THE ECONOMICS OF PATIENT SAFETY IN PRIMARY AND AMBULATORY CARE

Flying blind

OECD

BETTER POLICIES FOR BETTER LIVES

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Acknowledgements

Key messages

1. **Primary and ambulatory care is the foundation and the key to high-performing, sustainable and resilient health systems.** Most health activity takes place in this setting: over <u>8 billion encounters each year</u> in OECD countries alone. Ensuring safety in primary and ambulatory care is a fundamental policy priority in all countries. But harm continues to happen, incurring significant burdens and costs on societies, and diminishing the benefit of having access to care. The resources needed to improve safety are dwarfed by these costs. Investing in strategies to ensure safety <u>provides a good return and generates value</u> from scarce health resources. Committing to and improving safety can also result in a political dividend.

2. **Safety lapses in primary and ambulatory care are common; many of them can be avoided.** Estimates show that as many as <u>20%-25% of the general population</u> <u>experience harm in this setting</u> in developed and developing countries respectively. Some estimates say that as many as <u>4 out of 10 patients are harmed</u> in the primary/ambulatory setting. Most harmful are errors related to diagnosis and prescription and the use of medicines. Up to 80% of harm in primary and ambulatory settings can be avoided.

3. **Half of the global disease burden arising from patient harm originates in primary and ambulatory care.** While harm sustained in this setting is less visible than that acquired in hospital given the sheer volume of care delivered in primary and ambulatory care, the aggregate amount of harm should not be ignored. In developed countries, the burden of this harm can be compared to <u>some types of neoplasms (e.g. malignant melanoma or thyroid cancer)</u>. In developing countries, it is comparable to <u>typhoid fever</u>. Given that the health needs of populations are becoming more complex, the occurrence and the consequences of harm can be expected to increase unless concrete action is taken.

4. **The financial and economic costs of safety lapses are high.** Available evidence estimates the direct costs of harm – the additional tests, treatments and health care - in the primary and ambulatory setting to be around <u>2.5% of total health expenditure</u> - although this likely underestimates the true extent. Harm in primary and ambulatory care often results in hospitalisations. Each year these may account over <u>6% of hospital bed days</u> and more than <u>7 million admissions</u> in OECD countries - this is in addition to the 15% of acute care activity caused by harm occurring in hospitals alone. The broader, flow-on societal costs of harm in primary and ambulatory care are high. Estimates suggest that in developed countries this can approach <u>3% of GDP</u>. Without corrective action <u>this problem is likely to grow</u> in line with the increased prominence and responsibility of the primary and ambulatory care sector in addressing population health needs.

5. **The fragmentation of the sector and lack of adequate information must be overcome.** Fragmented processes, governance and information systems are the key challenges to improving safety in primary and ambulatory care. <u>Digitalisation holds great potential</u>. Implementing an integrated information infrastructure must be a priorities, so as to (a) <u>capture occurrence of harm</u>, (b) <u>enable learning from safety lapses</u>, and (c) <u>ensure flow of clinical information among providers and their patients across settings</u>. Developed countries as well as emerging economies should implement <u>interoperable electronic health record (EHR) systems</u> to facilitate this. Such systems must ensure <u>privacy and data security</u>.

6. **Stronger governance and oversight is required.** Unified and nationally consistent <u>safety standards,</u>

linked to accreditation of providers, facilities and organisations, are needed across the primary and ambulatory care sector. These should align with broader health system governance and management. More must be done to encourage and incentivise care co-ordination and collaboration between providers, integrate care and clinical communication across settings and engage patients. All of this must be underpinned by investment in human capital, especially education and training of the health workforce.

7. **Greater patient involvement is the key to safer primary and ambulatory care.** The elements of safety in primary and ambulatory care are illustrated in the figure below. At the apex are patients, who must be engaged and empowered as active participants in their care *and* in systematic reporting on safety lapses including 'near misses'. Practical interventions in developed countries include shared decision making (SDM) protocols, shared clinical records and patient access to their EHR. In developing countries, health literacy programmes are also useful. Engaging patients is not expensive and represents a good value. If done well it can reduce the burden of harm by up to 15%, saving billions of dollars each year – a very good return on investment.

8. **Leadership is needed at all levels of the health system**. Regardless of a country's stage of development, none of the elements described, and summarised in the chart below, are possible without a buoyant, positive safety culture focused on collective improvement and teamwork. This can only be achieved with leadership at all levels of the health system. Political leadership is essential.

Source: The authors

1. Introduction

1.   The systems delivering health care in the modern era are complex, adaptive and dynamic. Meanwhile the populations and individual patients these systems serve are becoming clinically more challenging. In previous centuries, the key challenges for health care were managing injury and combatting infectious diseases. By and large, the challenge was conquered through advances in technology, practice and prevention.[1]

2.   For some time now the growing burden of chronic, non-communicable disease has been the preeminent problem in developed countries, and a public health concern. As developing countries cross the epidemiological transition they now face the same challenges. While preventing these diseases through social and public health interventions must be a major focus, it is inevitable that more people will suffer from these types of health problems. Compounding the challenge is the fact that they often occur in combination, adding to clinical complexity.

3.   Technology and expertise exist to manage these conditions and limit their health impact over time, ensuring that people and populations afflicted can remain active and independent. These health problems are most effectively and efficiently detected and managed in primary and ambulatory care (see Box 1.1 for a definition). This setting is now the most common place for people to receive health care. Over 8 billion consultations with the primary and ambulatory care providers occurred in OECD countries in 2015, an average of 6.9 consultations per capita (OECD, 2017). The activity and responsibility of care in this setting can only be expected to increase due to demographic and epidemiological change. Many health systems are also deliberately transferring healthcare activity out of the hospital and sub-acute settings in order to provide services closer to where people reside and manage health expenditure.[2]

4.   A strong primary and ambulatory care sector is therefore of paramount importance in both developing and developed countries. Ensuring care provided in this setting is safe, effective and focused on the needs of the patient must be a top priority for policy makers and practitioners. Safe primary and ambulatory care improves the health and wellbeing of individuals, communities and societies. It also has financial and economic benefits. The reverse, of course, is also true. Unsafe primary and ambulatory care results in greater morbidity, higher healthcare usage and economic costs.

5.   The 2017 OECD report on the economics of patient safety examined the cost of safety lapses in health care, and the most effective and efficient way to minimise these across entire health systems (Slawomirski, Auraaen & Klazinga, 2017). The key findings were:

- Patient harm caused by potentially preventable safety lapses during the provision of health care exerts a considerable health burden across the globe. The extent of this burden can be compared to diseases such as malaria and tuberculosis.

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[1] Although excessive use of antimicrobial agents has created a new threat: resistant organisms.

[2] For example Denmark has over several years reduced its hospital activity, transferring the responsibility to other settings that include primary / ambulatory care (OECD & European Observatory on Health Systems and Policies, 2017)

- The direct financial cost of harm on health systems and on societies is considerable. In developed countries, 15% of hospital expenditure goes towards the additional tests and interventions needed to treat the direct effects of harm.
- The broader economic impact of this harm, as it ripples through societies and economies – through reduced productivity, lost income and tax revenues - is estimated at over a trillions dollars per annum in the United States.
- A range of system-, organisational- and clinical-level strategies and interventions exist to significantly improve safety at a fraction of the cost of harm.

Box 1.1. Defining primary and ambulatory care

Given the various ways in which ambulatory/primary care is defined and classified in different health systems, this report uses a broad definition and scope that includes: **non-acute health services delivered in the community setting by a range of providers including general practitioners, nurses, allied health professionals (e.g. pharmacists, dieticians). The services are principally aimed at longitudinally managing the health of individuals and populations.**

This includes:
- First contact care where patients need not be referred by a 'gate-keeping' provider
- Provided in an ambulatory, non-institutional setting close to (or in) people's homes

It excludes:
- Acute hospital care including emergency care
- Discrete procedures/interventions provided in an outpatient setting; e.g. diagnostic interventions (colonoscopy); day surgery (cataract removal, knee arthroscopy); other interventions (e.g. dialysis, home dialysis, home birth).
- Acute or sub-acute care provided in the home environment ('hospital in the home')
- Sustained non-acute care provided in care facilities (e.g. long term care; residential care)
- Population focused activities provided by public health agencies

Below are some published definitions that align with the scope of this report.

- **Starfield (1994): "**… [this setting] provides entry into the system for all new needs and problems, provides person-focused (not disease oriented) care over time, provides for all but very uncommon or unusual conditions, and coordinates or integrates care provided elsewhere by others".
- **IOM (1994):** "… healthcare services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."
- **Kringos et al. (2014): "**… the first level of professional care …. Where the majority of the population's curative and preventive health needs are satisfied."

- **EC Expert panel on effective ways of investing in health (2014): "**… integrated person-centred, comprehensive health and community services provided by a team of professionals accountable for addressing a large majority of personal health needs. These services are delivered in a sustained partnership with patients and informal caregivers, in the context of family and community, and play a central role in the overall coordination and continuity of people's care."

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6.   However, the majority of evidence focuses on acute care. While some literature on the occurrence, costs and amenability of harm in the primary and ambulatory setting was identified, it was nowhere near as rich and detailed as the examination of this subject in hospitals – especially economic analyses. Indeed a previous comprehensive review concluded that *"very little is known about patient*

safety in the ambulatory setting, and next to nothing about how to improve it. Studies of ambulatory patient safety have too often been small, used differing and sometimes conflicting taxonomies and categories, and derived from work in unique practice settings that might not provide generalizable results. Studies of interventions to improve the safety of ambulatory care have been extremely rare." (Lorincz et al 2011).

1.1. This report makes the economic case for safety in the primary and ambulatory care sector

7.   The aim of this report, which can be considered a follow-up to the 2017 OECD report, is to examine the economics of patient safety specifically in primary and ambulatory care given (a) the growing importance of this setting in maintaining population health against the background of health and financial challenges, and (b) its critical role in ensuring the sustainability and resilience of the broader health system.

8.   Economics in this context concerns the most effective and efficient allocation of scarce resources to meet a specified goal - to improve patient safety and to reduce harm (for a discussion on harm, see Section 1.2). Resources are those dedicated to the provision of health care and the operation of the system through which it is organised.

9.   The fundamental case for improving patient safety is moral – minimising the harm to people, families, and the community is a fundamental responsibility of healthcare providers, managers, financiers and policy makers that govern the system. But, as detailed in the 2017 report and outlined above, a very strong economic case can also be made. Patient harm exerts a considerable and unnecessary drain on scarce health resources and on society's resources more broadly. This has a negative impact on social welfare.

10.   Improving patient safety in established health systems is of course not free, at least in the short run. Strategies to reduce harm can be seen as a cost or as an investment that creates value through reducing the costs of failure. As other high risk industries and some forward-thinking healthcare organisations have discovered, the marginal costs of systematic reduction of harm are small compared to the costs of failure – even if only the direct costs of failure on the health system - the additional tests, medical treatment and care required as a result of lapses in safety - are considered.[3]

11.   Section 1.2 of this introductory chapter discusses what patient safety and patient harm mean when applied to primary and ambulatory care. This reflection is necessary because safety and harm are traditionally approached in the context of acute care. Owing to the fundamental differences between acute services and primary/ambulatory care, the definitions and concepts need to be refined for the purpose here.

12.   Chapter 2 examines the occurrence, frequency and severity of safety lapses in primary and ambulatory care. It explores different avenues for capturing patient harm in primary and ambulatory care settings, shedding light on shortcomings of methodologies, knowledge gaps and the main causes of harm.

13.   Chapter 3 discusses the cost of patient harm in primary and ambulatory care in terms of disease burden, the direct cost of safety lapses through the additional resources required to ameliorate

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[3] It is not suggested that harm can be eliminated altogether in a high-risk industry like health care. At the margin, the cost of preventing every last case of harm would approach, and eventually exceed, the costs of failure, principally because - in a system with finite resources - beneficial activity would need to be diverted, or stopped altogether, in order to remove all risk (see section 1.2).

and manage the sequelae of harm, and the broader (indirect) economic and social impact of safety lapses in this setting. The latter is illustrated drawing on a small number of studies. However, a comprehensive macro-economic analysis of the downstream effects of harm is not undertaken for reasons outlined in the previous report (Slawomirski, Auraaen & Klazinga 2017).

14.   Chapter 4 describes strategies, interventions and examples to improve safety in primary/ambulatory in a cost-effectively manner and with a view towards maximising value for money. It also discusses the challenges and enablers of success, and provides some examples. The final chapter presents the conclusions and policy recommendations that can be drawn from the findings of the report.

15.   The findings and recommendations here are based on a literature scan and a snapshot survey of experts. Both focused specifically on primary/ambulatory care. Details regarding the survey method, questions and respondents are provided in Annex 1. As safe primary and ambulatory care is critically important in *all* countries strengthened through policies –striving for – universal access to health care, this report considers where possible low- to middle-income countries (LMICs) and upper-middle and high-income countries (henceforth 'developed countries' or simply HICs).[4] In a sense, less developed nations have the advantage of building the necessary structures and institutions into their health systems as these are built and established. Developed nations, on the other hand, have the difficult task of retrofitting safety into fully formed systems (WHO et al 2018).

16.   The perspective adopted is again that of national health systems. While the findings and recommendations will be of interest to healthcare providers and organisations, the principal audience of this report are policy makers looking to improve patient safety in primary/ambulatory care in a context of constrained resources.

1.2. Safety in primary and ambulatory care reflects the unique challenges of this setting

17.   The key concepts and terms used in this report (safety, harm, adverse event, error and preventability) are discussed in Box 1.2. They are similar to the terminology in the previous report but are modified to the characteristics, priorities and specific risks of the primary and ambulatory setting.

18.   In the hospital setting, the majority of treatments, procedures and interventions are delivered during episodes of care clearly delineated by admission and discharge. In the majority of health systems, patients cease to be the responsibility of the hospital or healthcare facility discharge, particularly for problems that were not the principal diagnosis on admission.[5]

19.   The primary and ambulatory setting is different. It represents the entry point to health care in most countries and an important point of contact between the population and health care and covers a very broad range of services including disease prevention, screening, population health, chronic disease management, rehabilitation and end-of-life care. More importantly primary and ambulatory care is sustained and longitudinal. Contact between the patient and health services may be sporadic, infrequent and (often) brief. But people remain in the 'care' of the primary/ambulatory system for prolonged periods of time – sometimes their entire life course.

20.   Another distinguishing feature is that this system comprises a complex network of providers, organisations and other actors: practice and community nurses, general practitioners (GPs) or family physicians, community-based specialists, diagnostic services (radiology or pathology), allied health practitioners, optometrists, social workers, and community pharmacists who, it must be noted, are

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[4] See Annex 1 for definitions of these categories.

[5] Although ensuring the necessary information is transmitted to the patient and their follow-up care providers at discharge is the hospital's responsibility.

often the first, and most frequent, source of medical advice for many. The system is often fragmented. In many cases these actors will operate under different governance and institutional arrangements.

Box 1.2. Key concepts and definitions

The subject of this report centres on the concept of **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 medical care, which includes treatment, intervention, procedure and diagnostic tests, as well as the continued monitoring of health, and signs and symptoms of disease over time. The latter distinguishes the primary and ambulatory setting. The term patient also encompasses the person's family, carer(s) or other surrogates who would be involved in, and affected by the 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 medical treatment indicated by the evidence in combination with the patient's signs, symptoms. Patient harm can be caused by a specific incident (**adverse event**) or a cascade of events (miscommunications, delays, errors or omissions) which are individually innocuous but collectively result in harm. Common adverse events relevant to the primary and ambulatory care setting discussed in this report include an **incorrect or delayed diagnosis** (diagnostic error), a **delay in indicated/necessary treatment** and **adverse drug events** (harmful medication errors)

An **error** is the failure to carry out a planned action as intended or application of an incorrect plan to achieve an through either doing the wrong thing (commission) or failing to do the right thing (omission) IOM 1999. Error can occur at the planning, monitoring or execution phase of health care.

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).

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.

But 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.

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21.   The complexity of primary and ambulatory care systems is the first factor that raises the risk of harm. Safety lapses can be attributable to one incident at a specific point in time: a misdiagnosis mislabelled diagnostic report, or drug dosing error. The second factor is the longitudinal nature of care in this setting, which means that harm can be difficult to attribute to a singular event. Rather it can develop over time. For example, a set of miscommunications or failures in information transfer, lack of recommended follow-up. Even diagnosis in this setting is rarely a discrete occurrence but a process that

evolves over time and is a team-based activity involving the patient and a varied set of service providers (National Academies, 2015).[6]

22.   Safety in primary and ambulatory care will therefore not only concern single adverse events but also prolonged delays, omissions of care, failures to monitor and respond to changed health status, and – by extension - failure to ensure access to services as this can result in delayed identification and management of disease. Patients and the community would consider this to be a type of harm and an avoidable safety lapse.

23.   As harm in this setting can evolve over months, years even decades, mitigation and avoidance requires a system-wide perspective. Access to care at population level will - in the majority cases - be outside of the control of individual practitioners and providers. Extending the scope of harm and of safety in this way is <u>not intended to place a greater burden of responsibility on individual practitioners</u>. It is, however, necessary in order to conceptualise and define these terms from the perspective of patients, communities and the health system – all of whom will feel the impacts and costs of sustained safety lapses in this care setting.

24.   It is also impractical and unsustainable for ambulatory/primary care to remove all possible health risk for all patients.[7] In terms of discrete events, no medical intervention is completely devoid of risk. Many medical interventions do, in fact, entail known injurious effects such as discomfort. 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

25.   And in terms of sustained omissions and 'longitudinal harm', care in the primary and ambulatory setting, risk is intimately connected to leading a fulfilling life. It therefore can never be eliminated fully while also adhering to the principles of individual autonomy and agency (most people do not wish to spend every waking moment managing their health and/or their disease). This is another reason to adopt a systems approach and limit the expectation on, and responsibility of, individual practitioners for all harm.

26.   The most appropriate definition of patient safety in this setting is therefore **<u>managing risk to maximise benefit and minimise harm over time</u>** over the course of a patient's life and disease progression, as proposed by Vincent and Amalberti (2016), with specific consideration given to:

- Patient autonomy and preferences
- Provider autonomy
- Scarcity of health resources
- Preferences of the communities served by the health system.

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[6] The multi-provider, team environment is especially germane in patients with multiple health problems and complex needs – the very patients at greatest risk of safety lapse and harm. This is addressed later in the report.

[7] See Footnote 3

2. Measuring patient safety in primary and ambulatory care

27.   Several different methods for measuring patient harm exist. But a "gold standard" method and common approach for measuring it, including agreement on the most appropriate unit of measurement - is notably absent in primary and ambulatory care. This compromises comparability of estimates and the accuracy of frequency, preventability and severity estimates. Consistent and comparable information is lacking and shrouded. For this reason, primary/ambulatory can be compared to 'flying blind'.

28.   Keeping in mind these limitations, this chapter discusses measuring the occurrence of patient harm in primary and ambulatory care settings based on findings in the literature and responses from an OECD survey of patient safety and policy experts referred to in this document as 2018 Patient Safety Snapshot Survey. It describes the main causes of harm – adverse drug events (ADEs), diagnostic errors, administrative errors and delays in treatment - the preventability of harm and patient-based risk factors associated with safety lapses.

2.1. Methods for capturing the occurrence of patient harm in primary and ambulatory care remain underdeveloped

29.   Primary and ambulatory care is at the heart of health care provision, but most research on patient harm to date has focused on hospitals. The lack of robust evidence of the patient safety measurement in primary and ambulatory care settings can partly be explained by the fragmented nature of this setting described in the introduction. In fact, survey responses suggest that the fragmented nature of primary and ambulatory care 'systems' , and lack of overall system governance, are the most important barrier to implementing safety measurement and interventions (see Chapter 4).

30.   A major consequence of this fragmentation is the absence of an integrated information infrastructure.[8] Many providers do not have electronic health records or use different software and recording systems with limited interoperability. This means information can rarely be linked. These technical barriers may prohibit capturing accurately the full picture of the frequency and magnitude of patient harm occurring along the patient pathway. This may go some way to explain why patient safety measuring and monitoring in primary care settings are the exception rather than the rule, but other reasons are also likely.

31.   Underdeveloped detection methods have been impeding the progress of understanding and preventing safety lapses in primary care. The gold-mine of information that exists in electronic health care records and administrative databases could - with the right tools such as 'flags' identify cases of harm and used for gaining insight into the origin of errors (Singh et al 2012). Routine audits of medical records, adapting the global trigger tool method[9] to the

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[8] Indeed it can also be seen as the cause, and can be expressed as a lack of integration of disparate information units *into* the broader health system infrastructure.

characteristics for the primary/ambulatory care setting can contribute to broadening the understanding of patient harm in this care setting.

32.　　　　Research also shows that the choice of applied methodology may impact both the occurrence rates as well as the type of harm detected. Wetzels et al (2008) applied five contrasting methods to identify patient harm in this setting: (i) **physician-reported harm**, (ii) **pharmacist reported harm**, (iii) **patients' experiences of harm**, (iv) **assessing a random sample of medical records**, and (v) **assessment of all deceased patients**. Almost no overlap of the type of harm was identified. Notably, the patient survey accounted for the highest number of events and the pharmacist reports for the lowest number. Little overlap in detected harm between the methods was observed.
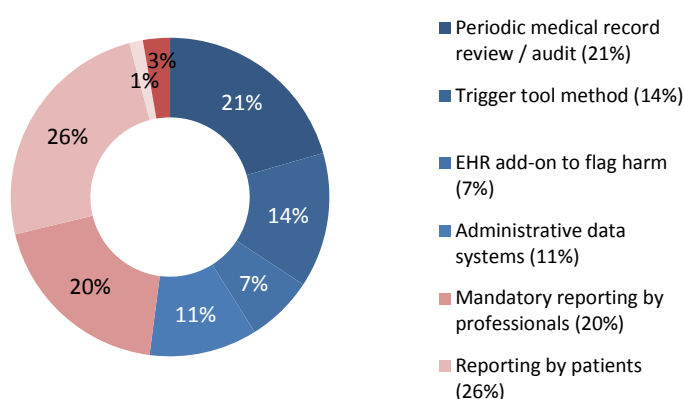
33.　　　　To complement physician-entered data, patient safety research has increasingly discussed the importance of patients' perceptions and their role in ensuring their own safety (Lang et al, 2016). Patients are the most continuous aspect in an often fragmented primary care process. Therefore, patients' point of view can contribute to measuring and learning from safety lapses.

2.1.1. Survey respondents advocate a mixed approach to measurement

34.　　　　 The difficulties in measuring patient harm and the complexity of the primary care setting make it desirable that a combination of methods is applied to map the landscape of patient safety. Tam et al (2008), promote choosing a complementary approach by using an effective incident reporting system from patients and providers as well as regular chart reviews for detection and monitoring of medication misadventures in general practice.

35.　　　　The patient safety experts surveyed in 2018 also favour a mixed approach to measurement. Respondents were asked about the most suitable ways to systematically measure the incidence, nature and impact of patient harm in primary and ambulatory care. Responses for developed countries are presented in (Figure 2.1). Measurement as a foundation of improving safety is discussed further in Chapter 4.

Figure 2.1. Complementary measuring methods favoured by survey respondents (developed countries)

- Periodic medical record review / audit (21%)
- Trigger tool method (14%)
- EHR add-on to flag harm (7%)
- Administrative data systems (11%)
- Mandatory reporting by professionals (20%)
- Reporting by patients (26%)

Note: Based on responses to the question: *What should be done to systematically measure the incidence, nature and impact of patient harm across the ambulatory/primary sector? Please choose three from the options provided. (73 selections)*
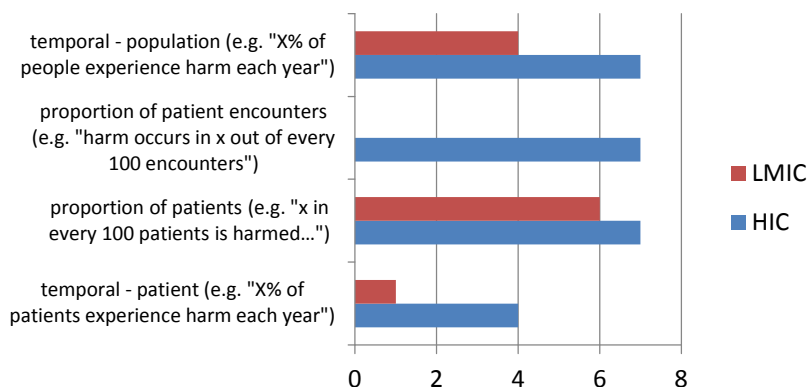*Source*: OECD Patient Safety Snapshot survey, 2018 (n=26)

2.2. Estimating and comparing the occurrence of patient harm is challenging

36.   The heterogeneity of studies and measuring methodologies makes it difficult to provide a point estimate of the occurrence of patient harm in primary and ambulatory care settings. Few comparable global estimates can be gleaned from the literature. A systematic review found that studies reported **between 1 and 24 patient 'safety incidents' per 100 consultations.** (Panesar et al 2016). O'Beirne et al (2011) identified 1.4 reports of patient harm incidents per month across 19 family practices in Australia. Disagreement exists even on the best metric to capture occurrence.

37.   Similar issues are reflected in the responses to the snapshot survey. Responses did not converge on any one specific unit of measurement for capturing patient harm in primary and ambulatory care. For developed countries, three of the four suggested units (temporal – population; proportion of painted encounters; proportion of patients) attracted identical response numbers. For LMICs the preferred unit of measurement is proportion of patients (Figure 2.2).

Figure 2.2. Lack of consensus among experts among most appropriate unit of measurement

Note: Response to the question: *In your opinion what is the most appropriate way to quantify the incidence of harm in ambulatory/primary care?*
Source: OECD Patient Safety Snapshot Survey, 2018 (n=26)

38.   When asked to estimate the occurrence of patient harm using their preferred unit of measurement, responses varied greatly. In developed countries, the reported proportion of patients experiencing harm range from 1-35% or in 0.1-10% of encounters with health services. Low-middle income countries attracted fewer estimates, which were also scattered but – notably – higher than the estimated HIC figures.

39.   The literature is richer when it comes to concrete causes of harm (adverse event types), although the problems around comparability remain. Scrutinising the published literature on cause-specific harm in patient and ambulatory care settings, Panesar et al (2016) found ADEs and diagnostic errors as the most common causes of harm, occurring in 1-90% of all prescriptions issued and 4-45% of all patient safety-related incidents respectively. Also the respondents to the snapshot survey identified the same main causes of harm (Figure 2.3), in addition to flagging communication failure as the most common 'root' cause.

Figure 2.3. Adverse drug events and wrong diagnoses are the most common causes of patient harm in primary and ambulatory care settings
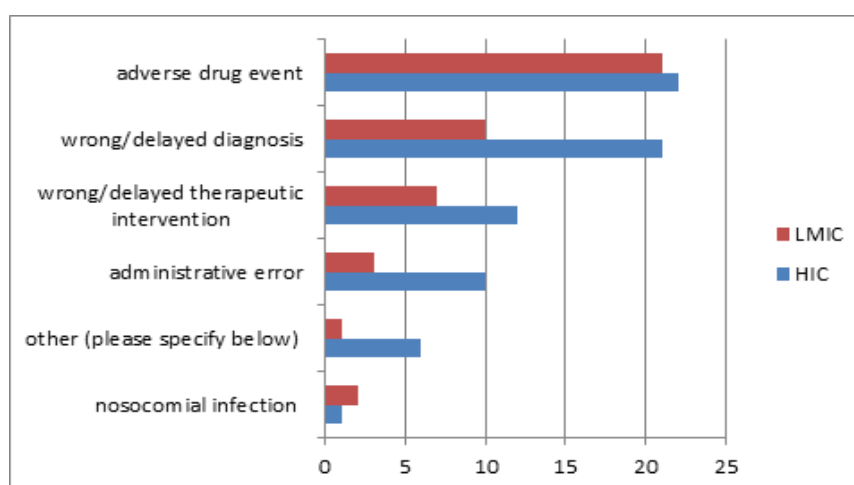
Note: Responses to the question: *What are the most common causes of patient harm in ambulatory/primary care?*
Source: OECD Patient Safety Snapshot survey, 2018 (n=26).

Box 2.1. Evidence on patient safety in primary care settings in LMICs is lacking

Limited evidence is available on the nature, frequency and cause of patient harm in primary and ambulatory care settings in low-middle income countries. The complex nature of both primary care settings as well as capturing patient harm in these settings may be explaining the knowledge gap. Some studies on medication and diagnostic errors have been identified. In Indonesia, a study identified ADEs in 226 out of 229 prescriptions in the outpatient setting, out of which 99.12% was due to prescription errors (incomplete prescription error the most common), 3.66% dispensing errors and 3.02% pharmaceutical errors (Perwitasari et al, 2010).

A cross-sectional study of patient harm across 12 primary care clinics in Malaysia reported a prevalence of diagnostic errors at 3.6% (95% CI 2.0 to 5.5), but as many as 61.9% of medical records had inconclusive diagnoses suggesting an underestimation of the prevalence (Khoo et al, 2012).

Although it may not be representative of the situation in all low-middle income countries, diagnostic errors are often indicative of health care systems' vulnerabilities. Diagnosis poses even greater challenges as the process is further complicated by limited access to care and diagnostic resources, a paucity of qualified primary care providers and sometimes of specialists, and pre-electronic recording-keeping systems. These factors likely suggest a higher rate of diagnostic errors in such settings compared with high-income countries, although evidence for this is scarce (Singh et al, 2017).

2.2.1. Most harmful events occurring in primary and ambulatory care are preventable

40.   The literature suggest that 23.6% - 85% of all harmful events occurring in primary and ambulatory care are preventable (O'Beirne et al, 2011; Michel et al 2017). Survey responses align with these findings. On average, results suggest that about 50% of harm in primary and ambulatory care is considered preventable in high-income countries, but estimates varied from over 80% to less than 20%. In low-middle-income countries the average estimated figure is slightly higher (60%). It should again be noted that preventability is not static and changes with new knowledge and innovation.

41.   Despite wide-ranging estimates, findings strongly suggest that there is a considerable potential for saving and liberating resources if patient harm is avoided. It also highlights that having the right safety learning systems in place could contribute to the broadening of knowledge on the nature and epidemiology of patient harm which further could also improve the quality of care provided to patients in ambulatory care settings.

2.2.2. The severity and sequelae of harm range from minor to hospital admission

42.   Harm in primary and ambulatory settings may be less visible compared to harm related to hospital based interventions such as surgery, but given the volume of care provided the total impact is not less. Studies suggest that as many as half of all safety lapses in primary/ambulatory care have the potential of causing moderate to severe harm (Singh et al, 2013). Diagnostic errors caused harm in 58% of the cases, while 8% and 11% of medication errors resulted in harm (Panesar et al, 2016). Diagnostic and prescribing errors were associated with most severe harm.

43.   Survey responses appear to confirm this (Figure 2.4). For developed countries, 48% of the harm was classified as negligible or low, 30% as moderate, 14% as high and 7% as severe. For LMICs the results were similar with smaller differences between severities. Just over 30% of harm was classified as low while almost 20% was classified severe.

Figure 2.4. Severity of harm is typically low in this setting
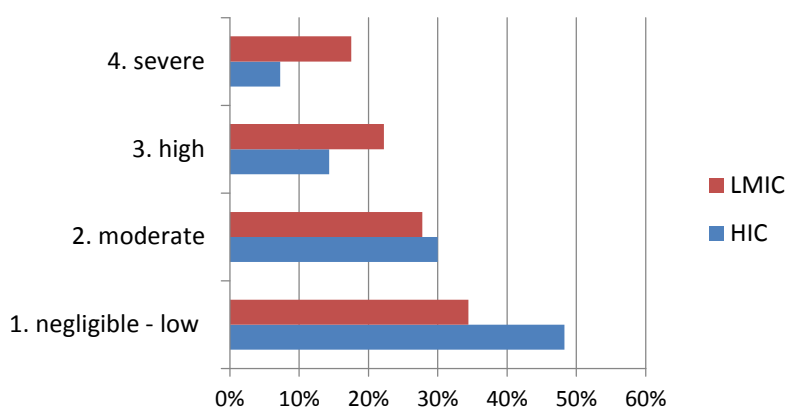
Note: Responses to the question: *How severe is the patient harm in ambulatory/primary care? Please distribute 100 points over the four categories listed below?*
Source: OECD Patient Safety Snapshot Survey, 2018 (n=26)

44.   One of the most frequent consequences of safety lapses in primary and ambulatory care settings is additional need for care, including hospital admissions. Woods et al (2007) examined 14700 hospital discharge records in Colorado and Utah (United States) finding 70 ambulatory care adverse events in the sample. Most common place of occurrence was the physician's office (43%). The most common source of harm was diagnostic error (36%). Based on these findings, approximately **170,000 hospitalisations per year in the United States** are caused by harm in ambulatory care.[10]

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[10] The study included day surgery and emergency care in its definition of ambulatory care.

45.   Survey respondents cited hospital admission, additional primary/ambulatory care and further diagnostics as the most common sequelae in developed countries (Figure 2.5). Notably death was not cited by any respondent in the HIC context. Fewer responses were received for LMICs. The notable difference being that death was considered as the third most common consequence after hospitalisation and additional primary/ambulatory care.[11]

Figure 2.5. Typical sequelae of harm in primary/ambulatory care
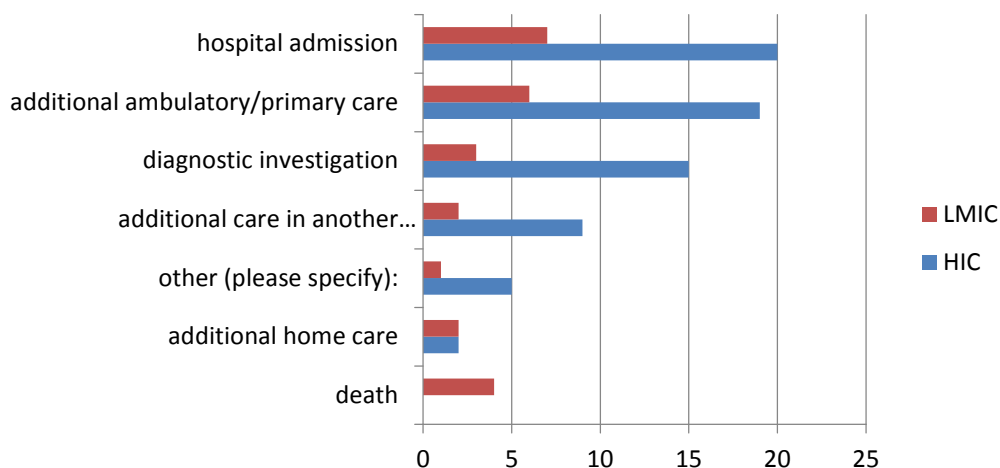
Note: Response to the question: *What are the three most common consequences related to healthcare use of patient harm in ambulatory/primary care?*
Source: OECD Patient Safety Snapshot Survey, 2018 (n=26)

2.2.3. Many diagnostic errors remain undetected due to insufficient measurement methodologies

46.   In the literature, diagnostic errors are often referred to as missed opportunities, implying that something different could have been done to prevent safety lapses (Box 2.2). But diagnostic errors are both difficult to detect and to measure. It is estimated that about 5%, or 12 million US adults every year, experience diagnostic errors in outpatient settings (Singh et al, 2014). Previous work from the same research group suggests that up to one-half of those harmed will experience severe consequences, which corresponds to 6 million outpatients each year (Singh, et al 2013). The most common allegation in medical negligence claims in primary and ambulatory care is diagnostic errors, which are also found to result more often in death than all others (Saber Tehrani et al, 2013).

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[11] The impact of avoidable hospitalisations is examined in Section 3.2.2

Box 2.2. Relationship between diagnostic errors, missed opportunities and patient harm

Studies of diagnostic errors often involve some degree of hindsight bias—a type of bias in judgement about a diagnosis coloured by retrospective knowledge where earlier warning symptoms and signs are later found to be either overlooked or not considered seriously yet being less obvious at the time of the actual encounter. Not all delayed/wrong diagnoses are accompanied by evidence of missed opportunities (areas C and D in the figure below) and not all missed opportunities are harmful (area A). Although the goal is to focus on preventable diagnostic harm (area B), this will require learning from all types of diagnostic error.
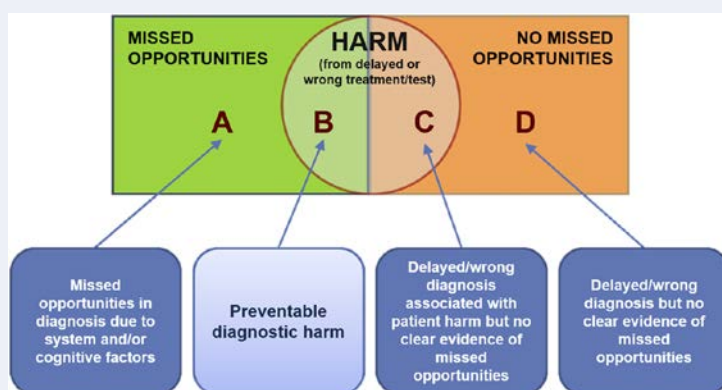
Source: Singh H. Editorial: Helping health care organizations to define diagnostic errors as missed opportunities in diagnosis. Jt Comm J Qual Patient Saf 2014;40:99–101.

Singh, H. et al (2017). The global burden of diagnostic errors in primary care. BMJ Qual Saf 2017;26:484–494. doi:10.1136/bmjqs-2016-005401

47.   Some studies suggest that the aforementioned traditional methods used for capturing diagnostic errors are only able to detect the tip of the iceberg (Schwartz et al, 2012; Box 2.3). Still, conventional data sources, such as medical record reviews and reported harmful events, produce mounting evidence of the importance and frequency of diagnostic errors across several types of conditions.

48.   Heart conditions and cancers are particularly susceptible to diagnostic harm and may also lead to severe impact for those affected. Studies of multiple consultations in the presentation of cancer provide a powerful predictor of speed of receiving a timely and correct diagnosis. One in five patients presenting 'red flag symptoms' and who recently were diagnosed with cancer had three or more consultations with primary care doctors being referred to relevant specialists. Although the majority of those patients had cancers that are considered particularly difficult to diagnose, it does reflect an avoidable delay (Lyratzopoulos et al, 2014).

Box 2.3. Applying *Unannounced Standardised Patients* method reveal a whole new type of diagnostic errors

Traditionally, patient harm and diagnostic errors are captured in routine chart reviews and patient-reported harmful events. However, these methods have significant shortcomings when it comes to measuring diagnostic errors in primary and ambulatory care settings. Sending unannounced, standardised patients (USPs) into clinical practice settings incognito has been proposed as the 'gold standard' of physician's performance since it provides more information on the extent to which the physician attends to red flags, biomedical confounders and contextual factors. Actors are trained to present with complaints indicative of significant conditions and providers are assessed on how they respond according to evidence-based treatment guidelines. Schwartz et al (2012) demonstrated how this method can reveal things that would not be detected by the traditionally applied methods for capturing diagnostic errors;

One of our study cases was a patient presenting with worsening asthma as a result of inability to afford his daily brand-name inhaler due to losing his job. Physicians who failed to attend to the red flags about job loss in this case treated the patient by increasing the dosage (and associated cost) of the medication the patient already could not afford. The medical record, however, would reflect a patient with worsening asthma who had been (apparently appropriately) prescribed a more potent maintenance medicine. The cost of such a misdiagnosis would not become apparent unless the patient returned (possibly in status asthmaticus) to the same facility and a more astute interviewer asked about how he uses his inhaler and why.

In this study, the researchers found that errors due to the inattention to biopsychosocial and contextual factors were more frequent than more apparent errors that would be captured in a medical record review. Moreover, the immediate costs of contextual errors were higher than those related to a failure to address biomedical symptoms, suggesting that a physician who is better at listening and contextualising care may have fewer errors than a physician who is mainly focusing on biomedical aspects.

2.2.4. Adverse drug events are most prevalent among polypharmacy patients

49.   Medication errors and resultant ADEs are one of the most common adverse events in primary and ambulatory care, although estimates vary. For example, Makeham et al's (2006) systematic review found that retrospective studies yielded a lower estimate **(3%)** than prospective evaluations of **10%** (Martinez Sanchez et al (2011). Meanwhile in a Swedish study based on a random population survey, at least one ADE was reported in the last month by almost **20% of respondents** (Gyllensten et al 2013).Therefore, it is difficult to draw firm conclusions about the frequency at which these errors occur, however, studies do indicate particular patient groups that are at elevated risk for experiencing ADEs.

50.   Frequency estimates were higher in studies where particular patient groups deemed to be at higher risk of an ADE, notably polypharmacy. Gandhi et al (2003) found that the only significant predictor of harm related to an ADE was the number of medications a patient took at the time of the harmful event. The mean number of events per patient **increased by 10% for each additional medication**. Polypharmacy was also cited by survey respondents when

asked if any specific conditions predisposed a patient to a greater risk of harm. Between 17-30% of errors were correlated with polypharmacy that could be reduced through the use of reminders in an electronic prescription /ordering system (Meredith et al, 2001).

2.2.5. Patients with complex health and social needs are generally at greater risk of harm

51.   Perhaps unsurprisingly, patient complexity is a key risk factor of safety lapses in primary and ambulatory care settings. Complexity can be clinical as well as biopsychosocial. Aranaz-Andrés et al (2011), found that 58% of patients who experienced harm had the following risk factors: hypertension (31.5%), diabetes (17.5%), obesity (14. 3%), dyslipemia (12.6%) and depression (10.6%). Generally, these patients need continuity of care, close follow-up and a lapse in their treatment course may lead to a deterioration of their health status and well-being. Survey results suggest that in developed countries multi-morbidity, psychiatric conditions, diabetes, polypharmacy and immunocompromised are important clinical risk factors of patient harm (Figure 2.6).[12]

Figure 2.6. Clinical risk factors of harm
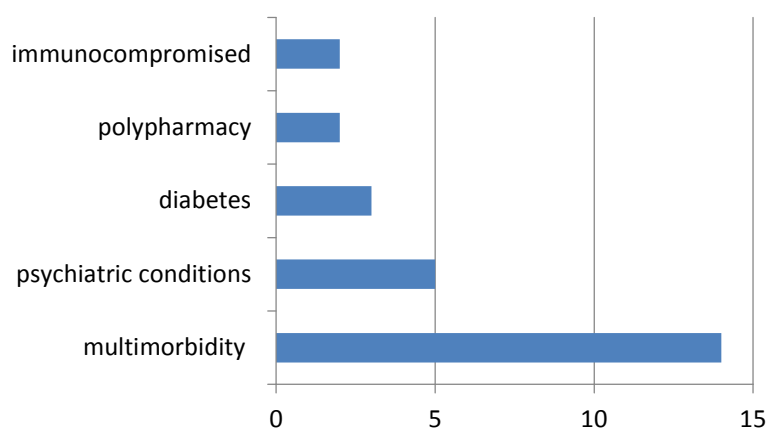
Note: Response to the question*: Are patients with specific conditions (or a combination of conditions) at a greater risk of harm in ambulatory/primary care?   Please describe in the space provided.*
Source: OECD Patient Safety Snapshot Survey, 2018 (n=26)

52.   But other non-clinical patient characteristics also increase the risk of harm. For developed countries, the most common factors selected by the survey respondents were vulnerability defined by age, socio-economic status, and social and geographic isolation. For LMICs, socio-economic deprivation, geography and age were most commonly selected (Figure 2.7).

53.   Notably, Tsang et al (2013) found that patients registered at the same general practice for longer periods of time are less likely to experience safety lapses. This finding implies that a long-standing relationship between the patient and their primary/ambulatory care providers (meaning perhaps more than an individual practitioner but the entire 'institution' comprising clinical as well as support and administrative staff) reduces the risk of safety failure. The

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[12] Too few responses were received for LMICs to comment.

mechanism is likely to be rooted in improved documentation, communication and knowledge by both parties.

Figure 2.7. Risk factors for patient harm
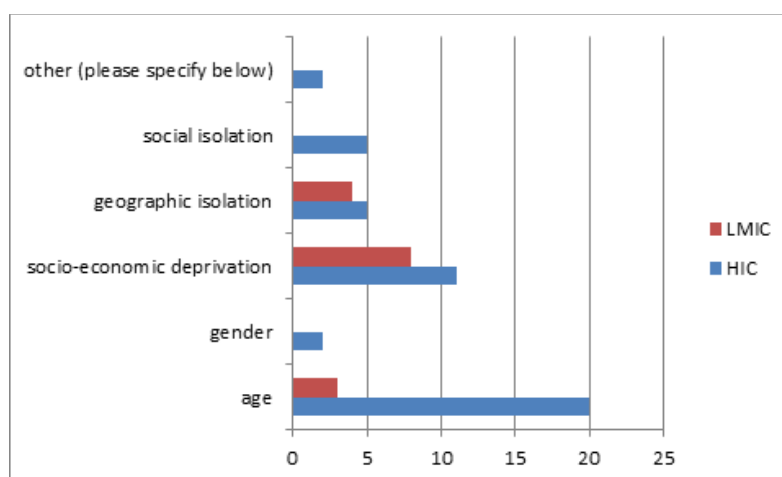
Note: Response to the question: *Do any patient characteristics influence the risk of harm in ambulatory/primary care? Please choose two from the drop-down list.*
Source: OECD Patient Safety Snapshot Survey, 2018 (n=26)

54.   Another implication of these findings is that as populations become more complex (both clinically and in a broader biopsychosocial sense) the risk of harm in the primary and ambulatory care setting – where a growing number of these patients will be treated - will rise. It follows that the clinical and economic consequences of harm will also grow unless concrete and systematic action is taken.

2.2.6. Failures in communication, access and coordination create most safety lapses

55.   While some types of harm cannot be prevented, harm in primary and ambulatory care settings is mainly rooted in process-related factors, notably failures of access, communication and coordination. It may arise either in the interaction between patient and provider, or the failure of following up with other care providers; failing to act on test results or respond to gradual deterioration. The causes are often system-level limitations such a fragmented information infrastructure.

56.   Administrative error relates to issues such as incomplete, incorrect unclear or unavailable documentation, inappropriate monitoring of laboratory results, insufficient communication between providers or between professionals and patients (Mitchell et al, 2013). 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).

57.   Although hard data on the occurrence of adverse events and patient harm in primary and ambulatory care settings are lacking, the pieces of information that are available illustrate the magnitude and seriousness of the problem. The next chapter will explore what the consequent burden of disease and the costs of harm

3. The health, financial and economic burden of safety lapses

58.   This chapter estimates the burden of patient harm in primary and ambulatory care settings. As previously discussed, given the lack of a standardised taxonomy for how to categorise and measure harmful incidents, the global burden of harm in primary and ambulatory care settings is difficult to estimate accurately. This section therefore aims to quantify the burden of harm using different units of measurement; DALYs, financial and broader economic costs.

3.1. Half of the global health burden exerted by patient harm stems from primary and ambulatory care

59.   The disease burden exerted by patient harm is at number 14 of global disease rankings (Jha et al, 2013). Assuming that most health care services are delivered in primary care settings, a considerable share of patient harm could therefore be expected occur in those settings. Survey results assign between 30-50% of this burden to errors occurring in primary care settings. These findings are also comparable to the results from 2017 survey from the Institute for Healthcare Improvement in the United States, where more than half of adults (54%) with medical error experience state the error occurred in outpatient settings[13], 34% of these in general practice (NORC, 2017).

60.   Translating the global burden of patient harm into DALYs[14], estimations from the Institute of Health Metrics and Evaluation show that adverse effects of medical treatment has decreased by 7% since 1990 (GBD DALYs and HALE, 2017).

61.   Applying the 30%-50% threshold indicated by experts and literature, **the average burden of harm sustained in the primary/ambulatory setting in the OECD countries is estimated at 10-17.5 DALYs per 100 000 population.** This can be compared to the burden of malignant melanoma, thyroid cancer, peripheral vascular disease and multiple sclerosis (Hay et al 2016). In the United Kingdom, the disease burden of harm in primary and ambulatory care (approx. 23,000 DALYs can be compared to the burden of cervical cancer or interpersonal violence (approx. 30,000 DALYs). Based on previous research, the health burden of patient harm in primary and ambulatory care in LMICs can be compared to that of typhoid fever (Jha et al 2013; Hay et al 2016).

3.2. Direct financial costs of harm may account for up to 5% of countries' expenditure on health

62.   The previous chapter detailed that occurrence of harm estimates vary. Consequently limited published literature exists on the financial and economic impact of harm.

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[13] Outpatient setting includes: doctor's office/health centre or clinic; emergency room; outpatient surgical settings; dentist's office; drugstore/walk-in clinic; at home.

[14] The disability-adjusted life year (DALY) is a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. One "DALY" can be thought of as one year of "healthy" life lost.

The literature identified mainly concerns specific causes of patient harm, notably diagnostic and ADEs (Table 3.1). Not only are incidents related to diagnosis and prescribing the most common in primary and ambulatory settings, but they have been found to most likely result in more serious harm to patients and therefore result in both considerable costs and consumption of overall health resources.

3.2.1. Costs of diagnostic error and adverse drug events are the most costly

63.   The diversity of applied methods in the studies below reduces the comparability of findings. The choice of study design may also lead to an underestimation of the costs. This is demonstrated by Schwartz et al (Box 2.3 in Chapter 2). In the study, a broader definition of diagnostic errors was applied, including contextual as well as biomedical factors. The estimated costs using the expanded context of medical error were **twenty times higher** than what could be identified from a medical record review alone.

64.   Cost studies are also often based on malpractice claims data. Misdiagnosis or delayed diagnosis rooted in primary and ambulatory settings accounted for nearly 70% of all claims in the United States (Saber Tehrani et al 2013). Over 25 years, the total amount of diagnostic related payments was equivalent to **USD 38.8billion**. As many as 71% of all outpatient claims related to disability or death, which may suggest an underestimation of the overall burden since those experiencing less severe harm are also less likely to report the incident..

65.   The second most common cause of harm in primary and ambulatory care settings are adverse drug events (ADEs). Bourgeois et al (2010) report **over 4.3 million ADE-related visits** annually to outpatient clinics and emergency departments in the United States, resulting in **107,468 hospitalisations** each year**.**

66.   Gyllensten et al (2014) estimated the direct financial impact of ADEs in Sweden. ADEs accounted for approximately 10% of all direct health costs in a random sample of 5,000 Swedish adults during a 3-month study period. Assuming that at least half of these ADEs originate in primary and ambulatory care, this corresponded to **USD10.5 million per 100 000 population** in 2008, which equates to approximately **2.5% of Swedish health expenditure** in 2008. Hospitalisation accounted for 54% of the direct cost of ADEs.

67.   In order to estimate the financial burden of ADEs in Germany, Stark et al (2011) based the cost study on a model originating from the American healthcare system. Their estimations quantified health care costs related to ADEs emerging from ambulatory care settings to a total of **€816 million**, or 0.22% of German health expenditure in 2011. Almost 60% was due to hospitalisations, 11% to emergency department visits and the remaining 21% from expenditures made in long-term care. However, these costs are only approximations.

68.   Pirmohamed et al (2008) looked at costs of ADEs resulting in a hospital admission in two hospitals in the UK. Eighty percent of all ADEs led to a hospital admission, which accounted for **4% of the hospital bed capacity** in 2008. The projected annual costs of these admissions to the NHS amounted to **€706 million (USD847m)**. These costs are expected to be an underestimation, as most ADEs occurring in primary care do not lead to hospitalisation, but still result in an elevated need for health care. These costs are not taken into account.

Table 3.1. Summary table cost studies.

	Authors and title	Key points
Diagnostic error	Saber Tehrani AS, et al. (2013), *25-Year summary of US malpractice claims for diagnostic errors 1986–2010: an analysis from the National Practitioner Data Bank*	*Malpractice claims data* The inflation-adjusted, 25-year sum of diagnosis-related payments was **US$38.8 billion** (mean per-claim payout US$386 849; median US $213 250; IQR US$74 545–484 500) Mean per-claim payment (SD). USD 384 851 (USD 489 797) Median per claim payment (IQR) $232 050 ($86 275–$509 850)
	Schwartz et al (2012). *Uncharted territory: measuring costs of diagnostic errors outside the medical record*	*Unannounced Standardised Patient method*s and Medicare cost-based reimbursement data. Overall, errors in care resulted in predicted costs of approximately **$174 000** across **399 visits**, of which only $8745 was discernible from a review of the medical records alone.
ADEs	Gyllensten H, et al. (2014) *Economic Impact of Adverse Drug Events – A Retrospective Population-Based Cohort Study of 4970 Adults.*	*Population-based observational retrospective cohort* ADE across all care settings has estimated direct costs of **USD 21 million per 100 000 inhabitants/year** Over the three-month study period, direct costs per ADE patient was equivalent to **USD 445** and total societal COI per ADE patient was estimated at **USD 6235**, indirect costs constituted half of this **44%** of direct costs caused by ADE occur outside of inpatient settings
	Stark et al. (2011), *Health care use and costs of adverse drug events emerging from outpatient treatment in Germany: A modelling approach.*	*Cost-of-illness model study* For Germany, the base case postulated that about 2 million adults ingesting medications have will have an ADE in 2007. Health care costs related to ADEs in this base case totaled **816 million Euros**; mean costs per case were **381 Euros**.
	Pirmohamed M. et al (2004). *Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients*	*Prospective observational study* Out of 1225 admissions related to adverse drug reactions (ADR), giving a prevalence of 6.5% with the ADR leading directly to hospital admission in 80% of cases. Projected annual such admissions to the NHS estimated at **£466m (€706m or $847m).**

69.   Estimating costs of patient harm in primary and ambulatory care settings is limited by data availability and data quality. All the cost studies that were identified in the literature, including the ones summarised in the table, argued that the figures are likely to be an underestimation of the direct costs.

3.2.2. Safety lapses in non-acute settings consume tens of millions of bed days each year

70.   Hospitalisation is among the most common sequelae of harm in primary and ambulatory care. The previous section identified that the majority of the direct costs stemming from safety lapses such as diagnostic error and ADEs generated by the need for hospitalisation. Consumption of hospital resources carries a direct cost – bed days and activity – and an opportunity cost – other admissions foregone (assuming hospitals are operating at high occupancy).

71.   The study by Woods et al (2007) cited earlier suggests that 170,000 admissions in the United States are a direct result of patient harm in ambulatory care. Based on the average

length of a hospitalisation in the United States in that year, these hospitalisations consumed just over **1 million bed days** in 2007**.** The Burgeois (2010) finding of over 107,436 hospitalisations due to ADEs each year in that country equates to approximately **650,000 bed days**.

72.   But the impact of safety lapses on hospital care may be extended further. This report defines patient safety in the primary and ambulatory setting as managing risks over extended periods of time. The literature and the snapshot survey of experts identified delays in diagnosis and inappropriate therapeutic interventions as key sources of patient harm in this setting. It follows that failure to detect the onset or deterioration of a chronic health condition can be counted as harm. For several chronic diseases a timely diagnosis, advice and treatment in primary and ambulatory care enables patients to manage their condition over time. Failure to diagnose and treat results in deterioration of health and a clinical condition resulting in a higher likelihood of hospitalisation.

73.   Such hospitalisation can be avoided for many illnesses. Five chronic conditions are typically singled out as particularly amenable to management in primary and ambulatory services: (i) diabetes, (ii) hypertension, (iii) heart failure, (iv) chronic obstructive pulmonary disease (COPD) and bronchiectasis, and (v) asthma. Hospitalisation should be the exception.

74.   In 2014, just over **5.4 million hospitalisations** with a principal diagnosis[15] of one of these five conditions took place in a panel of 27 OECD countries for which data were available.[16] As almost 105 million hospital admissions took place in these countries that year, this amounts to about **5.2% of all admissions**. Most admissions were for heart failure (1.75 million), followed by COPD and bronchiectasis (1.43 million), diabetes (1.04 million), hypertension (717,000) and asthma (493,000). The average length of stay (LOS) across all five diagnoses was 8.9 days, ranging from 10.1 days (heart failure) to 6.4 days (asthma) (Table 3.2).[17]

Table 3.2. Impact of avoidable hospital admissions for five chronic conditions, 27 OECD countries, 2014

	Diabetes	Hypertensive diseases	Heart failure	COPD & Bronchiectasis	Asthma	Total
Admissions	1,041,407	717,028	1,750,617	1,427,355	492,741	**5,429,148**
% of all admissions	1%	0.7%	1.7%	1.4%	0.5%	**5.2%**
Average LOS (bed days)	9.5	8.8	10.1	9.5	6.4	**8.9** (avg)
Total bed days	11,216,160	5,997,288	17,326,227	13,525,078	3,366,991	**51,431,744**
Proportion of all bed days	1.3%	0.7%	2.0%	1.6%	0.4%	**5.9%**
Typical admissions* foregone	1,338,147	652,696	2,182,225	1,967,705	475,956	**6,616,730**

Note: A 'typical admission' is the average LOS of admissions for all diagnoses and conditions treated in hospital. Foregone admissions assume that hospitals are operating at near full capacity.
Source: OECD.stat

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[15] A principal diagnosis is the reason for admission based on the initial clinical assessment.

[16] See Figure 3.1.

[17] Data collected includes only admissions with a minimum of one night's hospital stay. Not counted are 'same-day' admissions (e.g. a patient with acute on chronic COPD admitted for observation but discharged a few hours later). While technically not registering as a bed day, these admissions consume hospital resources.

75.　　　Over 51 million bed days were consumed by admissions for these five diagnoses in the selected countries. This amounts to **5.9% of total bed day capacity** in 2014 in these countries, and equates to approximately **6.6 million typical hospital admissions** (Table 3.2).[18]

76.　　　By country, the mean LOS across the five diagnoses ranged from 22.8 days (Korea) to 4.9 days (Sweden). But for the majority of countries the mean LOS was within two bed days of the international average. As a proportion of all bed days, admission for the five diagnoses had the greatest impact in Turkey (11.1%), and the least in Israel (2.5%). However, in the majority of countries the proportion was between 4% and 7% (Figure 3.1).

Figure 3.1. Proportion of bed days accounted for by hospitalisation for five conditions, 2014

Admissions for 1. diabetes, 2. hypertension, 3. heart failure, 4. COPD/ bronchiectasis, or 5. asthma
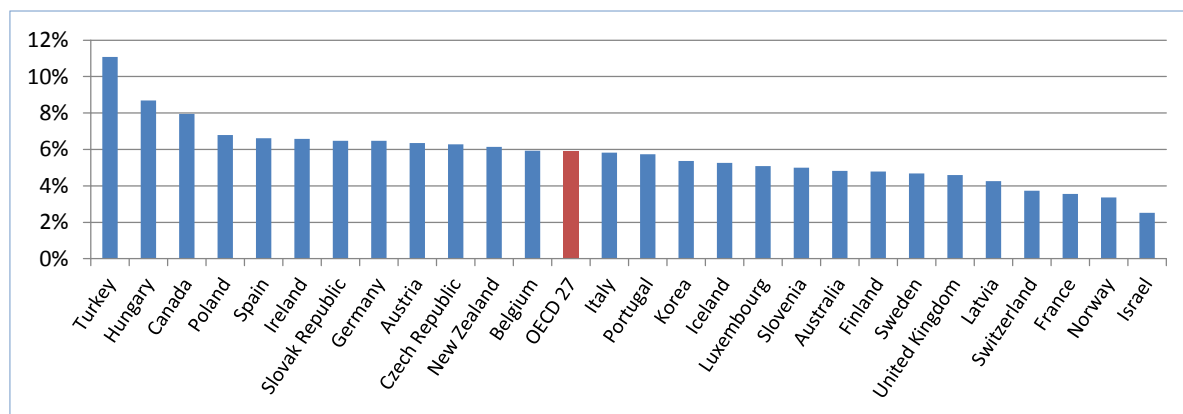
Note: Results for Canada use 'curative' admissions as the denominator. Curative admissions are a subset of all admissions (used for all other countries). This is likely to inflate the Canadian proportion.
Source: OECD.stat

77.　　　Two important considerations must be addressed. First, the intensity of care - tests, interventions and attention from hospital staff - required will vary between admissions for these five diagnoses and will differ to other admission types. For example, severe trauma, bypass surgery or stroke will consume more hospital resources per bed day than an admission for asthma or diabetes. Weighting the total bed day consumption of each diagnosis was performed (see Annex 2) producing just over **2.7 million weighted admissions** in the 27 countries examined. This equates to **2.41% of all admissions** (whose aggregate activity weighting will, by definition, equal 1). This serves as an approximation of the direct resource-cost of hospital admission for these five conditions. Weighting the bed day totals produces 4.2% of total bed days, lower than the headline figure of 5.9%.

78.　　　Second, not all of the hospitalisations with a principal diagnosis of diabetes, hypertension, COPD/bronchiectasis, heart failure or asthma can be avoided. While, as discussed, preventability is a fluid concept - and will no doubt also vary between the five conditions - some admissions will be necessary and unavoidable due to factors such as the patient complexity, their age, comorbidities and their personal circumstances. Survey findings suggest that that half of the admissions with any of these five principal diagnoses may be preventable. Halving the admission numbers would reduce these figures to **2.6%** of crude admissions and **1.2%** of weighted hospital admissions.

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[18] See Annex 2 for a description of the methods.

79.   Calculating the impact on bed days in this manner is more problematic. Because some admissions last one day while others stretch beyond 100 days, reducing admissions by factor x will not reduce the bed days by the same factor The calculation would require the bed-day distribution of admissions for each diagnosis in each country. Avoidable admissions are likely to be less complex, and LOS can serve as a marker for complexity.[19] Swerissen & Duckett (2016) propose that only admissions of 1 and 2 days should be considered avoidable in Australian hospitals, and suggest that - defined this way - 'avoidable' admissions for the five conditions examined here (plus anaemia) generated additional hospital expenditure of **AUD272 million** in 2015-16.

80.   However, the varied distributions across the five diagnoses vary considerably and a 2-day preventability benchmark may not be appropriate across the board. An alternative is to consider the shortest 50% (or other proportion) of all admissions as preventable. Admissions data from one of the countries examined here suggests that this ranges from 1 day (asthma admissions) to 5 days (heart failure). Applying this method produces a total bed days figure over **213,000** for the five diagnoses (Table 3.3). This amounts to approximately 1% of all bed days consumed, and to over **38,000 typical hospital admissions annually**, in this country.

Table 3.3. Admission lengths accounting for the shortest 50% of all admissions for the five conditions and total bed days in one OECD country, 2014

	Diabetes	Hypertensive diseases	Heart failure	COPD & Bronchiectasis	Asthma	Total
LOS accounting for shortest 50%	1-3 day	1& 2 day	1-5 day	1-4 day	1 day	n/a
Total bed days	27,914	5,552	81,680	83,729	14,237	**213,112**
Typical admissions	5,075	1,009	14,851	15,223	2,589	**38,748**

Source: OECD data collected for R&D purposes.

81.   It would be tempting to assume similar distributions in other countries and apply this method across all of the data examined here. However, a comparison of the distribution for diabetes admissions with that of another country's reveals that this would be inappropriate (Annex 2). To provide an accurate reflection, each country's results would have to be calculated separately. This is beyond the scope of this report. Nevertheless a rough calculation based on aggregate hospital activity shows that 1% of hospital activity across the 27 countries examined equates to approximately **USD298 billion** in 2014.

82.   Nevertheless these numbers are considerable, even when factoring in preventability. They are also likely to underestimate the true impact of this 'longitudinal' type of safety lapse - for two reasons. First, same-day admissions are not included. Based on data supplied by one country a significant proportion of patients for the five conditions examined here are discharged on the day of admission. While these patients do not stay overnight, they do consume hospital resources during their stay.

83.   Second, only five diagnoses are examined here. A range of other conditions exist for which hospitalisation may be preventable - or at least reducible - through safer primary care. These include musculoskeletal problems such as low back pain, mental and behavioural

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[19] This assumption may not always hold. For example, safety lapses in hospital are known to considerably extend LOS. Such admissions were not necessarily complex to begin with and could be considered avoidable.

disorders, angina, depression, iron deficiency, and rheumatic heart disease. Including the entire set of conditions in this analysis could potentially increase the cost of avoidable hospitalisation to around **10% of bed days** or **5% of weighted hospital activity**.

3.3. Harm in primary and ambulatory care impacts society and the economy

84.   The costs of safety lapses in primary and ambulatory care extend beyond the health system, to societies and economies more broadly. Harm manifesting in ongoing disability results in lost income and productivity for patients (and carers), loss of tax revenue and increased social support payments. The broader economic costs of harm across all settings has been estimated at over USD1 trillion in the United States alone (Andel et al 2012)

85.   Gyllensten et al (2014) examined the direct (healthcare) cost and the societal cost of ADEs in a Swedish population sample. The societal cost of ADEs in patients who experienced this type of harm (12% of the sample) was estimated at USD6,235 per patient compared to USD2,440 per patient without ADEs[20] – a 1.5-fold difference. Based on the authors' calculations this equates to a marginal societal cost of USD179 million per 100,000 population or about **3% of GDP** in the Swedish context.

86.   A survey-based study of 7,000 Swedish residents by the same authors (2013) suggests that the cost-of-illness is more than twice as high for respondents with ADEs (19.4% of the sample) than those with some form of morbidity but without ADE. Health-related quality of life scores were significantly lower for respondents with ADEs compared with other respondents. Consequently, **productivity loss due to long term sickness and disability increased for people who had suffered ADEs compared to other respondents.**

87.   In a similar sense, safety lapses in people with chronic diseases – aside from consuming healthcare resources (explored in Section 3.2) may also carry broader economic cost. If the patients are of working age, the worsened health caused by harm may prevent them from participating in the workforce resulting in lost productive life years. Beyond the negative impact on self-esteem and personal economic loss from reduced income, the flow on effects include higher support and care needs, increased welfare dependency and loss of taxation revenue.

88.   An Australian study modelled the impact of chronic disease on lost productive life years using the Australian Bureau of Statistics Survey of Disability, Ageing and Carers. The 2015 results indicate that 380,000 productive life years were lost by people aged 44-64 due to a range of conditions.[21] The total income forgone due to the lost productive life years was estimated at AUD12.6 Billion. Additional cost to the government was AUD9.3 Billion, comprising AUD6.2 Billion in increased welfare payments and AUD3.1 in foregone taxation revenue. The reduction in GDP was estimated at AUD44.5 billion, or 2.5% in 2015 (Schofield et al 2015; Schofield et al 2016). [22]

89.   The proportion of the disease burden of a sufficient severity to prevent employment that can be attributed to safety lapses in primary and ambulatory care is an open question. Given the evidence presented earlier (occurrence, morbidity and hospital admission) it

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[20] Medical records were used, therefore non-ADE patients also utilised health care and suffered from morbidity.

[21] Including those examined in the previous section as well as back problems, arthritis, mental health problems, cancer and other conditions amenable to management with timely diagnosis and intervention

[22] Only people not working due to chronic illness were counted. Those continuing to work in a reduced capacity were excluded.

may be reasonable to assume that - in a developed country with universal access health care - perhaps 10-15% of chronic illness severe enough to prevent a working-age person from employment is due to safety lapses.

90.   Using the Schofield et al results suggests that the broader economic impact of delayed or wrong diagnosis and delayed treatment for chronic illness could approach **0.5% of GDP,** which represents approximately **5% of health expenditure** in most OECD countries. Half a percent of GDP in the United States amounts to just over **USD90 Billion**. In Japan it is **2.6 trillion Yen**. But given the different disease and demographic profiles of the US and Japan respectively to Australia, these figures may be higher.

91.   Despite all the limitations and assumptions built into the presented calculations, the cost impact of safety lapses in primary and ambulatory care is substantial enough to warrant attention.

4. Improving safety in the primary and ambulatory care sector

92.   This report has so far established that patient harm due to safety lapses in primary/ambulatory care is significant. While the level of harm is on average less severe than in the acute care, given the high (and growing) volume of care provided in primary/ambulatory settings, the aggregate cost of these safety lapses is considerable. This chapter explores the available interventions, strategies and programmes that can be deployed to improve safety across an entire primary and ambulatory care 'system'. Findings are predominantly sourced from the snapshot survey and also from the literature. The chapter focuses on distilling approaches that are cost-effective, and represent value for money to policy makers and to society.

4.1. Interventions to improve patient safety in primary and ambulatory care must be built on good information

93.   A key finding of this report is how little is known about the extent of harm in the primary and ambulatory setting. Surveyed experts and the literature estimate not only a wide range of occurrence rates and severity levels, but a variety of measurement units to begin with. Given that the first principle of improvement is solid information, it is unsurprising that survey respondents most commonly suggested strategies concerning **measurement and reporting** for both developed and LMICs (Figure 4.1). This does not mean measuring for the sake of measuring, or public reporting of safety lapses. Rather, it concerns the accurate and systematic collection of information on safety and harm for the purposes taking informed action at local and system level. Measurement is a very important means to enable learning and improvement.

Figure 4.1. High-level strategies to improve safety of care
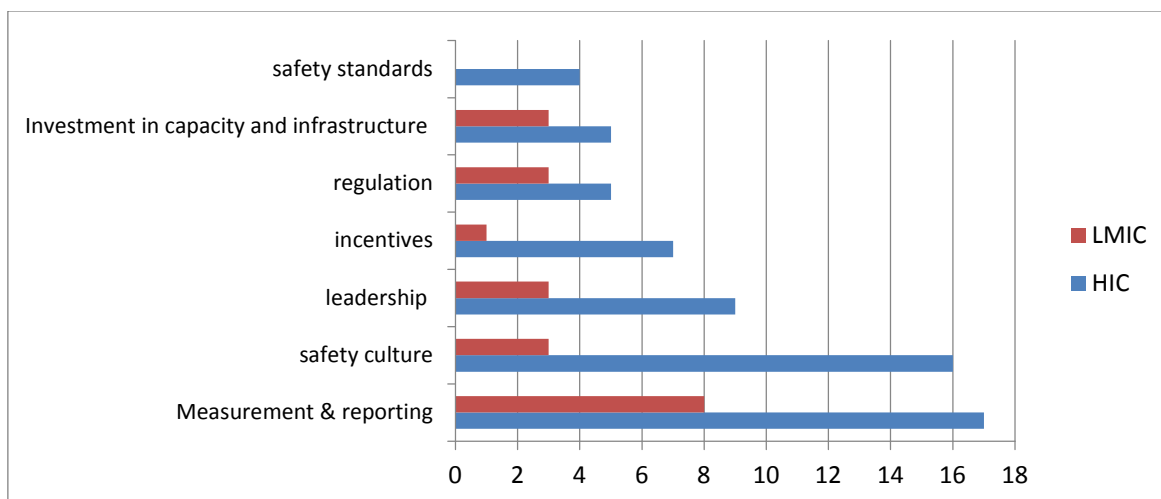
Note: Response to the question: *What high-level strategies and policies should decision makers prioritise to improve safety across the ambulatory/primary care sector? Please provide 3 items in free text. Please use high-level terms such as 'measurement' 'regulation' 'financing' 'culture' 'leadership' and provide a brief description.*
Source: Add the source here. If you do not need a source, please delete this line.

94.   Safety culture was a close second, followed by leadership, incentives, regulation, investment and safety standards. These strategies require considerable coordination across a fragmented sector comprising disparate organisation, actors and governance arrangements - fragmentation is discussed later. Suggestions regarding incentives comprised not just financial incentives for quality over volume of care, but also incentives to collect and report data on safety (i.e. 'pay for data').

4.1.1. Patient reporting must be part of a safety measurement and improvement system

95.   An earlier survey question asked for methods that should be deployed to systematically measure harm. The responses for both LMICs and developed countries (Table 4.1) confirm that a various approaches are needed to provide a complete picture of harm. The key components of a patient safety measuring system should comprise patient-reported measures, periodic audits of medical records (be they paper-based or electronic), mandatory reporting and potentially the trigger tool method. The results emphasise the importance of the patient opinion and experience in obtaining a fuller picture of patient harm and lapses in safety.

Table 4.1. Recommended patient safety measuring methods in LMICs and developed countries

HICs	LMICs
Patient reporting (18)	Periodic medical record audit (6)
Periodic medical record audit (15)	Mandatory reporting (5)
Mandatory reporting (14)	Patient reporting (4)
Trigger tool method (10)	Administrative data (4)
Administrative data (8)	EHR flag (2)
EHR flag (5)	Trigger tool (1)
Other: voluntary reporting (2)	Liability claims (1)
Liability claims (1)	Other (0)
73 selections made	**23 selections made**

Note: Based on responses to the question: *What should be done to systematically measure the incidence, nature and impact of patient harm across the ambulatory/primary sector? Please choose three from the options provided*
Source: OECD Patient Safety Snapshot survey, 2018 (n=26)

96.   Importantly, reporting should include information on safety lapses that result in harm as well as 'near misses', which can often hold valuable information that can prevent harm in a future situation. This is a key ingredient of learning health systems at local and aggregate level.

4.1.2. Education, culture, patient involvement, team-based care and regulation are important levers to improve safety

97.   In addition to the high-level strategies respondents were also given a list of 19 more specific interventions to select from (Figure 4.2). In developed countries, **education** of professionals and **systematic patient reporting** were the most frequently selected, followed by improving **organisational culture**, an **integrated national incident database**, more **incentives for team-based care**, and **patient involvement** strategies. This aligns with the high-level strategies suggested. Less popular were risk stratification linked to financial incentives, P4P,[23] universal access, cause of admission flags in hospital datasets, and longer consultation times. The

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[23] Financial penalties ore rewards for (not) achieving specified safety metrics.

latter is interesting given the rushed nature of consultations is often cited as a factor in safety lapses.

98.   Education was the most selected intervention in the LMICs, followed by health literacy initiatives and patient empowerment. Interesting is that ensuring universal access to primary care is seen by respondents as a safety lever.

Figure 4.2. Most effective patient safety interventions
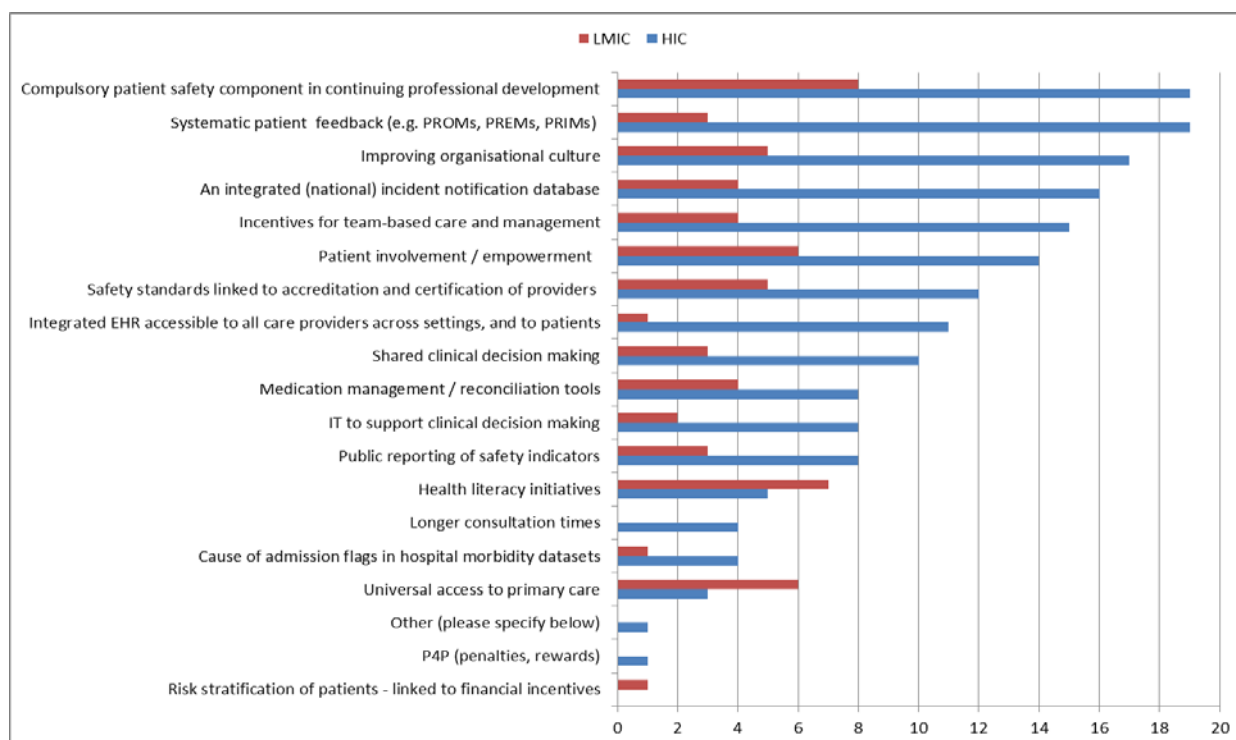
Note: Response to the question: *More specifically, what seven interventions would you choose to improve safety/reduce harm in this setting? Please choose from the 21 options in the drop-down list in each cell. (You can view these 21 options on sheet c.) Please provide other initiatives and more detail in the space provided.*
Source: OECD Snapshot survey 2018

99.   As in the 2017 survey, education is seen as an important improvement intervention. The need to **involve the patient – both in their care *and* in incident reporting** - resonates strongly and is consistent with the responses on measuring harm. The popularity of incentives to **encourage team-based care** is interesting. It suggests a potential move towards alternative remuneration models (population-based or bundled payments). It also suggests that a breakdown in integrated care can be seen as a safety lapse – therefore adding weight to avoidable hospitalisations as a safety issue (Section 3.2.2).

4.1.3. Current national measurement approaches leave a lot to be desired

100.   Seven of the 29 responding countries to the survey were not aware of any health systems that routinely and systematically measured patient harm across the primary and ambulatory care sectors. Most of the countries that were aware of systematic reporting practices pointed towards the system in place in NHS, England.

101.   Online reporting of patient harm in primary and ambulatory care settings has been developed and implemented in the United Kingdom since 2015. In England alone, more than 360 million consultations with primary care providers take place each year. Aiming to encourage the reporting of patient harm in primary care, the NHS England launched a new e-form enabling general practice staff to quickly and easily report patient safety incidence to the NRLS – the national patient safety incident database. The fact that reporting is voluntary and anonymised for both practitioners and patients has been a welcome feature by the general practice staff in England. Despite this, the number of safety incidents reported to the National Reporting and Learning System (NRLS) from primary care remains low compared to the almost 1.5 million reports each year from hospital-based care.

102.   Practices vary greatly among the countries that have implemented systematic voluntary or mandatory reporting systems of patient harm in primary/ambulatory care. Some countries, like Japan, Iceland and Spain, have mandatory reporting in place for harmful events of various severities. In Japan, ambulatory clinics are obliged to submit a report through the 'Medical Accidents Investigation System' following adverse events in patient leading to death. Mandatory reporting is also in place in general practice and primary care in Iceland, although uptake and compliance with these regulations to date have been unsatisfactory. In Spain, however, the Ministry of Health has developed a Primary Care Clinical Database at the national level containing coded, standardised clinical data collected annually about the care delivered in primary care centre settings as well as serving as a reporting and learning system.

103.   New methods on how to measure patient harm in primary care settings are currently being developed. Norway has mainly focussed reporting of patient harm on inpatient settings up until now, but will from 2018 establish a National Health Accident Investigation Board that will investigate harmful events occurring in primary care settings – though reporting of these events is voluntary. In Mexico, reporting practices are moving towards including primary care in their National Registry, while Slovenia is working closely with Danish experts to modernise and adapt their reporting system. Sweden is currently implementing medical record review in home care settings in combination with a global trigger tool following similar guidelines as to what has already been put in place for adverse event reporting in hospital settings and psychiatric care.

104.   Even though some countries have comprehensive reporting databases, the information is generally not systematically analysed and used to inform patient safety in primary and ambulatory care. Survey responses suggest limited use of these comprehensive reporting systems

4.2. Better information systems, patient involvement and care coordination are key pillars for building safety with limited resources

105.   Survey respondents were asked if any of the strategies and interventions were most cost effective to implement across an entire sector. In other words where are the value and the 'best buys' where the benefits outweigh the costs of implementation, the costs of harm, and the opportunity costs of other priorities?

106.   For developed countries, an **integrated electronic health record system accessible to all care providers and to patients** was the most frequently cited intervention. Provider **education**, safety **culture** and the implementation of **safety standards** linked to accreditation, incentives **for team-based care**, **patient involvement** and shared decision making were also seen as cost effective (Figure 4.3). Answers were sparse in the LMIC context but

education, patient involvement and health literacy, organisational culture as well as universal access to primary care were seen good value initiatives.

Figure 4.3. 'Best buys' in the list of safety interventions
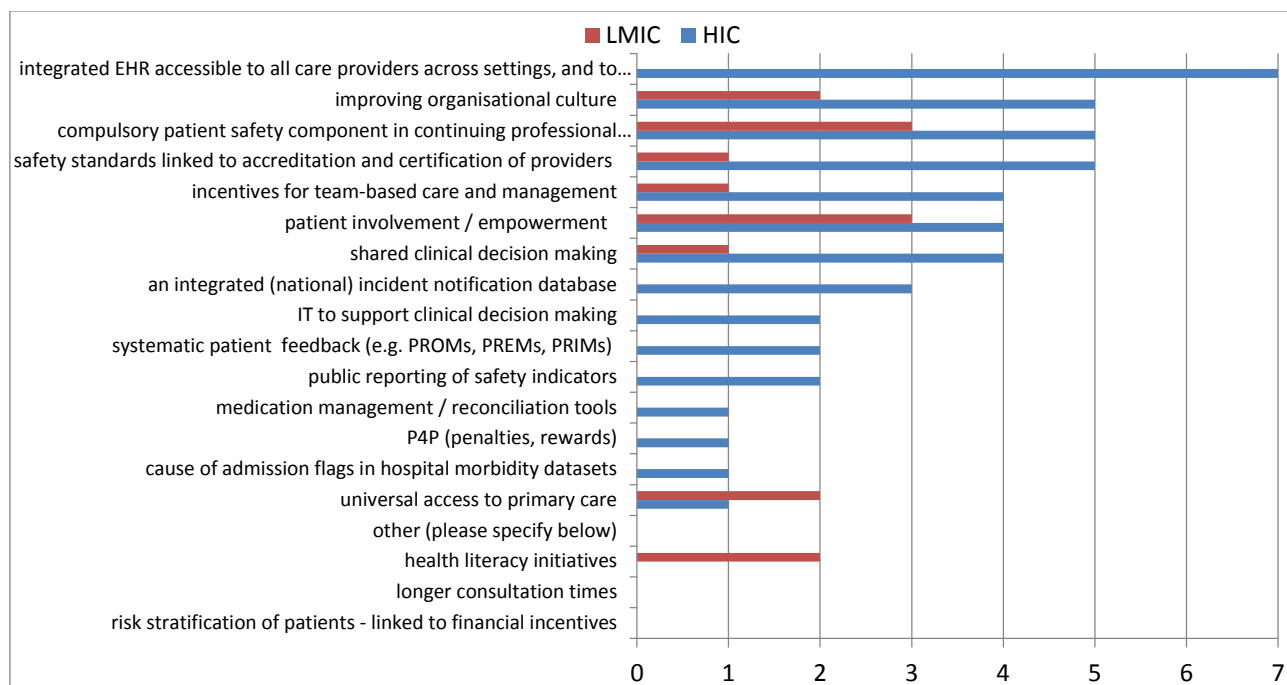
Note: Response to the question: *Which of the interventions listed in Q14 (and sheet c) - or others you may have suggested - are particularly cost-effective to implement across the entire sector? In other words - which are the 'best buys' where the costs of implementation clearly outweigh the costs of harm, and the resources are best invested in this way as opposed to other priorities.*
Source: OECD Patient safety snapshot survey 2018 (n=26)

107.   While an integrated EHR may seem an expensive undertaking, in reality such infrastructure serves several purposes - including safety. Costs are therefore distributed. Also, the key feature of this intervention is allowing all providers and the patient access to clinical information. This includes physicians as well as community nurses, pharmacists and allied health providers. Enabling such access represents good value if the underlying system(s) is already in place, even if additional portals and security measures need to be developed (marginal cost may be low).

108.   The importance patient involvement was again strongly reflected in the responses. The absence of **health literacy initiatives** in responses for developed countries, and its higher popularity in the LMIC setting is somewhat perplexing. An explanation could be that in high-income countries a population-based health literacy programme is seen as an expensive endeavour, with a similar pay-off to targeted (cheaper) initiatives to empower patients (e.g. shared decision making). Meanwhile in LMICs the cost of providing health literacy to an entire population may be lower, and the dividend greater given the likelihood of less reliable access to care and thus greater emphasis of self-care in these settings.

4.2.1. Engaging patients in their care is shown to influence outcomes and is a good investment

109.   Nevertheless, involving patients in their care *and* in helping measure and assess the safety of their care is very important, and is supported by the literature. The care experience predominantly concerns the quality of communication. The previously cited study by Tsang et al (2013) suggests a long-standing relationship between patients and providers improves safety over time.

110.   More recently Bell et al (2017) examined the effects of 'OpenNotes' - the open sharing of medical records between providers and patients in ambulatory care in the United States. They found positive influences on the patient-provider relationship (from both stakeholders' perspective), on trust and the care experience, particularly in vulnerable and disadvantaged populations – those at greater risk of suffering a safety lapse.

111.   Patient engagement and health literacy can influence care outcomes and the occurrence and severity of harm. Engaged patients have been found to experience 17% fewer adverse events (Berkman et al 2011; Schumacher et al 2013; HIN 2016). Strategies to improve patient engagement need not be expensive but can result in fewer and less severe harms, particularly if targeted at high-risk groups (vulnerable patients, polypharmacy). In terms of health literacy, little evidence exists on its impact on safety, but people with low *literacy* are up to 3-times more likely to experience a poor care outcomes up to 3-fold (DeWalt 2004).

112.   Overall, sound and systematic implementation of patient engagement strategies and health literacy programmes could **reduce aggregate harm by up to 15% -** a very good return on investment.

4.2.2. Interventions to tackle specific types of harm– such as diagnostic and medication errors are cost-effective

113.   Given the problem of medication safety and ADEs in this setting it was surprising to see interventions aimed at better medication dispensing and management rank comparatively low across the choices provided in the survey. Some useful studies highlight the value of an inter-professional approach to medication safety.

114.   Polypharmacy patients, often elderly, have already been highlighted as having a higher risk for harm in primary and ambulatory settings. Studies show that closer follow-up of these patients can produce lower costs and reduce harm to patients. Medication review with follow-up of elderly polypharmacy patients provided by community pharmacists generated both health benefit to patients (in QALYs) [24] and savings of €273 per patient year. The cost-benefit ratio revealed that for every €1 invested in medication follow-up, a benefit of €3.3 to €6.3 was generated (Malet-Larrea et al, 2017).

115.   The adoption of computerised provider order entry system (CPOE) is another way to improve medication safety in primary and ambulatory settings. However, the implementation of COPE often requires large upfront investments. Studies in inpatient settings have found that CPOE is cost-effective, but very few studies have been carried out looking at the primary and ambulatory settings. Forrester et al (2014) estimated the cost-effectiveness of CPOE versus traditional paper-based prescribing in reducing medication errors and ADEs in the ambulatory

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[24] The QALY is a generic measure of disease burden used in economic evaluation to assess the value for money of medical interventions. One QALY equates to one year in perfect health.

setting of a midsized (400 providers) multidisciplinary medical group. Implementing CPOE cost **$18 million less than paper prescribing and was associated with 1.5 million fewer medication errors and 14,500 fewer ADEs**.

116.   Communication and coordination across levels of care remains a key challenge in patient safety in all settings. The need for hospitalisation following safety lapses in primary/ambulatory care has been discussed in Chapter 3. But nearly one in five hospital discharges result in adverse events in the community setting. A third is preventable by improved hand-over. Generic service delivery interventions, e.g. improving nurse-to-patient ratios and changing safety culture, have the potential to improve safety in the transition between different of care. However, due to the diffuse effects of generic service delivery interventions are so widespread and affect many clinical processes and outcomes that often are not captured in traditional cost-minimisation studies that have been published to date.

117.   Aiming to incorporate more variables, Yao et al (2012) developed a method to estimate the cost-effectiveness of a generic service delivery intervention to improve clinical handover. [25] The results from the prospective evaluation modelled on a large European hospital with 50,000 discharges each year. Adverse events attributable to handover errors were found to generate a cost of nearly €3.5 million and the intervention to improve handover would reduce the incidents by one-third. Under the base case (21% effectiveness), 515 quality-adjusted life years (QALYs) could be averted. The intervention was highly cost-effective, at about €214 per QALY gain. The annual cost savings were estimated at €771,602, which is considerable at the hospital level. Although the methodology developed represented a novelty in the world of generic service delivery evaluation, it points towards considerable potential savings if the transition from one level of care to another is strengthened.

4.3. Improving safety requires leadership at all levels

118.   The primary and ambulatory care sector is a notoriously complex and unwieldy component of the broader health system. The fragmented nature, various actors and governance levers involved in delivering care at this level – and the consequent difficulty in gathering comprehensive information on safety and other care outcomes - have been outlined in Chapter 2. Improving safety across an entire sector is therefore a difficult undertaking for he policy maker. This section briefly examines the key barriers and enablers of doing this.

119.   The key challenges and enablers for improving safety in this setting suggested in the survey (across both LMICs and developed countries) are presented in Table 4.2. F**ragmentation**, a lack of **resources** and **workforce**, **patient complexity**, **busy practitioners** and fear of **sanction** were all mentioned. Several of these challenges are interrelated, and most appear to pertain to system-level strategies such as governance and regulation. The enablers suggested in strongly align with the strategies and interventions mentioned earlier: better **information infrastructure, leadership, patient involvement, culture, education, collaboration** and **incentives**.

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[25] The EU-funded project HANDOVER sought to develop an education intervention to improve patient care at the point of discharge from hospital to the community. In this specific study, Yao et al (2012), use the most intensive for on the intervention, which consists of classroom instruction supported by a number of internet-based educational resources known as the 'Handover Toolbox'.

Table 4.2. Challenges and enablers

Challenges	Enablers
fragmented nature of this care setting (5)	Data infrastructure (6)
lack of resources (5)	National leadership (4)
Patient complexity (4)	Patient-centeredness (4)
Busy practitioners (3)	No-blame culture (2)
Fear of sanction (3)	Education (2)
Workforce shortage (3)	Incentives (2)
Resistance to change (2)	Collaboration (2)

Note: In response to the question: *Please describe the challenges and enablers of implementing safety strategies across ambulatory/primary care settings at national or regional level.*
Source: Snapshot survey 2018 (n=26)

120.   These answers are quite revealing, and suggest that – much like the last survey – policy makers can do a lot to set the foundations for better safety in primary and ambulatory care. Information infrastructure appears to offer the most hope for policy solutions. For example, fragmentation in the sector is clearly a key challenge. It would be wildly ambitious to rebuild an entire sector into a cohesive system with unified governance, authority and accountability structures.

121.   But a pragmatic way to reduce fragmentation – thus improving cohesion and coordination in primary/ambulatory care (and better link it to with other sectors) would be to invest in an integrated information infrastructure with which all the disparate aspects can connect and communicate with. This would not only enable more complete and comprehensive capture of harm and other (un)desirable outcomes, it can also improve the quality of care through better communication among providers, with patients, and across transitions of care. In practice, enabling disparate information systems to be babe to 'talk' to one another would require interoperability standards, investment in technical R&D, and privacy safeguards. While not easy, this is possible and has been demonstrated in various places (OECD 2015; Oderkirk 2017).

122.   Inviting patients to access this information infrastructure through – for example – their electronic health record, enabling communication with providers and reporting care outcomes and experiences can go some way to boost the patient centeredness and the quality of care. Education and investment in human capital, as always plays a part as an enabler and facilitator of change. Incentives need not be financial – although different payment models to encourage collaboration and coordination of care must form part of the picture – but can also be based on, for example, better and more timely provision of performance data and even financial rewards for collecting and reporting data in a specified format. Where possible incentives should not be punitive, and should avoid publicly singling out providers where possible.

123.   And all of these strategies require – and contribute to – building a safety culture and a spirit of collaboration. None of this is possible without leadership from policy makers, from clinicians and providers, from administrators. Of course patients must be invited to lead and be involved at all stages of the process.

Box 4.1. Examples of national efforts to improve safety in primary/ambulatory care

The Norwegian Ministry of Health has launched several initiatives to promote patient safety in recent years. One of these initiatives is to develop standardised patient pathways for patients with complex needs. Experts and specialists from primary and hospital care work together in 'knowledge networks', which has resulted in the development of standardised patient pathways for the following patient groups; elderly, chronically ill and patients receiving mental health care and/or addiction treatment (the patient-types identified previously as being at greater risk of harm). The goal of this work is to ensure continuity of care for patients with complex needs, as well as improve overall quality and safety of the care provided.

Slovenia's Family Medicine Model Practice is regarded as a promising step in improving quality of care for those with complex needs and polypharmacy patients. The Family Medicine Model Practice provides a systematic multi-disciplinary team approach to patient care. Particularly for patients who use more than eight medications, the model practice offers regular consultations with a clinical pharmacist, to monitor medication adherence, control for drug interaction and improve medication safety.

Education and access to information are another two areas where countries have increased efforts to improve patient safety in primary and ambulatory settings. In Japan, patient safety courses and leaflets raising awareness of patient safety in primary and ambulatory settings have been provided to primary care practitioners. In Sweden, health registries comprising patient-level data on diagnostics, outcomes and patients' perspective have been of great importance to improve patient safety in primary and ambulatory settings. The health registries have contributed to the development of new treatment methods, compliance with treatment programmes, detection of inappropriate care and updating clinical guidelines.

5. Summary of findings and recommendations

124.   Most health activity across the world occurs in the primary and ambulatory care sector. This setting is rightly regarded as the entry point, the foundation, and the key to high-quality, sustainable health systems in most developed and developing countries. Safe primary and ambulatory care improves the health and wellbeing of individuals, communities and societies. It also has financial and economic benefits. Conversely, unsafe care has negative health, economic and social implications.

125.   This report examined the safety in primary and ambulatory care from an economic perspective – in terms of the (a) costs of unsafe care from a financial, economic and burden of illness perspective, and (b) potential strategies to improve safety across the sector in a resource-constrained environment. Given the unique nature of this setting – in contrast to hospital and long-term care – a broad and longitudinal definition of safety is adopted. Patient harm can result from a single incident, but can also develop over time through delayed diagnosis or treatment. The report was informed by a literature scan and a survey of 26 experts in patient safety from a total of 29 countries.

126.   The first finding is that – compared to the hospital setting – very little is known about the occurrence and the impact of patient harm in primary/ambulatory care. There are many reasons for this. The fragmented nature of this setting in most countries, the lack of overarching governance structures, and the accompanying absence of a central information repository, make it difficult to capture, measure and compare harm. Given the more integrated and comprehensive data infrastructure in hospitals, safety in that setting is potentially seen as more inviting for researchers.

5.1. Occurrence of harm is high in primary and ambulatory care

127.   Despite these difficulties, a number of highly innovative studies have examined safety in primary and ambulatory care. But the lack of consistent data and a range of methods used to measure harm have delivered very wide-ranging results. Systematic reviews suggest that safety lapses occur between **1 and 24 times in every 100 primary/ambulatory care consultations**. The harm most commonly stems from diagnostic errors (and subsequent delays in treatment or therapy) and adverse drug events (ADEs). The literature suggests that the frequency of harmful events in these categories may be as high as **30%** and **20% of the general population** respectively. Approximately 70% of all harmful incidents are due to administrative error, with poor communication and information transfer playing a major part.

128.   Survey results are equally varied. Respondents suggested that the occurrence of harm ranges from **2-35% of patients**, **0.1-10% of patient encounters**, and **1-20% of the general population** over time in developed countries. In LMICs the occurrence was assessed to be equally varied but higher, approaching **25% of the population** and **40% of patients**. Some studies suggest that the occurrence of harm – especially from diagnostic errors may be vastly underestimated. About 5% of adults in the United States will experience a diagnostic error each year. Put simply every adult in the United States will experience at least one diagnostic error in their lifetime.

129.   The health consequences of diagnostic error can be grave, but the sequelae of harm are generally lower in the primary and ambulatory setting than in acute care. However, given the volume of health care delivered in this setting (**8 billion encounters per year in the**

OECD alone) the aggregate amount of harm is a significant issue. Harm in primary and ambulatory care may be less visible compared to harm related to hospital based interventions such as surgery, <u>but the total impact is not less</u>.[26]

130.   Patients with complex clinical and biopsychosocial needs are at greater risk of harm. As populations age and become more complex the risk of harm in the primary and ambulatory care setting – where a growing number of these patients will be treated - will rise. It follows that the clinical and economic consequences of harm will also grow unless concrete and systematic action is taken.

131.   Estimates of the preventability of harm vary greatly, ranging from 23-85% depending on the type of harm. But it can generally be assumed that **at least 50% of harm is preventable** given the knowledge and technology at a given time. Patients with complex clinical and social needs, polypharmacy and social/geographic isolation are at much greater risk of suffering harm.

5.2. The disease burden exerted by patient harm in primary and ambulatory care is comparable to some cancers or typhoid fever

132.   Based on findings in the literature and the snapshot survey, it can safely be assumed that half of the global burden of patient harm (which can be compaed to that of malaria and tuberculosis) originates in primary and ambulatory care. This translates to **10-17.5 DALYs per 100,000 population** on average in OECD countries. The burden can be compared to **some cancers**. In the developed world, the burden can be compared to that of **typhoid fever**. However, given that the extent of harm in this setting very likely to be an underestimate, this figure (and therefore the aggregate, global figure) is probably higher.

133.   Harm in the primary/ambulatory setting creates additional healthcare activity thus exerting a direct cost on health systems. Adverse drug events (ADEs) alone generate over **100,000 hospitalisations per year** in the United States. In Sweden, the direct cost of ADEs may be as high as **2.5% of total health expenditure**. In the United Kingdom, ADEs may account for **4% of hospital capacity** at an estimated cost of **EUR706 million** each year.

134.   Safety lapses in primary/ambulatory care most often result in hospital admission - the most significant source of direct costs. Hospitalisation for five common chronic conditions[27] that can be managed in the primary/ambulatory setting account for a substantial proportion of hospital resources. The headline figure is approximately **6% of all bed days** across a panel of 27 OECD countries. Cumulatively this adds up to over **6.6 million typical admissions** each year. Including other chronic conditions for which hospitalisation should be the exception, and the remaining OECD countries for which admissions data were not available, would inflate this figure **beyond 7 million.**

135.   While not all of these hospitalisations may be avoidable, even halving the impact still amounts to a considerable amount of resources. Counting only the 50% 'shortest' admissions for these five chronic conditions (a proxy for avoidability) can still amount to more than **USD300 billion** across the OECD.

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[26] The ubiquity of care in this setting is highlighted in the fact that harm can be measured as a percentage of the population (as opposed to patients or consultations).

[27] Diabetes, hypertension, heart failure, COPD/Bronchiectasis, asthma.

136.   Of course the costs of harm flow beyond the health system. These costs are difficult to model accurately, but one study suggests that the societal costs of harm could be up to **3% of GDP** of a Nordic country. Lost productivity due to safety lapses in patients with chronic disease could result in a **reduction of 0.5% of national GDP**.

137.   Much less is known about the costs of harm in LMICs but given the evidence on occurrence and severity of harm, one can assume that the costs on health system and on society are comparable to those in developed countries.

5.3. Cohesive policy and leadership are needed to improve safety in this setting

138.   The key challenges to improving safety in both developed and LMICs relate to the fragmented nature of primary and ambulatory care, no integration of information and measurement systems, and under-resourcing. These challenges cannot be overcome without leadership, co-ordination and culture change. Figure 5.1 illustrates the key elements that can help improve safety in this setting in a cost-effective manner.

Figure 5.1. Key elements for improving safety in primary and ambulatory care at national level

Source: The authors

139.   The most important and pressing policy action is implementing an **integrated information infrastructure** that enables (a) capture of adverse events and harm across settings and over time, (b) information to flow freely between providers and patients across different data platforms, and (c) a multi-modal approach to reporting harm that includes **reporting by patients.**

140.   An **integrated electronic health record** system that allows interoperability across data platforms and can be accessed by providers and patients across all health settings was

seen by survey respondents as the 'best buy' intervention. Such a system would go some way to addressing several of the challenges of the primary/ambulatory sector (particularly fragmentation). The information infrastructure must be equipped not only to capture harm but also to ensure that meaningful action can be taken. Data security and protection of privacy must be a priority of this implementing such a system.

141.　　　　Stronger **governance and oversight** of the sector is required. The most practical way is to implement national safety standards linked to accreditation for providers and facilities. Provider education in safety principles and quality of care is – as always – very important. And incentives to improve care coordination and work in clinical teams must also be part of the policy mix. This may include new funding models but non-financial incentives to integrate care across providers and patients are also important. Solutions for workforce shortages – such as task substitution – should also be entertained.

142.　　　　At the practice level, the **involvement of patients in their care *and* in the measurement and reporting of harm and other outcomes** of their care is the most resonant finding of this report. Both the literature and the survey findings suggest that patient empowerment is one of the leading strategy and intervention to improve safety. Patient involvement can be achieved through *inter alia* shared decision making, open medical records, and systematic patient-reported measurement of outcomes and experience of care. In the LMIC context the picture was slightly different. Education and patient empowerment are also key, but equally important are broad-based **health literacy programmes** and **universal access to care**. Safety and universal access must, however, be bedfellows.

143.　　　　In all contexts, implementing and sustaining these changes requires a buoyant safety **culture focused on collective improvement and teamwork**. This can only be achieved with leadership at all levels of the health system. This includes **political leadership**. Due to the high visibility of safety failures, pragmatic and political reasons exist for reducing harm across a health system.

144.　　　　Committing to safety - and achieving the goals - can **produce a political dividend** as expressed in the *Patient Safety 2030 Report*: "*Few issues are more upsetting to members of the public than the idea that they could be harmed while under the care of a healthcare provider. In many countries, failures in this area are the only instances in which healthcare is discussed on the front pages of newspapers or on television. Committing to improving patient safety, and achieving this goal, can be a winning political proposition for politicians.*" (Yu et al 2016)

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Annex 1. OECD Snapshot survey 2018

145.   As with the report prepared for the Bonn summit of 2017, this report is partly based on a snapshot survey of nominated and identified experts in the area of patient safety. The 2017 survey focused on the best ways to improve patient safety across all settings of health care. Given the paucity of evidence on primary and ambulatory care, the survey informing this report also asked about occurrence, severity and impact of safety lapses as well as the best ways to improve safety in this setting. The survey was developed by the authors and sent out in December 2017. Twenty-six responses were received (Table 0.1).

Table 0.1. Survey respondents

Respondent name	Institution	Nominated by
Braithwaite, Jeffrey Mumford, Virginia	Australian Institute of Health Innovation, Macquarie University	OECD
DeBrujne, Martine	VU University, Department of public and occupational health & Amsterdam Public Health research institute	OECD
Hamilton, Michael	Institute for Safe Medication Practices Canada	Canada
Koizumi, Shunzo	Saga University, Japan	OECD
Seifert, Bohumil	First Medical Faculty, Charles University, Prague	Czech Republic
Singh, Hardeep	Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine	OECD
Kossey, Sandi	Canada Patient Safety Institute	Canada
Mudronka, Francisek	Ministry of Health	Czech Republic
Májek, Ondřej Pokorná, Andrea	Institute of Health Information and Statistics	Czech Republic
Raid, Ulla	Ministry of Social Affairs	Estonia
Perrin, Michéle	Ministry of Social Affairs and Health	France
Härtel, Ingo	Federal Ministry of Health	Germany
	Directorate of Health by the Ministry of Welfare	Iceland
Arad, Dana	Ministry of Health	Israel
Nagoshi, Kiwamu	Ministry of Health, Labour and Welfare	Japan
Stupele, Liva	Centre for Disease Prevention and Control of Latvia	Latvia
Naujokaitė, Alvyda Jakaitienė, Radvilė	Ministry of Health	Lithuania
Backer, Martine Remy, Philipe	Ministry of Health Directorate of Health	Luxembourg
Wong Leong Kheng, Samuel Cheng, Soon Hooi	Asajaya Health Clinic, Minsitry of Health	Malaysia
García Saisó, Sebastián	General Directorate for Quality of Health and Education, Ministry of Health	Mexico
Batalden, Celcilie Mo	Ministry of Health and Care Services	Norway
Coelho, Anabela	Directorate General of Health	Portugal
Zupančič, Vesna Mate, Tanja	Ministry of Health	Slovenia
Agra, Yolanda	Ministry of Health, Social Security and Equality	Spain
Nylén, Urban	National Board of Health and Welfare	Sweden
Häusler, Elvira	Office for Public Health	Switzerland

Source: OECD Patient Safety Snapshot Survey, 2018

146.   The survey comprised 19 questions, and requested a response to each for lower middle-income countries (LMICs) and for upper-middle and high-income countries

(see Box 0.1). More responses were received for the latter, with respondents citing lack of knowledge and evidence for LMICs to justify a response.

Box 0.1. Income-based classification of countries

Definitions of high-income and low-middle income country are based on World Bank 2018 categories.

Lower middle-income countries (LMICs) are countries with a Gross Domestic Product (GDP) per capita between USD1,006 and USD3,955. Examples: Angola, Bolivia, Georgia, Egypt, India, Moldova, Philippines, Uzbekistan, Ukraine, Vietnam.

Upper middle-income countries have a GDP per capita between USD3,956 and USD12,235. **High-income countries** have a GDP per capita above USD12,235.

Examples (upper middle-income): Argentina, Brazil, China, Costa Rica, Croatia, Iran, Malaysia, Mexico, Peru, South Africa, Turkey.

Examples (high-income): Australia, Austria, Canada, Chile, France, Germany, Japan, Korea, Portugal, Slovenia, Spain, UK, USA.

For more information please visit : https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

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Annex 2. Avoidable hospitalisations - data and methods

147.   The OECD collects information on hospital admissions by ICD category. The data are available at http://stats.oecd.org/. The ICD-10 codes for the five conditions are:

- E10-E14: Diabetes mellitus
- I10-I15: Hypertensive diseases
- I50: Heart failure
- J40-J44, J47: Chronic obstructive pulmonary disease and bronchiectasis
- J45-J46: Asthma

148.   Admission and length of stay (LOS) data were most complete for most (27) OECD countries 2014. The aggregate bed days were calculated by multiplying admissions and average LOS in each country.

Weighting for resource-intensity

149.   Weighting these potentially preventable hospitalisations for resource-intensity against 'typical' admission was performed by examining price weights (complexity adjustments) for the five diagnoses in Australia, where this information is publicly available for the year in question. The weightings were just about 1 for diabetes and for heart failure, and approximately 0.5 for the remaining three (Table A2.1).[28] The price weights are categorised using AR-DRGs (not ICD codes). Weightings for cases without complications and comorbidities (minus CC) were used.

Table 0.2. Complexity weights for AR-DRGs corresponding to the five diagnoses examined

K60B Diabetes	F67B Hypertension	F62B Heart failure	E65B COPD	E69B Bronchitis & Asthma
0.914	0.5825	0.4253	0.9727	0.4869

Source: www.ihpa.gov.au/publications/national-efficient-price-determination-2014-15

Bed-day distribution of the admissions examined

150.   To assess what proportion of these hospitalisations lasted 1 day, 2 days, 3 days and so on, admission data for these five diagnoses - by ICD code for 2013-14 and 2014-15 from one of the countries in the panel of 27 were consulted (these data were supplied by an OECD member country for R&D purposes).

151.   Distributions for all five have a 'long tail' - with a small but not insignificant proportion of admissions lasting beyond 20 bed days (see Figure xx 'Country A').

152.   One-day (or overnight) admissions were most frequent for diabetes (20%), hypertension (27%) and asthma (35%).The most common LOS for heart failure admissions was 2 and 3 bed days (just over 10% each). For COPD and bronchiectasis 1-, 2- and 3-day admissions each accounted for about 12% of all admissions (36% in total).

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[28] This means that the average admission with a principal diagnosis of asthma, COPD or hypertension consumes approximately half of the resources as a typical hospital admission. Admissions for heart failure and diabetes consume approximately the same amount as a typical admission.

153.　　　　Same-day ('zero' bed day) episodes were also provided. These were the most frequent admissions for diabetes, second-most common in hypertension and asthma, and 3rd and 4th most common in COPD/bronchiectasis and in heart failure admissions respectively. This suggests that the calculations based on OECD data (which do not count same-day admissions) are likely to underestimate the impact on hospital resources.'

154.　　　　The assumption of similar distributions in other countries was deemed inappropriate by comparing those with one other country for which similar (but less detailed) data are publicly available. The distributions for diabetes admissions in these two countries are displayed in Figure 0.1. This suggests quite different approaches to hospital care for diabetes in these two countries, and more importantly dissuades the extrapolation across the entire panel of 27 countries in this study.

Figure 0.1. Diabetes admissions by LOS in two OECD countries
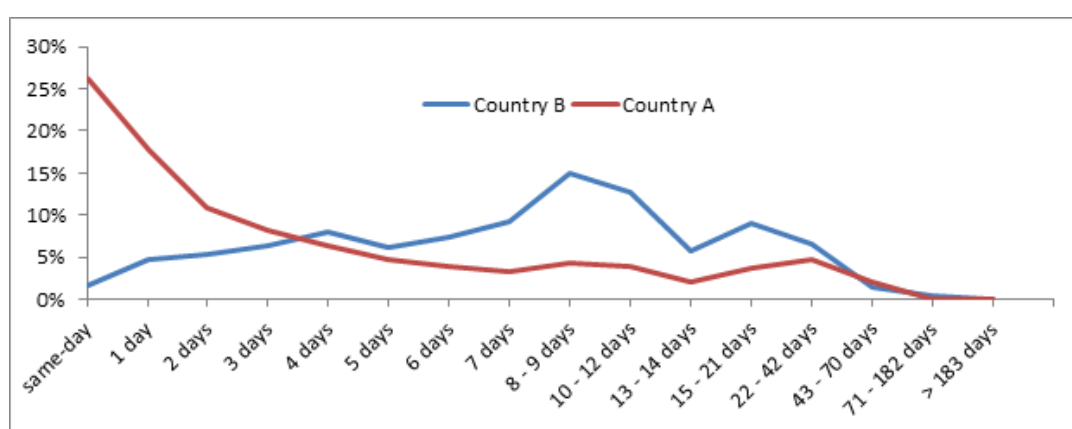
Source: Country A data provided in confidence; Country B http://www.gbe-bund.de/oowa921-install/servlet/oowa/aw92/dboowasys921.xwdevkit/xwd_init?gbe.isgbetol/xs_start_neu/&p_aid=3&p_aid=64271223&nummer=544&p_sprache=D&p_indsp=-&p_aid=72437483