. Remuneration is one of these. Unlike many healthcare providers, pilots, aircraft maintenance engineers, and air traffic controllers are paid agreed wages as opposed to widgets: the number of flights performed, passengers carried, parts replaced, or aircraft guided to take off or land. The behavioural drivers created by remuneration no doubt play an important role.

A peak body responsible for safety should play a part

A national body responsible for patient safety is considered by many as an important institution to promote safety across a health system and lead to reductions in harm (Slawomirski, Auraaen and Klazinga, 2017[5]). The establishment, powers and responsibilities of such an organisation can vary but it is commonly understood that its principal responsibility would be to prevent patient harm by

institutionalising and embedding patient safety practices by aligning policies, methods, capacities and resources across an entire health system. This would comprise several functions including:

- Strategy and stakeholder engagement
- Data collection and analysis of safety and harm
- Developing and maintaining standards
- Research and analysis to inform the policy development process
- Assisting health services with local improvement efforts
- Developing and testing new safety concepts

An important goal of such an institution is ensuring that patient safety is on the political and policy agenda. Involvement of key stakeholders especially patients and clinicians in its establishment and functions is critical. It need not be a large, costly bureaucracy. A strong argument can be made for such a body to play a role in a safety governance framework, with tightly defined strategic and operational functions to promote safety and reduce harm.

It may also include the oversight of health service accreditation against safety standards. Accreditation can take several forms and range from rigid adherence to set standards to flexible approach based on local improvement. It can have a far-reaching impact, for example, influencing organisational culture (Andres et al., 2019[103]). However, the evidence on the value of current accreditation schemes is mixed (Castro-Avila, Bloor and Thompson, 2019[120]; Falstie-Jensen et al., 2015[121]; Jha, 2018[122]; Lam et al., 2018[123]).

A national institution dedicated to safety may play an important role in developed and developing countries alike. For example, a review of national policies and strategies to improve patient safety in Lebanon and Jordan found that both had successfully instituted safety and quality in national health plans and strategies, introduced licensing requirements for health professionals and organizations, and invested in health information systems. However, both lacked an explicit national policy for quality improvement and patient safety. Instead, a spread of several pieces of legal measures and national plans results in fragmentation and lack of clear articulation of responsibilities across the system. Incentive systems that link contractual agreement, regulations, accreditation, and performance indicators were underused or absent. Notably, both countries lack national sets of care quality indicators for performance measurement and benchmarking (El-Jardali and Fadlallah, 2017[124]).

The costs of safety governance are felt at both the central coordination point and the provider level. Implementing and adhering to the various functions and requirements of a governance model require time, money and resources. (Blanchfield, Acharya and Mort, 2018[125]) estimated the direct annual cost of maintaining the quality and safety governance requirements in a large United States healthcare organisation at USD 30 million, or 1.1% of net patient service revenue. Costs comprised measurement and reporting, safety, quality improvement and training and communication. Approximately 80% of costs was associated with satisfying the requirements of regulators, accreditors and payers. Just under 50% of these costs were associated with public reporting.

Such costs may or may not be prohibitive. If the result is even a modest reduction in harm this is likely to represent a good investment. Nevertheless, reducing the administrative burden of compliance through technology and process innovation should form part of the safety governance agenda (see Box 4 below for an example).

Analysis and action rely on a solid information infrastructure

Data and information are critical to the success of any intervention to improve patient safety, at any level of the health system. The potential value of interoperable digital platforms where data follows patients was discussed earlier in this section. But data are also highly useful for secondary purposes.

Timely information on performance has been shown to be a critical component in local improvement efforts. Data can be used for public reporting, patient information and governance and policy decisions.

For example, clinical quality registries (CQRs) have been found to improve safety and quality of care by providing feedback to healthcare systems about specific areas in need of attention.

implementing recommendation of the Surgical Quality Improvement Programme (NSQIP) in the United States on preventing specific surgical post-operative events (glucose fluctuations and VTE) cost USD 8 321 per event avoided from the hospital perspective[49] (Hollenbeak et al., 2011[126]). The incremental cost of post-surgical VTE to a hospital admission is about USD 21 200 (Anand, Kranker and Chen, 2019[22]), and generates 2 DALYs (Jha et al., 2013[25]). This would suggest a savings-to-cost ratio in the vicinity of 2.5, at just over USD 4 000 per DALY avoided – a decent ROI.

Thanh, Baron, and Litvinchuk (2019) examined the impact of the NSQIP on the incidence of SSI and CAUTI in five Canadian hospitals. They found significant reduction in rates and their consequent treatment costs resulting in a savings-to-costs ratio of 4.3, which was subsequently revised to 3.4 in a systematic review (Lee et al., 2019[127]).

(Woolley et al., 2006[128]) found that a reduction in sepsis following abdominal surgery stemming from information fed back by the Victorian Spleen registry (Australia) came at a cost of USD 18 000 (2017) per life year gained over the lifetime of affected patients. The savings-to-cost ratio of five Australian CQRs was found to range between 2:1 and 7:1, subsequently revised to 1.6 - 5.5 by (Lee et al., 2019[127]).

These studies have the obvious limitation of drawing a causal link between information provided by a registry and the results of safety improvement, which may have been secular or temporary. On the other hand, registries are developed for a range of reasons, whereas the studies focused on specific adverse events. The overall ROI of a registry is therefore likely to be greater if all its intended effects are considered. However, the studies did not include the implementation costs of the efforts to reduce harm. Nevertheless, the results can be used to make a case for the value of registries, especially the costs of creating and maintaining them are reducing with advances in data analytics, analytics and digital technology (OECD, 2019[94]).

Nevertheless, developing, maintaining and adhering to good data management can be expensive. Incident reporting systems, databases containing information on the causes and effects of patient safety incidents, are seen as an important aspect of closing the information loop that can enable learning from harmful incidents as well as near misses.

The value of such incident reporting systems is a source of ongoing debate. (Carter, Mossialos and Darzi, 2015[129]) explored the costs of the National Reporting and Learning System (NRLS), set up in 2002 to collect information from incident reports across England and Wales. Between 2001 and 2012, the implementation and management of the NRLS was conducted by the National Patient Safety Agency (NPSA) at an *average* cost of GBP 18.2 million per annum. Since the closure of the NPSA in 2012, average costs have reduced to about GBP 1.1 million (the NRLS is now managed by a NHS trust). This reduction is likely to reflect the transition of the NRLS form establishment to operational phase.[50]

Nevertheless, these figures reflect only the central costs of managing the database. They exclude the resources needed at the health service level to generate the reports, which vary in complexity and

[49] i.e. not including the central costs of maintaining the registry

[50] This GBP 18 million figure would be inflated by the start-up cost of the NRLS. The annual operating cost would be considerably lower.

length, and require the time and effort of trained staff. Nor do they capture producing feedback as well as local follow-up on recommendations that the incident reports may produce.

(Blanchfield et al., 2018[130]) estimated that the administrative cost of reporting serious reportable events (SREs) to be USD 8 029 per SRE, ranging USD 6 653 for an environmental-related SRE to USD 21 276 for a device-related SRE. Care management SREs occurred most frequently, costing an average USD 7 201 per SRE. Surgical SREs, the most expensive on average, cost USD 9 123. Investigation of events accounted for 64.5% of total cost, public reporting for 17.2%, internal reporting for 10.2%, finance and administration for 6.0%; and other costs accounted for 2.1%. The 17.2% incremental cost of public reporting is substantial. While SREs require more resources to report than other events, the incremental value of public reporting must always be assessed against its (opportunity) costs in a resource-constrained environment.

That said, digital technology, automation and other innovations can make reporting more efficient and less burdensome. A useful example is the Sentinel initiative of the United States FDA, which has automated a pharmacovigilance process that previously relied on voluntary reporting (Box 3.2).

Box 3.2. The Sentinel pharmacovigilance initiative

Although a pharmacovigilance scheme, the Sentinel initiative of the United States FDA is a model that could be adopted for improving as well as evaluating patient safety across a health system. The model is an example of efficiently using existing data to build valuable knowledge, while at the same time protecting individual privacy and the rights of data custodians.

Sentinel, launched in 2008, accesses personal health data of over 223 million United States residents to monitor the previously unknown adverse effects of approved pharmaceuticals and medical devices in routine clinical use. The data are scattered across a constellation of health care organisations, payers, providers and agencies. The key feature of this programme is its distributed nature which maintains data security. Custodians maintain full control over their data, which remain behind existing firewalls. At no stage does the Sentinel programme take possession of any data. The distributed system is based on common standards to ensure that all data are formatted to agreed specifications. This enables Sentinel to send electronic queries about the safety of technologies in current use to which the partner returns only the results. Notably, administrative (claims) data form the backbone of the Sentinel system due to their reliability in providing complete longitudinal information on the application and outcomes of biomedical interventions. However, the infrastructure also enables links with EHR and registry data.

The initiative has generated important knowledge not discernible from clinical trials, to enable several important regulatory decisions that have prevented considerable harm compared to previous method of mandatory reporting. It has also eliminated the need for expensive post-marketing studies in several products, saving millions of dollars.

Source: (OECD, 2019[94])

An important consideration in establishing an information infrastructure for safety is protecting privacy and ensuring the security of personal health data. These data are highly privacy-sensitive, but also highly valuable to public and private actors. Even if de-identified or anonymised, linkage across different data sets increases the risk of identification. Strong data governance frameworks are needed. These enable personal health data to be used for purposes such as measuring safety and risk, while also ensuring that these data remain secure and individual privacy is protected.

Again, such arrangements are not without costs. However, the costs are worth bearing given the benefits of secondary use of data flow many other areas of the health and biomedical ecosystem – for example the discovery of new therapies.

Ensuring sufficient nursing capacity is essential

Many types of harm, such as pressure ulcers, CLABSI, CAUTI and patients falls, are called nurse sensitive indicators because they mostly depend on nursing practice and care rendered in healthcare facilities. Section 3.2 outlined the value of education in safety at the organisational level, and the need for adequate staffing in healthcare facilities. However, the world is a broader facing nursing and midwifery shortage (WHO, 2020[131]), which must be addressed by policy makers. Countries affected by shortages will need to increase funding to educate and employ at least 5.9 million additional nurses. Additional investments in nursing education are estimated to be in the range of USD10 per capita in low- and middle-income countries (see Box 3.3).

Further investments would be required to employ nurses upon graduation. In most countries this can be achieved with domestic funds. Actions include review and management of national wage bills and, in some countries, lifting restrictions on the supply of nurses. Where domestic resources are constrained in the medium and long term, for example in low-income countries and conflict-affected or vulnerable contexts, mechanisms such as institutional fund-pooling arrangements can be considered (WHO, 2020[131]).

Development partners and international financing institutions can help by transferring human capital investments for education, employment, gender, health and skills development into national health workforce strategies for advancing primary health care and achieving universal health coverage. In addition, investment in the nursing workforce can also help drive job creation, gender equity and youth engagement.

The Covid-19 pandemic has served to underscore the importance of nurses – as well as all healthcare workers – in safe, high-quality health care. Safety is impossible without keeping workers safe, sufficiently equipped, and adequately prepared for what their unpredictable working environment presents (de Bienassis, Slawomirski and Klazinga, 2021[21]).

Box 3.3. Costs and benefits of educating nurses and midwifes

While nurses and midwives form more than half of the global health workforce, the spending on nursing and midwifery education is around a quarter of the global expenditure on health worker education. According to estimates published in 2010, the average global cost per nursing graduate is USD 50 000, ranging from USD 3 000 in China to over USD 100 000 in North America. The variation can be attributed to the proportional share of the public and private sectors in financing, owning and managing educational institutions, as models for financing nursing education differ both within and between countries (WHO, 2020[131]).

Another factor driving variability in the cost of nursing education is the different levels of qualification that coexist and diversity in the duration and prequalification of the education programmes. More and better data on nursing and midwifery graduates, and the cost of education and training, are needed to guide investments to meet the estimated shortages by 2030 (WHO, 2020[131]).

Investing in nurses and midwives can reduce healthcare costs without compromising health outcomes. For example, quality midwifery care is linked with rapid and sustained reductions in maternal and neonatal mortality and morbidity, reduced interventions in labour, enhanced psycho-social outcomes and increased birth spacing and contraceptive use (Sandall et al., 2016[132]). Nurses to deliver primary healthcare services instead of physicians could lead to similar or better patient health and higher patient satisfaction (Laurant et al., 2018[133]).

Evidence from the United Kingdom suggests that healthy women with low risk pregnancies birthing in a midwifery led unit, and multiparous women birthing at home, experience fewer interventions than those planning to birth in an obstetric unit with no impact on perinatal outcomes (Brocklehurst et al. 2012). Expanding midwife-led maternity services for eligible women may offer a means of reducing costs compared to the current leading model of care (Ryan et al., 2013[134]).

Incentives play an important part in ensuring safer care

Incentives – the behavioural motivations exerted by potential rewards and punishment -- play a central role in any human activity. These can be intrinsic or extrinsic. Intrinsic incentives include the satisfaction for providers when care is executed well and patient improves as expected, or the sadness and disappointment when things don't go to plan. Extrinsic incentives relate to rewards or punishments. Generally, these are thought of as financial rewards but need not be. For example, favourable comparison of one's performance against that of peers is considered an important motivator and a rationale for performance reporting.

Financial incentives revolve around the expected remuneration of an action or behaviour versus another. These can be explicit or implicit. Explicit incentives are the basis for pay-for-performance (P4P) schemes in health care, where (typically) a small part of providers' remuneration depends on achievement of agreed measures, which may include metrics on patient harm. P4P can be applied in several ways, as rewards or punishments based on, for example, overall performance, relative performance against benchmarks, or degree of improvement.

P4P schemes to improve safety and quality of care have proliferated in recent years. Implementation is fraught with difficulty given the wide range of endogenous and exogenous factors that contribute to patient outcomes. The size of the incentive, how and who it affects and reaches (individual clinicians, teams, management), how schemes are implemented and what complementary interventions are deployed (e.g. reporting) all play an important role in the success of P4P.

Overall, the evidence for the desirable impact of P4P schemes on patient outcomes remains equivocal (Frakt and Jha, 2018[135]; Mathes et al., 2019[136]; Mendelson et al., 2017[137]; Papanicolas et al., 2017[138]). The HAC Reduction Program described above appears to be successful in reducing the rates of common adverse events (AHRQ, 2019[14]). However, its sister scheme - the Hospital Readmissions Reduction Program also administered by the Centers for Medicare and Medicaid (CMS) as part of its Value-Based Purchasing scheme[51] - has been shown to disadvantage hospitals serving higher-risk patients (Roberts et al., 2018[139]).

Implicit financial incentives are arguably more powerful as they are baked into the way health systems operate through everyday funding and remuneration. Funding models therefore have powerful implications for a range of outcomes including safety. For example, some countries fund hospital care based on activity and throughput based on classifications such as Diagnosis-Related Grouping (DRGs). This payment model has advantages but is often criticised because payment is contingent on the level of patient complexity, which can include conditions that are acquired during hospital stay. In other words, an adverse event increases patient complexity and can therefore generate a higher payment, acting as a perverse incentive.

However, Australian data suggest that this presumption may be false if the overall cost of harm is considered. (Duckett and Jorm, 2018[23]) demonstrate that in Australian public hospitals, the payment 'bump' due to complications of care is lower than the additional cost of the admission during which the complication occurred. In fact, the additional cost of treating complications can be 2-times greater than the additional revenue they generate. Hospital managers and CFOs may be unaware of this differential.

The authors suggest that rather than penalising the occurrence of harm financially, not all of which is avoidable and may also encourage inaccurate coding, the data on 'lost revenue' could be provided to hospitals to serve as an incentive to improve safety. Data on harm could instead be collected and reported for comparison and benchmarking.

Aligning clinical, corporate and professional risk

In broad terms, the adequate management of clinical risk is not compatible with most activity-based or fee-for-service funding models. The consequences of a safety lapse are often latent, and manifest in another part of the health system. A hospital only bears the financial costs of harm during the same admission. Once the patient is discharged, the costs of additional treatment or investigations are often borne by other payers or funding silos.

In primary care, a provider may remain unaware when harm occurs if the patient is admitted to hospital or decides to continue care with another practitioner. In all cases, further additional costs are also borne by patients and the community more broadly, hence the considerable drag on economic prosperity exerted by patient harm outlined in Section 2.

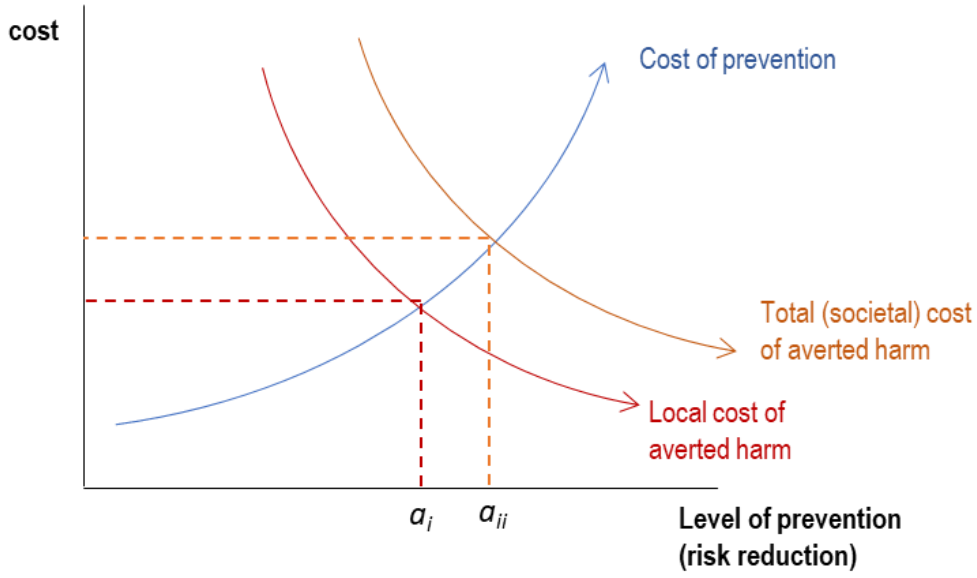
Figure 3.4 revisits the marginal cost functions from an earlier sub-section to illustrate how the aggregate costs of harm extend beyond the local situation and the health system itself. The economically rational decision at local level is to invest in prevention harm a_i, where the marginal cost of local prevention intersects with the local cost of failure. This may not necessarily be due to avarice, but simply a lack of awareness of the total cost. Nevertheless, there is currently little financial incentive to invest in the socially optimal level of prevention, located at a_{ii} on the horizontal axis, as this incurs a financial loss to the local provider while the benefits flow beyond the local sphere.

Correcting this is a major policy challenge. In fact, creating a funding framework that ensures investment in preventing harm reflects, and is aligned with, the cost of harm is the holy grail of patient safety. At

[51] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs

the local or organisational level, this means ensuring providers have 'skin in the game' (Taleb, 2017[140]) when it comes to safety and that the consequences of unsafe care are felt at their origin. At the system level, the total (i.e. the direct *and* indirect) cost of harm must be considered when making decisions and trade-offs for allocating resources towards safety.

Figure 3.4 Local costs of unsafe care do not reflect the total costs leading to sub-optimal investment in prevention



Source: adapted from (Zsifkovits et al., 2016[53])

Funding models must be seen as part of improving safety

Safety, from a whole-of-system perspective, requires funding models that rewards safe practice, align corporate risk with clinical risk, and create incentives that ensure the cost of harm is borne by the respective provider.

This can be difficult in in systems where one patient is treated by multiple providers and services, often for the same condition let alone multi-morbidity. One way to align incentives that draws on intrinsic motivation is to provide information on outcomes beyond the threshold of their care. This was difficult in the days of paper records. With the advent of EHRs it is much easier but only if patient records are integrated into a common data exchange platform.

For example, a primary care practitioner can be alerted when one of their patients is admitted to hospital if it is for a condition that can be managed in the community setting. Conversely, a hospital can be alerted if a patient seeks care in the community setting or is re-admitted to a different facility due to a hospital-acquired condition. This need to be linked to financial penalties, merely providing the information can provide an incentive to reflects, assess and correct and problems that may have contributed to the negative outcome.

Pooling financial risk is another approach. This can be achieved through novel remuneration models such as bundled payments. Instead of paying each provider involved in the care of a patient for their individual service component, remuneration is distributed retrospectively and can be contingent on a set of agreed milestones and outcomes. This approach maintains the interest of all providers in the overall outcome of care, even those at the very beginning of the patient journey. For example, under

this model the surgical team performing a joint arthroplasty will be more directly invested in the outcome after 12 months of rehabilitation, as opposed to discharge following the initial stay. Any safety-related problems will be felt at their origin as well as where they eventually manifest. This can be important for latent harm such as VTE.

Bundled payments are being implemented in several countries and have had some isolated success in the United States (Liao et al., 2019[141]; Navathe et al., 2018[142]; OECD, 2016[143]; Wadhera, Yeh and Joynt Maddox, 2018[144]). They are generally more palatable to providers and payers than block grants or population-based reimbursement, which have advantages but are difficult to administer. Again, such a longitudinal model would have been difficult in the pre-digital era, but improved information infrastructure, data linkage and computer processing make bundling a tangible possibility that should be explored (OECD, 2019[94]).

Another new financing model that bears promise in the field of safety is performance-based budgeting. Here performance data, such as risk-adjusted measures of mortality or other health outcomes at the regional or hospital level, indicators related to the process of care, or patient-reported measures can be used to inform budgeting and resource allocation across programs or regions. Allocation need not be punitive but can be targeted at areas where more resources are needed to improve safety.

At this stage, only a few countries explicitly link performance measurement systems and resource allocation, and performance-based budget allocations do generally not represent a significant share of the overall budget. An OECD survey conducted between November 2017 and May 2018 suggests only Chile, Italy, Finland, Lithuania, and Luxembourg reported using data from a national performance monitoring system to adjust budget allocations to devolved health care payers or individual provider organisations. Norway has adopted a performance-based budgeting system to determine budget allocations to its four regional health authorities based on indicators related to health outcomes, health care processes and patient experience (OECD, 2019[94]).

In short, incentives – be they implicit, explicit, financial or other – are critical in guiding the behaviour of all actors in health care. Any system-level approach to improve safety must harness incentives that promote behaviours to optimise patient safety. This includes the misalignment between clinical, corporate risk and professional risk – a common feature of health funding models. But it also includes the reporting of data on safety outcomes to providers, patients and the public.

While P4P schemes should continue to be tested, the most value is likely to reside in examining underlying financing models in terms of how they incentivise safety and other important policy considerations. Fee-for-service is a useful model for some purposes but contains inherent tensions with safety and other aspects of healthcare quality. Other models that encourage sharing of risk and take a longitudinal view of care should be tested. The advent of more data and digital technology to manage and analyse them makes many of the new approaches more feasible.

3.4 Policy makers must adopt broader system and societal perspectives when thinking about safety

This report has suggested that, individually, several specific interventions appear to deliver a very good ROI. Those aimed at the big-ticket items such as infection, VTE, medication errors, pressure injury, falls and care transitions appear to generate the greatest improvement per dollar invested. These events exert a large proportion of the unsafe care burden and are also amenable to improvement. They represent a low-hanging fruit for health systems looking to maximise value through better outcomes *and* lower costs.

At the local level, within health services and clinical microsystems, it is prudent to assess where the safety problems are and address these based on the available evidence for targeted interventions.

Chances are high that nosocomial infection, VTE, and diagnostic or medication error exert a significant burden, and present the best opportunity to drive better outcomes using interventions that have been tested, with some adaptation to local needs and consideration of marginal effects as the interventions mature.

However, the task for policy makers wishing to generate value through better safety across an entire national health system is more complex. It involves more than picking a set of clinical interventions with the highest ROI and rolling these out across the system without any regard for institutional factors that may enhance or inhibit implementation success. Context matters, and interventions are not deployed in a vacuum. Considerably higher returns may be generated when they are implemented on a platform comprising a good information infrastructure, sound governance, a conducive culture, and consideration of how the incentives baked into the institutions that determine behaviours across a health system influence safety-oriented behaviour. While difficult to pin down empirically, qualitative evidence suggests that these are important organisational and system-level strategies where investment can pay off.

The questions then become: how much investment, to what point and where? What is the ideal combination of resourcing across the number of local and system-wide options that will maximise allocative efficiency and value?

The economic margin is critical here. Health systems will rarely be allocating resources to safety 'from scratch'. Decisions must therefore be based around where the next quantum of resources will generate the most return, which will (eventually) begin to diminish the more is invested. A critical decision can often be when to *stop* investing in one area given the range of programmes and other priorities. This applies to activities that add little marginal benefit and/or exert a high marginal cost, which should be defunded to make the fiscal space for interventions to reduce harm.

Investment will ideally balance the costs of prevention with costs of failure, which also change at the margin (Figure 3.4). Most important, however, is to ensure the *total* cost of harm is considered, not simply direct costs at local and system level. The optimal level of investment will be achieved when the broader costs – borne by patients and societies – are considered (some estimates of these were provided in section 2)

The task becomes even more challenging when the inevitable trade-offs are considered. Maximising efficiency across an entire system inevitably requires value judgements, especially if equity and distributive factors are a policy objective. Interventions to reduce harm target different areas and types of patients: young versus old, or hospital versus community care. Generating the most QALYs, or dollar savings, may mean investing all available resources to reduce infections and VTE in major metropolitan hospitals. The net gains will outweigh the net losses of failing to invest in safety in other settings and targeting other harms. However, not many decision makers would accept this utilitarian approach, which neglects some patient groups and certain geographic locations. In addition to efficiency, most policy makers will want to build equity into their conception of 'value'.

In short, optimising value through better safety across a system requires a deliberative approach that adopts a system-wide view. This relies on more than selecting the most cost-effective clinical interventions. The broader policy and institutional requirements for their implementation, the total costs of harm, and how benefits are distributed across entire patient populations need to be part of decision making, and consequent implementation and evaluation.

4. Conclusion: acting on patient safety needs urgency and leadership

Governments of G20 countries and beyond have a legal and moral responsibility to protect the public from harm. A recent manifestation of this requirement are the swift actions in response to the covid-19 pandemic with many countries imposing restrictions on their citizens, directing their health services to respond to the threat immediately, and mobilising huge amounts of resources to mitigate the health and economic impact.

Capacity management and rationing steered by governments have affected many aspects of health care systems. They have also challenged, and demonstrated, the importance of pre-existing mechanism to assure the safety of patients, health care staff and citizens. Overall, this has certainly confirmed that, in a public health crisis, governments and health systems *can* respond, and respond quickly.

This paper has discussed another global public health problem, albeit one that has been unfolding for some time and continues to do so every day, month and year: patient harm.

Safety lapses during health care claim well over 3 million lives per year. The global health burden of unsafe care is estimated at 64 million DALYs, on par with road accidents and HIV/AIDS. The economic costs are massive. The direct costs of treating *preventable* safety lapses approach 10% of total health expenditure. Moreover, patient harm exerts a brake on global growth, potentially reducing global economic output by trillions of dollars per year.

While the response to covid-19 has been appropriate given the gravity of the threat (with some observations in Box 4.1), it provides a stark contrast with action and urgency to prevent patient harm.

Box 4.1. Observations from the response to Covid-19

- Strong information infrastructure to help assess real time spread and clinical impact covid-19 inform both prevention measures and resource planning.
- Upscaling existing data systems to guide rationing, distribution and use of limited capacities (protective material, tests, ventilators, health care professionals)
- A rapid shift to telemedicine, with policy, practice and funding working in concert.
- Importance of governance (national/regional) that can overrule the boundaries of public/private care provision and take on integrated care delivery approach.
- Various agencies coming together, different government sectors collaborating to build stronger healthcare systems. For example, education system increasing the uptake of highly needed specialties such as nursing.
- Updating of regulatory mechanisms in response to emergency situations, and immediate upscaling and substitution of care by setting, professionals and type of delivery (respiratory support in home situation monitored virtually by GP, teleconsulting, nurses and physicians with different specialties now recruited to do hospital/ICU work).

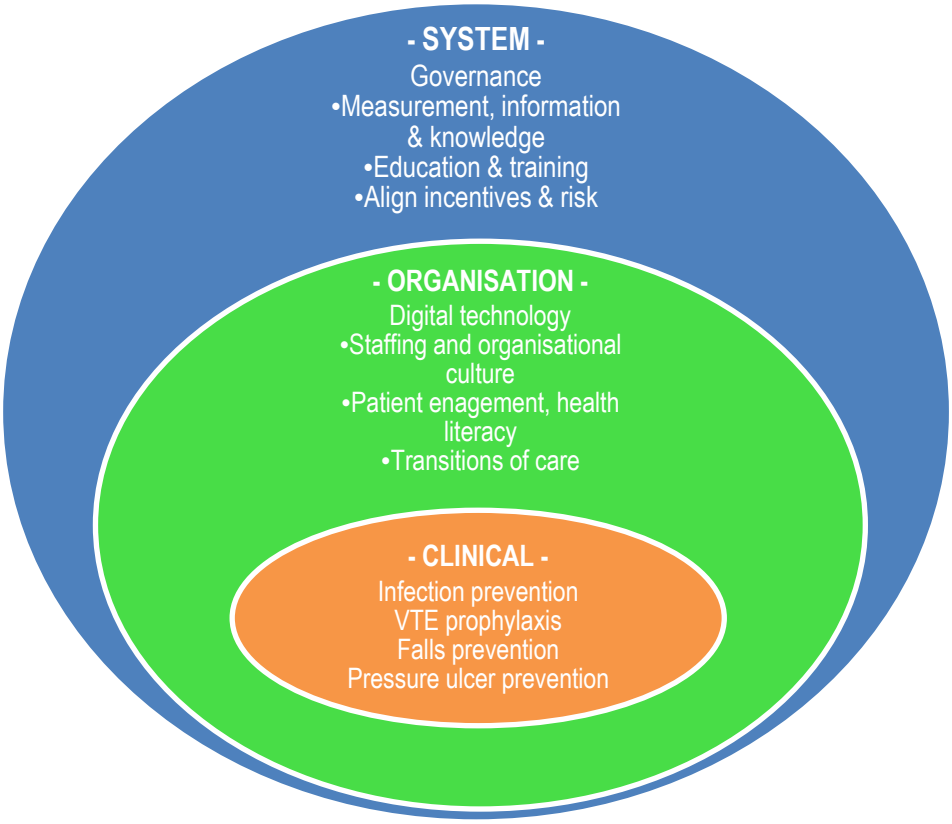
At the same time, diverting attention and resources towards managing the impact and spread of Covid-19 may increase risk of harm in other areas of health care, especially errors of omission by a system overloaded and distracted by a pandemic. With the exception of handful of countries, excess deaths compared to previous years have risen sharply throughout the pandemic and they outnumber official Covid-19 mortality by several orders of magnitude (Giattino et al., 2022[145]). Many of these excess deaths are actually due to Covid-19 and just not recorded as such. But not all of them. These consequent risks of responding to the crisis must also be considered.

In the end, it is incumbent on governments to protect the public from harm. This includes harm from unsafe care. More needs to be done given that risks are evolving constantly with the growing complexity of medical care as well as the patient population. While intervention requires mobilising significant resources, these are currently dwarfed by the direct and indirect costs generated by harm. Investing in safety is an excellent value-proposition because it simultaneously improves health outcomes, and reduces costs associated with harm, freeing up resources to be deployed where they will generate additional benefit.

Value can be created through considered allocation and investment at three levels of a health system: clinical, organisational and systemic. Specific interventions targeting healthcare-associated infections, VTE and other types of events deliver an exceptionally high return (as high as 7 dollars per dollar invested in some cases), as does better communication across healthcare settings. Digital technologies are emerging as a particularly ‘good buy’, although their value is heavily contingent on their design and implementation.

Cohesive implementation of interventions across the three strata is key as system-wide improvement requires, by definition, systemic behavioural and institutional change. This cannot be achieved with a fragmented approach. Rather, an overarching institutional and policy framework spanning all tiers of a health system is needed as a vehicle to generate greater returns on investment in safety (Figure 4.1).

Figure 4.1 Clinical- organisational- and system-level strategies can deliver ROI and value when implemented in concert



Source: Authors

Such a framework includes investing in good governance, education (especially in nursing and midwifery expertise), building resilience among key actors including patients and fostering the right organisational culture. It is underpinned by good information systems, and the requisite infrastructure and governance of personal health data. It must include an examination of whether incentives that drive behaviour across systems are conducive to improving safety to optimal levels, where the costs of prevention begin to approximate the costs of failure. Evidence suggests that all health systems fall well short in this regard.

Providing an 'off the shelf' package of interventions that would reduce the risk of harm to acceptable levels in any health system is not possible. The ideal mix will depend on several factors unique to a health system's structure and governance, as well as the current level of investment in safety and other policy priorities and objectives.

The right mix of interventions must be built on good governance and leadership, and a will to make genuine structural changes that enable the more targeted safety interventions to work best. The covid-19 response has shown that decisive action is eminently possible. Time will tell if the momentum is used to apply the same level or urgency and decisiveness to patient safety.

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Annex A. Assumptions and explanation of direct cost calculations

The calculations presented in Table A 1 are based on findings of the preceding OECD papers on the economics of patient safety (Slawomirski et al 2017; Auraaen et al 2018, de Bienassis et al 2020), as well as additional evidence published recently.

Table A 1 Estimating the direct cost of harm in health systems of OECD countries

	INPATIENT/ACUTE CARE	**AMBULATORY / PRIMARY CARE**	**LONG-TERM CARE**
MAIN TYPES OF HARM	VTE, ADEs, HAI	ADEs, Wrong/delayed Dx, Delayed Rx	PUs, ADEs, Falls, Malnutrition, HAI
COMMON SEQUELAE AND THEIR COSTS	Mortality; Morbidity req. prolonged admission; readmission; non-acute care	Morbidity requiring additional non-acute care; hospital admission; Mortality (rare)	Morbidity req. additional in-facility care; Hospital admission; Mortality (rare)
DIRECT COSTS	**Known**: 15% inpatient exp. = 4.5% h/exp. *Preventable = 3% h/exp.* **Unknown**: Non-acute expenditure; New Dx; Readmission; Unsafe transition of care → 20% of known harm = 0.9% h/exp	**Known** Avoidable admissions (5 conditions) = 4.2% bed days ~ 4% inpatient exp. = 1.2% h/exp *Preventable = 0.8% h/exp.* ADEs = 0.7-0.9% h/exp *Preventable = 0.6%* **Unknown:** Wrong/delayed Dx and treatment (other conditions); Additional non-acute care; Unsafe transition of care → 1x avoidable adm. costs .= 1.2% h/exp	**Known**: PUs = 3% health exp. *Preventable PUs = 2% health Exp* Hosp. admissions (all) = 6.25% inpt. exp = 1.875% health exp. *Preventable admissions = 0.75% health exp.* **Unknown:** malnutrition; costs borne locally (i.e. not resulting in hospital but requiring additional care in-facility) → not included
TOTAL AS % ALL HEALTH EXPENDITURE (H/EXP)	All harm = 5.4% (All known harm = 4.5%) All preventable harm = 3.6%	All harm = 3.3% (All known harm = 2.1%) All preventable harm = 2.2%	All harm = 3.875% --- All preventable harm = 2.87%
AGGREGATE ESTIMATES	• **All harm: 12.6% of health expenditure** • **Known harm: 10.5% of health expenditure** • **Preventable harm: 8.7% of health expenditure**		

Estimates should be considered typical for health systems of developed countries. They are derived from studies predominantly conducted in developed nations most of which are OECD member or partner countries. Variations between individual jurisdictions have not been considered.

Converting the denominator from inpatient expenditure to health expenditure was based on the average proportion of all health expenditure devoted to inpatient care in OECD countries of approximately 30%, based on data from the OECD system of health accounts (http://www.oecd.org/els/health-systems/health-data.htm) published in *Health at a Glance 2019*.

The preventability quotient is estimated separately for each AE type and each setting based on existing literature and the authors' judgement.

Acute care

- Included are harms that extend the length of the hospital admission during which the harm occurred, estimated to be 15% of hospital expenditure on average based on analysis by Slawomirski et al (2017).
- Excluded are 1. additional care or investigations in other settings to manage the original hospital-acquired harm, 2. inpatient harms resulting a new diagnosis (de facto triggering a new admission) and 3. harms stemming from transitions of care. The cost of these 'unknown' harms is assumed to be 20% that of the included costs.
- It is generally accepted that 50% of adverse events can be prevented. However, preventability *and* severity of incidents is higher in more costly specialties (Panagioti et al. 2019). As managing these harms will accounts for a greater share of expenditure, it is reasonable to assume that the cost of preventable harms will be greater than 50%. Two thirds (66%) of direct costs in acute care are therefore assumed preventable (i.e. the cost of all harm is reduced by a third to account for preventability). This preventability quotient is applied for known and unknown harm.

Ambulatory/primary care

- Included are costs of avoidable admission due to wrong/delayed diagnosis and treatment for 5 conditions modelled by Auraaen et al (2018) (heart failure, asthma, diabetes, COPD and hypertension). They account for 4.2% of bed days, but given their lower severity and complexity only 4% of inpatient expenditure. It is assumed that 75% of these admissions for the 5 conditions are truly avoidable.
- Also included are adverse drug events (ADEs), which are said to account for ADEs 2.5% of all health exp. (Sweden), 4% inpatient capacity (UK) and 3.6% hospital admissions (EU) (Auraaen et al (2018)). A figure of 0.9% of health expenditure is used, of which two thirds are assumed preventable.
- Excluded are avoidable admissions for conditions other than the 5 above as well as costs of failure during care transitions between settings. Together these are assumed to be equivalent to the admission costs of the 5 conditions.

Long-term care

- Included are the costs of pressure ulcers and hospital admission due to unsafe LTC.

- Figures for avoidable hospital admissions from LTC facilities are derived from de Bienassis et al 2020.
- Wood et al. (2019) reports that healthcare-acquired pressure ulcers are responsible 4% of health exp in the UK. A figure of 3% is used here as a more conservative estimate, and to account for a proportion of these occurring in acute care settings. The mid-range results of studies cited in (de Bienassis et al 2020) on the costs of preventable pressure ulcers is approximately 2% of health expenditure.
- Excluded are harms for which the costs are borne within the LTC facility but these are difficult to estimate and have not been accounted for.

Annex B. Gross World Product (GWP) projections

Table A 2 presents the actual GWP and what GWP would be if harm were eliminated based on the estimates discussed in Section 2.4. The calculations suggest that patient harm slows global economic growth by 0.73% per year. This amounted to over USD 65 trillion between 2000 and 2020. These numbers should be interpreted with caution. They do not factor in preventability of harm and are based on a cost-of-illness study for adult diabetes (Bommer et al. 2017). The study excluded people under 20 and over 79 years of age, which may result in costs being underestimated. However, while the disease profile of diabetes differs to that of healthcare-associated (iatrogenic) harm, there are some parallels:

- Both diabetes and iatrogenic harm have a global impact -- perhaps more so than other diseases of similar global health burden such as malaria, tuberculosis and HIV/AIDS, which disproportionately affect developing countries.
- The risk and impact of both are higher in older adults.
- Both account for over 3 million premature deaths a year globally.

Table A 2 GWP actual/projected and with harm eliminated, 2015-2024 (USD Billions)

	GWP ACTUAL (USD BILLIONS)	% CHANGE	GWP HARM ELIMINATED	% CHANGE	DIFFERENCE (USD BILLIONS)
2000	34,179	…	34,179	…	
2001	34,056	-0.36%	34,298	0.35%	**242**
2002	35,561	4.42%	36,067	5.16%	**507**
2003	40,185	13.00%	41,047	13.81%	**862**
2004	45,517	13.27%	46,823	14.07%	**1,307**
2005	49,623	9.02%	51,410	9.80%	**1,787**
2006	54,228	9.28%	56,580	10.06%	**2,352**
2007	61,836	14.03%	64,976	14.84%	**3,140**
2008	68,878	11.39%	72,888	12.18%	**4,011**
2009	66,287	-3.76%	70,645	-3.08%	**4,358**
2010	73,018	10.15%	78,371	10.94%	**5,353**
2011	81,493	11.61%	88,088	12.40%	**6,595**
2012	75,356	-7.53%	82,033	-6.87%	**6,677**
2013	77,427	2.75%	84,887	3.48%	**7,459**
2014	79,531	2.72%	87,812	3.45%	**8,281**
2015	75,101	-5.57%	83,509	-4.90%	**8,408**
2016	76,294	1.59%	85,438	2.31%	**9,144**
2017	81,182	6.41%	91,557	7.16%	**10,375**
2018	86,251	6.24%	97,965	7.00%	**11,714**
2019	87,555	1.51%	100,152	2.23%	**12,597**
2020	84,680	-3.28%	97,551	-2.60%	**12,871**
		Avg. 4.84%		**Avg. 5.59%**	
TOTAL	**491,063**		**556,173**		**118,040**

Source: IMF https://www.imf.org/en/Publications/WEO

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