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The economics of patient safety

STRENGTHENING A VALUE-BASED APPROACH TO REDUCING PATIENT HARM AT NATIONAL LEVEL

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JEL Classification: H51, I10, I18, I19

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THE ECONOMICS OF PATIENT SAFETY

Strengthening a value-based approach to reducing patient harm at national level

Luke Slawomirski, Ane Auraen and Niek Klazinga*

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ABSTRACT

About one in ten patients are harmed during health care. This paper estimates the health, financial and economic costs of this harm. Results indicate that patient harm exerts a considerable global health burden. The financial cost on health systems is also considerable and if the flow-on economic consequences such as lost productivity and income are included the costs of harm run into trillions of dollars annually. Because many of the incidents that cause harm can be prevented, these failures represent a considerable waste of healthcare resources, and the cost of failure dwarfs the investment required to implement effective prevention.

The paper then examines how patient harm can be minimised effectively and efficiently. This is informed by a snapshot survey of a panel of eminent academic and policy experts in patient safety. System- and organisational-level initiatives were seen as vital to provide a foundation for the more local interventions targeting specific types of harm. The overarching requirement was a culture conducive to safety.

RÉSUMÉ

Environ 1 patient sur 10 subit des dommages associés aux soins de santé. Ce papier examine le coût en santé mais aussi financier et économique de ces dommages. Les résultats indiquent que les dommages aux patients entraînent un coût en santé global considérable. Le coût financier pour les systèmes de santé est aussi considérable, et si l'effet d'entraînement économique est inclus, telle que la perte de productivité et de revenu, le coût des dommages atteint les trillions de dollars annuels. Puisque de nombreux incidents provoquant ces dommages peuvent être évités, ces échecs représentent un gâchis considérable des ressources en santé, et le coût de ces échecs diminue l'investissement nécessaire pour mettre en œuvre une prévention efficace.

Ainsi, ce papier examine comment les dommages aux patients peuvent être minimisés de manière effective et efficace. Ce travail s'appuie sur une enquête instantanée auprès d'un panel d'experts académiques et politiques renommés en sécurité du patient. Des initiatives au niveau des systèmes et des organisations sont vitales pour constituer une base à des interventions locales visant des cas spécifiques de dommages. Une culture propice à la sécurité étant l'exigence globale.

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EXECUTIVE SUMMARY

1. **Patient safety is a critical policy issue.** Patient harm - any unnecessary deleterious effects on those receiving health care – occurs in approximately one in ten healthcare encounters. Patient harm is estimated to be the 14th leading cause of the global disease burden. This is comparable to diseases such as tuberculosis and malaria. In some OECD countries, the burden of patient harm is similar to that of some chronic diseases. These findings are leading to calls for more leadership, engagement and action.

2. **The cost of harm to patients, healthcare systems and societies is considerable.** Patient harm imparts a high financial cost. Overall, the available evidence suggests that 15% of hospital expenditure and activity in OECD countries can be attributed to treating safety failures. This is likely to be a conservative figure. Patient harm is felt in the broader economy through lost capacity and productivity of patients and their carers. It is estimated that the aggregate costs amount to trillions of dollars each year. In the political economy, the cost of safety failure includes loss of trust in the health systems, in governments and in social institutions.

3. **Most of the burden is associated with a few common adverse events.** The most burdensome include healthcare-associated infections (HAI), venous thromboembolism (VTE), pressure ulcers, medication error and wrong or delayed diagnosis. For example, it is estimated that every adult in the United States will experience a diagnostic error at least once during their life time. The annual cost of common adverse events in England is equivalent to 2,000 GPs or 3,500 hospital nurses.

4. As well as examining the costs of failure in patient safety, this paper also explore how these failures could be prevented effectively and efficiently in a resource-constrained environment. This was informed by a literature review and a snapshot survey of experts in the patient safety field, resulting in the following findings.

- **Greater investment in prevention is justified.** Many adverse events can be systematically prevented through better policy and practice, with the cost of prevention typically much lower than the cost of harm. HAI or VTE prevention programs, for example, cost a fraction of the financial burden these events impart. It is estimated that in the United States USD 28 Billion has been saved between 2010 and 2015 by systematically improving safety.
- **Solid foundations for patient safety need to be in place.** A hierarchy of programs and interventions to improve safety exists. A national value-based approach - where harm is reduced using limited resources - should begin with investing in fundamental system-level initiatives such as professional education and training, safety standards and a solid information infrastructure.
- **Active engagement of providers and patients is critical.** Organisational-level initiatives such as clinical governance frameworks, patient-engagement and building a positive safety culture also form an important part of an integrated patient safety strategy.
- **Innovation at the clinical level is enhanced through national leadership.** With these structural reforms in place, micro-level interventions to prevent specific adverse event types at the clinical practice level can be implemented to minimise harm. Emphasis should broaden from safety in hospital settings to primary care and long term care. Vision and leadership at the highest levels of government is required to operationalise a systems approach to improving patient safety and ensure that health care is a high-reliability industry.
- **Practical approaches exist to identify national priorities for action.** A system-wide priority setting exercise with broad range of stakeholders can build consensus and inform safety strategies to reduce patient harm, releasing scarce resources to improve population health and wellbeing.

INTRODUCTION

5. A principal responsibility of healthcare providers, facilities and systems is to ‘do no harm’, and do everything to ensure that the benefits of an intervention outweigh its risks and deleterious effects. But harmful adverse events¹ have been a feature of health care throughout history. Starr (1982) reports that in the 19th century “[h]ospitals were regarded with dread, and rightly so. They were dangerous places; when sick, people were safer at home” (p.72). Subsequently, as medical technology advanced and the status and authority of medicine and health care grew, it was increasingly assumed that care was safe (Berwick 2016). Undesired, adverse clinical outcomes resulted from unavoidable complications caused by the patient’s condition and comorbidities, and harm was thought to be isolated to rare cases.

6. However, this assumption of safety started to be questioned in the 1980s and 90s as healthcare harm was investigated in a more structured and scientific manner. Reports such as *To Err is Human* (IOM, 1999), the *Quality in Australian Health Care Study* (Wilson et al 1995), and similar reports in European countries revealed that many as one in ten hospital patients were harmed unnecessarily and that a substantial proportion of patients died as a direct result of medical care. Unsafe care and resulting patient harm was not just a result of human fallibility but principally the result of system failures in the way care was organised and coordinated. Moreover, much of this harm was deemed preventable through improvement efforts targeted at the level of clinical practice, organisations and systems. The persistence of patient harm – in light of advancing complexity of care over the past century - represents a major challenge for healthcare providers, policy makers as well as political leaders.

7. The fundamental case for improving patient safety is a moral and ethical one. Patient harm exerts a burden on people, their families and loved ones, and the community. Maximising safety is therefore a fundamental responsibility of individual healthcare providers and healthcare systems.

8. A strong economic case can also be made as patient harm exerts a resource burden on the health system and on society more broadly. Patient harm manifests directly in the need for additional treatment, more diagnostic testing, (re)admission to hospital or prolonged hospital stay, and other additional use of scarce healthcare resources. The impact of preventable safety lapses on health system efficiency is receiving greater attention by policy makers (OECD 2017a). The broader economic effects of harm include ongoing morbidity, reduced lifetime productivity of patients as well as their carers. The economic impact also extends to the political economy, manifesting in reduced trust in the healthcare system and in social institutions.

9. Investing in the prevention of harm (prevention costs) can in theory create long term value² through the reduction of the costs that have to be made to address adverse events (failure costs). This is similar to other high risk sectors such as air travel, automotive and the oil industry, where investment decisions are made on balancing costs of preventing errors with the costs incurred by errors. Recent experiences of oil companies with costs related to environmental damage and the car industry with recalling series of cars because of safety risks, illustrate this. Failure costs do not only include repair costs, production loss and legal costs, but also the reputational damage and undermining of customer trust.

1 Some key concepts and definitions are provided in Box 1.

2 ‘Value’ is defined here in classical economic terms, as the net impact or effect in reducing patient harm per dollar invested. For a more extensive discussion on value in health care see OECD, 2017b (Chapter 2) www.oecd.org/publications/managing-new-technologies-in-health-care-9789264266438-en.htm

Box 1. Key concepts and definitions

Much of the discussion concerns **harm**, which is defined by 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” (WHO 2004).

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 who would be involved in, and affected by any deleterious effects of the patient's care.

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:

- Medication errors
- Healthcare-associated infections (sometimes also referred to as hospital-acquired or nosocomial infections)
- Patient falls
- Pressure ulcers (pressure injury)
- Venous thromboembolism (VTE) – comprising deep vein thrombosis (DVT) or pulmonary embolism (PE)
- Diagnostic error (incorrect or delayed diagnosis)
- Death during interventions with typically low mortality rates.

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 (WHO 2004).

The word **unintended** is important in this context, and serves to distinguish between adverse events and complications. No healthcare intervention is completely devoid of risk. Many do, in fact, entail known injurious effects such as discomfort and suffering. The probability of complications, side-effects and treatment failure in a proportion of patients is often known. These risks are typically weighed up against the expected benefit. A treatment is pursued with the expectation that these risks are preferred to the effects of the disease, injury or condition it is intended to ameliorate. If the risk of deleterious effects is communicated and consented to by the patient prior to treatment, these effects are typically not considered to constitute patient harm.

Another key concept is **preventability**. Not all adverse events can be prevented given the knowledge, information and the state of the art of medical care at the time of the incident. For example, an allergic reaction to a drug administered for the first time is an adverse event but would be considered unpreventable given the lack of pre-existing knowledge of the patient's idiosyncratic allergy. However, any subsequent administration of this drug to this patient would be – under most circumstances - considered a preventable medication error, and constitute a clear safety failure. It is incumbent on providers to ensure this information is recorded, and verified with the patient or their surrogates prior to administration.

However, preventability is a fluid concept. For example, the incidence of some types of healthcare-associated infections, previously considered unpreventable, has been reduced and even eradicated (Berenholtz et al 2011; Pronovost et al 2006). In the previous drug reaction example, preventability may improve through precision medicine – the ability to predict the likely outcome of administering a medication based on the patient's unique genetic or biological characteristics. While no adverse event is avoidable in every case, their aggregate incidence is certainly *reducible* through learning-based policy and practice intervention.

10. This report focuses on the economics of patient safety. Economics, in this context, concerns the most effective and efficient allocation of scarce resources to meet a specified goal. The goal in this case is to improve patient safety and to reduce harm. Resources are those dedicated to the provision of health care and the operation of the system through which it is organised. The report comprises two sections:

1. *The cost of failure.* Estimating the costs of lapses in patient safety. Costs are quantified in terms of disease burden (morbidity and mortality), and financial and resource impact on the healthcare system. This part of the report is informed by a review of the literature.
2. *Reducing harm effectively and efficiently.* Exploring a value-based approach to investing in patient safety in a resource-constrained context. The relative costs and impact of various interventions (and combinations thereof) targeting patient harm across healthcare systems are estimated using a snapshot survey of international patient safety experts and policy makers.

11. By estimating the costs of safety failures, as well as the costs and the impact of various courses of action to prevent these failures, the report aims to provide policy makers with (a) an idea of the burden exerted by patient harm, (b) estimates of the expected benefit of investing in safety improvement, and (c) information that could enable priority setting for policy makers between various, competing approaches of improving safety in a resource-constrained environment. The objective is to enable healthcare systems to implement policy and practice that would maximise value.

12. The perspective adopted is that of the healthcare system - principally the acute, primary and long-term care sectors. The available literature focuses predominantly on the impact of patient harm on healthcare budgets. It is therefore important to express the cost of harm in terms of health (disease) burden, as well as financial terms, as the former provides an insight into the broader societal costs of harm caused by unnecessary morbidity and premature mortality.

13. While it is important to explore the flow-on societal economic consequences of patient harm, this is recognized but not explicitly analysed here. These effects are many, and are a function of complex macro-economic factors and interactions. On the other hand, patient safety initiatives require investment and human capital. This has a stimulatory economic effect (as does, in fact, dealing with the effects of patient harm). An all-encompassing economic analysis would need to consider the incremental costs and benefits of the entire constellation of downstream effects, not to mention the political economy, and compare these to the alternative allocation of resources. Such a study would require considerable data collection and statistical modelling, and was not feasible given the resources and timeframe for this project.

14. Low- to middle-income, as well as high-income economies are examined. A substantial literature exists on the health burden of patient harm in the developing world, but there is a paucity of research on its financial cost in these countries. The report's scope includes all settings and sectors, but the available evidence and research is heavily skewed towards the acute care setting. Nevertheless the report aims to inform an economic, value-based approach to patient safety improvement at national level.

SECTION I: THE COST OF FAILURE

Box 2. Key findings on the costs of failure

- Patient harm is the **14th leading cause of the global disease burden**. This can be compared to tuberculosis and malaria. The majority of this burden falls on the developing countries.
- Most research on the cost of patient harm has focused on the acute care setting in the developed world where the disease burden can be compared to chronic conditions such as **multiple sclerosis and some types of cancer**.
- The financial impact of safety failure is considerable. Approximately **15% of total hospital activity and expenditure** is a direct result of adverse events. The most burdensome adverse event types include venous thromboembolism, pressure ulcers, and infections
- Less is known about harm in primary and ambulatory care. Research indicates that **wrong or delayed diagnosis** is a considerable problem. Some studies suggest that every adult in the United States can expect to be harmed as a result of diagnostic error at some point in their lifetime.
- The flow-on and indirect costs of harm include loss of productivity and diminished trust in the healthcare system. In 2008, the economic cost of medical error in the US was estimated to be almost **USD 1 trillion**.
- Many adverse events are preventable. Furthermore the **costs of prevention are dwarfed by the cost of failure**. For example improving patient safety in US Medicare hospitals is estimated to have **saved USD 28 Billion** between 2010 and 2015.

15. Health care has greatly contributed to human health, wellbeing and longevity. However, health care has always been, and continues to be, a risk-laden endeavour. Not only are modern therapies, diagnostics and interventions highly complex, but the patients these are administered to are increasingly sick and frail. Treatment is delivered by teams spanning across different organisations and settings, which requires effective and timely transfer of critical information. While modern medical science can certainly do more, the risks of complication, error and harm are commensurately greater.

16. Adverse events can occur at any point of a patient's care pathway - primary care, hospital care or long term care. The type of adverse event varies between settings, but similar causative factors can be attributed to most types of harm (Table 1). These relate to communication failures, absence of relevant information, insufficient education, knowledge and skills, and inadequate organisational culture. Underlying factors such as misaligned incentives for providers, payers, patients and other stakeholders also play a part. A more detailed outline of the causes and preventers of harm is provided in Section II.

Table1. Adverse events may differ between care settings

Level of care	Adverse event, specific to level of care	General drivers of adverse events independent of level of care
Primary care	Adverse drug events/ medication errors; diagnostic error/delayed diagnosis.	Lack of communication and information, lack of skills/knowledge, inadequate organisational culture, misaligned incentives.
Long-term care	Adverse drug events, pressure injury, falls	
Hospital care	Healthcare-associated infections, VTE, adverse drug events, pressure injury, wrong-site surgery.	

Source: Kingston-Riechers J. et al (2010), Etchells et al (2012), Levinson (2014)

17. Most research to date has focused on the hospital setting. Estimates vary, but around one in ten patients can be said to be harmed during hospital admission. The majority of adverse events relates to healthcare-associated infection, VTE, and adverse drug events or medication error. A Portuguese study of hospital records estimated that three out of five adverse events occurred in elderly patients. Most frequently adverse events were related to surgical procedures (27%), medication errors (18.3%) and healthcare-acquired infections (12.2%) (Sousa et al, 2014). In the long-term care setting, the most frequent adverse events include pressure injury and adverse drug events. For example, a study of facilities providing long term care to Medicare beneficiaries in the United States found that pressure injury, falls, aspiration pneumonia and drug-induced delirium to be the most common types of harm (Levinson 2014).

18. Primary care is the least studied setting, with a relative paucity of information on the type, extent and the economic impact of harm. Medication errors have traditionally been considered the most common adverse event type in this setting. More recently, the prominence of diagnostic error (missed opportunities to make a correct or timely diagnosis) has been identified as a prominent source of patient harm. It is estimated that about 5% of adult patients in the United States experience diagnostic errors in outpatient settings (Singh et al, 2014). Khoo et al (2012) report a diagnostic error rate of 3.6% across 12 primary care clinics in Malaysia. An Australian study identified medication error (50%) and diagnostics (14%) as the most common types of harm (Bhasale et al 1998). Results from a German study examining the determinants of harm in primary care suggest that the majority of adverse events were related to processes of care, of which 26.1% were due to the lack of knowledge/skills of the providers (Hoffmann et al, 2008).

19. Patient harm - in any setting - affects the healthcare system, society and, most importantly, individual patients and their families. Depending on the clinical severity of the adverse event, it may result in temporary or permanent disability and in some cases in premature death. The degree of severity will directly impact the care provision through additional medical procedures, treatments and diagnostics, admission or re-admissions to hospital, and extending the length of stay. So in addition to the morbidity and mortality burden, patient harm exerts a financial cost on the healthcare system, diverting resources from other areas of potential benefit within health care and beyond. A proportion of adverse events are considered preventable. The preventability is constantly changing as medical knowledge and patient safety science evolves. Preventable, or reducible, adverse events therefore exert a true opportunity cost on the healthcare system. This undermines effectiveness, efficiency and value of health care.

20. This section attempts to quantify patient harm in three ways. First, the impact of mortality and morbidity due to patient harm is explored in developing as well as developed countries. The metric used is Disability Adjusted Life Years (DALYs)³, which measures the total number of years lost due to specific diseases and risk factors - in this case iatrogenic harm. Second, the financial cost exerted by patient harm on health systems is described. These costs are presented in monetary terms and, where possible, in the percentage of relevant national healthcare expenditure to place the costs in their broader context. This part deals predominantly with costs in developed countries due to the absence of literature focusing on the developing world in this regard. Third, the notion of failure and prevention costs is introduced. This leads into the more detailed discussion on the most effective and efficient approaches to minimising patient harm in a resource-constrained environment, which is then explored in more detail in Section II.

1.1 Patient harm exerts a high public health burden worldwide

21. In developing countries the lack of access to basic healthcare services, particularly hospital care, remains a key policy challenge. Until now most efforts in developing countries focused on improving access to care for diseases that cause substantial morbidity and mortality such as malaria and HIV/AIDS.

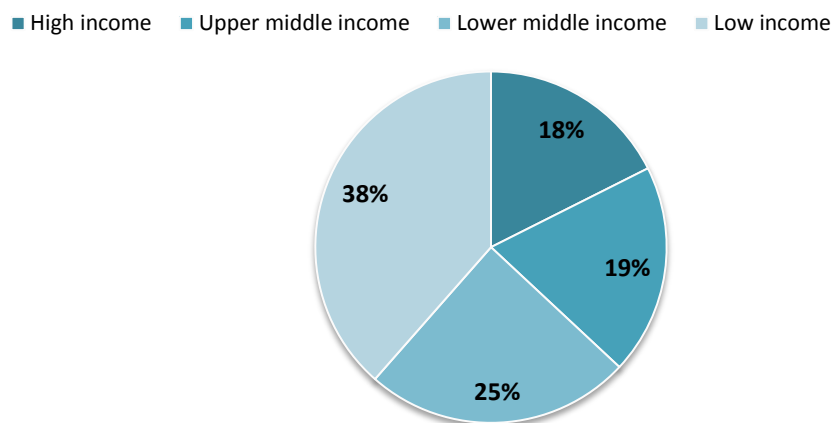
³ One DALY can be thought of as one lost year of "healthy" life. The sum of these DALYs across the population can be thought of as the burden of attributed to the disease or risk factor in question.

The extent to which this care is *safe* has historically received less attention in developing countries. To address this gap and acknowledge patient harm as a public health issue, WHO launched the Patient Safety Programme in 2004. This programme provides systematic and technical support to countries to improve patient safety and raise awareness of healthcare safety. It also fosters sharing of knowledge and expertise, which is key to improving patient safety the developing countries (WHO 2004).

22. Nevertheless, the global disease burden resulting from patient harm is profound. Adverse events are estimated to be the 14th leading cause of morbidity and mortality in the world (Jha et al 2013). This puts patient harm in the same league as tuberculosis and malaria, and makes it a genuine global public health concern. It suggests that global investment in patient safety may go some way to improve the health status of many people across the globe.

23. Despite the global efforts to reduce the burden of patient harm in developing countries, the situation does not appear to have changed over the past 15 years. WHO data from 2000 indicate that two-thirds of all adverse events occurred in low- and middle-income countries (Jha et al, 2013). More recent data from Institute for Health Metrics and Evaluation (IHME)⁴ suggest that the disease burden of adverse events is still weighing heavily on the health systems and populations in low- and lower-middle-income countries (Figure 1).

Figure 1. Low income countries carry the heaviest burden of mortality and morbidity caused by adverse events (2015)



Note: Percentage of DALYs/country. Classification of countries based on The World Bank categories.

Source: IHME 2015

24. Evidence examined suggests that the incidence of adverse events in low- and high-income countries falls within the same range (Table 2 and 7). Hospital-based studies from Australia, Canada, United States and European countries dating back to 1991 estimated the frequency of adverse events between 3% and 17%. A retrospective review of patients' hospital records across eight African countries⁵ estimated the frequency of patient harm at 8.2%. Similarly, in Vietnam, healthcare-acquired infections range between 5.9% and 10.9%, while medication errors in a geriatric hospital ward accounted for 20.4% in Indonesia (Wilson et al, 2012; Ernawati et al, 2014; Harrison et al 2015).

⁴ Institute of Health Metrics and Evaluation is an independent global health research centre at the University of Washington, USA.

⁵ Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa and Yemen.

25. Notwithstanding the methodological differences in how rates are estimated, the findings suggest that the severity of the outcome rather than the frequency of the adverse events may account for the differences in overall burden between developing and developed countries. The risk of patient death as a result of an adverse event appears to be much higher in developing countries. Indeed some estimates in developing countries suggest that as many as one in three adverse events result in the patients' death (Wilson et al, 2012). In comparison, studies from Australia, Canada, the United States and European countries suggest that this rate is between 2% and 16% (Baker et al, 2004; Soop et al, 2009).

26. A considerable proportion of adverse events occurring in developing countries can be avoided with a range of relatively simple interventions including better training and increased awareness among healthcare providers, and implementation and compliance with relevant patient safety protocols (Table 2). Evidence suggests that more than one in three adverse events in developing countries occur in non-complex clinical situations and up to 83% may be preventable. Two-thirds of all medication errors registered in a geriatric hospital ward in Indonesia was due to administration errors (Wilson et al, 2012; Ernawati et al, 2014). Further evidence from Indonesia shows that the clinical staff and healthcare workers, particularly in rural care facilities, had limited knowledge of hospital-associated infections and how they could be prevented. Over-reliance on verbal instructions and lack of compliance with written protocol comprised infection control in hospitals (Marjadi et al, 2010; Harrison et al, 2015).

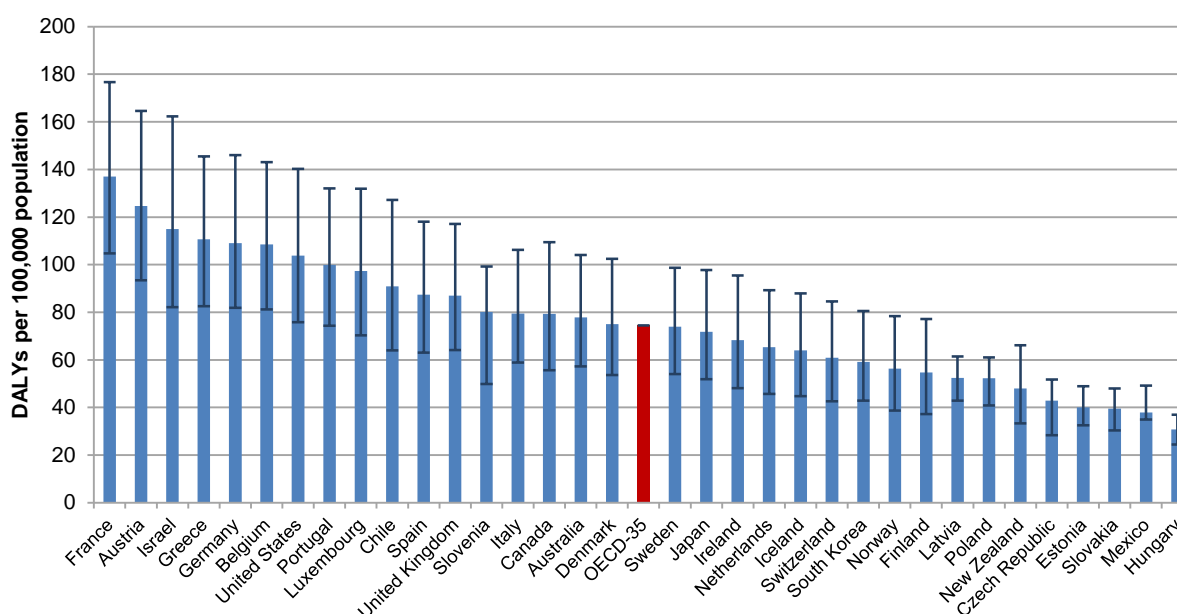
Table 2. Frequency rates of adverse events and outcomes for low and middle income countries

Study	Adverse event rate	% of events considered preventable	% of events resulting in or contributing to death	Average additional hospital days per patient
Prevalence of adverse events in the hospitals of five Latin American countries. (Aranaz-Andrés et al 2011)	10.5%	60%	6%	Not specified
Device-associated infections rates in adult, pediatric, and neonatal intensive care units of hospitals in the Philippines (Navoa et al, 2011)	4.9 infections per 1000 ICU-days	Not specified	3.8%-50%	Ranging from 5 – 15.4 days
Patient safety in developing countries (Wilson et al, 2012)	8.2%	83%	30%	Not specified

27. For OECD countries, IHME data suggest variation in the disease burden attributable to adverse events (Figure 2). However, these data should be interpreted with caution as they are influenced by several factors including the methods and approaches of measurement, as well as the 'reporting culture' of patient harm across a healthcare system.⁶ They may therefore not reflect the true disparity in levels of safety in the countries listed, but indicate the health system's ability to capture the health impact of adverse events. The 95% uncertainty intervals⁷ included in Figure 2 diminish the degree of variation between countries.

⁶ The method adopted can have a large influence on the results. For example a study by Makary and Daniel (2016) which found medical error to be the third-highest cause of death in the US was criticised for its method which was said to greatly overestimate the mortality burden (Baldor & Kravietz 2016). See also note below Figure 2.

⁷ For a description of uncertainty intervals see Kassenbaum et al 2016.

Figure 2. DALYs attributable to patient harm in OECD countries, with 95% uncertainty intervals⁷ (2015)

Source: IHME 2015

Note: Values are calculated by combining Years of Life Lost (YLL) and Years Lived with Disability (YLDs). For more information see the Global Burden of Disease Protocol www.healthdata.org/sites/default/files/files/Projects/GBD/GBD_Protocol.pdf

28. Hauck et al (2017) estimated the disease burden exerted by six adverse event types in English hospitals (sepsis; pressure ulcers; inpatient hip fractures due to falls; VTE; central line infections; deaths in low-mortality conditions⁸) by analysing all inpatient episodes in England over four years (2006-10). Each year approximately 36,000 healthy life years were lost to these six adverse event types across England, or 68 per 100,000 population. This can be compared to the annual burden of diseases such as HIV/AIDS, tuberculosis and cervical cancer. IHME estimates suggest that the aggregate burden of patient harm in England is greater than multiple sclerosis (Table 3).

Table 3. Disease burden of 6 adverse event types compared to chronic conditions in England

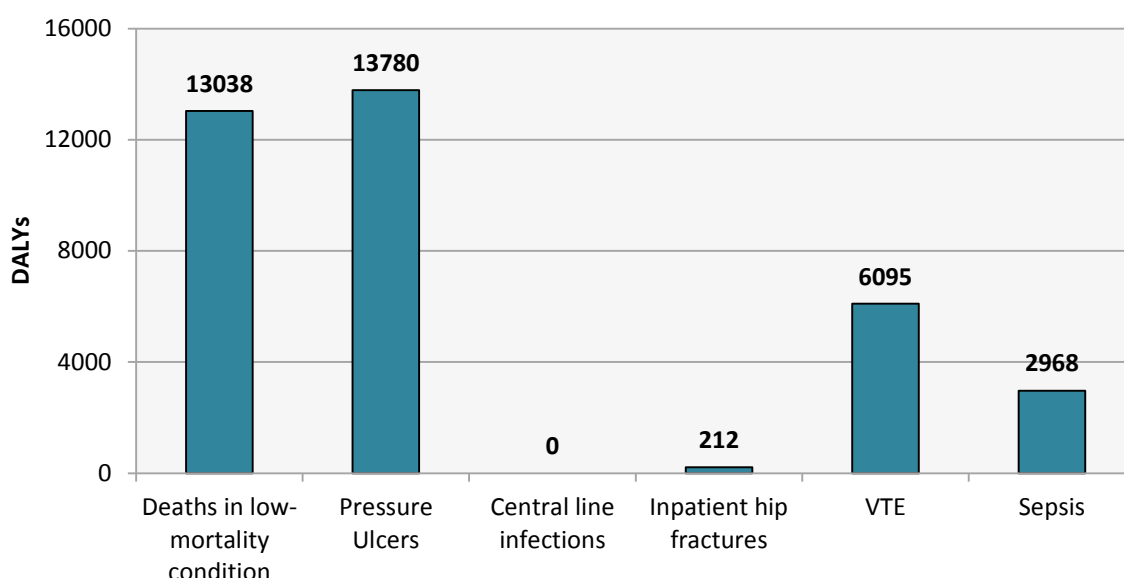
Disease	Annual burden per 100,000 pop/n	Total annual burden across England
All adverse events*	86 DALYs	46,491 DALYs
Multiple sclerosis	80 DALYs	42,400 DALYs
6 adverse event types	68 DALYs	36,000 DALYs
HIV/AIDS and Tuberculosis	63 DALYs	33,400 DALYs
Cervical cancer	58 DALYs	30,740 DALYs
Interpersonal violence	57 DALYs	30,200 DALYs

Source: Hauck et al (2017), *IHME (2015)

⁸ Deaths in low-mortality condition refer to a list of non-complex, low-risk conditions or procedures that are typically uncomplicated and have a low mortality risk of death. These include minor surgery, soft tissue injuries, normal delivery and caesarean section. For the full list see www1.imperial.ac.uk/resources/8C711D9E-FF83-4A60-A2D6-2C80933A92BD/psis.oct08.pdf (accessed 2 Feb 2017)

29. The greatest burden was exerted by pressure ulcers (13,780 DALYs) and deaths in low-mortality conditions (13,038 DALYs) (Figure 3). Many of these adverse events are considered preventable. Central line infections and inpatient hip fractures did not exert a high health burden on the population due to relatively low rates of incidence.

Figure 3. Healthy life years lost due to six adverse events, annual totals across England



Source: Hauck et al (2017)

30. Overall, the available evidence suggests that the morbidity and mortality burden exerted by unnecessary patient harm in all healthcare settings is a significant global public health issue. While the developing world carries the majority of this burden, a considerable amount of death and disability is caused by adverse events in OECD countries.

31. These findings align with a recent report of the National Academy of Science, Engineering and Medicine in the US that underlines the importance of reducing diagnostics errors (National Academy of Science, Engineering and Medicine, 2015). Getting the right diagnosis (at the right time) is a key aspect of health care as it provides an explanation of a patient's health problem and informs subsequent health care and treatment decisions. The report *Improving Diagnosis in Health Care* is a continuation of the landmark IOM reports (1999 and 2001).

32. The report further emphasises that diagnostics, in particular the occurrence of diagnostic errors, has been largely underappreciated in efforts to improve the quality and safety of health care. This is mainly due to paucity of data and reliable measures. Nevertheless, the best estimates available indicate that consequences of diagnostic errors are significant. The report's conclusion aligns with other evidence suggesting that most US adults will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences (National Academy of Science, Engineering and Medicine, 2015; McGlynn et al 2015). Sound training, developing knowledge and skills and adopting a strong safety culture is essential to providing safe care to patients in developing as well as in developed countries (WHO 2011; Yu et al 2016). The elements of prevention are explored further in Section II of this report.

1. 2 Financial and resource costs of patient harm are high

33. Not only does patient harm impose significant burden on patients and their loved ones, it also generates a considerable strain on health system finances. Adverse events necessitate the use of additional resources and increased levels of care. As much as one dollar in seven is spent treating the effects of patient harm in acute care (Jackson, 2009). These estimates resonate with the findings in a study from New Zealand, which suggests that \$ NZ 0.30 of every dollar spent in a public hospitals goes toward treating an adverse event (Brown et al, 2002). Following the recent financial crisis, the economic burden patient harm constitutes to health systems and measures to reduce waste have the attention of policy-makers. According to the Council of the European Union, patient harm represents both a severe public health issue as well as a high economic burden on limited health resources for their member countries (Council of the European Union, 2009).

34. Costing studies have been criticised for underestimating the true financial burden patient harm imposes on to healthcare budgets. In some cases details and clear definitions of cost components, quantity, prices and time horizon are missing, making it difficult to assess the quality of the estimates as well as the implication of the findings (Fukuda and Imanka, 2008). Other studies use a wide range of methods for attributing and estimating costs, which further challenges the international comparability of the findings. As part of its focus on patient safety, in 2016 the European Commission published a report in collaboration with *Gesundheit Österreich Forschung und Planung GmbH* and *Sogeti* on the costs of unsafe care and cost-effectiveness of patient safety programmes (Zsifkovits, J. et al, 2016). The report sought to estimate the financial burden of patient harm, identify cost-effective patient safety programmes in EU Member States and assess the cost-effectiveness and efficiency of investments in patient safety programmes. A systematic literature review was conducted identifying international studies attempting to quantify the financial costs of adverse events. A lack of clear consensus on a costing methods was noted (the findings are reported below).

35. The majority of studies estimating the financial burden of patient harm are focused on the hospital setting. A range of approaches are used to estimate these costs, based on estimates of adverse event rates. Currently, the ‘gold standard’ method of identifying these rates is considered to be the retrospective review of patient records (Jackson, 2009). Other methods used to estimate adverse event rates include examining billing data for insurer reviews, hospital discharge data, voluntary clinical incident reporting data, or extrapolation of results from previous studies. Once the rate of adverse events is identified, the average extended length of stay is estimated and multiplied by average or disease-specific per diem costs, and extrapolated to the area of interest.

Box 3. Reducing harmful events could free up resources to unmet needs in Canadian hospitals

A recently developed method to capture data on patient harm in Canadian hospitals creates the basis for the Hospital Harm Indicator, which will be routinely reported and monitored. The approach draws on existing data on all discharges from acute care hospitals across Canada from the Discharge Abstract Database, an administrative dataset. The 2016 Measuring Patient Harm in Canadian Hospitals report uses this new approach to measuring patient harm occurring in hospitals.

The report found that patient harm occurred during one in 18 (**5.6%**) hospitalisations in Canada. In 2014-2015, **12.5%** of these admissions resulted in death, four times the mortality rate of patients who did not experience an adverse event (3,1%). However, these data were not risk adjusted and may be partly explained by the fact that more complex patients who may be at a greater risk of dying are also more likely to suffer an adverse event. The highest proportion of episodes with adverse events was in medical care patients (56% compared to 20% for surgical patients).

Using the Hospital Harm Data, the report estimates that patients having experienced an adverse event spent more than **half a million additional days in hospital** during 2014-2015. This equates to about **four large hospitals** or 1 600 hospital beds per day. The aggregate financial burden of patient harm in Canadian hospitals was **CAD685**

million in 2015-15.

Healthcare-associated infections were a major source of harm occurring in 1 in 41 hospitalisations (2.4%) and costing the healthcare system **CAD281 million** (CIHI, 2016).

36. Despite the lack of standardised costing methods, a review of the literature identifies national studies clearly demonstrating that patient harm adds substantially to the costs and other healthcare resources. In an attempt to compare the national costs of patient harm identified in the literature, the costs are, where possible, presented as share of the relevant healthcare expenditure, as reported to the OECD System of Health Accounts for the year referred to in the study. Using this method, costs related to adverse events occurring in hospitals range between 1.3% and 32% of public hospital spending. The remainder of the section is in three parts: *condition- and event-specific costs*; *costs across all adverse event types*; and *costs of adverse events deemed preventable*.

Condition- and event-specific costs are considerable

37. Based on the available literature, healthcare-associated infections account for a considerable proportion of costs (Table 4). In Belgium, the mean excess cost of healthcare-associated infections was in 2006 close to 6% of public hospital spending. Healthcare-associated infections alone cost NHS England almost GBP 1 billion every year, or 2.6% of the public hospital spending (Department of Health, 2000).

38. The majority of adverse events related to VTE are hospital-acquired, with annual hospital costs estimated to range between EUR 1.5 – 13.5 billion in the 28 EU countries, and \$ 7.5 to \$39.5 billion in the United States, or up to 3.8 % and 6% of the public hospital spending respectively. The costs of adverse drug events in Australian hospitals amounted to AUD 1.2 billion in 2011, or 3.95% of the public hospital spending. In Germany this figure is about 1.7% (Mahan et al 2011; Barco et al 2016).

39. Treating patients who have experienced an adverse event results in additional medical examinations, treatments and prolonged hospital stays. On average these patients stayed 10.2 days longer in Dutch hospitals (Hoonhout et al 2009). Adverse events associated with invasive surgical procedures prolonged hospital stay by up to 16 days (Zerey et al, 2007). Hospital-acquired sepsis extended hospitalisation by 29.8 days in Belgian hospitals (Pirson, 2008). Indeed, hospital-acquired sepsis accounts for a large proportion of additional hospital days, standing out as one of the most expensive and most clinically complex condition to treat, not only due to its severity but also because it often is accompanied by additional complications such as pneumonia (Arefian et al 2016).

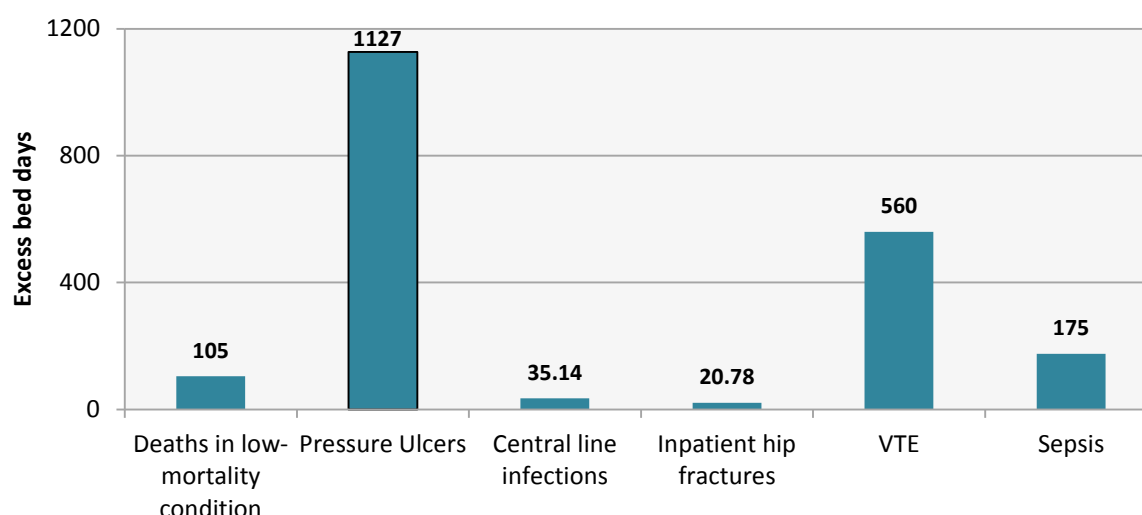
Table 4. Financial burden due to specific adverse events or conditions (as share of public hospital spending)

Adverse drug events and medication safety			Share of public hospital budgets
Rottenkobler, D. et al (2012)	Germany	Nationwide extrapolation of adverse drug events occurring in German hospitals resulted in annual total treatment costs of €1.058 billion in 2008.	1.7%
Roughhead L et al (2013)	Australia	\$AUS 1.2 billion costs of patient harm due to medication safety in 2011	3.95%
Healthcare-associated infections			
Department of Health (2000)	United Kingdom	Hospital-associated infections are estimated to cost NHS England GBP 1 billion.	2.6%

Vrijens F, et al (2009)	Belgium	Hospital associated infections were estimated to cost in overall excess median cost is 204.3mill€, mean 384.3mill€.	5.95% (3.2%)
Venous thromboembolism (VTE)			
Mahan, C. et al (2011)	United States	VTE cost models ranged total cost from USD 5 – 26.5 billion	1% -6%
Barco, S. et al (2016).	EU-28	Total costs ranged from 1.5 – 13.2 billion EUR 2014 PPP	0.4%-3.8%

40. The aforementioned study by Hauck et al (2017) examining the disease burden caused by six types of harm⁹ in English hospitals also assessed the cost in terms of additional length of stay. Across England the total excess bed days due to these six adverse events was close to 500,000 per annum. This equates to almost 70,000 typical hospital admissions. The highest bed day losses were attributed to pressure ulcers and VTE (Figure 4). In contrast to healthy life years lost, the effects of mortality on excess bed days are low - the cost of these tragic outcomes falls on families and on society. The effect of central line infections and hip fractures on excess hospital stay are low due to low incidence rates.

Figure 4. Bed days lost due to six adverse events, annual totals for a typical English hospital



Source: Hauck et al (2017)

41. These excess bed days amount to GBP 21.3 million.¹⁰ This equates to over 2,000 salaried GPs and more than 3,500 hospital nurses across the country. Expressed in a more local context, 2,024 bed-days - or GBP 617,000 - are consumed by these six events in the average English hospital each year. This equates to 285 potential admissions foregone per year. Alternatively, 9 salaried general practitioners or 15 hospital nurses could be employed for this sum (Table 5).¹¹

⁹ Deaths in low-mortality conditions, pressure ulcers, central line infections, inpatient hip fractures, VTE and sepsis.

¹⁰ Based on the 2015-16 NHS England reference costs www.gov.uk/government/publications/nhs-reference-costs-2015-to-2016.

¹¹ Calculations based on OECD data (www.OECD.stat).

Table 5. Annual impact of 6 adverse events in a typical English Hospital

	Bed days lost	Cost of bed days lost	Admissions foregone	Salaried GPs	Hospital nurses
Across England	495,020	GBP151 million	69,721	2,218	3,574
Avg English Hospital	2,024	GBP 617,000	285	9	15

Source: Hauck et al (2017); OECD.stat

The overall financial impact of adverse events constitutes a large proportion of expenditure

42. The financial burden across all categories of adverse events occurring in hospitals varies from 1.3% to 32% of public hospital spending (table 6). This variation can partly be explained by the studies' different approaches to estimating the burden, for example in terms of the incidence rates, cost components and prices that are used to quantify the costs. Overall, the research suggests that patient harm and adverse events in hospitals consume approximately 15% of acute care expenditure in a healthcare system of a typical developed country. With the exception of long term care facilities in the United States, a national level figure for other settings is not readily identifiable. Nevertheless, the annual cost of adverse events in hospital care would aggregate to hundreds of billions, if not trillions, of US dollars across the OECD.

43. Demonstrating the diversity of costing methods, the Dutch study only includes tangible costs measuring the direct medical costs related to index admission, re-admission and additional medical procedures. Treating the clinical effects of patient harm corresponded to 1.8% of the public hospital spending (Hoonhout et al, 2009). The Canadian Adverse Events study based its acute care cost estimates on a systematic literature review of all studies published from 2000-2011 and adapted the findings to the Canadian system. Acute care spending attributable to adverse events amounted to \$ CAN 1.1 billion, or 4.2%, in 2009. Similar methods were applied by Zsifkovits et al (2016) when estimating the financial burden of adverse events in Europe. Despite limited available literature, cost estimates of adverse events range between 0.2% and 6% of total health expenditure. In the same year, the Irish National Adverse Event study initiated retrospective review of patient records to learn more about adverse event and the corresponding costs. The findings estimated to cost Irish hospitals more than EUR 194 million a year, about 4% of the health care acute services' budget (Rafter et al., 2016).

44. A 2013 Australian study suggests that conditions acquired by patients during their hospital stay (e.g. healthcare-associated infection; pressure ulcers) accounted for 12-16% of hospital expenditure (Health Policy Analysis, Australia, 2013). These findings accord with those of Jackson (2009) and other studies examining safety in the acute care setting, which indicate that patient harm and adverse events add between 13% and 16% to hospitals costs. These studies identified 'mundane' but frequent adverse events as the principal cost drivers: low-grade pressure ulcers and catheter-associated urinary tract infections, for example. One notable exception was sepsis, an expensive and relatively frequent harm category.

45. Costs estimated for New Zealand are substantially higher than any other costs presented in this report. The study used retrospective examination of medical records in 13 public hospitals (with 100 hospital beds or more) to identify additional medical procedures and additional hospital days attributable to the adverse events. Due to the nature of the patient data it was impossible to retrieve specific consumable resources attributable to each patient. Instead, prices charged to international hospital patients were used to estimate the cost of health care resources. In total, adverse events are estimated to cost the health system \$NZ870 million, or 32% of public hospital budgets in 2001 (Brown et al, 2002).

46. Patient safety is also an important challenge in long-term care facilities. Costs related to hospitalisation following adverse events in skilled nurse facilities of Medicare beneficiaries accounted for

2% of all Medicare spending in the United States. Many of the events identified were preventable, which confirms that there is a need to raise awareness of nursing home safety and seek to reduce patient harm through methods used to promote patient safety in hospitals (Levinson, 2014).

Table 6. Economic burden due to adverse events in acute care or hospital care (as share of public hospital spending)

Adverse events in hospitals			Share of public hospital spending
Brown, P. (2002)	New Zealand	The results suggest that treating adverse events costs hospitals over \$870 million.	32%
Rafter et al., (2016)	Ireland	Adverse events relate to adult inpatient amounted to 194 million€ in 2009	4%
Etchells et al (2012)	Canada	Financial burden of adverse events in Canada in 2009– 2010 was \$CAN 1,071,983,610	4.2%
Jackson (2009)	Canada	Administrative data.	14%
Health Policy Analysis, Australia (2013)	Australia	Hospital-associated conditions modelled to range between AUD 634 million and AUD 896 million	12 % – 16.5%
Ehsani etl al (2006)	Australia (Victoria)	Impact of adverse events modelled from hospital administrative data was AUD 6,800 per episode or AUD 460 Million in aggregate.	15.7%
Zsifkovits et al (2016)	Europe	Direct costs for the public care sector ranged from 2.8 billion euros to 84.6 billion euros	0.2%-6% *
Hoonhout L. et al (2009)	Netherlands	Costs estimated at a total of €355 million for all adverse events in hospitals	1.8%
Adverse events in long term care			
Levinson, D.(2014)	United States	Long-term care 2% of all Medicare spending is associated with treatment of adverse events.	2%

Note: Share of total public health expenditure

47. Healthcare utilisation data in OECD countries permits further quantification of the impact of patient harm on healthcare resources. The crude number and share of all hospital bed days or hospital stays spent on treating harmed patients can be estimated from studies where data on excess stay is available. These estimates, where possible, using previous studies of the resource impact of patient harm are presented in Table 7. The proportion of all hospital days due to the excess length from patient harm ranged from 3.3% in Germany (Rottenkobler et al 2009) to 21% in Australia (Wilson et al 1995). These estimates broadly align with the proportion of public hospital spending on the consequences of adverse events presented above.

48. Strikingly few adverse event cost studies focus on the primary care setting despite that, in most countries, most encounters with the healthcare system take place in primary care. On average, residents of OECD countries consulted a doctor or outpatient specialist four times in 2014. Germany ranked third highest among the OECD countries with 10 consultations in 2014 (likely to be an underestimate as only the initial consultation is accounted for). An analysis of healthcare activity data in Germany conducted by the *Zentralinstitut für die Kassenärztliche Versorgung* (ZI) indicated annual consultations of 17 in 2007 (ZI, 2013). 15-22% of healthcare expenditure in Germany is in primary care.¹² Even a conservative comparison

¹² The OECD System of Health Accounts Experts have developed two definitions when estimating primary care spending; the narrow definition limits all primary care activities to ambulatory health providers, which in Germany corresponds to 15% of current health spending. In addition, the wider definition includes outpatient specialist services, such as cardiologists, and preventive services irrespective of provider setting, which in Germany increases the share of primary care spending to 22%.

of the primary care setting with the levels and impact of harm in acute care would likely reveal a considerable cost burden.

Table 7. Studies of adverse event rates in various countries, extrapolated to determine their impact on hospital bed days

Study	Adverse event rate	% of events considered preventable	% of events resulting in or contributing to death	Average additional hospital days per patient	% of all hospital days in the country investigated in the study attributable to adverse events
Harvard Medical Practice Study, United States (Brennan et al., 1991)	3.7%	27.6% of events due to negligence (preventable not specified)	13.6%	Not specified	N.A.
Quality in Australian Health Care Study (Wilson et al., 1995)	16.6%	51.0% of events	4.9%	7.1	21.4%
Adverse Events in British Hospitals (Vincent et al., 2001)	10.8%, and when including multiple events, 11.7%	48.0% of events	8.0% of patients with adverse events died	8.5	14.1%
Danish adverse events study (Schjøler et al., 2001)	9.0%	40.4% of events	6.1% of admissions with adverse events	7.0	14.7%
Canadian Adverse Events Study (Baker et al., 2004)	7.5%	36.9% of patients with adverse events	15.9%	7.7 in small hospitals, 3.6 in large hospitals, 6.2 in teaching hospitals	6.0%
Spanish National Study of Adverse Events (Aranaz-Andrés et al., 2008)	8.4%	42.6% of events	4.4% of patients with adverse events died	6.1	6.9%
Systematic review of eight studies in Australia, Canada, New Zealand, United Kingdom, United States (de Vries et al., 2008)	Median incidence 9.2%	Median percentage preventable 43.5%	7.4%	Not specified	N.A.
Incidence of Adverse Events in Swedish Hospitals (Soop et al., 2009)	12.3%	70.0% of events	3.0%	6.0	13.0%
Adverse events and potentially preventable deaths in Dutch hospitals (Zegers et al., 2009)	5.7%	39.6% of events	7.8%	Not specified	N.A.
Costs of adverse drug events in German hospitals (Rottenkobler et al., 2009)	1.14% of all hospitalisations	Not specified	Not specified	2.9 days	3.3%
Nosocomial Infections in Belgium, part 2: Impact on Mortality and Costs (Vrijens et al., 2009)	6.2% of all hospitalisations	Not specified	2.1%	6.7 days	5.3%
Irish National Adverse Events Study (Rafter et al., 2016)	10.3%	72.5% of events	6.7%	6.1	10.5%

Note: The calculations behind the number of admissions freed if adverse events were avoided were based on the average length of stay reported to OECD Health Statistics the latest year available.

The costs of patient harm are underestimated and spill over beyond healthcare systems

49. Studies calculating the incidence of adverse events, particularly preventable ones, have been criticised for underestimating the true magnitude of patient harm. Since these often form the basis for the costing studies, the underestimate would be reflected in the costs suggesting that the true financial impact of patient harm is considerably higher than previously estimated. Also, the cases where patient harm results in temporary or long-standing sequelae of adverse events are rarely acknowledged and accounted for.

50. The costs of adverse events presented in this report do not estimate the true financial burden of patient harm. The true, societal cost of patient harm will include the impact on healthcare resources but also on lost time to injury, lost productivity and other consequences of harm on individuals, their loved ones and the communities they live in. An Australian report estimated that, in 2008, the overall economic cost of VTE was \$1.72 billion (0.15% of GDP in 2008). This comprised productivity lost primarily due to premature death, taxation forgone, government health expenditures and direct health system expenditure. The disease burden (disability and premature death) was calculated at a further \$19.99 billion (1.74% GDP), based on the value of a statistical life. The report examined all VTE, but given that the majority of VTE is acquired in health care most of these costs can be attributed to health care (Access Economics 2008).

51. Andel et al (2012) report that, in 2008, the direct cost of medical errors in the United States was \$19.5 billion. About 87% of this was associated with additional medical cost. The broader economic impact is estimated to be much higher, and may approach \$1 trillion annually when the resulting DALYs are costed (Andel et al 2012).

52. The costs of patient harm also cascade into the political economy. These costs concern, for example, the undermining of public trust in the healthcare system. It also includes political costs to leaders, decision makers and other social institutions. While these are beyond the scope of this report, it is important to bear them in mind when assessing the aggregate cost of safety failure. Levels of public trust in healthcare systems in many countries are already low (OECD 2017a). Given the importance of trust in the effective delivery of health care (Gilles et al 2015) as well as in the uptake of public health and preventive interventions and other government services, this type of failure cost— although underexplored in the literature – should not be ignored as a genuine concern and reason for action.

Much of the cost can and should be avoided

53. Preventability is fluid over time, but health care is and will continue to be a high risk industry. Trade-offs are made between the risks and benefits of medical interventions. Up to 17% of all hospitalisations are affected by one or more adverse events, with 30-70% potentially preventable (Table 7). In addition to the occurrence of adverse events, patient safety studies often estimate the share of adverse events that could have been prevented if adequate patient safety measures were in place.

54. The information presented in table 7 can be used to estimate how many hospital-days are wasted by failing to stop preventable adverse events given the state methods and interventions available at the time. Australia and United Kingdom could have freed 500 000 hospital days if half of the adverse events were prevented. Spain and Sweden could have freed 154 000 and 129 000 respectively. These are all resources and hospital bed days that could have been made available to meet other demands for care and clearly reduced the overall pressure on the health system as well as saved the patients from unnecessary suffering.

55. Six studies estimate the national costs of adverse events that are considered preventable and may partly represent savings if the frequency rates are reduced (Table 8). In the United Kingdom, for example,

about half of the adverse events occurring in hospitals are deemed to be preventable. Preventable costs estimates range from 2% to 10% of public hospital spending. In France nine identified preventable adverse events¹³ cost the health system 700 million EUR in 2007. In Swedish surgical wards, the cost of additional treatments for patients who had experienced a preventable adverse event was 1.4 billion SEK (Sjödahl, 2014). This equates to 1.6% of Swedish national public hospital spending in 2014.

56. Two studies examine health resources that could have been saved if appropriate VTE prophylaxis was in place; in the United States between 1 –4% of public hospital spending and up to 2% for the European Union as a whole. By following and implementing prophylaxis guidelines, many healthcare-acquired VTEs could be prevented (Table 8).

Table 8. Economic burden due to adverse events that are considered preventable

Condition- or site-specific costs of preventable adverse events		
Nestrigue, C and Or Z. (2011)	France	In 2007, the total cost of care incurred by these nine adverse events was estimated near 700 million Euros
Sjödahl, R. et al (2014)	Sweden	Preventable adverse events in surgical units 1.4 billion SEK (2014)
Barco, S. et al (2016)	EU-28	Preventable VTE costs 0.7-7.3 billion in 2014 EUR PPP
Mahan, C. et al (2011)	United States	VTE cost models ranged preventable costs from with USD 2.5 – 19.5 billion
Aggregate hospital costs of preventable adverse events		
Hoonhout L. et al (2009)	Netherlands	The adverse events considered preventable added up to 161 million EUR
Etchells et al (2012)	Canada	Economic burden of adverse events in Canadian hospitals 2009-2010, where the burden attributable to preventable adverse events was estimated at \$ CAN 397 million
Frontier (2014)	Economics United Kingdom	Detailed case reviews: ranges from £1 billion when applying conservative estimates to £3.8 under alternative scenarios (including litigation costs).
Brown et al (2002)	New Zealand	Economic burden of preventable adverse events in public hospitals in New Zealand costed the healthcare system \$ NZ 590 million in 2001

1.3 The costs of harm dwarf the costs of preventing it

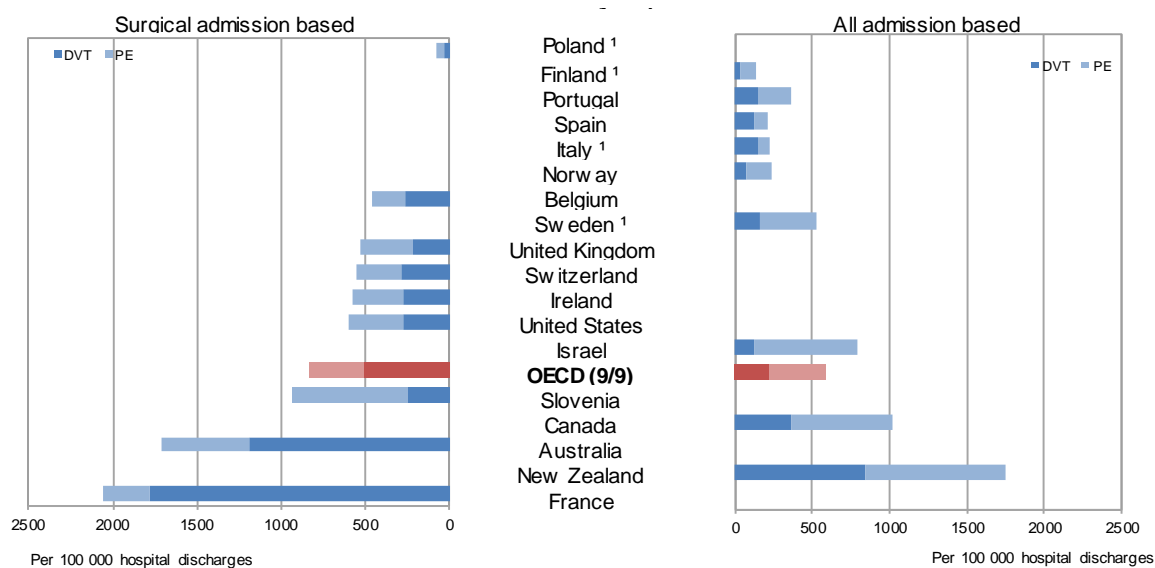
57. Compared to other high-risk industries, a systematic assessment of risks and a rational approach towards addressing system wide prevention and failure costs has traditionally not been common in health care.

58. Various international studies estimating the financial cost of adverse events have been presented. However, few of these studies estimate the prevention costs as well as the potential savings that can be

¹³ Decubitus ulcer, foreign body left during procedure, infections due to medical care, postoperative metabolic and metabolic derangement, postoperative pulmonary embolism or deep vein thrombosis, postoperative sepsis, technical difficulty during procedure, obstetric trauma vaginal delivery with/without instrument

made and few of these studies base their estimates on empirical data. With some notable exceptions, these arguments may not be convincing enough to encourage change in policy and clinical practice. Comparing the disease-specific treatment costs to the costs of prevention may motivate policy-makers and health care professionals to focus more on implementing and rigorously following preventive guidelines. For example, preventing VTE can require minor investments to improve safe care and may result in important financial and outcome gains. Through its Health Care Quality Indicator program the OECD has over the past 7 years worked on the international comparability of patient safety indicators based on administrative data. Healthcare associated VTE is an example. Figure 5 illustrates the differences between countries to capture this type of information systematically.

Figure 5. Postoperative venous thromboembolism in hip and knee surgeries (2013 or nearest year)

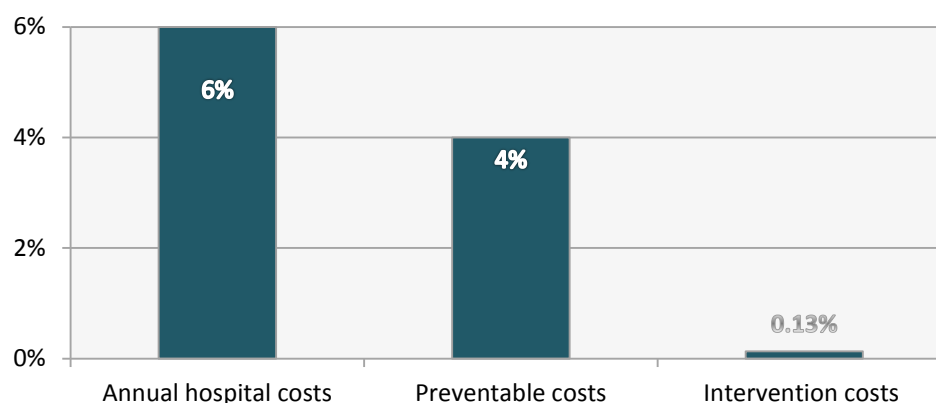


1. The average number of secondary diagnoses is < 1.5.

Note: Rates have not been adjusted by the average number of secondary diagnoses.

Source: OECD Health Statistics 2015, <http://dx.doi.org/10.1787/health-data-en>.

59. Between 59% and 75% of all VTEs are healthcare-acquired, and approximately two thirds of VTE-related deaths occur in hospitalised patients every year, making it one of the most preventable causes of death during hospitalisation. The costs of preventable healthcare-acquired VTE in the United States ranged from \$6.8 to \$27 billion in 2010, while the costs related to appropriate prophylaxis for patients at risk is estimated to be less than \$600 million (Mahan et al, 2011). As share of the public hospital spending in the US, the prevention costs accounted for only 0.13% while the costs of failure (healthcare-acquired VTE) accounted for 4%-6% (Figure 6).

Figure 6. Annual hospital costs of venous thromboembolism dwarf the costs of prevention

Source: Mahan et al, 2011

60. Pressure ulcers are another example of prevalent harm in acute and long-term care settings that can be avoided by implementing of preventive measures. Demarré et al (2015) conducted a systematic review to compare treatment-related and preventive cost estimates. Despite large differences in method, findings from the review do reveal that pressure ulcers are a big threat for patient safety and well-being and the costs to treat a severe pressure ulcer is substantially higher than the cost of prevention (Table 9).

Table 9. Prevention costs for pressure ulcers are lower than treatment costs

	Failure cost (national, annual cost)	Prevention cost (national, annual cost)
Across all levels of care	121.44 million – 2.59 billion EUR	195,27 – 291,33 million EUR
Hospital care	140.47 million EUR- 210.70 million EUR	33.2 million EUR (technical approach) 76.79 million EUR (human approach)
Long-term care	N.A.	12.58-16.27 million EURO

Source: Bayoumi et al 2008, Schuurman, JP et al 2009

61. Staff composition may be an effective strategy to mitigate patient harm, for example preventing pressure ulcers by regularly turning bedridden patients. Hospitals with high staffing of registered nurses reported higher quality of care, shorter length of stay and 2-9% lower complication rates (Øvretveit, 2009). The most fragile patients are admitted to the intensive care unit (ICU). Almost every single patient admitted to an ICU suffers a preventable adverse event. By staffing ICUs with specialists, studies have found hospital mortality reduction between 10%- 30% (Pronovost et al, 1999; Birkmeyer 2001). Estimated net savings for 12-bed ICU hospital and 18-bed ICU hospital were \$ USD 2 million and \$ USD 3.5 respectively (Pronovost et al 2002).

62. With regard to more complex process and organisational changes, the potential to reduce the incidence of adverse events and to save money is greater but so are the risks (Øvretveit, 2009). Financing schemes and changes in the revenue of healthcare providers may incentivise the implementation of patient safety interventions by better aligning clinical and corporate risk. Occurrence of adverse events in American hospitals is associated with more than \$30 000 greater contribution margin per privately insured patients compared to less than \$ 2 000 for Medicare beneficiaries (Eappen et al 2013). Programs to reduce

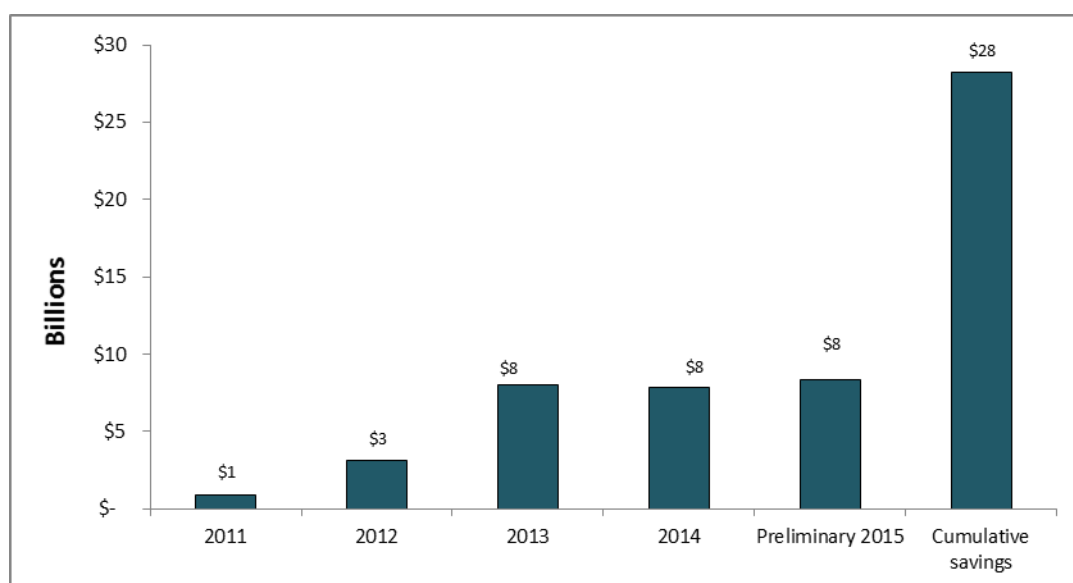
complications may worsen their near-term financial performance and hence not be of interest to hospital managers seeking to improve safety.

63. In order to reduce preventable patient harm in hospitals, the United Kingdom and the United State have implemented ‘penalty-based’ financing reforms. Among the conditions for which healthcare providers do not receive reimbursement are namely pressure ulcers and VTE. Additionally, the English NHS has stopped reimbursing providers for patients’ death or severe harm during maladministration of insulin by a health professional during an inpatient stay. Medicare launched the second wave of the penalty reform approach in 2015, by also applying penalties for higher rates of healthcare-acquired infections than expected (Kristensen, 2016).

National efforts to reduce harm and improve safety can deliver considerable savings

64. The Agency for Healthcare Research and Quality (AHRQ) publishes annually the rates of healthcare-acquired conditions (HACs)¹⁴ in Medicare patients treated in US hospitals. Preliminary results indicate a 21% decline in HACs between 2010 (145 HACs per 1,000 discharges) and 2015 (121 HACs per 1,000 discharges). This translates to 3.1 million fewer HACs that would have occurred if 2010 rates had been maintained. AHRQ estimates 125,000 deaths avoided as a result of the improvement, and a cumulative saving of approximately USD 28 Billion (Figure 7). This amounts to 1.2-1.3% of the total Medicare budget (AHRQ 2016).

Figure 7. Total Annual and Cumulative Cost Savings (2010 Baseline) in USD Billions



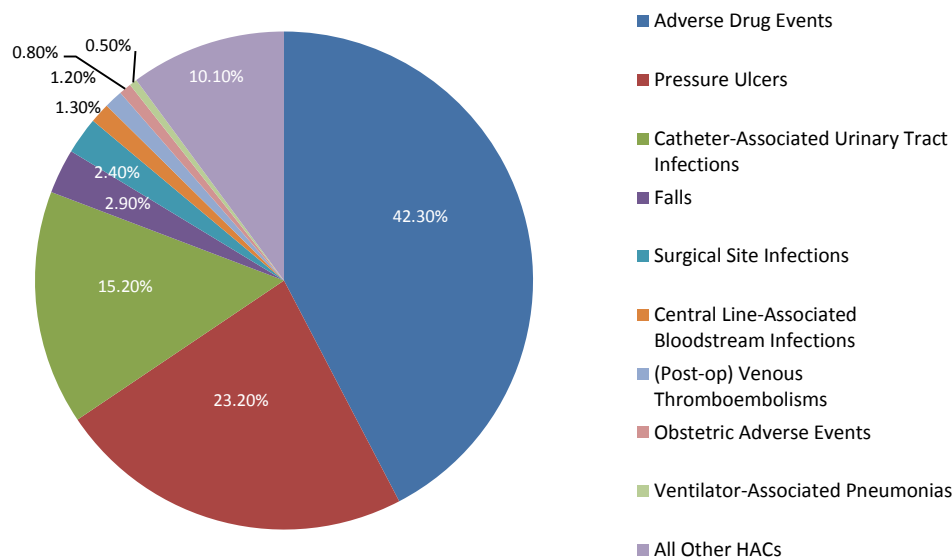
Source; AHRQ 2016

65. The greatest aggregate reductions occurred for adverse drug events (42%), pressure ulcers (23%) and catheter-associated urinary tract infections (CAUTI) (15%) (Figure 8). Comparing reductions within individual HAC categories over the time period, the greatest gains were made in reducing central line-associated bloodstream infections (CLABSI) (a 91% reduction between 2010 and 2015) and post-operative

¹⁴ The AHRQ collects data on a set of conditions acquired during hospital admission including a range of HAIs as well as VTE, falls, pressure ulcers, adverse drug events and post-operative complications. See <https://www.ahrq.gov/professionals/quality-patient-safety/pfp/index.html> HACs are acquired during admission and may in many cases be analogous to adverse events.

VTE (76% reduction). The impressive reductions in these two types of adverse events correspond with Hauck et al (2017) who found relatively low rates of CLABSI and VTE in English hospitals, and may reflect the success of the sustained focus on reducing these two harms in both countries over the past decade.

Figure 8. Decrease in healthcare-acquired conditions, 2011-2015 (Total = 3,097,400)



Source: AHRQ 2016

66. Several factors could potentially explain these improvements in patient safety, including: transparency and public reporting of hospital-level results; financial incentives implemented by the Centers for Medicare & Medicaid Services (CMS) and other payers over this time; investment in knowledge development, technical assistance and improvement efforts led by AHRQ and CMS; and implementation and improved use of electronic health records (EHRs) (AHRQ 2016). Notably, there has been a corresponding reduction in hospital re-admissions in the same patient cohort over this time period, attributed to hospitals responding to incentives to reduce re-admissions including financial penalties (Zuckerman et al 2016).

67. In the US context at least, national strategies to reduce harm and improve patient safety by using a combination of targeted and broad-based interventions can deliver results in terms of reducing morbidity, mortality and cost. While the costs of implementing the patient safety initiatives that led to these reduction in harm are not available, based on studies above (e.g. Mahan 2011; Demarre 2015) it is reasonable to assume that these would be considerable lower than the estimated 5-year saving of USD 28 billion.

68. So far, attempts to compare prevention costs with failure costs have focussed on specific patient safety issues such as VTE and pressure ulcers. Overall assessment of system wide prevention costs and failure costs, addressing prevention of adverse events in primary care, hospital care and long term care, has to our best knowledge, not been performed in any country. However, the question to explore the most effective mix of patient safety strategies in a resource-constrained environment based on its specific patient safety problems seems highly relevant. Such a value-based approach to reduce patient harm at national level is explored further in the next section.

SECTION II: REDUCING HARM EFFECTIVELY AND EFFICIENTLY

Box 4. Key findings on reducing harm effectively and efficiently

- The causes of patient harm are complex and dynamic - reflecting the increasing complexity of health care - and reside in the structures, processes and delivery points across all levels of a healthcare system. **A range of interventions, programs and initiatives** exists to tackle harm and improve patient safety.
- To shed light on how countries might prioritise action to improve safety, **a survey was distributed to a panel of expert policy makers and academics**. The experts were asked to assess and compare the cost and impact of a selection of interventions across three levels; system-level, organisational/institution-level and clinical level.
- Survey results suggest that a national approach to reducing patient harm should adopt a **system-perspective**. The relative **impact and costs rating favour clinical-level interventions** targeting the most burdensome adverse events: VTE prophylaxis, protocols to minimise central-line catheter insertion, pressure injuries, urinary catheter associated infections, procedural and surgical check lists. These highest rated interventions are backed by sound evidence.
- **General concordance was identified between academic and policy experts' responses**. Nonetheless, there were some notable differences between the two panels. The policy panel reported more positive ratios, and favoured interventions targeting clinical level. The academic panel was less optimistic about the relative impact of the interventions, in addition to less variation between the system, organisational and clinical level.
- Patient safety strategies are rarely implemented in isolation. When selecting interventions for **'best buys'**, prioritisation elevated the importance of system- and organisational level interventions. For OECD countries system- and organisational levels were most selected interventions (52% and 37% respectively); **professional education and training, clinical governance systems, safety standards, person, and patient engagement strategies**. Developing a **culture conducive to safety** was seen as critical.
- While the pattern of patient harm was different in low-to-middle income countries, the strategies of how to improve patient safety were quite similar. Expert panels favoured system- and organisational level interventions (45% and 39% respectively) and emphasised fundamentals such as **professional education, safety standards** and interventions targeting **healthcare-associated infections** and **nationally specified patient safety priority themes**.

69. Having established the considerable cost of patient safety failures in terms of their disease burden as well as the financial and economic impact, this section examines strategies to mitigate these failures across healthcare systems in a resource-constrained context where choices and trade-offs are required.

70. Before examining how a country might prioritise action to improve patient safety in a value-based manner, it is worth briefly exploring the causes and determinants of patient harm a little more. This section first provides an overview of the underlying causes of harm, and the ensuing strategies, interventions and practices to improve safety. This frames the discussion and introduces the conceptual framework for the snapshot survey that forms the basis of this section of the report. The results of this survey of experts on the costs and impacts of a range of patient safety interventions are then presented. This leads to recommendations to policy makers and providers of care on a value-based approach to investing in safety.

2.1 The causes of harm - and strategies to minimise it

71. Modern health care is a very complex endeavour, requiring input from various participants working in separate institutions and interacting with complex technologies, machinery and technical infrastructure. There are many opportunities for things to go wrong and, as was demonstrated in Section 1, they do in a substantial high proportion of cases.

72. The causes of harm are therefore complex, dynamic and diverse stretching across all facets of healthcare delivery and system behaviour – from planning and education and training, to financing, down

to administration and clinical activity. While many defences and barriers are in place to prevent failure, human fallibility and variation combined with inherent faults in the system safeguards can result in patient harm (Reason 2000).

73. Adverse events, and the resulting harms, play out at the clinical interface. But due to the complexity of health care systems and the vast array of services they deliver, the root causes of these failures are more fundamental - structural, cultural and process-oriented. For example, the vast majority of patient harm – from the operating room to the community clinic - can be traced to failures in communication, where critical and important information has not been transmitted to the right actors at the right time (these actors include the patient). The causes of these communication failures can often be found in the structures – the hierarchies and cultures - of organisations and systems (Francis 2013). Communication is also both as a determinant and consequence of an organisational culture conducive to safety (see below). Overarching strategies to improve patient safety must therefore always address questions of communication - within the clinical microsystem, throughout organisations and across entire systems. The open communication and disclosure of adverse events must also feature in these considerations (Hannawa 2105 & 2016; ACSQHC 2013).

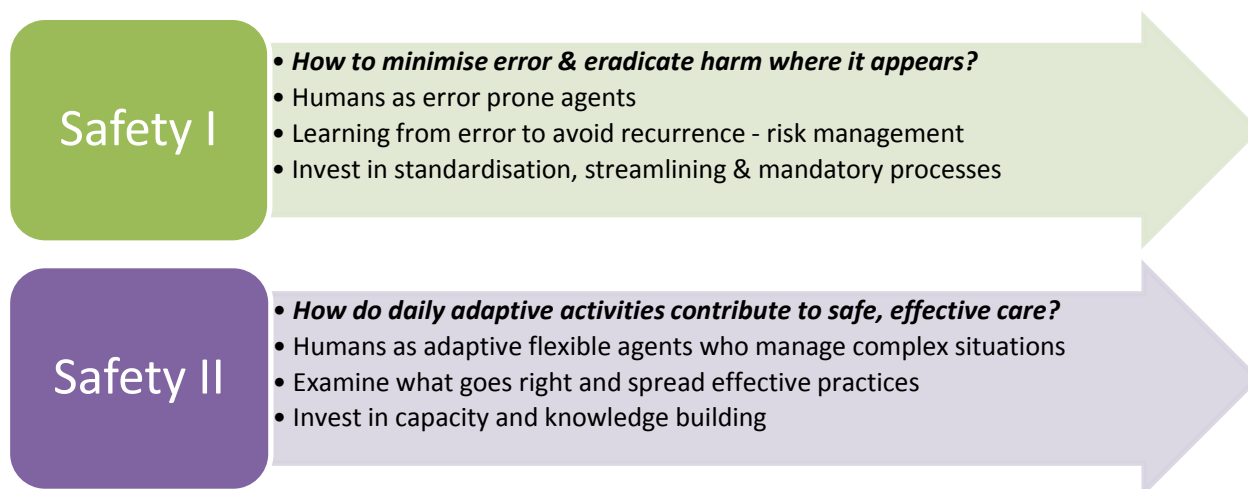
74. A brief examination of 'high reliability' organisations within healthcare as well as other industries (e.g. aviation, nuclear, oil and gas) reveals, firstly an explicit and rational approach to balancing failure costs and prevention costs (see Section I). Secondly, in terms of preventing harm, a fastidious preoccupation with established processes, safeguards and protocols. This is underpinned by the explicit recognition of human factors in individual and system failure, and the greater the complexity of the task the more safeguards are required. Failure is seen as an opportunity to learn, and all stakeholders or participants are encouraged to intervene ('speak up') when they are made aware of a potential risk. This suggests that broader and more fundamental factors may be important in the context of safety.

Patient safety culture and a systems perspective are important

75. Modern healthcare organisations serve as a good example of 'complex adaptive systems' (Braithwaite & Donaldson, 2016). As the levels of complexity and unpredictability continue to rise, the more intangible determinants of patient safety are being given increasing prominence and recognition, as is the need for a more integrated, system-based view of safety. Just as modern healthcare interventions involve a combination of processes and activities actioned by a network of actors, so too the determinants of quality, safety and outcomes cannot be easily decomposed into its component parts. The idea that patient safety initiatives should therefore be implemented and assessed as part of a suite anchored within an overarching framework is gaining traction (Yu et al 2016).

76. An increasing number of experts argue that the traditional focus on measuring and learning from what goes wrong in health care could be complemented by a more proactive approach. 'Safety I' focused on finding error, learning from it putting in place strategies and safeguards to preventing it - all important activities that must continue. 'Safety II' is defined as "the ability to make things go right and note merely the absence of failure or adverse outcomes" (Brathwaite et al 2015), and promotes learning from what goes right, from examples of resilience, and from positive deviance or innovative safety-creating behaviours. While the two are complementary, some distinctions are illustrated in Figure 9.

Figure 9. 'Safety I' and 'Safety II' are complementary



Source: Authors' adaption of Braithwaite & Donaldson (2016) and Braithwaite et al (2015)

77. Organisational culture is increasingly recognised as one of the most fundamental, upstream determinants of outcomes in health care (Yu et al 2016; NPS Lucian Leape Institute, 2016; Francis 2013). Culture can be broadly defined as the collective values, attitudes, beliefs and principles – or the unwritten rules of an organisation. The 'right' culture provides an environment for safety to flourish. Key aspects of a safety culture may include openness, transparency, reflection and learning, honesty, respect, team work, breaking clinical silos and hierarchies, and a move away from blaming to shared responsibility. Equally, the 'wrong' culture can facilitate failure. Arguably the most tractable approach to culture in the safety context is patient-engagement - putting patients at the core of all activities and decision making (NPS 2014). Patient engagement has received increasing attention from providers and policy makers as its links to higher safety levels, improved outcomes and flow-on benefits such as improved trust emerge from the literature.

78. The right culture can rarely be fostered through a single, dedicated program or intervention, although there are some initiatives that can promote it.¹⁵ Rather, it is a product of many initiatives and policy settings (e.g. 'soft' strategies such as education and socialisation of healthcare professionals, or dedicated patient and community engagement programs, and no-fault medical negligence legislation). Healthcare financing mechanisms may also play a role. How money is spent articulates certain values over others. In doing so it sets the institutional tone that may foster a certain culture. Again, an all-encompassing as opposed to a reductionist view of patient safety improvement is needed to assess and appreciate the value of culture and other upstream factors in setting the right environment for reducing harm. Building the right culture therefore requires leadership across all levels of the healthcare system.

Structures, processes and end-point delivery practices determine success or failure

79. Donabedian's 'structure-process-outcome' model for quality (Donabedian 1966) serves as a useful framework to combine these approaches into a universal framework. Donabedian saw "structures"

¹⁵ For example, the Resilience In Stressful Events (RISE) implemented at Johns Hopkins Medicine (US) program has been designed to provide multidisciplinary, peer-to-peer support for healthcare workers (often called the 'second victims' of harm) after they experience a stressful event. This program has been found to have a positive impact on attitudes and has been assessed as cost-effective (are (Moran et al 2017). Similarly, a policy of open disclosure following adverse events is also said to foster a positive safety culture throughout a healthcare organisation (ACSQHC 2012).

as the settings, institutions, and administrative systems through which care takes place; “processes” as the components of care delivered; and “outcomes” as recovery, restoration of function, and survival (including any harms associated with care). These concepts remain the foundation of assessing healthcare quality even today as they encompass specific interventions along with the more upstream, fundamental determinants.

80. Figure 10 adapts Donabedian’s model to the patient safety context. Working backwards from the right, patient outcomes (positive or negative) are a consequence of behaviours and processes (both clinical and administrative) dictating clinical care. These are, in turn, determined to a large extent by structural factors of the organisation or system in which they are occurring. Many of these are the fundamental determinants such as culture outlined above. As a whole, patient safety is the results of these upstream and downstream factors, and how they interact with one another.

Figure 10. Donabedian’s model applied to patient safety



Source: Authors' adaptation of Donabedian (1966)

81. Section 1 identified several adverse event categories (outcomes) that exert considerable burden and cost on health systems and societies in the developing and developed world. The previous section also provided a brief introduction to the possible strategies, interventions and practices that can prevent failure in patient safety focusing on the most burdensome adverse events such as VTE, infections and pressure ulcers, all of which can be accommodated within Donabedian’s framework. The remainder of this section examines the various available interventions in terms of their impact on safety as well as their costs.

2.2 A value-based approach to improving patient safety across healthcare systems

82. A wide range of policy and practice interventions exist to reduce harm across the board and/or focusing on specific types of harm. Policy makers wishing to improve patient safety in a resource-constrained environment face a number of choices requiring trade-offs and sacrifices. While there is a growing body of evidence on the effectiveness of certain approaches (skewed towards micro-level interventions on clinical practice in the hospital setting), less work has been done to assess and compare the cost of prevention with the cost of failure. A paucity of literature exists on the comparative cost-effectiveness of patient safety programs available to health policy makers and practitioners. Consequently little empirical evidence is available to guide resource allocation decisions aimed at maximising the return on investment in patient safety.

83. Moreover, since initiatives are rarely applied in isolation and are likely to be more effective in concert with other strategies and interventions, there is even less evidence on complementary suites or bundles of patient safety initiatives that may represent 'best buys' for policy makers faced with constrained budgets and limited resources.

84. Aiming to address this deficit, a snapshot survey was designed requesting respondents to rate a set of patient safety interventions for their cost of implementation and their impact on reducing harm, both

in isolation as well as part of a suite that would have maximum impact at minimum cost to the healthcare system. Drawing on Donabedian's Structure-Process-Outcome model, the interventions were classified into the three categories below. All interventions included in the survey are listed in Table 11. A full description of these interventions and more detail about the survey method is provided in Annex 1.

- **CATEGORY 1:** System (macro)-level patient safety strategies, programs and initiatives that are best approached and implemented across an entire system. Implementation would typically require legislative or high-level policy levers, and often benefit from broad (societal level) public engagement. Examples include financing and pay for performance initiatives, and no-fault compensation schemes.
- **CATEGORY 2:** Organisational and institutional (meso)-level patient safety programs, initiatives or practices that - while often aimed at particular clinical area or patient type – should be implemented across an entire healthcare organisation or institution. Examples include clinical incident reporting and management systems, and hand hygiene initiatives.
- **CATEGORY 3:** Clinical (micro)-level patient safety practices that may span organisations but are optimally initiated at practice level, and managed within the clinical microsystem (which includes the involvement of patients and their surrogates, and administrative staff working with practitioners and patients). Examples include catheter insertion bundles and surgical safety checklists.

85. A nominal group technique was deployed drawing on a panel of expert academics and policy makers. Sixteen prominent researchers, academics and thought leaders in the patient safety field were identified and asked to complete the survey by email. Eight (8) responses were received from this academic panel (Table 10). Fifteen (15) national policy expert respondents identified through nominations by official OECD delegations responded to the survey: **Australia, Belgium, Canada, Czech Republic, France, Israel, Japan, Latvia, Luxemburg, Norway, Poland, Slovak Republic, Spain, Sweden and Switzerland.**

Table 10. Academic respondents

Berwick, Don	Emeritus President and Senior Fellow, Institute for Healthcare Improvement (IHI)
Braithwaite, Jeffrey & Mumford, Virginia	Director, Australian Institute of Health Innovation (AIHI), Macquarie University Post-doctoral Research Fellow, AIHI
Darzi, Ara	Director, NIHR Imperial Patient Safety Translational Research Centre
De Bruijne, Martine	Associate Professor Public and Occupational Health, EMGO Institute, VU University Medical Center, Amsterdam
Donaldson, Liam	Chancellor, Newcastle University, UK. Patient Safety Envoy, WHO
Michel, Philippe & Amalberti, René	Professor, Université Claude Bernard Lyon 1; President, Institut pour la qualité et la sécurité en santé, France Professor of medicine, physiology, and ergonomics. Senior Advisor, Patient Safety, Haute Autorité de Santé, France
Runciman, Bill	Professor of Patient Safety, University of South Australia
Vincent, Charles	Emeritus Professor, Department for Experimental Psychology, University of Oxford

86. Survey results are presented in two parts based on the survey structure (see Annex 1). First the ratings of the interventions in isolation, followed by analysis of the 'best buys' bundles suggested by respondents. This is then followed by the conclusions of the survey results.

Table 11. Patient safety interventions included in the snapshot survey

1. System level interventions	2. Organisational (institutional) level interventions	3. Clinical-level interventions
1.1 Safety Standards linked to accreditation and certification	2.1 Clinical governance systems and frameworks related to safety	3.1 Medication management / reconciliation
1.2 Public reporting of patient safety indicators	2.2 Clinical incident reporting and management system	3.2 Transcribing error minimisation protocols
1.3 Mandatory reporting of specified adverse events	2.3 Integrated patient complaints reporting system	3.3 Smart infusion pumps and drug administration systems
1.4 Pay-for performance schemes for patient safety	2.4 Monitoring and feedback of patient safety indicators	3.4 Aseptic technique protocols and barrier precautions
1.5 Professional education and training	2.5 Person- and patient-engagement initiatives	3.5 Urinary catheter use and insertion protocols
1.6 Electronic Health Record (EHR) systems	2.6 Clinical communication protocols and training	3.6 Central line catheter insertion protocols
1.7 No-fault medical negligence legislation	2.7 Digital technology solutions for safety	3.7 Ventilator-associated pneumonia minimisation protocols
1.8 System-level public engagement and health literacy initiatives	2.8 Human resources interventions	3.8 Procedural / surgical checklists
1.9 National interventions based on specific safety themes	2.9 Building a positive safety culture	3.9 Operating room integration and display checklists
1.10 A national agency responsible for patient safety	2.10 Infection detection, reporting and surveillance systems	3.10 Peri-operative medication protocols
	2.11 Hand hygiene initiatives	3.11 VTE prevention protocols
	2.12 Antimicrobial stewardship	3.12 Clinical care standards
	2.13 Blood and blood management protocols	3.13 Pressure injury (ulcer) prevention protocols
	2.14 Medical equipment sterilisation protocols	3.14 Falls prevention protocols
		3.15 Acute delirium & cognitive impairment management programs
		3.16 Response to clinical deterioration
		3.17 Patient hydration and nutrition standards
		3.18 Patient identification and procedure matching protocols

Source: OECD patient safety snapshot survey 2017

Clinical-level interventions targeting burdensome adverse events received the most favourable ratings

87. In part 1 of the survey, respondents were asked to rate relative impacts and costs for each of the 42 interventions. The average impact rating across all respondents was 3.66 out of 5. The average cost rating was 2.77. The interventions with the highest and lowest average ratings are presented in Table 12. The highest impact and highest cost interventions comprise predominantly system- (category 1) and organisational-level (category 2) interventions, with four featuring in both lists (**2.7**, **1.6**, **1.9** and **2.4**). The only clinical-level (category 3) intervention to be rated high cost was **3.9**. Interventions rated with the lowest impact were from the system- and clinical-level categories. The seven lowest-cost interventions were exclusively from the clinical-level category.

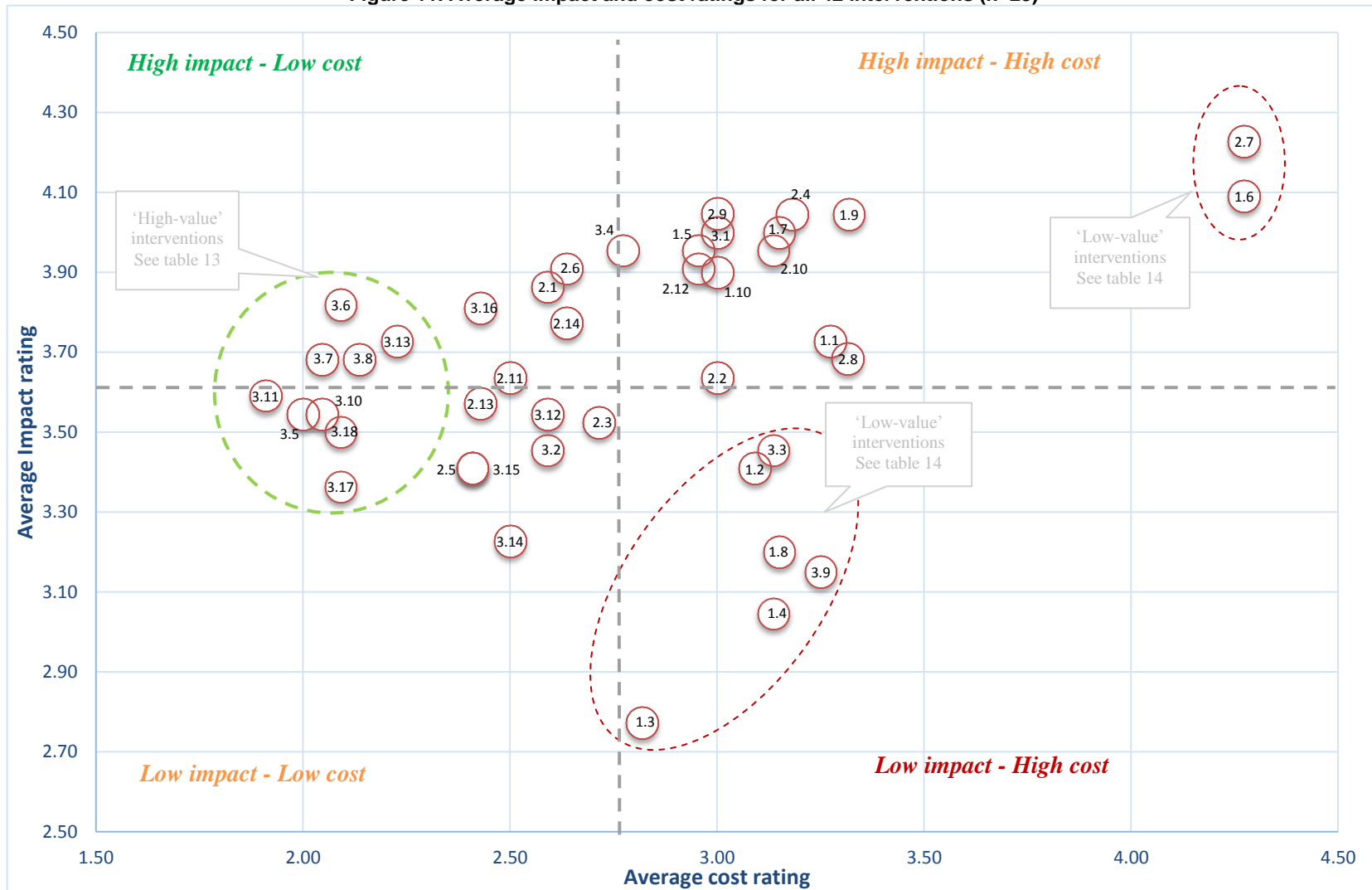
Table 12. Highest and lowest impact and cost ratings for individual interventions, all respondents (n=23)

Highest impact ratings	Rating	Highest cost ratings	Rating
2.7 Digital technology solutions for safety	4.23	2.7 Digital technology solutions for safety	4.27
1.6 Electronic Health Record (EHR) systems	4.09	1.6 Electronic Health Record (EHR) systems	
1.9 National interventions based on specific safety themes	4.05	1.9 National interventions based on specific safety themes	3.32
2.4 Monitoring and feedback of patient safety indicators		2.8 Human resources interventions	
2.9 Building a positive safety culture		1.1 Safety Standards linked to accreditation / certification	3.27
1.7 No-fault medical negligence legislation	4.00	3.9 Operating room integration and display checklists	3.25
3.1 Medication management / reconciliation		2.4 Monitoring and feedback of patient safety indicators	3.18
Lowest impact ratings		Lowest cost ratings	
1.3 Mandatory reporting of specified adverse events	2.77	3.11 VTE prevention protocols	1.91
1.4 Pay-for performance schemes for patient safety	3.05	3.5 Urinary catheter use and insertion protocols	2.00
3.9 Operating room integration and display checklists	3.15	3.7 Ventilator-associated pneumonia minimisation protocols	2.05
1.8 System-level public engagement and health literacy initiatives	3.20	3.10 Peri-operative medication protocols	
3.14 Falls prevention protocols	3.23	3.18 Patient identification and procedure matching protocols	2.09
3.17 Patient hydration and nutrition standards	3.36	3.17 Patient hydration and nutrition standards	
		3.6 Central line catheter insertion protocols	

Source: OECD patient safety snapshot survey, 2017

88. Figure 11 plots the average impact (y axis) and cost (x axis) ratings for all 42 interventions. This enables visualising the favourability of the ratings. To assist, the chart is divided into quadrants using grey dotted lines (set at the median value on each axis). The top left quadrant features interventions with the most favourable ratings (i.e. high impact / low cost). Four clinical-level interventions showed particularly favourable ratings: **3.6**, **3.7**, **3.8** and **3.13** (see Table 13). The bottom left quadrant contains interventions with low ratings for both impact and cost. Most of these interventions are in the northern (higher impact) sector of the quadrant.

Figure 11. Average impact and cost ratings for all 42 interventions (n=23)



89. Both the top- and bottom-left quadrants contain predominantly clinical-level interventions, some organisational-level and no system-level interventions (Figure 11). The cluster of nine interventions at the left side of the chart – demarcated by the green circle - represent the best 'value' (highest impact/lowest cost) based on part 1 survey responses. All are clinical-level interventions aimed at the most burdensome adverse event types identified in Section I. They are presented in Table 13 ranked by the ratio between their average impact and cost ratings.¹⁶

Table 13. Interventions with most favourable impact and cost ratings by average impact/cost ratio (n=23)

Intervention	Avg. impact/cost ratio
3.11 VTE prevention protocols	1.88
3.6 Central line catheter insertion protocols	1.83
3.7 Ventilator-associated pneumonia minimisation protocols	1.80
3.5 Urinary catheter use and insertion protocols	1.77
3.10 Peri-operative medication protocols	1.73
3.8 Procedural / surgical checklists	1.72
3.18 Patient identification and procedure matching protocols	1.67
3.13 Pressure injury (ulcer) prevention protocols	1.67
3.17 Patient hydration and nutrition standards	1.61

Source: OECD patient safety snapshot survey, 2017

90. Interventions in the top right quadrant of Figure 11 received both high impact and high cost ratings. Respondents perceived these to have considerable benefits but also large costs of implementation and maintenance. These were mostly system- and organisational-level interventions. Only one clinical-level intervention - **3.1 Medication management/reconciliation** - appears in this quadrant. The notable outliers in the top right are **1.6 EHR systems** and **2.7 Digital technology solutions for safety**, both interventions drawing on digital technology. The bottom right quadrant contains interventions rated by respondents as low-impact and low-cost. Interventions with the least favourable ratings across all results are demarcated by the red ellipses in Figure 11 are presented in Table 14.

Table 14. Interventions with least favourable ratings by quadrant and average impact/cost ratio (n=23)

Quadrant	Intervention	Avg. impact/cost ratio
<i>Low impact High cost</i>	3.9 Operating room integration and display checklists	0.97
	1.4 Pay-for performance schemes for patient safety	0.97
	1.3 Mandatory reporting of specified adverse events	0.98
	1.8 System-level public engagement and health literacy initiatives	1.02
<i>High impact High cost</i>	2.7 Digital technology solutions for safety	0.99
	1.6 Electronic Health Record (EHR) systems	0.96

Source: OECD patient safety snapshot survey, 2017

91. The level of agreement among respondents on the impacts and costs varied between the listed interventions. Table 15 presents interventions with the most consistent and least consistent impact and cost ratings across respondents (based on standard deviation). Seven of the 10 interventions with the most consistent ratings are from category 3 (clinical-level). Only one category 3 intervention (3.3) featured among the least consistently-rated, which are otherwise comprised of category 1 and 2 interventions.

¹⁶ A ratio of 2 suggests the average impact rating was twice as high as the average cost rating (e.g. 4 / 2 or 2 / 1). A ratio of 0.5 means that cost ratings were double that of impact ratings (e.g. 1 / 2 or 2 / 4).

Table 15. The most- and least-consistently rated interventions for cost and impact (n=23)

Most consistent ratings	
3.11 VTE prevention protocols	3.17 Patient hydration and nutrition standards
3.13 Pressure injury (ulcer) prevention protocols	2.7 Digital technology solutions for safety
3.10 Peri-operative medication protocols	3.9 Operating room integration and display checklists
1.9 National interventions based on specific safety themes	3.18 Patient identification and procedure matching protocols
1.6 Electronic Health Record (EHR) systems	2.10 Infection detection, reporting and surveillance systems
Least consistent ratings	
2.9 Building a positive safety culture	2.13 Blood and blood management protocols
1.3 Mandatory reporting of specified adverse events	2.5 Person- and patient-engagement initiatives
1.8 System-level public engagement and health literacy initiatives	1.1 Safety Standards linked to accreditation and certification
1.4 Pay-for performance schemes for patient safety	2.8 Human resources interventions
3.3 Smart infusion pumps and drug administration systems	1.2 Public reporting of patient safety indicators

Source: OECD patient safety snapshot survey, 2017

92. Examining the academic and policy experts' responses separately shows general concordance, with a relatively strong correlation between results ($r^2=0.71$) but some notable differences. The policy experts' average impact/cost ratios ranged from 2.00 (**3.8 Procedural/surgical checklists**) to 0.96 (**1.4 Pay-for-performance schemes**). Interventions rated most favourably by the policy experts (the highest ratios) were predominantly from category 3.

93. The academics were generally more pessimistic about the impact of the listed interventions relative to cost. The average impact/cost ratio for academic respondents was 1.24 compared to the policy experts' 1.44. Results ranged from 1.87 (**3.11 VTE prevention protocols**) to 0.63 (**1.8 System-level public engagement and health literacy**). While clinical-level interventions also dominated the ratings, the three categories were more evenly represented across the academics' results. Organisational- and system-level interventions with favourable impact and cost ratings included **2.1 Clinical governance systems and frameworks**, **1.7 No-fault legislation** and **2.5 Person- and patient-engagement**. The category 3 intervention **3.1 Medication management and reconciliation** was more prominent in the academic panel's overall ratings. See Annex 2 for more detailed results.

The highest-rated interventions are backed by sound empirical evidence

94. Rating of costs and impacts in part 1 of the survey heavily favoured clinical-level interventions aimed at some of the most burdensome adverse event types in the hospital setting. One explanation may be that these have been more extensively studied – both in terms of the burden of the adverse event they target as well as their effectiveness and their costs – compared to their counterparts in other care settings where the literature and evidence is still less mature.¹⁷

- As outlined in Section I, **VTE** exerts a considerable morbidity, mortality and cost burden. VTE prevention protocols (#3.11) typically comprise risk assessment and consequent prophylactic interventions (pharmaceutical and mechanical). VTE is thought to be highly preventable with these protocols resulting in a significant reduction in overall occurrence, decreasing healthcare burden and unnecessary deaths (AHRQ 2016; Beckman et al 2016).

¹⁷ This may also explain the overlap between favourability and consistency of the ratings across the interventions (i.e. those with less variance in respondents' ratings also featured in the more favourable rankings).

- **Central-line catheter insertion**, and **ventilator-associated pneumonia** minimisation protocols have been demonstrated to be effective in reducing associated HAIs (Berenholtz et al 2011; Pronovost et al 2006). Moreover, a recent systematic review of 505 studies found interventions to reduce central line infections to be cost effective by an incremental factor of 3.15 (i.e. at the margin, every \$100,000 invested in preventing central line catheter associated infections was associated with \$315,000 of savings) (Nuckols et al 2016).
- **Pressure injury** prevention protocols (#3.13) also rated favourably. This type of adverse event exerts a high morbidity and burden, and is considered quite preventable in the acute and long-term care setting (Demarré et al 2015).
- **Urinary catheter associated infections** - while not as severe as central line and ventilator associated infections - due to their frequency exert a considerable cost burden on healthcare systems (Health Policy Analysis, Australia 2013). Protocols to guide their use and insertion can reduce the incidence of these infections effectively and efficiently, and it is unsurprising to find this intervention rated favourably (#3.5).
- Since the release of the WHO Surgical Safety Checklist in 2008, several studies have supported the use of **procedural and surgical checklists** (#3.8) in reducing post-operative complications and mortality across settings and in various economic contexts (Haynes et al 2009; WHO). However, there have been others that fail to demonstrate an effect on outcomes (Urbach et al 2014). The importance of sound implementation, including team training as well as the foundations of clinical governance and a safety culture have been emphasised (Borchard et al 2012; You-Xu 2011; Neily 2010, Conley 2011). **Patient identification** (#3.18), and **peri-operative medication protocols** (#3.10) are often part of surgical safety checklists, and it is unsurprising to find these among the top-rated interventions.
- Ensuring basic standards of care in the acute and long-term care setting such as sound **patient hydration and nutrition** (#3.17) is important in ensuring better clinical outcomes as well as preventing clinical deterioration and a range of adverse events. Poor hydration and nutrition can be a gateway for other harms including HAI, pressure injury and falls (Shekelle et al 2013). The importance of these basic standards – and the consequences of failure - came to light during the Mid Staffordshire inquiry in the UK (Francis 2013).

There were some notable omissions

95. Absences among the favourably-rated interventions are noteworthy. **3.1 Medication management and reconciliation** is generally regarded as very cost-effective and one of the most encouraged initiatives for implementing across healthcare systems (Shekelle et al 2013). It featured in the high-impact/high-cost quadrant of Figure 11, most likely due to the need to employ pharmacists to effectively carry out this intervention. The importance of **hand-hygiene** (#2.11) in reducing HAIs (among the most frequent adverse events in health care) has been established (WHO, 2009) although implementing these initiatives successfully across entire organisations is complex and achieving consistent compliance has proven difficult (Huis et al 2012). The cost of full and successful implementation is perhaps the reason for this intervention being given less favourable rating.

96. Evidence and literature for the majority of listed system- and organisational-level interventions, is comparatively underdeveloped. This is partly a function of the inherent complexity of investigating interventions that are broad, upstream in the care process, and which may have a range of effects, consequences and costs. For example, it is methodologically simpler to isolate and examine the effectiveness of a central line catheter insertion protocol compared to – for example - safety standards linked to accreditation, the establishment of a positive safety culture, or health literacy programs.

97. The least favourably rated interventions included **mandatory reporting of specific adverse events** (#1.3) typically called sentinel events, are favoured in several jurisdictions but were rated less favourably here. Studies of **pay-for-performance in safety** (#1.4) continue to produce equivocal results, and this may explain the poor relative ratings for this intervention. System-level public engagement and **health literacy initiatives** (#1.8) were rated costly with limited impact while more targeted, clinical and organisational-level engagement strategies were favoured.

98. Ratings for **1.6 EHR systems** and **2.7 Digital technology solutions for safety** were also noteworthy. These digital strategies received both the highest impact and cost ratings. Given the critical nature of timely access to information in improving patient safety and quality of care, an integrated medical record system that enables providers across settings to access clinical information would have been thought to be a useful initiative (particularly as the costs and benefits of an EHR system can manifest across many areas of the health system – quality of care, system management, and research and innovation). There is also growing evidence suggesting that EHR can reduce adverse events and improve safety (Furukawa et al 2016; Hydari et al 2014). Zsifkovits et al (2016) estimated savings of EUR 6 billion through electronic medication ordering system comprising computerised physician order entry and Clinical Decision Support System to prevent adverse drug events. However, several respondents commented on the complexity of implementing digital solutions that fulfils its potential in this regard. This difficulty was reflected in the cost rating (responses for this intervention were the most consistent among policy experts).

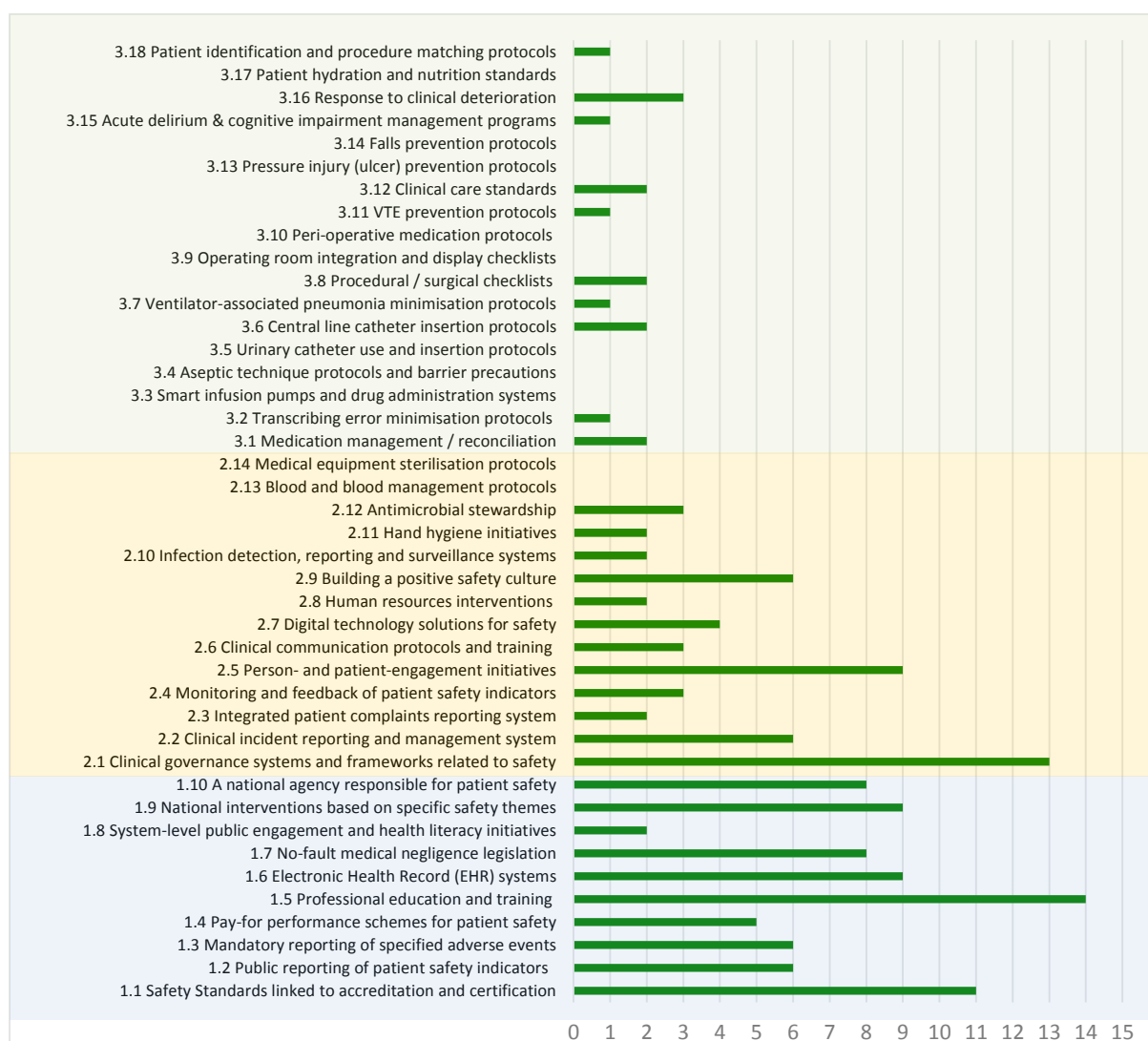
However, the need for prioritisation elevated the importance of system- and organisational-level interventions

99. In part 2 of the survey, respondents were asked to list up to seven patient safety interventions that would – as a suite or bundle applied across entire healthcare systems - generate the most impact per dollar invested. The aim was to encourage the experts to examine synergies between patient safety interventions across all three categories, and explicitly consider the trade-offs and sacrifices that are faced by decision makers in a resource-constrained environment. A 'best buys' bundle was requested for the OECD context and one that would work best in lower- to middle-income countries (LMICs).

100. Most respondents used up their entire allotment providing seven interventions for both contexts. Three respondents completed only the OECD context bundle, citing lack of knowledge about the specific needs in LMICs. One policy respondent provided simply one intervention (1.5 Professional education and training) for the OECD context, and none for LMICs.

101. For the OECD context, the most frequently selected interventions were system- and organisational-level initiatives (78 or 52% and 54 or 37% of all selections respectively). Clinical-level interventions were selected only 16 times (11%) (Table 16). Across all respondents the most frequently selected interventions for the OECD context were (Figure 12):

- **1.5 Professional education and training** (14 times)
- **2.1 Clinical governance systems and frameworks** (13 times)
- **1.1 Safety standards linked to accreditation and certification** (11 times)
- **2.5 Person- and patient-engagement strategies** (9 times)
- **1.6 EHR systems** (9 times)
- **1.9 National interventions based on specific safety themes** (9 times)
- **1.7 No-fault medical negligence legislation** (8 times)
- **1.10 A national agency responsible for patient safety** (8 times).

Figure 12. Frequency of interventions included in OECD context ‘best buys’ bundles (n=22)

Source: OECD patient safety snapshot survey, 2017

102. The clinical-level interventions featured in the OECD-context bundles aligned with the ratings in part 1 of the survey (central line catheter insertion, ventilator-associated pneumonia, surgical checklists, VTE prevention). In addition, **3.16 Response to clinical deterioration**, **3.1 Medication reconciliation**, **3.15 Acute delirium & cognitive impairment management** and **3.12 Clinical care standards** – notable for their unfavourable individual impact/cost ratings - were nominated by several respondents.

103. The policy experts’ selections for the OECD context heavily favoured system- and organisational level interventions. Academic respondents’ selections were more evenly distributed among the three categories, although still skewed towards the macro-level (Table 16).

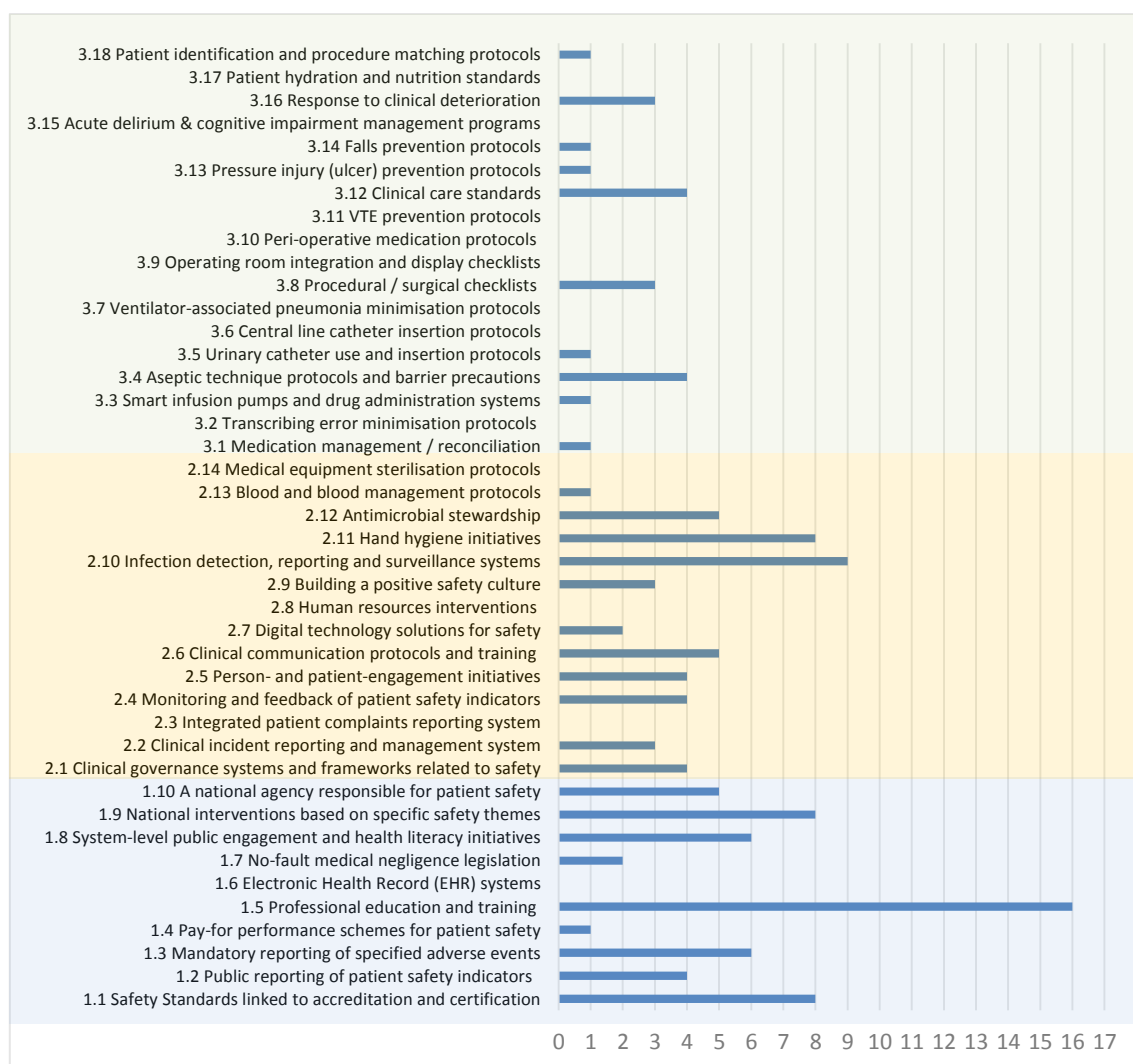
Table 16. Counts of interventions by category in OECD context ‘best buys’ bundle by panel

	Policy Panel (14)	Academic Panel (8)	Combined (22)
System-level	56 (58%)	22 (42%)	78 (52%)
Organisational-level	35 (36%)	20 (38%)	54 (37%)
Clinical-level	5 (5%)	11 (21%)	14 (11%)
Total	96	53	149

Source: OECD patient safety snapshot survey, 2017

104. The LMIC ‘best buys’ selections across all respondents also favoured system- and organisational-level interventions (45% and 39% of selections respectively) but were more evenly spread across the three categories compared to OECD context selections (Figure 13).

Figure 13. Frequency of interventions included in LMIC context ‘best buys’ bundles (n=19)



Source: OECD patient safety snapshot survey, 2017

105. The most frequently selected interventions for the LMIC context across all respondents were:

- **1.5 professional education and training** (16 times)
- **2.10 Infection detection and surveillance systems** (9 times)
- **2.11 Hand hygiene initiatives** (8 times)
- **1.9 National interventions based on specific safety themes** (8 times)
- **1.1 Safety standards linked to accreditation and certification** (8 times)

106. The most frequently selected clinical level interventions were **3.4 Aseptic technique**, and **3.12 Clinical care standards**. Overall, interventions targeting HAI featured prominently in the bundles selected.

107. Selections by expert group suggest similar differences to the OECD context, with the academics' selections again more evenly distributed across the three categories (Table 17). Both groups selected similar interventions most frequently, focusing on those targeting HAI.

Table 17. Counts of interventions by category in LMIC context 'best buys' bundle by panel

	Policy Panel (12)	Academic Panel (7)	Combined (19)
System-level	38 (49%)	18 (39%)	56 (45%)
Organisational-level	30 (38%)	18 (39%)	48 (39%)
Clinical-level	10 (13%)	10 (22%)	20 (16%)
Total	78	46	124

Source: OECD patient safety snapshot survey, 2017

Associations among key 'best buy' interventions were identified

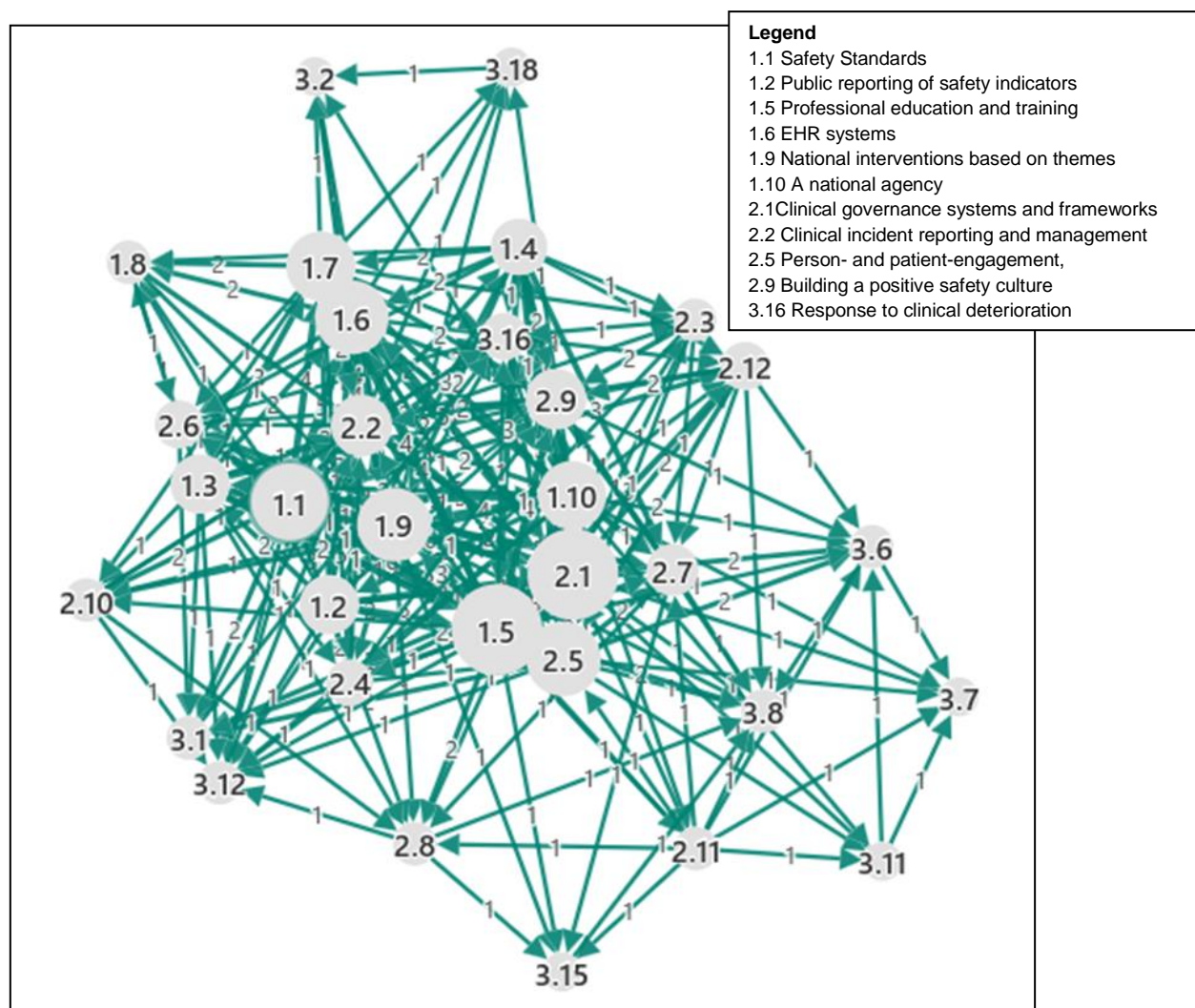
108. In order to establish associations and dependencies between interventions, and to identify if any were more frequently selected in combination across the selected 'best buys' bundles, a network visualisation analysis was performed using the Gigraph™ software add-on for MS Excel. This function maps the relationships between different nodes (interventions) in a sample, providing a visual representation of the associations between interventions selected in part 2 of the survey.

109. The network map for OECD-context selections across all respondents is presented in Figure 14. The size of the node represents how often the intervention features in the sample, and the distance between nodes and the thickness of the arrow between them represents how often they occur in tandem.¹⁸ Several category 1 and 2 interventions feature prominently using this analysis. Strong associations were observed between:

- *1.5 Professional education and training, 2.1 Clinical governance systems and frameworks related to safety, 2.5 Person- and patient-engagement, 2.9 Building a positive safety culture and 1.10 A national agency responsible for patient safety.*
- *1.1 Safety Standards linked to accreditation and certification, 1.9 National interventions based on specific safety themes, 1.2 Public reporting of safety indicators and 2.2 Clinical incident reporting and management system.*

¹⁸ The direction of arrows is arbitrary. It is simply a function of how interventions were numbered in the survey.

Figure 14. Network visualisation of interventions included in best buys list, OECD context

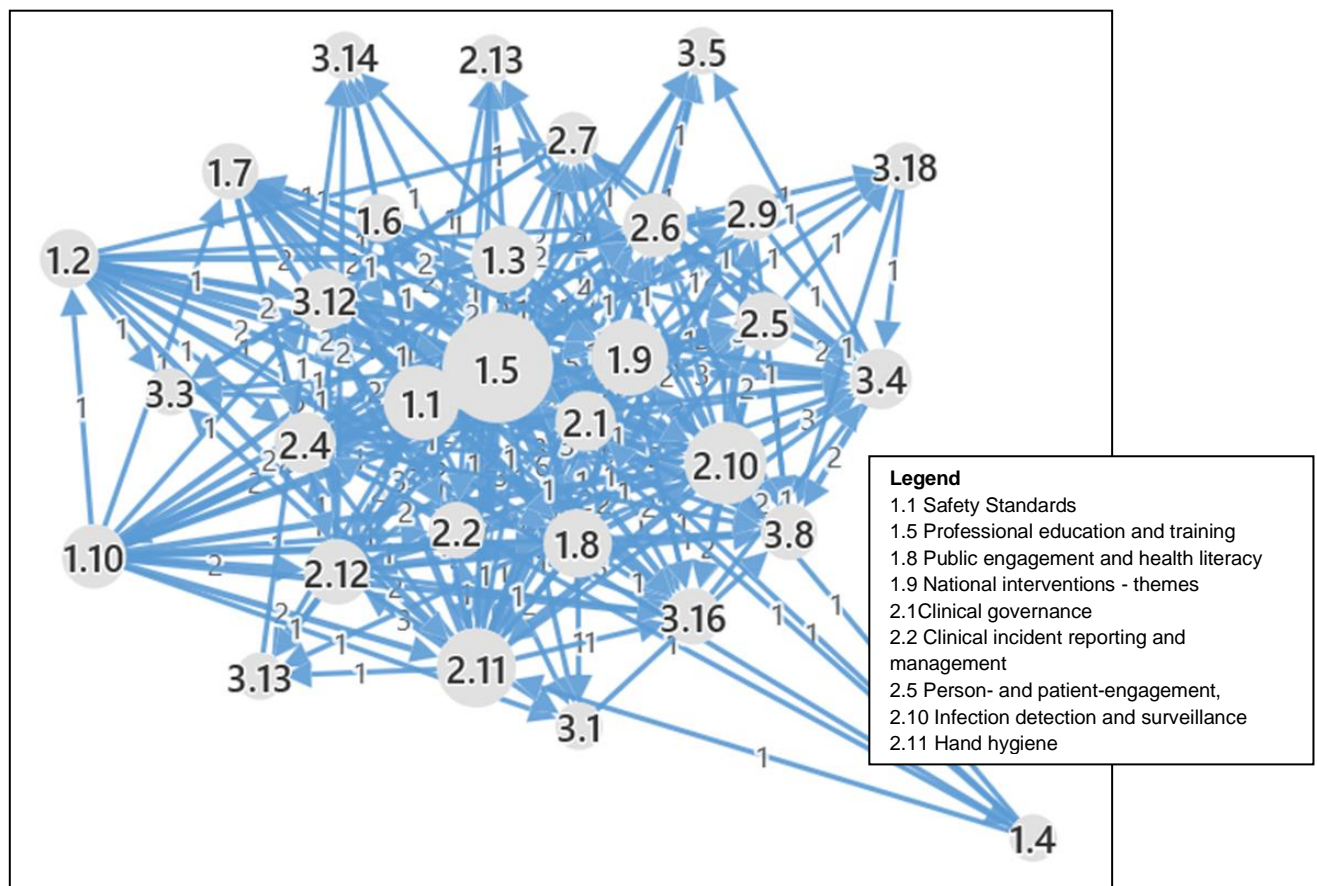


Source: OECD patient safety snapshot survey, 2017

110. The relative prominence of **1.6 EHR systems** in the network is noteworthy, indicating association with most other featured interventions. With the exception of **3.16 Response to clinical deterioration**, clinical-level interventions are quite peripheral in the network analysis for the OECD context ‘best buys’ bundles.

111. The network map for LMIC-context selections is presented in Figure 15. There is some overlap with the OECD context results. 1.5 Professional education and training, 1.1 Safety Standards linked to accreditation and certification, 2.1 Clinical governance and 1.9 National theme-based interventions feature centrally and prominently. The prominence of 2.10 Infection detection and surveillance systems and 2.11 Hand hygiene initiatives is noteworthy. Overall, there is less clustering of nodes compared to the OECD-context network (Figure 14) 1.4 Pay-for-Performance schemes for patient safety is notably peripheral for a category 1 intervention (selected by only one respondent), indicating little association with selection of other interventions as part of the bundles for LMICs.

Figure 15. Network visualisation of interventions included in best buys list, LMIC context



Source: OECD patient safety snapshot survey, 2017

Workforce education, training and socialisation are fundamental

112. The contrast between part 1 and part 2 survey results is stark. In part 1, where a rating of impact and cost for each of the 42 listed interventions was requested in isolation, the ‘downstream’ clinical-level interventions— procedural checklists, and clinical care protocols and standards - were dominant. The results reflected the strength and volume of the available evidence on adverse event burden and effectiveness of specific interventions. As a result, interventions aimed at adverse events occurring in the hospital setting were particularly dominant.

113. However, when faced with trade-offs and explicitly directed to set priorities among the array of available interventions (part 2), respondents gravitated to the upstream initiatives that require broad implementation and behaviour change across entire systems and organisations. The prominence of patient-engagement initiatives, safety standards, clinical governance and, in particular, professional education and training in the ‘best buys’ bundles is particularly noteworthy. In addition EHR systems and pay-for-performance schemes featured strongly in the bundles despite receiving unfavourable impact and cost ratings in part 1. The interventions favoured in part 2 can be described as setting the context, structures and processes for the more clinically-oriented interventions favourably rated on part 1 to be implemented. However, empirical evidence for the costs and impacts of these macro- and meso-level initiatives is comparatively lacking.

114. The distinction between part 1 and 2 responses also concerns the care setting. While part 1 responses favoured interventions aimed at improving patient safety in hospitals (and to some extent long-term care) as opposed to primary and long-term care, the macro-level strategies favoured in the ‘best buys’ bundles apply to all settings and sectors across a healthcare system. For example,

including elements of patient safety such as human factors and cognitive bias in education and training of healthcare professionals can set the foundations for addressing diagnostic error, the source of considerable harm in primary care settings (Singh et al 2016; McGlynn 2015).

115. Given the strong performance of **1.5 Professional education and training** in part 2 of the survey it is important to specify two things. First, this intervention as described in the survey goes beyond teaching clinical skills, but encompasses socio-technical competencies that are important in the modern healthcare setting: communication, team-work and self-reflection. It also includes how healthcare professionals are socialised, which can establish and embed collaborative inter-professional relations that influence the safety and quality of care provided over time.¹⁹ Second, this and other prominent system-level interventions have a long lead time, meaning that the effects may not be felt for a number of years. Respondents were, however, instructed to adopt a 10-year time horizon in their ratings and selections (see Annex 1).

116. There may be several reasons for these results. The contrast suggests that respondents didn't simply insert the seven interventions with the highest impact/cost ratios into their bundles. Rather, the intent behind part 2 was understood - the bundles represent more than the sum of their parts and interplay and dependencies between interventions were considered. The *de novo* assumption adopted in the survey may also have played a part. It would be difficult to implement clinical-level interventions without the underpinning structures and governance. It may be that respondents recognised that implementing the downstream, clinical interventions is more effective when the upstream factors such as standards, reporting and surveillance systems, information infrastructure - and a safety culture - are in place. This is captured in a comment from one of the respondents (emphasis added):

*"Organisational culture change is an overarching challenge which, if successful, will **increase receptiveness to, and adoption of, other more specific, patient safety initiatives**. Therefore, efforts such as professional education and 'nudge' approaches to professional behaviour change, as well as creating an environment where it feels 'safe' for staff and patients alike to raise safety-related concerns, have the potential to **create fertile ground in which the more specific initiatives can grow**. Analysis of the socio-cultural factors influencing the uptake of patient safety interventions and patient safety behaviours - especially those related to professional socialisation - is a potentially fruitful long-term investment".*

A patient safety culture is critical

117. As suggested in the above comment, the differences between part 1 and part 2 results may also be seen through the lens of safety culture. This was among the listed interventions in the survey (**2.9 Building a positive safety culture**). While it featured quite prominently in 'best buys' bundles, it was given a relatively unfavourable impact/cost rating in part 1.

118. As outlined earlier, organisational culture is now accepted as a key determinant and upstream factor in quality improvement. Culture is determined by most things that are done (and not done) across health systems, healthcare organisations and within the clinical microsystem. This relationship is bi-directional, and culture can be seen as 'woven into' most interventions aimed at improving patient safety and eradicating harm, as well as fundamentals including professional education and socialisation and a no-fault medical negligence system (signalling a no-blame culture).

119. Another comment from a survey respondent illustrates this point (emphasis added):

¹⁹ Included in how the intervention is described in the survey is: "...more extensive tuition about broader socio-technical factors (e.g. organisational culture), and teaching of 'soft skills' such as communication and team work. This approach may extend to how trainees and young clinicians are socialised, and how clinical leadership sees its role in shaping the next generation of professionals from a patient safety perspective. It may also include considerations of how trainees are initially selected, based on attributes that extend beyond academic ability..."

*“All interventions at the system, organisational and clinical level should be applied in combination. It is very difficult to separate out the cost impact of each in isolation - most cost impact numbers are not “pure” for each intervention. The aim of a coherent national [...] system is to apply all interventions so that they integrate with each other. Hand Hygiene is a good example - it has to have elements of system, organisational and clinical level to operate effectively. System is the [national] Hospital Associated Infection [activity], while organisation is the application and **cultural change at the hospital level**, clinical level is the clinical engagement and actions.”*

A value based approach to safety targets all levels of the healthcare system

120. The survey results suggest that improving patient safety using limited resources (a value-based approach) should adopt a systems approach that considers contextual requirements and the interplay between macro-, meso- and micro-level interventions in an overarching framework. A hierarchy of initiatives and interventions was identified.

121. First there is a need to ‘prepare the ground’ by implementing the ‘hard’ and ‘soft’ infrastructure and processes across the system. Based on the survey results, priority would be given to initiatives such as:

- patient safety in professional education and training (including socialisation)
- integrated electronic health record systems
- patient-engagement
- national interventions based on specific evidence-based safety themes
- safety standards linked to accreditation and certification
- clinical governance frameworks
- public reporting of safety indicators
- no-fault medical negligence scheme

122. Once these have been instituted, the survey results suggest that the most improvement in patient safety per dollar invested can be achieved by promoting a range of interventions aimed at clinical practice to reduce high-burden adverse events, including:

- VTE prevention strategies
- Infection control interventions (protocols to improve safety of central line catheters, urinary catheters and managing ventilated patients)
- Procedural checklists
- Medication management and reconciliation (across settings)
- Pressure injury prevention protocols
- Patient hydration and nutrition standards

123. This approach is illustrated in Figure 16 using some of the interventions listed above. To promote value-based investment in patient safety, countries may wish to conduct a similar mapping exercise such as the one carried out here, using a survey and nominal group technique or other approach (e.g. Delphi). This can identify specific priority areas based on local context and expertise, and thus identify the optimal mix of components of a national patient safety strategy. This requires high-level leadership from Ministers, and strong engagement of the clinical community, providers, patient groups and academia.

Figure 16. A systems approach to improving safety at national level

124. For the LMIC context, part 2 survey results suggest that clinical- and organisational-level interventions, especially those targeting HAI, are important components of a suite of interventions in combination with more upstream programs such as a safety focus in professional education and training, and safety standards linked to accreditation and certification.

125. While the fundamental strategies apply across all healthcare sectors, the local interventions suggested favoured the hospital setting. This may be because most research has traditionally focused on acute care. More in-depth analysis and follow-up may be warranted, including eliciting survey responses from policy experts in LMIC settings. For instance, a clearer focus on primary and long-term care may be fruitful; or changes in 'best buys' lists if the underlying assumption of the health system's *de novo* position along the patient safety development curve were altered.

126. More broadly, continued examination is required to explore the changing approaches and to address the evidence gaps. The aforementioned 'Safety II' approach incorporates recognition of the local, context-dependent interventions of resilience and high quality whose promotion and spread is complemented by upstream macro-level initiatives. Investigating such approaches as genuine patient safety interventions and measures is needed. More investment in researching the costs and effects of system- and organisational-level initiatives, as well as interventions aimed at reducing harm in the non-acute care sectors, would be of great value to advancing patient safety across the globe. Contextual and implementation factors should be routinely embedded in such investigations to enable transferability of findings.

CONCLUSION

127. A principal objective of health care is to do no harm and to ensure that the benefits of treatment outweigh its deleterious effects. However, **unnecessary harm to patients has been part of health care for as long as medicine has been practiced and continues to occur**. In recent decades a greater research focus has examined and quantified the extent and costs of patient safety failure across countries and healthcare settings. The increasing complexity of health care also means a higher risk of harm requiring greater vigilance, focus and investment to ensure care is as safe and effective as possible. This report (a) estimates the **cost of patient harm**, and (b) outlines a **strategy for policy makers and healthcare leaders to improve patient safety with limited resources**.

128. Safety lapses incur considerable economic costs on healthcare systems and societies. It is estimated that patient harm is the **14th leading cause of the global disease burden**, putting it the same league as tuberculosis and malaria. While the majority of this burden falls on the developing world, in OECD countries the health burden from adverse events can be compared to chronic diseases such as multiple sclerosis and cervical cancer.

129. The financial and resource costs of patient harm are considerable. Most research has focused on the acute setting, where it is estimated that approximately **15% of hospital activity and expenditure** is consumed by the direct sequelae of patient harm. Because many adverse events can be avoided, this represents a waste incurring a considerable opportunity cost. For example, the financial cost from six adverse event types in English hospitals is equivalent to **over 2,000 salaried GPs or over 3,500 hospital nurses each year**.

130. A large proportion of healthcare activity occurs in the **primary, ambulatory and long-term care settings**. Even a modest comparison with levels of harm in acute care therefore implies considerable costs of patient harm in these settings.

131. A lack of comprehensive data means that **these figures are likely to be conservative**. They also fail to account for the broader economic and social costs associated with patient harm. These include physical and psychological **impairment**, pain and suffering, **reduced economic productivity** and a **loss of public trust in health systems** and other social institutions. Estimates of the broader economic losses due to patient harm run into the trillions of dollars each year.

132. Healthcare systems have a range of interventions at their disposal to improve patient safety. While efforts to reduce harm are not free, the **costs of prevention are dwarfed by the costs of failure** (Figures 6 and 7). This reflects the approach in other high-risk industries where cost of failure is routinely assessed against the cost of prevention in a rational, evidence-based manner. To inform such an approach to improving patient safety at national level, a nominal group technique using a **snapshot survey of a panel of experts** was conducted.

133. Survey results suggest that a national patient safety strategy should adopt a systems perspective and that a hierarchy of programs and interventions can be identified. Firstly, investing in fundamental long-term programs such as **professional education, safety standards linked to accreditation** and a **sound information infrastructure** is needed. Organisational-level initiatives such as **Clinical governance, patient-engagement** were also seen as important aspects of a systemic safety strategy. The importance of building an overarching **safety culture** was identified as critical.

134. With these fundamentals in place, the most burdensome adverse events such as **venous thromboembolism, pressure ulcers, infections and medication error** can be targeted through evidence-based interventions at the clinical level. Equal emphasis must be given to primary and long-term care settings, where the knowledge and evidence are still relatively underdeveloped, and where **delayed or incorrect diagnosis** exerts a considerable burden.

135. In low-to-middle-income countries, the pattern of the patient harm burden is slightly different. However, the suggested approach to improvement was similar, with fundamentals such as **professional education** and **safety standards** emphasised, as well as interventions targeting **healthcare-associated infections**.

136. A national safety strategy requires **vision** and **leadership** across all levels of the healthcare systems, beginning with Ministers. The ideal mix of safety programs and initiatives will depend on the local context as well as where countries are in their healthcare improvement journey. A **system-wide mapping exercise** using a method like the one deployed in this report is a useful way to **build consensus** around the key safety issues and solutions, and determine the specific strategies for a **value-based approach** to reducing patient harm at national level.

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ANNEX 1. SNAPSHOT SURVEY DESIGN AND METHOD

137. A list of programs, interventions and initiatives aimed at improving patient safety across entire health systems (i.e. all settings and sectors) was generated using existing peer-reviewed literature as well as reports by established quality improvement agencies and organisations (Shekelle et al 2013, Yu et al 2016, NPS 2016 & 2015, Gluyas & Morrison, 2013, WHO 2015, Wachter 2012, IOM 2012, Lorincz et al 2011, Vincent et al 2010). Drawing on Donabedian's Structure-Process-Outcome model, the interventions were classified into three categories: **System (macro)-level, organisational and institutional (meso)-level, and clinical (micro)-level** initiatives. The 42 interventions included in the survey were presented in Table 10 (more complete descriptions are provided in Table A1 below). The survey comprised two parts.

Part 1 survey

138. Respondents were first asked to rate the impact of each intervention in terms of its benefits (reducing patient harm) and costs (impact on the aggregate healthcare budget) if implemented completely. Both dimensions were rated on a scale of 1-5 in relative terms – i.e. compared to other patient safety interventions - and not against other areas of healthcare or social spending. The perspective adopted was that of the entire healthcare system and budget. Costs and impacts of category 2 and 3 initiatives should be for full implementation in relevant parts of the system, with implementation complexity accounted for in the cost rating and a 10-year time horizon adopted (see Box A1).

139. Given the lack of empirical evidence on this aspect of the listed interventions, respondent experts were asked for their 'best estimate' of the cost, and the impact, of each intervention and that this estimate can be based on empirical evidence (if any exists), experience and observation, and intuition. It was stressed that, in some cases, this may be simply an educated guess.

140. Respondents were also instructed to consider costs and impacts of implementing the interventions *de novo*, and that underlying infrastructure would need to be developed from scratch. However, for several interventions such as Electronic Health Records, and professional education and training, this requirement was qualified (see Table A1 for more detail).

Box A1. Snapshot survey instructions on rating costs and impact of patient safety interventions

COST: Estimated direct financial cost of full implementation across an entire healthcare system. Scale 1-5: 1=low/negligible; 5=high cost relative to other patient safety interventions in all three categories in this survey. The frame of reference is the healthcare budget. Costs predominantly comprise system resources, infrastructure and human capital. The complexity of implementation is a cost - the necessary investment of resources to make the intervention work successfully. Unintended consequences of interventions may also be considered. Please do not consider (a) opportunity cost of foregoing alternative areas of spending, (b) time cost of money (for programs requiring a high level of up-front investment) or (c) any costs borne outside of the healthcare system.

Accounting for incremental effects: Costs will rarely be uniform over time. They may be high during initial implementation, then reduce in the medium- to long-run as the program becomes embedded. In order to account for these incremental effects, adopt a 10-year time horizon for your estimate.

IMPACT: Estimated effectiveness of the interventions measured in terms of reducing patient harm across the system. If it were to be measured, metrics such as the Disability Adjusted Life Year (DALY) could be applied. Typically the impact will be a function of two factors: (a) the extent of the problem that the initiative is trying to address (this will be more relevant for interventions aimed at specific safety topics or clinical specialties), and (b) the effectiveness of the initiative. Unintended consequences of interventions should also be considered. Scale 1-5: 1=low/negligible; 5=high impact.

The baseline is 'doing nothing' (i.e. assume the program is implemented *de novo*), and scale responses against the impact of all other interventions featured in this survey (i.e. the most 'effective' intervention(s) across all three sheets of this survey will receive '5s'; the least effective '1s'). The frame of reference again is the

healthcare system (i.e. the assessment extends to iatrogenic harm, and not any follow-on societal impact such as increased economic productivity, trust etc.).

Accounting for incremental effects: As with costs, the impact of schemes will not be uniform over time (it may ramp up with implementation). Adopt a 10-year time horizon for your estimate to smooth out short term fluctuations at the margin.

141. The experts responding to the survey were international, and working in various epidemiological, political, institutional, and cultural contexts, and in systems where ‘patient safety’ may be at different stages of development. In order to standardise the results, experts were instructed to tailor answers to a hypothetical healthcare system serving a ‘typical’ OECD country distinguished by:

- relative prosperity, with higher than average GDP per capita and standard of living
- universal access to health care financed predominately by third party payers (public, private or a combination)
- comparatively high literacy and numeracy rates among the general population
- internationally comparable standard of clinical education
- sound healthcare and medical infrastructure.

Part 2

142. The second part of the survey asked respondents to consider any synergies between the various available safety interventions. Might combinations favourably affect the cost/impact signatures of individual interventions? Here respondents were invited to 'best buys' bundle of up to seven interventions from across all three categories - not as a league table of interventions applied in isolation, but rather, aiming to identify a set of initiatives, programs and interventions that would work well in concert and reinforce one another. For example, some of the Category 2 and 3 interventions may be more actionable, less costly and have a greater impact if implemented alongside (or within) a Category 1 initiative. Here experts were asked to provide two best buys lists: one for the OECD context as described above, and the other from a developing world perspective of a typical low- to middle-income country (LMIC).

Table A1. Description of patient safety interventions listed in the survey

1. System level interventions
1.1 Safety Standards <i>Health services can be required to meet a set of minimum standards of practice. These Standards are designed minimise clinical risks and enhance patient safety. Adherence is verified through periodic inspection or audit, or linked to an official accreditation or certification scheme (e.g. Joint Commission or Australian National Safety and Quality Health Service Standards). Such schemes are often described as an important 'leitmotif' for patient safety practices, as well as embedding a requisite culture throughout health services and systems. Experts are therefore encouraged to suggest additional initiatives, programs or practices that could work well in concert with a system-wide safety standards scheme. Relevant to all settings and sectors (Acute care; Day surgery facilities; Primary care; Community care; Mental Health; Long-term care)</i>
1.2 Public reporting of patient safety indicators <i>A range of indicators of performance on patient safety exist: adherence to established safety practice and processes (e.g. hand hygiene compliance); outcomes (readmission; infection; mortality rates); patient-reported measures (complaints or patient experience); and compliance with a set of safety standards (see 1.1). Indicators can be publicly reported - in periodic reports or on publicly accessible websites - by geographic region, health service, institution, clinical team or individual clinician. The choice of indicator(s), level of reporting, presentation and 'visibility' are all important variables that will partly depend on context. Experts are encouraged to suggest the optimal composition of such a scheme, or general principles on which it may be adapted to a specific context. Relevant to all settings and sectors.</i>
1.3 Mandatory reporting of specified adverse events

Several healthcare systems mandate the reporting by health services of a specified adverse events (AEs) to a central authority. The types of AEs included in such a scheme can vary, but usually the list comprises serious and preventable incidents. The intention is to encourage health services and providers to focus on preventing these egregious incidents, to develop a better reporting culture, and to encourage mutual learning. Results can be reported publicly (and often are at jurisdictional or health service level) but punitive measures generally do not form part of such a scheme so as to not discourage AE reporting and undermine the fundamental mechanism of such an initiative. Relevant to all settings and sectors.

1.4 Pay-for performance (P4P) schemes and financing for safety

Financial incentives for individual and organisational behaviour that will influence safety and risk of harm are inherent in any healthcare financing system. For example, upward payment adjustment triggered by complications of care is a recognised safety (dis)incentive embedded in DRG-based prospective payment mechanisms (see Eappen et al 2013). Removing these can be viewed as a P4P initiative. Explicit financial incentives can also be applied, based on an agreed set of safety measures or indicators. These can be structural measures, and process (e.g. adherence to hand hygiene protocols) and outcome indicators (adverse event rates). These schemes can be configured in a range of ways. They can be punitive - with financial penalties for poor performance. They can reward good performance in absolute terms (e.g. compared to peer institutions), or based on improvement based on past performance. Design and implementation are powerful determinants of success of these schemes, and the size of the incentive plays an important role. Relevant to all settings and sectors.

1.5 Professional education and training

The explicit inclusion of patient safety in medical training curricula (including nursing and allied health). This can range from basic training on the causes of patient harm and training in human factors science, to more extensive tuition about broader socio-technical factors (e.g. organisational culture), and teaching of 'soft skills' such as communication and team work. This approach may extend to how trainees and young clinicians are socialised, and how clinical leadership sees its role in shaping the next generation of professionals from a patient safety perspective. It may also include considerations of how trainees are initially selected, based on attributes that extend beyond academic ability. Experts are encouraged to comment on any specific aspects of such an approach they consider important or critical. Relevant to all settings and sectors.

1.6 Electronic Health Record (EHR) systems²⁰

An EHR system is longitudinal electronic record of an individual patient that contains or virtually links records and information from multiple sources that can be shared across health care settings. It aims to contain a history of contact with the health care system for individual patients. In short, an EHR system is an integrated information platform that covers all settings and sectors. In theory this offers potential of preventing mis-communication, and improving the access and exchange of information – common root causes of medical error and patient harm. The potential to reduce diagnostic error is particularly germane. Consideration should also be given to the risks regarding (a) privacy and security of sensitive information, and (b) unintended consequences of system redesign that digital transformation inevitably requires. Relevant to all settings and sectors.

1.7 No-fault medical harm compensation scheme

Learning from harm is a critical aspect of improving patient safety. An important threshold issue to enable learning is acknowledging and reporting harm when it occurs. One of the objectives of a no-fault compensation system, where harmed patients and their surrogates are compensated through pooled, centralised insurance as opposed to a tort-based litigation system, is to remove at least one barrier to transparency (other barriers such as professional pride and reputation must be acknowledged and approached through other methods). Experts are encouraged to comment on specific issues regarding context and implementation, especially concerning social norms and values. Relevant to all settings and sectors.

²⁰ EHR systems will rarely be implemented for the sole purpose of improving patient safety, although a reduction in adverse event rates is among the expected benefits an integrated clinical information platform such as the EHR. A well-designed and implemented EHR is a costly socio-technical transformation but, equally, can enable considerable direct and downstream benefits (improvements in the efficiency and effectiveness of clinical care as well as enabling secondary uses such as research and monitoring). For the purpose of this survey, please consider only the proportion of the cost and the impact of implementing an EHR related to patient safety only.

1.8 System-level public engagement and health literacy initiatives

Health literacy and engagement in care are now accepted levers to reduce iatrogenic harm. At system level such initiatives target health literacy and awareness in the general population. This can be (a) broad-based, aiming to increase public awareness of risks of health care, encouraging people to engage in their care and that of their loved ones (e.g. ask questions; double check information and processes) (b) focus on specific topics (e.g. infection control, antimicrobial prescribing, venous thromboembolism (VTE)) that are difficult to implement without a degree of public awareness and engagement, and (c) a combination of the two. Experts are encouraged to provide comments on context and implementation. Relevant to all settings and sectors.

1.9 Theme-based national safety initiatives

Typically this will be a nationally coordinated approach to address specific safety themes that combine top-down (ministerial level) and bottom-up (clinical) engagement. Themes are based on specific type of harm (e.g. infection; pressure injury) or a contributing factor to harm (e.g. clinical handover). The scheme is a co-ordinated approach typically based on an established methodology that includes several factors including measurement, reporting and improvement. Such a scheme may involve multiple health services or providers forming networks for reporting, trialling of interventions and mutual learning. See for example the Dutch National Safety Program (PaSQ 2012). Relevant to all settings and sectors.

1.10 A national agency responsible for patient safety

A legislated, statutory body whose principal functions include improving patient safety across the entire healthcare system may play an important role in steering and governing efforts to reduce patient harm. Relevant to all settings and sectors.

2. Organisational (institutional) level interventions**2A Systemic (several target areas)****2.1 Clinical governance frameworks and systems for patient safety**

This concerns the explicit inclusion of clear roles, responsibilities and accountability, and performance monitoring in the governance of health services. It would typically include formal processes and levers for organisational leadership to monitor, and act on patient safety performance. Relevant to all settings and sectors.

2.2 Clinical incident reporting and management system

Learning from adverse events is a key part of any quality and safety improvement strategy at institutional level. This is based on sound reporting systems that are usually voluntary in nature. Reducing cultural and legislative barriers to do so plays an important role (see no-fault legislation item in Category 1). A reporting systems also ensures that incident reports are reviewed and investigated when necessary to establish the root causes of the incident and to generate learnings. This is then communicated and implemented where relevant throughout the health service (see 2.3). Relevant to all settings and sectors.

2.3 Integrated patient complaint- and incident-reporting

Related to 2.2, patients and surrogates can provide a unique perspective on adverse events, and identify deficiencies that can be missed in reports by providers and health service personnel. Reporting systems can often include patient and carer complaints as well as structured reports of adverse events, such as patient-reported incident measures (PRIMs). This information can be gathered through structured dialogue following harm, such as an 'open disclosure' processes. Relevant to all settings and sectors.

2.4 Monitoring and feedback of patient safety indicators

Feedback of performance indicators to health services, clinical teams and individual providers can be a powerful lever for reflection, learning and improvement, especially if benchmarked against peers. There are a range of indicators available: clinical (e.g. infection rates; avoidable admission to hospital) and patient-reported measures (experience and outcomes including harm). Indicator selection will depend on context, and productive synergies may be achieved through combining with other programs and interventions across all three levels of this survey. Relevant to all settings and sectors.

2.5 Patient-engagement initiatives

At institutional level, patient engagement strategies are aimed at improving condition-specific health literacy among patients, encourage a more proactive engagement in their care and communication with care providers. For example, patients can be provided with material describing, and encouraging them to, ask a set of questions to reduce the risk of specific types of harm. Another is combining evidence-based shared decision making protocols in clinical interactions and in the provision of informed consent to treatment. Impact may be enhanced if measured and fed back to providers and managers as part of an overarching clinical governance and performance reporting system (see above). Relevant to all settings and sectors.

2.6 Clinical communication protocols and training

One of the most common factors underlying adverse events is poor communication - failure to transmit and receive important clinical information. A particularly risk-laden aspect are transitions of care within and between institutions and settings). There is a range of evidence-based interventions targeting transitions of care, but experts are asked to consider all types of protocols or training interventions aimed at improving clinical communication (see below for digital technology). Communication may also include fundamental development of 'soft skills' (e.g. active listening, teamwork). An important factor in sound clinical communication may be patient engagement (see above). Relevant to all settings and sectors.

2.7 Digital technology solutions to improve safety

There are digital technologies that can be applied at health service level. Electronic medical records can improve access to important clinical information within an organisation (e.g. information about specific allergies prior to administration of a drug). This includes interventions such as computerised provider order entry (CPOE) and clinical decision support systems (CDSS). For example, machine-learning computer programs designed to analyse patient information with other data on evidence and outcomes may assist in diagnostics and risk stratification that can complement human clinical decision making (potentially an avenue to address the problem area of diagnostic error). Modern computer algorithms are matching (and sometimes exceeding) human capacity to interpret radiological investigations. As there is a range of applications, and these are heavily dependent to implementation and context, experts are encouraged to provide further comment on this category. Relevant to all settings and sectors.

2.8 Human resources interventions

This category includes interventions such as controlling of clinical staff ratios, occupancy, and shift lengths as well as minimum competencies and clinical staffing mix. Respondents may wish to consider workload, staffing ratios and skill-mix separately and indicate the relative importance of these in the comments. Relevant to all settings and sector.

2.9 Building a positive safety culture

In addition to fostering a culture conducive to safety through policy and practice levers across all three categories, an organisational level initiative aimed at building a positive culture may include training and development, team building and communication strategies, inclusive management structures, staff culture surveys and safety awards. An example is the TeamSTEPPS system (www.ahrq.gov/teamstepps/about-teamstepps/index.html). Relevant to all settings and sectors.

2B Interventions aimed at specific topics or themes

2.10 Infection detection, reporting and surveillance systems

Reporting and monitoring of HAI can inform efforts to inform practice improvement, and identify problem areas and risks. Strongly dependent on diagnostic and laboratory process and infrastructure. Relevant to all settings and sectors.

2.11 Hand hygiene initiatives

A hand hygiene initiative would typically involve an entire organisation. Theoretically the cost of implementation is low, however efforts required to change organisation-wide may increase the complexity and therefore the cost. To heighten the potential for success, perhaps combined with audit, monitoring and reporting (see above). Relevant to all settings and sectors.

2.12 Antimicrobial stewardship

Controlling the spread of antimicrobial resistance is a priority for all healthcare systems around the world. Antimicrobial stewardship is a patient safety concern as well as a global public health issue. This is a complex undertaking that requires organisational leadership at all levels, patient engagement, and measurement and reporting. Failure costs - globally - are potentially catastrophic. Experts are, however, asked to consider only the costs and the impact on patient safety. Relevant to all settings and sectors.

2.13 Blood and blood product management protocols

Managing blood and blood products constitutes considerable clinical risk. Protocols include making clinical decisions, obtaining recipient samples and assessing compatibility with donated products, safely administering the products to the intended recipient, disposing of the product, reporting and investigating any adverse reactions or incidents. Relevant predominantly in the acute care setting.

2.14 Medical equipment sterilisation protocols

Reliable and effective sterilisation of medical equipment is an important part of any infection control strategy. It is an obvious strategy that is likely to be already implemented across the majority of health services in developed and developing countries, nevertheless ongoing vigilance in light of continual and evolving infection risks, and antimicrobial resistance, is required. This strategy is therefore included in the survey. Relevant to all settings and sectors.

3. Clinical-level interventions**3A. Adverse drug events****3.1 Medication management / reconciliation protocols**

This concerns the periodic review and reconciliation of an individual's medications. It may be supported by clinical pharmacists and enhanced by digital technologies such as ordering systems, electronic medical records and EHRs more broadly. However this principally concerns implementing processes and procedures to ensure systematic review and reconciliation. Relevant to all settings and sectors.

3.2 Transcribing error systems and protocols

Adverse drug events can be precipitated by failures in transcribing, labelling or misinterpretation of written orders. Several practices can be grouped under this intervention. 'Tallman lettering' is used to distinguish medication with similar names and avoid administration of the wrong drug. 'Do not use' lists of abbreviations exist in most languages and healthcare systems. Labelling standards for medications prepared and stored in vials are another strategy. Relevant to all settings and sectors.

3.3 Smart infusion pumps and drug administration systems

Intravenous drug administration is vulnerable to errors of administration and monitoring, and carries considerable risk of harm. Smart pumps and administration systems contain software that reduces the risk of error through alerts, dose limits, decision support, and patient identification functions (e.g. barcodes). These innovations can also be applied to high-risk non-IV drug administration. Relevant mainly to the acute care setting.

3B. Healthcare associated infection (HAI)**3.4 Aseptic technique protocols and barrier precautions**

*This concerns formal protocols to ensure a sterile clinical environment can reduce infection risk. Barrier precautions apply to certain patients diagnosed with carrying specified microorganisms (e.g. *C. difficile*) and may include gowns and gloves for all patient contact, use of dedicated or disposable examining equipment, and physical separation or cohorting of patients and staff. Relevant to all settings and sectors.*

3.5 Urinary catheter use and insertion protocols

Catheter-associated urinary tract infections (CAUTI) are frequent and costly in aggregate. Interventions that guide appropriate use, proper insertion and management of catheters may reduce CAUTI rates. May have interaction with resourcing, particularly in terms of staffing. Relevant mainly to the acute care and long term care settings.

3.6 Central venous catheter insertion protocols

This concerns evidence-based protocols or bundles to guide the insertion and management of central venous catheters designed to reduce the incidence of related infection, including sepsis. Bundles are founded on aseptic principles but can also include tools such as ultrasound guided insertion. Relevant mainly in the acute care and long term care setting.

3.7 Ventilator-associated pneumonia minimisation protocols

This concerns evidence-based protocols or bundles to reduce airway infection risk in ventilated patients. Bundles may include practices such as head-of-bed elevation, sedation vacations, oral care with chlorhexidine, and subglottic-suctioning endotracheal tubes. Relevant mainly in the acute care setting.

3C. Perioperative safety**3.8 Procedural / surgical checklists**

Pre- and peri-operative checklists (such as the WHO Surgical Safety Checklist) are designed to reduce surgical adverse event, and complication rates. Checklists are designed to reduce the risk of individual error, and to improve the general communication among the care team. Relevant mainly to acute care but can be adapted to any setting where the procedure or interventions that involves multiple components and/or actors.

3.9 Operating room integration and display technology

Modern operating rooms are crowded with displays and monitors. Segregated display of information can divide the attention of the care team and increase the risk of lapses and undermine coordination. Integration and display technology provide a consolidated, high-level summary of the information available across all devices in theatre. Relevant mainly to acute care settings.

3.10 Peri-operative medication protocols

Evidence-based protocols for administering medications (beta blockers, antimicrobial agents, and anticoagulants) in the peri-operative period can reduce the incidence of as cardiac events, VTE and infections. These protocols can be combined with other interventions such as checklists. Relevant mainly to acute care settings.

3D. Other target areas**3.11 Venous thromboembolism (VTE) prevention protocols**

Health care that requires subsequent periods of inactivity increases the risk of VTE, with potentially disastrous consequences for the patient. VTE protocols include risk assessment, and interventions that may include anticoagulants (administered based protocols that consider bleeding risks), mobilisation, compression stockings and adequate hydration. VTE can manifest latently, and vigilance across care settings is required. This interventions is therefore relevant to all settings and sectors.

3.12 Clinical care standards

These are standardised protocols for diagnoses and conditions where a high level of agreement and evidence for optimal care exists. Examples may include low back pain, acute coronary syndrome, fragility hip fracture, and stroke care. The majority of patients who present with these conditions should receive the standardised intervention(s). Experts may wish to specify which areas of care are best suited to standardisation. Relevant to all settings and sectors.

3.13 Pressure injury (ulcer) prevention protocols

Pressure injuries exert a large morbidity and cost burden across healthcare systems. Protocols aim to reduce incidence using evidence-based interventions and practices. Relevant to the acute care and long term care settings.

3.14 Falls prevention initiatives

Falls are frequent and exert a considerable burden on healthcare systems. Prevention initiatives aim to reduce the incidence of falls through risk assessment and multi-component and interdisciplinary intervention. Relevant to the acute care and long term care settings.

3.15 Acute delirium & cognitive impairment management initiatives

Patients in a state of delirium are at a much greater risk of suffering iatrogenic harm. These interdisciplinary initiatives comprise protocols to improve the detection as well as the management of delirium/cognitive impairment. Relevant to all settings and sectors.

3.16 Response to clinical deterioration

This includes protocols and processes to rapidly identify identifying and manage clinically deteriorating patients in order to avert serious adverse events and considerable harm. may have synergies with staffing and human resource, and digital interventions. Most Relevant in acute care, long term care and in the mental health settings (suicide risk detection and response).

3.17 Patient hydration and nutrition standards

Malnourished and dehydrated patients are at increased risk of suffering an adverse event. Protocols to ensure basic nursing and care standards are met are therefore an important clinical risk management strategy across all patient types and clinical specialties. Relevant in the acute care, long term care and mental health settings.

3.18 Patient identification and procedure matching protocols

Misidentification of patients or anatomy marked for a procedure is still a frequent safety lapse that can potentially catastrophic adverse events (e.g. wrong site surgery). Patient identification protocols reduce this risk. Relevant to all settings and sectors.

ANNEX 2. SURVEY RESULTS

	ACADEMIC EXPERT PANEL (8)					POLICY EXPERT PANEL (15)					ALL RESPONDENTS (23)				
	Avg. Cost	Avg. Impact	S.Dev Cost	S.Dev Impact	Impact/ Cost	Avg. Cost	Avg. Impact	S.Dev Cost	S.Dev Impact	Impact/ Cost	Avg. Cost	Cost S.Dev	Avg. Impact	Impact S.Dev	Impact/ Cost
1.1 Safety Standards linked to accreditation and certification	3.38	3.25	0.92	1.04	0.96	3.21	4.00	1.37	4.07	1.24	3.27	1.20	3.73	1.20	1.14
1.2 Public reporting of patient safety indicators	2.88	2.25	0.83	0.71	0.78	3.21	4.07	1.25	4.15	1.27	3.09	1.11	3.41	1.18	1.10
1.3 Mandatory reporting of specified adverse events	2.75	1.88	1.16	0.83	0.68	2.86	3.29	1.41	3.16	1.15	2.82	1.30	2.77	1.34	0.98
1.4 Pay-for performance schemes for patient safety	2.75	2.75	1.28	1.28	1.00	3.36	3.21	1.39	3.16	0.96	3.14	1.36	3.05	1.36	0.97
1.5 Professional education and training	2.38	3.25	1.41	1.04	1.37	3.29	4.36	0.99	4.38	1.33	2.95	1.21	3.95	1.05	1.34
1.6 Electronic Health Record (EHR) systems	4.50	3.50	0.53	1.31	0.78	4.14	4.43	0.86	4.39	1.07	4.27	0.77	4.09	1.02	0.96
1.7 No-fault medical negligence legislation	2.75	4.00	0.89	0.76	1.45	3.42	4.00	1.16	4.08	1.17	3.15	1.09	4.00	0.92	1.27
1.8 System-level public engagement and health literacy initiatives	3.43	2.14	1.40	0.90	0.63	3.00	3.77	1.29	3.83	1.26	3.15	1.31	3.20	1.40	1.02
1.9 National interventions based on specific safety themes	3.13	3.25	0.64	0.71	1.04	3.43	4.50	0.94	4.54	1.31	3.32	0.84	4.05	0.90	1.22
1.10 A national agency responsible for patient safety	3.50	3.50	1.22	1.05	1.00	2.79	4.07	1.19	4.08	1.46	3.00	1.21	3.90	1.07	1.30
2.1 Clinical governance systems and frameworks related to safety	2.38	3.63	0.74	0.92	1.53	2.71	4.00	0.99	4.00	1.47	2.59	0.91	3.86	0.99	1.49
2.2 Clinical incident reporting and management system	2.75	2.75	0.89	1.04	1.00	3.14	4.14	1.23	4.08	1.32	3.00	1.11	3.64	1.18	1.21
2.3 Integrated patient complaints reporting system	2.43	3.29	0.53	1.25	1.35	2.86	3.64	0.95	3.62	1.28	2.71	0.85	3.52	1.12	1.30
2.4 Monitoring and feedback of patient safety indicators	3.00	3.63	0.93	1.06	1.21	3.29	4.29	1.33	4.23	1.30	3.18	1.18	4.05	0.95	1.27
2.5 Person- and patient-engagement initiatives	2.13	3.00	1.36	1.41	1.41	2.57	3.64	1.02	3.62	1.42	2.41	1.14	3.41	1.26	1.42
2.6 Clinical communication protocols and training	2.75	3.38	0.71	0.92	1.23	2.57	4.21	1.28	4.37	1.64	2.64	1.09	3.91	1.11	1.48
2.7 Digital technology solutions for safety	4.13	3.75	0.64	1.28	0.91	4.36	4.50	0.93	4.54	1.03	4.27	0.83	4.23	0.97	0.99
2.8 Human resources interventions	3.83	3.67	0.75	1.03	0.96	3.08	3.69	1.50	3.82	1.20	3.32	1.34	3.68	1.11	1.11
2.9 Building a positive safety culture	2.86	3.14	1.77	1.57	1.10	3.07	4.50	1.14	4.46	1.47	3.00	1.34	4.05	1.16	1.35
2.10 Infection detection, reporting and surveillance systems	3.13	3.88	0.83	0.83	1.24	3.14	4.00	1.17	4.00	1.27	3.14	1.04	3.95	0.84	1.26
2.11 Hand hygiene initiatives	2.75	3.38	1.04	1.30	1.23	2.36	3.79	1.01	3.77	1.61	2.50	1.01	3.64	1.14	1.45
2.12 Antimicrobial stewardship	3.00	3.75	1.07	0.71	1.25	2.93	4.00	1.33	4.00	1.37	2.95	1.21	3.91	0.92	1.32
2.13 Blood and blood management protocols	2.63	3.25	1.06	0.89	1.24	2.31	3.77	1.18	3.91	1.63	2.43	1.12	3.57	1.25	1.47
2.14 Medical equipment sterilisation protocols	2.63	3.75	0.74	0.71	1.43	2.64	3.79	1.01	3.84	1.43	2.64	0.90	3.77	1.11	1.43
3.1 Medication management / reconciliation	2.25	3.50	0.89	0.76	1.56	3.43	4.29	1.16	4.31	1.25	3.00	1.20	4.00	0.82	1.33
3.2 Transcribing error minimisation protocols	2.25	2.88	1.04	0.64	1.28	2.79	3.79	1.19	3.77	1.36	2.59	1.14	3.45	1.10	1.33
3.3 Smart infusion pumps and drug administration systems	2.75	2.88	1.16	0.83	1.05	3.36	3.79	1.15	3.84	1.13	3.14	1.17	3.45	1.18	1.10
3.4 Aseptic technique protocols and barrier precautions	3.00	3.63	1.07	0.74	1.21	2.64	4.14	1.01	4.15	1.57	2.77	1.02	3.95	1.00	1.43
3.5 Urinary catheter use and insertion protocols	1.75	3.13	0.71	0.99	1.79	2.14	3.79	1.03	3.91	1.77	2.00	0.93	3.55	1.10	1.77

	ACADEMIC EXPERT PANEL (8)					POLICY EXPERT PANEL (15)					ALL RESPONDENTS (23)				
	Avg. Cost	Avg. Impact	S.Dev Cost	S.Dev Impact	Impact/ Cost	Avg. Cost	Avg. Impact	S.Dev Cost	S.Dev Impact	Impact/ Cost	Avg. Cost	Cost S.Dev	Avg. Impact	Impact S.Dev	Impact/ Cost
3.6 Central line catheter insertion protocols	1.88	3.50	0.64	0.93	1.87	2.21	4.00	1.05	4.07	1.81	2.09	0.92	3.82	1.01	1.83
3.7 Ventilator-associated pneumonia minimisation protocols	1.75	3.13	0.71	1.13	1.79	2.21	4.00	1.05	4.07	1.81	2.05	0.95	3.68	1.13	1.80
3.8 Procedural / surgical checklists	2.00	3.38	0.93	0.74	1.69	2.21	3.86	1.19	3.85	1.74	2.14	1.08	3.68	0.84	1.72
3.9 Operating room integration and display checklists	3.00	2.75	0.93	0.71	0.92	3.42	3.42	0.79	3.45	1.00	3.25	0.85	3.15	0.99	0.97
3.10 Peri-operative medication protocols	2.13	3.13	0.99	0.83	1.47	2.00	3.79	0.68	3.84	1.89	2.05	0.79	3.55	0.91	1.73
3.11 VTE prevention protocols	1.88	3.13	0.35	0.83	1.67	1.93	3.86	0.62	3.92	2.00	1.91	0.53	3.59	1.01	1.88
3.12 Clinical care standards	2.63	3.00	1.06	0.76	1.14	2.57	3.86	1.16	3.99	1.50	2.59	1.10	3.55	1.06	1.37
3.13 Pressure injury (ulcer) prevention protocols	2.38	3.63	0.74	0.92	1.53	2.14	3.79	0.86	3.84	1.77	2.23	0.81	3.73	0.88	1.67
3.14 Falls prevention protocols	2.50	2.50	1.07	1.20	1.00	2.50	3.64	0.85	3.69	1.46	2.50	0.91	3.23	1.27	1.29
3.15 Acute delirium & cognitive impairment management programs	2.75	3.38	0.89	1.19	1.23	2.21	3.43	0.89	3.46	1.55	2.41	0.91	3.41	1.10	1.42
3.16 Response to clinical deterioration	2.86	4.00	0.69	1.41	1.40	2.21	3.71	0.89	3.77	1.68	2.43	0.87	3.81	1.08	1.57
3.17 Patient hydration and nutrition standards	2.00	3.00	0.76	1.20	1.50	2.14	3.57	2.15	3.68	1.67	2.09	0.75	3.36	1.05	1.61
3.18 Patient identification and procedure matching protocols	2.00	2.75	0.76	0.71	1.38	2.14	3.93	0.77	3.99	1.83	2.09	0.75	3.50	1.10	1.67
Averages	2.70	3.22	0.92	0.98	1.24	2.81	3.91	1.11	3.95	1.44	2.77	1.03	3.66	1.08	1.37

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