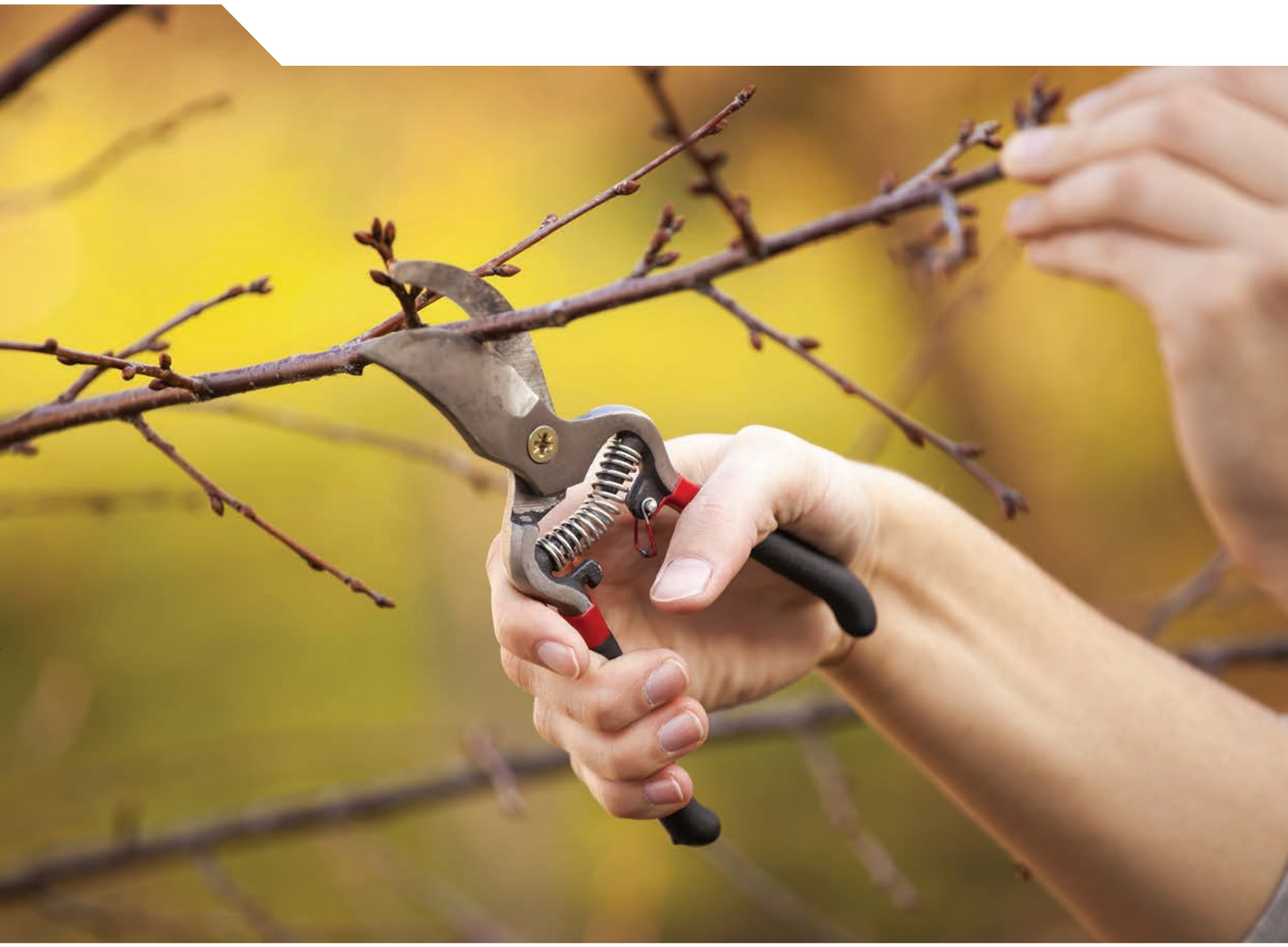
Tackling Wasteful Spending on Health



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Tackling Wasteful Spending on Health

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Foreword

Across OECD countries, a significant share of health care system spending and activities are wasteful at best, and harm our health at worst. One in ten patients in OECD countries is unnecessarily harmed at the point of care. More than 10% of hospital expenditure is spent on correcting preventable medical mistakes or infections that people catch in hospitals. One in three babies is delivered by caesarean section, whereas medical indications suggest that C-section rates should be 15% at most. Meanwhile, the market penetration of generic pharmaceuticals – drugs with effects equivalent to those of branded products but typically sold at lower prices – ranges between 10-80% across OECD countries. And a third of OECD citizens consider the health sector to be corrupt or even extremely corrupt.

At a time when public budgets are under pressure worldwide, it is alarming that around one-fifth of health expenditure makes no or minimal contribution to good health outcomes. Put in other words, governments could spend significantly less on health care and still improve patients' health. Efforts to improve the efficiency of health spending at the margin are no longer good enough.

This report suggests that policy makers can make smarter use of health care budgets and cut waste with surgical precision, while improving patients' health. Actions to tackle waste are needed in the delivery of care, in the management of health services, and in the governance of health care systems. Strategies include stopping spending on actions that do not result in value – for example, unnecessary surgeries and clinical procedures. Swapping inputs or changing approaches when equivalent but less pricy alternatives of equal value exist are valid strategies, too – for example, encouraging the use of generic drugs, developing advanced roles for nurses, or ensuring that patients who do not require hospital care are treated in less resource-consuming settings.

Of course, this agenda is complex and difficult. Change requires challenging embedded habits and vested interests and investing in credible alternatives to existing costly solutions. Crucially, it also requires development of better, more appropriate data systems to monitor progress. Patients, providers, managers and regulators all play a role in generating waste and ineffective spending. With as much as 9% of GDP spent on health care systems across the OECD, three-quarters of which is by governments, all stakeholders must now contribute to the solution. The evidence of waste in health care is indisputable. Now is the time to act upon it.

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Executive summary

Health care systems in OECD countries are better than ever at promoting improved health and longevity, yet they involve major budgetary commitments that countries struggle to keep in check. Pressure is ever-mounting to provide greater and more equitable access to quality care and new treatments to ageing populations.

A significant share of health spending in OECD countries is at best ineffective and at worst, wasteful. One in ten patients is adversely affected during treatment by preventable errors, and more than 10% of hospital expenditure is allocated to correcting such harm. Many more patients receive unnecessary or low-value care. A sizable proportion of emergency hospital admissions could have been equally well addressed or better treated in a primary care setting or even managed by patients themselves, with appropriate education. Large cross-country variations in antibiotic prescriptions reveal excessive consumption, leading to wasted financial resources and contributing to the development of antimicrobial resistance. The potential for generic medicines remains underexploited. Finally, a number of administrative processes add no value, and money is lost to fraud and corruption. Overall, existing estimates suggest that one-fifth of health spending could be channelled towards better use.

This report takes a systematic approach to: i) identifying ineffective and wasteful activities within health care systems; ii) analysing their causes and the actors involved; and iii) providing a catalogue of suitable countermeasures. Acknowledging the existence of ineffective spending and waste might not be easy for health workers, managers and even the politicians responsible for health care systems. But this report highlights the positive corollary to this difficult admission: opportunities exist to release resources within the system to deliver better value care. Cutting ineffective spending and waste could produce significant savings – for policy makers struggling to cope with ever-growing health care expenditure, the opportunity to move towards a more value-based health care system is one that must be pursued decisively.

This report pragmatically deems as "wasteful": i) services and processes that are either harmful or do not deliver benefits; and ii) costs that could be avoided by substituting cheaper alternatives with identical or better benefits. Linking actors – patients, clinicians, managers and regulators – to key drivers of waste – errors and suboptimal decisions, poor organisation and co-ordination, incentives misaligned with health care system goals, and intentional deception – helps to identify three main categories of wasteful spending:

- Wasteful clinical care covers avoidable instances when patients do not receive the right care. This includes duplicate services, preventable clinical adverse events – for instance, wrong-site surgery and many infections acquired during treatment – and low-value care – for instance, medically unnecessary caesarean sections or imaging.

- Operational waste occurs when care could be provided using fewer resources within the system while maintaining the benefits. Examples include situations where pharmaceuticals or medical devices are discarded unused or where lower prices could be obtained for the inputs purchased (for instance, by using generic drugs instead of originators). In other instances, costly inputs are used instead of less expensive ones, with no additional benefit to the patient. In practical terms, this is often the case when patients seek care in emergency departments, end up in the hospital due to preventable exacerbation of chronic disease symptoms that could have been treated at the primary care level, or cannot be released from a hospital in the absence of adequate follow-on care.
- Governance-related waste pertains to resources that do not directly contribute to patient care. This category comprises unneeded administrative procedures, as well as fraud, abuse and corruption, all of which divert resources from the pursuit of health care systems' goals.

All OECD countries are already seeking to tackle waste. At least 10 countries produce atlases to identify variations in health care activities that may not be medically justified, and 19 countries use Health Technology Assessment (HTA) to help determine the value of some new treatment options. Nearly half of OECD countries are actively striving to promote greater prescription of generic drugs. At least 14 countries have strengthened access to primary and community care services to divert inappropriate visits from emergency departments. To date, though, only a few have set up comprehensive and transparent adverse event reporting systems, which encourage learning and foster prevention of future problems, or systematic approaches to detecting fraud and abuse. Overall, significant opportunities still remain for more systematic efforts.

Better information is key. Generating and publishing indicators (such as those on unnecessary or low-value care, overprescription of antibiotics, and delayed hospital discharges) is required to bring the scale of the problem to the attention of a wider public. Today, no country can report on the unnecessary use of magnetic resonance imaging for low back pain and only five can link antibiotic prescription to diagnostics. Data on delayed discharges are available for only three countries. Such data are needed to inform policies to target waste through regulations, incentives, and organisational and behavioural changes.

Sustainable change can be achieved if patients and clinicians are persuaded that the better option is the least wasteful one. Approaches such as the *Choosing Wisely®* campaign illustrate what is possible. This clinician-led initiative aims to reduce low-value care by encouraging patient-provider conversations about whether specific services truly add value. It is now active in at least a third of OECD countries. Changing habits is often a necessary and key way to tackle waste – whether to improve adherence to clinical guidelines, increasing the safety of care, or to convince patients not to rush to the emergency department or request antibiotics at the first sign of a cold.

Incentives also matter. Policy makers should create an environment that rewards provision of the right services rather than their quantity – for example, by moving towards payment systems that promote value for patients across the stages of care delivery. As many as a third of OECD countries already seek to reward different types of providers for results achieved rather than for the number of interventions. To reduce the incidence of unnecessary health care services and wasteful failures in co-ordination, a handful of payers, most notably in the United States but also in Sweden, Portugal and the Netherlands, have moved towards bundled or population-based payments, with some promising results.

In addition, direct interventions to prompt organisational changes and co-ordination among providers are required to reduce wasteful spending. Good practice examples include the development of explicit discharge planning – seen in at least five countries – or the joint procurement of hospital pharmaceuticals. Many revolve around ICT-enabled sharing of information among different stakeholders – although efforts to develop a more complete picture of the full care pathways can be impeded by inadequate health data governance frameworks. Finally, regulation can have a role to mandate or expand desired practices – such as the use of HTA in coverage decisions, or accreditation to impose safety standards – or to ban undesired ones – for instance, self-referrals or inappropriate marketing.

Strategies to reduce waste can be summed up as: i) stop doing things that do not bring value; and ii) swap when equivalent but less pricy alternatives of equal value exist. While these solutions may not always require profound remodelling of health care systems, they do involve investment and behavioural changes. Substantial room exists to release resources by tackling health care system waste across the OECD.

Acronyms and abbreviations

ACA	Affordable Care Act
ACSCs	Ambulatory Care Sensitive Conditions
AHRQ	Agency for Healthcare Research and Quality
ALOS	Average length of stay
AMR	Antimicrobial resistance
CDC	Centers for Disease Control and Prevention
CHF	Congestive heart failure
CME	Continuing medical education
CMS	Centers for Medicare & Medicaid Services
CNAMTS	Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés
CoI	Conflict of interest
COPD	Chronic obstructive pulmonary disease
CPOE	Computerised physician order entry
CT	Computed tomography
DDD	Defined daily dose
DRG	Diagnosis-related group
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ED	Emergency department
EHR	Electronic health record
EMEA	European Medicines Agency
FFS	Fee-for-service
GDP	Gross domestic product
GP	General practitioner
HHS	Department of Health and Human Services (United States)
HMO	Health Maintenance Organisations
HTA	Health Technology Assessment
ICER	Incremental cost-effectiveness ratio
ICT	Information and communications technology
IHI	Institute for Healthcare Improvement
INN	International Non-proprietary Name
IOM	Institute of Medicine
LTC	Long-term care
MRI	Magnetic resonance imaging
MRSA	Methicillin-resistant *Staphylococcus aureus*
NHA	National Health Accounts
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OOH	Out-of-hours

P4P	Pay-for-performance
PCP	Primary care physician
PHI	Private health insurance
PPP	Purchasing power parity
PREM	Patient-Reported Experience Measure
PRIM	Patient-Reported Incident Measure
PROM	Patient-Reported Outcome Measure
QALY	Quality-adjusted life-year
RDT	Rapid microbial diagnostic test
SHI	Social health insurance
WHO	World Health Organization

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Chapter 1

Ineffective spending and waste in health care systems: Framework and findings

by
Agnès Couffinhal *and* Karolina Socha-Dietrich

This chapter presents the overall framework and approach that guided development of the report as well as its main findings. Starting with a simple and pragmatic definition of waste, the first section identifies and groups various categories of waste. This framework is later used to identify policy levers to tackle these different types of waste. The next three sections provide an overview of the report's findings regarding wasteful clinical care, operational waste and governance-related waste, respectively. The concluding section points to the benefits of tackling different categories of waste and presents the organisation of the overall report.

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The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Introduction: Why tackling waste is an effective value-enhancing agenda for health care systems

Most people involved in the health care system – policy makers, managers, workers and even patients – have opinions on how additional resources could be used efficiently to deliver better health services. Health Technology Assessments (HTAs) reveal which new treatments are better than old ones and should be accessible. Operational data indicate where services are overstretched. Investments in e-infrastructure are postponed due to lack of funding. Give a health minister an extra billion euros, a hospital administrator an extra 10 million, or a general practitioner (GP) an extra 10 000, and each will – probably – spend the money wisely and improve health services.

But it is a different matter when the same people are asked to take money *out* of the system to prevent the escalation of health expenditure. Introduction of new treatments is rarely accompanied by disinvestment in older inferior ones. Regional authorities or managers struggle to close down or merge hospitals to realise the economies of scale that could improve quality and reduce costs. Patients insist on extra tests or prescriptions just "to be sure", just to get back to work faster, ignoring the risks to their own health and despite the lack of evidence that they would make a difference. Yet to keep public budgets in check, policy makers have to decide how to curb health expenditure.

Analysts – especially in the context of the response to the global financial crisis of 2008 – often distinguish between cost-cutting measures and structural reforms (Clements et al., 2014). The former may have proven effective but can be unsustainable or even detrimental to outcomes. For instance, cuts in public health expenditure undermine efforts to prevent the onset of diseases; increases in co-payments have impoverishing effects. On the other hand, structural reforms are expected to increase efficiency and eventually "bend the curve" of public expenditure growth (Coady et al., 2014; OECD, 2015a). Without denying their necessity, the reality is that many structural reforms require complex changes on multiple fronts and sustained efforts, and evidence on their impact, especially in the short run, is weak.

This report contends that in the current debate on the choice between cost-cutting measures and structural reforms, an often missing piece is tackling ineffective spending and waste. In fact, cutting waste is an intermediate objective worth pursuing as it can: i) bring strategic savings; ii) support a transformative focus on value in health care systems; and iii) substantially contribute to enabling long-term structural reforms.

Health care systems should deliver care that maximises value for patients. The vast majority of OECD citizens can access the care they need, in a timely way, without incurring disproportionate out-of-pocket costs. Life expectancy at birth is now over 80 years and OECD citizens are far less likely to die after a heart attack or stroke than they were a decade ago. Although the prevalence of chronic conditions like diabetes is rising, health care systems are getting better at effectively managing them and reducing harmful complications.

Yet a significant share of health spending makes only a modest contribution to improving patient outcomes. Worse, some health resources are not just spent on low-value care, they are wasted (Box 1.1 presents country-specific estimates). Acknowledging this may not be easy for health care system actors but this report highlights the positive corollary to this difficult admission: opportunities most certainly exist to release resources within the system to deliver better-value care. In other words, cutting ineffective spending and waste can produce significant savings – a strategic move for policy makers. In addition, it mobilises stakeholders around the transformative value-based agenda many commentators argue must drive reforms (Porter and Teisberg, 2006). The report highlights that many "waste-tackling" policies are consistent with – and in fact pave the way for – longer-term structural reforms.

Box 1.1. **Country-specific estimates of potential savings from eliminating waste**

- A conservative estimate suggests that waste represents more than 20% of total expenditure in the United States, with an upper bound nearing 50% (Berwick and Hackbarth, 2012).
- An investigation suggested that nearly one-third of total health expenditure in Australia could be deemed wasteful (Swan and Balendra, 2015).
- A study in the Netherlands estimated that 20% of the budget for acute care could be saved by reducing overutilisation and increasing integration of care (Visser et al., 2012).

This chapter presents the overall framework and approach that guided the report's development as well as its main findings. Starting with a simple and pragmatic definition of waste, the first section identifies three main categories of waste. This framework later helps to identify policy levers to tackle these different types of waste. The next three sections provide an overview of the report's findings regarding wasteful clinical care, operational waste and governance-related waste, respectively. The final section briefly concludes and presents the organisation of the overall report.

1. Framing "waste": Definition, classification of wasteful activities, and policy options

The case that a significant share of health care spending can be deemed wasteful was first systematically argued less than ten years ago (New England Healthcare Institute, 2008; Bentley et al., 2008; Berwick and Hackbarth, 2012). But these US-centred analyses, or subsequent ones, provide neither a simple definition of waste nor a consistent classification of wasteful activities conceptualised in a way that can be transposed across health care systems. Moreover, no agreement exists among authors about how waste and efficiency relate. This brief section defines waste and presents three main categories of wasteful activities; these are identified by linking health care system actors involved in generating waste to reasons why they might do so. This approach helps organise categories of policy options to tackle waste.

This report pragmatically deems as "wasteful":

- services and processes that are either harmful or do not deliver benefits
- costs that could be avoided by substituting cheaper alternatives with identical or better benefits.

This characterisation covers health care spending that could be eliminated without undermining achievement of health care systems' objectives. At the level of the health care system, this roughly corresponds to the notion of "productive efficiency", which describes a situation where a given result is obtained at the lowest possible cost. Tackling waste – as defined here – thus does not require rationing or systematically reallocating resources from one category of patients to another or even from one category of care to another. In other words, the "waste" policy agenda does not expand to the broader question of whether a different combination of inputs could bring better aggregate results (allocative efficiency and redistribution). Waste is a category of inefficiency but not all inefficiencies constitute waste.[1]

Wasteful activities involve different stakeholders in the health care system and occur for various reasons. Using these two dimensions to characterise each type of wasteful activity, the framework proposed distinguishes three categories of waste. Actors potentially involved in generating waste fall into four categories: patients, clinicians, managers (who operate at the level of a facility or at a more macro level – e.g. in health care system administration)[2] and the system regulator (this can be a single entity or many). These actors have different objectives and incentives but overall the health care system's organisation should align their behaviours so they contribute to achieving the health care system's goals.

Four main reasons can explain why individual actors might contribute to wasting resources:

- First, they do not know better: cognitive biases, knowledge deficits, risk aversion and habits lead to suboptimal decisions and errors and deviations from best practice.
- Second, they cannot do better: the system is poorly organised and managed and co-ordination is weak.

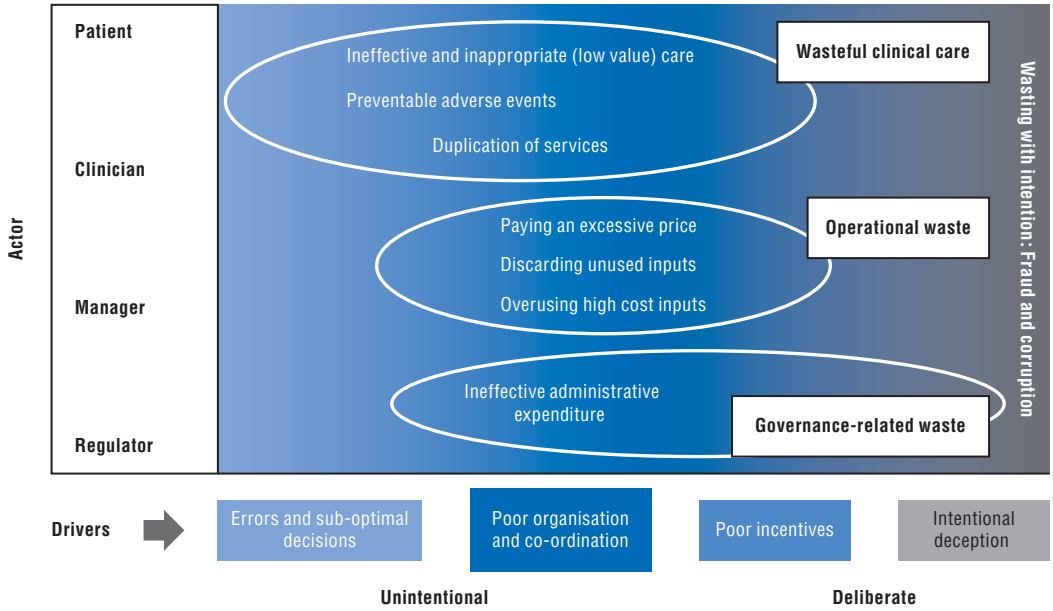
In these first two situations, for the most part, actors do not intend to generate waste and are doing their best but the outcome is suboptimal:

- Third, actors could stand to lose by doing the right thing; this occurs when economic incentives are misaligned with system goals – for instance, when clinicians are paid for providing services irrespective of whether the services add value.
- Fourth, all categories of actors might generate waste intentionally, with the sole purpose to serve their self-interest. This last driver is in fact a variation on the third (poor incentives) but it more explicitly points to fraud and corruption.

Linking actors and drivers, Figure 1.1 helps identify three categories of waste: wasteful clinical care, operational waste and governance-related waste:

- Wasteful clinical care covers instances when patients do not receive the right care. This includes preventable clinical adverse events, driven by errors, suboptimal decisions and organisational factors, notably poor co-ordination across providers. In addition, wasteful clinical care includes ineffective and inappropriate care – sometimes known as low-value care, mostly driven by suboptimal decisions and poor incentives. Last, wasteful clinical care includes the unnecessary duplication of services.
- Operational waste occurs when care could be produced using fewer resources within the system while maintaining the benefits. Examples include situations where lower prices could be obtained for the inputs purchased, where costly inputs are used instead of less

Figure 1.1. **Three categories of waste mapped to actors involved and drivers**



expensive ones with no benefit to the patient, or where inputs are discarded without being used. This type of waste mostly involves managers and reflects poor organisation and co-ordination.

- Governance-related waste pertains to use of resources that do not directly contribute to patient care, either because they are meant to support the administration and management of the health care system and its various components, or because they are diverted from their intended purpose through fraud, abuse and corruption. It thus comprises two distinct types of waste. The first is administrative waste, which can take place from the micro (manager) to the macro (regulator) level. Again, poor organisation and co-ordination are the main drivers. Second, fraud, abuse and corruption, which divert resources from the pursuit of health care systems' goals, are also wasteful. Any of the actors can be involved, and in fact, a comprehensive analysis of the topic requires the inclusion of businesses/industries operating in the health sector. In any case, the intention to deceive is what primarily distinguishes this last type of waste.

At a strategic level, two broad options are available to tackle waste: i) stop doing things that do not bring value; and ii) swap when equivalent but less pricy alternatives of equal value exist.[3] Presenting evidence-based options for governments to release misspent resources is challenging. Countries' experiences and track records in identifying, measuring and explicitly dealing with the various types of waste reviewed are very uneven and not systematically documented. To fill this gap, a policy questionnaire was sent to OECD countries.[4] The report draws heavily on the countries' responses, as well as on published documents from all OECD countries. In many instances though, evidence on the impact of policies remains limited or mixed and is highly context-specific.

Operationalising the waste-tackling agenda requires more generation, publication and use of information. Information is the basis of evidence-based leadership but is also important in the design of specific policies that use other policy levers.

In parallel, policies that target the actors involved in the generation of waste and address the drivers of their behaviours are needed. Four categories of policy levers are relevant:[5]

- Economic and financial incentives that seek to influence the behaviour of patients, clinicians or managers; these are most relevant when poor incentives are the root cause of the wasteful behaviour.
- Behaviour change policies and information support – including education, persuasion and training – to address barriers to optimal decisions.
- Organisational changes, which include policies that modify the location, role, number, co-ordination and tools available to accomplish specific tasks of various stakeholders.
- Regulations to mandate changes in behaviour, organisation or information.

The following sections of this chapter present the main findings of the report on wasteful clinical care, operational waste and governance-related waste in turn. Each section clarifies and provides examples of waste, elaborates on the root causes, and summarises available evidence on the magnitude of the problem and the challenges related to measuring it. Finally, it highlights strategies to tackle waste and groups them using the categories of levers they involve.

2. Wasteful clinical care: When patients do not receive the right care

Wasteful clinical care refers to situations when patients do not receive the right care, for reasons that could be avoided. It comprises preventable adverse events that lead to patient harm as well as low-value care.

2.1. Care that adds little value or is even harmful is not rare

Adverse events are devastating for patients, wasteful for health care systems and often preventable

Adverse events threaten patient safety. The Harvard Medical Practice Study (Brennan et al., 1991) defined an adverse event as "an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalisation, produced a disability at the time of discharge, or both". In a similar vein, the Institute for Healthcare Improvement defined an adverse event as "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment, or hospitalisation, or that results in death" (*www.ihi.org*). A "clinical error" may lead to an adverse event or may not, if detected in time or simply through good fortune (Reason, 2000).

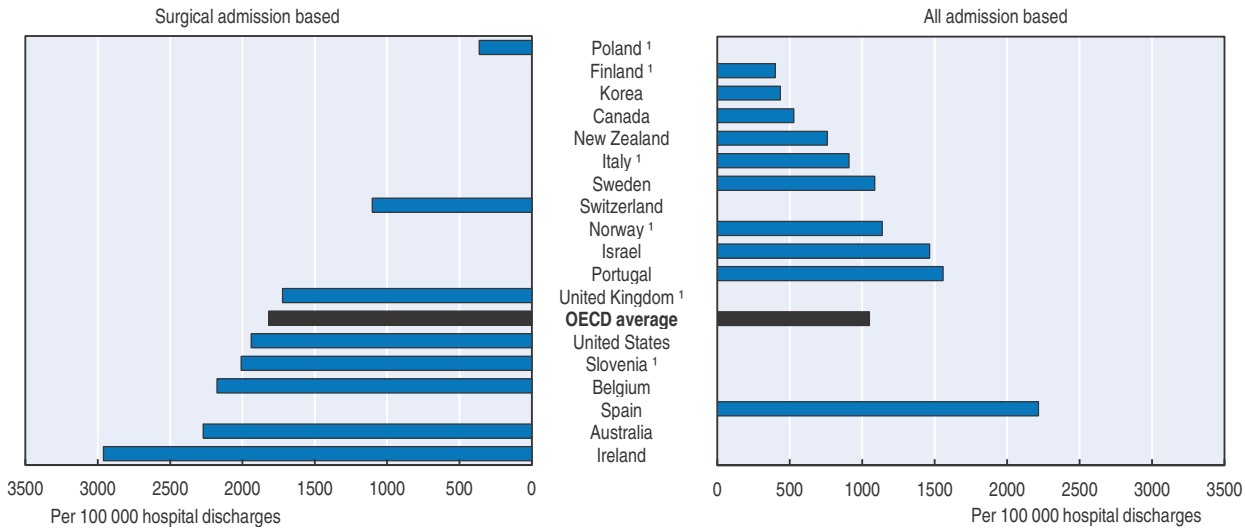
Despite providers' best intentions, preventable adverse events persist in health care systems. The delivery of care inherently involves risk and, as such, may lead to adverse events. Some unexpected or undesirable outcomes are not avoidable and should not be defined as waste. However, adverse events are frequently preventable. The most striking occurrences of avoidable adverse events are the so-called "never events" or "sentinel events", which should never occur and are always preventable. These rare events include the failure to remove foreign bodies after surgery and operating on the wrong site on a patient's body, such as removal of the wrong kidney. However, health care-associated infections, medication errors and post-operative complications such as blood clots are much more frequent and, to a large extent, preventable. Preventable adverse events often lead to morbidity and mortality in patients as well as costs to payers for additional health care services.

Available numbers suggest that the magnitude and costs of adverse events are significant:

- A recent report suggesting that medical errors might be the third cause of death in the United States starkly calls attention to the problem (Makary and Daniel, 2016).
- International studies indicate that adverse events in hospitals add between 13% and 16% to hospital costs (Jackson, 2009) and that between 28% and 72% of them are considered avoidable upon expert examination (Brennan et al., 1991; Rafter et al., 2016, among others).
- Data on primary care are scarce, but the Primary Care International Study of Medical Errors showed that approximately 80% of errors could be classified as "process errors", the vast majority of which are potentially remediable (Makeham et al., 2002).

The OECD collects data on four adverse events (Figure 1.2). Numbers show close to a ten-fold variation in the reported rates across health care systems. It is extremely unlikely that these figures reflect "real" variations; rather they illustrate the enormous differences in the willingness of individuals in different systems to admit that mistakes were made.

Figure 1.2. **Postoperative sepsis in abdominal surgeries, 2013 (or nearest year)**



Note: Rates have not been adjusted by the average number of secondary diagnoses. The OECD average includes eight countries (left panel) and ten countries (right panel).

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

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933443941

Avoidable adverse events are driven by errors and suboptimal decisions as well as organisational shortcomings that allow them to happen. Examples include clinicians' failures to follow standard practice (negligence) that are not detected early enough, or organisations' failure to establish such practices and familiarise personnel with them. Similarly, failures in communication between medical staff can lead to adverse events but only in the absence of systems that make such failures visible and then intercept them.

Low-value care can occur at all stages of the care pathway

The vast majority of clinicians strive to select the care best adapted to each patient and ideally they are mindful of cost. Low-value care refers to situations when these

objectives are not met. Low-value care comprises ineffective care, i.e. interventions not proven to bring clinical value, and interventions for which the risk of harm exceeds the likely benefit. It extends to inappropriate care: interventions that can be effective for specific patient groups but are performed in a way that either does not conform to evidence-based clinical guidelines or does not reflect patients' preferences. Factoring costs in, low-value care also includes interventions that provide marginal or no health benefit over less costly alternatives and more broadly, care whose benefit is disproportionately low compared to the costs – in other words, not cost-effective.

Low-value procedures can be found at all stages of the care pathway, starting with overtesting, which refers – for instance – to the excessive or premature use of imaging (for low back pain, headaches). It can lead to overdiagnosis – the diagnosis of a person with a condition that will not cause harm. For instance, a Cochrane review found for every 2 000 women invited for breast cancer mammograms during ten years, one will have her life prolonged and ten healthy women will be treated for cancer unnecessarily (Gøtzsche and Jørgensen, 2013), implying that a more targeted approach to screening may be necessary. Other instances of low-value care include unnecessary surgical interventions (e.g. unwarranted caesarean sections, knee arthroscopy for osteoarthritis). An analysis of Australian hospitals revealed that five procedures not supported by clinical evidence took place more than 100 times a week. The five "do-not-do" procedures were: vertebroplasty for painful osteoporotic vertebral fractures; knee arthroscopy for osteoarthritis; laparoscopic uterine nerve ablation for chronic pelvic pain; removal of healthy ovaries during a hysterectomy; and hyperbaric oxygen therapy for a range of conditions including cancer, Crohn's disease and cerebrovascular disease (Duckett et al., 2015). Medicines can also be involved. The prescription of antimicrobials[6] is a perfect example of a life-saving treatment whose inappropriate use is not only wasteful but poses a systemic threat to society's health (Box 1.2).

Low-value care is nowhere fully quantified, but the extent of the problem is undeniable. Geographical variations in clinical patterns are the main and most powerful tool offering insights into the magnitude of waste due to low-value care. Indeed, the considerable variations observed in the quantity of care delivered to patients cannot be explained by demand factors, such as morbidity and socio-economic differences, or by supply factors, such as accessibility of particular interventions or diagnostic tools. A 2014 OECD study reviewed geographical variations within and between 13 countries for ten procedures. Rates of cardiac procedures varied more than three-fold between countries and up to six-fold within-country. Rates of knee replacements varied more than five-fold between different regions in Canada, Portugal and Spain (OECD, 2014). It is difficult to imagine that these variations reflect differences in need. Rather, individuals in some regions must receive interventions that in other regions are considered unnecessary, or else severe underprovision of services occurs in those regions with the lowest intensity of interventions.

The drivers of low-value care are primarily suboptimal decisions interacting with incentives that are misaligned with health care systems' goals. Discrepancies between how care should be delivered as prescribed by guidelines and how care is delivered in practice can be driven by knowledge deficits, cognitive bias, or resistance to changing traditional practice, despite evidence that an old practice is outdated. The rise of defensive medicine, driven mainly by fear of missing a low-probability diagnosis and fear of litigation, can also fuel overtreatment, notably the ordering of unnecessary tests. Patients' requests for

Box 1.2. **Low-value care with high stakes: Tackling overprescription of antimicrobials**

The inappropriate use of antimicrobials has a detrimental impact:

- Antimicrobial therapies play an essential role in modern medicine but their inappropriate use – a form of low-value care – is the most important factor responsible for increasing levels of antimicrobial resistance (AMR). Excess use in agricultural livestock constitutes another significant portion of the total inappropriate consumption of antimicrobials.
- In recent years, total antimicrobial consumption stabilised or even decreased in some countries but it continues to grow in others, despite growing concerns.
- Inappropriate use of antimicrobials represents about 50% of all antimicrobial consumption by humans (Wise et al., 1998). In long-term care and general practice, however, inappropriate consumption may be as high as 90% of all prescriptions (Wang et al., 2014). Medical conditions at higher risk for inappropriate use include viral respiratory tract infections and urinary tract infections, due to empiric prescribing.
- The economic consequences of inappropriate use of antimicrobials are significant. Large negative externalities are incurred by society as a consequence of the development of AMR. Patients infected with AMR organisms suffer from prolonged and severe morbidity, and increased risk of mortality. In 2007, this expenditure summed to EUR 940 million in Europe while the Centers for Disease Control and Prevention (CDC) calculated that in 2012 AMR cost USD 20 billion in the United States (ECDC and EMEA, 2009; CDC, 2013). Modelling predicts that compared with a world with no AMR, the economic impact associated with current rates of AMR may reach 0.03% of gross domestic product (GDP) in 2020 and 0.16% of GDP in 2050 in OECD countries, a cumulative loss of USD 2.9 trillion (Cecchini et al., 2015).
- Inappropriate antimicrobial consumption is predominantly driven by human factors underpinning the behaviour of physicians (prescription habits) and patients (who insist on an antimicrobial prescription or self-medicate). Organisational barriers, for instance insufficient availability of rapid diagnostic tests (RDTs), might also result in inappropriate prescription of antimicrobials (Cabana et al., 1999).

More rational antimicrobial consumption can be achieved by combining four policy levers.

- Interventions can trigger behavioural changes in the actors involved:
  - Development and implementation of evidence-based clinical guidelines that allow clinicians to benchmark their prescribing in a larger framework of good medical practices and rationalisation of antimicrobial use.
  - Antimicrobial stewardship programmes combining multidisciplinary activities to regulate and persuade both prescribers and the public towards appropriate use of antimicrobials. Activities can include guidelines, monitoring, education and campaigns. Well-designed stewardship programmes can decrease both antibiotic prescription rates (median change up to -40%) and AMR (median change up to -68% of resistance) (Davey et al., 2013). For example, the Kaiser Permanente group in the United States achieved a 45% decrease in some antibiotic prescriptions after implementation of a multifaceted programme targeting prescribers (Epson, 2015).
  - Multimedia campaigns help inform care-seekers of the effects of inappropriate use of antimicrobials. Belgium implemented mass media campaigns targeting the general population as part of a broader strategy aimed at rationalising use of antimicrobials. Between 2000 and 2015 antibiotic use decreased by 39%, producing cumulative savings of about EUR 642.2 million (Goossens, 2015).

Box 1.2. **Low-value care with high stakes: Tackling overprescription of antimicrobials** *(cont.)*

- Organisational changes can help clinicians better target their antibiotic use:
  - Mandating the use of RDTs whenever available allows physicians to make evidence-based judgement on the use, selection and duration/dosage of antimicrobials, and to manage patient expectations on prescription of treatment. According to a Cochrane systematic review and meta-analysis, the use of point-of-care tests can reduce antibiotic prescription by 22% compared to empiric prescribing (Aabenhus et al., 2014). In France, the increase in RDT use produced a 39% decrease in antibiotic prescriptions by participating primary care doctors (Michel-Lepage et al., 2014).
  - Re-organisation of procedures to enforce delayed prescription can be implemented in primary care and outpatient settings to reduce prescribing for cases that can be managed without immediate antimicrobial use.
- Economic incentives targeting providers and care-seekers can steer appropriate antimicrobial consumption:
  - Perverse incentives, such as concurrent prescribing and sales by physicians or pharmacists, should be eliminated by dissociating these functions. Pay-for-performance (P4P) schemes can motivate adherence to specific, tangible and measurable good practice targets. In Sweden, a modest performance incentive closed a third of the gap between existing and targeted prescription rates (Anell et al., 2015).
  - Raising the out-of-pocket cost to patients of antimicrobials that are more likely to be used inappropriately can help but this intervention needs a careful design to avoid unintended impacts. For instance, introduction of a reimbursement cap for fluoroquinolones in Canada produced an 80% decrease in the number of fluoroquinolone prescriptions that was partially offset by an increase in prescriptions for other antibiotics (MacCara et al., 2001).
- Finally, countries should continue to maintain and support development of effective surveillance systems in two directions: monitoring: i) the prevalence of AMR; and ii) trends of antimicrobial consumption. Policy makers should understand how to interpret data depending on the collection strategy (sales versus drug reimbursement), and aim to obtain representative information on the volume, cost and temporal and geographical patterns of antimicrobial use across all relevant disciplines of health care.

additional treatments are another important driver of low-value care. In the patient's mind, "doing nothing" or "doing less" may be indistinguishable from doing harm. The provision of low-value care is driven also by financial incentives, such as case-based payments or fee-for-service (FFS) to providers or coverage of procedures irrespective of the value they bring to patients. Insured patients and providers, represented by both clinicians and facilities' managers who are paid for their services, have no incentive to avoid low-value care.

2.2. Changing behaviours is central to the promotion of high-value care

More and better information is required to scope and curb the incidence of adverse events and low-value care

The transparency and quality of reporting of adverse events remain limited on average. When it comes to adverse events, overcoming the instinct – or even incentives – to underreport incidents is complex. Moving to a culture of transparency requires trust – that

the objectives of data collection are not to assign blame but to learn – and confidence – that lessons will be drawn and corrective actions taken to prevent future occurrences. Such changes require strong and sustained leadership so data collection improves with its use. Not all OECD countries have implemented adverse event reporting and learning systems, and systems usually do not capture adverse events beyond inpatient hospital care – that is, those occurring in outpatient care, in nursing homes or at home. The culture of reporting and learning could usefully be extended to other providers, as in New Zealand, where ambulance services, hospices, and aged residential care organisations and other non-hospital providers are included (Health Quality & Safety Commission New Zealand, 2015).

In the domain of low-value care, substantial progress on data collection has been achieved. At least ten OECD countries use atlases to identify variations in health care activities and outcomes across geographical areas. Overall though, countries are at varying stages of developing indicators and consensus is needed on which indicators to use and how to standardise and interpret numbers. An additional constraint is that assessing the appropriateness of a specific procedure often requires information on conditions (disease codes) and other patient characteristics. Administrative databases seldom include enough details. The OECD is working with the *Choosing Wisely®* campaign (see below) to develop internationally comparable indicators of inappropriate care.

Finally, better integrating patients' perspectives in data systems, and ultimately in decision making, is needed. Identifying wasteful clinical care requires understanding and rating the benefits and negative outcomes of clinical procedures. This is traditionally done from a clinical perspective, but clinicians and patients may have different views and both should be incorporated in decision making. Collecting data directly from patients in the form of Patient-Reported Experience Measures (PREMs), Patient-Reported Outcome Measures (PROMs) and Patient-Reported Incident Measures (PRIMs) can facilitate this. Information from PREMs and PROMs can be used to ensure that patients get care that is aligned with the outcomes that matter to them – which is fundamental to appropriate care. PRIMs can help patients assure the safety of their own health care (Box 1.3). Filling such information gaps is crucial for awareness-building and subsequent development of an evidence-based toolbox of policy levers and for bringing about change.

Box 1.3. **Improving patient safety in OECD health care systems: Patient Reported-Incident Measures in Norway**

As part of Norway's patient safety campaign that began in 2011, the Patient-Reported Incident in Hospital Instrument was included in the national patient experience survey. The instrument asks 13 questions about patient-perceived safety in hospitals, including staff handwashing and medication errors. Rates of patient-reported incidents were found to correlate well with objective measures of patient safety, such as the Global Trigger Tool (Bjertnaes et al., 2015). More information can be found in Box 2.7.

Behaviour change policies and incentives both matter when it comes to tackling wasteful clinical care

For low-value care, soft policy levers designed to change behaviour include public reporting, audit and feedback, and providing doctors and patients with guidelines and information to encourage dialogue between them. For example, a combination of

enhanced feedback and educational reminder messages was associated with a reduction of more than 20% in test ordering by doctors in Scotland (Thomas et al., 2006). Clinical guidelines have the potential to improve the process and outcomes of care, reduce the use of unnecessary interventions and save costs. In the United States, an evaluation of a programme for patients with non-small cell lung cancer found outpatient costs were 35% lower for those who followed a programme using evidence-based guidelines compared to patients not in the programme (Neubauer et al., 2010).

Eliminating low-value care requires that clinicians' and patients' perceptions of inappropriate care are aligned. This can be achieved through intensive dialogue between them, which can be facilitated. Tools to support shared decision making between clinicians and patients can help patients understand, for instance, that the desire to detect harmful cancer early may result in harm due to unnecessary treatment of non-threatening cancers. Such decision aids have been shown to improve decision-related outcomes for breast cancer treatment including surgery, radiotherapy, endocrine therapy and chemotherapy (Zdenkowski et al., 2016). They have also been shown to reduce rates of hip and knee replacement by 20-40% (Arterburn et al., 2012). Building on these principles, the *Choosing Wisely*® campaign aims to reduce low-value care (Box 1.4).

Box 1.4. **Reducing low-value care in OECD health care systems: The *Choosing Wisely*® initiative**

The *Choosing Wisely*® campaign, initiated by clinicians, aims to reduce low-value care by encouraging patient-provider conversations about whether certain treatments add value. The campaign began in the United States in 2012, and subsequently spread to several other countries. An analysis of early trends among seven services subject to *Choosing Wisely*® recommendations in the United States found a modest decrease in the use of two services. Use of imaging for headache decreased from 14.9% to 13.4%. Cardiac imaging for low-risk patients decreased from 10.8% to 9.7% (Rosenberg et al., 2015). However, the use of two other services increased and trends were stable for three other recommendations. This suggests that *Choosing Wisely*® should be used in conjunction with other interventions. More information can be found in Box 2.8.

In terms of safety, ensuring the systematic use of fairly simple checklists has proven effective (Bliss et al., 2012), as well as initiatives targeting health workers' hand hygiene to reduce health care-acquired infections (Box 1.5). To be effective, however, checklists and similar tools need to be embedded within broader educational, monitoring and feedback activities. The end goal must always be to sustain a *culture* of quality and safety improvement, rather than to merely implement several disconnected initiatives.

In addition to soft policy tools, modifications to existing economic incentives as well as organisational changes can support delivery of high-value and safe care. Some OECD health care systems have experimented with different reimbursement approaches, including blended payment systems that add a pay-for-performance (P4P) element to the existing case-based payments or FFS. In Denmark, under a pilot initiative, selected hospitals are reimbursed according to patient outcomes, instead of the diagnosis-related group (DRG) payment system. France sets financial sanctions for doctors who are outliers in prescribing practices and a P4P scheme in ambulatory care rewards appropriate prescribing of

Box 1.5. **Improving patient safety in OECD health care systems: Encouraging handwashing in Australia and the United States**

In audits of Australia's *National Hand Hygiene Initiative*, which encourages health care workers to practice hand hygiene, compliance rose from 63.5% in 182 participating hospitals in August 2009, to 83.2% in 890 participating hospitals in October 2015 (Hand Hygiene Australia, 2015). A US-based trial evaluated health workers' hand hygiene in an intensive care unit with the use of remote video auditing, with and without feedback. Cameras with views of every sink and hand sanitiser dispenser were used to record hand hygiene activity. During the 16 weeks before feedback, hand hygiene rates were less than 10.0%. In the 16 weeks after feedback, the rate rose to 81.6%. This increase was maintained 75 weeks later, at 87.9% (Armellino et al., 2012). More information can be found in Box 2.10.

benzodiazepines. These initiatives have not yet been systematically evaluated. To improve patient safety, some health care systems impose financial sanctions if adverse events occur. For example, Israel defined four "never events" for which hospitals cannot bill health insurers. Financial incentives can also be directed at patients by introducing co-payments for care that is considered low-value or by excluding it from coverage.

Organisational changes include measures such as improved use of technology and improvements to care co-ordination. Computerised physician order entry (CPOE) improves safety by overcoming issues such as poor handwriting, ambiguous abbreviations or lack of knowledge on the part of clinicians when medications or tests are prescribed (Bates et al., 1998). CPOE can be combined with guidelines or decision support tools to avoid low-value care. A systematic review found that using CPOE was associated with improved compliance with guideline advice, fewer tests, a significant reduction in the median time to appropriate treatment, and reduced cost (Georgiou et al., 2007). Many countries are working towards implementation of electronic health records (EHRs) that will contain all relevant information about each patient. Technical, legal and cultural challenges mean that many systems are years from full implementation, however. In the meantime, some countries have established more targeted information-sharing systems, focused on medications (e.g. Germany and Denmark) or specific diseases (e.g. SveDem, the Swedish dementia registry).

These policy levers can be accompanied by more forceful regulatory measures. This may include requiring provider accreditation as a tool to limit adverse events caused by organisational shortcomings, as in Australia. In the domain of low-value care, tools such as pre-authorisation for certain overused interventions were tried in Israel. More importantly, disinvestment in obsolete technologies and the mandatory use of tools such as HTA are needed to gauge the effectiveness of interventions before they are funded through public means. On another front, some countries moved from a tort-based system to compensate medical harm to a government-funded, no-fault system to discourage low-value care driven by defensive medicine.

Table 1.1 summarises the findings on wasteful clinical care. For each category, it highlights actors involved and main drivers (relatively less important ones are shown in grey). The "information" column points to information systems and data that can be used to better capture and monitor the problem. The next column provides a summary of policy options, organised around the four categories of policy levers. In the final two columns, examples of policy impact and good practice are given where possible.

Table 1.1. **Who, why and what to do? Summary of findings on wasteful clinical care**

Category of waste	Actors	Main drivers	Information systems required	Policy levers	Policy impact	Country examples
Preventable adverse events		Organisational shortcomings, suboptimal decisions, poor incentives	Adverse event reporting systems, PRIMs	**Behaviour change:** clinical guidelines, checklists, standards of practice, safety campaigns	+	**Spain:** A five-point checklist is used in intensive care units to reduce catheter-related bloodstream infections
				Organisational change: improved co-ordination and use of ICT	+	**Germany, Denmark and Sweden:** More targeted information-sharing systems focused on medications or specific diseases
		Organisational shortcomings, poor incentives		**Incentives:** financial penalties for "never events", change in tort law towards no-fault systems	+	**Israel:** The Ministry of Health defined four "never events" in which hospitals cannot bill health insurers
				Regulation: mandatory accreditation of providers	+	**Australia:** All hospitals must meet ten national standards as part of mandatory accreditation
Low-value care		Suboptimal decisions, poor incentives		**Behaviour change:** audit and feedback, guidelines (do-not-do lists), campaigns promoting dialogue between patient and clinician (Choosing Wisely®, advanced directives, decision aids)	+	**United States, Netherlands, Italy, Canada, Australia, New Zealand, United Kingdom (and others):** Choosing Wisely® campaign
		Suboptimal decisions, poor incentives	Atlases of health care variation, PREMs and PROMs	**Incentives:** bundled, performance- and value-based payments, patient co-payments for low-value interventions, disinvestment from low-value care, change in tort law towards no-fault systems	?	**England:** Maternity Pathway Payment removed the financial incentive for caesarean section **United States:** Value-based programmes link payment to quality and value **France:** Rates of reimbursements for drugs based on their effectiveness for a given indication and condition severity
		Poor incentives		**Regulation:** systematic HTA, pre-authorisation of certain procedures	+	**Israel:** Pre-authorisation centre for heart catheterisation reduced unnecessary stenting
Overprescription of antimicrobials		Suboptimal decisions, organisational shortcomings, poor incentives	Prescription monitoring systems	**Behaviour change:** guidelines, campaigns	+	**France** implemented a continuing medical education (CME) programme for communicable diseases
		Suboptimal decisions, poor incentives		**Organisational change:** rapid diagnostic tools, stewardship programmes	++	**Belgium** one of the few countries to carry out a full cost-benefit analysis of its mass media campaign
				Incentives: performance-based payments, patient co-payments	+	Stewardship programmes were widely implemented and proved to be effective in the **United States, France** and other countries

Manager; Clinician; Patient.

+ Some evidence of positive impact but limited and system-dependent; ++ Positive impact; **?** Impact so far unknown.

3. Operational waste: When care could be produced using fewer or cheaper resources

In contrast to wasteful clinical care, operational waste covers instances when the care patients receive is what they need but the same (or superior) benefit could be achieved using fewer resources.

Health care requires human and capital resources such as medical professionals, pharmaceuticals and other medical supplies, technology and equipment as well as buildings. Inefficiencies arise when any one of these resources is:

- purchased at an overly high price, which can occur for instance when procurement is poorly organised
- purchased but not used and subsequently discarded (pharmaceuticals) or simply underused (fixed assets)
- used to treat patients when less expensive and equivalent alternatives exist; examples include treating patients in the hospital when equally suitable outpatient alternatives exist, prescribing originator brands instead of generics, or using highly specialised health staff to provide basic care.

In keeping with the general definition of waste, the focus is on activities that could be stopped or for which opportunities to use a cheaper alternative may be found within any given system's prevailing architecture. A review of countries' experience identified two main domains in which such operational waste can be reduced: pharmaceuticals and the use of hospital services.

3.1. A range of opportunities exist to spend less on pharmaceuticals

Across OECD countries, one out of every five health dollars is spent on purchasing pharmaceuticals (Belloni et al., 2016). This section starts with a discussion of waste that occurs when purchased pharmaceuticals (or other medical supplies) are unused and discarded. Next, the section proceeds to opportunities for substituting originator medicines with cheaper and therapeutically equivalent generics. Finally, the discussion moves to the complex issue of procurement.

Discarding unused medical supplies is more often than not unnecessary

The value of discarded medical supplies is difficult to capture but is probably underestimated since in most countries, only data on returns to authorised collection points are reported. Even less is known about the value of medical supplies discarded by hospitals. Some amount of discarding is inevitable because patients recover before the dispensed medicines have all been taken or their therapies are changed. Nevertheless, approximately 50% of the value of discarded pharmaceuticals is likely to be avoidable cost (Trueman et al., 2010).

- In Australia, a 2013 audit revealed that the annual value of medicines returned to collection points by patients is around AUD 2 million (Monash University, 2013).
- When prescription medicines discarded by patients at home are included, as is the case for National Health Service (NHS) England's estimates, the annual cost could be as high as GBP 200 million (Trueman et al., 2010).

- Among large US academic medical centres, which represent 4% of all hospitals nationwide, every year medical supplies worth at least USD 15 million are discarded despite being recoverable (Wan et al., 2015).

Patients and providers are primarily responsible for wasting medicine. For instance, excessive volumes are dispensed for repeated prescriptions that are not effectively reviewed by physicians or pharmacists. Some patients do not complete their course of medication due to lack of knowledge, doubts or confusion, with potential detrimental effects for themselves or beyond (e.g. in the case of antibiotics, this contributes to AMR). Organisational shortcomings in management of supplies and stocks might play a role at health care facilities but these are less studied.

Tackling the problem requires changing behaviours through guidelines, education initiatives and campaigns. To motivate health professionals and patients to prescribe/use medicines as cost-effectively as possible, these tools must emphasise the benefits of medication rather than waste alone (see Box 1.2 on AMR). Such a strategy involves encouraging good communication between clinicians and patients, aimed at enabling as many patients as possible to resolve medication-related concerns (Trueman et al., 2010). Trial-based evidence from England and Sweden suggests that providing face-to-face or telephone support to patients starting new treatments can cost-effectively reduce the volume of discarded medicines (Clifford et al., 2006; Schedlbauer et al., 2007). Also, e-prescription or other prescription review systems (Denmark, the United Kingdom) can improve the monitoring of dispensed medicines. Evidence on their effectiveness is less clear, however.

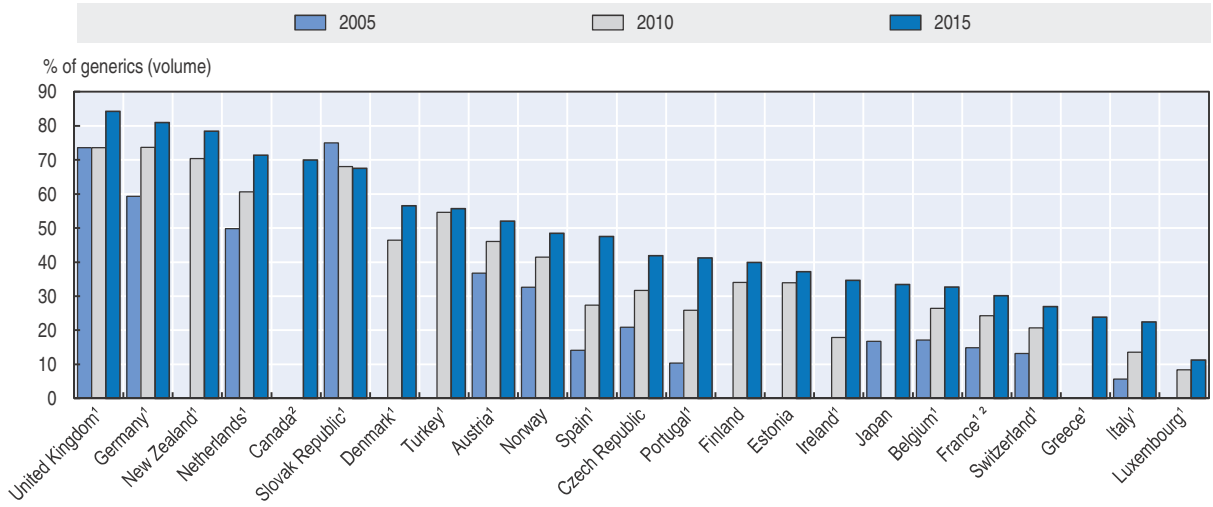
The potential for generics substitution is still underexploited

The use of generic drugs is a good opportunity to free up resources within health care systems. In the United States where the generics market is very dynamic, the price of a generic drug is on average 80-85% lower than that of the originator (IMS Institute for Healthcare Informatics, 2013). In fact, the shift to generic drugs and the so-called "patent cliff" (a large number of drugs losing patent protection) are responsible for the recent decline in overall pharmaceutical spending observed across OECD countries (Belloni et al., 2016). Yet some OECD countries do not fully exploit this potential (Figure 1.3) – the share of generics in pharmaceuticals covered by basic health benefits varies between 10% and 80%.

Efforts to increase the use of generics can be hampered by suboptimal decisions and regulatory obstacles. The former include the established practice of using the originator drug among clinicians and patients. The latter exist when physicians are not allowed or mandated to prescribe using International Non-proprietary Name (INN), which is still the case in some OECD countries (Belloni et al., 2016). Moreover, entry-level legislation might delay the launch of generics onto the market (Vogler, 2012).

Policies to promote the use of generics start with regulatory adjustments to increase opportunities for generics entry and substitution. This includes early-entry legislation, which allows generic drug producers to complete the regulatory requirements prior to the patent expiry of the originator, as well as promoting substitution for all classes of drugs where the option exists. In addition, facilitating drug prescriptions using INN can further enhance substitution of originator drugs with generics. Several OECD countries (Denmark, Finland, Spain and Sweden) implemented regulatory measures mandating pharmacists to substitute the medicine prescribed with the cheapest generic (Vogler, 2012).

Figure 1.3. **Trends in generics market shares by volume in OECD countries between 2005 and 2015 (or nearest year)**



1. Data refer only to reimbursed pharmaceutical market.
2. Most recent available data are for 2013.

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink *http://dx.doi.org/10.1787/888933443952*

These regulatory policies can be accompanied by financial incentives. For clinicians, France introduced a P4P scheme rewarding prescription of generics while Japan introduced bonuses linked to the share of generics in prescribed medicines. In most countries, patients are incentivised to choose generics through lower co-payments (Belloni et al., 2016).

Other measures targeting patients include information campaigns explaining generics' equivalence to originator drugs (Denmark, France, Portugal and Spain). In Norway, pharmacists are obliged to inform patients about the possibility of a cheaper alternative (Medicines for Europe, forthcoming; Belloni et al., 2016).

While no formal evaluation is available, policies associated with patent expiries certainly contributed to the significant increase in generics market share observed over the past decade in most countries (Figure 1.3).

In parallel with generic drug competition, health care systems could realise significant savings by opening the market to biosimilar competition. Biosimilars are generic versions of biological medicines (i.e. medicines made by or derived from a biological source, such as a bacterium or yeast). A growing number of conditions are treated with biological medicines. In particular, these innovative medicines opened a new era of precision therapies for cancer, although these are very expensive (e.g. USD 25 000-200 000 per year) (Belloni et al., 2016). Hence, the emergence of biosimilars brings the promise of more affordable therapies and relief for health care budgets. Adoption of biosimilars faces the same obstacles that had to be removed to realise the potential of generics, however (Box 1.6).

Between and within-country price variations are partially unwarranted and amenable to improved procurement

Comparing prices of pharmaceuticals, especially across countries, is not straightforward. Prices can be measured at different stages (from ex-factory to retail); and differences in prices – which are in part determined by market forces – may also reflect the

Box 1.6. **Current and future savings from the use of biosimilars**

In parallel with generic drug competition, opening the market to biosimilar competition could realise significant savings for health care systems. For example, between 2016 and 2020 eight key biologics are scheduled to lose patent protection. Analysis of data available for five European countries (France, Germany, Italy, Spain and the United Kingdom) and the United States suggests that a 20% reduction in price per treatment-day across these eight products could result in cumulative savings exceeding EUR 50 billion in aggregate by the end of 2020 (IMS Institute for Healthcare Informatics, 2016). In 2015, following the introduction of biosimilar competition in one of the most often used classes of biologics – erythropoietins (EPOs) – the observed price reduction (across the class, i.e. for originators as well as biosimilars) varied from 39% in France to 55% in Germany (IMS Institute for Healthcare Informatics, 2016).

Regulation of market entry for biosimilars varies significantly between countries. The European Union approved the first biosimilar in 2006 and is the leader in the number of approved products: 20 as of June 2016. Yet biosimilars' use shows wide variation in the EU. Even the first biosimilar still has little or no uptake in some countries (e.g. Greece, Ireland and the Slovak Republic), while in Poland it is used in almost all relevant therapies (Ekman and Vulto, 2016). The United States adopted the legislative framework for licensing biosimilars in 2010, but the first biosimilar was approved only in March 2015 (Belloni et al., 2016).

Some policies discussed in this chapter to increase uptake of generics can also be applied to biosimilars. For example, physicians and patients often worry that biosimilars will compromise quality of treatment (IMS Institute for Healthcare Informatics, 2016). Thus regulators should communicate their knowledge more actively and, most importantly, strive to take clear positions on interchangeability between biologics and biosimilars. In Norway and Denmark, where physicians are at the heart of decision making, uptake of biosimilars was rapid and sustained. Similarly, biosimilar competition is strong in Germany, where insurance funds invested in communication with physicians on the subject and subsequently introduced prescribing quotas for biosimilars (IMS Institute for Healthcare Informatics, 2016). A number of countries took a clear position on allowing a switch to biosimilars in the course of treatment, including Denmark, Finland, France, Germany and Norway (Ekman and Vulto, 2016).

different values countries attach to health outcomes in relation to their income. Further, official and actual prices may differ, as manufacturers can provide discounts to countries subject to non-disclosure agreement. In sum, not all price differences are measurable or unwarranted. Yet large variations within a country and between similar countries can be a sign of inefficient procurement:

- Prices of the same hospital pharmaceutical differ by up to 23% between geographical areas in Italy (Baldi and Vannoni, 2015).
- The price paid for a simple patient identification wristband by different NHS England trusts varies more than two-fold (NHS, 2014).
- Studies in the past decade show that Denmark, Germany, Sweden, Switzerland and the United States tend to be high-priced countries for originator drugs, whereas prices for originator drugs in Greece, Mexico, Portugal, Spain and, more recently, the United Kingdom rank at the lower end. For example, for a number of cancer drugs, differences in ex-factory prices between the highest- and lowest-priced country vary between 28-388% (Vogler et al., 2016).

Relatively high prices can reflect passive procurement practices that do not fully exploit the potential for building market power through bulk purchasing. This occurs either because small insurers or providers contract separately for limited volumes of medicines or large buyers do not actively use their market power. The latter means that buyers, for example, do not engage in negotiations with suppliers and/or cover all products within a therapeutic class equally (often not distinguishing between more and less cost-effective medicines). In consequence, none of the suppliers has prospects for selling relatively higher volumes. In other words, buyers simply do not induce competition between suppliers of similar products.

Indeed, in many OECD countries, individual health care providers, notably hospitals, or local government units carry out procurement separately. This not only precludes volume-related discounts but also creates unnecessary task repetition by each buyer. Individual buyers have limited leverage to negotiate more innovative contracts or, in the case of tenders, to develop more advanced product specifications and auction designs that support moving from predominantly price-based towards value-based procurement. In other countries, large regional or national insurers are not permitted to actively negotiate with suppliers or cannot choose a preferred supplier among products within the same therapeutic class (this is the case for Medicare and Medicaid in the United States) (Kesselheim et al., 2016).

With the aim of improving procurement, several OECD countries (e.g. Denmark, Greece, Italy, Mexico, New Zealand and Norway) adopted various forms of collaborative procurement and report considerably reduced prices (Box 1.7). Collaborative procurement (consortia buying, group purchasing, etc.) increases buyers' market power and supports lower prices, understood not only as price per item but also as better value for money. Moreover, collaborations support the development of buying strategies tailored to a situation in a specific market segment. The various legal frameworks and organisational structures of health care systems led to development of a wide range of collaborative procurement forms. These forms range from national and regional government-led agencies or private consortia, which legally bind collaborating members, to public or private hybrid collaborations that are voluntary. The most recent examples include three government agencies established at national level:

- A central procurement agency created in Mexico saved around USD 2.8 billion between 2007 and 2010 compared to the budget planned based on the performance of the former decentralised system (OECD, 2013).
- Italy's central purchasing agency (46 employees) paid on average 20-23% lower prices than the remaining decentralised buyers between 2009 and 2012 (Baldi and Vannoni, 2015).
- Greece's centralisation of procurement in one agency (26 employees) created savings of EUR 180 million compared to the expected budget for 2011 (Kastanioti et al., 2013).

Transparent information sharing is another powerful tool to promote better procurement. Countries should try to systematically capture and publish data on within-country price variations, as is done in Australia and England. Consideration could also be given to sharing price information internationally. At the very least, the question should be asked whether any "private" discount a country receives is actually meaningful in light of the actual price other countries may pay.

Box 1.7. **Collaborative procurement's benefits: Reduced prices, improved stock management and expertise**

Mexico – Until 2007, the procurement function of the Mexican Institute of Social Security (IMSS) was embedded in 60 separate entities. The IMSS's centralisation efforts, undertaken gradually since 2007, resulted in price reductions of pharmaceuticals and other medical supplies, improved stock management and creation of a centre of excellence in procurement that currently serves all public health care stakeholders. This resulted in cumulative savings of USD 2.8 billion between 2007 and 2010 (OECD, 2013).

Greece – In 2010, government undertook efforts to unify the annual tenders for pharmaceuticals and medical devices carried by public hospitals. In the first year of operations, the centralised agency – the Health Procurement Committee (EPY) – consisting of only 26 employees, achieved 10% overall price reduction for pharmaceuticals and 20% price reduction for selected medical devices. Additionally, payment times were significantly shortened (previously exceeding three years on average) and stock management improved, allowing for transfer of redundant stocks between hospitals (Kastanioti et al., 2013).

New Zealand – Since 1993, PHARMAC, a New Zealand government agency, has been the sole purchaser of publicly funded pharmaceuticals. According to PHARMAC estimates, based on pharmaceutical prices in 2005 mapped onto actual prescribing activity, joint procurement allowed for cumulative savings of about NZD 5.1 billion between 2005 and 2015, including about NZD 1.9 billion in 2014/15 (PHARMAC, 2015).

Denmark and **Norway** – For more than two decades, both countries have operated single procurement agencies for hospital pharmaceuticals (including pharmaceuticals for home therapies) and report significant annual savings, ranging from 30% to over 60% compared to list prices or average wholesale prices in a group of neighbouring countries. Notably, these mature collaborative procurement agencies are based on voluntary participation; i.e. they do not have any legal tools to influence member hospitals' decision making. Their success appears to be linked to the fact that clinicians remain at the heart of decision making. In consequence, these collaborative procurement agencies became leaders in strategic selection of preferred suppliers (within a class of therapeutic products), which not only induces competition but also facilitates rapid and large-scale adoption of generics and biosimilars.

3.2. Use of resource-intensive hospital care can be better targeted

Hospitals should focus on their mission to provide highly technical services in the most efficient way. Yet various opportunities exist to reduce instances when patients could be treated equally well without draining such expensive resources. In particular, effective treatment at the primary care level could replace a substantial share of the workload in emergency departments (EDs) and prevent hospitalisations for chronic conditions. Furthermore, an increasing number of minor surgeries can be performed on a same-day instead of an inpatient basis. Indications also suggest that some patients are discharged from hospitals with an unnecessary delay.

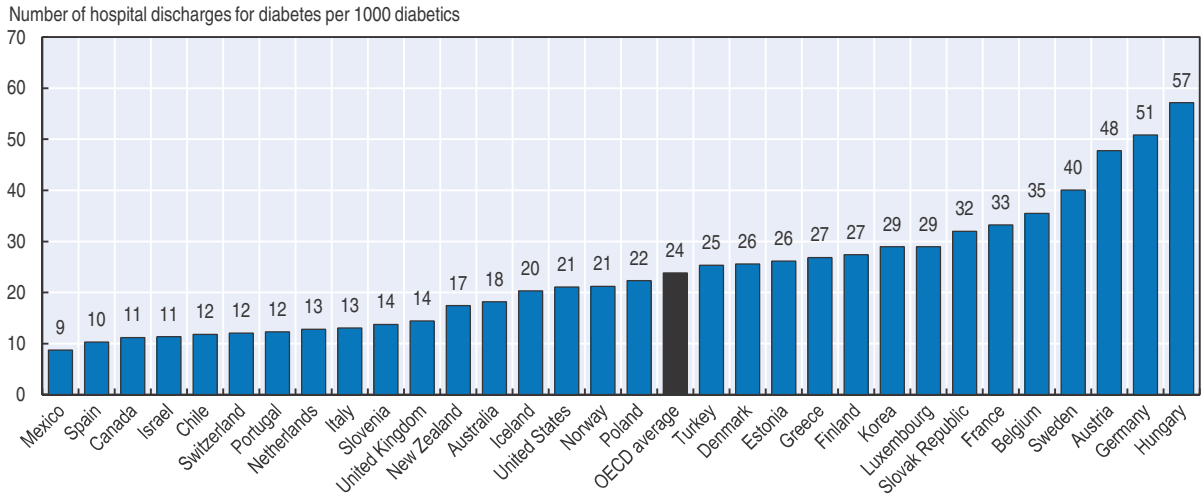
Emergency department visits, hospital admissions and length of hospital stay can be reduced

A substantial portion of ED visits are inappropriate. Similarly, OECD data reveal large cross-country variations in hospital admissions for chronic conditions such as diabetes, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD) and asthma.

For these diseases, early and appropriate primary care treatment has been proven to prevent hospital admissions (Longman et al., 2015), indicating the potential to reduce the use of hospital care. Finally, advances in medical technologies make it possible for an increasing number of surgical procedures to be performed on a same-day basis for most patients, reducing the need for inpatient stays (Fischer and Zechmeister-Koss, 2014):

- Inappropriate ED visits account for nearly 12% of ED visits in the United States and England, 20% in Italy and France, 25% in Canada, around 30% in Portugal and Australia, and 56% in Belgium (Berchet, 2015).[7]
- In England the cost of inappropriate ED visits was estimated at nearly GBP 100 million between 2011 and 2012 (McHale et al., 2013), and in the United States at around USD 38 billion yearly (NEHI, 2010).
- A nearly six-fold cross-country variation exists in rates of hospital discharges per 1 000 patients with diabetes (Figure 1.4) (OECD, 2015b).
- Large cross-country variations exist in the share of minor surgeries delivered on a same-day basis. For example, on average 83% of cataract surgeries are provided on a same-day basis but the rates vary from 27% to 100% between countries (OECD, 2015c).

Figure 1.4. **Diabetes-related admissions per 1 000 patients with diabetes, 2011 (or nearest year)**

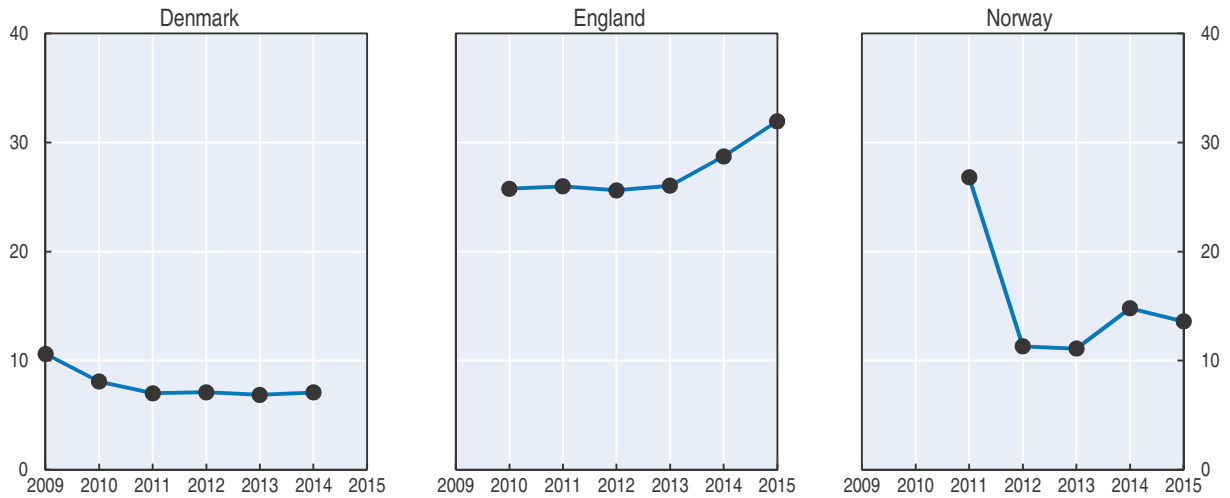


Note: The OECD average includes 31 countries.
Source: OECD (2015), "Improved Control of Cardiovascular Disease Risk Factors and Diabetes: The Central Role of Primary Care", *Cardiovascular Disease and Diabetes: Policies for Better Health and Quality of Care*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264233010-7-en*.

StatLink http://dx.doi.org/10.1787/888933443962

Even when inpatient hospital admission is necessary, poor care co-ordination creates situations when patients who are ready to leave hospital cannot do so because ongoing care has not yet been arranged. Some countries (e.g. Canada, Denmark, Norway, Sweden and the United Kingdom) collect data on situations when a patient remains in hospital after a doctor declares him ready to be discharged (Figure 1.5). Additional time spent in hospital is, according to the doctor's opinion, not beneficial for the patient – and may even be harmful if he could be treated more effectively in another setting – yet it has a significant cost. While data may not be strictly comparable, significant variation arises in the scope of delays in hospital discharges: Denmark reported around 10 additional bed days per 1 000 population

Figure 1.5. **Delays in transferring patients from hospitals in three OECD countries (total number of days per year per 1 000 population), 2009 to 2015**



Source: OECD analysis of data from NHS England, the Norwegian Directorate of Health and the Danish Ministry of Health. Please note that data from different countries may not be comparable.

StatLink http://dx.doi.org/10.1787/888933443975

in 2014 and England more than 30. Some countries have seen notable changes over time: Norway saw a significant drop in 2012, which coincided with introduction of reforms to improve care co-ordination, while England has seen an increase in delays since 2013, largely caused by people waiting for social care services to be arranged.

Drivers of hospital overuse are varied and complex

The complex and interlinked drivers of unwarranted use of hospital care include behavioural factors of clinicians and patients, financial incentives misaligned with system objectives, and shortcomings in organisation and co-ordination. The latter cover two sets of issues: i) a lack of alternatives to hospital care (such as primary care or community care); and ii) failures in co-ordination of care between hospitals and other settings.

Lack of access to alternative options, in particular primary and community care, is a key driver of unnecessary hospital use. A significant proportion of patients face barriers in access to primary care either because of a lack of out-of-hours (OOH) services or because of long waiting times (Berchet and Nader, 2016). Others stay in hospital for longer than necessary due to lack of community care. Even when alternative services exist, poor communication and co-ordination between hospitals and other care settings can unnecessarily extend hospital stay. One reason for this may be a misalignment of financial incentives between providers (often mirrored by misalignment of funding sources). For instance, typically, if the ongoing care provider (financed by the social care system) causes the delay, the cost is borne by the hospital (financed by the health authority).

Inappropriate ED visits and avoidable hospital admissions also relate to the quality of services delivered within primary care settings. Primary care provider variation from evidence-based care guidelines is associated with increased patient complication rates and inpatient admissions at hospitals. The evidence is particularly marked for chronic conditions where suboptimal monitoring is shown to be a cause of preventable hospitalisations (Freund et al., 2013).

Co-payments for outpatient care create incentives for patients to seek free care in EDs, as in Greece and Portugal (Eurofound, 2014). Poverty, minority status, low educational attainment and lack of social support are additional factors positively associated with excess hospital admissions and ED visits (Nishino et al., 2015). Patient preferences for seeking emergency care have also traditionally been high because a full range of medical services is accessible 24 hours a day, 7 days a week (Durand et al., 2012).

Policy levers can reduce hospital overuse

Policy options aiming to change how patients move around the system range from simple, incremental changes – such as putting a stop to wasteful activities – to transformative policies around system redesign and disease management. The discussion here purposely focuses on the first group of policies.

A first category of policies consists of availing the less costly option, including primary care, community care services or intermediate care facilities, in the right place at the right time (Box 1.8).

Box 1.8. **Making alternatives to hospital care more widely available**

Many people in OECD countries are admitted to hospital for care that could be delivered just as effectively in other settings, and at a lower cost. Often this is because the other care settings do not exist or are not accessible when needed. OECD countries are trying to address this by: i) increasing the availability of existing primary and community care, and ii) introducing new models of care that can serve as an alternative to hospitals:

- Some people end up in hospital simply because their primary care provider is closed at certain times of the day. *Out-of-hours (OOH) primary care* aims to address this gap. In the Netherlands, large-scale organisations of OOH primary care, such as general practice co-operatives, effectively improved timely access to appropriate primary care services while increasing patient and physician satisfaction (Giesen et al., 2011).
- *Locating primary care services within hospitals* can redirect non-urgent patients to primary care settings and speed up their discharge. Fast-track systems in **France**, the United Kingdom, the United States and **Canada** reduced inappropriate use of cost-intensive EDs by treating non-urgent patients in a dedicated area staffed by professionals with the competencies to make discharge decisions (Cour des Comptes, 2014; Rogers et al., 2004). In the Netherlands and **Switzerland**, primary care practitioners are placed within EDs to assess and redirect non-urgent patients. This cost-effectively lowered the use of emergency services (Thijssen et al., 2013, Wang et al., 2013).
- *Different types of care settings* can offer alternatives to hospital care. Community care centres in **Australia, Ireland, Italy** and the United States led to a reduction in ED visits and hospitalisations (Bruni et al., 2013). Intermediate care services provide short-term care for patients who are at risk of hospitalisation, or who have just been discharged. Evidence from **Norway** suggests that these services can benefit patients and save money (Garåsen et al., 2007), but experiences in **England** and the Netherlands highlight the importance of ensuring that these new models of care are well-integrated with the existing system (Mur-Veeman and Govers, 2011, Plochg et al., 2005). The "hospital at home" model is an interesting initiative to offer patients the option of receiving hospital-level care at home for conditions that can be safely treated there. Evidence from the United States shows that providing hospital at home is not only cheaper but also leads to improved health outcomes, reduced mortality rates and increased satisfaction rates (Klein et al., 2016).

Reductions in operational waste can be achieved by improving the efficiency of internal processes within hospitals. In this respect, health providers have begun to learn from other sectors. "Lean Management" was first developed to improve the efficiency of car factories, but applying its techniques in health care – for example, by clearly defining standard procedures or implementing more efficient stock replenishment systems – has led to higher productivity and less waste (Mazzocato et al., 2010; D'Andreamatteo et al., 2015).

A shift in financial incentives can support development or choice of less resource-intensive care. In Japan, additional fees are provided to hospital EDs to encourage patient discharge to primary care clinics (Japanese Ministry of Health, Labour and Welfare 2014). Hungary reduced payments for inpatient admissions for minor surgeries to incentivise greater uptake of same-day surgery. On the demand side, removing co-payments at the point of care for outpatient primary care visits improves patients' access (as seen in Canada, Denmark, Germany, Italy, Poland, Spain and the United Kingdom) (Berchet, 2015).

Financial incentives are used in some countries to target specific failures of co-ordination at the interface between hospital care and other services. In Norway, Denmark and England financial sanctions apply to local authorities in case of delays in discharging patients from hospital. In Norway, this approach significantly reduced delayed discharges after 2011 (Figure 1.5).

Soft tools are important to increase the quality of primary care and convince patients to change their care-seeking habits. Evidence-based clinical practice guidelines support clinical decisions and reduce unwarranted variation in care, particularly for chronic conditions. Improved adherence to clinical practice guidelines for asthma, COPD and diabetes by primary care providers is associated with fewer hospital admissions (AHRQ, 2001). For example, targeted incentives on compliance with clinical practice guidelines had favourable effects on diabetes outcomes in the United Kingdom (Latham and Marshall, 2015). Education programmes and counselling can help patients develop a better understanding of their own health conditions, and the appropriate place to seek care.

Table 1.2 summarises the policy options to reduce operational waste.

4. Governance-related waste

4.1. Spending on administration is unavoidable but needs to be well targeted

Spending on administration is often seen as one of the first areas from which to cut waste. Administrative costs are incurred at the regulatory (macro) level, as well as all levels of administration and management, including by individual health care staff at the provider (micro) level. Administrative waste occurs when administrative tasks do not add any value, are unnecessarily repeated, or are performed in a way that is more expensive than required (for instance, reporting obligations that do not translate into actual monitoring, duplication of competencies across agencies, or physicians taking on administrative tasks that could be done by non-medical staff). In other words, administrative waste comprises activities that can be either eliminated or executed using fewer and/or less expensive inputs. At the health provider level, one element of the latter is waste in human resources through suboptimal organisational management and staff absenteeism; this combines elements of administrative and operational waste and is an issue for all industries including the health sector.

Table 1.2. **Who, why and what to do? Summary of findings on operational waste**

Category of waste	Actors	Main driver	Information systems required	Policy levers	Policy impact	Good practice examples
Discarded pharmaceuticals and other medical supplies		Suboptimal decisions	Monitoring of patient adherence to medication Monitoring of prescriptions Monitoring of stocks in health care facilities	**Behaviour change:** guidelines, training and campaigns	+	**England:** Pharmacists provide face-to-face or telephone support to patients starting new treatments
		Organisational shortcomings		**Organisational change:** e-prescription systems, improved management of stocks in health care facilities	?	**Denmark, United Kingdom:** Physicians receive periodical reviews of prescriptions
		Organisational shortcomings				
		Inadequate regulation				
Expensive originator drugs used instead of generics		Inadequate regulation		**Regulation:** prescription by INN, early-entry legislation, mandatory substitution of a prescribed medicine with the cheapest generic	?	**Denmark, Finland, Spain, Sweden:** Mandatory generics substitution by pharmacists
		Inadequate regulation, poor incentives	Monitoring of prescriptions and the use of generics	**Incentives:** P4P, patient co-payments, internal reference pricing	?	**France, Japan:** P4P for prescribers based on share of generics in prescribed medicines
		Suboptimal decisions, poor incentives		**Behaviour change:** guidelines, campaigns	?	**Denmark, France, Portugal, Spain:** Information campaigns on generics for patients
Overly high prices paid for pharmaceuticals		Organisational shortcomings, inadequate regulations	Atlases of price variations Price disclosure programmes Market intelligence	**Organisational change:** collaborative purchasing, advanced contracts and auction designs, user friendly e-procurement platforms, analysis of price variations	++	**Greece, Mexico:** Central procurement agency replaced decentralised system
		Organisational shortcomings				**Denmark, Norway:** Pooled procurement through voluntary collaboration of purchasers
High-cost hospital care used where less expensive alternatives exist		Organisational shortcomings, poor incentives	Monitoring of inappropriate and avoidable hospital admissions Monitoring of variations in primary care practice	**Organisational change:** development of OOH primary care, community and intermediate care services, improved co-ordination of services, better hospital discharge management	++	**Norway:** Larger primary care centres (intermediate care facilities) with 24-hour, 7-day a week access
		Suboptimal decisions		**Incentives:** bundled and performance-based payments, payments encouraging same-day surgery, co-payments (removing outpatient co-payments, charging for unnecessary use of emergency)	++	**United States:** Stronger community care centres
		Poor incentives, suboptimal decisions				**France, United Kingdom, United States, Canada:** Fast-track systems for emergency services
		Inadequate regulation		**Behaviour change:** guidelines, patients' education and campaigns	++	**Hungary:** Removed budget caps for same-day surgery

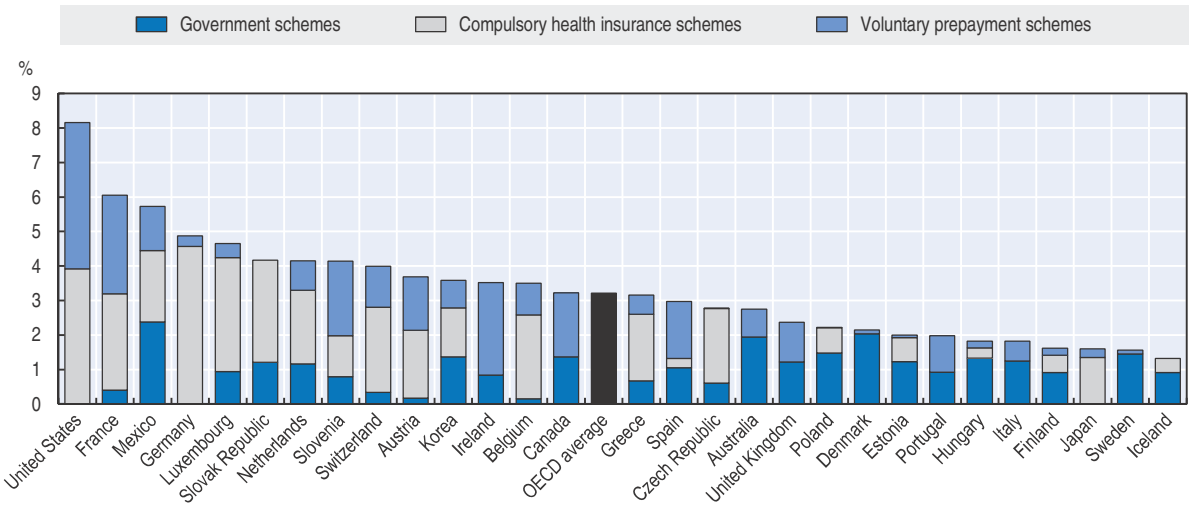
Regulator; Manager; Clinician; Patient.

+ Some evidence of positive impact but limited and system-dependent; ++ Positive impact; **?** Impact so far unknown.

Administration represents a modest share of total expenditure but opportunities to increase efficiency exist

Administrative expenditure includes the resources that go into administration of the financing, governance and service delivery of a health care system. At the system level, spending on administration comprises a modest share of overall health spending: OECD countries spent an average of 3% of total health spending on administration in 2014. The share was double that level in France and even higher in the United States. On the other hand, a number of countries report administrative expenditures at less than half of that level (Figure 1.6) (OECD, 2016).

Figure 1.6. **Administration as a share of current health expenditure by financing scheme, 2014 (or nearest year)**



Note: Compulsory health insurance schemes predominantly refer to social health insurance funds but can also refer to compulsory health insurance provided by private insurers. Voluntary prepayment schemes mainly refer to voluntary health insurance schemes. The OECD average includes 30 countries.

Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en*.

StatLink http://dx.doi.org/10.1787/888933443984

The level of administrative expenditure depends, to some extent, on the nature of a country's health financing schemes. Figure 1.6 suggests that systems organised around social health insurance (SHI) funds or some kind of compulsory insurance might generate higher administrative expenditure than those in which the general government manages coverage. Further mapping of the data to organisational features shows instead that single-payer systems (whether the payer is a social security fund or a government entity) tend to have comparable levels of administrative spending, lower than those of multiple-payer systems, especially when payers compete and consumers can choose their source of coverage (Mossialos et al., 2002). Moreover, private insurance generates a relatively high share of total administrative expenditure, especially in light of its limited role in pooling in most countries. The possibility for insurers to generate profit from their operations can also explain some of the observed variation. Variations across financing schemes can be partly explained by the differences in resources that schemes devote to specific administrative functions, such as collection and pooling of funds or marketing.

Differences in administrative expenditure at the level of individual health care providers, such as hospitals and individual clinicians, are less studied. Of those nations where data allow for a comparison of administrative costs in health care organisations, Scotland reported the lowest share, at 11.6% of total hospital costs, whereas this figure was more than double in the United States (Himmelstein et al., 2014). Demarcating costs related purely to administration in health care facilities is challenging, though, because many functions have both an administrative and a clinical purpose. Administrative costs of health providers also vary within countries. For instance, a recent report analysing variations in productivity and performance in NHS England finds that costs for corporate and administrative staff vary between 6-11% of total income among NHS England trusts (Department of Health, 2016). Regarding individual clinicians, observational studies conducted across settings in different countries found that physicians' time spent on "documentation" ranges from 8% to as much as 27% (Ammenwerth and Spötl, 2009; Mache et al., 2011; Arabadzhiyska et al., 2013; Westbrook et al., 2008). In that context, waste occurs when relatively simple administrative activities are carried out by highly qualified clinicians whose time could be better used to treat patients.[8] Extending the notion of "administrative waste" to include missed managerial opportunities to optimise the use of human resources raises the question of staff absenteeism, which can be an issue of concern. For instance, across NHS trusts in England the average level of sickness absence is around 4%, higher than both the public (2.9%) and private (1.8%) sector averages. Reducing the sickness absence rates in NHS England trusts by 1% could save GBP 280 million in staff costs (Department of Health, 2016).

Administrative expenditures are often seen as the first target areas when implementing austerity measures. The common view is that excessive bureaucracy and "red tape" are burdensome (Morra et al., 2011; Cutler et al., 2012). Comparing how countries differ in the way they administer their health care system can serve well in identifying policy pointers. But simple international comparisons of the level of spending on administration can be misleading, since such comparisons reflect differences in governance and financing structures of health care, and only illustrate the costs, not the potential benefits of administrative expenditures.

It needs to be stressed that administration *per se* should not be seen as "bad". Paying for performance, for instance, can be expected to generate a higher administrative burden for providers and payers as it typically involves the reporting and analysis of additional data for a substantial number of indicators of health care quality (OECD and WHO, 2014). In the same manner, HTA generates costs but promotes more informed decisions on coverage of new and current services. Likewise, elaborate follow-up of clinical recommendation adherence by inspectorates is not free of cost but might improve clinical practice. What is important is to balance out the costs of administrative activities against their potential benefits, which are difficult to measure.

Despite the complexities in establishing the magnitude of administrative waste, its drivers are relatively straightforward to conceptualise. Administrative waste can be caused by the usual organisational deficiencies and incongruous regulation, which lead to efforts being spent on tasks that bring no added value or to duplication of activities. Additionally, poor co-ordination of administrative tasks between different actors within or between organisations leads to waste in a manner similar to the way that poor co-ordination between different health care providers underpins operational waste.

System-specific investigations are required to identify possible administrative efficiency gains

At all levels of the health care system, strategies to reduce administrative waste are centred on organisational changes identified through detailed investigations of administrative activities. In particular, comprehensive functional analyses of organisations or in-depth stocktaking of the administrative burden of health providers are promising approaches to identify areas where action is required to cut wasteful spending:

- Australia commissioned a functional and efficiency review of the Commonwealth Department of Health. Efficiency gains of around AUD 106 million were found in operations, partly by removing duplication of administrative activities.
- In Germany and the Netherlands, different bottom-up approaches involving all major stakeholders including providers were taken to measure administrative spending and identify potential wasteful activities. In Germany, the review identified EUR 4.3 billion of administrative costs related to documentation and reporting and recommended 20 measures to improve administrative efficiency (Statistisches Bundesamt, 2015).

The key recommendations with regard to organisational changes emerging from these reviews are typically country- and system-specific and range from small adjustments to re-organisation of regulatory functions. They can be broadly clustered into the following categories:

- making better use of information and communications technology (ICT) in communication between payer and provider
- simplifying administrative procedures
- finding the right size of administrative bodies.

ICT solutions can reduce paperwork, particularly in the interaction between payers and providers. Upfront development costs can be high but efficiency gains are expected in the long run. Measures of this kind were taken in a number of countries, including Belgium, France, Norway, Slovenia, Switzerland and Estonia (see Box 1.9). This can refer to electronic reporting of performance measures, implementation of e-prescription and/or e-referrals, development of electronic patient records, or more generally, use of a digital platform to exchange information between providers and payers. In many cases, higher-quality data and improved patient safety are secondary aims of the increased use of ICT at the provider level. Regulatory processes too can be simplified with the help of ICT. In Israel, for example, the move towards digitalised procedures for medical graduates to receive their medical licenses and to apply for compulsory clinical internships sped up these processes considerably. It also led to a better matching of hospitals and interns, who are now more likely to work in the hospital of their choice. Other simplification measures may include the streamlining of forms used by physicians for billing purposes or prescription forms.

Recommendations to improve administrative efficiency can include a merger or a separation of administrative institutions. Whether agencies are merged or separated depends on the country-specific context but countries are trying to find the most appropriate organisational size to achieve efficiency gains.

Box 1.9. **E-prescription in Estonia**

Estonia embarked on a comprehensive e-health strategy, with e-prescription as one element to improve efficiency. E-prescription was launched in 2010 and is integrated in a platform that also incorporates electronic health records (EHRs), a digital image archive, a patient portal, an e-laboratory and e-emergency care solutions.

All e-prescriptions issued by physicians are sent to a national database that can be accessed by pharmacies, other physicians and the health insurance fund. Patients can pick up their medication at any pharmacy by identifying themselves with their ID card. Repeat prescriptions can be issued by physicians after an email or a phone call, no longer requiring physical visits to the doctor. Digitalisation reduced the administrative workload of pharmacists; the health insurance fund gained better information about the pharmaceutical market and can now monitor prescription habits more effectively. It also improved efficiency for the Estonian health insurance fund: staff costs related to administering incorrect prescriptions reduced by more than 90% between 2009 and 2015. The database can provide an overview of all prescriptions issued for a patient and help signal possible interactions between different pharmaceuticals. By May 2011, 84% of all prescriptions were issued digitally and over 95% of pharmacies were ready to process e-prescriptions. Over 90% of patients are satisfied with these services.

Source: Estonian Health Insurance Fund (2016), *www.haigekassa.ee/en/digital-prescription*.

Many countries try to improve administrative efficiency through a variety of regulatory levers. Levers vary a lot in scope and range from measures that increase transparency to budget ceilings set for administrative spending:

- Germany and the Netherlands introduced a legal requirement to estimate any additional administrative burden associated with each new piece of legislation discussed in parliament.
- Ceilings/efficiency targets were defined to strengthen governance of health expenditures in Denmark and France (for the main public insurer, CNAMTS).
- The Swiss Office of Public Health (FOPH), the oversight body for statutory health insurance, surveys the financial records of health insurance companies and can require insurers to reduce their administrative costs below a defined limit if they are deemed excessive.
- In the United States, the Affordable Care Act (ACA) stipulates a Medical-Loss-Ratio requiring insurers to spend at least 80-85% of premiums on medical claims. After its introduction in 2011, the share of non-medical overhead costs in net premiums decreased, resulting in accumulated savings of USD 3.7 billion by 2013. The extent to which these savings can be attributed to the new regulation remains unknown (McCue and Hall, 2015).

Finally, depending on their managerial autonomy, health care providers may themselves engage in reducing administrative costs without involvement of payers or the regulator. Like other industries, providers can strive for leaner management structures and more flexibility in staff sizes or better organisation of hospital management to cut administrative costs. Relying on e-solutions to optimise hospital staff can save money by limiting the use of additional temporary staff. To address costly staff absenteeism, a recent report in England made a number of recommendations both at the national and regional level, mainly centred on improvements in staff health and well-being (NHS Employers, 2014).

4.2. Wasting with intention: Fraud, abuse, corruption and other integrity violations in health

The final category of waste reviewed in the report essentially comprises resources illegitimately and deliberately diverted from health care to serve the self-interest of a few. From this report's perspective, it is easy to conceptualise these behaviours as wasteful. Depending on the system and culture, the behaviours range from morally reprehensible, to legally sanctionable, to part of the normal way of doing business; they may be small or large, rare or systemic. Terms to designate these behaviours include fraud, abuse, corruption, patronage and bribery depending on the specific circumstances. To avoid semantic debates, the report coins them "integrity violations", an umbrella term for various types of dishonest behaviours that divert resources from their intended purpose. People or entities engaging in these behaviours may commit them in their own self-interest or in the interest of the business or even the industry they work for. Finally, any of the key stakeholders listed in the waste framework can be involved (Figure 1.1). In addition though, integrity violations may involve any business operating in the health sector that produces or distributes goods and services, both specific to the sector (e.g. pharmaceuticals or medical equipment) and not (e.g. construction, software, insurance services, etc.).

Building on Savedoff (2006), who linked transactions that can be corrupt to various stakeholders in the sector, a comprehensive mapping exercise of integrity violations in health care systems suggests that they take place in the context of: i) service delivery and financing; ii) procurement and distribution; or iii) the pursuit of general business objectives. Integrity violations in service delivery and financing mainly involve patients, payers and providers. Problems in procurement and distribution involve suppliers or manufacturers at the expense of payers or providers and may even, in the case of counterfeit medicine, originate from criminal organisations and pose a threat to health in addition to being wasteful. The last category of integrity violations can involve any "business" operating in the health sector, including those delivering services or developing, producing or selling medicines. All of these operators have legitimate business objectives that some may, in practice, seek to achieve in unethical and ultimately wasteful ways. Table 1.3 provides some examples for each of these three categories.

How corrupt is the health sector?

A number of theoretical considerations suggest why the health sector might be particularly prone to integrity violations (European Commission, 2013). In particular, and perhaps more than other sectors, health is characterised by a multiplicity of stakeholders with complex interrelationships, a high degree of uncertainty, and a vast range of transactions that are often based on delegation of responsibilities between actors with diverging interest who have access to different information and knowledge. To give a few examples, health care providers have specialised knowledge to decide on the treatment of any given patient; patients may not share all the information about their health; and industries have information about the cost of development of a new pharmaceutical product and its potential benefit. The combination of these characteristics makes it difficult to standardise services, monitor behaviours and ensure transparency in the health care system. Consequently, integrity violations can occur.

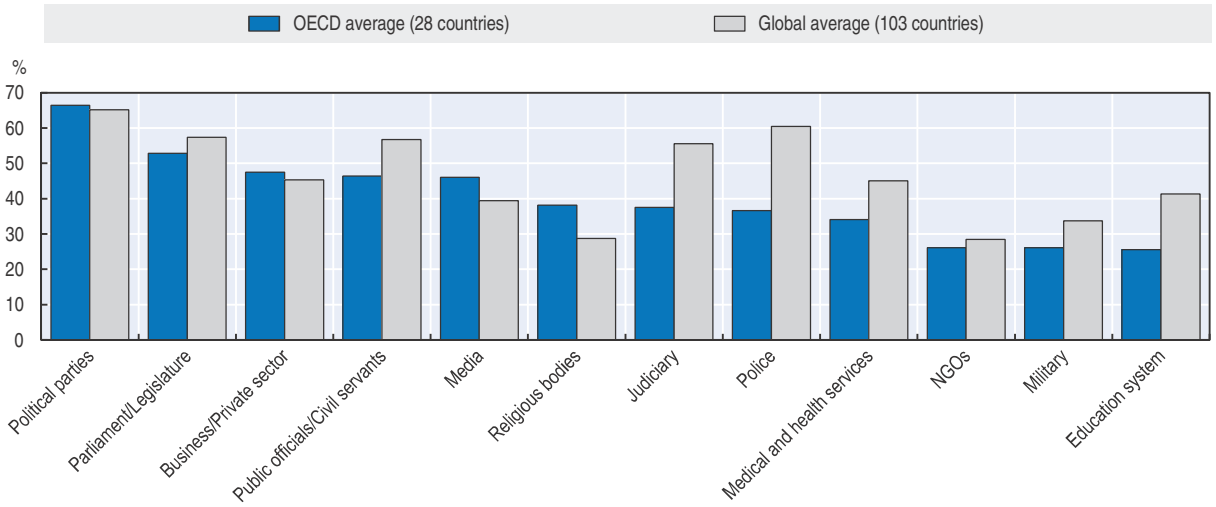
Integrity violations in health, as in any sector of the economy, are notoriously difficult to measure and compare across systems. A first reason is the lack of a uniform understanding of what constitutes fraud, abuse and corruption. More importantly, since most activities are

Table 1.3. **Examples of integrity violations in health linked to potential perpetrators**

Service delivery and financing	
Patients	Fraud to obtain unjustified coverage; wrongful claims; bribery
Payers	Unjustified denial of coverage, benefits or payments; misuse of resources
Providers	Informal payments; overprovision; overbilling; phantom care; misuse of resources; absenteeism/payroll fraud
Procurement and distribution	
Suppliers/manufacturers	Inappropriate influencing of procurement processes; wrongful bidding; collusion
Suppliers	Counterfeiting; falsified or substandard medical products
Inappropriate business practices (in relation to legitimate business objectives)	
Businesses operating in the sector seeking to influence payer, regulator, prescriber or patient: • directly • through other institutions (patients' associations, research institutions, scientific journals, medical societies, opinion leaders)	Inappropriate promotion of a business-friendly regulatory environment: Revolving door; political corruption; financing of political campaigns, parties or candidates to influence legislation Inappropriate influence to gain market entry: Provision of erroneous information (diploma/characteristics of facility); distortion of evidence on safety, efficacy or effectiveness (clinical trial methodology, selective publication of results); exertion of direct influence on decision-making authorities (inspectorates, advisory committees, etc.) Inappropriate methods to increase demand for products or services: Medicalisation of new health problems; inappropriate detailing, kickbacks, self-referrals

reprehensible and some at least can be sanctioned, they naturally tend to be covert. Surveys capturing perceptions of corruption are among the only tools available to gauge the scale of integrity violations in health. Transparency International (2013) provides a recent cross-country comparison of the perceived level of corruption across a range of sectors, including health. Figure 1.7 shows that although in OECD countries the health sector is ranked in the bottom third of corrupt institutions, a third of citizens nevertheless deem the sector as corrupt or extremely corrupt (versus 45% globally).

Figure 1.7. **Percentage of global and OECD countries' population that considers various sectors corrupt or extremely corrupt**



Source: Transparency International (2013), "Global Corruption Barometer", *www.transparency.org/gcb2013/report*.

StatLink *http://dx.doi.org/10.1787/888933443997*

When it comes to levels of spending wasted on integrity violations, published numbers tend to be quite low, if only because while detecting anomalies might be fairly simple, establishing intent is often a lengthy legal process. To give a couple of examples, the French CNAMTS recovered EUR 200 million lost in health care fraud in 2014, representing 0.1% of health insurance benefits. The US Centers for Medicare & Medicaid Services (CMS) recovered USD 2.3 billion in restitution and recoupment for fraud in 2014 (HHS and DOJ, 2015), corresponding to 0.2% of the total amount of expenditures on these programmes. But these numbers refer to detected and proven integrity violations, which are difficult to separate out from simple errors. A yearly publication purportedly reporting data from methodologically sound measurement exercises subjected to external validation from seven OECD countries estimates that the loss from fraud and error combined is an average 6% of related health expenditure, with most estimates ranging between 3% and 8% (Gee and Button, 2015). As countries are only able to recoup much lower percentages, there are reasons to improve measures that aim to prevent and tackle integrity violations in health within OECD countries.

Policy levers can mitigate integrity violations in health

This final section focuses on strategies to tackle integrity violations specific to the health sector. As public funding dominates health in most OECD countries and the sector is heavily regulated, what happens in the health sector is framed by the overall quality of governance, particularly public sector governance in domains such as public finance and budgeting, public financial management, public procurement and civil service management. A poor level of governance in a given country is likely to permeate the health sector. Conversely, if the civil service or public procurement is corrupt, the health sector is unlikely to be able to address the problem through sector-specific measures alone. With this in mind, the report focuses on two domains where at least some OECD countries have introduced sector-specific interventions: service delivery and financing and inappropriate business practices.

A handful of countries established specific systems to tackle integrity violations in service delivery and financing. OECD countries differ quite significantly in the level of effort spent on addressing integrity violations in service delivery and financing. The response is primarily organisational in the sense that it involves assigning responsibility for detecting or tackling integrity violations in service delivery and financing to specific institutions and sometimes defining how it will be done. Survey responses identified four countries with dedicated central or government programmes or institutions (Belgium, England, Japan and Portugal). Others delegate these responsibilities to payers, either public ones (France, Germany and the United States for Medicare and Medicaid) or private health insurance companies (the Netherlands and Turkey). A number of OECD countries do not have a health-specific dedicated institution for tackling integrity violations, but rely on general counter-fraud and anticorruption organisations instead.[9] Especially when counter-fraud responsibilities are placed in the hands of private organisations, additional legal obligations or incentives may be required to guarantee efforts, as fraud detection can be costly and tackling integrity violations does not necessarily have a positive cost-benefit ratio for private insurance providers.

Fraud detection activities can be more or less pro-active. They can rely on simple audits, controls and/or the investigation of complaints, and systems may or may not be in place to encourage the reporting of integrity violations – for instance through hotlines. More advanced countries use analytical tools to detect integrity violations, including data mining.

When it comes to addressing integrity violations, practitioners highlight the importance of having a stepwise, comprehensive and credibly enforceable response. The first step relies on soft behavioural tools. This mostly consists of raising awareness about a specific type of problem (for instance, overprescription of specific tests, unusual frequency of repeated visits, etc.) by communicating information and data to all or a subset of providers, and – if needed and possible – by generating technical consensus around the fact that the behaviour is inappropriate. This alone can bring about change in behaviours (because perpetrators know the behaviour is under observation or through peer pressure). If the problems persist and/or the scale of the issue requires it, the next step is to investigate specific cases and outliers, using forensic techniques and medical experts who can check facts and carry out investigations but need to be empowered to access medical information. The last step is to take administrative sanctions and/or initiate civil or criminal legal proceedings. Overall, efforts must go into engaging and communicating with health professionals, recognising that errors can happen and that special circumstances can dictate deviations from good practices.

Self-regulation probably remains the norm, but some countries set limits to specific business practices. To tackle inappropriate business practices, countries' responses are typically regulatory in nature and consist of limiting or banning certain practices. Little attention is paid to actively detecting these types of integrity violations. Instead, countries rely on whistle-blowers to report integrity violations or on investigation of and reaction to a specific crisis, particularly when the health consequences are detrimental. The three main domains where some countries have introduced regulation seek to limit self-interested referrals by health providers and the means by which the pharmaceutical industry is allowed to promote sales – including Sunshine regulations (Box 1.10). The

Box 1.10. **Momentum for Sunshine regulations in OECD countries**

- Sunshine regulations consist of requiring that payments made by pharmaceutical and device industries to stakeholders in the health sector be systematically reported to authorities. In the last 15 years a number of countries introduced specific and comprehensive legislation, notably France, Portugal, the Slovak Republic and the United States. Another set of countries including Australia, Belgium, Denmark, Germany, Italy and Spain have rules on disclosure but these are typically less comprehensive (McDermott et al., 2015).
- The scope of Sunshine laws varies across countries. In the United States, industries must report relationships with physicians and teaching hospitals, whereas in France disclosure covers ties with all health professionals and associations representing them, scientific societies, patients' associations and the press. The type of transition disclosed is also variable. In the United States, all payments and transfers of value must be reported and disclosure can be delayed for some payments related to research. In France, fees and honoraria levels are not disclosed. Typically, information is centralised and made public in more or less user-friendly ways, for instance through a researchable online database.
- Critics of such regulation contend that it may damage providers' reputation, even if they do not act inappropriately or even reduce funding for innovation or medical education. On balance though, disclosure is gaining momentum and additional countries are considering legislation in that sense. Interestingly, the code of conduct of the European Federation of Pharmaceutical Industries and Associations requires that companies report all transfers of value to providers as of June 2016.

Table 1.4. **Who, why and what to do? Summary of findings on governance-related waste**

Category of waste	Actors	Main driver	Information systems required	Policy levers	Policy impact	Good practice examples
Administrative waste		Organisational shortcomings, inadequate regulation	Evaluation of costs and benefits of administrative activities Collection and disclosure of information on administrative performance	**Organisational change:** merging/separating/sharing among administrative institutions; improved co-ordination of administrative activities within and between institutions; user guides and protocols, improving management quality; improved use of ICT **Regulation:** removal of administrative tasks; legislative principles; budget ceilings; simplification of procedures; standardisation of forms and reporting requirements	?	**Australia:** Functional and efficiency review of the Commonwealth Department of Health assessing the efficiency and effectiveness of the Department's operations, programmes and administrations **Estonia:** Introduction of paperless e-prescription, reducing time spent to issue prescriptions and medication and for verification by provider and insurers
		Organisational shortcomings, inadequate regulation			+	**Germany, Netherlands:** Collaborative efforts of all stakeholders to quantify and agree on reduction of administrative reporting requirements that add little value
		Organisational shortcomings, inadequate regulation			?	**United States:** Stipulating the share of premiums that private insurers have to spend on medical claims
Integrity violations in service delivery and payment				**Organisational change:** setting up/empowering dedicated institutions/programmes; data mining	+	**Belgium:** INAMI (the National Institute for Health and Disability Insurance) uses data mining to detect integrity violations and a step-wise strategy to deal with integrity violations, and can take administrative sanctions (fines)
		Intentional deception	Publication of estimates; large-scale collection of treatment and billing data	**Behaviour change:** reporting hotlines, feed-back to outliers	?	**United Sates:** CMS uses contractors to detect error and possible fraud. Zone Program Integrity Contractors are authorised to conduct investigations and co-ordinate with law enforcement
				Regulation: administrative and legal sanctions	?	The **European Healthcare Fraud and Corruption Network** (EHFCN) serves as a knowledge exchange platform for countries interested in tackling these integrity violations
Inappropriate business practices		Intentional deception	Disclosure of information on potential for conflict of interests Disclosure of clinical trial data	**Regulation:** setting limits or banning specific practices (direct to consumer marketing, gifts and hospitality, self-interested referrals, etc.)	?	Countries with comprehensive and well-established Sunshine regulations include **Australia, France, Portugal, the Slovak Republic and the United States**

Industry; Regulator; Manager; Clinician; Patient.
+ Some evidence of positive impact but limited and system-dependent; **?** Impact so far unknown.

question of how to ensure the integrity of research, particularly regarding clinical trials and conflict of interest, is also gaining attention. In general though, industry self-regulation remains the norm.

Overall, many OECD countries need to strengthen their efforts to curb integrity violations in health, not only to reduce waste and increase efficiency, but to enhance transparency, improve the sector's integrity and contribute to patient safety as well (Table 1.4).

Conclusion: Additional benefits of tackling waste

In sum, this overview chapter highlights that waste manifests itself in many different segments of OECD health care systems and creates an unnecessary financial burden. To give a few examples:

- Adverse events in hospitals add between 13-16% to hospital costs, 28-72% of which are deemed avoidable according to international studies.
- Examples of unnecessary or inappropriate care abound at all points of the care pathway, starting with overtesting and overdiagnosis. Unnecessary use of surgical procedures is not an exception. For example, data collected by OECD reveal unwarranted variations across and within countries in rates of cardiac procedures (more than three-fold) and knee replacements (more than five-fold). Excessive use of medicines is also an issue; for instance, half of antimicrobial prescriptions are inappropriate.
- Between 12% and 56% of emergency hospital admissions are for conditions that could have been equally well or better treated in the less costly primary care setting.
- The potential for freeing up financial resources through the use of generic drugs is often not fully exploited – the share of generics in pharmaceuticals covered by basic health benefits varies between 10% and 80% in OECD countries.
- Administrative expenditure on health varies more than ten-fold across OECD countries. The cost depends on the design of the system. Increased complexity may bring about benefits and accountability for results, but duplication of competencies across agencies or reporting obligations that do not translate into actual monitoring are wasteful.
- Loss associated with fraud and error is on average 6% of payments for health care services.

Evidence is thus emerging that a significant share of health care system resources can be released and put to better use by eliminating activities that do not contribute to improving outcomes and by exchanging costly activities with cheaper alternatives that deliver identical or better outcomes.

This chapter and the rest of the report show that although waste is pervasive and takes many different forms, policy makers can act upon it. They need more information to set the relevant priorities. National and international initiatives are in place to collect and publish data on adverse events, low-value care or other types of waste. Successful programmes should be emulated and generalised. Mobilizing stakeholders can help raise awareness about waste in a given system. The Netherlands, for instance, launched a campaign in 2013 inviting people to report instances where they encountered waste (Box 1.11).

Box 1.11. **Mobilising stakeholders to identify and tackle waste in health and long-term care: The Dutch experience**

- In 2013, the Ministry of Health, Welfare and Sports launched a campaign to encourage citizens and professionals to report instances of waste they encountered.
- The virtual and anonymous reporting tool yielded more than 16 000 responses in three months, reflecting patients' experience with unnecessary use of care (wasteful clinical care), operational waste and governance-related waste (administrative burden and fraud).
- Subsequently, the Ministry launched a number of initiatives to address waste in three domains: medicines and medical devices, long-term care and curative health care. In consultation with stakeholders, specific action plans were formulated by steering committees chaired by independent experts. Initiatives included actions to: prevent the non-use of provided medical devices by pro-actively informing new users about the functionalities of their device; increase physicians' cost-awareness of their decisions regarding care; and prevent unnecessary visits to the emergency department.
- Additionally, pilots were initiated to: limit food waste in health care facilities; reduce unused medicine in end-of-life care; and avoid unplanned hospital readmissions through improved discharge management.
- Best practices were highlighted on the Ministry website to inspire other health care providers, and people who reported instances of waste were informed about progress via a quarterly digital newsletter.

Source: Lafeber, F. and P. Jeurissen (2013), "Reducing Waste in Health and Long-Term Care in the Netherlands", *Euro Observer*, Vol. 19, No. 4, pp. 34-37; and the Netherlands Ministry of Health, Welfare and Sports.

All OECD countries already have in place policies that tackle waste, implicitly or not. Yet opportunities remain for more systematic efforts. Strategic implications differ across categories of waste.

- Governance-related waste is present in all systems and should not be tolerated. Still, the magnitude of potential savings in OECD countries remains commensurate with the extent of the problem. For instance, strategically cutting back on administrative costs, which represent on average 3% of expenditure in OECD countries, will not alone put health care systems on a financially sustainable path. At the same time, well-targeted efforts to reduce governance-related waste can produce savings: in 2013-14, the US Department of Health and Human Services saved more than USD 12 for every one invested in its integrity programmes (HHS, 2016). More than savings perhaps, tackling governance-related waste is about improving governance, transparency and ultimately citizens' trust in health care systems.
- Reducing avoidable adverse events and low-value care could potentially release significant amounts of resources. At the same time, a top-down approach will not suffice. Sustainable progress towards better value from health care can only be achieved if patients and especially health care providers are on board, hence the importance of encouraging, emulating and learning from bottom-up initiatives such as local patient safety initiatives and *Choosing Wisely®*. Policy makers can create an environment that incentivises providing the right services rather than many of them – in other words, moving towards payment systems that promote value for the patient across stages of care delivery. More systematic use of HTA would also help reduce low-value care.

- Eliminating operational waste (in other words, ensuing that the lower-cost option to deliver a given benefit to patients becomes the natural or preferred option) is perhaps the most complex endeavour. In some cases (for instance, encouraging the use of generic drugs), pursuing available policy options is a matter of political priority and will. In others (for instance, reducing unwarranted use of hospital care), reforms can become complex and require far-reaching changes. Whether reforms can produce actual savings depends on a country's context and remains difficult to prove empirically. Reducing operational waste paves the way for efficiency-enhancing systemic reforms, though. For instance, any change that contributes to hospitals focusing on their mission to deliver highly technical and specialised services rather than less resource-intensive care is worth pursuing, as it ultimately supports the case for restructuring hospital networks.

The report has three subsequent parts. The first part discusses wasteful clinical care. It focuses on preventable medical errors and low-value care (Chapter 2) and, as a case study of low-value care, evaluates inappropriate antimicrobial prescription (Chapter 3). Chapters 4 and 5 cover operational waste and discuss prices and the use of high-cost inputs, respectively. Governance-related waste is disaggregated into administrative cost (Chapter 6) and integrity violations in the health sector (Chapter 7).

Notes

1. By way of illustration, the following considers whether specific inefficiencies are "wasteful" according to the convention adopted in the report:
   - Wrong site surgery: yes.
   - Robot-assisted surgery: yes – very costly and evidence is lacking that it improves outcomes (Wright et al., 2013; The Lancet, 2016).
   - Inpatient surgery when the outpatient option exists: yes, provided the cost is lower.
   - Insufficient investment in public health: no – additional investment may increase efficiency in the long run, but this does not help identify activities that should be dropped or replaced with cheaper alternatives while maintaining results for specific patients.
   - Insufficient co-ordination of care: it depends. Co-ordination can improve outcomes and efficiency in the long term, but not all shortcomings in co-ordination are wasteful. Maintaining a patient in the hospital because no follow-on care is organised is a wasteful failure in co-ordination.
   - Systematic imaging for low back pain: wasteful in most cases. Longer-term structural savings may require optimising the number and location of costly diagnostic imaging equipment.
2. It is worth highlighting that the distinction between clinicians and managers is somewhat artificial as many clinicians are responsible for managing resources.
3. As highlighted earlier, the report deals more with productive than allocative efficiency, while recognising that, outside of a textbook, distinguishing one from the other is partly a matter of judgement. The focus is on policies that can reduce waste, rather than all efficiency-enhancing reforms, such as investment in public health or the reconfiguring of hospital networks, which are more long-term.
4. Fifteen countries provided responses: Australia, Belgium, Denmark, France, Germany, Israel, Japan, the Netherlands, Norway, Poland, Slovenia, Spain, Switzerland, the United Kingdom and the United States.
5. This classification of policy levers is adapted from Roberts et al. (2008).
6. The term antimicrobials refers to a broad family of agents including any agent killing or inhibiting the growth of microbes. There are many classes of antimicrobials depending on the type of microbes targeted or the composition of the antimicrobial. Antibiotics (or antibacterials) are a sub-category of antimicrobials specifically targeting bacteria.
7. The differences should be interpreted with caution as definitions and estimation methodologies are subject to debate and differ across countries.

8. The opportunity to substitute clinical tasks among staff with different level of qualifications is considered under operational waste.
9. Including: Austria, the Czech Republic, Denmark, Estonia, Finland, Hungary, Ireland, Italy, Poland, the Slovak Republic, Slovenia, Spain and Sweden.

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PART I

Wasteful clinical care in health care systems

Wasteful clinical care refers to situations when patients do not receive the right care, for reasons that could be avoided thus – from a system perspective – unnecessarily expending resources to achieve a given outcome. Wasteful clinical care includes preventable clinical adverse events, as well as ineffective and inappropriate care – sometimes known as low-value care. Last, wasteful clinical care includes the unnecessary duplication of services.

In Part I of the report, Chapter 2 offers a comprehensive analysis of these various forms of wasteful clinical care and discusses options to tackle them. Chapter 3 examines in detail the inappropriate use of antimicrobials, which, in addition to being wasteful, encourages the development of antimicrobial resistance. Such a development could compromise the effectiveness of an entire range of life-saving health care services, with a potentially significant detrimental impact on the broader economy.

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PART I

Chapter 2

Producing the right health care: Reducing low-value care and adverse events

by
Ian Forde *and* Carol Nader

"Value" measures the health outcomes that matter to patients for every dollar spent. Health services that fail, for avoidable reasons, to maximise outcomes given available resources can be considered wasteful clinical care. Strong evidence exists that it persists in health care systems. Wasteful clinical care manifests itself in many forms: as avoidable adverse events and as care that is ineffective, inappropriate or poorly cost-effective – from the diagnosis of cancers that will not cause harm, to the sensitive matter of providing futile care near the end of life.

This chapter begins by describing the extent of wasteful care and exploring its drivers. Persistent challenges include a lack of metrics to quantify wasteful care and the need to sustainably engage both clinicians and patients to change practices. The chapter concludes by discussing the information systems needed to detect wasteful care and the policy levers to tackle it.

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The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Introduction

In general, patients receive good care in OECD health care systems, through the joint efforts of clinicians and patients to achieve the best possible outcomes. Risk is intrinsic to the process of diagnosis and treatment, and harm sometimes occurs even in the best care. But in many cases, clinicians and patients may not know (or may overlook) the most safe, effective or appropriate approach to dealing with a health care need. Disagreement over the "best" course of action may also arise. In many situations, therefore, patients receive health care that offers little or no benefit, or that leaves them worse off than before, for reasons that could have been avoided.

A treatment's cost and possible harm should not transcend its benefits. "Value" relates the health outcomes that matter to patients to the health care resources spent (Porter and Teisberg, 2006). Higher spending on health care does not necessarily equate to value. This is readily illustrated by looking at national health system accounts. The United States, for example, spends 16.4% of gross domestic product (GDP) on health care – almost double the OECD average of 8.9% (OECD, 2015a). Yet the United States does not achieve better outcomes on a range of health outcome measures, including life expectancy. One likely explanation is that some health care resources are spent in a wasteful manner.

Wasteful clinical care broadly refers to situations when patients do not receive the right care for reasons that could be avoided, thus – from a system perspective – unnecessarily expending resources to achieve a given outcome. Such cases include giving care that has no biologically plausible way of working; giving care that works for only some groups to patients unlikely to benefit; carrying out interventions that patients do not want; giving care that causes a serious complication that could have been avoided; or giving a person a service she has already had, such as repeated blood tests.

Given such diversity in the manifestations of wasteful clinical care, a key challenge in understanding and tackling the phenomenon is to better conceptualise it. Several terms are used to describe wasteful clinical care in the literature. Box 2.1 defines the terms used in this chapter and Table 2.1 provides a conceptual framework that serves as a guide throughout this chapter.

Reducing wasteful clinical care presents the dual opportunities of improving both quality of health care and efficiency. By gaining a better understanding of how these issues can be tackled, significant resources may be reallocated to provide more effective patient care and value for money. Section 1 of this chapter sets up the problem of low-value care; Section 2 focuses on adverse events; Section 3 considers the information systems needed to detect, analyse and prevent wasteful clinical care; and Section 4 concludes by describing policy levers adopted by OECD health care systems to deal with these challenges. Given the unparalleled population health risks associated with the wasteful overuse of antibiotics, this topic is dedicated a separate chapter (Chapter 3).

Box 2.1. **Wasteful clinical care: Definitions of key terms**

Wasteful clinical care refers to situations where patients receive health services that fail to maximise health outcomes, given the available resources, for reasons that could be avoided. Wasteful clinical care comprises two elements:

Preventable adverse events, which are unwanted and potentially harmful incidents that arise as a direct result of health care. Care may intrinsically be of high risk and lead to adverse events. In many instances, however, adverse events could have been prevented. Preventable adverse events can occur due to human factors and systemic failures such as poor care co-ordination.

Low-value care, which occurs when the benefit of an intervention is deemed too low given its cost and inherent risk. Low-value care exists in the form of:

- *Ineffective care:* Interventions whose clinical effectiveness is no better, or worse, than less expensive alternatives. This includes care that has no biologically plausible way of working and duplicated interventions, such as diagnostic tests, that are repeated due to inadequate information exchange or care co-ordination between providers.
- *Inappropriate care:* Interventions whose clinical effectiveness is no better, or worse, than less expensive alternatives for particular patient groups or in certain situations. Inappropriate care also includes interventions that are administered but are unwanted by the patient *and* unaligned with wider social values (some preventive healthcare may not be wanted by the individual but would still be appropriate, given externalities).
- *Poorly cost-effective care:* Interventions whose clinical effectiveness may be better than alternatives, but whose cost is disproportionately greater.

All types of low-value care can be preference-sensitive and/or supply-sensitive, to use the terminology of the Dartmouth Institute (*www.dartmouthatlas.org*).

Table 2.1. **Wasteful clinical care: Conceptual framework and terminology**

Category of wasteful clinical care	Intuitive formulation of the problem	Formal assessment criteria	
Preventable adverse events	Harm exceeds benefit	**SAFETY**	
Low-value care	Benefit not proven, or not better than less costly alternative, in some or all patients. Possibility of patient outcome being worse	**EFFECTIVENESS** ALL patients have the potential to benefit from an intervention	**APPROPRIATENESS** SOME patients have the potential to benefit from an intervention
	Benefit of an intervention better than alternative, but disproportionately more costly	**COST EFFECTIVENESS**	

Source: Adapted from Busse, R. et al. (forthcoming), "Can We Lower Low-value Care? Policy Measures and Lessons in Australia, Canada, England, France, and Germany", The Commonwealth Fund, New York.

1. Low-value care in OECD health care systems

Decision making about an individual's treatment should be a careful balance between a patient's preference and a clinician's judgement, taking into account the responsible use of resources. Instances when this alignment is not achieved can result in low-value care. This section first points to the inherent difficulty in defining what constitutes low or high value, given that the clinician, patient and payer may approach this concept in different ways. It then documents how low-value care can take place at difference phases of the care

pathway – from preventive care, to the use of medication, surgical interventions and medical devices, and the more sensitive issue of what care patients should receive as they approach death. The section closes by setting out the drivers of low-value care.

1.1. What constitutes "low-value" care depends on the perspective taken

Any discussion on the value of health care must start by recognising that "value" is a multifaceted concept, and that individuals and groups (such as patients, clinicians and payers) may understand it differently. Even if consensus was achieved on the elements of health care "value" and their relative weighting, quantification and comparison would remain difficult. Identifying "low-value" care, then, is challenging in practice.

In particular, what clinicians and patients consider to be the best course of action for a perceived health care need can be misaligned. Clinicians' specialist knowledge can create a power imbalance in the relationship. In a clinician's eyes, low-value care most probably refers to deviations from standard practice, which may be codified in clinical guidelines or protocols. Most of these are based on trials that draw on classic outcomes such as survival, complication rates and quality of life. These outcomes do not necessarily reflect the mix of results valued by individual patients. Trials' strict inclusion and exclusion criteria mean that their findings may not even relate to the typical patient.

On the other hand, patients' perception often relates to the health outcomes they wish to attain. In cancer care, for example, it is important that patients can weigh the various risks of treatment against their personal evaluation of the mix of outcomes such as survival and quality of life. In other instances, in the patient's mind, "doing nothing" may be indistinguishable from doing harm. Likewise, an approach strictly guided by clinical evidence may not be what they want. Managing patients' expectations has become more challenging because health care ethics have moved away from a simple injunction to "do no harm" to an emphasis on patients' right to actively participate in decisions about their own care. While the role of patients in participating in their care must be respected and encouraged, alignment needs to be sought with clinicians' judgement and the responsible use of resources.

Evidence regarding the extent of misalignment in perceptions of value is not hard to find. In a study of more than 1 000 patients with incurable cancer in the United States, for example, 69% of those with lung cancer and 81% of those with colorectal cancer responded in a way that showed they did not understand that chemotherapy was "not at all likely" to cure their cancer (Weeks et al., 2012). The use of coronary artery stents (for heart disease) demonstrates how the patient's perception can be at odds with that of the clinician. A study found 88% of patients who had committed to this type of procedure believed that it would reduce their risk of heart attack, while 63% of cardiologists believed benefits were limited to symptom relief (Rothberg et al., 2010). Such "preference misdiagnosis" is wasteful, because well-informed patients might choose to consume fewer health care resources (Mulley et al., 2012).

When overtreatment is considered from a payer and policy maker perspective, considerations go beyond effectiveness of treatment and patient safety to encompass costs. Classic approaches are cost-effectiveness analysis or cost-benefit analysis to inform decisions about whether a treatment's possible benefits are worth its costs. This information can help to make decisions about whether treatment should be reimbursed from collective means. Potential individual outcomes are judged against collective

outcomes, as well as feasible alternatives. In addition to making these assessments from a societal perspective, the costs can also be considered from a health care system or health services perspective, in the form of a cost-impact analysis.

In sum, it is important to recognise that the definition or what constitutes low-value care depends on societal and individual preferences, may differ across health care systems, and is bound to evolve. Still, it is possible to find consensus on some core components and to show that low-value care permeates all stages of the care pathway.

1.2. Low-value care almost certainly exists at all stages of the care pathway, from health promotion to end-of-life care

Overtreatment often begins with overtesting (that is, tests that are not needed to maintain or improve an individual's health) and overdiagnosis (that is, diagnosis of a condition that will not cause harm to the individual). The more we search for abnormal findings, the more we are likely to find them – even if they have no relevance to an individual's health. The search is ever easier and more powerful thanks to new tests for novel clinical parameters, cheaper technology, increased sensitivity of screening tools and public demand. The consequence is that healthy individuals are subjected to unnecessary clinical care, implying an opportunity cost of wasted resources that could have been better spent on higher-value health care activities. Substantial psychosocial costs are also implied, in the form of heightened anxiety or despair on the part of those labelled patients, and possibly stigma associated with some diagnoses.

Low-value care may begin with well-intentioned efforts to offer preventive care. For instance, general health checks are offered by some health care systems to whoever requests one. Yet little evidence exists that general health checks are associated with lower rates of mortality or morbidity. Such checks may increase the number of diagnoses and the use of medication (Krogsbøll et al., 2013). A particularly challenging illustration of the problem relates to cancer screening. While appropriately targeted screening can be life-saving, in some cases cancers detected are non-progressive or grow so slowly it is likely that people will die from something else before the cancer causes symptoms. The difficulty for clinicians is they cannot always identify tumours unlikely to cause harm, so they often treat all cancers found. This has been described as "pseudo disease" (Welch and Black, 2010).

Cancer survival statistics used to pronounce the success of screening may in fact be artificially enhanced by changes in diagnostic practices detecting cancer in healthy people who would not have died from the disease (Welch et al., 2000). This encourages more screening and results in higher disease prevalence, and subsequent unnecessary and wasteful treatment. A substantial literature documents the overdiagnosis of cancer (Box 2.2).

The overuse of vitamins and minerals, believed by some to be a natural way to prevent disease, prompted an editorial in the *Annals of Internal Medicine* declaring "enough is enough" (Guallar et al., 2013). The editorial was accompanied by three studies showing such supplements had no benefits on cognitive function (Grodstein et al., 2013), did little to prevent cancer or cardiovascular disease (Fortmann et al., 2013), and did not reduce cardiovascular events after a heart attack compared with a placebo (Lamas et al., 2013). The editorial also cited studies indicating overuse had possible harms. For example, Miller et al. (2005) found high dosages of vitamin E supplementation may increase all-cause mortality.

Box 2.2. **Overdiagnosis of cancer**

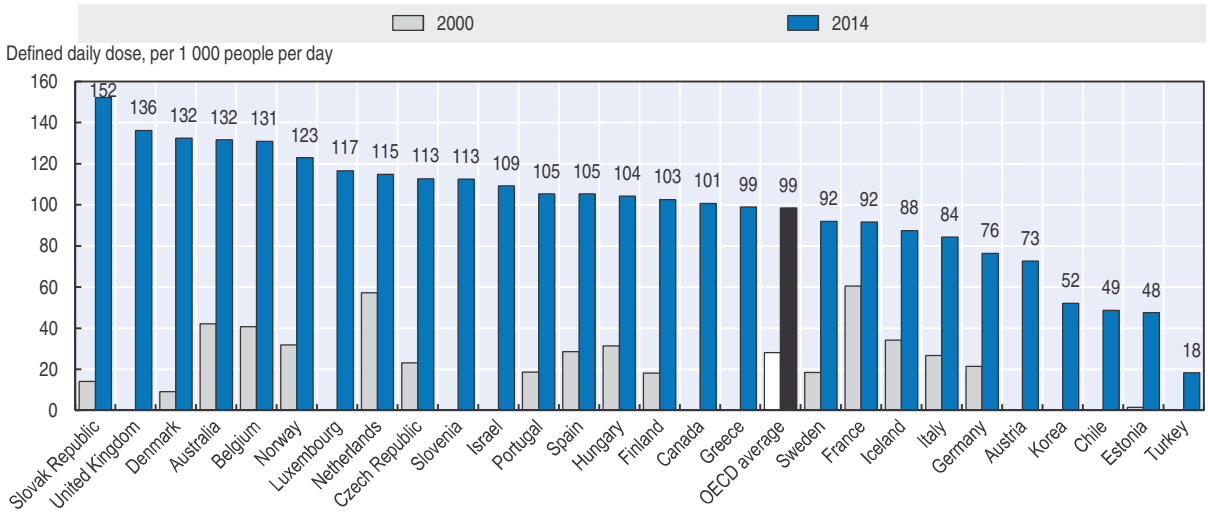
While screening plays an important role in improving breast cancer survival through early detection, several reviews indicate overdiagnosis is a problem. A Cochrane review found for every 2 000 women invited for breast cancer screening with mammography during ten years, one will have her life prolonged and ten healthy women who would not have been diagnosed had they not been screened will be treated unnecessarily (Gøtzsche and Jørgensen, 2013), suggesting the need for a more targeted approach. A review in the United Kingdom estimates that for every 10 000 British women aged 50 years invited to screening for the next 20 years, 43 deaths from breast cancer will be prevented and 129 cases of invasive and non-invasive breast cancer will be overdiagnosed and treated (Independent UK Panel on Breast Cancer Screening, 2012).

A study of the National Lung Screening Trial (NLST) in the United States found a 20% decrease in mortality from detecting lung cancer with low-dose computed tomography (CT) scan compared with radiography (National Lung Screening Trial Research Team, 2011). However, an analysis of data from the NLST found more than 18% of lung cancers detected seemed to be indolent, pointing to overdiagnosis (Patz et al., 2014). Concerns persist that higher radiation doses in CT scans can increase the risk of harmful cancer. One study estimated that about 29 000 future cancers could be related to CT scans performed in the United States in 2007, mostly scans of the abdomen and pelvis, chest and head (Berrington de González et al., 2009). A cost-effectiveness analysis of screening in the NLST found screening with low-dose CT – as compared with no screening – had an incremental cost-effectiveness ratio (ICER) of USD 81 000 per quality-adjusted life-year (QALY) gained (Black et al., 2014). While the ICER threshold at which an intervention is considered cost-effective is being internationally debated (see Box 2.10), the national implementation of such a scheme should balance the benefits gained against the high costs and the potential harm.

A European randomised trial of prostate cancer screening found a reduction in mortality due to screening, equivalent to 1 death averted per 781 men invited for screening, or 1 per 27 additional prostate cancers detected (Schröder et al., 2014). However, overdiagnosis of prostate cancer is estimated to range between 1.7% and 67.0%. These differences are due to variations in calculations, populations and screening practices (Loeb et al., 2014).

Low-value care is also an issue in secondary prevention and the management of chronic disease. For instance, in a study of adults with controlled type-2 diabetes in the United States, McCoy et al. (2015) found that more than 60% received too many HbA1c tests, used to assess blood glucose levels. Another example concerns statins, which lower cholesterol levels in the blood, reducing the risk of heart attack and stroke. Despite the existence of clinical guidelines, there is evidence of patients being given statins despite not meeting the criteria for treatment. A study in the United States found overuse of statins among 69% of patients undergoing primary prevention, and among 47% of patients undergoing secondary prevention (Abookire et al., 2001). At the same time, undertreatment of statins persists among those who have a medical reason to take them according to guidelines (Abookire et al., 2001; Tonstad et al., 2004). Between 2000 and 2014 the use of cholesterol-lowering drugs more than tripled, from 28 to 99 defined daily dose (DDD) per 1 000 people per day in OECD countries (Figure 2.1).

Figure 2.1. **Cholesterol-lowering drug consumption, 2000 and 2014 (or nearest year)**



Note: The OECD average includes 27 countries.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink *http://dx.doi.org/10.1787/888933444002*

Low-value care is also widespread at times of acute care. For instance, caesarean section rates are worryingly high in most countries (see Section 1.3). Another example concerns the use of Percutaneous Coronary Intervention (PCI), a procedure in which a device called a stent is used to open blocked blood vessels. The use of stents in some higher-risk patients can reduce the risk of cardiovascular events. In more stable patients, there is little evidence that stents reduce the risk of death and other poor outcomes (Hochman et al., 2006; Boden et al., 2007), yet stents continue to be used in this group. In a study in the United States, almost all acute PCIs were classified as appropriate. However, 12% of non-acute indications were classified as inappropriate, 38% as uncertain, and only half as appropriate (Chan et al., 2011).

Evidence exists of overtreatment with many other costly interventions. In an analysis of Australian hospitals, for example, five procedures not supported by clinical evidence took place on average more than 100 times a week. The five "do not do" procedures were: vertebroplasty for painful osteoporotic vertebral fractures (a surgical procedure to treat compression fractures in the spine); knee arthroscopy for osteoarthritis; laparoscopic uterine nerve ablation for chronic pelvic pain (a small segment of ligament that carries nerve fibres is destroyed); removal of healthy ovaries during a hysterectomy; and hyperbaric oxygen therapy for a range of conditions including cancer, Crohn's disease and cerebrovascular disease (Duckett et al., 2015). Box 2.3 lists some other common instances of overuse.

Overtreatment can even be an issue in areas long considered the exclusive domain of undertreatment. In the case of malaria, undertreatment can result in disease progression and death. This prompted "presumptive" treatment for all patients with fever in endemic areas where diagnostic testing was not available. This response led to overtreatment with antimalarials. Despite the increasing availability of rapid diagnostic tests (RDTs), overtreatment remains a problem (Ochodo et al., 2016). The rise of antibiotic consumption is a special case that has now become an urgent global priority for action, as discussed in detail in Chapter 3. Overtreatment also encompasses matters that are less straightforward, such as end-of-life care (Box 2.4).

Box 2.3. **Common instances of overdiagnosis or overtreatment**

- Imaging for low back pain.
- Imaging for headaches.
- Antibiotics for upper respiratory tract infection.
- Dual energy X-ray absorptiometry (used to measure bone mineral density).
- Preoperative testing in low-risk patients (electrocardiography, stress electrocardiography, chest radiography).
- Antipsychotics in older patients.
- Artificial nutrition in patients with advanced dementia or advanced cancer.
- Proton pump inhibitors in gastro-oesophageal reflux disease.
- Urinary catheter placement.
- Cardiac imaging in low-risk patients.
- Induction of labour.
- Cancer screening (cervical smear test, CA-125 antigen for ovarian cancer, prostate-specific antigen screening, mammography).
- Caesarean section.

Source: Adapted from Hurley, R. (2014), "Can Doctors Reduce Harmful Medical Overuse Worldwide?", *British Medical Journal*, Vol. 349, g4289, *http://dx.doi.org/10.1136/bmj.g4289*.

1.3. Significant uncertainty remains about the extent of low-value care, but patterns of practice variation suggest widespread occurrence

The cost associated with wasteful overtreatment in the United States was estimated to be between USD 158 billion and USD 226 billion in 2011 (Berwick and Hackbarth, 2012). Estimates are rare, however. Health care systems still struggle to quantify the true extent of low-value care, partly because of the lack of consensus on how to define it. This handicap should not deflect attention from the issue in each and every health care system – prodigious variation in clinical practice across regions, unexplained by need, suggests an urgent need to quantify and tackle low-value care.

A rare exception to the lack of consensus on defining low value concerns births by caesarean section. The internationally accepted consensus is that the ideal rate for caesarean sections is between 10% and 15% of all births (WHO, 2015a). No OECD countries fall within this band (Figure 2.2). In 12 OECD countries, at least 30% of births are delivered by caesarean section, and on average the caesarean section rate across the OECD rose from 20.3% in 2000 to 27.5% in 2014. These data demonstrate that many caesareans are inappropriate and, from a system point of view, represent low value. The drivers behind this phenomenon are considered in Box 2.4.

Another example where the idea of appropriateness is clear concerns the use of benzodiazepines, prescribed for anxiety and sleep disorders. For the elderly, most guidelines advise complete avoidance (that is, an ideal rate of 0%) because of the risk of dizziness, confusion and falls (Sithamparanathan et al., 2012). The OECD recently published international comparisons of the use of these medications in the elderly. Currently, 13 OECD countries report on long-term use, and 14 report on use of long-acting formulations (Figures 2.3 and 2.4). The data demonstrate wide variation between countries, and show that in some countries inappropriate prescribing is a major issue.

Box 2.4. **Overtreatment and end-of-life care: Striking a sensitive balance**

A recent systematic review of 38 studies estimates that 33-38% patients near the end of life received non-beneficial treatment, such as chemotherapy in the last six weeks of life or admission to an intensive care unit for patients with terminal disease (Cardona-Morrell et al., 2016). The provision of intensive care for the terminally ill is an emotive debate for patients, their families and clinicians. Intensive care consumes substantial resources, accounting for about 20% of the total hospital budget (Tan et al., 2012). The use of costly resources in intensive care units, which often run at close to full occupancy, is a difficult issue for policy makers. Finding the balance between the responsible use of resources while being sensitive to the wishes of patients so they experience a "good" death is no easy feat.

Decisions about how such resources are used should be made prudently. Yet they should not be guided by cost and high occupancy rates alone. Providing unwanted and futile intensive care for people who have expressed a preference to spend their last days at home unnecessarily prolongs their suffering, and can be traumatic for their families and the clinicians administering the treatment.

The wide variation between countries in the use of intensive care at the end of life suggests that some of this care is unwarranted. In a study of patients older than 65 who died of cancer in seven countries, 40% of those in the United States had an intensive care unit admission in the last 180 days of life, compared with 8% in Germany and 10% in the Netherlands. However, the United States also had the lowest proportion of people dying in hospital (22.2%), compared with more than 50% in Belgium and Canada (Bekelman et al., 2016).

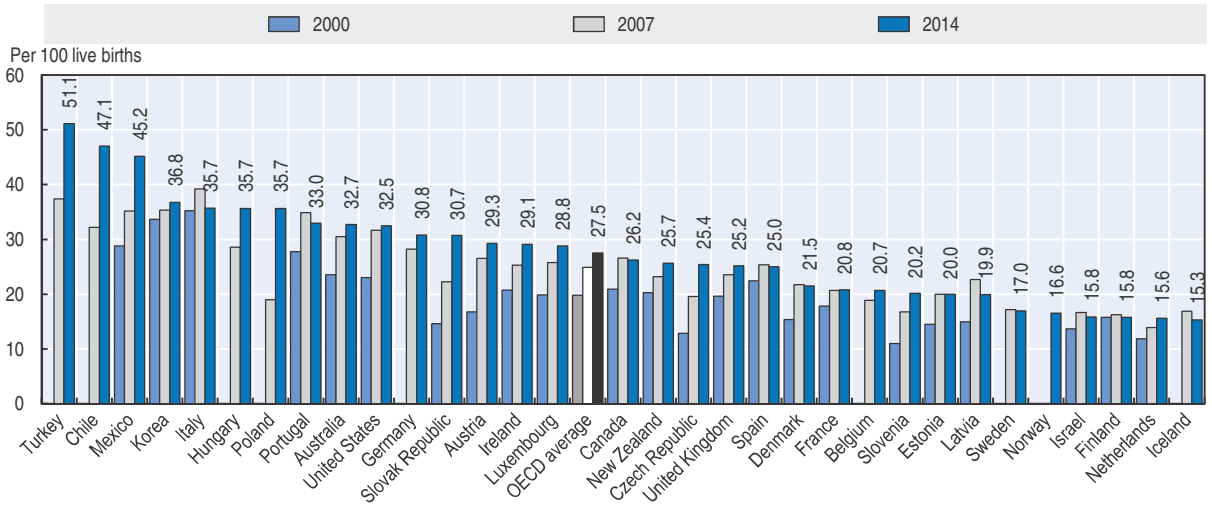
Chemotherapy may be prescribed to cancer patients near the end of life in the belief that it may improve quality of life in their final days. Yet evidence suggests that chemotherapy does not necessarily improve quality of life near death, and may even worsen it in some cases (Prigerson et al., 2015).

These decisions are more challenging when patients' wishes are unknown, as clinicians treat them out of caution, inadvertently defying patients' preferences. Families may also issue emotive appeals to "do whatever you can" – possibly contravening the patient's wish.

In one stark example, Marik (2014) writes of an 86-year-old patient who spent almost three months in the intensive care unit of a hospital before her death. The patient was assessed as having a negligible chance of leaving the intensive care unit alive. While she did not have an advance directive, she had apparently expressed the wish that she did not want to be on a machine. Despite this, in consultation with the family, the surgical team continued "all aggressive supportive measures". The protracted treatment and the patient's suffering had an emotional toll on her health care providers. The aggregate hospital charge was more than USD 820 000. With elderly patients accounting for almost 60% of all intensive care unit days, a disproportionate number of these days are spent by elderly patients before their death, representing unnecessary suffering for patients and a considerable cost for health care systems (Marik, 2014).

Caesarean sections and benzodiazepine prescription for the elderly are special cases because: i) an ideal rate has been defined; and ii) the relevant population (women and the elderly, respectively) is easy to identify in most administrative databases. These two conditions are not met for most other health care interventions. Even if consensus on an ideal rate was achieved for more interventions, most databases fail to link health care activities to needs or outcomes. This makes it near-impossible to establish the extent of inappropriate or ineffective care.

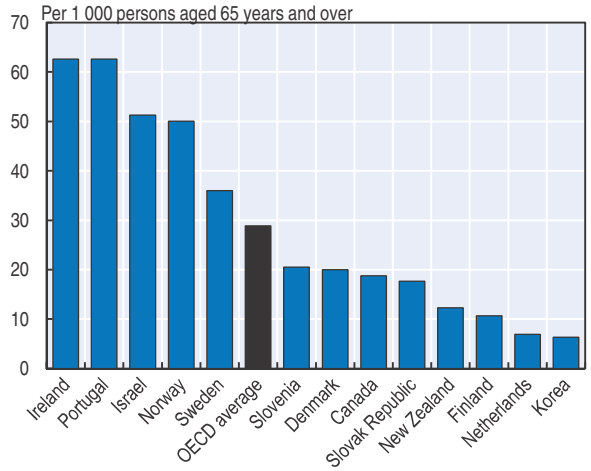
Figure 2.2. **Changes in caesarean section rates, 2000 to 2014 (or nearest year)**



Note: The OECD average includes 32 countries.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444013

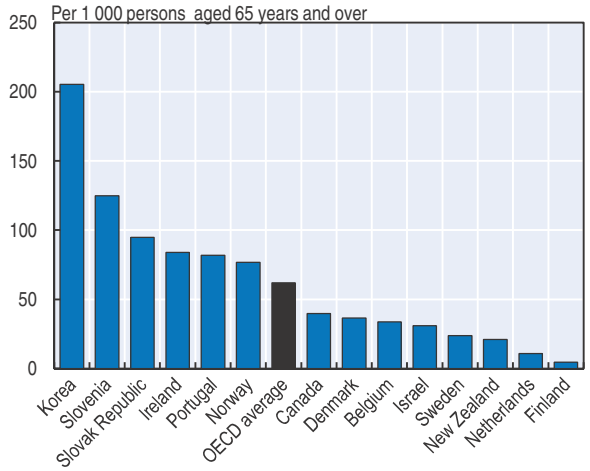
Figure 2.3. **Elderly people prescribed long-term benzodiazepines or related drugs, 2013 (or nearest year)**



Note: The OECD average includes 13 countries.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444023

Figure 2.4. **Elderly people prescribed long-acting benzodiazepines or related drugs, 2013 (or nearest year)**



Note: The OECD average includes 14 countries.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444039

Despite these difficulties, analysis of medical practice variation between providers and regions is increasingly being used by several OECD countries to identify where inappropriate care may be taking place. Some countries developed atlases of variation to help identify unwarranted variation that can be indicative of inappropriate care (Box 2.5). Significant variation in both diagnostic and therapeutic interventions is evident across OECD health care systems. Even in the absence of an ideal rate, or an administratively easy way to identify the population whose health care needs make the intervention (in)appropriate, much higher rates of an intervention in one place compared to another raise the possibility of low value.

Box 2.5. **Drivers behind the international rise in caesarean sections**

There is extensive international debate about the extent to which maternal preference is contributing to the rise in caesarean sections. In Turkey, where caesareans account for half of births (Figure 2.2), a study of more than 400 women who had a caesarean delivery found that only 16% had real indications for the intervention, while the rest had the potential for a vaginal delivery. About 44% reported preferring caesarean delivery due to labour pain and fear, and 15% thought it was healthier for the baby. Another 15% had a repeat caesarean (Akarsu and Mucuk, 2014). This differs from the experience of other countries. For example, an Australian study found that maternal and infant factors and a shift towards private hospital care explained only 24% of the increase in caesareans, suggesting other factors have an influence (Roberts et al., 2012). A study in the United States found the relative contribution of maternal request to the total increase in primary caesarean rate was only 8% (Barber et al., 2011).

Physicians' perceptions and behaviour may be driving the trend. In the Turkish study, 69% of women reported it was their doctors' preference, 18% said it was a joint decision with their doctor, and 13% said the choice was their own (Akarsu and Mucuk, 2014). In a survey in the United States, 25% of mothers who had a caesarean reported experiencing pressure from a health professional to have the intervention (Declercq et al., 2013).

The rise may also be due in part to doctors embracing defensive medicine. Murphy et al. (2007) showed an association between rising professional liability premiums and an increase in the rate of primary caesarean delivery. Jena et al. (2015) found that obstetricians with higher caesarean rates had lower subsequent rates of alleged malpractice.

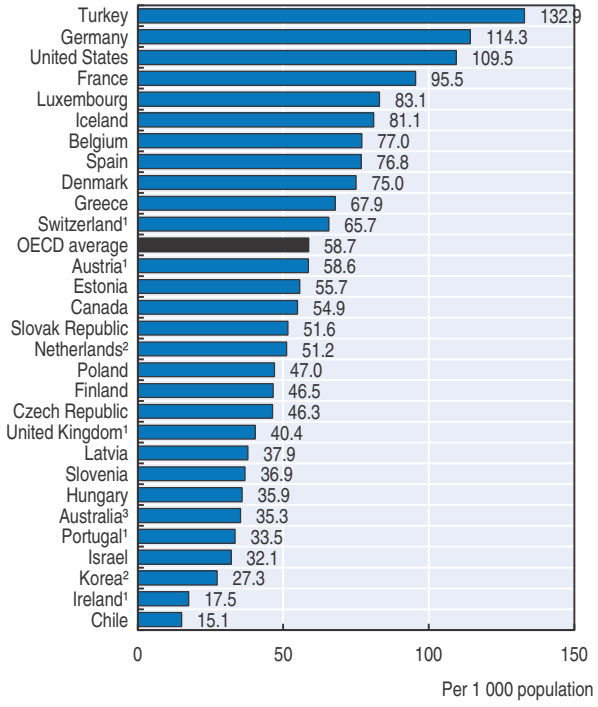
Financial incentives for providers appear to be another driver. In a Greek study, among women who delivered in a private hospital, 65% with private insurance had a caesarean, compared with 24% of uninsured women. The considerably higher private health insurance reimbursement for caesareans versus that for vaginal birth gave physicians an incentive to perform caesareans (Mossialos et al., 2005).

Gruber et al. (1999) found that larger fee disparities between caesarean and vaginal delivery across states' Medicaid programme led to higher caesarean rates. Further, the lower fee differences between caesarean and normal childbirth under the Medicaid programme than under private insurance explained between one-half and three-quarters of the difference between (lower) Medicaid and (higher) private caesarean delivery rates, suggesting that cutting reimbursement for caesarean delivery under Medicaid lowered the intensity of treatment of childbirth. A more recent Canadian analysis found that doubling the compensation received for a caesarean section relative to a vaginal delivery increased the likelihood that a birth was delivered by caesarean section by 5.6 percentage points (Allin et al., 2015). In contrast, an analysis by Grant (2009) found that financial incentives had, at best, a small effect on delivery method. In 2008 dollars, an increase of USD 1 000 in the reimbursement for performing a caesarean would increase caesarean delivery rates by little more than 1 percentage point.

At the very least, these studies indicate a need for greater exploration of the extent to which financial factors are driving up rates of unnecessary caesarean section. The use of financial incentives as an instrument to change physician behaviour is discussed more in Section 3 of this chapter.

Differences in rates of magnetic resonance imaging (MRI) and CT scans are one illustration. While the use of these technologies has grown across all health care systems, the extent of their inappropriate use is less clear. OECD data demonstrate wide variation in rates of both MRI and CT exams (Figures 2.5 and 2.6). Since the data capture only the overall rates and do not specify the medical indication for the exams, it is difficult to establish the extent of overuse. The variation between countries suggests some inappropriate use. For example, rates of CT exams are nearly eight times higher in the United States than in Finland (255 compared with 32 per 1 000 population, respectively).

Figure 2.5. **MRI exams, 2014 (or nearest year)**



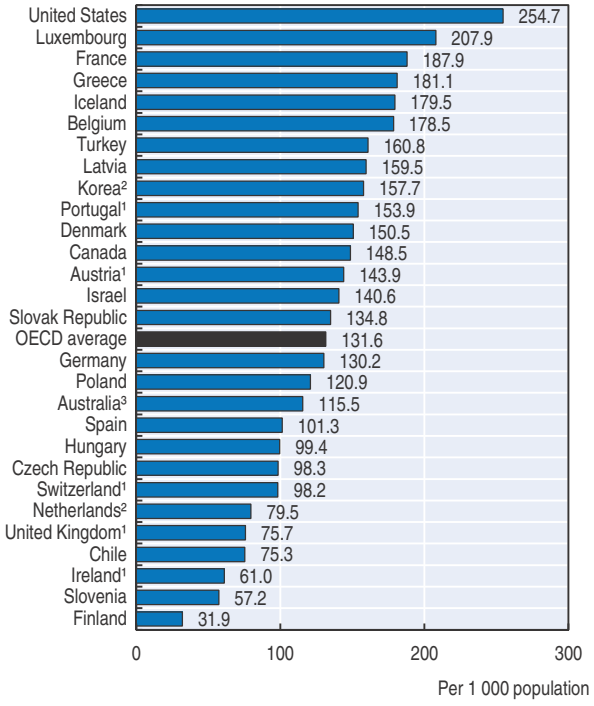
Note: The OECD average includes 29 countries.

1. The exams outside hospital are not included (in Ireland, exams in private hospitals are also not included).
2. The exams privately funded are not included.
3. The exams on public patients are not included.

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444047

Figure 2.6. **CT exams, 2014 (or nearest year)**



Note: The OECD average includes 28 countries.

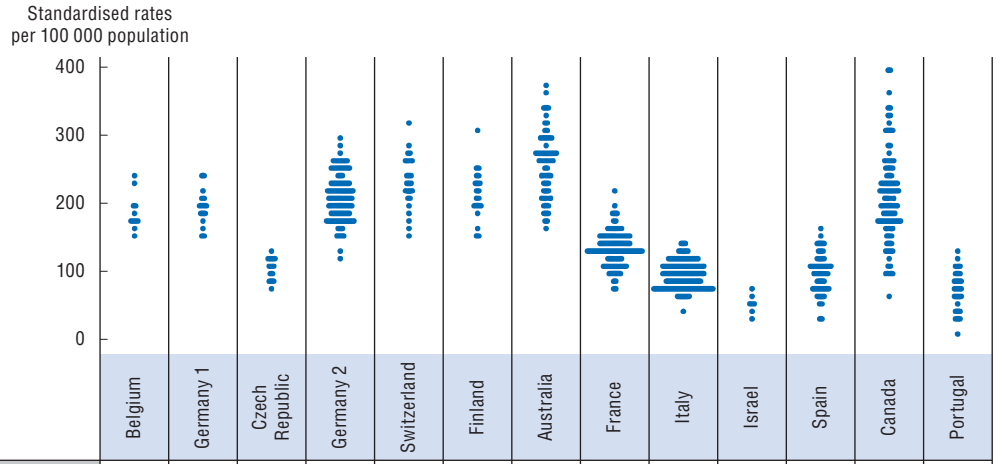
1. The exams outside hospital are not included (in Ireland, exams in private hospitals are also not included).
2. The exams privately funded are not included.
3. The exams on public patients are not included.

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444052

Practice variation exists within as well as across health care systems. The OECD explored the extent of this for ten procedures in 13 countries. Rates of knee replacement (adjusted for age and sex) are an illustration. These vary more than four-fold across countries (Figure 2.7): in Australia, Canada, Finland, Germany and Switzerland, rates are more than 200 per 100 000 population aged over 15, compared to 56 per 100 000 in Israel. The figure also demonstrates within-country variation. Each dot represents an administrative area within the national health care system. Knee replacements are shown to vary by two- to three-fold within most countries, and by more than five-fold within Canada, Portugal and Spain (OECD, 2014). The data are purely descriptive, however, and do not take into account patients' preferences or professionals' beliefs.

Figure 2.7. **Knee replacement rate across and within selected OECD countries, 2011 (or latest year)**



	Belgium	Germany 1	Czech Republic	Germany 2	Switzerland	Finland	Australia	France	Italy	Israel	Spain	Canada	Portugal
Crude rate	210	215	113	215	257	240	238	133	122	45	106	193	77
Std rate	186	194	105	209	230	213	257	135	96	56	98	213	74
Coeff. of variation	0.14	0.15	0.16	0.17	0.17	0.18	0.19	0.19	0.20	0.28	0.31	0.32	0.39

Note: Each dot represents a territorial unit. Rates are standardised using OECD's population over 15 years. Countries are ordered from lowest to highest coefficient of variation within countries. Data for Portugal and Spain only include public hospitals. For Spain, the rates are reported based on the province where the hospital is located. Germany 1 and 2 refers to Länder and Spatial Planning Regions, respectively.
Source: OECD (2014), *Geographic Variations in Health Care: What Do We Know and What Can Be Done to Improve Health System Performance?*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264216594-en*.

1.4. Drivers of low-value care include poor decision making, poor organisation and poorly designed incentives

Many of the drivers of health care system waste set out in Chapter 1 underpin low-value care. Poor decision making affects both clinicians and patients. Clinicians' propensity to deliver low-value care may be driven by a knowledge deficit ("I do not know any better"), a cognitive bias ("this is how everybody does it"), or a resistance to changing traditional practice ("this is how we have always done it"). It may be also be driven by fear. "Defensive medicine" refers to practice that seeks to minimise the risk of litigation. This often manifests as ordering unnecessary tests to reduce the risk of missing something serious. In a study of 435 emergency physicians in the United States, more than 85% believed too many diagnostic tests were ordered in their own emergency departments (EDs), and 97% said at least some of the advanced imaging they personally ordered was medically unnecessary. The main perceived contributors were fear of missing a low-probability diagnosis and fear of litigation (Kanzaria et al., 2015).

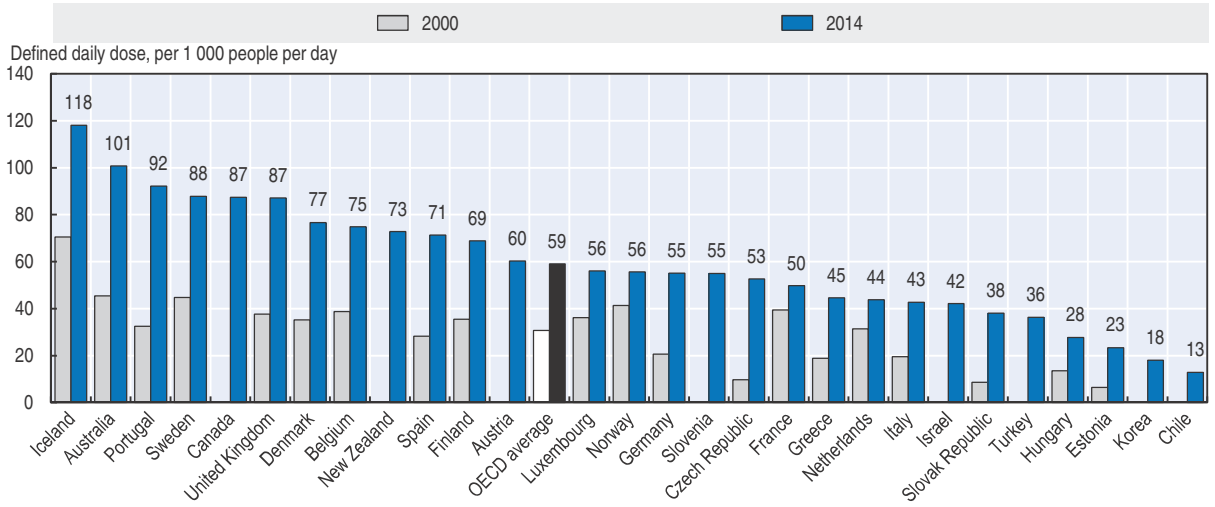
Low-value care may also be driven by patients' decisions. Democratisation, through the Internet, of specialist knowledge that previously defined the clinical professions can drive patient-induced demand. This can exert pressure on clinicians to order additional investigations, prescribe medication, or arrange interventions that offer little benefit. Health care companies may seek to influence patient preference. The United States and New Zealand are rare examples of countries that permit direct advertising of prescription drugs to consumers. Providing the public with more information may improve their understanding and help address the problem of undertreatment, but it can also promote inappropriate prescribing if patients make a brand-specific request or request an inappropriate, ineffective or poorly

cost-effective treatment (Kravitz et al., 2005; Murray et al., 2003). Patients with health care insurance may be more insistent upon additional services than those who pay out-of-pocket, since they have little incentive to avoid low-value care.

Both clinicians' and patients' behaviour can be shaped by the social construction of disease and the medicalisation of normal human experience. This has resulted in expansions in the definition of disease. In some cases, members of working groups making decisions about changing definitions have financial links with pharmaceutical or clinical supplies companies; this raises concerns about the potential for conflicts of interest to influence prescribing behaviour. The practice also jeopardises the credibility of the guidelines and the public's trust in their veracity. One study found that of 16 publications on 14 common conditions, 10 proposed changes widening definitions. Only one proposed changes narrowing definitions. Among 14 panels with disclosures, an average 75% of members had industry ties, and 12 were chaired by people with such ties (Moynihan et al., 2013).

In another example, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), published by the American Psychiatric Association (APA), provides the standard criteria for the classification of mental health conditions. The most recent fifth addition (DSM-V) was accused of medicalising grief by removing the exclusion of the death of a loved one as a criterion for a major depressive episode lasting less than two months. Mojtabai (2011), in calling for the grief exclusion to remain, found that the risk of new depressive episodes among participants with bereavement-related, single, brief episodes was significantly lower than among participants with episodes unrelated to bereavement, but similar to the risk among the general population with no history of depression. On its website, the APA says the cost of developing DSM-V "came from APA's reserves and the association received no commercial or government funding for the development of DSM-V" (APA, 2014). However, Cosgrove and Krimsky (2012) found 69% of DSM-V taskforce members reported ties to the pharmaceutical industry, and in three-quarters of the workgroups, a majority of their members had financial ties to pharmaceutical companies. Between 2000 and 2014 the use of antidepressant medication almost doubled, from 31 to 59 DDD per 1 000 people per day in OECD countries (Figure 2.8).

Figure 2.8. **Antidepressant consumption, 2000 and 2014 (or nearest year)**



Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444060

Poor organisation and co-ordination between providers can result in the poor transfer of information, miscommunication or misunderstandings, compromising patient care. Consequently, patients may be given medication that they do not need or that adversely interacts with other medication. This issue is particularly acute in the care of elderly individuals, who may receive treatment for a number of chronic illnesses and who may be less able to navigate complex pathways of care. How to improve the smooth functioning of teams in the health care setting is receiving increasing attention from academics and policy makers, with some looking to techniques used in industry for inspiration (such as "Lean Management", explored in greater depth in Chapter 5).

Poorly designed incentives are also relevant. In particular, payment systems that reward clinicians for large volumes of activity can create an incentive for overtreatment. Under traditional fee-for-service (FFS) or case-based payment systems, for example, clinicians are paid to provide more care, not necessarily better or more efficient care. Additionally, clinicians may make more money if they perform more intensive interventions (see Box 2.5). Another idiosyncrasy of the system is that hospitals may be rewarded for adverse events, as patients often require longer hospital stays or re-admission and more intense treatment as a consequence.

Drivers of low-value care should not be viewed in isolation, but rather as a series of interacting influences. A poor decision early on in a patient's care, for example, can propagate low-value care indefinitely in a causal chain that is sustained by multiple factors. One illustration concerns dependence on prescribed medication. Opioids prescribed for short-term pain, for example, can set some patients up for long-term use (Alam et al., 2012; Clarke et al., 2014). An analysis of Medicaid patients in the United States found that prescriptions for opioids were filled by 42% of patients within seven days following surgical tooth extraction. Yet non-opioid analgesics are often more appropriate (Baker et al., 2016). The combined influence of multiple drivers is also illustrated by the increasing prevalence of caesarean sections across OECD health care systems (Box 2.5).

2. Adverse events in OECD health care systems

Patient safety is one of the most emotive issues in health care, and one of the most clinically and politically challenging. Despite the best efforts of patients, clinicians and managers, unintended outcomes, including health care-associated infections, post-operative complications and medication errors, persist in health care systems. The complexities and uncertainties of medicine mean there will always be a chance of something going awry, but a great deal can be done to minimise the risk of these events. This section documents the human and health care system costs of adverse events.

2.1. Adverse events are devastating for patients, wasteful for health care systems and often preventable

Adverse events threaten patient safety. The Harvard Medical Practice Study (Brennan et al., 1991) defined an adverse event as "an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalisation, produced a disability at the time of discharge, or both." In a similar vein, the Institute for Healthcare Improvement (IHI) defines an adverse event as "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated

medical treatment), that requires additional monitoring, treatment, or hospitalisation, or that results in death" (*www.ihi.org/*). A "clinical error" may lead to an adverse event or may not, if detected in time or simply through good fortune (Reason, 2000).

Adverse events cannot always be avoided given the complex and high-risk nature of some procedures. Safe, high-quality care may still have an adverse outcome, such as post-operative sepsis. Nevertheless, many adverse events are preventable (a systematic review suggests that at least 20% of hospital-acquired sepsis is probably preventable [Harbarth et al., 2003]), so increased incidence at an aggregate level may indicate a systemic problem (OECD, 2015a).

Within the set of adverse events, a subgroup of "never events" can be identified. These rare events include the failure to remove foreign bodies (such as clips or swabs) after surgery, and operating on the wrong site, such as removal of the wrong kidney. These should never occur in health care systems and are always preventable. The terms "never events" and "sentinel events" are sometimes used interchangeably.

The drivers of adverse events are multiple, but the root causes more often lie in systemic failures rather than individual lapses of judgement. Tasks may have been inappropriately delegated to ill-qualified or poorly supervised people. Failures in communication and a lack of information-sharing between staff are also associated with error (Mazzocco et al., 2009). Cases of communication breakdown are often due to status asymmetry and ambiguity about responsibilities (Greenberg et al., 2007), and can be exacerbated by fatigue from long hours, poor morale or lack of support among health care staff.

Financial and human resource limitations can create the conditions for adverse events to occur. An association between weekend hospital admission for stroke and increased mortality has been demonstrated, likely due to reduced resources and expertise on weekends (Saposnik et al., 2007). Weekend admission is also associated with a higher likelihood of "never events" (Attenello et al., 2015). Other studies found an association between nurse staffing below target levels and increased patient mortality (Needleman et al., 2011; Tourangeau et al., 2007). Epstein et al. (2012) identified an association between high levels of ED crowding and risk of preventable errors (Table 2.2). The occurrence of such errors was more than two-fold higher during higher levels of crowding, even when adjusting for the confounders of diagnosis and site (Table 2.2).

Table 2.2. **Examples of preventable clinical errors in emergency departments**

Error	Outcome
Initial electrocardiography (ECG) showed STEMI (heart attack) but no mention in physician notes, and cardiac treatment delayed for several hours	Cardiac arrest, death
Patient given both beta-blocker and calcium-channel blocker	Severe hypotension (abnormally low blood pressure), required IV (intra-venous) fluids
Patient given rapid transfusion of packed red blood cells to correct minor anaemia	Onset of acute heart failure, required intubation (tube placed inside the windpipe to keep the airway open)
Patient not given any corticosteroids for serious asthma exacerbation	Returned to ED within 24 hours for worsened exacerbation, hospitalised
Patient with markedly elevated blood glucose not given insulin	No apparent harm (considered a non-intercepted near miss: a potentially harmful error that unexpectedly does no detectable harm, due to patient characteristics or chance)

Source: Epstein, S.K. et al. (2012), "Emergency Department Crowding and Risk of Preventable Medical Errors", *International Emergency Medicine*, Vol. 7, No. 2, pp. 173-180, *http://dx.doi.org/10.1007/s11739-011-0702-8*.

2.2. Numerous studies quantify the extent of adverse events but differences in definitions and reporting practices limit international comparison

Two reports released in 2000 played a pivotal role in making patient safety an international priority. One was the Institute of Medicine (IOM)'s *To Err is Human: Building a Safer Health System*, released as part of the IOM Quality of Health Care in America Committee's "call to action to make health care safer for patients". It estimated that as many as 98 000 Americans die in hospitals each year as a result of medical errors (Kohn et al., 2000). The other was *An Organisation with a Memory*, written by an expert group chaired by the Chief Medical Officer of the United Kingdom (Department of Health, 2000). Among its findings was that each year, adverse events occurred in about 10% of admissions in National Health Service (NHS) England hospitals, costing an estimated GBP 2 billion per year in additional hospital stays. About half might be avoidable. Hospital-acquired infections, of which 15% may be avoidable, cost NHS England almost GBP 1 billion every year.

A number of other studies build the understanding of the extent of adverse events. These studies, nearly all independent reviews of case notes rather than analyses of self-reported adverse events, estimate adverse events to affect between 4% and 17% of admissions, with around 30-70% judged preventable (Table 2.3). The differences in estimates are largely due to differences in methodologies and lack of an internationally standardised approach to defining and detecting adverse events. Some studies capture the prevalence of patients or admissions with an adverse event, and others measure the

Table 2.3. **Selected studies of adverse events in hospitals, 1991 to 2016**

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

incidence of events per 100 admissions. Some patients experience multiple adverse events and hospital admissions, which can also affect estimations. Improved reporting may have increased estimates in recent years, although reporting systems still tend to underestimate the incidence of adverse events, compared to independent clinical reviews.

One of the earliest estimates of adverse events comes from the Harvard Medical Practice Study, based on more than 30 000 hospital records in 51 hospitals in New York State in 1984. It estimated that adverse events occurred in 3.7% of hospitalisations (Brennan et al., 1991). Subsequent studies estimated a much higher rate of events, and sought to calculate the costs associated with adverse events due to the more intense use of hospital resources. Estimates of additional hospital days range from 3.6 to 8.5 per patient on average.

Much less is known about error in other segments of service delivery, such as mental health care and primary health care. This may be explained by the concerted focus given to the more acute care end of the system, where the consequences can be more serious when things go wrong. It may also be due to the fact that more progress has been made in measuring hospital performance. Measurement in other subsectors – particularly primary care and mental health care – remains less developed in many countries.

In Spain, a study found 10% of patients in primary care experience some adverse effect; of those, 70% of cases were considered "clearly preventable", 23% were "slightly unpreventable", and only 6.7% were unpreventable (Spanish Ministry of Health and Consumer Affairs, 2008). An Australian study found that when an anonymous reporting system is set up, two errors are reported for every 1 000 patients seen by a general practitioner (GP) (Makeham et al., 2006).

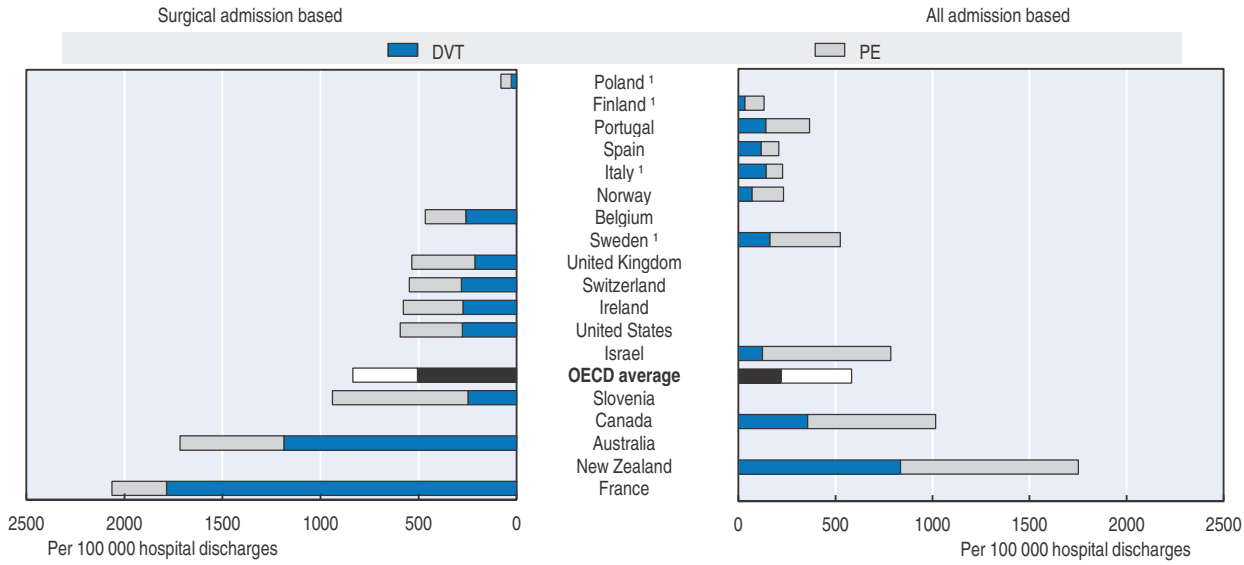
In addition to the obvious distress and suffering they cause, a strong economic case to reduce adverse events can be made. International studies indicate health care-associated injury and ill health add between 13% and 16% to hospital costs (Jackson, 2009). Using the IOM figure of 98 000 deaths, Andel et al. (2012) estimated a loss of USD 73.5 billion to USD 98 billion in QALYs for those deaths. At a time of austerity, adverse events were estimated to cost Irish hospitals more than EUR 194 million a year, about 4% of the Irish health care acute services' budget in 2009 (Rafter et al., 2016). Preventable adverse events are likely to cost NHS England between GBP 1 billion and GBP 2.5 billion annually (Frontier Economics, 2014). The United States' experience in reducing clinical error demonstrates how much can be saved – both in terms of human and financial cost. A 17% decline in hospital-acquired conditions in the country from 2010 to 2014 amounted to about 87 000 fewer people dying in hospital, and savings of USD 19.8 billion in health care costs. The decline followed concerted action by hospitals to reduce adverse events, in part spurred by Medicare payment incentives (AHRQ, 2015b).

2.3. The OECD indicators of patient safety represent substantial progress in standardising international methodology for measuring rates of adverse events

The OECD reports international comparative incidence rates for a set of adverse events including pulmonary embolism and deep vein thrombosis after hip or knee replacement surgery; postoperative sepsis in abdominal surgeries; and a foreign body left in during a procedure (Figures 2.9 to 2.11). All four events can result in death; the first three are usually preventable while the fourth is a "never event" that is always avoidable. The left panel of each graph shows the rate if the adverse event occurred during the same hospital

admission as the original surgical operation. The right panel shows the rate if the adverse event occurred during admission or re-admission to any hospital within 30 days of the original surgical operation. This second measure requires a unique patient identifier to track the patient's progress, which only around ten countries can provide.

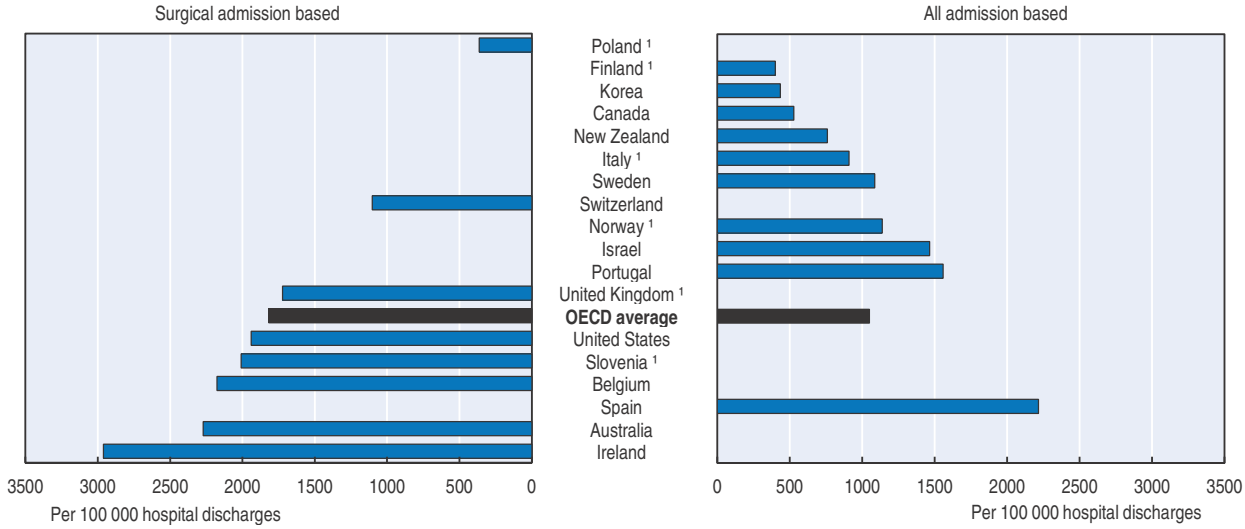
Figure 2.9. **Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT) in hip and knee surgeries, 2013 (or nearest year)**



Note: Rates have not been adjusted by the average number of secondary diagnoses. The OECD average includes nine countries.
1. The average number of secondary diagnoses is < 1.5.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444079

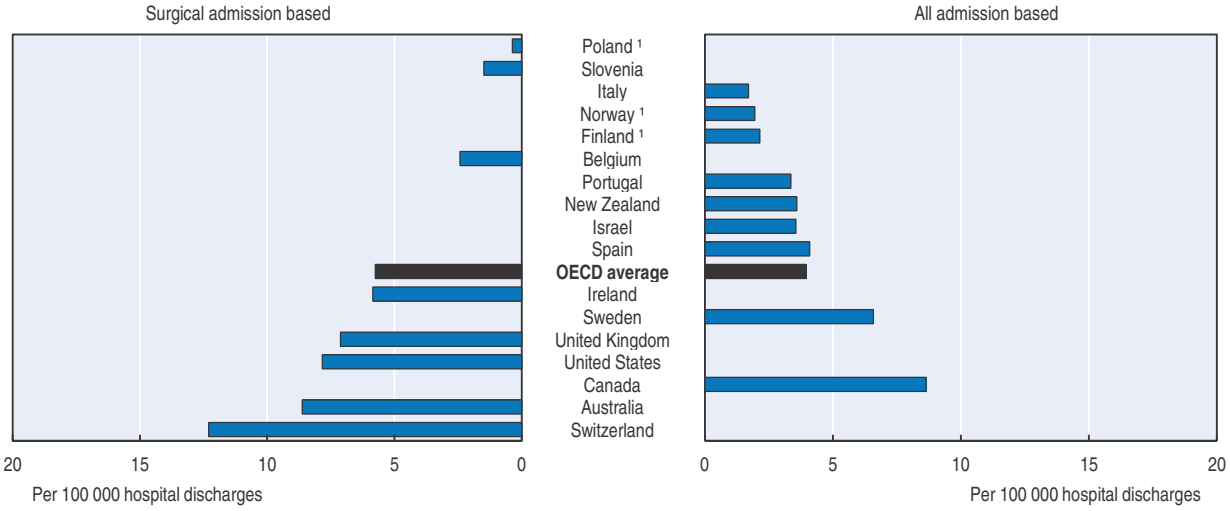
Figure 2.10. **Postoperative sepsis in abdominal surgeries, 2013 (or nearest year)**



Note: Rates have not been adjusted by the average number of secondary diagnoses. The OECD average includes eight countries (left panel) and ten countries (right panel).
1. The average number of secondary diagnoses is < 1.5.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444086

Figure 2.11. **Foreign body left in during procedure, 2013 (or nearest year)**

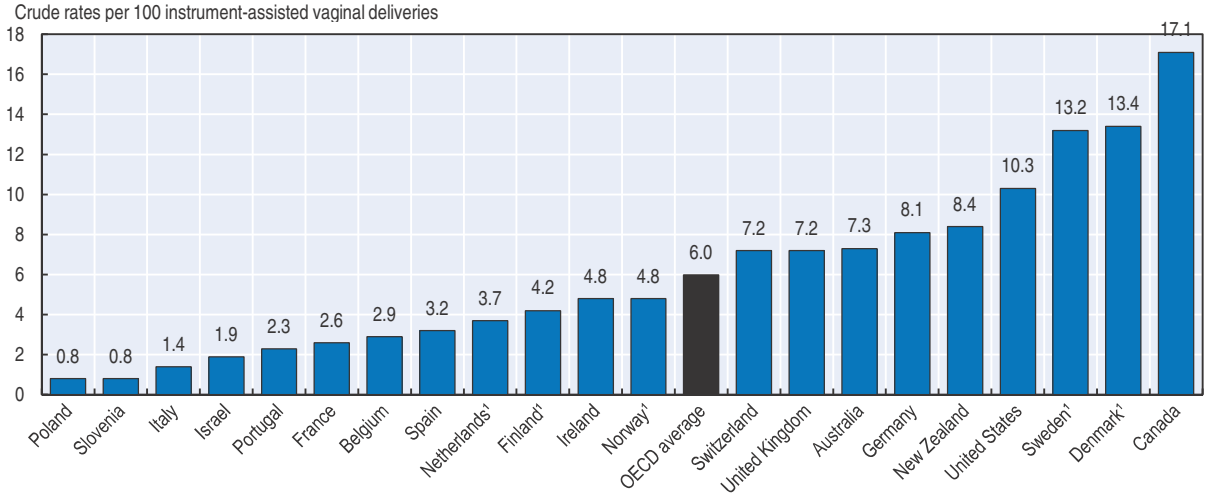


Note: Rates have not been adjusted by the average number of secondary diagnoses. The OECD average includes eight countries (left panel) and nine countries (right panel).
1. The average number of secondary diagnoses is < 1.5.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444094

OECD data on patient safety during childbirth include indicators of obstetric trauma during vaginal delivery with and without instruments such as forceps and vacuum extraction (Figures 2.12 and 2.13). Tears to the perineum during vaginal delivery are not always possible to prevent, but in some cases may be avoidable with appropriate labour management, and therefore can be considered an indicator of quality of obstetric care. The use of instruments to assist in delivery increases the risk of such tears.

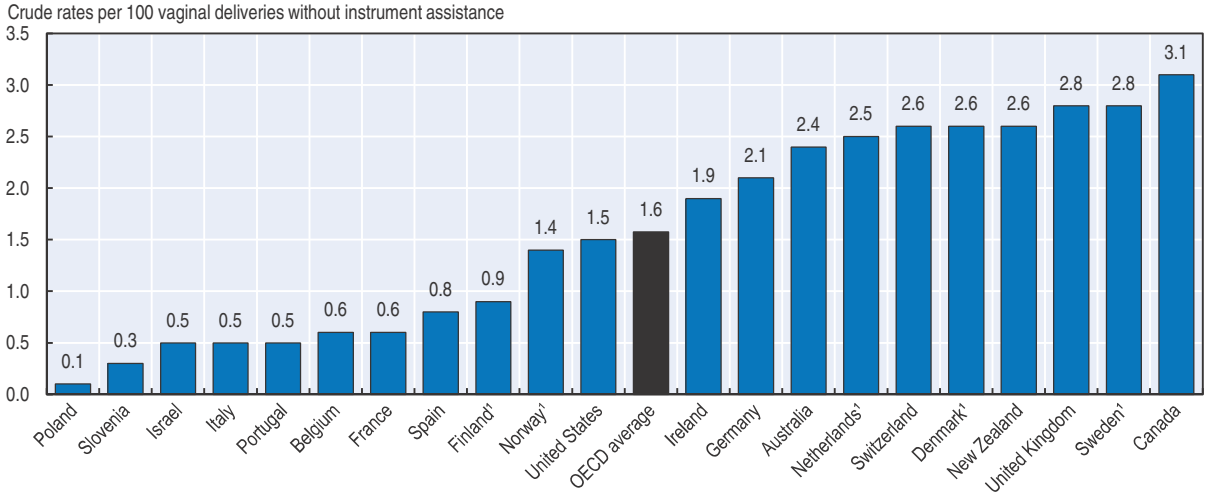
Figure 2.12. **Obstetric trauma, vaginal delivery with instrument, 2013 (or nearest year)**



Note: The OECD average includes 21 countries.
1. Based on registry data.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444108

Figure 2.13. **Obstetric trauma, vaginal delivery without instrument, 2013 (or nearest year)**



Note: The OECD average includes 21 countries.
1. Based on registry data.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444117

Wider variation between countries exists for obstetric trauma where an instrument has been used. Canada reports the highest rates for both indicators, with a rate almost three times the OECD average for delivery with instruments, and almost double the OECD average for delivery without instruments. This may be due to more concerted efforts to report such incidents.

OECD patient safety indicators show wide variation between countries. Caution should be applied when comparing countries on performance in patient safety, due to differences in how countries record diagnoses and procedures. Higher adverse event rates do not necessarily mean a country is performing more poorly than a country with lower adverse event rates; it may instead reflect that the country is more developed in monitoring patient safety and has a robust culture of reporting. Similarly, a country that appears to have low rates of adverse events may have relatively underdeveloped patient safety monitoring systems. In particular, adverse events may appear as "secondary diagnoses" in hospital databases. Clinicians or systems that are not in the habit of conscientiously recording all secondary diagnoses, therefore, may underreport adverse events. Health care systems where this appears to be a problem (fewer than 1.5 secondary diagnoses per admission on average) are flagged in Figures 2.8-2.10.

If health care systems are to make serious progress in improving patient safety, investing in implementation of robust monitoring systems is essential. This and other initiatives to reduce the risk of low-value care and adverse events are discussed in the next section.

3. Information systems to detect, characterise and prevent wasteful clinical care

The drivers of wasteful clinical care are multiple and complex. To address these, health care systems need better information on where wasteful clinical care is happening and what, at system and at service level, might be driving it. Even with better understanding of these issues in place, further steps to bridge the "know-do" gap are

needed. Such actions include financial and non-financial incentives, organisational changes and regulation. Together, these have the potential to trigger lasting changes in the way that care is delivered.

Section 3 focuses on how policy makers can strengthen the information systems capable of detecting, analysing and preventing low-value care and adverse events. Greater transparency on the instances and drivers of wasteful clinical care is an essential first step in tackling the problem. Fundamental to tackling waste is better informing patients themselves about interventions that offer little benefit or may cause harm.

3.1. Robust information systems are needed to identify low-value care

Transparent public reporting of quality and performance is essential to high-value care. A major challenge in reducing low-value care is that no standard way to measure and report it is in place. No core set of indicators of inappropriate care exist across OECD countries. Nevertheless, an increasing number of countries publish atlases of health care activity to identify variations across geographical areas (Box 2.6). These can be used to identify outliers with high rates of activity and gain an understanding of where low-value care may be occurring. Conversely, relatively low rates of activity may indicate problems with access to health services.

By identifying where significant variation is occurring, atlases can identify priority areas for action. Targets can be set to reduce variation. For example, Belgium's rates of MRI and CT exams are among the highest in the OECD (Figures 2.5 and 2.6). In 2009, within the country, the rate of MRI exams in Limburg province was almost 80% higher than in Luxembourg and Namur provinces. MRI exams and CT exams were inversely correlated, with higher MRI exam rates generally associated with lower CT exam rates and vice versa – suggesting some substitution between the two. The country developed a strategy with stakeholders to reduce variations in medical imaging. This was accompanied by an information campaign to educate the public and clinicians about excessive exposure. By 2013, significant reductions were made, although not all targets were achieved (OECD, 2014).

Beyond atlases of health care activity, health care systems generally lack means to identify low-value care. As discussed earlier, a core challenge is the lack of consensus on what constitutes low-value care, compounded by difficulties in measurement. Most databases fail to link health care activities to needs or outcomes, making the extent of inappropriate or ineffective care very hard to quantify. In a survey of OECD health care systems for this publication, for example, none reported being able to link – at national level – CT or MRI scans of the low back to patients' symptoms or diagnosis. Some progress is being made at the subnational level. In the same survey, it was reported that Alberta, Canada, for example, monitors the rate of CT scans, MRI scans and X-rays in patients with low back pain. There, 30% of such patients had at least one scan within six months of a physician visit, with male, older, high-income and rural patients having higher rates of CT and MRI scans.

3.2. Reliable reporting and learning systems are needed to reduce adverse events

More than 15 years have passed since the publication of the landmark reports *To Err Is Human* and *Organisation with a Memory*. Both reports cited the lack of standardised and robust ways to identify failures in standards of care and to systematically learn from them as pervasive weaknesses in health care systems. In recognition of this, several health care

Box 2.6. **Atlases of health care variation**

Australia: The Australian Commission on Safety and Quality in Health Care released the first Australian Atlas of Healthcare Variation in 2015. It covers antimicrobial dispensing, diagnostic interventions, nine surgical interventions (including knee arthroscopy, hysterectomy, radical prostatectomy and cataract surgery), opioid dispensing, and interventions for chronic disease and mental health.

Belgium: The Belgian Healthcare Knowledge Centre published an atlas on a selected set of procedures, and on certain conditions such as the diagnosis and treatment of cancer. The Ministry of Health's annual atlas of pathologies publishes hospital admissions for a large number of conditions by district.

Canada: The Institute for Clinical Evaluative Sciences atlases cover procedures and conditions for the population of Ontario, the most populous Canadian province. The Centre for Health Services & Policy Research atlases cover pharmaceutical prescriptions across Canada and British Columbia, the third-largest province. The Canadian Institute for Health Information reports on variations in selected surgical procedures, hospitalisations and diagnostic procedures, wait times, health status and health outcomes.

France is in the process of developing an atlas of variation. In 2011, it developed a programme to reduce variation in medical practice for 33 services, particularly high-volume surgical procedures for which there were large variations, including hysterectomy, prostatectomy, caesarean section and tonsillectomy. The programme is accompanied by guidelines to develop regional monitoring tools including target indicators, maps, etc.

Germany: The Bertelsmann Foundation produces atlases including national age- and sex-standardised rates for procedures such as caesarean sections, prostatectomies, coronary artery bypass grafting (CABG), and inpatient treatment for depression and diabetes. The atlases also include information on health outcomes and explore possible reasons for over- or underuse of these procedures. The Institute of Statutory Health Insurance physicians has undertaken analyses on different regional levels, mainly on outpatient care-related activities (e.g. antibiotic drug prescriptions, use of screening and office visits). The data are drawn from office-based physician billing codes and diagnosis, and outpatient prescriptions.

Netherlands: The National Institute of Public Health and the Environment atlas covers public health indicators. The Dutch Atlas of Healthcare Variation reports data on variations in medical practice at the provincial and municipal level for a range of procedures.

Spain: The Atlas of Variations in Medical Practice in the Spanish National Health System covers many procedures (e.g. acute myocardial infarction admissions, surgery in breast cancer, knee replacement), categorised based on the value they bring to patients: effective care, lower-value care, or uncertain benefit.

United Kingdom: The first NHS Atlas included more than 30 procedures covering 17 service areas (e.g. cancer, organ donation, diagnostic services). A number of thematic atlases have been published (e.g. children and young people, kidney disease, and diabetes).

United States: The Dartmouth Institute for Health Policy and Clinical Practice produces atlases covering common procedures and treatments and reports activities by hospital referral regions for the Medicare population (people aged 65 and over). Rates of use can be matched with data on population characteristics or health care resources.

Source: Adapted from OECD (2014), *Geographic Variations in Health Care: What Do We Know and What Can Be Done to o Improve Health System Performance?*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264216594-en*.

systems implemented reporting and learning systems to detect adverse events and prevent future occurrences (Box 2.7). Incidents and patterns of adverse events should be carefully analysed, and root causes identified. This should result in clear recommendations to reduce the risk of similar events, and implementation of those recommendations should be monitored and information fed back to patients, clinicians and managers. Collecting information about "near misses" (that did not actually result in harm) presents an additional learning opportunity.

Although these reporting and learning systems are vital steps in making health care safer, it should be noted that incomplete reporting remains a challenge. The US Office of the Inspector General found hospital staff did not report as many as 86% of adverse events to incident reporting systems (Levinson, 2012). Improving reporting and learning requires not just information systems, therefore, but culture change as well. In particular, health workers need to be assured that the intent of reporting is not punitive, but to share knowledge that can be used to prevent future events.

Among those at the forefront of attempts to improve adverse event reporting in a non-punitive way is the US-based IHI. The IHI developed a Global Trigger Tool that aims to detect patient harm, whether or not the result of an error. IHI recommends sampling ten patient records from all discharged adult patients every two weeks. The records are reviewed (by at least three people) for the presence of "triggers", such as acute dialysis, patient fall, pressure ulcers, re-admission within 30 days or a change in procedure. The presence of a trigger means that further investigation is required to determine if an adverse event occurred (Griffin and Resar, 2009). Using the tool, Classen et al. (2011) reported that adverse events in hospitals were probably ten times greater than previously believed, and estimated that adverse events occurred in about one-third of hospital admissions.

Some hospitals, such as Brigham and Women's Hospital in the United States, now regularly publish clinical errors and near misses in a patient-facing blog (*http://bwhsafetymatters.org*), with an explanation of what went wrong and what the hospital is doing to reduce the risk of repeating the same mistake.

3.3. Collecting patient-reported data will make health care systems safer and of better value

Obtaining information directly from patients about their health care experience and outcomes can help identify low-value care. If 25% of patients report that their pain and mobility are no better after a hip replacement than before, this is a clear indication of low-value care (irrespective of whether the surgeon considers the operation a success). Coupling this information with atlases of variation in health care activity offers health care systems a powerful way to identify and tackle wasteful clinical care.

Patient-Reported Experience Measures (PREMs) are standardised and validated surveys that seek patients' opinion about the quality of their care. They are increasingly used across OECD health care systems to monitor and improve quality. Patient-Reported Outcome Measures (PROMs) are standardised and validated instruments used to assess outcomes from patients' point of view, such as whether they are in less pain after surgery. PROMs are less well-established in OECD health care systems. England is one of very few countries to have implemented PROMs (after hip and knee replacements, varicose vein removal and hernia repair) across the health care system, using results in its pay-for-performance (P4P)

Box 2.7. **Selected initiatives to identify and report adverse events in OECD health care systems**

In **Australia**, state-level data on three measures of adverse events are publicly reported: health care-associated infections; adverse events treated in hospitals, considered selected adverse events in health care that resulted in or affected hospital admissions; and falls resulting in patient harm in hospitals. Additionally, all public hospitals are required to report on eight sentinel events: 1. Procedures involving the wrong patient or body part, resulting in death or major permanent loss of function; 2. Suicide of a patient in an inpatient unit; 3. Retained instruments or other material after surgery, requiring re-operation or further surgical procedure; 4. Intravascular gas embolism resulting in death or neurological damage; 5. Haemolytic blood transfusion reaction resulting from blood group incompatibility; 6. Medication error leading to the death of a patient, reasonably believed to be due to incorrect administration of drugs; 7. Maternal death associated with pregnancy, birth or the puerperium (usually considered the first six weeks after delivery); and 8. Infant discharged to the wrong family (SCRGSP, 2015).

In **Belgium**, hospitals are encouraged to develop adverse event reporting and learning systems. Patients are encouraged to report adverse events.

Denmark has a national reporting system for adverse events that includes hospitals and primary care. Reporting is mandatory for health workers. Patients and their families can also report events.

England's *National Reporting and Learning System* encompasses hospitals, mental health services and primary care organisations. Patients and carers can also report events.

France's *National Patient Safety Programme* comprises four pillars: the patient as partner; improving the reporting and learning from adverse events; creating a culture of safety; and innovation and research. The second of these focusses on blame-free reporting and disseminating learning, at both local and national level.

Israel has mandatory reporting of adverse events that result in severe, irreversible damage. Voluntary reporting of near-miss events is encouraged.

In **Japan**, specific hospitals are obliged to report medical accidents and incidents. The results of analyses are published to promote safety awareness.

New Zealand is one of the few OECD countries where adverse event reporting is extended to ambulance services, hospices, aged residential care organisations and other non-hospital providers.

Norway publishes a regular review of adverse events using the Global Trigger Tool method. Participation is mandatory for all 19 public hospital trusts and 5 private hospitals. The review is co-ordinated by the *Norwegian Patient Safety Programme, In Safe Hands 24/7*.

In **Slovenia**, indicators of quality and safety, including patient falls, are nationally collected and published. A national sentinel events reporting and learning system analyses the most serious adverse events.

Spain has a voluntary national *Patient Safety Events Reporting and Learning System*. Data are anonymised and aggregated information is prepared at the regional and national level for publication. Hospitals and regions are responsible for designing action plans for improvement.

Switzerland publishes caseload and mortality data for about 40 diagnoses and interventions for each acute care hospital.

In the **United States**, the Patient Safety Quality Improvement Act enables providers to report patient safety incidents in a standardised way, without fear of disclosure. The data are part of a national database reporting on incidents, near misses and unsafe conditions. Report users can compare their organisation with all events reported nationwide (AHRQ, 2015a).

Source: OECD policy survey on low-value care, unless otherwise specified.

scheme. Another example is the Danish government's agreement with its five regions to promote the use of PROMs in the areas of chemotherapy, epilepsy and prostate cancer, to assess whether patients need check-ups, tests and other treatment.

Patients can enhance their own safety by reporting adverse events that are not identified by clinical staff or not recorded in their medical records (Friedman et al., 2008). Although most reporting and learning systems allow patients or their carers to report an adverse event, pro-active and systematic collection of safety events reported directly by patients is rare. Instruments to enable this are being developed, known as Patient-Reported Incident Measures (PRIMs). In Norway, as part of a national patient safety campaign that began in 2011, the Patient-Reported Incident in Hospital Instrument (PRIH-I) was included in the country's patient experience survey (Box 2.8) (Bjertnaes et al., 2013) and was found to

Box 2.8. **Patient-Reported Incident in Hospital Instrument (PRIH-I) in Norway**

1. Do you believe you were incorrectly treated by the hospital in any way (as far as you yourself are able to judge)?
2. Did you get a wrong or delayed diagnosis in connection with your hospital stay?
3. Did you suffer any unnecessary injury or unnecessary problem as a result of a surgical procedure or examination?
4. Did you receive the wrong medication, or were you incorrectly medicated in any other way?
5. Did you experience insufficient hand hygiene (hand washing) among the staff?
6. If you experienced mistakes or unnecessary problems in connection with your hospital stay, did the staff handle the mistake or problem in a satisfactory way?
7. Did you experience that important information about you had reached the right people?
   Possible answers to questions 1 to 7: ❒ Not at all; ❒ To a small extent; ❒ To some extent; ❒ To a large extent; ❒ To a very large extent; ❒ Don't know; ❒ Not applicable.
8. Did you experience any administrative mistakes during your hospital stay (e.g. disorganised paperwork, did not receive test results, not called in for an appointment as agreed, agreed-upon examinations were not scheduled)?
9. Did you experience that the staff forgot to check your identity?
10. Did you experience that the staff forgot to give you important information?
    Possible answers to questions 8 to 10: ❒ No; ❒ Yes, once; ❒ Yes, several times.
11. Did you get an infection in connection with your hospital stay (e.g. inflammation/pus in surgical wound, lung infection, blood poisoning or urinary tract infection/bladder inflammation/catarrhs?
    ❒ No; ❒ Yes; ❒ Had infection before being admitted.
12. Was an updated list of your medications reviewed with you when you were discharged from hospital?
    ❒ Yes; ❒ No; ❒ Not applicable.
13. When you were admitted, did you bring along an updated list of medications you were taking?
    ❒ Yes; ❒ No; ❒ Was not taking any medications.

Source: Bjertnaes, O. et al. (2013), "The Patient-Reported Incident in Hospital Instrument (PRIH-I): Assessments of Data Quality, Test-retest Reliability and Hospital-level Reliability", *BMJ Quality & Safety*, Vol. 22, pp. 743-751, *http://dx.doi.org/doi:10.1136/bmjqs-2012-001756*.

correlate well with objective measures of patient safety, such as the Global Trigger Tool (Bjertnaes et al., 2015). This is a rare example of PRIMs being implemented at system level. Importantly, the most recent research extends the use of PRIMs into primary and ambulatory care (Lang et al., 2016; Ricci-Cabello et al., 2016).

OECD health care systems should invest in the collection and reporting of PREMs, PROMs and PRIMs. To be meaningful, these instruments need to be locally acceptable and validated and internationally comparable. This disclosure promotes trust between providers and patients. Patients should be involved in survey design to ensure these measures capture information that is relevant to them. To encourage participation, the burden of participation should be low for both patients and clinicians. Collection of these data has the potential to drive improvements in patient safety and quality of care. Performance data should be accompanied by a communication strategy that helps the media and public to interpret the information.

3.4. Information campaigns that target both clinicians and patients have particular power

Interventions may be more effective when they aim to educate both patients and their clinicians. For example, the Women's Health Initiative (WHI) was a randomised controlled trial that showed an increased risk of breast cancer, cardiovascular disease and stroke in women taking hormone replacement therapy (HRT) after menopause (Rossouw et al., 2002). One intervention used the WHI results to educate both physicians and patients by providing them with information tailored appropriately to their needs. In addition, a "pharmacy alert" placed in the electronic chart of each patient using combination HRT was designed to encourage conversations between patients and doctors. Doctors in the study were almost five times more likely to discontinue combination HRT use after the intervention than they were after the WHI study results were released but before the additional intervention (Roumie et al., 2004).

A promising initiative that brings together evidence and leadership from physician groups is the *Choosing Wisely*® campaign (Box 2.9). The campaign reaches out to both patients and physicians, so that discussions may help align their perspectives. The "do not do's" are instructive for doctors and simultaneously empower patients. An analysis in the United States of 11 of the services deemed low-value by *Choosing Wisely*® identified significant geographical variation in use among Medicare beneficiaries aged over 65. The average annual prevalence of services was highest for pre-operative cardiac testing for low-risk, non-cardiac procedures (46.5%) followed by use of antipsychotics in dementia patients (31%) and of opioids in migraine patients (23.6%). Non-indicated use of antipsychotics in dementia patients had the highest amount of associated spending (USD 765.1 million). Overall, use of low-value services was associated with greater per capita spending, a higher specialist-to-primary care ratio and a higher proportion of minority beneficiaries (Colla et al., 2015).

The OECD is working with the *Choosing Wisely*® campaign to develop three internationally comparable indicators of inappropriate care. The first concerns CT and MRI scans for uncomplicated low back pain. These tests do not assist people in healing more quickly and are costly. Yet many primary care physicians do not comply with evidence-based guidelines for low back pain (Webster et al., 2005). The second concerns prescribing antibiotics for upper respiratory tract infection, which should be avoided for most infections except for proven infection by Group A *Streptococcal* disease and pertussis. Yet in

Box 2.9. ***Choosing Wisely®* to encourage appropriate care**

The *Choosing Wisely®* campaign had its genesis in the United States in 2012, and has since expanded to more than ten countries. Its mission is to "promote conversations between clinicians and patients" by helping patients choose care that is supported by evidence, does not duplicate other tests or procedures patients have already received, is free from harm, and is truly necessary.

The bottom-up initiative, founded by the American Board of Internal Medicine (ABIM) Foundation, provides a list of "do not do's" across multiple medical specialties. Lists are written for doctors, with accompanying lists for patients in more consumer-friendly language. The lists identify inappropriate care across a range of medical specialties, with the aim of curbing its practice.

The premise of the campaign is to pull evidence-based medicine out of scientific journals and into the public domain. While the lists' content may differ between countries, the message to clinicians and the public is the same: less is often more. The recommendations also share the common goal of reducing inappropriate care and harm, while at the same time reducing costs to the health care system. Central to doing this is persuading physicians and patients to talk to one another about inappropriate care.

In other countries, *Choosing Wisely Canada* was established, as was *Wise Choices* in the Netherlands. Italy has a *Doing more does not mean doing better* campaign. NPS MedicineWise, a non-profit organisation funded by the Australian government, started the *Choosing Wisely Australia* campaign. New Zealand is focusing on applying the concept of *Choosing Wisely®* to chronic obstructive pulmonary disease (COPD) and ischaemic heart disease, while Germany is in the planning stages (Hurley, 2014).

In the United Kingdom, the Academy of Medical Royal Colleges began a *Choosing Wisely®* campaign in 2015. The Academy developed a *Waste Reduction Toolkit*, providing doctors with a step-by-step guide to identify their wasteful practices, and alerting them when there is a need for "waste correction" (Academy of Medical Royal Colleges, 2014). Wales' NHS has *Prudent Healthcare*, which follows principles such as "do only what is needed, no more, no less"; "do no harm"; and "reduce inappropriate variation using evidence-based practices consistently and transparently" (Welsh Government, 2016). Japan now publishes a list of *Choosing Wisely®* recommendations. In Switzerland, the Swiss Society of General and Internal Medicine has *Smarter Medicine*, including a "top five" list.

The lists can be used by providers to improve clinical practice and patients' outcomes and to reduce costs. In one example, the Swedish Medical Centre, which has several hospitals in the United States, had a problem with high rates of daily lab test ordering. Providers can either order tests after each patient evaluation, or schedule tests to be automatically done every day a patient is in hospital. *Choosing Wisely®* recommends that tests be ordered when clinically relevant, as opposed to automatically every day. In 2013, the Swedish Medical Centre began emailing the team data about who was ordering daily labs, and provided educational resources and simple recommendations. Data were provided regularly so everyone in the team could see each other's results. This intervention resulted in about 25% fewer labs ordered overall, about 14 000 fewer tests annually. Before the intervention, 30% of all labs were ordered daily, compared to only 6% after the intervention (Washington Health Alliance, 2014).

The impacts of these campaigns, including any unintended potentially harmful consequences, should be evaluated in every country. An analysis of early trends among seven services subject to *Choosing Wisely®* recommendations in the United States assessed differences in use before the campaign's implementation, up to the third quarter of 2013. It found a modest decrease in the use of two services. Use of imaging for headache decreased from 14.9% to 13.4%. Cardiac imaging for low-risk patients decreased from 10.8% to 9.7%. However, the use of two services increased: use of NSAIDs (nonsteroidal anti-inflammatory drugs) in some conditions increased from 14.4% to 16.2%, and human papillomavirus (HPV) testing in younger women increased from 4.8% to 6.0%. The trends were stable for three other recommendations: antibiotic use for sinusitis, and pre-operative chest X-rays and imaging for low back pain. The authors concluded that additional interventions are necessary for wider implementation of *Choosing Wisely®* recommendations, such as data feedback, financial incentives, patient-focused strategies and clinical decision support in electronic health records (Rosenberg et al., 2015). Among the study's limitations is that it was based on administrative claims data that do not capture the clinical context in which the services were ordered.

a study of more than 52 000 people with upper respiratory tract infection in the United States, 65% received antibiotics (Gill et al., 2006). The third concerns prescribing sedatives for the elderly. Benzodiazepines and other sedative-hypnotics should not be the first choice for older people to treat insomnia, agitation or delirium as discussed earlier in the chapter (Figures 2.3 and 2.4).

With the exception of benzodiazepine prescribing in the elderly, countries are overwhelmingly not collecting these indicators of low-value care. In response to a recent OECD policy survey, no participating countries reported measuring the rates of CT and MRI scans to investigate uncomplicated low back pain. Belgium does not officially collect data on uncomplicated low back pain, but the College of Radiology estimates that 81% of CT spine scans are not justified (Vrijens et al., 2016). In addition, few countries reported collecting data on rates of antibiotic prescribing in primary care for upper respiratory tract infection. Australia, Denmark, France, Germany and Slovenia are among the countries able to provide estimates on antibiotic prescribing on the basis of this diagnosis.

4. Initiatives to prevent and mitigate wasteful clinical care

Better information on the extent and causes of wasteful clinical care may not, in itself, be sufficient to deliver more efficient health care. A broad set of policy levers must be used to turn information into action. These include initiatives to shift clinicians' and patients' behaviours away from wasteful types of care, changes to the incentives and regulations that determine clinical practice, and organisational changes at service and system level that would support better value care. The role of patients in this regard has historically been overlooked and should be better harnessed to build more transparent, better-value health care systems.

4.1. Supporting behaviour change starts with defining safe, effective and appropriate care through standards and guidelines

The application of behavioural economics to health care is gaining international interest, in recognition that a range of tools can change how physicians and patients make decisions. Incentives targeted to providers and patients may nudge them in the direction of appropriate and safe care. First, however, physicians and patients need to be equipped with the knowledge to make the right decisions.

Clinical guidelines are one way of setting out that knowledge. They have the potential to improve the process and outcomes of care, although the magnitude of the improvements varies. Guidelines also have the potential to reduce the use of unnecessary interventions and save costs. For example, Alfirevic et al. (2004) found women who delivered in hospital units with clinical guidelines for the use of continuous intra-partum cardiotocography (to monitor foetal heart rate and uterine contractions) were more likely to achieve normal vaginal deliveries. The use of written guidelines for partogram (a graphical record of maternal and foetal data during labour) was associated with fewer caesarean sections for foetal distress. Clinical guidelines can potentially reduce the practice of defensive medicine through creation of a "safe harbour". The clinician could use the "safe harbour" as a defence, although patients could still present evidence that the guidelines were not applicable to their specific situation (Emanuel et al., 2012).

In addition to clinical guidelines, simple reminders, such as a checklist that clinicians routinely follow, are shown to have a positive impact on clinical practice. In the United States, Pronovost et al. (2006) developed a checklist to reduce bloodstream

infections in intensive care units. More than 100 hospitals in Michigan participated in the trial. The overall median rate of catheter-related bloodstream infection decreased from 2.7 infections per 1 000 catheter-days to zero infections three months after the intervention was implemented, and this was sustained during 18 months of follow-up. The intervention was more recently replicated in Spain. The so-called *Bacteremia Zero* project encompassed 68% of intensive care units in the country and used the same five-point checklist. After 18 months, catheter-related bloodstream infection was reduced from a median 3.07 to 1.12 episodes per 1 000 catheter-days (Palomar et al., 2013).

The World Health Organization (WHO) uses checklists as part of its patient safety initiatives. Among them is the surgical safety checklist, which takes in the period before the induction of anaesthesia, before skin incision and before the patient leaves the operating room. The checklist is part of its global campaign, *Safe Surgery Saves Lives*. It includes a set of evidence-based safety standards that can be used in all health care systems (WHO, 2009).

The Joint Commission developed a *Universal Protocol* to prevent wrong-site, wrong-procedure, wrong-person surgery. It documents three steps accredited hospitals are required to follow:

- Conduct a pre-procedure verification process. Address missing information or discrepancies before starting the procedure. Verify the correct procedure, for the correct patient, at the correct site. When possible, involve the patient in the verification process.
- Mark the procedure site. At a minimum, mark the site when there is more than one possible location for the procedure and when performing the procedure in a different location could harm the patient.
- Perform a time-out before the procedure. The procedure does not start until all questions or concerns are resolved. During this time, the clinical team agrees: that the patient's identity is correct; that the site is correct; and on the procedure to be done (Joint Commission, n.d.).

One study estimated that if applied properly, the *Universal Protocol* could have prevented about two-thirds of actual wrong-site surgical cases that were reported to a US liability insurance provider (Kwaan et al., 2006). It should be stressed, however, that checklists and similar tools should exist within a broader set of activities focussed on education, monitoring and feedback. Health care systems and services must aim to embed and sustain a culture of continuous quality and safety improvement, rather than simply apply piecemeal interventions.

Another Joint Commission initiative aims to improve medication safety via a "Do Not Use" list of medical abbreviations (Table 2.4) as part of its standards for information management. The list aims to reduce confusion and subsequent error due to the use of medical abbreviations. Brunetti et al. (2007) found that almost 5% of all errors reported to MEDMARX, a national medication error reporting programme in the United States, from 2004 to 2006 were attributable to abbreviations. When clinicians are managing many patients at once, the use of abbreviations may be a tempting way to save time, but they create a risk of medication errors. Another study found that education interventions reduced the use of unsafe abbreviations from almost 20.0% to 3.3% over eight months (Abushaiqa et al., 2007).

Table 2.4. **Joint Commission's "Do Not Use" list[1] of medical abbreviations**

Official "Do Not Use" List[1]

Do not use	Potential problem	Use instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four) or "cc"	Write "unit"
IU (international unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "international unit"
Q.D, Q., q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D, QOD, q.o.d., qod (every other day)	Period after the Q mistaken for "I" and the "O" mistaken for "I"	Write "every other day"
Trailing zero (X.0 mg)[2]	Decimal point is missed	Write X mg
Lack of leading zero (.X mg)		Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write "morphine sulfate"
MSO_4 and $MgSO_4$	Confused for one another	Write "magnesium sulfate"

1. Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.
2. Exception: A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sizes. It may not be used in medication orders or other medication-related documentation.

Source: Joint Commission (2015), "Facts about the Official 'Do Not Use' List of Abbreviations", *www.jointcommission.org/standards_information/npsgs.aspx* (accessed 19/02/2016).

In a similar fashion, the Institute for Safe Medication Practices (ISMP) publishes tools to promote the safe use of medicines. Among them is a more substantial list of "error-prone abbreviations, symbols, and dose designations" that should never be used by health professionals, particularly when exchanging information. ISMP also developed a list of "high-alert medications" for use in hospitals as well as community and ambulatory settings. The list aims to alert health professionals to medication that has a higher risk of causing patient harm when used erroneously. Providers are encouraged to use the list to minimise risk, for example by limiting access to high-alert medications or developing extra safeguards in their use. Another ISMP tool is a list of "confused drug names", comprising names of medication that look or sound similar to other medication. The list again aims to help providers determine which drugs require extra safeguards to minimise the risk of harm (ISMP, 2015).

4.2. National campaigns seek to bring about system-wide, sustained improvements in health care value and safety

Several patient safety campaigns have aimed to change the behaviour of providers. Among them is the *100 000 Lives Campaign*, co-ordinated by the IHI in 2004. The campaign mobilised hospitals across the United States to implement six evidence-based interventions: deployment of rapid response teams to patients at risk of cardiac or respiratory arrest; evidence-based care for acute myocardial infarction; prevention of adverse drug reactions through medication reconciliation; prevention of central-line infections; prevention of surgical site infections; and prevention of ventilator-associated pneumonia. The campaign defined a life saved as a patient successfully discharged from a hospital who would not have survived without the changes achieved during the campaign (Berwick et al., 2006). Hospitals submitted mortality data to the IHI during the 18-month campaign. The IHI later announced it exceeded its goal, and together the more than 3 000 hospitals enrolled prevented an estimated 122 300 deaths (IHI, 2006).

The IHI followed this initiative with the *5 Million Lives Campaign*, which asked hospitals to prevent 5 million incidents of medical harm over two years. While both campaigns received criticism for difficulties in measurability to gauge a true idea of their success, arguably a more important achievement is that they brought patient safety to the centre of

attention. The campaigns demonstrated that thousands of hospitals wanted to improve their practices to reduce harm to patients. This willingness came about with the influence of strong leadership. Another global campaign that has sought to change health care providers' behaviour is encouraging them to adopt the simple yet highly effective practice of hand hygiene. Health care-associated infections remain one of the most concerning episodes in health care systems. Stringent infection prevention and control are crucial to preventing such events (Box 2.10).

Interventions targeting behaviour change should begin when physicians are in training, as it is during these formative years that longer-term patterns of behaviour may be established. Chen et al. (2014) found physicians trained in lower-spending regions continued to practise in a less costly manner once they completed their training, even when they moved to higher-spending regions, and vice versa.

4.3. Adherence to standards and guidelines needs to be monitored, with findings fed back to clinicians

Once high-value and safe practices are established, audits of adherence (and comparison to guidelines, targets or standards) offer vital feedback on individual clinic's or individual clinician's performance. A Cochrane systematic review found that audit and feedback can have substantial effects on clinical behaviour. The review found that audit and feedback are most effective when clinicians are not performing well to begin with; when the clinician discusses audit findings with a supervisor or colleague; when feedback is provided more than once; when feedback is given both verbally and in writing; and when feedback includes clear targets and an action plan (Ivers et al., 2012). Supplementing performance feedback with additional information is particularly effective. Thomas et al. (2006) found the rate of test ordering could be reduced with educational messages and reminders of best practice. Feldman et al. (2013) showed that giving doctors information about the cost of a diagnostic test at the time they were ordering it was associated with a modest decrease in test ordering. In Australia, the National Prescribing Service's feedback to GPs on their rates of referrals for CT scans for low back pain was associated with an 11% fall in referral rate, equivalent to some 50 000 scans.

In addition to feedback, some evidence suggests that public reporting can be a powerful incentive to lift quality and improve outcomes – particularly where poor-performing outliers are identified. For example, the New York State Department of Health began collecting annual data on risk-adjusted mortality following coronary artery bypass grafting (CABG) surgery by hospital and surgeon in 1989. In the programme's first four years, risk-adjusted mortality fell more than 40% – from 4.17% in 1989 to 2.45% in 1992 (Hannan et al., 1994). Another prominent example of public reporting to drive quality care is the American College of Surgeons' *National Surgical Quality Improvement Program: Surgical Outcome Measures*. Risk-adjusted data are collected and fed back to participating surgeons and hospitals to stimulate quality improvement. Hospital-level data are reported on Medicare's *Hospital Compare* website, and hospitals are ranked as "better than average", "average", or "worse than average".

Monitoring and reporting clinical performance must be done sensitively. In particular, it is critical to find the right balance between robust accountability, avoiding blame and expecting change. Another challenge is to encourage, or require, clinicians to change practice when this may mean discarding some profitable lines of work. Financial incentives, discussed later, may facilitate this. It would be wrong, though, to assume that financial

considerations are uppermost in clinicians' minds. The *Choosing Wisely®, 100 000 Lives* and other campaigns, discussed earlier, demonstrate profession-led initiatives whose entire aim is to improve the safety, effectiveness and appropriateness of care.

Box 2.10. **Reducing health care-associated infections through improved hand hygiene**

Florence Nightingale significantly reduced deaths by improving sanitary conditions in hospitals. Yet more than a century on, many health care workers do not routinely adopt the simple act of performing hand hygiene during patient care. Evidence exists that hand hygiene is an effective intervention to reduce health care-associated infections such as methicillin-resistant *Staphylococcus aureus* (MRSA) (Marimuthu et al., 2014). These adverse events are harmful to patients and costly for health care systems, making their reduction a priority.

A key global initiative is the *WHO SAVE LIVES: Clean Your Hands* initiative, which mobilises hospitals worldwide to improve hand hygiene. As of November 2015, 18 365 hospitals and health care facilities in 174 countries or areas had registered since the initiative began in 2009. Each year the initiative takes a different focus, with hand hygiene during surgery the focus for 2016. The campaign engages clinicians through education and advocacy, and a toolkit hospital staff can use to improve hand hygiene. Central to the initiative is a poster depicting the "five moments for hand hygiene": before touching a patient; before clean/aseptic procedure; after body fluid exposure risk; after touching a patient; and after touching patient surroundings (WHO, 2015b).

Among the countries involved in the WHO initiative is Germany, where more than 700 health services have participated since 2010. The voluntary programme includes education, the WHO "five moments" model, and data collection. Overall, hand hygiene compliance increased by 11.0% in 62 hospitals that observed compliance before and after the intervention. The 129 hospitals that provided data on alcohol-based, hand-rub consumption for three years achieved an overall increase of 30.7% (Reichardt et al., 2013).

Spain uses indicators to monitor the compliance of hospitals in the programme. These include: the proportion of beds and intensive care units with alcohol-based product at the care-providing point; consumption of alcohol-based product; the proportion of hospitals complying with the "five moments"; and training in hospitals and primary care centres. An evaluation shows an improvement on most indicators between 2009 and 2013, with the exception of primary care training (Spanish Ministry of Health, Social Services and Equality, 2015).

Australia participates through its *National Hand Hygiene Initiative* (NHHI). An audit in October 2015 included 890 participating public and private hospitals, and the average compliance rate was 83.2%. By contrast, an audit conducted in August 2009 involved only 182 participating hospitals, with an average compliance rate of 63.5% (Hand Hygiene Australia, 2015). The NHHI was found to be cost-effective in some Australian states, with cost savings from reduced length of stay and intensive care bed use because infections were prevented. The largest reduction in rates of *Staphylococcus aureus* bacteraemia risk was in the Australian Capital Territory (28%), which was sustained for 12 months. For the six jurisdictions that provided data, total annual costs arising from the NHHI were AUS 2.9 million, for a return of 96 years of life, an ICER of AUS 29 700 per life-year gained against a threshold of AUD 42 000 per life-year gained. However, the ICER exceeded the threshold in three states (Graves et al., 2016).

Some hospitals are trialling the use of technology to enforce hand hygiene. One such trial in the United States evaluated health workers' hand hygiene in an intensive care unit, with the use of remote video auditing, with and without feedback. Cameras with views of every sink and hand sanitiser dispenser were used to record hand hygiene activity. During the 16 weeks before feedback, hand hygiene rates were less than 10.0%. In the 16 weeks after feedback, the rate rose to 81.6%. This increase was maintained 75 weeks later, at 87.9% (Armellino et al., 2012).

4.4. Patients should be enabled to recognise unsafe, ineffective or inappropriate care

Giving patients information and evidence on what constitutes safe, effective and appropriate care has the potential to influence clinical decisions. Krol et al. (2004) found that 24% of patients sent an information leaflet emphasising the need to reduce inappropriate use of proton pump inhibitors stopped or reduced their use of this treatment, compared with 7% in the control group. In another example, poster-sized "commitment letters" were posted in doctors' examination rooms for 12 weeks. The letters featured clinician photographs and signatures, stating their commitment to avoiding inappropriate antibiotic prescribing for acute respiratory infections. In a study exploring the effect of these posters, inappropriate prescribing rates decreased from 42.8% to 33.7% in the intervention group, whilst increasing from 43.5% to 52.7% in the control group (Meeker et al., 2014). The United States' *Partnership for Patients* initiative, built upon patient, family and community engagement, was associated with a 17% reduction in the number of hospital-acquired conditions (such as ulcers and infections) from 2010 to 2014.

Arming patients with more information can help to make their health care safer. In Denmark, the lead organisation for improving health care safety is the Danish Society for Patient Safety, a not-for-profit organisation that emphasises patients and carers as key partners in improving safety. Among the tools to support this is the Society's *Patient Handbook*, which includes safety tips empowering patients such as: speak up if you have any questions or concerns; let us know about your habits; you can let somebody else handle your consultation; ask about your operation; and tell us if it hurts (OECD, 2013). Patients also have a role to play in ensuring that the health care workers involved in their care perform strict hand hygiene to reduce the risk of infection. Surveys indicate that many patients would ask their health care worker whether they had performed hand hygiene if they knew it reduced the risk of infection. Many others, however, report feeling uncomfortable asking this question (McGuckin et al., 2011). Empowering patients so they feel emboldened to ask this simple question may provide them with greater protection from health care-acquired infections.

Giving patients as much information as possible ensures that providers obtain true informed consent, which is vital for high-value, safe care. This is more challenging for patients who are more vulnerable, come from disadvantaged backgrounds, or have cognitive difficulties or poor health literacy. Obtaining informed consent needs to be treated as more than a legal obligation; it may reduce the risk of medical errors and make health care safer. "Teach-back" methods, for instance, ask patients to repeat what they have been told during the informed consent process, so that clinicians can be confident that patients understand the information they have been given. Tools to help patients make decisions and consider the trade-offs regarding options for their own care have been shown to improve decision-related outcomes for breast cancer treatment decisions including surgery, radiotherapy, endocrine therapy and chemotherapy (Zdenkowski et al., 2016). These tools may also assist in reducing overtreatment. In a systematic review, these "decision aids" were found to reduce the number of people choosing discretionary surgery, while having no apparent adverse effects on health outcomes or satisfaction (Stacey et al., 2014).

Linked to the notion of consent, documenting patient preference is a way of ensuring that patients' wishes are respected for extended or more complex episodes of care. This is particularly important when considering sensitivities around end-of-life care, and the decision to provide or withhold costly and aggressive treatment. Often the decision to treat or not is made when patients do not have the cognitive capacity to give informed consent.

The use of advance directives may avoid unnecessary suffering when patients are given invasive treatment against their wishes. In examining the deaths of a sample of older adults in the United States, Silveira et al. (2010) found that, among those who had required decisions about care at the end of life, 70% lacked decision-making capacity. Those with prepared advance directives received care that was strongly associated with their preferences (Box 2.4 discusses these issues in more detail).

4.5. Financial incentives can nudge clinicians towards high-value and safe care

The design of payment systems (both to clinicians and facilities) strongly influences how care is delivered. FFS systems, for example, can encourage large volumes of services without necessarily providing any incentive to improve quality, and so may drive up costs without adding value. A number of OECD health care systems are developing their FFS systems to specify more precisely how service items should be linked to a patient's needs or particular outcomes. This makes it easier to reward value appropriately. In parallel, countries are taking a more ambitious approach to defining a "service". In Japan, for example, activities in the FFS schedule that seek to encourage high-value and safe care include: setting up co-ordinated community care plans upon a patient's discharge; setting up cancer care plans; and providing co-ordinated management plans for patients with two or more of hypertension, diabetes, dyslipidaemia or dementia.

Other approaches are capitation payments, which are fixed payments per patient for a defined period of time. Capitation should remove some of the incentive to oversupply services. "Bundled payments" can be considered to sit somewhere between FFS and capitation schemes. They pay for a package of care for a defined population with complex care needs, over a specific time period. Some countries are experimenting with blended payment systems that add a P4P element, and even financial sanctions related to adverse events (OECD, 2016c). For example, Israel defined four "never events" for which hospitals cannot bill health insurers. Box 2.11 sets out some of the financial incentives and payment systems OECD countries are using to try to reduce low-value care and adverse events.

Box 2.11. **Use of financial incentives to reduce low-value care and adverse events**

In the **Australian** state of Queensland, health authorities withhold payments to hospitals for six "never events". In addition, payments are reduced for two adverse events: hospital-acquired bloodstream infections and stage 3 and 4 pressure injuries (OECD, 2015b).

In **Denmark**, several hospitals piloted value-based management, where they are reimbursed according to patient outcomes, instead of through the diagnosis-related group (DRG) payment system. In addition, the regions bear the cost of financial compensation to patients, giving them incentive to reduce adverse events.

England implemented a Maternity Pathway Payment that effectively removes the financial incentive for caesarean section by paying the same for the intervention and for natural birth. While the payment has not been evaluated, the rate of caesarean sections in England appears to have plateaued since the payment was implemented.

France sets rates of reimbursements for drugs based on the drug's effectiveness for a given indication and condition severity. A point system exists for prescribers who meet objectives, such as monitoring diabetes. Doctors who are outliers in prescribing practices can incur financial sanctions. The P4P scheme in ambulatory care rewards appropriate prescribing of benzodiazepines. Quality and safety of care indicators are linked to financial rewards for quality improvement.

Box 2.11. **Use of financial incentives to reduce low-value care and adverse events** *(cont.)*

Israel's Ministry of Health defined four "never events" for which hospitals cannot bill health insurers: wrong-site surgery, foreign body left during surgery, second- or third-stage burn occurring during surgery, and errors related to blood product transfusion that lead to patient death.

In **Japan**, hospitals that treat patients under the public health insurance system are evaluated based on their measures to prevent medical accidents. Those evaluated highly for their safety measures can be rewarded in the medical fee system.

Korea's *Value Incentive Programme*, established in 2007, began by focusing on acute myocardial infarction and caesarean section rates, for which Korea has among the highest rates in the OECD. Although the programme has not been rigorously evaluated, one analysis suggests variation in quality decreased, and average quality increased (Kim et al., 2012).

Slovenia encourages hospital accreditation by imposing financial penalties on those that do not have accreditation. Faced with the possibility of such penalties, 22 out of the country's 26 hospitals underwent accreditation. The other four hospitals are at different stages of the process.

The **United States'** Department of Health and Human Services (HHS) recently announced the goal of moving 50% of FFS Medicare payments to alternative payment models, and tying 90% of FFS payments to value-based payment models by 2018. By January 2016, 30% of payments had shifted to alternative models – meeting targets almost a year ahead of schedule. These programmes depend on mandatory reporting of quality measures tied to bonus payments, penalties or both to provide incentive to reduce low-quality care. The Centers for Medicare & Medicaid Services (CMS) uses prospective payments that effectively put providers at financial risk if they deliver low-value care in some circumstances. The Affordable Care Act (ACA) introduced value-based programmes – the *Hospital Value-Based Purchasing Program*, the *Hospital Readmissions Reduction Program*, and the *Hospital-Acquired Condition Reduction Program* – that link payment to quality and value. Value-Based Purchasing links indicators, including 30-day risk-adjusted hospital mortality for acute myocardial infarction, to Medicare reimbursement. The Hospital Readmissions Reduction Program penalises hospitals if 30-day re-admission rates for specified conditions are higher than expected. A recent study found re-admission rates for targeted and non-targeted conditions began to fall faster in April 2010, after passage of the ACA. The decline was more substantial in targeted conditions. Re-admission rates continued to decline from October 2012 to May 2015, during the programme's implementation, albeit at a slower rate (Zuckerman et al., 2016).

The ACA also established integrated care systems called Accountable Care Organisations (ACOs). Doctors and other providers involved in such a network are together accountable for the total cost of care for a particular population, and are effectively rewarded with shared savings. This gives providers incentive to provide fewer services and therefore reduce inappropriate care such as unnecessary hospitalisations. At the same time, ACOs aim to improve the quality of care for patients with chronic disease by providing more co-ordinated and efficient care.

Another CMS initiative is a separate payment for advance care planning to recognise additional time for doctors to have conversations with patients about the type of care they wish to have at the end of life.

Source: OECD policy survey on low-value care, unless otherwise specified.

The evidence examining the impact of financial incentives is mixed. A Cochrane review concluded financial incentives may be effective in changing health care professional practice, although the evidence has methodological limitations. In addition, no evidence examined the effect of financial incentives on patient outcomes (Flodgren et al., 2011). It is important to note that financial incentives should be accompanied by other policy levers aimed at changing behaviour, since this amplifies the impact. For example, Dreischulte et al. (2016) showed that a combination of professional education,

financial incentives, and an informatics tool that identifies patients needing review and provides weekly updates on high-risk prescribing reduced high-risk prescribing and was associated with reductions in related ED admissions.

Financial incentives can also be offered to patients. Evidence is mixed on the extent to which financial incentives influence patient behaviour. In a study without a control group, Volpp et al. (2008) found that a lottery-based financial incentive combined with a reminder system improved adherence to warfarin. In a randomised controlled trial of a lottery-based intervention, Kimmel et al. (2012) found the intervention was associated with improved anticoagulation control among the subgroup of patients at higher risk of poor adherence. It was not, however, associated with a significant improvement in control among participants overall. This suggests that population-wide use of financial incentives may not necessarily be prudent, but more targeted approaches may be merited.

Some countries use cost-sharing as a means of nudging patients in the direction of high-value care. France has no or low cost-sharing for prescription drugs that are highly effective and higher cost-sharing for less effective drugs. Finland determines cost-sharing levels based on patients meeting certain clinical conditions that determine the cost-effectiveness of the drug. For example, patients pay a lower co-insurance rate for hypertension drugs if a physician certifies that their blood pressure exceeds a specified threshold (Thomson et al., 2013).

Patients often cannot distinguish between high-value and low-value care. Caution should be applied in the use of co-payments, therefore, as there is a risk that they may prompt patients to avoid both necessary and unnecessary care. This may cause harm, and may result in the need for more costly health care in the long run. In one study, the introduction of cost-sharing was associated with a decreased use of essential drugs by 9% in elderly people and 14% in welfare recipients. The use of less essential drugs by these two groups decreased by 15% and 22%, respectively. The reduction of essential drug use was associated with more serious adverse events, with the rate increasing from 5.8 per 10 000 person-months to 12.6 in elderly people, and from 14.7 to 27.6 per 10 000 person-months in welfare recipients. ED visits increased by 14.2 per 10 000 person-months in elderly people and by 54.2 among welfare recipients (Tamblyn et al., 2001). Adopting a carrot (reduce or waive co-payments and provide incentives for high-value care) rather than a stick approach (increase co-payments for low-value care) may present a lower risk of harm to the most vulnerable.

4.6. Organisational changes, such as the improved use of technology, can shape decision making of clinicians and patients and improve care co-ordination

Information and communications technology (ICT) can help facilitate appropriate care. ICT systems include electronic health records (EHR) for patients and computerised decision support systems. These algorithms generate recommendations about individual patients' care based on their specific needs and clinical history characteristics. Systematic reviews indicate that computerised clinical decision support systems can potentially improve health practitioner performance and clinical practice (Garg et al., 2005; Kawamoto et al., 2005). They have also been shown to reduce the rates of medication errors, so patient safety is also improved (Bates, 2000). Computerised physician order entry (CPOE) enables clinicians to enter instructions regarding a patient's treatment into a computer, instead of taking handwritten notes. CPOE improves safety by overcoming issues such as poor handwriting, ambiguous abbreviations or lack of knowledge on the part of the clinician when medications or tests are prescribed (Bates et al., 1998). CPOE can be combined with guidelines or decision

support tools to avoid low-value care. A systematic review found that using CPOE was associated with improved compliance with guideline advice, fewer tests, a significant reduction in the median time to appropriate treatment, and reduced cost (Georgiou et al., 2007). Other potential uses of ICT include digitising the entire clinical workflow and developing data systems that link patient needs to activities, outcomes and cost.

An important way in which countries are seeking to reduce errors, adverse events and low-value care is through better co-ordination across providers. This is particularly important in the care of individuals with multiple, complex conditions. Several countries have launched initiatives targeted to this group to improve co-ordination of care. In France, for example, the *PAERPA (Personnes Âgées En Risque de Perte d'Autonomie)* programme aims to support individuals aged over 75 to avoid hospitalisation and continue living at home as long as possible, through better co-ordination of health and social care services. A locally led, multi-agency approach seeks to identify individuals at risk, focus on critical transitions in their care pathway, and develop new services, such as intermediate care facilities.

Better sharing of patient information, particularly through the use of EHRs, is the most important element underpinning better co-ordination. Many countries are working towards implementation of EHRs that will contain relevant information about each patient, with Canada, Denmark, Finland, Israel, Korea, New Zealand, Singapore, Sweden and the United Kingdom particularly notable for their progress (OECD, 2015c). Even in these health care systems, technical, legal and cultural challenges mean that in many cases their systems are years from full implementation. Israel, for example, already implemented an information-sharing system between all hospitals and ambulatory care providers, but has not made as much progress as hoped in tackling wasteful care because of differences in terminology between providers (standardisation should be achieved by 2019). At the same time, some countries established more targeted information-sharing systems, focused on medications (such as in Germany and Denmark) or specific diseases (e.g. SveDem, the Swedish dementia registry).

To fully capitalise on the promise of ICT in reducing overtreatment and error, incentives are needed to encourage its adoption among clinicians and to encourage the exchange of information between providers to improve care co-ordination and reduce the risk of error due to lost information. The use of EHRs can facilitate patients taking greater ownership of their health care. Implementation of information systems comes with high financial costs. Cultural challenges may also arise in overcoming resistance from hospital staff accustomed to doing things a certain way. These issues need to be carefully managed to ensure a smooth transition.

With communication breakdowns among health care teams associated with adverse events, behavioural interventions need to target teamwork. Identifying effective interventions in this regard is more difficult. A systematic review indicates the evidence for technical or clinical benefit from teamwork training is weak (McCulloch et al., 2011). Among the studies it cited was one that found error could be reduced and teamwork improved in the ED through an intervention involving teamwork training drawn from aviation crew resource management programmes. This is based on the premise that EDs share some of the same characteristics as the aviation industry, such as time-stress, dispersed and complex information, multiple players and high-stake outcomes. The clinical error rate decreased from 30.9% to 4.4% in the intervention group (Morey et al., 2002). This is a promising finding, but more research is warranted in this area.

4.7. Regulatory measures are needed to reduce adverse events and low-value care in health care systems

Robust reporting systems combined with softer policy levers designed to educate and empower clinicians and patients should be accompanied by more forceful regulatory measures. In the case of reducing low-value care, one approach is to require prior approval where there is potential to use services inappropriately. In Israel, for example, one of the largest insurers created a pre-authorisation centre for heart catheterisation, which reduced unnecessary stenting. Another approach is to re-assess the use of existing technologies as new evidence emerges that they have become obsolete, or where high variations between providers signal inappropriate care is taking place. A potentially powerful approach is "disinvestment" of low-value technologies. This may result in an intervention considered ineffective no longer receiving government funding, or the conditions in which it is available becoming more limited.

In 2015, the Australian government announced the formation of a taskforce to review the Medicare Benefits Schedule (MBS) to identify which of the more than 5 700 items were obsolete. At the end of the year, the first "tranche" of items clinical committees identified as obsolete and recommended be removed from the MBS was released for public consultation. It included items in five domains: diagnostic imaging; ear, nose and throat surgery; gastroenterology; obstetrics; and thoracic medicine. While many of these items are seldom used, examples arose of items considered no longer part of contemporary clinical practice that were subject to substantial spending. For example, direct examination of the larynx (vocal cords) attracted more than 36 000 services in 2014-15, at a cost of more than AUS 5.5 million. This was an increase of 156.5% since 2009-10 (Australian Government Department of Health, 2015). The consultation process is continuing.

In the United Kingdom, a pilot of an ineffective treatments programme by the National Institute for Health and Clinical Excellence (NICE) concluded there were few candidates for total disinvestment. To discourage the use of low-value interventions, NICE publishes monthly "recommendation reminders" reinforcing existing guidance against use of interventions. NICE also compiles on its website a "do not do" database of low-value interventions that should be avoided (Garner and Littlejohns, 2011).

In Spain, a programme of "identification, prioritisation and evaluation of potentially obsolete health technologies" was conducted in 2008. In addition, a guideline was developed to set up a process to evaluate candidates for disinvestment. The authors of the guideline stress the importance of involving physicians in the process, and explaining the reasons for disinvestment to physicians and patients to facilitate acceptance. Possible incentives to promote disinvestment could be professional recognition to participate at the individual level; prioritising new technology purchasing at the service level; and prioritising resource allocation at the hospital level (Ibargoyen-Roteta et al., 2010).

Total disinvestment is not straightforward, particularly when there has been no case of patient harm to explain to the public the basis of the decision. In some cases, total market withdrawal of an intervention is justified as a necessary prohibitive measure to prevent possible harm. For example, in the United States, in the 1990s, despite reports that two anti-obesity drugs were associated with pulmonary hypertension and heart valve abnormalities, their use did not decrease until they were withdrawn from the market (Stafford and Radley, 2003).

Politically, withdrawal of funding or failure to fund a new drug or technology can be challenging for governments to manage, particularly when concerns arise that disadvantaged populations will be deprived of treatment. Public education campaigns providing evidence that an intervention has no benefit need to accompany disinvestment plans. Decisions need to be transparently explained to clinicians and hospitals facing a possible loss of income due to disinvestment. This will require careful negotiation to reach a consensus. In one example, the Australian government a few years ago announced it would cut the rebate for cataract surgery, because advancements in technology made the procedure faster and less expensive. The announcement received strong public opposition from ophthalmologists. The government later compromised with the Australian Society of Ophthalmologists on a more modest reduction, as well as a review of ophthalmology items that could be cut. This example demonstrates the importance of engaging stakeholders in the process and embarking on a consultation period before decisions are made.

In the case of allocating funding for new technologies, decisions need to be a careful balance between fiscal responsibility and sensitivity to populations' health needs. The use of costly new interventions needs to be justified by proving they produce better outcomes than existing, cheaper alternatives. Carrying out routine Health Technology Assessment (HTA) can ensure that publicly funded interventions represent high value for both payers and patients (Box 2.12).

Governments may attempt legislative means to reduce low-value care driven by the practice of defensive medicine. Much international debate centres on whether tort law reform is needed to protect doctors from medical malpractice litigation. New Zealand moved from a tort-based system to compensate medical harm to a government-funded system in the 1970s, effectively banning medical malpractice litigation. More recent changes expanded the eligibility for compensation, making it a true no-fault system. There is concern that such systems will become unaffordable because they are perceived to encourage more compensation. However, such schemes are affordable when a country has a strong social security system, and compensation awards are lower and more consistent compared with those on a malpractice basis. Most entitled patients do not seek compensation and may be unaware they have suffered an adverse event. The other benefit is that the system does not have large legal and administrative costs (Bismark and Paterson, 2006).

Several other countries have long had no-fault systems, including each of the Nordic countries. Their primary motive is to ensure compensation for the injured, as opposed to sanctioning providers. Disciplinary action against clinicians is conducted through a separate process. These countries also promote the use of an "avoidability" standard instead of negligence to determine eligibility for compensation (Kachalia et al., 2008). The evidence is less clear on the impacts of a no-fault system on reducing costs due to inappropriate care driven by defensive medicine. One study in the United States focusing on imaging – a key driver of defensive medicine – found that a 10.0% increase in average malpractice payments per physician within a state was associated with a 1.0% increase in Medicare payments for total physician services and a 2.2% increase in the imaging component of these services (Baicker et al., 2007). Another analysis indicated that the savings resulting from a decline in medical malpractice premiums would be less than 1% of total medical costs in every specialty (Thomas et al., 2010). Other potential benefits of moving to a no-fault system include removal of the adversarial nature of litigation, which would make the process less stressful and more congenial for clinicians and patients. It would enable more timely access

Box 2.12. **Use of Health Technology Assessment to reduce low-value care**

HTA aims to systematically and transparently evaluate the potential impacts of introducing technologies into health care systems, and whether they achieve value for money. HTA concentrates its evaluation on three main domains: clinical evidence (such as the efficacy, safety and appropriateness of a particular intervention); economic evaluations; and in some countries, ethical and societal considerations. This provides an evidence-based means of informing policy makers' decisions about the allocation of public resources. With rapid technological advancements bringing more costly technologies, HTA's use will become increasingly important.

HTA use varies across countries. The United States, which spends more on health care than any other country, does not have a nationally co-ordinated HTA programme. In the OECD Health Benefits Basket Questionnaire, 19 OECD countries reported systematic use of HTA to decide whether a new medicine should be covered. Only nine countries did so for decisions regarding new medical procedures, and eight for new medical devices. Five countries reported systematic use of HTA to inform coverage for all technologies: Chile, France, Israel, Korea and Poland. Only a minority of countries, such as the Czech Republic, Japan and the United States, never or rarely use HTA as a formal part of decision making, but rather use HTA to determine reimbursement level or price-setting for new technologies (OECD, 2016b). Japan intends to begin rolling out a cost-effectiveness assessment in 2016 to evaluate whether pharmaceuticals and medical devices should be reimbursed under the public health care insurance scheme.

One of the main components of HTA is economic analysis. Some countries conduct cost-utility analysis to estimate the incremental cost per QALY gained, which can be interpreted as the additional cost per unit of health benefit gained in choosing one intervention over another. This is often expressed as a dollar amount per QALY, where one QALY amounts to one year of perfect health. This approach is an imperfect science and is widely debated, but remains a useful tool in determining the cost-effectiveness of new interventions.

A precise ICER threshold at which an intervention is considered cost-effective is difficult to determine, but the WHO suggests that health interventions with an ICER up to three times GDP per capita would be considered cost-effective (Bertram, 2015). The OECD Health Benefits Basket Questionnaire indicates that countries are reluctant to define and publish an ICER threshold beyond which an intervention will not be covered, partly because of the difficulties in setting up such a benchmark. Few countries have published an ICER threshold range, and it rarely serves as a cut-off point above which coverage is systematically denied. Other criteria are often given greater weight when making coverage decisions (OECD, 2016b).

The rise in the use of robotic surgery, particularly for prostate cancer, is an example of a costly intervention whose cost-effectiveness has been questioned. In Canada, an HTA noted that given the limitations of the available evidence and uncertainty about the clinical relevance of the size of benefits, decisions about the uptake of robot-assisted surgery should be made carefully (Ho et al., 2011). In Ireland, an HTA raised questions about the poor quality of studies examining clinical effectiveness (Health Information and Quality Authority, 2012). In Belgium, where patients have to pay about EUR 1 200 for the procedure, an HTA cited "no clear evidence to prove or refute the superiority of robot-assisted surgery" (Camberlin et al., 2009).

In England, an HTA found that higher costs of robotic prostatectomy may be offset by modest health gain, provided more than 150 cases were performed each year. The ICER was GBP 18 329. In the United Kingdom, the maximum threshold is generally considered GBP 30 000, suggested by NICE. However, the HTA cited uncertainty in the absence of directly comparative randomised data (Close et al., 2013).

It would be useful for countries to determine an ICER threshold range, while still permitting some flexibility in exceeding it under specific circumstances, such as the introduction of new high-cost technologies. While it is not necessarily appropriate to make judgements about whether an intervention should be funded based solely on its ICER, all health care systems should have in place robust and transparent mechanisms to determine whether the high costs of an intervention justify its use. An intervention that is beneficial for high-risk groups may not be cost-effective for the broader population, and flexible thresholds do exist for these purposes.

to justice and compensation for patients, and eliminate legal costs. It is hoped that it may also encourage reporting of adverse events, as clinicians would not be held back by fear of litigation. Opportunities to learn from patient safety incidents would improve. These benefits make the no-fault system an idea worthy of exploration.

To improve patient safety, several OECD countries adopted hospital accreditation as a tool to improve quality of care. The Joint Commission provides accreditation globally to hospitals and other providers. Accreditation can publicise a hospital's excellence in delivering high-quality care. As part of its accreditation programme, the Joint Commission developed National Patient Safety Goals, each accompanied by guidance on how to meet the goals. Hospital accreditation is mandatory in some countries and voluntary in others. Australia uses mandatory hospital accreditation to drive safe clinical practices. Accreditation is tied to meeting ten National Safety and Quality Health Service Standards. Among them are requirements on preventing and controlling health care-associated infections, medication safety, and preventing falls. In the Netherlands, accreditation and implementing a safety system are part of the contracts between insurers and providers. In France, public hospitals and private clinics are required to undergo accreditation with the National Authority for Health every four years. Poland's hospital accreditation standards were updated to meet new safety requirements. Providers with certifications of quality receive additional points that may have an impact on obtaining better contract conditions with the National Health Fund. Scotland has shown leadership in bringing patient safety to the forefront of public attention; its patient safety programme helped the country position itself as a world leader in patient safety (Box 2.13).

Box 2.13. **Patient safety in Scotland**

Scotland launched its *Patient Safety Programme* in 2008. The emphasis began with preventing mortality and harm in hospitals, before extending to primary care, mental health and maternal and child health services. The country's close collaboration with the IHI was instrumental in helping Scotland become a leader in patient safety. Its safety programme is based on the IHI's Breakthrough Series Collaborative Model, which comprises a series of learning sessions enabling NHS Boards in Scotland to exchange knowledge and learn from one another.

The *Patient Safety Programme* initiatives were designed in recognition of common adverse events, such as sepsis and mental health-related harm. The programme includes performance measurement at both a local and national level. Most results from the safety work are reported locally, and national data are not published in a systematic manner. However, since the programme's 2008 launch, the results include a 25.5% reduction in surgical mortality, a 15.9% reduction in the hospital standardised mortality ratio, an 80.0% reduction in clostridium difficile rates in people aged 65 and over, and an 89.0% reduction in MRSA cases. A total of 300 000 surgical pauses were recorded, akin to a time out before surgery to avoid wrong-site or wrong-patient errors.

In other initiatives, Scotland adopted a duty of candour, with a new requirement from 2017 that all patients be informed in writing of incidents of harm affecting them. In addition, the government is exploring the possibility of introducing a no-fault compensation scheme.

Scotland has national learning systems for adverse events, but events are reported locally. This is a deliberate approach to foster local ownership and response, but could be criticised for failing to aggregate events at national level. This would allow patterns of rare incidents to be apparent more quickly.

Source: OECD (2016a), *OECD Reviews of Health Care Quality: United Kingdom 2016 – Raising Standards*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264239487-en*.

Conclusion

Wasteful clinical care refers to care that fails to maximise health outcomes that matter to the patient, given available resources. This includes care that leads to preventable adverse events, as well as ineffective, inappropriate or poorly cost-effective care. Wasteful clinical care can be found at all stages of the care pathway, from low-value prevention and screening to invasive end-of-life care that offers little benefit to the patient.

Although awareness of wasteful clinical care is increasing, health care systems are still doing far too little to tackle it effectively. Rates of cardiac procedures vary more than three-fold between OECD health care systems and up to six-fold within countries, for example, and rates of knee replacements vary by more than five-fold between different regions in Canada, Portugal and Spain. It is difficult to imagine that these variations reflect differences in need. Rather, many of these interventions are likely to reflect idiosyncratic differences in personal and organisational ways of working. Preventable adverse events also remain pervasive: studies estimate adverse events to affect between 4% and 17% of admissions, with around 30-70% judged preventable.

The drivers of wasteful clinical care include poor decision making by both clinicians and patients, in part driven by incentives that are misaligned with the health care system's broader goals. Poor treatment decisions can be driven by a knowledge deficit, a cognitive bias, or a resistance to changing traditional practice. The rise of defensive medicine, driven mainly by fear of missing a diagnosis and of litigation, can also fuel unnecessary care. Similarly, patients' requests for additional treatments can be hard to decline. In the patient's mind, "doing nothing" or "doing less" may be indistinguishable from doing harm.

Addressing the issue of wasteful clinical care needs a multifaceted approach. Health care systems first need to identify instances of wasteful care more systematically, and then use a mixture of informational and financial incentives, coupled with regulation where appropriate, to reduce it. Although better information is key, consensus is needed on which indicators of wasteful clinical care to measure, as well as how to standardise and interpret numbers:

- In the domain of low-value care, some progress on measurement has been achieved. At least ten OECD countries use atlases to identify variations in health care activities and outcomes across geographical areas. The OECD is working with the *Choosing Wisely®* campaign to develop internationally comparable indicators of inappropriate care.
- In contrast, the quality of reporting of adverse events remains highly variable across OECD health care systems. Low rates of adverse events are more likely to signal underdeveloped reporting rather than safer care. Strong health care system leadership is needed to create a culture of transparency, where the intention is not to assign blame but to learn.
- Patient-Reported Experience Measures (PREMs), Patient-Reported Outcome Measures (PROMs) and Patient-Reported Incident Measures (PRIMs) are vital sources of information of health care system performance. Health care systems are investing in tools to collect these, but better co-ordination is needed to ensure that they are both locally valid and internationally comparable. The OECD is working with international partners to accelerate this work.
- Financial incentives that seek to influence the behaviour of patients, clinicians or managers can be powerful drivers of change. Most OECD health care systems are exploring innovations in payment schemes, including blended payment systems that add pay-for-performance (P4P) to fee-for-service (FFS) or capitation arrangements.

- Checklists and clinical guidelines can potentially reduce the use of unnecessary interventions and save costs. But they must be backed up by reliable monitoring, coupled with audit and feedback to individual clinicians and facilities to create a culture of continuous quality improvement.
- Regulation to reduce wasteful clinical care may include mandatory accreditation to limit adverse events caused by organisational shortcomings or, in the domain of low-value care, pre-authorisation for overused interventions. Disinvestment in low-value technologies is a potentially powerful, but rarely used, tool.
- A small number of countries moved from a tort-based system to compensate medical harm to a government-funded, no-fault system to discourage low-value care driven by defensive medicine. More OECD health care systems should explore this route – transparency, reporting and learning from adverse events are the bedrock of patient safety.
- Patients are valuable and needed partners in any effort to create a culture of safety and continuous improvement. Health care systems should direct more investment towards enabling patients to recognise, report and prevent unsafe care, as well as ineffective or inappropriate care.

Placing wasteful clinical care within the broader framework of ineffective health care system spending demonstrates that policy makers need to tackle the issue by both stopping activities that do not bring value and swapping activities when less expensive alternatives of equal benefit exist. Considerable resources could be released in this way. Changing the embedded behaviours of patients, clinicians and systems is a challenging task that will require a comprehensive, nuanced and sustained approach from policy makers.

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PART I

Chapter 3

Low-value health care with high stakes: Promoting the rational use of antimicrobials

by
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Inappropriate use of antimicrobials is perhaps one of the most threatening forms of wasteful clinical care. This is because inappropriate use of antimicrobials encourages the development of antimicrobial resistance (AMR). This chapter builds on available evidence to present a comprehensive set of policy actions to promote an effective use of antimicrobials. The chapter is divided into five sections. The first section analyses trends in consumption and estimates the share of inappropriate use of antimicrobials in OECD countries. This is followed by an assessment of the current and future health and economic burden caused by inappropriate use of antimicrobials and AMR. Section three spells out the main determinants underlying inappropriate antimicrobial use. Section four assesses the potential effectiveness of policy actions to promote an effective use of antimicrobials. Special emphasis is devoted to education and information activities; to organisational changes; and to a broader use of new technologies. A final section summarises the key policy implications of the chapter.

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Introduction

Since their discovery, antimicrobials[1] have played an essential role in the treatment of infections and their use has significantly improved population health. The era of antimicrobial chemotherapy started at the beginning of the 20th century and has revolutionised medicine (Zaffiri et al., 2012). For example, the introduction of penicillin dramatically changed the health outcomes of patients with bacterial pneumonia and bloodstream infections, from a case fatality rate of about 90% to a survival rate of about 90% (Austrian and Gold, 1964). In addition, by preventing the development of hospital-acquired infections and by decreasing surgical infection rates from 40% to 2% (Wallace et al., 2000), antimicrobials allowed the introduction of complex medical interventions such as organ transplantations, advanced surgery and care of premature neonates. The number of clinical situations in which the use of antimicrobials is essential is countless and includes the treatment of cancers, traumas and wounds, and elective surgery (White, 2011).

But widespread inappropriate use of antimicrobials constitutes perhaps one of the most threatening forms of wasteful clinical care. Inappropriate use of antimicrobials wastes resources and unnecessarily puts patients at risk. This is because inappropriate antimicrobial use encourages development of antimicrobial resistance (AMR) and the spread of resistant infections, resulting in increased risks to patient safety and compromising the effectiveness of an entire range of life-saving health care services. It is therefore a threat to global public health. Given the stakes, this chapter puts the spotlight on antimicrobials.

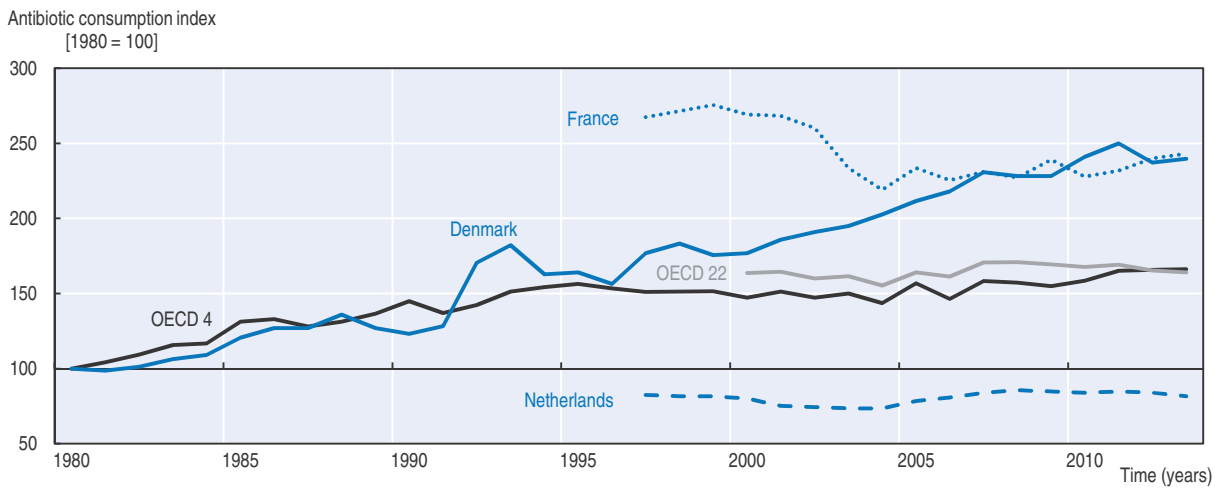
The primary aim of this chapter is to support governments' immediate priority to promote rational use of antimicrobials. In addition, it illustrates some of the more general lessons outlined in the previous chapter on low-value care. The chapter starts with a presentation of trends in antimicrobial consumption, followed by a discussion of the health and economic consequences caused by inappropriate antimicrobial use and the resultant AMR. The main determinants underlying irrational use are discussed in the third section. The final section presents a comprehensive list of policy options to promote rational use of antimicrobials, their potential effectiveness and an overview of their implementation in OECD countries.

1. Stabilised antimicrobial consumption but high levels of inappropriate use

Worldwide antimicrobial consumption has steadily increased over time. Starting with penicillin, antimicrobials have been considered a "miracle" drug. Compared to many other health interventions commonly delivered by health care services, most antimicrobials are relatively inexpensive (Falagas et al., 2006) and have excellent cost-effectiveness ratios when used rationally. It is not surprising that their consumption steadily increased over time until reaching a plateau in OECD countries, signalling a saturated market.

Figure 3.1 shows the consumption of antibacterial therapies for systemic use in OECD countries. For four OECD countries – the Czech Republic, Denmark, Finland and Iceland – it is possible to track consumption back to the early 1980s. In these countries, between 1980 and 2013, antimicrobial consumption increased by more than 66%, reaching an average consumption of about 20.6 defined daily dose (DDD)[2] per 1 000 inhabitants. Most of this increase occurred between 1980 and 1995, with consumption rates remaining substantially stable thereafter. Data for 22 OECD countries are available since 2000. In this broader sample, data also suggest that consumption remained stable during the last 10 to 15 years.

Figure 3.1. **Trends in antimicrobial consumption for systemic use in selected OECD countries and groups**



Note: Data were normalised to average antimicrobial consumption in OECD 4 in 1980 (equal to 100). Data for missing years were estimated by linear interpolation. OECD 4 includes the Czech Republic, Denmark, Finland and Iceland.
Source: Authors' analysis of *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en*.

StatLink *http://dx.doi.org/10.1787/888933444126*

OECD averages, however, mask considerable differences across countries. In Denmark, for example, the data for 2013 suggest that antimicrobial consumption is 2.5 times higher than in 1980, a more significant increase than in many other OECD countries. Conversely, some countries successfully decreased their levels of consumption, mainly tackling the inappropriately consumed fraction. France (depicted in Figure 3.1) and Greece initially showed consistently high levels of consumption, but more recently achieved significant reductions. Within each country, significant differences may also exist across classes of antimicrobials. For instance, while many OECD countries show decreasing trends in the consumption of trimethoprim and tetracyclines, the use of fluoroquinolones consistently increased across countries (van Boeckel et al., 2014).

A significant share of antimicrobial consumption is unnecessary and inappropriate. Inappropriate antimicrobial use is the use of an antimicrobial when no benefit is possible, or is suboptimal under responsive conditions. According to the World Health Organization definition (WHO, 2012), the inappropriate use of antimicrobials is the overprescription, under prescription, and prescription and dispensing of unnecessary antimicrobial combinations. This includes the use of unnecessarily broad-spectrum antimicrobials, incorrect dosage and/or duration, and poor adherence to prescribed course by the patient or administrator (Box 3.1).

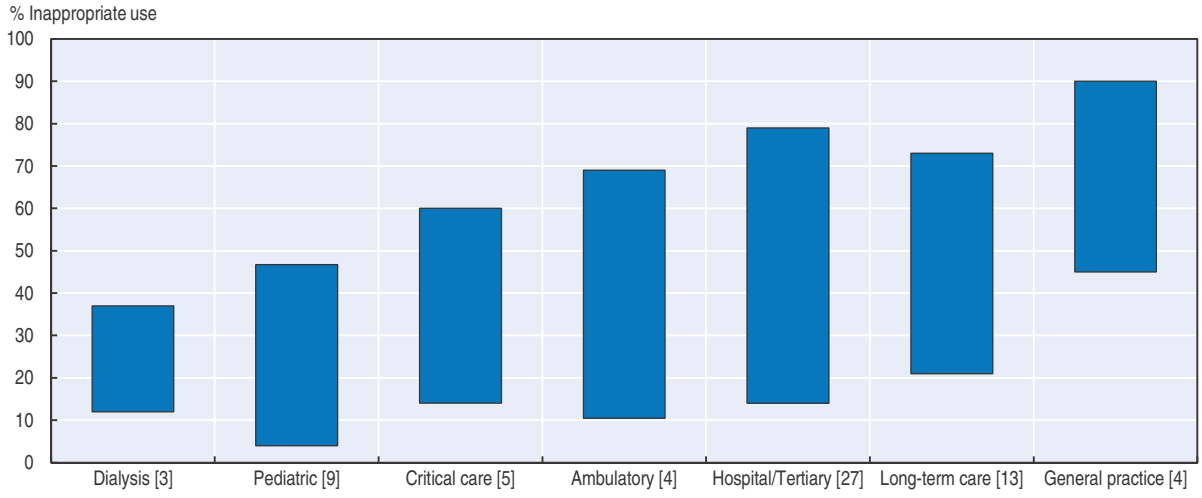
Box 3.1. **Defining the rational use of antimicrobials**

The rational use of medicines, including antimicrobials, is defined according to four criteria (WHO, 2001). First, the drug should be appropriate to the patient's clinical needs. In the specific case of antimicrobials, this also entails the drug to be of good quality and the bacteria to be susceptible to the antimicrobial. Second, the dose should meet the patient's individual requirements both in terms of disease severity and patient-specific characteristics. Third, the drug should be used for an adequate period of time. Both prolonged and inadequate lengths of treatments are types of inappropriate antimicrobial use. Fourth, the treatment should be carried out at the lowest cost for the patient and the community.

Antimicrobial use has health consequences and costs for both the single patient and society, as misuse increases the likelihood of enriching antimicrobial-resistant microorganisms by artificial selection, which may colonise other members of society.

Inappropriate use of antimicrobials is prevalent but differs across types of health care specialties. Overall, inappropriate use may account for up to 50% of all antimicrobials consumed in human health care (Wise et al., 1998). Analysis of published literature spanning data from 31 countries, including 27 OECD member countries, found a large range in the proportion of inappropriate use within each type of service, ranging from 4% to 90%, due to cross-country, cross-facility variances (Figure 3.2) (see Annex 3.A1 for a list of literature reviewed). General and long-term care services are the areas of most concern, as consistently high levels of inappropriate use are reported, and because each discipline consists of a high volume of patients. For example, 13 publications reported inappropriate antimicrobial use in long-term care facilities within the range of 22% to 73%, and four reported 45% to 90% of inappropriate use in general practice.

Figure 3.2. **Estimated proportion of inappropriate use of antimicrobials by type of health care service**



Note: Numbers in brackets indicate the number of studies used to determine the range of inappropriate use.
Source: OECD analysis of available evidence published in literature listed in Annex 3.A1.

StatLink http://dx.doi.org/10.1787/888933444132

The review suggests that the diagnoses for which antimicrobials are most frequently inappropriately prescribed in general practice and long-term care services are viral upper respiratory tract infections and asymptomatic bacteriuria. Other situations frequently reported by the available literature as major reasons for inappropriate use are prescriptions without microbiological confirmation, unnecessary prophylactics and prolonged uses.

2. Consequences of inappropriate antimicrobial use: A significant health burden and increased health care costs

The misuse of antimicrobials has large detrimental health and economic impacts in addition to the cost of purchasing the antimicrobial. Patients can develop adverse health consequences as a direct effect of inappropriate use while the original illness cannot be improved. Adverse drug events caused by allergies to antimicrobials and development of side effects in patients who would not benefit from antimicrobial prescriptions trigger use of health care services that could otherwise be avoided. The health care expenditure associated with treating these events, as well as the resources and time for prescribing and administering these antimicrobials, is inefficient.

At the same time, antimicrobials are the only class of drugs for which higher use induces quicker obsolescence. In their desire to quickly recover from diseases, patients are not interested in the negative remote consequences that their treatment (particularly if ineffective) may have on them or other members of society in the future. Misuse of antimicrobials is, in fact, the most important factor responsible for increasing levels of AMR, with potentially significant economic impacts (Box 3.2).

Box 3.2. **Antimicrobial resistance: An economic perspective**

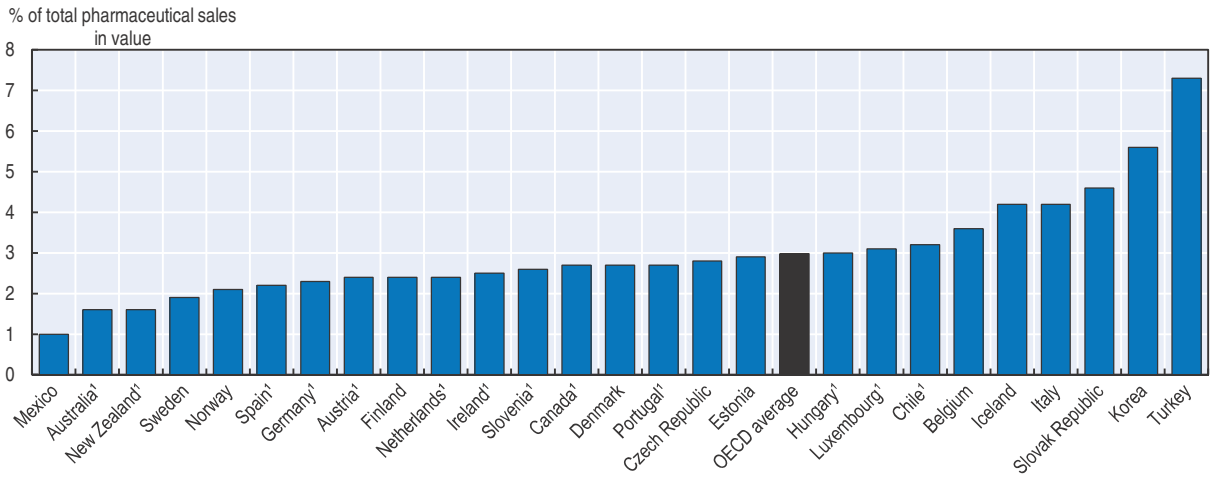
Economists often refer to AMR as a negative externality associated with the use of antimicrobials. An externality exists when a choice of behaviour has some effects on another individual who is not directly involved in the transaction. In the case of antimicrobials, the use of the drug today is associated with externalities if a resistant strain emerges in the same individual and/or infects other susceptible people in the community in the future. Externalities caused by inappropriate antimicrobial use include the costs associated with the extended burden of disease and deaths attributed to the lack of available antibiotic treatment to infection caused by resistant pathogens, and other advanced medical treatments disabled by the lack of antibiotic prophylaxis. For example, Kaier and Frank (2010) estimated that consumption of some of the most common antimicrobials in the control of methicillin-resistant *S. aureus* (MRSA) is associated with an externality of EUR 5 to EUR 15 per dose. Another analysis calculated that externalities associated with antimicrobial use for hospital-acquired infections ranged from EUR 101 to EUR 143 per dose (Kaier and Volkswirt, 2012).

Inappropriate use of antimicrobials is one of the main causes underlying the welfare deadweight loss associated with AMR. Deadweight loss is the result of an allocative inefficiency that emerges when the allocation of resources (in this case antimicrobial products) is not Pareto optimal. When antimicrobials are not used in an appropriate fashion, the benefits produced by a dose of antimicrobials tend to zero because the antimicrobial does not produce any positive health effect. At the same time, the cost of the externalities associated with antimicrobial consumption increases. Thus, inappropriate antimicrobial use is a situation in which the burden of future resistance maximally outweighs the benefits of antimicrobial use. Elbasha (2003) estimated that in 1996 in the United States, the deadweight loss to societal welfare attributable to inappropriate use of amoxicillin (the most commonly prescribed antimicrobial in the United States in that year) was USD 225 million.

2.1. Misuse of antimicrobials is intrinsically wasteful

Money spent on the purchase of inappropriately prescribed antimicrobials is wasted. Figure 3.3 shows antimicrobial drug sales as a share of the total value of pharmaceutical sales across OECD countries in 2014. On average, antimicrobials account for 3% of the total value of pharmaceutical sales. In addition, total pharmaceutical expenditure is estimated to consist of approximately 20% of the total health care expenditure, valued at about USD 800 billion (Belloni et al., 2016). Therefore, the commercial value of antimicrobials *per se* is relatively limited, and even a sharp rationalisation would have only a small direct impact on total health care expenditure.

Figure 3.3. **Share of antimicrobial drug sales out of total pharmaceutical sales across OECD countries, 2014**



Note: The OECD average includes 26 countries.

1. Countries for which only retail sales data are available (i.e. hospital sales are excluded). Reported figure should be interpreted as an underestimate of actual total antimicrobial drugs sales in the country.

Source: Authors' analysis of *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en*.

StatLink *http://dx.doi.org/10.1787/888933444143*

Beyond the market cost for pharmaceuticals, misuse of antimicrobials is a crucial source of other significant waste in the health care sector. For example, wasted resources include the time and costs associated with prescribing and administering antimicrobials by relevant health care personnel (e.g. physicians, nurses and pharmacists) as well as costs incurred by patients (transportation, time, expenditure in medicines, etc.). Costs for treating unwanted consequences of inappropriate prescriptions should also be included. Some studies evaluated that about 19% of ambulatory care visits (Zhan et al., 2005) and 18% of visits to an emergency department (ED) (Budnitz et al., 2006) for a drug-related adverse event are caused by consumption of antimicrobials. In the United States, Shehab and colleagues (2008) calculated that about 142 505 visits to an ED were caused annually by an antimicrobial-related adverse event.

The health burden directly caused by misuse of antimicrobials includes cases of side effects and allergies that could be averted if the treatment was not prescribed. Side effects are usually mild and often only affect the digestive system, but in some cases, antimicrobial use may cause permanent soft-tissue damage (e.g. muscles, joints and the central nervous system) (USFDA, 2016). An estimated 10% of people using antimicrobials

may experience side effects (NHS, 2016). Allergic events are more serious and involve obstructions to breathing or, to a more severe extent, anaphylaxis, which is potentially fatal. In the United Kingdom, about 7% of the population is allergic to antimicrobials (NHS, 2016). It is also estimated that between 1 and 5 in 10 000 people may develop anaphylaxis (Bhattacharya, 2010). In the United States alone, up to 27 million people may be at risk of anaphylaxis from consumption of an antimicrobial (Neugut et al., 2001). Each year, about 125 million patients across OECD countries are admitted to a hospital. About 10% to 15% of these patients develop an adverse drug reaction (including both side effects and allergies), and one in five cases are caused by an antimicrobial (Thong and Tan, 2011). Assuming a rate of inappropriate use close to 50% (which is in line with the results of the review presented in Figure 3.2), a conservative estimate of 1.3 million cases of adverse events directly due to inappropriate antimicrobial use may be averted.

2.2. The health and economic burdens caused by AMR are a significant challenge

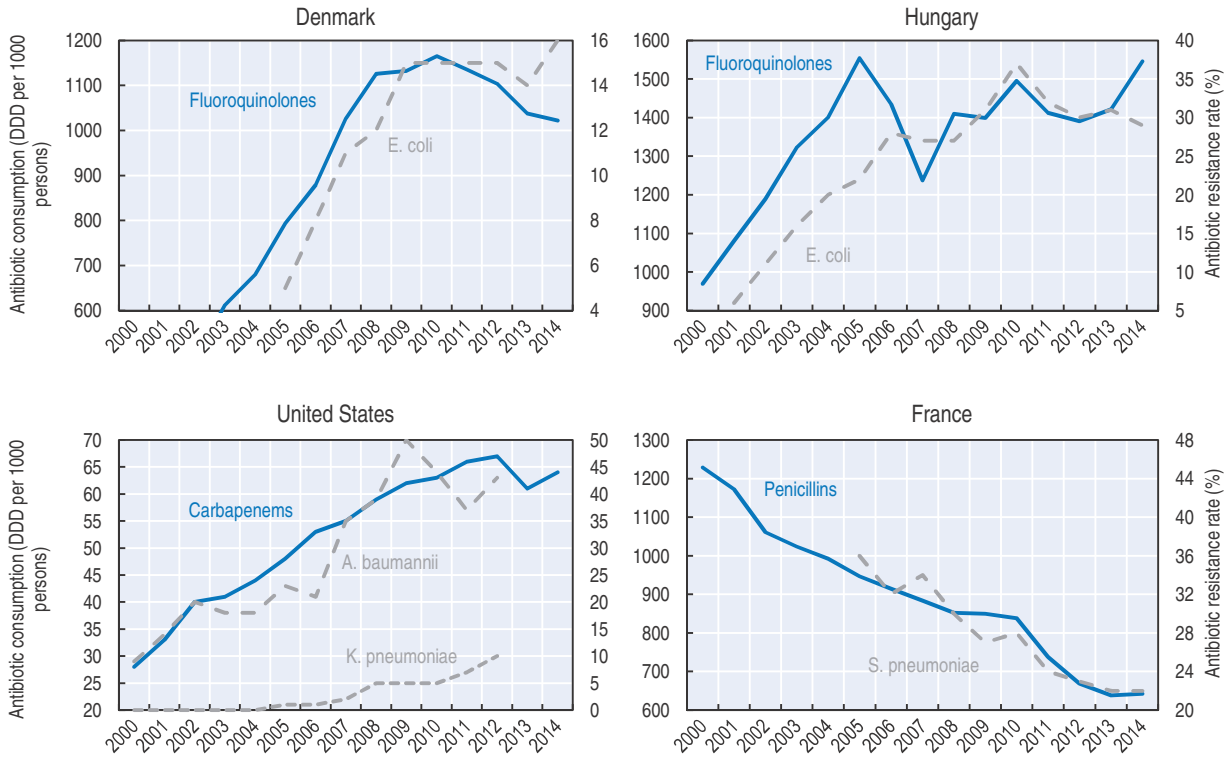
The indirect effects of inappropriate antimicrobial use, resulting in changes in resistance of microorganisms among patients interacting with the health care system, have potentially greater consequences than the direct effects. Together with insufficient hygiene in health care facilities and antimicrobial use in the livestock sector, the volume of antimicrobial use in humans is one of the main drivers of increasing levels of AMR. Inappropriate antimicrobial use is particularly dangerous because it has a negligible (if any) effect on treating diseases but, at the same time, has a significant impact on the selection and enrichment of resistant microorganisms (Box 3.3). This may affect individual patients directly but may also affect other patients if organisms are transferred from the former to the latter. Conversely, promoting the rational use of antimicrobials is associated with decreasing trends of AMR.

Box 3.3. **What is antimicrobial resistance? How does it develop and spread?**

AMR is a natural part of the evolution process of bacteria. Like any living organism, bacteria can undergo random evolutionary changes in their genomes. Genetic mutations can produce new or altered traits that sometimes enable new abilities or capacities. In the case of AMR, a bacterium develops the ability to withstand attacks by antimicrobial drugs. Mechanisms by which microorganisms exhibit resistance range from drug inactivation by the production of protective substances, to a decrease in drug permeability into the bacteria. New traits are passed "vertically" to offspring during reproduction or "horizontally" across bacteria of the same generation through the exchange of mobile genetic elements. As has occurred for animals and humans, bacteria exhibiting helpful traits become more common through natural selection. However, compared to animals or humans, natural selection in bacteria occurs much more quickly, as bacteria can reproduce as often as every 20 minutes. For example, ampicillin, a largely used antibiotic, despite having been developed only half a century ago, is now widely tolerated by many microorganisms. Nearly 100% of hospital-acquired *Klebsiella* infections in developing countries are now ampicillin-resistant (Laxminarayan et al., 2013). AMR is maintained and enriched by persistent exposure to selective pressure enabled by high volume use of antimicrobials. The enrichment process can be reversed by reducing the selective pressure imposed by inappropriate use of antimicrobials.

Figure 3.4 reports a set of case studies from Denmark, France, Hungary and the United States showing that the frequency of AMR parallels the rate of antimicrobial use. In Hungary between 2001 and 2010, consumption of fluoroquinolone increased by 38% while the proportion of fluoroquinolone-resistant *E. coli* isolates increased from 6% to 37% of total isolates. Similarly, in Denmark between 2005 and 2010, consumption increased by 47% while the proportion of resistant *E. coli* isolates rose from 5% to 15%. The use of carbapenems, a last resort antimicrobial, increased by 125% in the United States between 2000 and 2010, triggering an increase in the proportion of carbapenem-resistant isolates of *A. baumannii* (from 9% to 44%) and *K. pneumoniae* (from 0% to 5% in 2010, and to 10% in 2012). On the other hand, in France, the prevalence of penicillin-resistant *S. pneumoniae* decreased by 8% following the decreasing trend of penicillin consumption between 2005 and 2010. In general, changes in volumes of antimicrobial consumption are followed shortly thereafter by changes in AMR prevalence (e.g. in Hungary between 2006 and 2008). Decreases in prevalence rates tend to be smaller than decreases in consumption, though. Reverting to lower levels of AMR in countries with high or increasing AMR is thus still possible, but may take some time and will require effective action.

Figure 3.4. **Trends in antimicrobial consumption and antimicrobial resistance, 2000-14**



Source: Authors' analysis of CDDEP (n.d.), "Resistance Map – Beta", *http://resistancemap.cddep.org/*.

StatLink http://dx.doi.org/10.1787/888933444152

Infections by AMR bacteria impose severe health consequences on patients. Compared to patients infected by susceptible bacteria, individuals infected by resistant strains require a longer period to recover. In addition, they are more likely to develop complications ranging from local progression of the infection to serious medical

complications in the cardiovascular and central nervous systems. In some cases, infectious microorganisms enter the circulatory system to spread, causing sepsis (i.e. a whole-body inflammatory response to an infection) and septic shock.

Patients infected by resistant bacteria show a significantly increased risk of mortality. Different reviews conclude that the risk of death may increase two- to three-fold if the patient is infected by a resistant bacterium (WHO, 2014; Maragakis et al., 2008). The most recent estimates suggest that at current resistance rates, about 23 000 and 25 000 deaths per year are directly attributable to AMR in the United States (CDC, 2013) and Europe (ECDC and EMEA, 2009), respectively. If appropriate policies are not put in place, the rates of resistance may increase by an additional 40%, and the global health burden due to AMR may reach 10 million deaths per year between 2015 and 2050, of which 0.7 million will occur in North America and Europe (Review on AMR, 2014).

A range of basic life-saving procedures, such as trauma and intensive care, and advanced and often invasive medical procedures, such as surgery and cancer therapeutics, are enabled by the appropriate use of antimicrobials (White, 2011). Antimicrobials prevent and cure opportunistic infections that can develop in the course of these medical procedures. For example, prophylactic use in hip replacement surgery reduces postoperative infection rates of susceptible organisms by up to 50% and death due to such infections by 30% (Smith and Coast, 2013). Patients particularly at risk are those with a less effective immune system and include, for instance, preterm children and old and fragile patients. AMR has the potential to completely nullify the protective effects of antimicrobials and threatens patient survival from medical procedures that, one day, may become too dangerous to perform due to AMR.

Between USD 10 000 and USD 40 000 could be saved per AMR patient if the patient was instead affected by an infection treatable by antimicrobials (Cohen et al., 2010; Sipahi, 2008; Smith and Coast, 2012; Tansarli et al., 2013; WHO, 2014). Overall, AMR has significantly impacted health care systems' budgets. In Europe, about EUR 940 million was spent in 2007 for treating resistant infections caused by six prominent infective agents (ECDC and EMEA, 2009). In Canada in 2015, estimated medical costs of CAD 1 billion were associated with antimicrobial-resistant infections (Government of Canada, 2015). CDC (2013) estimated that, under certain assumptions, the economic impact of AMR may be as high as USD 20 billion per year. The main drivers underlying the additional expenditure are:

- More intensive forms of treatments, such as hospitalisation for community-acquired infections or, if patients develop a disease while hospitalised, transfer to intensive care units and isolation rooms.
- More intensive medical procedures; for example, the likelihood of undergoing surgery among patients infected with resistant organisms increases. Surgery may range from debridement of infected tissue to amputation (Cosgrove, 2006).
- Added length of stay or treatment until the infection is eradicated; this entails additional medical and nursing care (and consequently time) as well as the use of other hospital resources.
- Additional investigations, such as advanced laboratory tests to ascertain the most effective therapy for the specific agent involved, or imaging to monitor development of complications associated with the infection.

- Use of more aggressive antimicrobial therapies based on either second-line antimicrobials (which are usually more expensive) or combinations of different antimicrobials, or a series of tests with different treatment options before identifying the most effective strategy.

Inappropriate antimicrobial use could lead to unfavourable effects in the broader economy: lost income due to longer work absences, the costs associated with ill health and death. Increased morbidity also affects the supply of labour if the ill requires the attention of a relative who would otherwise be economically productive. Roberts and colleagues (2009) calculated that in the United States in 2000, the cost attributable to increased mortality and productivity losses due to AMR was about USD 38 000 per hospital patient, more than double the associated medical cost of treating the patient. Scaling up to the national level, in 2000 the United States lost USD 35 billion (or about 0.35% of national GDP) due to AMR. In Europe, productivity losses due to absence from work caused by AMR amounted to about EUR 600 million in 2007 (ECDC and EMEA, 2009).

3. Determinants of inappropriate antimicrobial use

The factors influencing the use, and the associated misuse, of antimicrobials are numerous and closely interrelated. All actors involved in the process, starting with the production and commercialisation of antimicrobials, to their final consumption, may play a role in triggering inappropriate antimicrobial use. And while in many cases diagnostic uncertainty is reported to be the main reason for overprescription, inappropriate antimicrobial use is often the result of rational behaviour by one or more actors, driven by cognitive biases or incentives. In other cases, inappropriate antimicrobial use is caused by illegal actions (see Box 3.4 for information on illegal drivers of inappropriate antimicrobial consumption).

Cognitive biases, perceived pressure and poor information are among the most commonly cited reasons for overprescription of antimicrobials by physicians.

- Previous practice and inertia may be stronger than knowledge of clinical guidelines. Consistent evidence (e.g. Sanchez et al., 2014) suggests that physicians can often identify the most appropriate antimicrobial therapy if specifically asked. But in their daily practice, doctors may decide not to follow these guidelines to privilege local attitudes and usual business practices. High prescribers tend to be older, have been out of the university longer (Mainous et al., 1998), and have spent longer time in the same practice (Steinke et al., 2000).
- Physicians may fear treatment failure. The fear of possible future complications due to secondary bacterial infections, especially in patients with co-morbidities and other risk factors such as old age and chronic diseases, often results in antimicrobial prescriptions even in the absence of a bacterial disease (Vazquez-Lago et al., 2012). For similar reasons, physicians may tend to choose broad-spectrum over narrow-spectrum antimicrobials (Gonzalez-Gonzalez et al., 2015).
- Physicians may try to meet real or perceived patients' expectations. A 2014 survey carried out among British general practitioners (GPs) found that 55% of them felt pressured to prescribe antimicrobials, even if they were not sure that an antimicrobial prescription was needed (Cole, 2014). Almost half (45%) of GPs admitted that they had prescribed an antibacterial for a viral infection even though they knew its use would be ineffective. More experienced GPs were most likely to be part of this group.

Box 3.4. **Illegal drivers of inappropriate antimicrobial consumption**

Use of counterfeit antimicrobials and sales of antimicrobials without a medical prescription are illegal drivers of inappropriate antimicrobial consumption.

Counterfeit antimicrobials approximate 5% of the world's antimicrobial market, with much higher consumption rates in developing countries than in developed countries (Delepierre et al., 2012). A recent report estimated that more than 70% of all counterfeit antimicrobials found destinations in Asia and Africa; 17% were sold in the European region, 10% in the Americas, and only 1% in Oceania (Kelesidis and Falagas, 2015). The specific prevalence is low in South Korea, Japan and countries in Australasia (WHPA, 2011). Therefore, counterfeit antimicrobials are generally a small concern in OECD countries due to the highly regulated standards testing and unified dispensing routes. Nonetheless, maintaining in place strong actions to discourage distribution of counterfeit antimicrobials should remain a priority. For instance, a prevalence study in 2014 involving 12 European countries discovered 21 000 dose units of counterfeit antimicrobials in one week (but an overestimation was suspected; Venhuis et al., 2015).

In OECD countries, antimicrobials can only be obtained legally by prescription. However, data suggest that common antimicrobials may be easily obtained from legal dispensing sources, such as pharmacies, without a medical prescription. In Greece, amoxicillin and ciprofloxacin were obtained without prescription 100% and 53% of the time, respectively (Plachouras et al., 2010). In Spain, 41% of antimicrobial users reported obtaining the drug without prescription (Väänänen et al., 2006). In the United States, antibiotics are freely available for purchase on the Internet without a prescription (Mainous et al., 2009). Tackling the illegal purchase of antimicrobials without a medical prescription entails a combination of education programmes directed to patients and increased regulation and enforcement of existing regulations.

- Misperception of the local levels of AMR. Doctors may modify their prescription behaviours and increase the prescription of second-line antimicrobials even to patients with infections susceptible to first-line antimicrobials if the prevalence of AMR is perceived to be high in the local environment (McNulty et al., 2011).

Organisational factors and incentives influence physicians' prescriptions:

- Organisational and resource-related factors may prevent physicians from effective prescribing (Cabana et al., 1999). Some of the most often cited barriers include: lack of time or resources (e.g. antimicrobial prescription as an inexpensive quick fix; lack of diagnostic test facilities), organisational constraints (e.g. patient's health insurance coverage; lack of oversight or guidelines), and lack of reimbursement (Teixeira Rodrigues et al., 2013). Poor implementation of actions to control hospital infections, and a consequent increase in AMR levels, may also underpin inappropriate patterns of antibiotic prescription.
- Reimbursement policies and other financial incentives may affect patterns of antimicrobial prescription. In South Korea, physicians and pharmacists could both prescribe and dispense drugs (including antimicrobials) until 2000. New legislation separating these two functions produced a significant drop in inappropriate prescribing (Park et al., 2005). Separation of prescribing and dispensing is a well-established practice across OECD countries but much less so outside the OECD. Other incentives may also underpin overprescription. For example, it was argued that Germany's reimbursement

system for GPs, based on a fixed budget determined by the number of patients, may foster higher use of antimicrobials because this practice minimises the risk of a short-term re-examination of the patient (Kaier et al., 2011).

- Promotional efforts by drug companies or resellers include direct advertisement to patients as well as different forms of promotion to physicians. Consistent evidence shows that promotional efforts may increase the likelihood of prescription of specific drugs (Wazana, 2000). Historically, antimicrobials have been among the leading drug classes for promotional expenditures (Ma et al., 1998). An analysis of marketing strategies (Gilad et al., 2005) found that advertisements are unlikely to mention AMR as an issue associated with antimicrobial overprescription.

Patients' inadequate knowledge and behavioural responses drive inappropriate use:

- Patients sometimes self-medicate using unnecessary or ineffective antimicrobials. A systematic review of studies concluded that across a sample of OECD countries, the frequency of non-prescription antimicrobial use varies between 3% and 44% (Morgan et al., 2011). Countries in Northern and Western Europe present lower frequency compared to countries in Southern and Eastern Europe as well as Mexico. Frequently cited sources of antimicrobials for self-medication are the pharmacy (Box 3.4) and leftover courses from home or friends. The most common reason for self-medication is relief of throat symptoms (Grigoryan et al., 2006).
- Poor adherence to antimicrobial prescriptions may lead to worsening of the infection as well as selection of antimicrobial-resistant strains of bacteria. A number of studies carried out in Europe and North America found that a significant share of individuals taking antimicrobials skip some doses (up to 44% of US interviewed patients; Edgar et al., 2009), modify the dosage or substitute with a different type of antimicrobial (about 10% of patients in an Italian study; Grosso et al., 2012), or stop taking the medication before the end of its course (about 10% in Spain and Sweden; Axelsson, 2013; Llor et al., 2014).
- When symptoms do not disappear promptly after the beginning of therapy, some patients seek additional care and antimicrobial prescriptions from multiple doctors. For example, Takahashi et al. (2016) reported that about 7.5% of all antimicrobial prescriptions in Japan in December 2012 were considered duplicative (i.e. a prescription for the same conditions from two or more health care providers in a month).

4. Tackling inappropriate antimicrobial use: Policy approaches across OECD countries

The inappropriate use of antimicrobials is a complex problem caused by various interacting factors and dynamics. Promoting effective utilisation of antimicrobials and achieving more rational use entails implementation of comprehensive strategies undertaken collectively by all key actors in the process.

In line with other chapters of the report, this section first looks at key organisational arrangements at the national level, including the implementation of global strategies, the definition of national targets, and the strengthening of surveillance systems. This is followed by a review of specific policy actions that can be included in national strategies. Policy options are divided into two broad categories: actions to inform and educate antimicrobial prescribers and consumers; and organisational arrangements to support antimicrobial rationalisation. Policies discussed in this section build upon the actions presented in the WHO Global Strategy (WHO, 2001) and the WHO Global Action Plan (WHO, 2015) to construct

a network of interventions specifically aimed to promote rational use of antimicrobials. For each identified intervention, evidence on its effectiveness is presented. In addition, the section provides an overview of the current level of implementation of such policies across OECD countries as well as examples of best practices and successful national policies.

In addition to the policy options described in this chapter, other types of interventions may provide positive contributions to the fight against inappropriate antimicrobial consumption and AMR. For example, policies aimed at enhancing immunisation for diseases with AMR potential (e.g. *S. pneumoniae*), interventions to contain infection spread (e.g. better hygiene in health care settings), and actions to limit the availability of counterfeited antimicrobials or use without a medical prescription may provide a substantial indirect contribution to rationalising antimicrobial consumption (Cecchini et al., 2015). Discussion of these policies falls beyond the scope of this chapter, which focuses exclusively on promoting rational antimicrobial use.

The findings presented in this section result from of a combination of primary and secondary research. A survey conducted in early 2016 in the 34 OECD member countries reviewed their initiatives to tackle inappropriate antimicrobial use. In total, 29 OECD countries (85%) responded to the questionnaire. Evidence collected through the questionnaire was complemented with a comprehensive literature review of academic articles, grey literature and national documents.

4.1. National strategies with clear targets, supported by comprehensive surveillance systems, provide the fundamental framework to address inappropriate antimicrobial use

Efforts to rationalise antimicrobial use are embedded in broader strategies to prevent AMR

Improving appropriate antimicrobial use has drawn increasing attention over the last 20 years. In 1998, the World Health Assembly called on WHO to develop a framework to tackle AMR (WHO, 1998). Efforts began with publication in 2001 of the Global Strategy for Containment of Antimicrobial Resistance (WHO, 2001) and culminated with release of the Global Action Plan on Resistance in 2015 (WHO, 2015). The plan calls on all member countries to develop and adopt a national plan by 2017. A considerable share of the recommended actions focus on promoting appropriate antimicrobial use. In the European region, since adoption of the set of recommendations on the prudent use of antimicrobial agents in human medicine by the EU Council in 2001 (European Commission, 2005, 2010), assessments have been underway to evaluate the effectiveness and use of these strategies.

More than half (60%) of the OECD countries responding to the questionnaire have produced strategies to rationalise the use of antimicrobials and an additional 37% are elaborating one. Strategies to rationalise antimicrobial use are always part of broader sets of policies to tackle AMR, which may also include other interventions such as increasing uptake of immunisation and improving hygienic practices to prevent the emergence and transmission of AMR organisms. Only one country reported that it does not have strategies related to rationalising antimicrobial use.

Most countries' strategies encompass all three major areas of health care: hospital care, primary care and long-term care. In fact, all national strategies for the rationalisation of antimicrobial use cover primary care settings, including general practice and dental care. Only 7% (2) and 13% (4) of countries do not yet have a strategy to optimise consumption in hospital care and long-term care facilities, respectively.

The setting of specific targets, based on national priorities, should be a crucial component of action plans. At the subnational level, these targets may be adapted and tailored to meet local challenges. Only 37% of countries have already set some targets; an additional 40% are in the process of developing national targets; and 23% have no specific national-level targets on antimicrobial use.

Targets can be divided into three broad categories (Table 3.1). A first category of targets focuses on the process and encompasses all procedures associated with antimicrobial prescription and its monitoring. Improving activities in surveillance data collection is often mentioned as a priority target. Targets in this domain aim to increase data collection on antimicrobial consumption and resistance and infection epidemiology. Data collection in the hospital sector often takes priority over data collection among other categories of health care providers. Some countries set goals to increase the volume of research and publications based on data collected. Increasing antimicrobial stewardship programmes and adhering to guidelines is another common type of target. Examples of targets include mandating all or the majority of health care institutions (usually hospitals) to implement stewardship programmes. Some countries aim to implement electronic prescriptions as a strategy to optimise choice of antimicrobial medication and to increase prescription validation. Recommendations are sometimes given to increase the use of rapid diagnostic tests (RDTs) for specific diagnostics, such as in patients presenting with pharyngitis.

Table 3.1. **Target benchmarks for rationalising antimicrobial consumption**

Target categories		Subcategory	Example
Process	Increase data collection	Antimicrobial consumption and resistance	Routine reporting of antibiotic use and resistance data to National Healthcare Safety Network (United States)
		Guideline adherence and recordkeeping	Indication statement of antibiotic therapy in the medical record in at least 90% of cases (Belgium)
	Implement stewardship programmes	Participation rate of hospitals	Antimicrobial stewardship programmes in all hospitals (Slovenia)
	Increase use of new technologies	Electronic prescription	Introduction of electronic prescriptions in the majority of hospitals (Slovenia)
		Use of rapid diagnostic tests (RDTs)	Strep test for the diagnosis of tonsillopharyngitis (Greece)
Outputs – reduce antibiotic consumption		Total consumption	Reduce by 2 DDD per 1 000 inhabitants per year (Turkey)
		Consumption of specific antimicrobials	Reduce consumption of quinolones from approx. 10% of total antimicrobial use today to 5% by 2018 (Belgium)
		Consumption for specific diseases	Reduce prescriptions for respiratory infections by 20% (Norway)
		Consumption in specific health care services	Reduce inappropriate consumption by 50% in outpatient and 20% in inpatient settings (United States)
Outcomes – realise specific medical outcome		Prevalence of resistance to specific antimicrobials	Further reduction of multidrug-resistant bacteria in health care (the Netherlands)
		Frequency of infections by AMR organisms	Reduce incidence of C. difficile infection by 50% of 2011 level (the United States)
		Mortality due to AMR infections	Decrease in or stabilisation of death due to AMR (the Netherlands)

Note: Most countries aim to achieve targets by the end of a five-year plan.
Source: Authors' analysis of countries' responses to the 2016 OECD questionnaire.

A second category of targets focuses on setting direct consumption goals and aims to reduce antimicrobial consumption. Targets in this category are by far the most common, particularly because their achievement is relatively easy to measure with the surveillance systems currently in place. Common benchmarks are set as percentage reduction of total antimicrobial consumption, or percentage of inappropriate share of consumption of the reference year. In general, countries plan to reduce consumption by a range of 20% to 50% in a five- to ten-year period. Some countries set targets on rationalising the use of specific antimicrobials, use in certain health care services, and/or use under specific indications or diseases (e.g. respiratory infections).

Finally, a few countries set a third category of targets focusing on more downstream goals. Rather than centring on specific activities or outputs in the health sector, these targets look directly at medical outcomes. Examples include reducing the prevalence of resistant strains in isolates or the frequency of AMR infections (specifically, hospital-associated infections and *C. difficile* infections), and reducing the rate of death associated with AMR infections.

Surveillance systems collecting information on antimicrobial consumption should be strengthened

Establishing an effective surveillance system is fundamental for developing and informing any strategy aimed to rationalise antimicrobial prescriptions and to tackle AMR (Madaras-Kelly, 2003; WHO, 2001). Surveillance systems should provide timely data in all areas of health care (e.g. hospital departments, community, long-term care services, etc.), be representative of the total population, and collect data in a standardised format to allow national and international comparisons. Well-designed surveillance systems addressing all these criteria would provide the data required to gauge the scope of inappropriate antimicrobial prescription, monitor its evolution over time, and determine the impact of actions. Combining a system of surveillance for prescription and consumption with existing surveillance systems on AMR (for example, the EARS-Net network in the European region; ECDC, 2016) would allow a more comprehensive view and interpretation of the collected data, which in turn, would help design or tailor interventions to the specific needs of a local setting (e.g. prescription guidelines).

More specifically, an effective antimicrobial surveillance system should fulfil the following functions (ACSWG, 2003):

- identification of antimicrobial utilisation patterns at the local, regional and national levels
- estimation of drug expenditure, for cost-benefit analyses of policies and prescribing interventions
- provision of information on local, regional and national policies and prescribing interventions
- geographical and temporal linking of antimicrobial use to AMR patterns
- early warning of abnormal usage patterns and targeted interventions
- audit of antimicrobial stewardship programmes
- research (on AMR in the field of epidemiology, health economics, public health, etc.).

Usually, data on antimicrobial consumption are collected at the population level (i.e. aggregate antibiotic use data summarised at various administrative levels) from either distribution or reimbursement systems. Distribution data are based on sales statistics from

wholesalers, pharmacies, etc. Reimbursement data are collected from health care financing agents based on reimbursement claims. Either approach may be subject to sources of bias that may hinder effective data collection (Vander Stichele et al., 2004). The major sources of bias include: incomplete population coverage (e.g. when a substantial share of the population is not covered by a reimbursement system; or when parallel antimicrobial import and export is significant); inadequate drug coverage (e.g. misclassifications of antimicrobial classes; underdetection biases for drugs excluded from reimbursement); and major inconsistencies between the place of purchase and the place of use (e.g. when hospital pharmacies dispense antimicrobials to outpatients).

Responses to the 2016 OECD questionnaire suggest that all OECD countries have a monitoring system in place (or in the preparatory stage) for antimicrobial consumption. About four in five (83%) monitoring systems are nationwide, while the remaining countries use data collected on the basis of specific care providers (hospital data) or financing agents (insurers). Fourteen (41%) countries collect data in all acute, community and long-term care settings. The area of long-term care is the least covered (59%) by monitoring systems, whereas hospital and community care setting prescriptions are relatively well covered, as 88% and 93% of countries have monitoring systems in these respective areas. In general, monitoring systems are very comprehensive and collect data on all antibacterials. Some monitoring systems extend surveillance to the consumption of antimycotics and antivirals.

Data collection on inappropriate antimicrobial use is still limited across the OECD. One-third of respondent countries (33%) have never assessed inappropriate antimicrobial consumption; three countries reported that they are currently undergoing such assessments. Even when assessments were carried out (as reported by 17 member countries [57%]), many of the studies (37%) only focused on inappropriate antimicrobial use in specific health care services or for specific providers; only 12 countries (55%) have assessed inappropriate antimicrobial consumption at the national level. Most assessments focused on hospitals (64% of countries) and primary care settings (77% of countries); only seven countries (32%) have reportedly assessed inappropriate consumption in long-term care. Without a comprehensive surveillance system to collect data in a sufficiently systematic fashion in these three health care settings, it is challenging to compare and understand the severity of inappropriate antimicrobial consumption (Box 3.5).

4.2. Education and information activities are at the core of most strategies to reduce inappropriate antimicrobial use

Mass media campaigns are commonly used but evidence of impact is seldom measured

Raising public awareness about the dangers associated with inappropriate antimicrobial prescription is commonly used across OECD countries as a way to promote rational prescribing. Information and education may be provided through different means covering various population groups. Many countries (e.g. Belgium, France and, more broadly, European countries; Earnshaw et al., 2009) have conducted nationwide mass media campaigns to sensitise public awareness of the issue. Generally, campaigns illustrate the beneficial (adverse) effects of rational (inappropriate) antimicrobial use and attempt to align patients' expectations about prescribing with good practice (Box 3.6).

Campaigns are usually delivered during the winter season through mass media, including TV, radio and billboards as well as new forms of media. In some cases, messages are reinforced at the health care service level (mainly in general practices) by providing

Box 3.5. **Antimicrobial consumption monitoring in the European Union and the European Economic Area**

Countries in the European Union (EU) and European Economic Area (EEA) jointly implemented a highly comprehensive and complete cross-country system to collect data on antimicrobial consumption. Created in 2001, the monitoring system has been co-ordinated by the European Centre for Disease Prevention and Control (ECDC) since 2007 and is based on different networks of national surveillance systems and ad hoc projects to assess specific dimensions. The system currently involves:

- The Europe-wide Network of National Surveillance Systems (ESAC-Net, formerly ESAC) collects national-level data on antimicrobial consumption in the community and hospital sectors in EU member states and EEA countries. Annual sales or reimbursement data for each country are validated and submitted by national networks as sources of consumption data (ECDC, 2016a).
- The Healthcare-Associated Infections Surveillance Network (HAI-Net) and the Point Prevalence Survey of health care-associated infections and antimicrobial use in European long-term care facilities (ECDC, 2016b) collect additional data on the use of antimicrobials in acute care and long-term care settings.

Outputs of these efforts are aggregated in publicly available databases, allowing a comprehensive overview and comparison of antimicrobial consumption at the national level, quality indicators for antimicrobial consumption in the community, trends of consumption over time, and disease- and sector-specific antimicrobial prescribing (ECDC, 2016c).

Alongside antimicrobial consumption data, antimicrobial resistance data are collected by the European Antimicrobial Resistance Surveillance Network (EARS-Net). These systems enable monitoring progress and shortcomings on key aspects of antimicrobial use and AMR.

Box 3.6. **Public education campaign in France**

"Les antibiotiques c'est pas automatique" (antibiotics are not automatic) has been a well-known slogan since 2002. It popularised the efforts of a major French media campaign during the winter months of 2002 to 2007 to educate the public on the prudent use of antimicrobials, especially for viral respiratory infections. The campaign was designed as a component of the broader National Strategy for Preserving Antibiotic Efficacy ("le plan national pour préserver l'efficacité des antibiotiques") to address high consumption of antimicrobials and high prevalence rates of antimicrobial-resistant *S. pneumoniae*, a common cause of community-acquired pneumonia. At the beginning of the campaign, France had the highest prevalence rates for both of these indicators in Europe (Sabuncu et al., 2009; Cars et al., 2001).

The campaign was widely successful. In conjunction with a stewardship programme for prescribers and other initiatives, it produced an overall 26% reduction in antimicrobial prescriptions, surpassing the programme goal of 25%. The rate of *S. pneumoniae* resistance to penicillins and macrolides reduced by 2% and 4%, respectively, between 2005 and 2008 and maintained a steady decline thereafter. More specifically, antimicrobial prescriptions for young children (i.e. those under 6) decreased by 30.1% while prescriptions for children aged 6-15 decreased by 35.8% (Sabuncu et al., 2009).

brochures or leaflets. In many cases campaigns are designed and managed by the national health authorities, but sometime the pharmaceutical industry contributes to their development (Huttner et al., 2010). Although the majority of campaigns do not target specific clinical conditions, in Australia and the United Kingdom, the common cold is the illness most frequently campaigned against with respect to antimicrobial misuse. Young children are at high risk for inappropriate prescription, so a number of campaigns are directed towards parents to address inappropriate prescription in this group.

Few studies have carried out formal quantitative assessments of the potential effectiveness of mass media campaigns. A meta-analysis by Thoolen et al. (2012) concluded that mass media campaigns have a small but statistically significant effect on the general population's attitudes and knowledge towards inappropriate antimicrobial use. While individuals exposed to the campaigns agree with proposed prescription standards and are less likely to expect a prescription of antimicrobials during a doctor's visit (Hemo et al., 2009), general knowledge about the viral nature of common infections and the inappropriateness of antimicrobials nevertheless tends to remain poor (Curry et al., 2006). The same meta-analysis (Thoolen et al., 2012) identified a small reduction in the use of antimicrobials. Three studies assessing the effectiveness of mass media campaigns in England (Lambert et al., 2007), Italy (Formoso et al., 2013) and the United States (Gonzales et al., 2008) concluded that implementation of a mass media campaign is responsible for a 4% to 9% decrease in antimicrobial prescriptions.

Belgium's effective mass media campaign targeted towards the general population is notable (Goossens, 2008). Since 2000, and annually during the winter season, Belgium has carried out national campaigns on AMR entailing advertisements on both electronic and paper media. The campaign informs the general population about the importance of preserving the use of antimicrobials for absolutely necessary conditions and explains the specific cases in which their use does not provide any medical benefit (e.g. viral infections). Between 2000 and 2015, antimicrobial use decreased by 39% (other interventions were implemented along with the mass media campaign), producing cumulative savings of about EUR 642.2 million. The committee overseeing the campaign calculated that for every EUR 1 invested, the campaign produced cumulative savings of about EUR 131 (Goossens, 2015).

Results of the 2016 OECD survey suggest that about three in four OECD countries have put in place public information campaigns to raise awareness against AMR. In a number of European countries, campaigns were part of the European Antibiotic Awareness Day campaign. Most member states of the Americas and Oceania have also produced educational campaigns on AMR. Some countries (e.g. Iceland) report ongoing campaigns, whereas other countries carry out public information campaigns on a periodic basis. At the subnational level, local and institutional efforts may be in place concurrent with or in continuation of finite, high-profile national campaigns. Only in 7% of countries were public information campaigns implemented solely at the subnational or institutional level.

Prescriber education and training

Appropriate antimicrobial prescription may be hindered on the part of the prescriber by habit, lack of knowledge and influence by the patient (Grol and Grimshaw, 2003). Implementation of educational and training programmes for prescribers is a strategy to improve prescribing behaviour. Educational activities can be held as a component of broader antimicrobial stewardship programmes, as continuing medical education (CME) or as part of licencing or accreditation requirements.

Prescriber education entails a wide range of informative activities to enhance physicians' knowledge of evidence-based medicine or to improve physicians' communication skills. Education can be delivered as coursework, workshops, dissemination of educational material, or one-on-one feedback. Educational material may cover general advice (e.g. use of diagnostic tests, timely re-assessment based on new diagnostic evidence, etc.) or disease-specific recommendations (e.g. for the diagnosis and treatment of suspected pneumonia or specific bacterial infections). Educational material may also specifically focus on evidence about the emerging AMR threat and strategies to mitigate it (CDC, 2014).

Interactive educational strategies (e.g. one-on-one performance review) tend to be more effective in changing prescribing behaviours than passive strategies (e.g. lectures, education booklets; Schaffner et al., 1983). A review of physician-targeted interventions against inappropriate antimicrobial use in respiratory tract infections found that multifaceted programmes that include prescriber education are at least four times more effective than interventions without an education component. Overall, antimicrobial prescription was reduced by 11.6% while appropriate first-line antimicrobial prescription increased by 9.6% (van der Velden et al., 2012). In a French primary care setting, introduction of CME focused on infectious diseases led to increased use of clinical decision tools, such as rapid microbial antigen diagnostic tests, and to a reduction of antimicrobial prescription by 39% (Michel-Lepage et al., 2014). Complementary evidence suggests that the positive effects of education programmes in primary care settings may be maintained for up to 4.5 years post intervention (Le Corvoisier et al., 2013; Ferrat et al., 2016). Prescriber education was shown to effectively reduce inappropriate prescription in a Spanish hospital from 53% to 26% after one year, and to avoid 1.8 prescriptions per 1 000 resident-days in a US nursing home (Cisneros et al., 2014; Zimmerman et al., 2014).

Close to half of the 2016 OECD survey respondents offer nationwide CME programmes focused on AMR, and another 37% have clinician education programmes offered at regional or employer level. CME programmes are sometimes implemented as a requirement for accreditation or certification, as in the United Kingdom and Canada, but in many countries attendance is not compulsory. Depending on the country, CME programmes can be offered by various types of organisations, including universities, professional associations, employers or local or national health authorities. Educational sessions may target specific prescriber groups, such as GPs and paediatricians, or specific groups of personnel involved in dispensing and administering antimicrobials, such as nurses in hospital and long-term care settings (Box 3.7).

Clinical guidelines and evidence-based recommendations

Clinical guidelines consist of evidence-based recommendations developed to guide medical personnel in their practice and to promote appropriate treatment for specific diseases and clinical conditions. Often, clinical guidelines are not implemented as mandatory rules, but are rather used as a benchmark to demonstrate how all steps of the diagnostic and therapeutic process fit together into a coherent framework. Clinical guidelines play a critical role in promoting rational antimicrobial use and provide physicians with a reference to assess their own clinical practice. National agencies for health care quality are increasingly engaged in the subject, particularly as part of countries' efforts to reduce health care-associated infections. Available evidence suggests that guideline adherence can improve the cost-effectiveness of care for infectious diseases like pneumonia (Nathwani et al., 2001).

Box 3.7. **Continuing medical education (CME) in Australia**

In Australia, CME on the prudent use of antimicrobials is mainly provided by NPS MedicineWise (NPS), a not-for-profit organisation funded by the Department of Health (NPS, 2014). Educational activities provided by NPS include clinically reviewed information to prescribers to optimise expenditure for pharmaceuticals and to promote discussion of basic medicine-related issues. Courses specifically focusing on prudent antimicrobial use encompass topics including antimicrobial prophylactic use and management of infections. Examples of educational interventions include antimicrobial online learning modules on surgical prophylaxis, community-acquired pneumonia, catheter-associated urinary infections and bacteraemia, and clinical e-audits on managing respiratory tract infections.

Attending courses gives participants credits that contribute to reaching specific standards required by the national Continuing Professional Development (CPD) scheme, a mandatory programme for health care professionals, including GPs, pharmacists and nurses (AHPRA, 2014). Additional incentives for CME uptake by GPs are provided by the *Quality Prescribing Incentive* initiative, according to which certain CPD courses also satisfy as credits contributing to financial incentives for GPs (NPS, 2015).

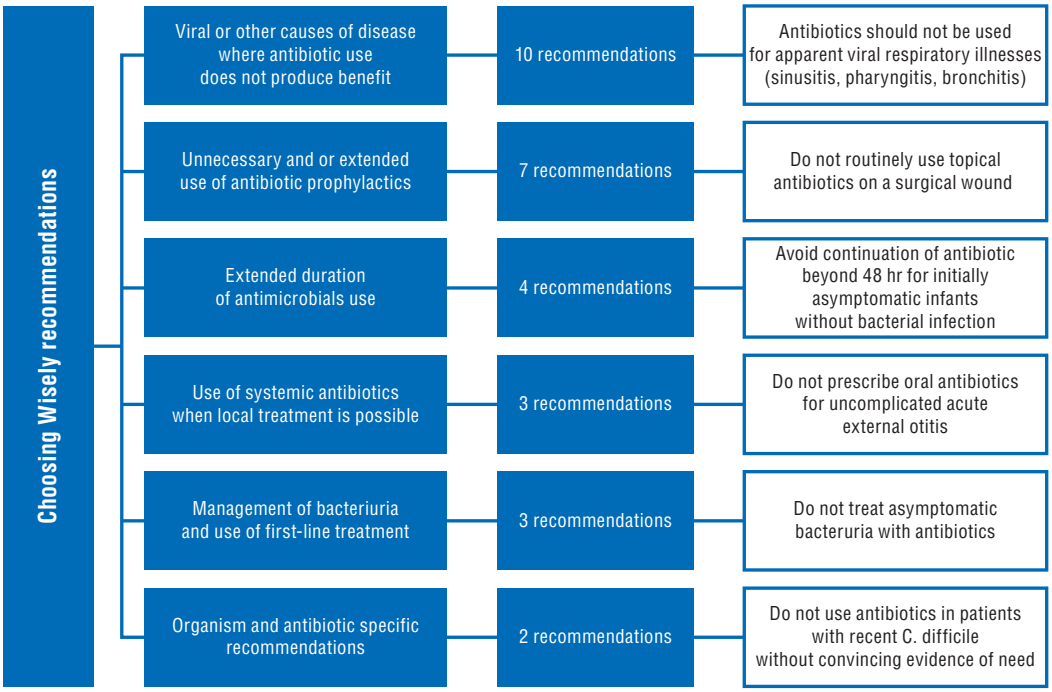
Early studies assessing the effectiveness of CPD modules on prudent antimicrobial use show encouraging results. For example, after the uptake of a CPD module on the clinical use of vancomycin, a group of hospital pharmacists achieved high knowledge scores on the presented issues (e.g. in a set of ten knowledge-testing questions, eight were answered correctly by at least 94% of the respondents; Phillips et al., 2016). A careful design of the modules may contribute to successful scaling up of the initiative. According to a study focusing on incentives and barriers for CPD in Australian nurses, factors promoting the acceptance of CPD include incorporation of CME into working hours and adaptability of the workplace to ongoing changes in best practice. Conversely, understaffing and CME activities extending outside working hours are barriers for undertaking CPD (Katsikitis et al., 2013).

The adoption of guidelines is not uniform among physicians. A comprehensive systematic review of 76 studies identified three main types of barriers to the implementation of guidelines: knowledge (the physician is not aware of the existence of a guideline or of its recommendations); attitudes (the physician does not believe that the clinical guideline will lead to the desired outcome or the physician trusts his usual practice more than the guideline); and behaviour (other external factors prevent implementation of the guideline) (Cabana et al., 1999). Guidelines are usually more influential on younger, less experienced clinicians who have not yet established their style of practice. For example, a Swedish study concluded that interns, residents and younger GPs had significantly higher adherence to guidelines compared to older GPs (Tell et al., 2015).

The use of medical guidelines for antimicrobial prescription may be enhanced by involving end-users in their development and by making them easy to understand and implement. A process of regular revision is needed to ensure that guidelines are updated, credible and accepted by the medical community. Adoption of a guideline may be improved by organising official launching events and by promoting wider dissemination through training. Use of feedback and audit schemes (e.g. as part of a broader stewardship programme) may help maintain higher rates of adherence (WHO, 2002).

The *Choosing Wisely®* campaign (ABIM Foundation, 2016), discussed in the previous chapter, is a good example of a successful initiative aimed at rationalising antimicrobial use. *Choosing Wisely®* is designed as a collection of specific and evidence-based recommendations, submitted by partner medical associations, to enable physician-patient dialogue, to reduce waste in the health care system, and to avoid risks associated with unnecessary treatment. Medical disciplines that have developed recommendations to promote rational antimicrobial use include, for example, paediatrics, geriatrics, surgery, infectious diseases and immunology. So far, 30 recommendations from 14 medical associations are related to the use of antimicrobials. The advice is to refrain from antimicrobial use in a comprehensive set of clinical conditions where its use is not effective or is potentially harmful. Figure 3.5 summarises the US version of *Choosing Wisely®* recommendations for antibiotics, divided into six main categories. The full list of US recommendations can be found in Annex 3.A2.

Figure 3.5. ***Choosing Wisely®* recommendations to promote rational use of antibiotics**



Note: Reported examples may have been reworded from their original version (reported in Annex 3.A2) to fit in the figure.
Source: Authors' analysis of ABIM Foundation (2016), "Choosing Wisely Website", *www.choosingwisely.org*.

Responses to the 2016 OECD questionnaire suggest that guidelines on the rational use of antimicrobials for treatment are in place in all OECD countries, whereas guidelines for prophylaxis use are adopted in all but three countries. For antimicrobial use in treatments, about 73% of countries have nationwide guidelines; the rest of the countries have guidelines that are only applied at the regional or institutional level. For antimicrobial use in prophylaxis, over 60% of countries have national-level guidelines, and 26% of countries have regional or institutional guidelines. Some countries do not have national-level guidelines but instead consult academically published guidelines or recommendations. Guidelines are most often issued by national medical specialty societies. Ministry of Health

roles differ across countries. In a significant number of countries, but with notable exceptions, Ministries reported a limited role in issuing guidelines. Conversely, some Ministries reported a role in promoting the adoption of guidelines.

4.3. Incentives and organisational changes could significantly decrease inappropriate antimicrobial consumption

Economic incentives and payment schemes

Economic incentives are widely applied in the health sector as an effective and efficient tool to encourage appropriate behaviours (Schaffer et al., 2015) and to rationalise the consumption of health care resources. In principle, economic incentives may be applied to the specific case of antimicrobial prescription and consumption to promote more rational use. Different types of economic incentives exist for different groups of people targeted for behavioural change (i.e. drug prescribers or drug recipients) and based on the nature of the incentive (i.e. rewarding desired behaviour or penalising undesirable behaviour).

Rationalisation in antimicrobial consumption may be achieved by addressing perverse and unintended negative incentives present in the system. For example, it is well known that combining prescribing and dispensing functions leads to overprescription of pharmaceuticals (Park et al., 2005) as the prescriber/dispenser has a financial incentive to sell more drugs and more expensive drugs. Similarly, patterns of inappropriate dispensing may be more likely if pharmacists' remuneration is linked to a percentage mark-up on drug sales and no other correcting mechanism is in place (e.g. switching to another product is allowed only if the cost is equal to or lower than the prescribed drug).

Literature looking at economic incentives to modify delivery of health care services generally focuses on the assessment of pay-for-performance (P4P) schemes. P4P schemes incentivise quality improvements by granting a reward for those health care providers reaching certain pre-defined performance targets. P4P programmes are more powerful when the monetary incentive is tied to intermediate outputs (e.g. share of prescriptions meeting certain criteria) that are easy to measure, rather than more general outcomes (e.g. regional prevalence of AMR)(Chi and Sutton, 2014). An antimicrobial prescription-targeted P4P scheme for GPs was put in place in Sweden between 2006 and 2013. An evaluation of this programme concluded that incentives were successful in steering physicians towards prescribing narrow-spectrum instead of broad-spectrum antimicrobials (Anell et al., 2015). Despite the small monetary value linked to this scheme, its implementation closed one-third of the gap between existing prescription rates and the targeted rates. France implemented a similar scheme to incentivise general practitioners to reduce antibiotic prescriptions as part of a broader programme named *Public Health Goals*. More specifically, French doctors receive additional remuneration if their number of antibiotic prescriptions per 100 patients aged 16 to 65 is ten points below the median prescription rate (Wang et al., 2015). Between December 2011 and December 2015, the prescription rate decreased by 6 points (from about 45 to 39 prescriptions per 100 patients), resulting in a decrease of about 1.8 million prescriptions (CNAMTS, 2016).

On the other hand, analysis of financial incentives for consumers mainly focuses on the effect of increasing antimicrobial price. Two studies carried out in the United States (Foxman et al., 1987) and Denmark (Steffensen et al., 1997) concluded that introduction of higher co-payments had significant impacts on the consumption of antimicrobials. In particular, the Danish study quantified an average decrease of 13% across all classes of

antimicrobials, with a higher impact on broad-spectrum antimicrobials (e.g. -42% for tetracyclines) and a non-statistically significant impact on narrow-spectrum penicillins. Likewise, in Nova Scotia (Canada), introduction of a policy limiting reimbursement for fluoquinolones produced an 80% decrease in the number of prescriptions (MacCara et al., 2001). However, this was associated with increased prescription of other classes of antimicrobials (e.g. prescriptions for sulfonamides and trimethoprim increased by 34.9%, cephalosporins by 17.0%, and macrolides and lincosamides by 16.5%). This suggests that clinician behaviour may be sensitive to patient price preferences and that their behaviour may respond to system changes but the design of such changes needs to be carefully considered to avoid unintended impacts in other areas that could minimise or negate the gains sought.

Any economic incentives to rationalise antimicrobial use should be carefully planned and designed from the early phases of the policy-making process. Some recommendations are as follows:

- The policy should be designed to specifically target inappropriate antimicrobial use as opposed to total antimicrobial use. An increase in the cost of the therapy is likely to decrease adherence to a prescribed therapy (Sinnott et al., 2013).
- The policy should maintain a balance between preventing overuse of antimicrobials and pre-empting lack of access for people with lower income. The lack of access to quality medicines at an affordable price may, in fact, motivate patients to switch to substandard medicines or to stop therapy before full recovery, which creates an ideal condition for antimicrobial-resistant organisms to develop (Alsan et al., 2015).
- The policy should specifically target prescribers and/or patients. In many OECD countries, patients do not pay directly for drugs. Therefore, simply increasing the price of antimicrobials may increase the expenditure of third-party payers (e.g. health insurance companies) without any tangible effect on consumption.
- The policy should consider potential substitution effects. For example, Filippini et al. (2007) found that an increase in the price of macrolides induced higher consumption of other newer-generation and more potent antimicrobials, such as commonly used second-line antimicrobials.

According to the results of the 2016 OECD survey, only Korea and Japan have countrywide, negative financial incentives (i.e. fines) for clinicians who do not meet certain prescription standards. In Japan, issuance of prescriptions not adhering to guidelines may result in disqualification for reimbursement of the drug costs by the national health insurance (Box 3.8). In Slovenia, some health care providers authorise disciplinary actions for clinicians with particularly poor prescribing records relative to institution-specific prescription guidelines. A number of countries (e.g. Sweden and England) use or are considering positive financial incentives targeting health care institutions or prescribers to encourage rational antimicrobial prescription.

Antibiotic stewardship programmes

Antibiotic stewardship programmes are a broad category of interventions that usually entail simultaneous implementation of multiple elements, including regulations, guidelines, monitoring, education and campaigns. These actions all aim to increase awareness and to rationalise antimicrobial prescription practices among health care personnel. Actions can be implemented in a prescriptive or persuasive manner. The former explicitly limits prescribers

Box 3.8. **Reimbursement of antimicrobials in Japan: Incentives for prudent use**

Since 1996, Japan's health care system has employed a reimbursement-based fee schedule for medical services and prescription medicine. The schedule contains embedded economic incentives in the form of bonuses to promote prudent use of medical resources, including the use of antimicrobials, in hospitals (Federal Ministry of Health, 2015). The most recent national action plan on AMR includes a set of policies to enhance capacity building and training on adaptation of diagnostic and treatment technologies, clinical and public health expertise on infectious diseases, and rapid response to AMR emergence. In fulfilling the level of activities dedicated to reducing inappropriate antimicrobial consumption, the programme sets out specific performance indicators, such as the number of antimicrobial stewardship seminars carried out each year and the number of cases of antimicrobial-resistant infections at each medical institution. Upon meeting specific targets, hospitals are rewarded reimbursement credits that can eventually be recovered as hospital revenues (AMR Special Group, 2016).

Conversely, health care providers can only be fully reimbursed by the insurer for the costs of prescribed antimicrobials when required stewardship precautions are demonstrated and the treatment of choice is judged prudent. Under the Health Insurance Act and the Act on Assurance of Medical Care for Elderly People, physicians are required to not prescribe medicines beyond necessity (Ministry of Health, 2016).

At the community level, additional economic incentives are in place to facilitate regional co-operation of hospitals regarding infection control through mutual audit and feedback. A support network of specialists in the community aims to increase awareness and provide adequate expertise and consultation to facilitate aspects of AMR prevention. Another potential network under consideration is an information system that allows professional and evidence-based communication among physicians to consult regional AMR patterns (AMR Special Group, 2016).

to a specific set of decisions by precluding inferior alternative options. The latter attempts to modulate physician practices via educational and behavioural interventions and is more effective if carried out with consideration of regional context and social norms of practitioner and patient behaviours (Gould and Lawes, 2016). Stewardship programmes are usually designed and conducted by multidisciplinary teams including specialised physicians (e.g. experts in infectious diseases or microbiologists) and pharmacists.

Antimicrobial stewardship programmes often provide important guidance at three main points during a patient's consultation. The first is the decision whether or not to administer antimicrobials to a patient for a clinical condition that may or may not improve after administration of the drug. The second pertains to the choice of the appropriate class of antimicrobials (with preference given to narrow-spectrum antimicrobials whenever possible). The third is the decision on the treatment's proper duration, which should be calibrated to a patient's clinical conditions and personal characteristics.

A large body of evidence supports the effectiveness of stewardship programmes in both hospital and community care settings. A Cochrane review (Davey et al., 2013) showed that implementation of a stewardship programme in a hospital setting decreases both antimicrobial prescription rates (median change up to -40%) and AMR prevalence rates (median change between -24% to -68%, depending on the type of infective bacteria). In

addition, effective prescribing is associated with a significant decrease in mortality due to pneumonia (-11% in risk of mortality). In the short term, stakeholders are more responsive to prescriptive interventions, but in the long term (i.e. one year and more), prescriptive and persuasive interventions show a similar magnitude of effects. The effectiveness of stewardship programmes is confirmed by a more recent systematic review and meta-analysis that concluded that programme implementation decreases antimicrobial consumption (-19% overall, but up to -27% for restricted antimicrobial agents), AMR (-1.7% to -10.4%, depending on the infective agent), and patients' length of stay (-9%) (Karanika et al., 2016). A set of guidelines published recently by the Infectious Disease Society and the Society for Healthcare Epidemiology of America includes strongly recommended strategies such as implementing guidelines to minimise duration of antimicrobial therapy, monitoring antimicrobial use, and transitioning from systemic to oral therapies whenever possible (Annex 3.A3; Barlam et al., 2016).

Nationwide programmes also have potential for impact. France achieved a 26% decrease in antimicrobial prescriptions during the course of a multifaceted programme from 2002 to 2007 that particularly targeted prescribers (Sabuncu et al., 2009; Bartlett et al., 2013). Antimicrobial stewardship played a major role in a recent Californian flagship programme that achieved a 9.4% decrease in methicillin-resistant *S. aureus* (MRSA) prevalence over a three-year period (Epson, 2015). After implementation of its stewardship programme, Kaiser Permanente, a US health care provider, obtained both an overall decrease in antimicrobial prescription rates (e.g. carbapenem consumption decreased by 45%) and a rationalisation of prescription practices and in particular increased prescriptions of narrow-spectrum antimicrobials.

Eighty-four per cent of countries that responded to the 2016 OECD questionnaire have implemented antimicrobial stewardship programmes. Nationwide programmes have been implemented in 50% or countries while the remaining 34% of have programmes organised either regionally or by independent health care providers. Similar features characterise audit and feedback programmes: close to 40% are nationally co-ordinated and another 40% are either regionally co-ordinated or managed by independent health care providers. In some countries, such as the United States and Sweden, antimicrobial stewardship participation goals are determined at the national level while specific programme activities are co-ordinated independently by participating institutions or local governments. This type of organisation permits construction of region- or institution-specific programme activities responsive to local AMR status, while satisfying national-level antimicrobial consumption and AMR goals (Box 3.9).

Delayed antimicrobial prescribing

Delayed antimicrobial prescribing is a strategy employed by prescribers to avoid unnecessary consumption of antimicrobials in outpatient and primary care settings. Under this arrangement, patients are asked to wait up to three days or for a deterioration of their health status before collecting a medical prescription for antimicrobials. This strategy both reduces antimicrobial consumption and educates patients that antimicrobials are not always necessary, especially for self-limiting illnesses (Jelley et al., 1999). Meanwhile, having a prescription, although delayed, provides a sense of safety for both the patient and the clinician if the illness deteriorates, and tends to satisfy patients' expectations about receiving some treatment (Spurling et al., 2013).

Box 3.9. **Regional antimicrobial stewardship programmes in Canada**

Do Bugs need Drugs? is a regional education-based antimicrobial stewardship programme implemented by the two Western Canadian provinces of Alberta and British Columbia (B.C.) since 2005. Key programme components include multimedia tools, classroom materials and social media, with specifically developed components targeting clinicians (physicians, nurses, pharmacists) and the public (children, parents, teachers, employers, long-term care facilities). Three main messages are consistent throughout the entire education effort: "Handwashing is the best way to stop the spread of infection"; "Bacteria and viruses are different and antimicrobials do not work against viruses"; and "Use antimicrobials wisely to limit development of AMR" (Carson and Patrick, 2015). As an example of key partnerships, the programme is involved in primary school Grade 2 curricula, delivered by medical and nursing students. By aligning the interests to both train future health care workers and educate young children about disease prevention and prudent antimicrobial use, the partnership contributes to the relatively low cost of the overall campaign (Carson and Patrick, 2015).

A 2011 assessment of the programme confirmed significant improvement in health care professionals' clinical knowledge of appropriate treatment against upper respiratory tract infections (McKay et al., 2011). Overall consumption of antimicrobials in B.C., including fluoroquinolones and macrolides, decreased by 7.5% between programme implementation and 2013. The proportion of overall inappropriate use of antimicrobials in the treatment of respiratory tract infections, except acute bronchitis has also declined (BCCDC, 2014). The largest decrease (25%) in the number of antimicrobial prescriptions was observed among children aged under 14. Evaluation of the extent of AMR showed that AMR against various clinically important antimicrobials declined or at least remained stable in a majority of pathogens after 2005. For example, resistance of MRSA to erythromycin declined from approximately 95% in 2007 to 82% in 2013 in B.C. (BCCDC, 2014).

Delayed antimicrobial prescriptions can be administered in three main ways (CDC, 2015). First, with a post-dated prescription, the patient may obtain an antimicrobial treatment only at a later point in time, by the date indicated within the prescription. The second way is to either re-contact a patient after an initial clinical visit for re-assessment, or to instruct the patient to retrieve the prescription at a later appointment. The third way is to verbally instruct the patient to delay filling the prescription.

Delayed antimicrobial prescription has been extensively studied, and several reviews and meta-analyses demonstrate that such practices reduce antimicrobial prescription rates. Based on the results of clinical trials spanning several OECD countries, Ranji et al. (2008) found a 15.0% to 74.5% reduction in the number of antimicrobial prescriptions filled, without any excess morbidity. The effect is greater in services where the patient may return to the clinic to obtain a prescription if the symptoms are not resolved (55% to 75% reduction), compared to a post-dated prescription (63% reduction), and to when the prescription is given upon the initial visit but with instruction to delay its filling (23% to 46% reduction; Arroll et al., 2003; Spurling et al., 2013; Little et al., 2014). The main conditions for which delayed prescriptions are used include upper respiratory tract infections and acute otitis media.

In the United Kingdom, a delayed antimicrobial prescribing policy was piloted in clinical trials in the 1990s, and has been recommended within the nationwide guidelines for patients presenting with respiratory and unitary tract infections since 2007. However, clinicians continue to face pressure from patients to prescribe immediately (NICE, 2015). A programme carried out in the County of Derbyshire (England) included a component to educate clinicians to implement a delayed prescription policy; an evaluation concluded that the programme increased adherence to the recommendations and decreased the use of cephalosporins and quinolones by 33% and 25%, respectively, compared to the regional averages (Harris, 2013).

Use of existing and new medical technologies such as rapid diagnostic tests

Decisions about whether or not to prescribe antimicrobials, and which antimicrobials to prescribe, are particularly challenging. Very often, particularly in primary care settings, prescribing decisions are based only on the clinical symptoms presented by the patient (e.g. Hopstaken et al., 2005). This approach was shown to be inadequate due to low sensitivity and specificity of diagnoses (Hoare and Lim, 2006; Metlay et al., 1997). In addition, prescription of antimicrobials based on a presumptive clinical diagnosis can result in the treatment of patients who do not actually have the diagnosed disease. This results in overtreatment and wasted resources and contributes to the development of AMR.

The use of RDTs can facilitate the appropriate prescription and selection of antimicrobials in clinical settings. RDTs provide results to distinguish between bacterial and non-bacterial causes of disease, and determine the antimicrobial susceptibility of the agents involved. Thus, broader use of RDTs would contribute to rationalise antimicrobial prescriptions at both the community care and hospital level. At the community care level, point-of-care RDTs can help identify patients for which an antimicrobial prescription would result in no additional clinical benefit (e.g. in patients with acute viral infection of the respiratory tract). At the hospital level, rapid susceptibility tests can guide the choice of antimicrobial agent used to treat infections in individual patients.

Wide assessment of the use of RDTs, especially point-of-care tests targeting biomarkers[3] for acute respiratory infections, has shown these to be an effective tool to optimise antimicrobial prescription in the community care setting (Aabenhus et al., 2014). A Cochrane review summarising all relevant evidence on this topic concluded that point-of-care tests can reduce antimicrobial prescriptions by 22% compared to empiric prescription, without negative effects on patients' morbidity. Authors calculated that about 6 to 20 cases need to be tested to save one antimicrobial prescription. Point-of-care tests enjoy high rates of acceptance in clinical practice by both doctors and patients (Butler et al., 2008; Wood et al., 2011). Finally, economic analyses suggest that these tests may have good cost-effectiveness ratios. For example, Oppong and colleagues (2013) calculated that standard inclusion of biomarker testing for acute respiratory infections is associated with a cost of about EUR 9 400 (i.e. about USD 10 500) per QALY gained, well below the threshold of USD 50 000 often referred to as a possible value to discriminate between efficient and inefficient interventions.

Rapid susceptibility testing may play a key role in the hospital setting, particularly as part of broader antimicrobial stewardship programmes. Traditional diagnostic and susceptibility tests are often based on culturing methods that generally take 48-72 hours to provide a response (Goff et al., 2012). During this period, patients are often treated empirically by broad-spectrum antimicrobials due to the initially unknown drug-resistance status of the microbial agent. On the other hand, RDTs based on imaging, antigen and

nucleic acid detection can provide a diagnosis in as short as one hour while maintaining relatively high specificity and sensitivity. For example, tests to detect MRSA infections (one of the most common causes of nosocomial infection worldwide; Deurenberg et al., 2007) have a sensitivity of 98% and a specificity of 100% (Wolk et al., 2009).

Replacement of traditional tests with rapid point-of-care diagnostic tests whenever possible permits earlier termination or switch of antimicrobial use, or directed use of narrow-spectrum antimicrobials. Unavailability of diagnostic testing is frequently mentioned by primary health care clinicians as a barrier to appropriate prescription decisions (Teixeira Rodrigues et al., 2013). Llor and colleagues (2014) found an 18.9% reduction in antimicrobial prescription due to implementation of point-of-care biomarker tests (rapid antigen detection for diagnosis of *S. pharyngitis* and C-reactive protein) in respiratory tract infection patients in the primary care setting. In a Spanish hospital setting, the cost savings associated with a rapid E-Test for ventilator-associated pneumonia were EUR 318 per case (Bouza et al., 2007). Another economic analysis assessing the use of rapid susceptibility tests in conjunction with a stewardship programme found that the intervention decreased the average hospital stay by 6.2 days, and the average cost per patient by about USD 21 400 (Bauer et al., 2010; Box 3.10).

Box 3.10. **Point-of-care microbial diagnostic tests and antimicrobial susceptibility tests**

Rapid microbial diagnostic and antimicrobial susceptibility tests are point-of-care tests that can be performed near the patient with technically simple procedures and relatively short waiting time. Point-of-care tests are significantly easier to use and quicker than traditional laboratory tests, which require transferring clinical samples to separate testing facilities and culturing samples in a process that can take a few days.

Rapid microbiological methods to diagnose bacterial infections (as opposed to other clinical conditions, including viral infections) consist of three categories: growth-based methods, direct measurement and cell component analysis (Brescia, 2013). Growth-based assays involve detecting signs of specific organisms after a short period of culturing. In contrast, direct measurement and cell component analysis use colour or fluorescent labelling to count and confirm the presence of bacteria.

Rapid antimicrobial susceptibility tests are used to assess whether a sample is resistant to specific antimicrobials and to select the most appropriate therapy. Rapid susceptibility tests employ automated instruments to monitor microbial activity and growth rate in a combination of antimicrobial and microbial samples. The test results are sufficiently rapid (3.5 to 16.0 hours) to conclude susceptibility status in clinical samples and to adapt antimicrobial therapies in a timely manner (Reller et al., 2009).

Results of the 2016 OECD survey suggest that RDTs are available nationwide in only about 40% of surveyed countries. In another 27% of countries, RDTs are only available from specific health care providers. Only two OECD countries require (or will require) compulsory use of RDTs for certain clinical conditions. For example, some critical antimicrobials can be prescribed only after their use is supported by results of a RDT and according to relevant guidelines. In 83% of the countries where RDTs are available nationwide, their use is not compulsory and the utilisation rates tend to be low. For

Box 3.11. **Policies to increase use of RDTs in Slovenia**

Administrative restrictive measures have been implemented in Slovenia since 2000 as a part of a broader antimicrobial stewardship policy to tackle the steep incline of antimicrobial consumption and resistance within the country. This includes restrictive prescription criteria for amoxicillin and clavulanic acid (co-amoxiclav), fluoroquinolones, third-generation cephalosporins and macrolides in community care and hospital settings (Cizman et al., 2015). For example, since implementation of the policy, fluoroquinolones can only be prescribed for urinary tract infections as a second-line treatment (i.e. when the first-line treatment does not produce any positive clinical effect) or when microbial susceptibility is demonstrated by diagnostic test results. Similar measures were implemented for other antimicrobials at high risk of inappropriate use. Introduction of this policy did not make use of RDTs compulsory but strongly incentivised their increased use. A higher use of RDTs was supported by concurrent introduction of educational interventions for professionals.

The policy resulted in a significant increase in the use of RDTs and positive effects on antimicrobial use and AMR. Between 1999 (the year before the new policy was introduced) and 2003, the use of two common RDTs (C-reactive protein and rapid streptococcal antigen detection test) in primary care settings increased by 220% (Cizman et al., 2005). Following a broader use of RDTs, overall antimicrobial consumption decreased by 20.3%, and consumption of restricted antimicrobials by 27.7% between 2000 and 2007. In parallel, penicillin resistance among invasive pneumococci decreased (Cizman, 2008).

example, in France, a test to diagnose pharyngitis of bacterial origin is available nationwide at primary care facilities and is fully reimbursable. Only 38% of GPs routinely carry out this test before making a prescribing decision, however (Box 3.11).

Conclusion

Inappropriate use of antimicrobials, a form of low-value care, has steadily expanded over time. About 50% of all antimicrobials consumed by humans do not meet guidelines for good prescribing. In long-term care and general practice, inappropriate consumption may be as high as 90% of all prescriptions.

Inappropriate antimicrobial consumption is predominantly driven by errors and suboptimal decisions underpinning the behaviour of physicians (prescription habits) and patients (who insist on antimicrobial prescription or self-medicate). Organisational barriers, for instance insufficient availability of RDTs, may also result in inappropriate prescription of antimicrobials.

By underpinning AMR, inappropriate antimicrobial consumption triggers significant health and economic consequences. People infected by resistant organisms are more likely to be admitted to a hospital and require more intensive, and costly, medical care. These patients also suffer from prolonged and severe morbidity and increased risk of mortality.

Governments are adopting a broad range of policy approaches to curb harm related to inappropriate antimicrobial use. These include actions triggering behavioural changes (e.g. stewardship programmes, educational interventions), organisational changes in the health sector (e.g. encouraging use of diagnostic tests or delayed prescriptions), and introduction of economic incentives targeting providers and care-seekers (e.g. P4P schemes or co-payments for specific antimicrobials).

Actions are often implemented in a piecemeal fashion as pilot studies, with single interventions carried out at the subnational level, or in specific health subsectors (e.g. in hospital settings but not in community care), or only by specific health care providers. Actions implemented on a non-compulsory basis tend to have lower uptake. Therefore, while the evidence supports the effectiveness of single interventions (although evidence on their cost-effectiveness is largely missing), their effect at the population level may be hindered by poor coverage.

The fight against inappropriate antimicrobial use and AMR should be further supported by establishment of action plans that are based on comprehensive sets of interventions and encompass specific targets based on national priorities. Development of effective surveillance systems to monitor trends of antimicrobial consumption and the prevalence of AMR in the health sector and the community is another crucial component, particularly to assess the effectiveness of policies over time.

Notes

1. The term "antimicrobials" refers to a broad family of agents including any agent killing or inhibiting the growth of microbes. There are many classes of antimicrobials depending on the type of microbes targeted or the composition of the antimicrobial. Antibiotics (or antibacterials) are a sub-category of antimicrobials specifically targeting bacteria. "Antimicrobial" is used in this chapter to specifically describe those agents that exert killing function against bacterial pathogens, or agents that work as treatment or prophylaxis against bacterial infections. In most contexts of this chapter, antimalarial, antifungal and antiviral medicines are not included under the term "antimicrobials".
2. DDD is a standard measure for drugs, calculated as the assumed average maintenance dose per day for a drug used for its main indication in adults (WHO, 2003).
3. Biomarkers are naturally occurring biological indicators, the measurement of which makes it possible to ascertain specific health states or medical conditions. For example, specific molecules, including proteins or components of the immune health system, can be used as biomarkers to detect the body's acute response to an infection.

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ANNEX 3.A1

List of articles for the estimation of the proportion of inappropriate use by type of health care service (Figure 3.2)

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ANNEX 3.A2

List of recommendations promoting rational use of antibiotics issued by the Choosing Wisely® *initiative*

Association	Recommendation
Group1: Recommendations for viral or other causes of disease where antibiotic use does not produce benefit	
American Academy of Allergy, Asthma & Immunology	Do not order sinus computed tomography (CT) or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis.
American Academy of Dermatology	Do not routinely prescribe antibiotics for inflamed epidermal cysts.
American Academy of Dermatology	Do not routinely use antibiotics to treat bilateral swelling and redness of the lower leg unless there is clear evidence of infection.
American Academy of Family Physicians	Do not routinely prescribe antibiotics for acute mild-to-moderate sinusitis unless symptoms last for seven or more days, or symptoms worsen after initial clinical improvement.
American Academy of Ophthalmology	Do not order antibiotics for adenoviral conjunctivitis (pink eye).
American Academy of Pediatrics	Antibiotics should not be used for apparent viral respiratory illnesses (sinusitis, pharyngitis, bronchitis).
American College of Emergency Physicians	Avoid prescribing antibiotics in the emergency department for uncomplicated sinusitis.
Infectious Diseases Society of America	Avoid prescribing antibiotics for upper respiratory infections.
Infectious Diseases Society of America	Do not use antibiotic therapy for stasis dermatitis of lower extremities.
American Urological Association	Do not treat an elevated PSA with antibiotics for patients not experiencing other symptoms.
Group 2: Recommendations against unnecessary and or extended use of antibiotic prophylactics	
American Academy of Dermatology	Do not routinely use topical antibiotics on a surgical wound.
American Academy of Ophthalmology	Do not routinely provide antibiotics before or after intravitreal injections.
American Academy of Otolaryngology – Head & Neck Surgery Foundation	Do not routinely use perioperative antibiotics for elective tonsillectomy in children.
American College of Emergency Physicians	Avoid antibiotics and wound cultures in emergency department patients with uncomplicated skin and soft tissue abscesses after successful incision and drainage and with adequate medical follow-up.
American Society for Metabolic and Bariatric Surgery	Avoid routine postoperative antibiotics.
American Urological Association	Do not prescribe antimicrobials to patients using indwelling or intermittent catheterisation of the bladder unless there are signs and symptoms of urinary tract infection.
Infectious Diseases Society of America	Avoid prophylactic antibiotics for the treatment of mitral valve prolapse.
Group 3: Recommendations against extended duration of antimicrobials use	
American Academy of Pediatrics – Section on Perinatal Pediatrics	Avoid routine continuation of antibiotic therapy beyond 48 hours for initially asymptomatic infants without evidence of bacterial infection.
Society for Healthcare Epidemiology of America	Do not continue antibiotics beyond 72 hours in hospitalised patients unless patient has clear evidence of infection.
Society for Healthcare Epidemiology of America	Do not continue surgical prophylactic antibiotics after the patient has left the operating room.
American Society of Plastic Surgeons	Avoid continuing prophylactic antibiotics for greater than 24 hours after a surgical procedure.

Association	Recommendation
Group 4: Recommendations against use of systemic antibiotics when local treatment is possible	
American Academy of Dermatology	Do not use oral antibiotics for treatment of atopic dermatitis unless there is clinical evidence of infection.
American Academy of Otolaryngology – Head & Neck Surgery Foundation	Do not prescribe oral antibiotics for uncomplicated acute external otitis.
American Academy of Otolaryngology – Head & Neck Surgery Foundation	Do not prescribe oral antibiotics for uncomplicated acute tympanostomy tube otorrhea.
Group 5: Management of bacteriuria and use of first-line treatment	
American Geriatrics Society	Do not use antimicrobials to treat bacteriuria in older adults unless specific urinary tract symptoms are present.
American Urogynecologic Society	Avoid using a fluoroquinolone antibiotic for the first-line treatment of uncomplicated urinary tract infections (UTIs) in women.
Infectious Diseases Society of America	Do not treat asymptomatic bacteruria with antibiotics.
Group 6: Organism and antibiotic specific recommendations	
American Academy of Allergy, Asthma & Immunology	Do not overuse non-beta lactam antibiotics in patients with a history of penicillin allergy, without an appropriate evaluation.
Society for Healthcare Epidemiology of America	Do not use antibiotics in patients with recent C. difficile without convincing evidence of need. Antibiotics pose a high risk of C. difficile recurrence.

ANNEX 3.A3

Guideline for antimicrobial stewardship strategies by the infectious disease society and society for healthcare epidemiology of America

Strategy	Type of recommendation	Quality of evidence
Measuring antibiotic costs based on prescriptions or administrations instead of purchasing data	Good practice	
Measures that consider the goals and size of the syndrome specific intervention should be use	Good practice	
In nursing homes and skilled nursing facilities, we suggest implementation of antibiotic stewardship strategies to decrease unnecessary use of antibiotics	Good practice	
Implementation of antibiotic stewardship interventions to reduce inappropriate antibiotic use and/or resistance in the neonatal intensive-care unit (NICU)	Good practice	
In terminally ill patients, we suggest antimicrobial stewardship programmes (ASPs) provide support to clinical care providers in decisions related to antibiotic treatment	Good practice	
Preauthorisation and/or prospective audit and feedback over no such interventions	Strong	Moderate
Antibiotic stewardship interventions designed to reduce the use of antibiotics associated with a high risk of C.difficile infection compared with no such intervention	Strong	Moderate
Hospitals implement pharmacokinetic monitoring and adjustment programmes for aminoglycosides	Strong	Moderate
ASPs implement programmes to increase both appropriate use of oral antibiotics for initial therapy and the timely transition of patients from intravenous to oral antibiotics	Strong	Moderate
ASPs implement guidelines and strategies to reduce antibiotic therapy to the shortest effective duration	Strong	Moderate
Incorporation of computerised clinical decision support at the time of prescribing into ASPs	Weak	Moderate
Rapid diagnostic testing in addition to conventional culture and routine reporting on blood specimens if combined with active ASP support and interpretation	Weak	Moderate
In adults in intensive-care units (ICUs) with suspected infection, we suggest the use of serial Procalcitonin measurements as an ASP intervention to decrease antibiotic use	Weak	Moderate
Suggest against relying solely on didactic educational materials for stewardship	Weak	Low
ASPs develop facility-specific clinical practice guidelines coupled with a dissemination and implementation strategy	Weak	Low
ASPs implement interventions to improve antibiotic use and clinical outcomes that target patients with specific infectious diseases syndromes	Weak	Low
The use of strategies (e.g. antibiotic time-outs, stop orders) to encourage prescribers to perform routine review of antibiotic regimens to improve antibiotic prescribing	Weak	Low
Suggest against the use of antibiotic cycling as a stewardship strategy	Weak	Low
Hospitals implement pharmacokinetic monitoring and adjustment programmes for vancomycin	Weak	Low

Strategy	Type of recommendation	Quality of evidence
In hospitalised patients, we suggest ASPs advocate for the use of alternative dosing strategies versus standard dosing for broad-spectrum β-lactams to decrease costs	Weak	Low
In patients with a history of β-lactam allergy, we suggest that ASPs promote allergy assessments and penicillin skin testing when appropriate	Weak	Low
Development of stratified antibiograms over solely relying on nonstratified antibiograms to assist ASPs in developing guidelines for empiric therapy	Weak	Low
Selective and cascade reporting of antibiotics over reporting of all tested antibiotics	Weak	Low
The use of rapid viral testing for respiratory pathogens to reduce the use of inappropriate antibiotics	Weak	Low
In patients with hematologic malignancy at risk of contracting invasive fungal disease, we suggest incorporating nonculture-based fungal markers in ASP interventions to optimise antifungal use	Weak	Low
Monitoring antibiotic use as measured by days of therapy (DOTs) in preference to defined daily dose (DDD)	Weak	Low
ASPs develop facility-specific guidelines for fever and neutropenia management in hematology-oncology patients over no such approach	Weak	Low
Implementation of ASP interventions to improve the appropriate prescribing of antifungal treatment in immunocompromised patients	Weak	Low

Note: The guideline for implementing antibiotic stewardship programmes is taken from recent publication by the Infectious Disease Society of America and the Society for Healthcare Epidemiology of America, which is based on literature review of existing evidences, and evaluated according to Infectious Disease Society of America guidelines (Barlam, 2016). The weighting of the quality of the evidence was made against the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology, which assess the overall level of confidence in primary study design, methodology, risk of bias, and results (US GRADE Network, 2015). The strength of the recommendation is determined by the social acceptability, which encompasses certainty of evidence, patient values, balance between benefit, harm and burdens, and resource costs. Good practice statements are recommended but are not evaluated against GRADE due generally beneficial nature of the practice (which yield strong recommendation) but the lack of confirmation by study evidences (Gyuatt et al., 2015).
The recommendations are categorised into five groups: interventions, optimisation of antibiotic administration, microbiology and laboratory diagnostics, measurement and analysis, and antibiotic stewardship in special populations.
Source: Barlam, T.F. et al. (2016), "Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America", *Clinical Infectious Diseases*, first published online 13 April 2016, *http://cid.oxfordjournals.org/content/early/2016/04/11/cid.ciw118.abstract*.

PART II

Addressing operational waste in health care systems: Opportunities to spend less on pharmaceuticals and hospital care

Operational waste points to situations where health care could be produced using fewer or cheaper resources within the health care system. Using an economic analogy, the discussion on operational waste is about the inputs used to produce care (human resources, capital, technology, pharmaceuticals and medical devices, etc.). In contrast to the first part of the report on wasteful clinical care, the assumption here is that the care patients receive is the one they need. The same benefit (or possibly superior outcomes) could be achieved in a way that is less expensive, however.

Operational waste occurs either when overly high prices are paid for such inputs or when costly inputs are used to treat patients, rather than less expensive but equally effective alternatives. Another category of operational waste, which can be referred to as pure waste, is when purchased inputs are not used at all. Pharmaceuticals and hospital care are two areas in which this type of ineffective spending is of particular concern.

Discussions about overly high prices often revolve around pharmaceuticals. In particular, the use of original brand name pharmaceuticals in place of cheaper and therapeutically equivalent generic drugs is repeatedly debated as an example of unnecessary use of costly inputs. In this part of the report, Chapter 4 more broadly reviews the circumstances in which ineffective pharmaceutical spending occurs, and potential policy solutions. In addition to the example above, the chapter includes the case of purchased pharmaceuticals and other medical supplies that are not actually used and subsequently discarded as well as methods to procure pharmaceuticals more efficiently, discussions that can be generalised to other inputs such as medical equipment.

Regarding overuse of costly inputs, the unnecessary use of hospital care is undoubtedly the most frequently debated topic, and hence is the focus of Chapter 5. While this does not exhaust the subject, the importance hospital care still has in total spending warrants a specific discussion. Many of the solutions to reducing the unnecessary use of hospitals lie outside of the hospital itself, so the policies discussed in this chapter relate to various parts of the health care system.

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PART II

Chapter 4

Reducing ineffective health care spending on pharmaceuticals

by
Karolina Socha-Dietrich, Chris James *and* Agnès Couffinhal

This chapter focuses on opportunities to spend less on pharmaceuticals and other medical supplies. It starts with a discussion of perhaps the most intuitive case of waste, which occurs when prescribed pharmaceuticals (and other medical goods) are discarded unused. Next, the chapter proceeds to the foregone opportunities associated with not substituting originator drugs with cheaper therapeutic alternatives, such as generics or biosimilars. The final issue explored is whether lower prices for pharmaceuticals and other medical supplies could be obtained with more efficient procurement processes.

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Introduction

Pharmaceuticals account for a significant share of overall health care expenditures across all OECD countries. Existing estimates suggest that when hospital use is included, one out of every five health dollars on average is spent on purchasing pharmaceuticals. As such, trends in pharmaceutical spending contribute largely to determining overall health spending patterns (Belloni et al., 2016). Making sure such pharmaceutical expenditures are well spent is therefore crucial to reducing waste and ineffective spending in health care systems.

Pharmaceutical spending that does not add value materialises at different stages of the value chain. This chapter starts with a discussion of perhaps the most intuitive case of waste in the area of pharmaceuticals (and other medical goods), which occurs when purchased products are unused and subsequently discarded. Next, the chapter proceeds to the foregone opportunities associated with not substituting originator drugs with cheaper therapeutic alternatives. The final issue explored is whether lower prices for pharmaceuticals could be obtained through better procurement processes.[1]

1. Discard of unused pharmaceuticals and other medical supplies

1.1. To what extent are discarded medicines and other medical supplies wasted?

Discard of unused, and often unexpired, medicines and other medical supplies imposes unnecessary additional costs on health care systems. But not all instances of discarding are avoidable and as such, not all discards can be deemed wasteful. This include situations when patients recover before all of their dispensed medicines have been taken or when therapies need to be stopped or changed because of ineffectiveness and/or unwanted side effects. This fine distinction as well as indications that most unused medicines are disposed of informally, notably in patients' homes, pose a challenge to assessing the scale of this type of waste (Trueman et al., 2010).

In fact, in most countries, the value of discarded prescription pharmaceuticals is likely to be underestimated, as only medicines returned to authorised collection points are included in official calculations. For example, in Australia, an audit of the contents of "Return of Unwanted Medicines" bins revealed discarded medicines worth AUD 2 million, of which nearly 70% were prescription medicines (Monash University, 2013). In National Health Service (NHS) England, survey-based estimates indicate that the annual cost of discarded prescription medicines could be in the order of GBP 300 million. This figure includes an estimated GBP 200 million of unused prescription medicines either retained by patients or returned to pharmacies and GBP 50 million of medicines disposed of by care homes, as well as the direct costs associated with fulfilling various legal requirements for safe disposal of medicines. Most importantly, the study estimates that approximately 50% of discarded medicines are likely to be preventable waste (Trueman et al., 2010).

Even less is known about the value of pharmaceuticals and other medical supplies unnecessarily discarded by hospitals. A systematic attempt to measure the extent of the problem was undertaken recently by a Johns Hopkins Hospital research team; among large

US academic medical centres, which represent 4% of all hospitals nationwide, simple medical supplies worth at least USD 15 million are discarded every year despite being recoverable (Wan et al., 2015).

Discard of pharmaceuticals used in hospitals often occurs due to the too-large package size of single-dose drugs. This is particularly true for drugs whose dosage is based on a patient's body weight or size and come in single-dose packages. Such packaging means that these drugs must be either administered or discarded once open. When packaging is such that a patient's body size is unlikely to match the amount of drug in a single dose, some is nearly always left over. For example, a recent study estimates that unused leftover infused single-vial cancer drugs cost an additional USD 2 billion annually in the United States (Bach et al., 2016). Notably, cancer drugs are the largest single category of specialty drug spending in many OECD countries (Belloni et al., 2016).

1.2. Errors, suboptimal decisions and organisational shortcomings drive unnecessary discard

Referring back to the drivers of waste identified in Chapter 1, pure waste of pharmaceuticals and other medical supplies is mostly driven by errors and suboptimal decisions of both clinicians and patients. Inappropriate prescribing, notably repeated prescriptions that are not effectively reviewed by physicians or pharmacists, leads to dispensation of excessive volumes of medicines. On the part of the patient, waste is driven by a lack of understanding of, or accidental non-adherence to, the course of medication, which particularly affects vulnerable individuals who cannot independently adhere to their treatment regimen (Trueman et al., 2010).

Alongside behavioural factors, some shortcomings in organisation can lead to unnecessary discard of medicines. In individual health care facilities, room likely exists for improvement in the organisation of supplies and stocks. Likewise, unexploited possibilities remain to improve organisation of stocks at a system level. In particular, distribution of excess supplies between health care facilities belonging to a given network, such as a local or regional hospital system, could be improved or still needs to be established.

To a smaller extent, waste can be induced by poor packaging standards. Distinct cases arise where unclear or lax regulations incentivise manufacturers to offer package sizes that lead to unnecessary discard. For instance, some medicines are used in single-dose presentations, meaning the entire dose of the drug must be either administered or discarded once open. Depending on regulation of packaging standards for these drugs, manufacturers might manage to offer doses that are too large on average, making buyers accept more of a given drug than needed (Bach et al., 2016).

1.3. Guidelines and education initiatives are the appropriate tools to tackle unnecessary discards

Policies aimed at tackling unnecessary discard of pharmaceuticals and other medical supplies need to focus predominantly on the above-described errors and suboptimal decisions of patients and clinicians. The appropriate tools are guidelines, education initiatives and campaigns. To motivate clinicians and patients to recognise the problem, these tools should emphasise improving health outcomes related to appropriate use of medication rather than waste reduction alone. To solve the problem, guidelines, education initiatives and campaigns should continuously encourage improvements in communication

between clinicians and patients to enable as many patients as possible to reveal and resolve medication-related concerns. Patients also need to be better educated about the importance of completing prescribed courses of treatment.

Controlled clinical trials carried out in the United Kingdom and Sweden reveal that wastage of medicine can be reduced by up to 30% if patients starting a new course of treatment are given an option to discuss their medication-related concerns on top of the one-time standard instruction given in the moment of prescribing. A telephone line dedicated to discussion of such concerns, where patients can reach trained pharmacists, was proven to cost-effectively reduce instances of patients' suboptimal decisions (Clifford et al., 2006; Schedlbauer et al., 2007).

Additionally, organisational solutions at the level of community care should be created to better support vulnerable patients in taking their medicines as prescribed, especially those who cannot independently adhere to their treatment regimens. For example, the training of (social) care workers could include a dedicated module on how to effectively provide medicine-taking support. This can be enhanced by introducing a targeted medication review undertaken periodically by community care providers to regularly follow patients' consumption of medication and establish their need (or lack of thereof) for a prescription renewal (Trueman et al., 2010).

Providing patients with information on prescription adherence is important. NHS England's *MedicineWaste* campaign is a promising example, although this policy has not yet been formally evaluated. The campaign, mostly disseminated through the Internet and posters at pharmacies and health care facilities, informs about common reasons for discarding medicines and describes simple steps that each patient should follow, usually with the help of the prescribing clinician or a pharmacist. The campaign also targets clinicians with a simple, short checklist to evaluate repeated prescriptions.

For physicians and pharmacists, organisational solutions such as e-prescription systems or electronic patient journals, which allow review of patients' medication history in one place (as introduced in Denmark), could reduce errors and suboptimal decisions in prescribing, especially for repeated prescriptions. As discussed in Chapters 2 and 3, such systems increase patient safety, notably by minimising the risk of medication errors, and help to tackle overprescription of antimicrobials.

Along with clinicians, patients should also have access and become routine users of electronic patient journals. For example, in Denmark during the 2013 launch of the National Health Record (NHR) – a global electronic patient journal – informational campaigns promoted it as a useful tool for self-monitoring of medication history, among others. In addition to NHR, the *Common Chronic Patient Data* project allows patients with diabetes to access cross-sectoral information on their treatment history, including detailed information on dispensed medication, and to analyse the data with support of decision aids and other educational material. One of the project's aims is to support actions promoting self-management among patients with diabetes (MedCom, 2012). Such improved and comprehensive information can help patients better monitor their medication use, thereby reducing waste.

Incentives can also be used to keep this kind of waste in check. A well-documented example is the use of continuous positive airway pressure (CPAP), an effective treatment for obstructive sleep apnea. Studies show that between 29% to 83% of patients do not adhere to the treatment (non-adherence is defined as a mean of less than four hours of use

per night) (Sawyer et al., 2011). In the United States, most insurers, including Medicare, condition reimbursement of the device on actual use, at least during a trial period. In France in 2014, the highest administrative court rejected an attempt by the health insurance fund to similarly condition reimbursement on use.[2]

Finally, reducing waste of pharmaceuticals and medical supplies requires managerial as well as regulatory efforts. Managers can identify organisational changes needed to improve the flow and use of goods within health care facilities such that unnecessary discards are minimised. Regarding transfers of excess medical supplies between health care facilities, notably hospitals, joint stock management and monitoring (in connection with joint procurement) is a suitable solution shown to improve management of stocks and reduce waste, as seen, for example, in Greece (Kastanioti et al., 2013) and Mexico (OECD, 2013a). The associated policies are discussed in greater detail in Section 3.

Regulators might attempt to systematically diagnose where regulation – or regulatory loopholes – can lead to unnecessary waste and take appropriate steps. For instance, regulators could require manufacturers to provide drugs in a reasonable set of variable package sizes to ensure that the amount of drug is more likely to correspond to a patient's body weight or size and that the amount left over is low. Alternatively, buyers could stipulate that there is no payment for the leftover drug or require manufacturers to refund the cost of leftover drugs. Moreover, clearer guidelines or rules on vial-sharing between patients could be issued (Bach et al., 2016).

2. The untapped potential for generic drug substitution

In the vast majority of cases, substituting an originator product with a generic can induce direct savings without any loss of benefit to the patient. Many countries effectively use a range of policy levers to ensure a high penetration of generics. But while this section focuses on generics, a more recent question raised is whether biosimilars could present analogous opportunities (Box 4.1).

2.1. The opportunity for cost savings from increased generics uptake remains substantial

Substituting originator medicine with cheaper and therapeutically equivalent generics[3] offers significant cost savings with no adverse health effects. In the United States, where the generics market is very dynamic, the price of a generic drug is on average 80% to 85% lower than that of the originator product (IMS Institute for Healthcare Informatics, 2013). Indeed, the shift to generic drug use and the so-called "patent cliff" (a large number of blockbuster drugs losing patent protection) are responsible for the recent decline in overall drug spending observed across OECD countries (Belloni et al., 2016).

Over time, most OECD countries increased generics uptake, with several countries expanding their efforts to encourage uptake after the onset of the global economic crisis of 2008. However, scope remains for improvement, as many OECD countries have still not fully exploited the potential cost savings from generics. In 2015, generics accounted for more than three-quarters of the volume of pharmaceuticals covered by basic health coverage in Germany, New Zealand and the United Kingdom, while they represented less than one-quarter of the market in Greece, Luxembourg and Italy (Figure 4.1).

Box 4.1. **Current and future savings from the use of biosimilars**

In parallel with generic drug competition, opening the market to biosimilar competition could realise significant savings for health care systems. For example, between 2016 and 2020 eight key biologics are scheduled to lose patent protection. Analysis of data available for five European countries (France, Germany, Italy, Spain and the United Kingdom) and the United States suggests that a 20% reduction in price per treatment-day across these eight products could result in cumulative savings exceeding EUR 50 billion by the end of 2020 (IMS Institute for Healthcare Informatics, 2016). In 2015, following the introduction of biosimilar competition in one of the most often used classes of biologics – erythropoietins (EPOs) – the observed price reduction (across the class, i.e. for originators as well as biosimilars) varied from 39% in France to 55% in Germany (IMS Institute for Healthcare Informatics, 2016).

Regulation of market entry varies significantly between countries. The European Union approved the first biosimilar in 2006 and is the leader in the number of approved products: 20 as of June 2016. Yet biosimilars' use shows wide variation in the European Union. Even the first biosimilar still has little or no uptake in some countries (e.g. Greece, Ireland and the Slovak Republic), while in Poland it is used in almost all relevant therapies (Ekman and Vulto, 2016). The United States adopted the legislative framework for licensing biosimilars in 2010, but the first biosimilar was approved only in March 2015 (Belloni et al., 2016).

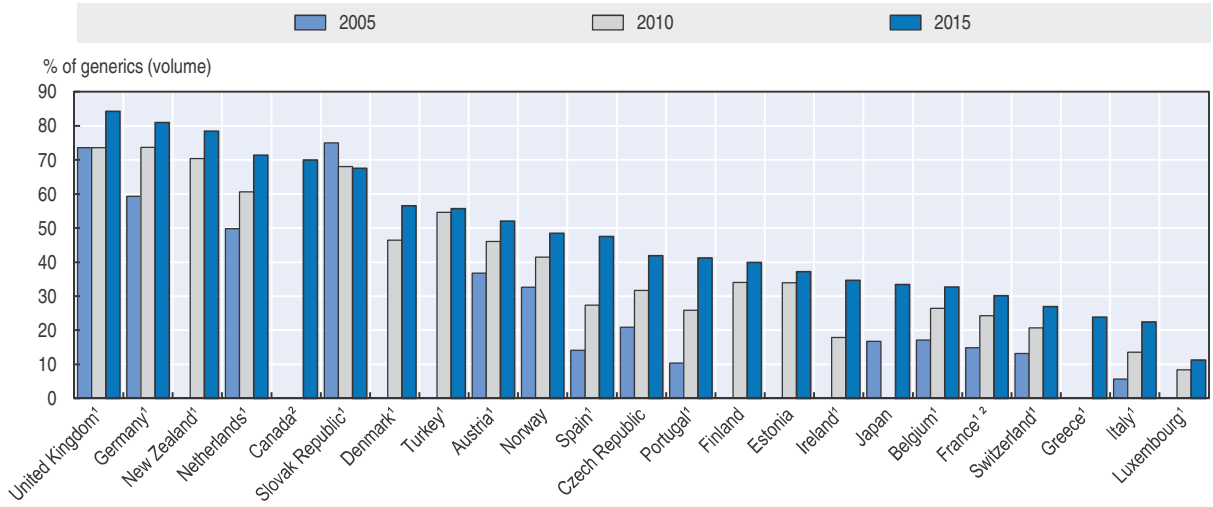
Some policies discussed in this chapter to increase uptake of generics can also be applied to biosimilars. For example, physicians and patients often worry that biosimilars will compromise quality of treatment (IMS Institute for Healthcare Informatics, 2016). Thus regulators should communicate their knowledge more actively and, most importantly, strive to take clear positions on interchangeability between biologics and biosimilars. In Norway and Denmark, where physicians are at the heart of decision making, uptake of biosimilars was rapid and sustained. Similarly, biosimilar competition is strong in Germany, where insurance funds invested in communication with physicians on the subject and subsequently introduced prescribing quotas for biosimilars (IMS Institute for Healthcare Informatics, 2016). A number of countries took a clear position on allowing a switch to biosimilars in the course of treatment, including Denmark, Finland, France, Germany and Norway (Ekman and Vulto, 2016).

2.2. Generics uptake and penetration can be slowed by regulation and stakeholder reluctance

Only some of the observed differences in generics uptake across countries can be explained by the fact that patents are country-specific and expire at different moments in time in different countries (leading to variations in the number of off-patent medicines and their generic substitutes) (Belloni et al., 2016). Generics uptake also depends very much on policies implemented by countries. In particular, systemic issues such as inadequate regulation often hinder penetration of the market by generics.

The use of generics might be hampered by suboptimal decisions taken by clinicians, pharmacists and patients, who fail to switch from the established practice of using the originator drug. Especially when generics are new on the market, patients but also clinicians may be reluctant to recognise their therapeutic equivalence with the original branded products. Concerns over generics' safety and effectiveness compared to originators largely reflect regulators' failure to address them adequately. Regulators often do not effectively communicate the benefits of generics and as such do not provide the necessary decision-making support for clinicians and patients.

Figure 4.1. **Trends in generics market shares in volume in OECD countries between 2005 and 2015 (or the nearest year)**



1. Data refer only to reimbursed pharmaceutical market.
2. Most recent available data are for 2013.

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink *http://dx.doi.org/10.1787/888933444162*

Economic incentives are often misaligned with the aim of increasing generics' share of prescribed or dispensed medicines. In most OECD countries, margins of pharmacies or dispensing clinicians are fixed and correspond to a certain percentage of the realised turnover. Thus dispensing clinicians' and pharmacies' income increases with the price of dispensed drugs. The incentive to stock and dispense cheaper generics is hence significantly lower than the incentive to stock and offer to patients the original brand name drugs.

In some OECD countries, the use of generics instead of originators produces only limited savings because of the price paid. This can be the case when regulations stipulate that generic drug prices are subject to price caps, set as a fixed fraction of the price of the original branded product (Kanavos, 2014) or when all therapeutically equivalent products (including originator and generics) are subject to the same reimbursement level – a practice referred to as Internal Price Referencing (IPR) (Seiter, 2010), discussed in more detail in Section 3. In these cases, generics manufacturers face a maximum price/reimbursement ceiling. While this prevents prices/reimbursement from growing above that ceiling, it incentivises generics manufacturers to set their prices at this ceiling and pay generous "professional allowances" to pharmacies to secure shelf space instead of eliminating competition by lowering the price below the ceiling. For example, numerous studies have shown that Canada, where regulations setting generic drug prices relative to the price of the original branded products were in place until 2013, had some of the highest generic drug prices in the world (IMS Institute for Healthcare Informatics, 2016). Similarly, a study of off-patent drug markets in 12 European countries revealed that countries with administrative controls on prices of generics experienced significantly slower price reductions over time than countries that do not have them (for example, Denmark and the United Kingdom) (Kanavos, 2014).

2.3. A large array of policies can effectively increase generics uptake

Policies encouraging uptake of generics can be grouped into two main categories: i) policies that aim to increase availability of generics on the market, including entry-level legislation and pricing methods; and ii) policies that steer main stakeholders such as physicians, pharmacists and patients towards the use of generics already available on the market.

Encouraging early entry of generics and competitive pricing methods create the potential for the generics market to develop

Policies to promote the use of generic medicines start with enhancing their availability in the market. Through early entry legislation, generics manufacturers can be allowed to complete their regulatory requirements prior to the patent expiry of the originator. In addition, market exclusivity can be granted to the first generics on the market to incentivise generics manufacturers to produce them and speed up market entry, although this can limit competition. In the United States, the first generic drug developed post-patent expiry has six-month market exclusivity (Belloni et al., 2016). Other regulatory measures include revisions of patent applications and oversight over competition law, which allow for early detection of activities carried out by manufacturers of originator drugs that aim at preventing or delaying market entry of generics. Such actions belong to the scope of inappropriate business practices and are discussed in more detail in Chapter 7, which deals with integrity violations in the health care sector.

Introduction of generics will not ensure the full potential of savings is realised, however, unless effective price competition exists in the generics market. Policies that promote a competitive market environment are the optimal way to achieve this goal. The majority of OECD countries rely on price regulations (except for Denmark, the Netherlands, Sweden, the United Kingdom and the United States). Within price-regulated systems, generic drug prices are often set either as a percentage of the price of the equivalent originator drug or as a maximum price based on external reference pricing (Box 4.2) (Medicines for Europe, 2016). But price regulation has certain drawbacks, as discussed in more detail in Section 3. In general, with regard to the number of generic drug producers attracted to a given market and the prices of generics, systems relying on price regulation appear to be inferior to systems in which prices are established through competitive mechanisms such as tenders or competitive negotiations between buyers and manufacturers (OECD, 2013b; Kanavos, 2014; IMS Institute for Healthcare Informatics, 2016; Vogler et al., 2016b).

After a generic enters a market, the extent of competition also depends on whether regulators consider the generic to be a substitute only for the equivalent branded originator drug (inducing narrow within-molecule competition) or also for similar patent-protected drugs belonging to the same therapeutic class (inducing broader within-class competition) and across related therapeutic classes (inducing the broadest possible competition). OECD countries differ with regard to how broadly competition is actually induced by a generic's entry. While any therapeutic substitution decisions should be transparently supported by robust evidence on the comparative safety and efficacy of the products, countries with different regulations should consider exchanging experience and knowledge to reach optimal decisions. For example, Norway, the United Kingdom and the United States actively encourage opportunities for generic drug substitution where the effectiveness and safety of a particular generic product is similar to a patent-protected product in the same or related class.

Box 4.2. **Pharmaceutical price regulations: Advantages and main drawbacks**

OECD countries use various price regulations to establish ceilings on pharmaceutical prices. The most common type is *external price referencing* (EPR), also known as external reference pricing or international price comparison/benchmarking. It is defined as the practice of using the price(s) of a medicine in one or several countries to derive a reference price for a medicine in a given country. Alternatively or in addition, countries can set a single price for equivalent drugs – a practice referred to as *internal reference pricing* (IRP) – where the price of the cheapest drug applies to all drugs within a therapeutic class. Also, the price of a generic drug within a given therapeutic class can be set as a percentage (e.g. 70%) of the originator's price.

Price regulations have several limitations. With EPR, it is necessary to recognise that list prices of pharmaceuticals in other countries do not necessarily reflect actual prices because buyers might receive discounts and rebates, which often are confidential. Thus referring to the list price as a measure for setting prices in another country may lead to unnecessarily high prices. More importantly, manufacturers of patent-protected drugs might succeed in maintaining narrow price bands across different markets, knowing that concessions in one country may lead to regulatory price adjustments in other countries (OECD, 2008; Seiter, 2010).

IRP models can also cause distortions that limit their effectiveness. Under this policy, manufacturers of equivalent products (competing within a given therapeutic class) tend to set their price at the reference price level, after which they seek to eliminate competition with non-price strategies such as offering "professional allowances" to wholesalers and/or pharmacists to secure shelf space. Such policies may put wholesalers and pharmacies into the role of "market makers" because they can decide which pharmaceutical brands they carry (IMS Institute for Healthcare Informatics, 2016). Effectively, the manufacturer's revenue for each item sold is reduced by the amount of "professional allowances" paid to pharmacies or wholesalers, but third-party payers such as governments and other insurers are not involved in the transaction and reimburse the full reference price, creating significant incremental profits for wholesalers and pharmacies (Seiter, 2010). This problem is increasingly observed in OECD countries, resulting in adoption of several countermeasures, such as regulatory ceilings on wholesalers' and pharmacies' margins or arrangements for profit-sharing between wholesalers/pharmacies and governments or insurance funds (European Commission, 2012).

In summary, price controls are useful but their advantages are diminished by strategic response from pharmaceutical manufacturers. Also, actors in the lower level of the supply chain, namely wholesalers and retail pharmacies, have opportunities to exploit the reference price setting to their sole benefit.

Physicians can be encouraged to prescribe generics

While the need to systematically promote the use of generic (i.e. bio-equivalent) medicines is widely accepted, the extent to and means by which the choice of cheaper therapeutic alternatives within a therapeutic class or across related therapeutic classes should be encouraged are more contentious. Cost-conscious physicians can be encouraged to prescribe cheaper products by explicit guidelines on the prescription of the cheapest alternative as first-intention medication or nudged by prescription software that highlights price differences, provided they accept that the products are therapeutically equivalent for the patient. Other measures include the encouragement or mandate to prescribe by International Non-proprietary Names (INN). Physicians are allowed to prescribe by INN in more than two-thirds of OECD countries and mandated to do so in five countries (Table 4.1). France implemented mandatory INN prescribing in 2015 (Belloni et al., 2016).

Table 4.1. **Policy tools to promote use of generics**

	Prescription in INN			Generic drug substitution			Incentives to prescribe/dispense/ purchase generics		
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians
Australia		X			X		F	F	-
Austria	X			X			-	NF	NF
Belgium		X		X			NF	F	F&NF
Canada[1]		X[1]	X[1]		X[1]	X[1]	F[1]	F[1]	[1]
Chile			X[2]		X		-	F	NF[2]
Czech Republic		X			X		..	F	F
Denmark		X				X	NF	F	NF
Estonia		X				X	-	NF	NF
Finland		X				X	NF	F	NF
France			X		X		F	F	NF&F
Germany		X				X	NF	F	F
Greece		X			X		-	F	NF
Hungary		X			X		NF	F	F
Iceland					X		..	F	..
Ireland		X			X		NF	F	NF
Italy		X				X	NF	F	NF
Japan		X			X		F	F	[3]
Korea		X			X		F	F	..
Luxembourg		X		X			..	NF&F	NF
Mexico			X		X			F	NF
Netherlands		X			X		F	F	..
New Zealand		X			X[4]		F	F	NF
Norway		X			X		F	F	NF
Poland		X			X		NF	F	-
Portugal			X		X		N	NF&F	N
Slovak Republic		X				X	NF	F	NF
Slovenia			X		X		NF	NF	NF&F
Spain		X				X	NF&F[5]	NF&F	NF&F[5]
Sweden		X				X	NF&F	F	NF
Switzerland		X			X		F	F	-
Turkey		X			X		..	F	-
United Kingdom		X			X		F	-	NF
United States[6]							F[6]	F[6]	-

Note: F = Financial incentive; NF = Non-financial incentives; .. = Information not available. For pharmacists, this table only considers incentives provided by drug coverage schemes. Market incentives (such as rebates from manufacturers, vertical integration, etc.) are not reported.

1. In Canada, the regulation of prescription and generic drug substitution differs across provinces and territories. Incentives for doctors, pharmacists and patients vary across drug plans.
2. Only in the public sector.
3. In Japan, there is no direct incentive for physicians, but an incentive for medical institutions exists. Generics prices are revised after market entry.
4. If the pharmacist has a substitution arrangement with the prescriber.
5. In some regions.
6. Legislation on prescription in INN and substitution is not uniform across states. Incentives for pharmacists, patients and doctors vary across drug plans. Patients' co-payments are generally lower for generics.

Source: Medicines for Europe (2016), *Market Review – European Generic Medicines Markets*; Belloni, A., D. Morgan and V. Paris (2016), "Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges", *OECD Health Working Papers*, No. 87, OECD Publishing, Paris, *http://dx.doi.org/10.1787/5jm0q1f4cdq7-en*; OECD (2010), *Value for Money in Health Spending*, OECD Health Policy Studies, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264088818-en*.

Financial incentives can be leveraged to encourage physicians to prescribe generics. Not many OECD countries use financial incentives targeting prescribers. One exception is Belgium, where since 2005, physicians who issue at least 400 prescriptions annually are evaluated on whether they prescribe a certain required percentage of "cheap medicines". The scheme, updated in 2015, envisages between 16% and 65% target share of "cheap medicines" in total prescriptions across different medical specialities, with an average of 42%. The target is set at 50% for general practitioners (GPs) and 75% for dentists (Belloni et al., 2016). Germany uses similar target levels and introduced financial penalties for physicians who do not reach them (Godman et al., 2012). In recent years, France (in 2009) and Hungary (in 2010) introduced incentives for GPs to prescribe generics through a pay-for-performance (P4P) scheme. Japan's scheme has been in existence for a while; in 2012, it increased the value of bonuses associated with reaching the target share of generics in total prescribing, leading to an increase in generic drug prescriptions (Belloni et al., 2016). In Greece, public hospitals are required to reach a 50% share of generics in total volume of administered pharmaceuticals.

Pharmacies have a role to play in increasing the take-up of generics

To encourage the dispensing of generics, pharmacists might be allowed to substitute the more expensive drug prescribed with a generic. As mentioned earlier, the possibility of allowing therapeutic substitution is controversial (i.e. the dispensing by pharmacists of a drug considered to be therapeutically equivalent to that initially prescribed including with specific prescriber permission). Generally, therapeutic substitution decisions should: i) be transparently supported by robust evidence on the product's comparative safety and efficacy; and ii) result from informed decisions by patients and clinicians. But such decisions could be encouraged more systematically and framed by a requirement to supply the cheapest drug unless otherwise specified by the prescriber or if an exceptions policy is in place.

Pharmacists are allowed to substitute brand name drugs with generics in a majority of OECD countries, and generics substitution is mandatory in a handful of countries (Denmark, Finland, Spain and Sweden). Italy introduced such a mandate in 2012, while in other countries (e.g. Norway) pharmacists are obliged to inform patients about the possibility of a cheaper alternative. In most countries, substitution is allowed when the generic exists, although a handful of countries maintain exceptions for some drugs (e.g. anti-epileptics). In contrast, substitution by pharmacists in France is limited to a list of molecules established by the National Agency for Medicines and Health Product Safety.

In addition, pharmacists need to be reimbursed in a way that encourages them to dispense the least expensive products. Instead of proportional mark-ups that encourage dispensation of more expensive drugs, fixed fees per prescription or regressive margins (the higher the drug price, the lower the margin) lead pharmacists to be either indifferent or willing to dispense generics, respectively. Some countries recently changed their policies to better incentivise pharmacists to dispense generics. In 2012, Portugal changed from linear to regressive remuneration. Other countries went a step further. In Switzerland and Belgium, for instance, pharmacists receive an additional fee for generics substitution. France introduced a P4P scheme for pharmacists in 2012 with a bonus for achievement of generic drug dispensing targets. Similarly, to further encourage substitution Japan in 2012 increased pharmacists' bonuses associated with target levels for dispensed generics.

Patients can be incentivised to opt for generics – if convinced

Patients have a financial interest to choose cheaper drugs when their co-payment is lower for generic drugs than for the branded equivalent. This is generally the case in all systems using a single reimbursement amount (IPR) for a cluster of products. Greece, Ireland and France recently introduced other incentives for patients. In Greece and Ireland, patients choosing the originator over the generic drug now pay the difference between their prices. Since 2010 in France, patients refusing a generic drug substitution have to pay in advance for their drugs and are reimbursed later, whereas purchase of generics does not require advance payment.

Recognising that few patients might actually be aware of the broader debate over generic medicines, several countries carried out information campaigns to promote the use of generics, explaining their equivalence to brand name drugs (e.g. Belgium, Denmark, France, Greece, Italy, Portugal and Spain) (Medicines for Europe, 2016). While no formal evaluation is available, these policies, associated with patent expiries of several blockbusters in recent years, certainly contributed to the significant increase in the market share of generics observed over the past decade in most countries. More specifically, the share of the generics market increased significantly over the past decade in some countries that had low levels in 2000. In Portugal, the generics market share grew from virtually zero in 2000 to 41.3% in volume in 2015. In Spain, the generics market share reached 47.6% in volume in 2014, up from 9% in 2000.

Table 4.1 provides an overview of policies incentivising the main stakeholders such as clinicians, pharmacists and patients towards use of generics. It indicates whether physicians are allowed to prescribe by INN and, if yes, whether it is optional or mandatory, as well as whether generic drug substitution by pharmacists is permitted.

While most of the policy debate on opportunities to substitute expensive originator drugs with cheaper and therapeutically equivalent alternatives focuses on generics, the emergence of biosimilar medicine brings in new perspectives for releasing resources. Biosimilars are essentially generic versions of original biologic medicines, with the latter a rapidly growing part of the global market for pharmaceuticals. By 2020, biologic medicines may account for nearly 30% of the value of the global market (IMS Institute for Healthcare Informatics, 2016). As such, biosimilars, their cheaper alternatives, open a significant potential for savings (Box 4.1).

A growing number of conditions are treated with biologic medicines. In particular, these innovative medicines opened a new era of precision therapies for cancer, but these are very expensive (e.g. USD 25 000-USD 200 000 per year) (Belloni et al., 2016). Hence, the emergence of biosimilars brings the promise of more affordable therapies and relief for health care budgets. Adoption of biosimilars faces the same obstacles that had to be removed to realise the potential of generics, however (Box 4.1).

3. Procurement as a core strategic instrument

3.1. *Ineffective procurement increases the prices paid for pharmaceuticals and other medical goods*

Pharmaceutical procurement is complex, but can still be strategically designed

Procurement of pharmaceuticals, and to a certain degree other medical goods, is a complex process. In contrast, the process for bringing over-the-counter (OTC) medicines[4] and basic medical goods to market is far simpler. But for pharmaceuticals and other

medical goods that require a prescription or those administered to patients within health facilities, the procurement process typically involves a number of activities that can be categorised into three broad stages, each of which has its own challenges:

- Pre-procurement. This involves licensing, selection of essential commodities, needs quantification and coverage decisions.
- Core procurement activities. This describes negotiation and tendering processes. It includes market research, communication with potential suppliers, determination of price and other conditions of supply, and ultimately supplier selection.
- Post-contract management. This relates to supply execution, supplier management and performance monitoring.

Complexity in procurement largely reflects the nature of the market. In particular, large, internationally operating manufacturers, whose products are often patent-protected, dominate the pharmaceutical market. While logical reasons explain why the pharmaceutical market developed this way, notably to encourage research and innovation, such a market structure limits competition with a consequent impact on prices. Further, patients' demand for prescribed drugs is derived rather than direct. Patients are not traditional consumers, who react to market prices and make their own choices. Rather, patients rely on health professionals to determine which medicines are right for them, and in OECD countries the associated costs are fully or partially covered by a third-party buyer such as the government or another insurer. Taken together, these factors make it challenging for buyers to ensure that prices paid for pharmaceuticals are not too high.

Yet even within this market structure, governments and other health insurers can reduce the costs of pharmaceuticals and other medical supplies. Similar to health care activities discussed in previous chapters, procurement of these products is not free of inefficient spending and waste. This final section identifies these shortcomings and discusses suitable policy solutions. The latter include building and meaningfully using market power, developing expertise, and improving contract designs and procurement tools such as e-platforms and standards.

The analysis herein focuses on the core procurement activities. In other words, the analysis assumes that the pre-procurement activities listed above are adequately performed.[5] This is a simplification, particularly as pre-procurement and core procurement activities often take place simultaneously; notably, coverage decisions are often taken in concert with pricing decisions. Nevertheless, negotiations and tendering processes and other such core procurement activities have the most crucial impact on price paid.

This section thus ultimately pinpoints shortcomings in procurement that lead to overly high prices being paid for pharmaceuticals and other medical supplies. Still, while pricing is the key indicator used to gauge inefficiencies in procurement, an exclusive focus on prices can generate unintended adverse effects. In particular, two other criteria are important: i) system responsiveness, the ability to ensure availability of the right products – as perceived by clinicians and patients – in the right quantities and on time; and ii) long-term economic sustainability, the objective that lower prices in one year should not be offset by non-proportional price hikes or lack of product availability in subsequent years. In other words, the dynamics in procurement over time should also be considered.

Between- and within-country price variations are striking and at least partially unwarranted

Having outlined some of the complexities in procurement of pharmaceuticals and other medical goods, it is useful to highlight actual variation in prices within and across countries, which reflect inefficiencies in procurement to a significant extent. Comparing prices, particularly across countries, is not a straightforward task. For example, prices can be measured at different stages (from ex-factory to retail); and differences in prices – which are in part determined by market forces – may reflect the different values countries attach to health outcomes in relation to their income. Official and actual prices can differ, as manufacturers can provide discounts to countries but typically condition them on non-disclosure agreements. As a result, price comparisons are difficult and not all price differences can be deemed wasteful. Yet as with the variation observed in the use of specific medical procedures (see Chapter 2), some price differences are certainly wasteful. In particular, most within-country price variation is probably a sign of inefficient procurement practices, and if comparable countries pay vastly different prices for the same drug, those who pay higher prices could probably question why this might be the case.

Within-country price variations tend to be non-negligible. For example, in Italy the same types of buyers pay prices differing up to 23% for the same pharmaceutical product intended for hospital use (Baldi and Vannoni, 2015). Similarly, within-country price variations exist for other medical goods, as documented by the *Procurement Atlas of Variation* published by NHS England (NHS, 2014, 2016). One of the most striking examples is that of the simple identification wristband for hospital patients, for which the price paid by different NHS trusts varied more than two-fold in 2014. Other examples from the *Atlas* include needles and blood sample tubes, with between-trust price variations of 47% and 25%, respectively.[6] Saving opportunities on these types of simple medical supplies were estimated to be between 5% and 8% of total spending for a majority of trusts, and up to 15% for some of them in 2014 (NHS, 2014).

Additional insights are offered by the experiences of countries that implemented changes in their procurement strategies, for instance modifying organisational structure (associated policies are discussed later). Such a move presents a natural experiment in which a comparison of prices before and after can reveal inefficiencies inherent to a given version of a procurement system. The most recent examples of such a change include Greece and Mexico, where substantial savings were achieved, proving that prices previously paid for pharmaceuticals were overly high. In Mexico, a move from decentralised to centralised procurement contributed to savings of around USD 2.8 billion between 2007-10 compared to the budget planned based on the performance of the former decentralised system (OECD, 2013a). A similar change in Greece in 2010 contributed to savings of EUR 180 million compared to the expected budget for 2011 (Kastanioti et al., 2013).

Regarding price variations between OECD countries, studies in the past decade show that Germany, Sweden, Switzerland and the United States tend to be high-price countries for originator drugs, whereas ex-factory prices for originator drugs in Greece, Mexico, New Zealand, Portugal, Spain and recently the United Kingdom rank at the lower end (Kanavos et al., 2013, Leopold et al., 2013; Vogler et al., 2016b). For example, for a selected group of medicines, ex-factory prices in Germany were up to 27% more expensive than the average price among the studied countries, versus Greece where prices were up to 32% cheaper than the average. Moreover, differences in ex-factory prices of a number of cancer

drugs, which in most countries are the top category in terms of value of pharmaceutical expenditures, varied from 28% to 388% between the highest- and lowest-priced country (Vogler et al., 2016a).

Between-country price variations do not seem to be well explained by differences in national income as measured by purchasing power and/or average wages. Indeed, a recent investigation into ex-factory prices of an innovative drug for hepatitis C in 30 countries reveals that after adjusting for purchasing power parity (PPP) or average wages, the price differences are magnified instead of reduced, and the highest paying countries by far in the OECD are Poland and Turkey (Iyengar et al., 2016).

3.2. Organisational shortcomings and misaligned incentives drive inefficiencies in procurement

Existing organisational structures frequently do not support economies of scale

Given the market characteristics discussed earlier, many manufacturers enjoy a monopolist advantage or face competition from only one or two other manufacturers of equivalent patent-protected products. In absolute monopolies (one manufacturer) and oligopolies (a few manufacturers), suppliers can set higher prices than under competition.

Manufacturers are not alone in their ability to exert market power. Buyers can powerfully influence prices, particularly when a single buyer operates in a sizeable market such as a country or a large region. For example, when multiple sources of equivalent products exist, a single buyer can incentivise manufacturers to compete on price. The single buyer's position is of course less effective against suppliers of single-source medicines (patent-protected medicines for which no alternatives exist). Nevertheless, even in this situation a single large buyer is in a better position to exert market power than a number of dispersed smaller buyers (Kesselheim et al., 2016; MHS and WHO, 2012).

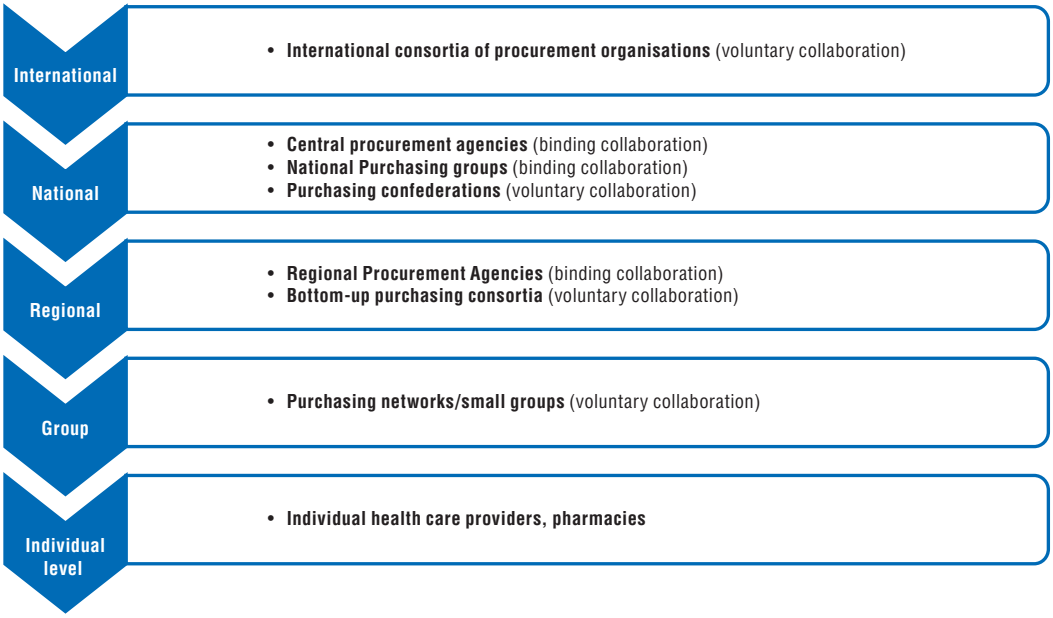
Relatively high prices of pharmaceuticals and other medical supplies may reflect organisational structures of the procurement system that hinder building market power through bulk purchasing. For example, this occurs when small insurers or providers contract separately for limited volumes of the same products. Indeed, in many OECD countries, individual hospitals, pharmacies and local government units and insurers carry out procurement separately (e.g. Belgium, the Czech Republic, Germany, the Slovak Republic, Slovenia, Sweden and Turkey). This not only precludes volume-related discounts but also creates unnecessary task repetition by each buyer.

A majority of OECD countries use price regulations to moderate prices for pharmaceuticals. These take the form of external and/or internal price referencing and occasional one-time price cuts to establish maximum prices in a country. But while price regulations contributed to pricing transparency and had the desired initial impact on pharmaceutical expenditures in many (but not all) countries, the impact declined over time (Vogler et al., 2015; Seiter, 2010). The main problem is that price regulations do not automatically engage the potential market power of a given health care system, and active procurement strategies can be more effective in that respect. Box 4.2 discusses the advantages and drawbacks of price regulations in more detail.

Buyers' size affects their ability to negotiate volume-related discounts

To illustrate how procurement systems in OECD countries exploit (or fail to exploit) their potential market power, this subsection classifies systems by the extent of collaboration/consolidation of purchases. This classification distinguishes between

Figure 4.2. **Levels of collaboration/consolidation of purchases in procurement systems**



Source: Authors' own compilation (2016).

procurement systems in which each buyer purchases independently and those that rely on larger or smaller collaborations of buyers. Moreover, the classification distinguishes between voluntary and binding forms of collaboration (Figure 4.2).

Collaboration in procurement is defined as co-operation between two or more organisations in one or more of the core procurement activities by bundling their purchasing volumes and/or sharing information and resources (Bakker et al., 2008; Schotanus and Telgen, 2007; Nollet and Beaulieu, 2003). The various legal frameworks and organisational structures of countries' health care systems led to a wide array of collaborative procurement forms. These forms range from national and regional government-led agencies or private consortia, which legally bind collaborating members, to public or private confederations in which collaboration is voluntary:

- Individual level (no collaboration): Individual pharmacies or providers purchase directly from suppliers, usually under regulatory price ceilings. This model exists in some OECD countries in the retail market for pharmaceuticals and medical supplies dispensed to patients in pharmacies (for example, Australia, the Czech Republic, Hungary, Portugal, the Slovak Republic and Turkey). In the majority of OECD countries, this procurement model applies to medicines administered to patients within health facilities, notably hospitals (except in Denmark, Italy, New Zealand, Norway, Portugal, Slovenia, Sweden, the United Kingdom and the United States).
- Regional/group level:
  - Purchasing networks/small groups: A few entities, usually hospitals or a local government, consolidate their purchases. These small groups might be informal and operate on an ad hoc basis rather than regularly (for example, small groups of hospitals in Germany or nursing homes in the United Kingdom).

- Purchasing consortia: Also referred to as co-operative purchasing, these are larger groups of pharmacies, hospitals (sometimes represented by a common health fund) or a smaller group of insurers regularly carrying out joint procurement activities. Consortia-type initiatives typically do not have dedicated staff but are run by a host organisation, which usually rotates between members. Consortia are bottom-up organisations and as such leave their members free to buy outside the established contracts, referred to as framework contracts; for example, local hospital consortia in France, Italy, the United Kingdom or a consortium of local governments in Sweden purchase medicines for pharmacies.
- Regional procurement agencies: These are similar in size to purchasing consortia; the main difference is the top-down instead of bottom-up nature of the collaboration, which means that buying outside the contracts is considered a violation of compliance or is limited by the procurement budget being allocated to the level of the agency. Among countries with a significant share of public health care, such agencies exist in England, Greece, Italy, Spain and Sweden. In countries with a significant private sector share of health care, such as the Netherlands and the United States, the corresponding form is Pharmaceutical Benefit Managers or large purchasing groups.

- National level:
  - Purchasing confederations: National-scale collaborations operate similarly to the above-described purchasing consortia, with the distinction that a central entity is created solely for the purpose of serving the collaboration and as such has its own staff. For example, confederations include all hospitals in a country or all regional governments – pan-Canadian Pharmaceutical Alliance, Norwegian Drug Procurement Cooperation (LIS), and Danish procurement collaboration (AMGROS). Members finance the central entity through contributions proportional to their size. Still, similar to purchasing consortia, collaboration is voluntary and based on framework contracts.
  - Central procurement agencies (also referred to as third-party purchasers) are separate organisations, usually a government agency, to which all procurement and budgetary powers are delegated. This form of centralised system is the most prevalent procurement mechanism in OECD countries for purchasing prescription pharmaceuticals for the retail market (for example, Greece, Poland and New Zealand). Central agencies are less present in the market for pharmaceuticals used in health care facilities, except in Italy and Spain.
- Supranational level: This is the domain of a few international projects in specified areas, such as equipment for the elderly or pandemic vaccines. One example is the European project HAPPI (supported by European Commission and Ministry of Social Affairs and Health, France), which brings together ten partners from six countries with the intention to enlarge the group with any European public authority involved in health care procurement. Its main functions include executing joint calls for tenders, with the first joint cross-border procurement successfully completed in 2015. Another example is a co-operation between 21 European Union governments that aims at joint procurement of vaccines for pandemics. Moreover, a number of collaborative projects are currently under construction, such as: the Nordic Pharmaceutical Forum; “Beneluxa” (Belgium, Luxembourg, the Netherlands and Austria); and a collaboration between Bulgaria and Romania.

Grouping procurement systems in the above-described manner reveals that in half of OECD countries, international manufacturers face relatively small and dispersed buyers. In such systems, potential for bulk purchasing remains largely unexploited, which seriously limits possibilities for obtaining favourable volume-related discounts. Moreover, for each product the contracting effort is unnecessarily repeated by different purchasing organisations.

The remaining countries rely on a range of collaborative procurement systems that differ with respect to the number of organisations represented and the voluntary versus binding character of the group. These collaborative procurement systems are better suited to exert market power.

Even large buyers often fail to obtain volume-related discounts due to communication problems and ineffective e-procurement tools

Relatively high prices of pharmaceuticals and other medical supplies can reflect passive procurement practices of large organisations that simply do not exercise their potential market power. Large organisations might fail to exploit economies of scale if they lack strategic perspective on procurement and treat it as an administrative function. This kind of failure often involves weak monitoring of consumption and unreliable forecasting, which do not give suppliers any guarantee of selling specific volumes. In other instances, large buyers do not even have the mandate to engage in negotiations with suppliers on more favourable purchase conditions, as is the case for Medicare and Medicaid in the United States (Kesselheim et al., 2016).

When several equivalent products for a given condition exist, large buyers frequently face obstacles in allocating the biggest share of the market to the most cost-effective product. For example, Medicaid is legally obliged to cover all authorised medicines so cannot exclude from its purchases even the least cost-effective product within a therapeutic category. US law requires similarly broad coverage for Medicare in some therapeutic classes, such as oncology (Kesselheim et al., 2016). Other large buyers could but do not manage to implement appropriate procurement strategies. Payers' willingness to respect therapeutic freedom may drive them to cover as many products as possible, but as already mentioned in the context of generics substitution, choice of the most cost-effective alternative should be encouraged whenever possible. Involvement of administering/prescribing clinicians in the design of procurement strategies is required for this. At a minimum, clinicians should have a transparent view of both the clinical- and cost-related factors that procurement organisations take into account in their decisions.

As large procurement organisations often fail to effectively communicate with clinicians, it remains difficult to convince them to accept the preferred product supplier, within a therapeutic class for example. If none of the suppliers has a prospect of winning a relatively higher market share, obtaining volume-related discounts is difficult for buyers. Even if a procurement agency is authorised to exclude some products within a class and give a larger market share to only one product, lack of insight into the decision-making process causes unnecessary frustration among clinicians. For instance, a survey among GPs in New Zealand revealed that only few participants were able to correctly identify the procurement strategies of the pharmaceutical management agency (PHARMAC) (Babar et al., 2015).

In addition to communication problems, ill-designed e-procurement tools impede bulk purchasing. In particular, in large voluntary collaborations, which offer their members an option (not an obligation) to procure through framework contracts, lack of user-friendly e-procurement tools might lead to purchases outside the collaboration since they appear to be simpler and faster. For instance in the 2000s in NHS England, adherence to framework contracts was estimated to be approximately 50% (Karjalainen et al., 2008; Lonsdale and Watson, 2005; Knight et al., 2003). Similar problems were reported in Finland (Karjalainen et al., 2008). In the worst-case scenario, a procurement collaboration plagued by compliance problems can be seen by suppliers as a "nuisance customer". This situation might have long-lasting negative effects as manufacturers might be less inclined to enter framework contracts and/or demand higher prices to compensate for their risk of not realising the expected volume of sales (Karjalainen et al., 2008).

Establishing and maintaining collaborative procurement requires efficient modes of communication to ensure transparency and minimise costs of collaboration, be it time or direct administrative costs. This is, however, not always the case. The bigger the collaboration, the greater the potential for savings through economies of scale. Yet a greater risk arises of creating complicated and opaque structures that might be abandoned by their members over time.

Poor tender designs might increase prices in the short and long term

Buyers rely on two general procurement methods: negotiations and tender-like mechanisms. Negotiations are the only choice for single-source pharmaceuticals and medical supplies. Otherwise, it is a common perception that prices of pharmaceuticals and other medical commodities should be set in competitive tenders whenever possible. Designing a well-performing tender mechanism is not straightforward, however. The practice has produced a number of examples of tenders with undesired effects in the form of selective provision or shortages of supplies and reduced competition, which in the long term naturally led to price increases (Merlob, 2010). In particular, as soon as a bigger share of a market is subject to tendering (for bulk purchasing), the optimal design of tenders gains importance. Under bulk purchasing, consequences of bad tendering not only affect individual buyers but can extend to the entire region or country and as such are much more likely to have long-term consequences. The following provides examples of issues that can arise.

Lack of transparency on how suppliers are selected, especially when non-price criteria are used in the selection, can seriously undermine a tender's efficiency. Indeed, price is never the only decisive criterion as other criteria such as suppliers' capacity to deliver a given volume, product quality standards, and performance obligations are equally important. If the weights of these criteria are not clear, some suppliers might be discouraged from participating in tenders in a given country or sector, while others might file complaints, causing disruptions in supply (Baldi and Vannoni, 2015). For example, tenders organised within the competitive bidding programme initiated by Centers for Medicare & Medicaid Services (CMS) in 2008 were subsequently cancelled by the US Congress due to complaints about unfair qualification procedures (Cramton and Katzman, 2010). In consequence, delays in product availability occurred and expensive ad hoc purchases had to be made. Similarly, in the Slovak Republic, lack of transparency in the tendering process as well as accompanying administrative burden effectively

discourage manufacturers from competing for the country's market. If the tenders take place but not more than one contestant participates, the whole exercise is rendered futile (European Observatory on Health Systems and Policies, 2016).

Moreover, in tender designs in which bids are not binding commitments, any tender winner can decline to sign a supply contract following the tender. This encourages suppliers to submit low bids, with which they acquire at no cost the option to win a contract, and withdraw should they find a more profitable market in the meantime. Such practices weaken the procurement system's credibility and frequently result in too few or sometimes even no units being procured – as illustrated by the example of post-2008 CMS auctions (Merlob, 2010). This situation has been known to arise when the contract price is determined by the value of the mean or median of a certain number (usually three to seven) of the lowest bids. The opportunistic low-bidding suppliers withdraw but this does not affect the contract price, which might be so low that not a single remaining supplier is ready to deliver at this price. The tender process must then be repeated with no guarantee that the next outcome will be any better.

The critical mass of bulk purchasing means that poor tender designs can have negative effects in the long term. In other words, under bulk purchasing, the trade-off between low prices achieved by a given procurement system today and the potential long-term risk of having fewer pharmaceutical products with which to treat patients in the future must be recognised (Bergman et al., 2015). An example of failure to ensure such balance is offered by the experience of NHS England on the market for prosthetics. In the early 2000s, annual tendering was replaced by three-year contracts with an option to extend for two more years. This change was aimed to reduce administrative costs related to more frequent tenders. Early on, these much longer contracts were seen as highly desirable for suppliers. It was not long, however, before suppliers and NHS buyers started to recognise that bulk purchasing (34 procurement centres tendering together) made suppliers more vulnerable. If a supplier did not win a contract, it was a long time (up to five years) before another significant opportunity arose to win business. This increased firms' incentives to cut their bid price to win business, just to maintain turnover. Eventually, only one firm survived the "race to the bottom", effectively creating a monopoly on the prosthetics market (Caldwell et al., 2005). Similarly, bulk purchasing combined with irregular tendering patterns locked suppliers of generics out of the market in Denmark, France and Sweden, seriously harming competition in the long term.

3.3. Policy solutions to improve procurement systems' performance

Better information is essential for improving procurement system performance

Solutions at a national level are becoming progressively harder to find, especially given the global nature of the pharmaceutical industry. Hence, countries should engage in dialogue regarding future policies addressing the complex societal challenges of high medicine prices. The global character of the market also means that all countries face the same challenges, so consideration should be given to sharing information about actual prices paid for pharmaceuticals. As discussed earlier, price comparisons, especially between countries, are difficult since official prices do not include rebates offered by manufacturers in exchange for non-disclosure agreements. This and the large differences in official list prices suggest that governments relying solely on external price referencing (EPR) in procurement are likely to overpay for pharmaceuticals and other medical supplies

depending on which countries are included in the EPR. And those governments that use EPR as a starting point for negotiation of discounts should ask themselves whether the discounts they obtain are meaningful in light of other countries' discounts.

Countries should try to more systematically capture and publish data on price variations within their territory. Such information will automatically pave the way towards more collaborative forms of procurement. For example, in 2014 NHS England launched the *Procurement Atlas of Variation* to deliver greater transparency by comparing prices paid by different hospitals for the same types of products. At present, the *Atlas* covers more than 500 product lines, predominantly medical devices and simple supplies. The aim is to allow buyers as well as suppliers to understand how they could improve performance (Box 4.3).

Box 4.3. **The NHS England Procurement Atlas of Variation**

In 2014, NHS England created the online *Procurement Atlas of Variation*. The *Atlas* shows differences in the amount hospitals pay for everyday items such as catheters, gloves and needles. The aim behind the *Atlas* is to help hospitals compare prices and identify where they need to drive down costs so they can release resources and invest more in patient care.

The *Atlas* contains data on products purchased through the NHS Supply Chain and the Crown Commercial Service – voluntary procurement collaborations that offer their members the option to purchase through framework contracts. The *Atlas* will also contain products from other sources in the future. The price information within the *Atlas* is for product lines, which contain multiple products – it is possible to see which products each line contains and which units were used to express the price. An extensive normalisation of unit price data ensures that prices are comparable. The portal includes detailed information on the methodology used.

Initially, the *Atlas* covered 100 product lines; at present it covers more than 500. Users can create interactive maps with hospitals color-coded according to the price they paid for each product line as well as overall performance on all products. Estimates of annual potential savings are also readily available.

Another successful example of benefits associated with increased transparency in pricing is the price disclosure policy implemented in Australia in the market for off-patent pharmaceuticals (including generics). Price disclosure requires suppliers of medicines listed on the F2 formulary (which consists of drugs with at least one competitor) to disclose information on sales revenue and incentives offered to community pharmacies to preferentially dispense their product. This information is used by the Pharmaceutical Benefits Scheme (PBS) –the Australian government's agency responsible for supplying/subsidising medicines to publicly insured patients – to work out the true average market price at which pharmacies are reimbursed for medicines dispensed to patients. Price disclosure now applies to approximately 350 drugs. Market price disclosures occur on 1 April and 1 October each year. The price disclosure programme resulted in significant price reductions and the consequent savings to the PBS are estimated to reach AUD 20 billion by 2019-20.

Various organisational changes can improve procurement

Moving towards collaborative procurement can help reduce prices. Consolidation of purchases through larger collaborative forms of procurement at regional, national and ultimately international level can help to reduce prices (Caldwell et al., 2005). Consolidation can support favourable agreements such as price-volume contracts, with free goods, or with further discount prices, triggered if an agreed volume threshold is passed (Kastanioti et al., 2013; Baldi and Vannoni, 2015; Sanderson et al., 2015). Consolidated purchase help payers transform into savings the surplus that might otherwise have benefited wholesalers and retail pharmacies (Box 4.2).

Collaborative forms of procurement can reduce not only unit costs per product but also the per transaction cost due to the reduced number of contracts to be negotiated, prepared and managed. In other words, elimination of unnecessary duplication of procurement activities by individual buyers leads to additional savings. Last but not least, large volume effectively serves as a tool for ensuring supplier compliance with terms of contract – suppliers have too much to lose in case of contract breach.

Moreover, collaboration allows for knowledge building, be it pooling of market information and experience with past purchases or greater ability to manage stocks effectively and attract expert staff. Collaboration facilitates dissemination of efficient standards and improved practices as well as collection of information on, e.g. supplier performance and product quality, which in turn supports more comprehensive valuation of contracts.

Section 1 mentioned the cases of Greece and Mexico, where the transition to centralised procurement contributed to considerable savings as compared to the budget planned based on the performance of the former decentralised systems. Until 2007, the procurement function of the Mexican Institute of Social Security (IMSS) was embedded in 60 separate entities. IMSS's gradual centralisation efforts resulted in price reductions for pharmaceuticals and other medical supplies: between 2007 and 2010, cumulative savings of USD 2.8 billion were realised due to improved stock management and creation of a centre of excellence in procurement, which currently serves all public health care stakeholders in Mexico (OECD, 2013a). In Greece in 2010, the government undertook efforts to unify the annual tenders for hospital pharmaceuticals and medical devices. In the first year of operations, the centralised agency – the Health Procurement Committee (EPY), comprising only 26 employees – reported a 10% overall price reduction for pharmaceuticals and a 20% price reduction for selected medical devices. Additionally, payment times were significantly shortened (previously exceeding three years on average) and stock management improved, allowing for transfer of redundant stocks between hospitals (Kastanioti et al., 2013).

In 2010, all 13 provinces and territories of Canada established the pan-Canadian Pharmaceutical Alliance with the aim of conducting joint procurement of pharmaceuticals. As of 2015, these collaborative efforts contributed to an estimated CAD 490 million in combined savings annually (Council of the Federation Secretariat, 2016). In the United States, the Marketplace@Novation purchasing alliance, including over 2 500 health care organisations, is another example of centralisation leading to increased procurement effectiveness through structural improvements and economies of scale. A study of 31 hospitals showed that each hospital saved USD 12 million annually by joining the alliance, particularly thanks to lower prices for pharmaceutical items, as well as by lowering transaction costs through commonly negotiated contracts (Derek et al., 2008).

Other countries such as Denmark, New Zealand and Norway can be considered veterans of collaborative procurement. Since 1993, PHARMAC, the New Zealand government agency, has been the sole purchaser of publicly funded pharmaceuticals. According to estimates, based on pharmaceutical prices in 2005 mapped onto actual prescribing activity, joint procurement allowed for cumulative savings of about NZD 5.1 billion between 2005 and 2015, including about NZD 1.9 billion in 2014-15 (PHARMAC, 2015). For more than two decades, Denmark and Norway have both operated single procurement agencies for hospital pharmaceuticals (including pharmaceuticals for home therapies) and report significant annual savings, ranging from 30% to over 60% compared to list prices or average wholesale prices in a group of neighbouring countries.

As illustrated by Figure 4.2, collaborative procurement is an option to be exploited at the international level. It is becoming progressively harder to find satisfactory solutions at national level in a strong, global market. Countries need to work together to continue effective management of medicine costs. Greater co-ordination between countries can result in greater volume discounts and reduce repetition of tasks at national level. Barriers such as variation of reimbursement processes between countries and different willingness-to-pay thresholds make joint purchasing difficult and experience with common procurement of medicines is currently limited. Issues also arise in terms of different packaging, labelling and indications for use that would affect joint procurement. However, this should not preclude countries with similar characteristics from pro-active collaboration on strategic procurement, within the limits of what current regulations allow (especially for EU countries).

Improving system responsiveness through better communication and e-procurement tools reduces waste. While procurement is largely perceived as payer-driven, be it a government or a private insurer, physicians must be at the heart of decision making (IMS Institute for Healthcare Informatics, 2016). Successful collaboration is much more than just bundling of similar purchases. It requires a well-thought-out design that ensures all relevant actors (notably clinicians) at hospitals, nursing homes and pharmacies are equally involved and understand the collaborative process. In an ideal situation, collaboration should be organised well enough to attract members without forcing them to participate (Schotanus and Telgen, 2007).

In other words, a successful collaboration performs well not just on volumes of purchase but also in terms of system responsiveness. Some centralised procurement systems with mature operating practices deliver the benefits of economies of scale without compromising system responsiveness (e.g. Denmark and Norway). Notably, these mature collaborative procurement agencies are based on voluntary participation; i.e. they do not have any legal tools to influence member hospitals' decision making. Their success appears to be linked to the fact that clinicians remain at the heart of decision making. In consequence, these collaborations are leaders in strategic selection of preferred suppliers (within a class of therapeutic products), which not only induces price competition but also facilitates rapid and large-scale adoption of generics and biosimilars (Box 4.4).

The multitude of collaborative forms as well as the fact that majority of them are voluntary is the result of countries addressing differently the need for communication, transparency and participation. These collaborative procurement systems reflect a trend towards strategic, evidence-based procurement as well as professional development and specialisation of procurement personnel. Rather than being a slow bureaucratic machine,

Box 4.4. **Norwegian Drug Procurement Co-operation (LIS)**

LIS was established in 1995 by public hospital enterprises including 80 hospitals as of 2016. LIS administration consists of six fulltime-equivalent employees. In each of the 80 hospitals, one contact person is designated to liaise with LIS. The organisation includes an expert committee with medical, pharmaceutical and procurement professionals – its five members meet several times per year. The committee provides advice on the criteria used in selection of products. Moreover, LIS works closely with boards of experts in relevant medical specialties, including members of the Norwegian Medicines Agency and patients' representatives. LIS activities are financed through annual fees paid by each member hospital – EUR 1 million in 2015. Hospitals' participation in the co-operation is voluntary. Nevertheless, all public hospitals are members of LIS.

LIS administration manages tenders and negotiations as well as the resulting agreements with suppliers. In 2016 LIS is managing 7 400 agreements. The agreements have a form of framework contract through which individual hospitals can but do not have to purchase medicines. Hence, LIS does not commit to buying any predefined volume of products. In each therapeutic class LIS issues non-binding recommendations on preferred products/suppliers. All the same, hospitals follow LIS recommendations and only with rare exceptions do they buy outside the framework contracts.

The range of medicines purchased by LIS gradually expanded and now includes a number of high-cost oncology drugs, hepatitis C drugs, growth hormones and immunostimulants, which are usually in the domain of medicines paid for from a separate government/health insurance budget and not hospitals' budgets. In 2015, the total value of the purchased hospital medicines exceeded EUR 800 000 million, with an average volume-related discount of 30.4% compared to list prices in neighbouring countries or to the average wholesale price.

How does LIS manage to obtain such sizable volume-related discounts despite the voluntary character of the co-operation and the non-binding recommendations on preferred suppliers? The answer seems to lie in its highly specialised procurement team and its maintenance of very close operational links with clinicians. Notably, clinicians have detailed insights into both clinical- and cost-related factors that are taken into account in the selection of suppliers. For LIS, involving clinicians and trusting them to make the right decisions is a key component of ensuring the collaboration's longer-term success. Thanks to this truly co-operative process for supplier selection, LIS's recommendations are followed, effectively leading to high-volume purchases from preferred suppliers and triggering the discounts.

The involvement of clinicians and transparency of the procurement process are reinforced through regular seminars during which LIS and hospitals' representatives meet the industry in the presence of media. The seminars have an academic character with regard to presentation of information and discussion on efficacy and cost-effectiveness of medicines. Both clinicians as well as competitors can challenge the presenting manufacturers. Seminars' outcomes are widely publicised and the culture to follow them is very well-developed among medical professionals. LIS also organises less formal seminars for representatives of collaborating hospitals to exchange experience on products and past purchases.

they belong to a different category of innovative solutions with low personnel costs (e.g. 6 employees in Norway, 20 in Denmark, 26 in Greece), and evolve continuously to address the increasing complexity and dynamics of the medical goods market.

Moreover, a collaborative procurement system requires efficient communication between individual units and the group. The most obvious is communication of requests for supplies, which are initiated at the individual unit level and from there communicated to the level of the system dealing with suppliers. In a fully centralised system, this usually involves an intermediate entity at the regional level. Keeping in mind that before organising a call for a tender or engaging in negotiations with suppliers a central procurement agency or regional purchasing group will likely explore the possibility of standardising similar requests, communication also flows back to each individual provider/hospital for appropriate alternations. Indeed, the need to communicate requests creates an additional stage(s) in the procurement process. Hence, it is crucial that these additional stages are not hurdles.

Tools facilitating collaboration and communication are e-procurement platforms and standards such as Common Vocabulary Codes (CVC), which assign a unique code to each product, ensuring that members of the collaboration use the same language when formulating their orders. E-procurement must be user-friendly; optimally it should have a "one-stop-shop" character, allowing for easy, fast completion of necessary steps and collection and revision of all necessary documents in one place. It should also increase transparency on spending to allow for identification of improvements and additional opportunities to save (Karjalainen et al., 2008).

Advanced contracts and tenders minimise prices while ensuring long-term economic sustainability. Collaboration in procurement allows going beyond the initial advantage connected with economies of scale alone to building expertise to address the increasing complexity and dynamics of the medical goods market. By pooling financial, administrative and human resources, collaborating buyers can afford to design and negotiate innovative contracts and tenders.

Procurement contracts, when tailored to fit a given market situation, increase value for money

To maximise both short- and long-term savings, procurement strategies need to move away from "one-size-fits-all" contracts to more sophisticated procurement tailored to fit a given market situation. For example, the Danish hospital procurement agency AMGROS adopted a product lifecycle-dependent procurement strategy. The agency performs a separate detailed analysis of the market situation for each product. The analysis defines six main categories of products depending on their market situation: single-source medicines; other monopolies; analogue competition between two or more patent-protected medicines; generics competition; market segments with decreasing number of suppliers; and market segments with supply shortages. For each product category, different primary procurement instruments apply, optimising the outcome of the process (AMGROS, 2016).

It is particularly important to recognise and distinguish between opportunities to induce different situations of product competition: competition between two or more equivalent patent-protected products; competition between originator and generic products; and competition between generic products and patent-protected products in the same or related therapeutic class. And as mentioned earlier, to stimulate competition in any of these situations, clinicians must be on board. In other words, if disagreements exist among physicians or between the procurement agency and physicians on whether the products are truly equivalent, the choice of preferred supplier will not be supported. The Norwegian Drug Co-operation (LIS) provides a good example of ensuring clinicians'

participation (Box 4.4). Similarly, in Denmark, AMGROS co-operates with the Danish Council for the Use of Expansive Hospital Medicines (RADS) that issues statements on whether given products are fully or partially substitutable (for example, whether biologics can be substituted by biosimilars and whether this can be done for all patients or only for those who start a given therapy).

Contracts should not only focus on the unit price but also reflect patient outcomes and total costs of care. A growing number of countries –particularly the United Kingdom and the United States – have experimented with innovative outcome-based procurement contracts for medicines in which the price of a therapy depends on patient outcomes. However as mentioned in Chapter 2, data on patient outcomes are not readily available and countries are still learning how to collect and use these data in a systematic manner. Consequently, many of these initiatives are deemed ineffective. Another reason behind the scepticism is the challenges encountered in enforcing suppliers' compliance with the terms of the contracts, particularly when it comes to clawing funds back in the absence of desired outcomes – as experienced by NHS England (OECD, 2016).

While it is indeed true that administration of outcome-based contracts requires additional resources, it is too early to discard them as too costly or too difficult to enforce, considering the current state of evidence (Kesselheim et al., 2016). Moreover, implementation of these contracts appears to have suffered from the same communication problems at the interface between procurement teams and clinicians, as discussed in the previous section. It is possible that physicians do not have enough insight into factors behind the choice of these contracts, and hence do not universally support collection and reporting of the required outcome data.

The use of outcome-based contracts could start with simple medical supplies such as gloves, wound care products or intravenous (IV) catheters. For instance, if a nurse can spend much less time dressing a wound because of an easy-to-use wound care product, the equivalent savings should be factored in the procurement decision. A recent report on procurement of medical devices highlights an example of low-cost IV catheters that broke easily, required considerable amount of time for proper handling by clinical staff, and posed a safety risk to staff (BCG and MedTech, 2015). Yet the extra personnel costs associated with the purchase of these products were not accounted for since they did not affect the procurement department's budget.

Tender design helps attract and retain reliable suppliers

The three cornerstones of efficient tendering are: binding bids; a mechanism for setting the tender price that incentivises manufacturers to reveal their real costs of production; and appropriate selection of the number of suppliers. The latter is particularly important for preserving the right balance between short- and long-term savings (OECD, 2013b).

Reliable suppliers are a cornerstone of effective procurement. While supplier reliability should not be strictly determined by the tendering techniques used in a given market, some practices are not desirable, such as non-binding bidding. In particular, in connection to tenders being awarded to a single lowest bidder, leaving the winner the option to withdraw exposes the system to additional risk of fluctuation in product availability. Bidding should be binding, meaning that the supplier that wins a tender must fulfil the contract according to the conditions set through the tendering procedure. A supplier may still not fulfil the contract. In this event, a procedure should be in place to effectively prevent unreliable suppliers from participating in tenders in a given market.

It is also not trivial to design an auction with an outcome that balances the interests of both buyers and suppliers. Each tender relies on a chosen auction mechanism in which participating suppliers reveal their prices and the final contract price is settled. As discussed in Section 3.2, the simplest lowest bid auctions might create shortages of supplies or induce suppliers to exit the market. An auction with good design properties is one that encourages suppliers to reveal their true costs but at the same time allows them to earn competitive revenue (Box 4.5).

Box 4.5. **Cornerstones of good tender designs: Alternative mechanisms for setting price**

An auction with good design properties is one that encourages suppliers to reveal their true costs but at the same time allows them to earn competitive revenue. The Vickrey-Clarke-Groves (VCG) auction mechanism offers high potential to achieve such an outcome. In a VCG auction the contract price is determined by *the first excluded bid*, as opposed to an auction in which the price is determined by *the value of the lowest bid* or *the mean value of the three lowest bids*. In other words, a VCG auction sets the price at the value of the fourth lowest bid, which is the first excluded bid. However, only the suppliers who submitted the three lowest bids are offered the contract. This creates an incentive for suppliers to make offers that reveal their true costs of production, so as to be included in the group of contract winners. At the same time, suppliers receive a guarantee that the contract price will actually be set above their costs and that they will be able to make reasonable profits.

The choice of the number of winners can have long-term implications for a given market segment. Awarding the entire volume of a contract to a single winner for a longer time period might lead to significant short-term savings that dissipate over time. This is due to market exit of other suppliers and the associated reduction in price competition in following years (Bergman et al., 2016). For example, Denmark, similar to other small countries such as Hungary, experienced product shortages and monopolies even in the generics market due to market exit of suppliers. A strategy based on tenders with two winners (split awards) kept multiple suppliers in the market to bid in the next round of tenders and provided insurance against failure to supply by one of the winners.

Any procurement system that splits tender awards routinely risks so-called "bid rigging" – a practice in which two or more suppliers agree beforehand what bids will be offered, with the realisation that all will benefit from a share of the pie. Hence, bid splitting is mostly advocated in countries making one huge annual purchase. Otherwise, instead of splitting the awards, countries can award a contract to a single bidder but increase the frequency of tenders to monthly or quarterly intervals. This limits the potential for adverse effects, such as non-winning bidders leaving the market, and prevents bid rigging. Sweden successfully implemented use of monthly tenders, while Hungary resorted to quarterly tenders. Again, clinicians' involvement is the necessary factor behind the success of such a strategy. Short-term tenders lead to a high turnover of products within a therapeutic class, which might cause confusion and unnecessary frustration if administering/prescribing doctors do not anticipate them or do not have sufficient insight into the reasons for such changes.

Conclusion

Pharmaceuticals account for a significant share of overall health care expenditures across all OECD countries (Belloni et al., 2016). Yet as discussed in this chapter, a share of the spending on pharmaceutical does not add value for patients. These instances result from suboptimal decisions of clinicians and patients, organisational shortcomings and outdated regulations.

- An enormous value of unused medicines and other medical supplies are unnecessarily discarded due to redundant repeated prescriptions, patients' non-adherence to the prescribed course of treatment, and shortcomings in hospitals' management of stocks.
- The potential to free up financial resources through the use of generic drugs is often not fully exploited – the share of generics in pharmaceuticals covered by basic health benefits varies between 10% and 80% in OECD countries.
- Large unexploited potential similarly exists in the market for biosimilars – estimates for five European countries and the United States suggest that savings could reach EUR 50 billion by the end of 2020.
- Between- and within-country price variations are striking and at least partially unwarranted; for example, the price of a simple patient wristband differs by a factor of two between trusts in NHS England. And in 2015, differences in ex-factory prices for a number of cancer drugs were as much as 388% between the highest- and lowest-priced country among a sample of 18 OECD countries.

Within the complex pharmaceutical market, a number of opportunities to reduce spending on pharmaceuticals remain unexploited. This chapter highlights those opportunities. The actions policy makers can take derive from the standard toolbox of policy interventions: behaviour change, economic incentives, regulation and systematic collection and use of information.

Regarding unnecessarily discarded pharmaceuticals and other medical supplies, solutions include empowering patients and improving their communication with clinicians, the same behaviour change tools advocated to address clinical waste.

When it comes to the foregone opportunities to increase penetration of generics and biosimilars in the market, a wider range of actions should be taken, starting with improving regulation of market entry for generics producers, through amending price regulation, to convincing clinicians and patients of the therapeutic equivalence of generics and the original branded products. Almost a half of OECD countries use at least one policy tool to achieve these objectives and their experience is encouraging. Those countries lagging behind have no reason not to follow this path.

Procurement is perhaps the most complex domain of inefficient spending, but at the same time it most likely offers the highest potential for releasing resources for better use. Procurement organisations frequently fail to exploit all options left to them to build market power that matches that of international manufacturers. By consolidating purchases and transforming procurement from a merely administrative function into a strategic tool for price setting, health care systems could release additional resources and expand treatment options to larger groups of patients.

Experiments with value-based contracts illustrate that procurement can be used as a lever for change, promoting the departure from price- or volume-based to value-based health care financing. In other words, addressing operational waste in procurement could simultaneously contribute to curbing wasteful clinical care.

Notes

1. Given the focus of this report on waste, the question of how to price innovations in relation to their benefit is not explored. It is, however, a core topic of the second background report to the 2017 Health Ministerial, "Managing New Technologies in Health Care: Balancing Access, Value and Sustainability" (NOTE THIS IS PROVISIONAL TITLE WILL NEED CHECKING AT LAST MINUTE).
2. *www.ameli-sante.fr/apnee-du-sommeil/le-traitement-de-lapnee-du-sommeil.html*, accessed 06/10/2016.
3. The word "generics" refers here to generics of small molecule medicines as opposed to biosimilars of large molecule (biologic) medicines.
4. For certain indications, third-party insurers also pay for selected OTC medicines in some countries. Yet in such cases a prescription is required to justify the reimbursement and the OTC medicines effectively become prescription medicines.
5. Although the selection of drugs and coverage decisions have a budget impact and can be strategically managed to keep expenditure down, these activities are unlikely to be intrinsically wasteful.
6. *http://ccgtools.england.nhs.uk/procurement/ProcAtlasOctober2014/atlas.html* (accessed 17/05/2016).

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PART II

Chapter 5

Addressing operational waste by better targeting the use of hospital care

by
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This chapter analyses a type of operational waste that consists of using more expensive than necessary inputs. The focus is on three prominent examples of wasteful use of hospital care: unnecessary hospital attendances; inefficient processes within hospitals; and delays in discharging patients. The chapter examines the extent and main drivers of unnecessary hospital use in OECD countries, and assesses whether certain services can be safely shifted from inpatient hospital care to less intensive care settings. Associated policy reforms are then analysed in terms of their effectiveness and ease of implementation, drawing from selected country experiences. Many of these policies are based on organisational reforms that: ensure that primary and community care options are available in the right place at the right time; offer better primary care services within hospitals; and improve care co-ordination. The policy potential of carefully designed financial incentives and non-financial policy levers is also discussed.

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The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Introduction

Hospitals are a crucial component of every country's health care system, providing specialised and technical care that cannot be delivered in primary care settings. But this specialised nature means hospitals are also expensive to operate, with high personnel, equipment and other running costs. Indeed, spending on hospital inpatient care comprises an average 28% of total health spending in OECD countries (*OECD Health Statistics*). Analysing whether certain services can be safely shifted from hospitals to less intensive care settings is therefore important, since it would allow these services to be provided using less costly resources. Such a shift would also reduce the burden on often overstretched hospitals, thereby allowing them to reduce delays and focus on treating more complex illnesses. Ultimately, this could reduce the need for services requiring hospital-based delivery and/or allow their concentration in fewer highly technical facilities.

A well-established evidence base shows that hospitals are used more than is necessary to provide services needed by the population. That is, the treatment of patients with a number of prevalent diseases can be delivered safely and effectively at the primary care level. Indeed, primary care strengthening has been globally recognised as a means to improve health care system performance for many years, and at least since the 1978 Alma-Ata Declaration (WHO, 2008). Effective treatment at the primary care level could replace a substantial share of the workload in emergency departments (EDs) and avoid hospitalisations for long-term (chronic) conditions without requiring fundamental restructuring of health care delivery. Furthermore, significant scope exists to improve efficiency within hospitals. For example, an increasing number of minor surgeries can be safely performed on a same-day basis (in hospitals or specialised outpatient clinics) without the need for an inpatient admission. Indications also suggest that some patients are discharged from hospitals with unnecessary delays.

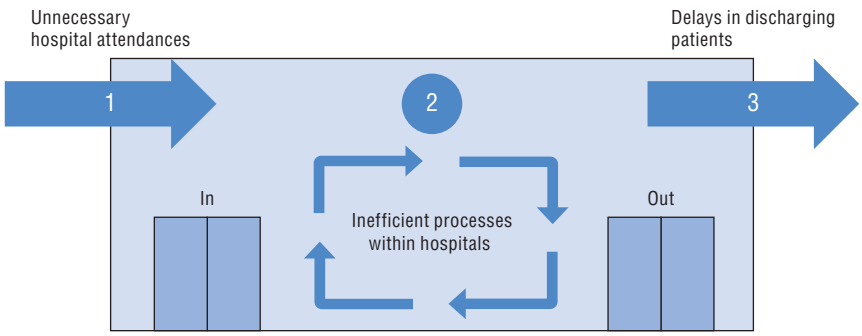
Better targeting the use of hospital care is therefore at the core of reducing operational waste. By reforming service delivery approaches, costly inputs can be used more efficiently or replaced by less expensive ones, offering substantial cost savings without any adverse impacts on the quality of care. Referring back to the framework presented in Chapter 1, facility-level managers and macro level administrators play a key role in addressing this type of waste by tackling shortcomings in organisation and co-ordination. Incentives are another powerful policy lever to which managers, administrators and clinicians might respond. Importantly, and in line with the overall scope of this report, many of the reform options do not require a profound transformation of the health care system. They are about incremental changes, such as changing where and how particular services are provided, rather than more fundamental questions about prioritising and reallocating resources from one category of patients or services to another. That is not to say reforms will be straightforward, but some options will be easier to implement than others. This chapter examines policy reforms in terms of their effectiveness and ease of

implementation, drawing from selected country experiences (Section 3). But before this, the extent (Section 1) and main drivers (Section 2) of unnecessary hospital use in OECD countries are analysed.

1. Wasteful use of high-cost hospital care in OECD countries

Unnecessary hospital use can broadly be grouped into three categories: unnecessary hospital attendances; inefficient processes within hospitals; and delays in discharging patients (Figure 5.1). This section examines the extent of the problems within each of these categories in turn.

Figure 5.1. **Categories of hospital overuse**



1.1. Unnecessary hospital attendances are widespread

A major driver of the overuse of hospitals is that many people turn up at hospital when they do not need hospital care. This often manifests as attendances at EDs for low-urgency problems that could be dealt with elsewhere in the health care system. A second group of hospital attendances is based on a genuine need for hospital care, but one that should have been avoidable, for example if a chronic condition had been better managed.

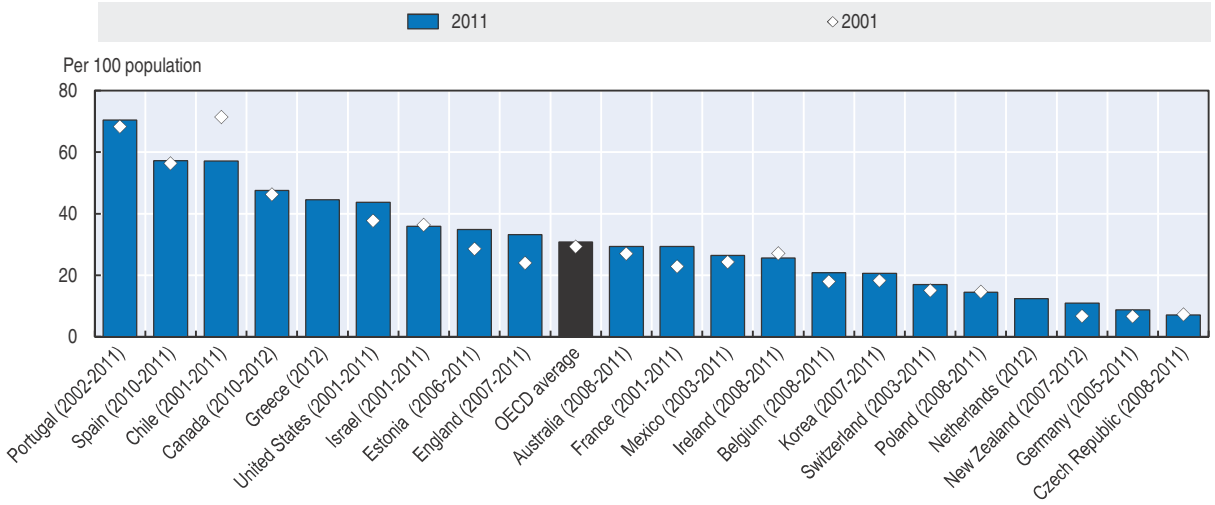
Unwarranted use of emergency services is costly and potentially harmful to patients

Injuries are the most common reason for using emergency services. In these cases, ED visits are necessary and appropriate. But many other ED visits are motivated by low-urgency problems that do not require emergency admissions. Such unnecessary visits could be avoided through better patient management in primary care settings or the community, whether by a primary care physician (PCP) or a broader primary care clinical team (McHale et al., 2013).

These ED visits can be costly and potentially harmful to patients. That is, they consume ED inputs and jeopardise the prompt treatment of more seriously ill patients. They also reduce the quality of care through prolonged waiting times and delayed diagnosis and treatment. Furthermore, they lead to overcrowding and disrupt patient flow within hospitals, which might adversely affect the quality of care.

The overall number of ED visits increased over time in 14 of 19 OECD countries for which data are available for more than one time period, reaching an average of 31 visits per 100 population in 2011 (Figure 5.2). The number of visits per capita was the highest in Portugal, with over 70 visits per 100 people. The number of visits to EDs was also well above the OECD average in Spain, Chile, Canada, Greece and the United States, with more than

Figure 5.2. **Number of visits to emergency departments per 100 population, 2001 and 2011 (or nearest year)**



Note: The OECD average includes 21 countries.

Source: Berchet, C. (2015), "Emergency Care Services: Trends, Drivers and Interventions to Manage the Demand", *OECD Health Working Papers*, No. 83, OECD Publishing, Paris, *http://dx.doi.org/10.1787/5jrts344crns-en*.

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40 visits per 100 people. At the other end of the scale, the Czech Republic, Germany, New Zealand, the Netherlands, Poland and Switzerland had fewer than 20 emergency visits per 100 people.

These figures represent overall ED visits. A number of studies further tried to define when ED visits were appropriate or not. These studies found inappropriate ED visits accounted for nearly 12% of ED visits in the United States and England,[1] 20% in Italy and France, 25% in Canada, 31% in Portugal, 32% in Australia, and 56% in Belgium. In Slovenia, current estimates show that more than 50% of ED visits are unnecessary. While these figures give a useful approximation of the scale of the problem, it is important to note that definitions and estimation methodologies are subject to debate and differ across countries, making cross-country comparisons difficult (Box 5.1).

Notwithstanding these definitional issues, the opportunity cost associated with inappropriate ED visits can be large. In England the cost of inappropriate visits was estimated at nearly GBP 100 million between 2011 and 2012 (McHale et al., 2013). In the United States, the New England Healthcare Institute estimated that overuse of EDs is responsible for around USD 38 billion of wasteful spending each year (NEHI, 2010).

Hospital admissions can be avoided for some long-term conditions

Ambulatory Care Sensitive Conditions (ACSCs) are conditions for which effective and accessible primary care can generally prevent the need for hospitalisation, or for which early intervention can reduce the risk of complication or prevent more severe disease (AHRQ, 2001). Diabetes, chronic obstructive pulmonary disease (COPD), asthma, angina, hypertension and congestive heart failure (CHF), bacterial pneumonia, dehydration, paediatric gastroenteritis, urinary tract infection, perforated appendix and low birth weight are all ACSCs with an established evidence base that much of the treatment can be delivered by outpatient care at the primary or community care level. Treated early and

Box 5.1. **Definition and criteria used to define (in)appropriate ED visits in selected studies**

Little agreement exists on how to identify and categorise inappropriate ED visits across OECD countries. As emphasised by the examples below, the criteria used to define such visits are diverse, ranging from the triage category to the need for tests or treatments, the need for hospitalisation or the possibility of treatment at a lower level of care. In part, this explains large inter-country variations in "inappropriate" ED visits. Some critics also express concern that the figures overstate the extent of the problem (Nagree et al., 2013).

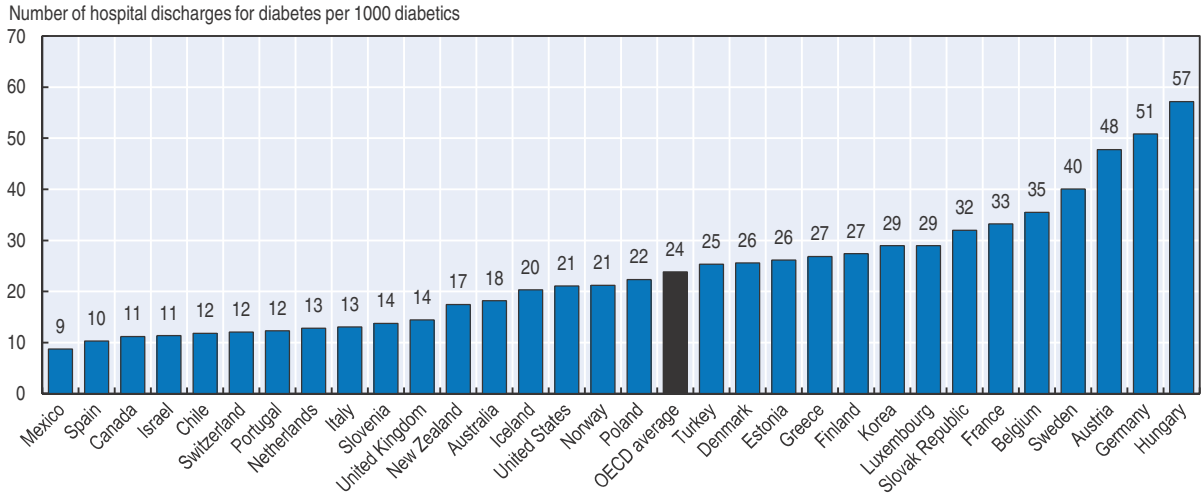
Australia – Source: AIHW (2013)	
Potentially avoidable presentations to EDs reflect the number of attendances at public hospital EDs that potentially could have been avoided through provision of non-hospital health services. They are defined as emergency presentations where the patient: i) was allocated a triage category of 4 (semi-urgent conditions for which assessment and treatment should start within 60 minutes) or 5 (non-urgent conditions for which assessment and treatment should start within 120 minutes); ii) did not arrive by ambulance, police or correctional vehicle; iii) at the end of the episode was not admitted to the hospital, was not referred to another hospital and did not die.	32.4% of ED visits are inappropriate
Belgium – Source: De Wolf and Vanoverloop (2011)	
ED visits are considered appropriate when the patient is referred by a general practitioner (GP) or by emergency helplines; when the patient is admitted to the hospital at the end of the episode; when the plaster room is used; when the patient dies on the same day; when it is a psychiatric emergency; or when child delivery is expected in the coming three months. Visits are considered inappropriate for all other situations.	56.0% of ED visits are inappropriate
Canada – Source: Afilalo et al. (2004)	
Inappropriate visits are measured as the non-urgent use of the ED. The Canadian Triage System (CTAS) is used to categorise non-urgent use. It corresponds to Code 5, which denotes a patient who can wait two hours before being seen by a physician. The condition may be acute but not urgent and may be part of a chronic problem but with or without evidence of deterioration. These patients could potentially be referred to and treated in primary care centres.	25.0% of ED visits are inappropriate
England – Source: McHale et al. (2013)	
Visits to EDs are considered inappropriate if the patient was self-referred; the attendance category was "initial ED attendance" or "unplanned follow-up"; the investigation code was "none" and the treatment code was either "none" or "guidance/advice only"; and the disposal method was discharge with no follow-up or discharge with follow-up from a GP. Visits to EDs are considered appropriate if the source of referral was any other than self-referred; the attendance category was "planned follow-up"; the attendance had a valid investigation code other than "none" or a valid treatment code other than "none" or "guidance/advice only"; and the disposal method was either admission, referral to clinic, transfer to other health care provider, referral to other health care professional or other.	11.7% of ED visits are inappropriate
France – Source: Cour des Comptes (2014)	
Avoidable visits result from patients seeking care for conditions that could have been treated in the community by the primary care system. The triage system, Classification Clinique des Malades aux Urgences (CCMU), is used to categorise avoidable visits. Patients falling under CCMU1 have a stable clinical condition for which it is not necessary to carry out additional medical tests.	19.4% Of ED visits are avoidable
Italy – Source: Bianco et al. (2003)	
An inappropriate visit to an ED is classified as a non-urgent visit according to the following criteria: the patient has no active symptoms or they were recent and minor; there is no feeling of emergency and the patient desires a check-up; and the patient seeks a prescription refill or a return-to-work release.	19.6% of ED visits are inappropriate
Portugal – Source: Pereira et al. (2001)	
An ED visit is considered appropriate if it results in patient hospitalisation; if death occurs in the ED; if the patient is transferred to another hospital; or according to explicit criteria based on specific diagnostic tests or treatment performed. Also if the visit requires imaging studies such as magnetic resonance imaging (MRI), ultra-sonographic studies, a computed tomography (CT) scan, and if treatment requires intravenous fluids, oxygen, prescription medications administered in the ED, transfusion of blood products, orthopaedic treatments, wound management (other than cleaning or bandaging minor abrasions), and removal of foreign bodies (in eyes, and digestive or respiratory tract). Visits are considered inappropriate for all other situations.	31.3% of ED visits are inappropriate
United States – Source: NEHI (2010)	
Avoidable ED use results from patients seeking non-urgent care or ED care for conditions that could have been treated and/or prevented by prior primary care.	12.1% of ED visits are inappropriate

Source: OECD Secretariat based on existing literature.

appropriately, acute deterioration in people with these conditions and consequent hospital admissions could be avoided (Purdy, 2010; Purdy et al., 2012; Longman et al., 2015; van Loenen et al., 2014).

OECD data show that avoidable admissions for diabetes, CHF, COPD and asthma are a concern in several OECD countries (OECD, 2015a). For example, in 2011 there were over 30 hospital discharges per 1 000 diabetics in seven OECD countries, with an average of 24 hospital discharges per 1 000 diabetics (among the 31 countries with available data). While a 0% admission rate is not realistic, international variation points to the potential for some countries to reduce hospital admission rates. Cross-country variations are nearly six-fold, with Mexico, Spain and Canada reporting the lowest rates and Austria, Germany and Hungary reporting rates at least twice the OECD average (Figure 5.3).

Figure 5.3. **Diabetes-related admissions per 1 000 patients with diabetes, 2011 (or nearest year)**



Note: The OECD average incudes 31 countries.
Source: OECD (2015), "Improved Control of Cardiovascular Disease Risk Factors and Diabetes: The Central Role of Primary Care", *Cardiovascular Disease and Diabetes: Policies for Better Health and Quality of Care*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264233010-7-en*.

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Potentially avoidable hospital admissions for other chronic conditions including asthma, COPD and CHF are also observed across OECD countries,[2] suggesting room for improvement in the quality of primary care. Although the majority of countries report a reduction in admission rates for these chronic conditions over recent years, avoidable admissions still put an important yet avoidable financial burden on health care systems (OECD, 2015a). For example, Tian et al. (2012) estimated that emergency admissions for ACSCs could be reduced by between 8% and 18% in England, producing savings of between GBP 96 million and GBP 238 million per year.

1.2. Inefficient processes within hospitals lead to unnecessary costs

Hospitals are complex organisations and their internal efficiency relies on the effective co-ordination of processes between multiple wards and across multiple professions. If processes are not well-designed, or if the right staff and the right equipment are not available when they are needed, then time and money can be wasted and patient care undermined. In general these problems are difficult to quantify at the macro level,

since the nature of the inefficiency may be different in each hospital. Approaches to identifying and eliminating inefficiencies are discussed later in this chapter. However, some widespread practices are known to be inefficient and can be monitored at a national level, such as admission of patients for minor surgeries that could be performed on an outpatient basis.

Many imaging, therapeutic and surgical procedures previously administered on an inpatient basis are now routinely administered on an outpatient basis. In many but not all OECD countries, oncological treatments and dialysis are primarily provided on an ambulatory basis, with superior clinical outcomes and better patient satisfaction. Data are not available to compare the range of services provided on an in- or outpatient basis across countries, with the exception of some routine minor surgeries. Advances in medical technologies, particularly the diffusion of less invasive surgical interventions and better anaesthetics, enabled their safe provision on a day-care basis for most patients[3] (OECD, 2015a), either within hospitals or ambulatory clinics. By shortening the treatment episode, same-day surgery can save important resources without any adverse effects on quality of care. It also frees up capacity within hospitals to focus on more complex cases or to reduce waiting lists.

A recent study investigating the 15 most frequently conducted surgeries in Austrian hospitals found a consistent evidence base for the following services to be safely and efficiently delivered on a day-case basis for most patients: arthroscopic knee surgery; cataract surgery; cholecystectomy (laparoscopic); repair of inguinal and femoral hernia; tonsillectomy/adenoidectomy; and vein litigation (stripping) (Fischer and Zechmeister-Koss, 2014).

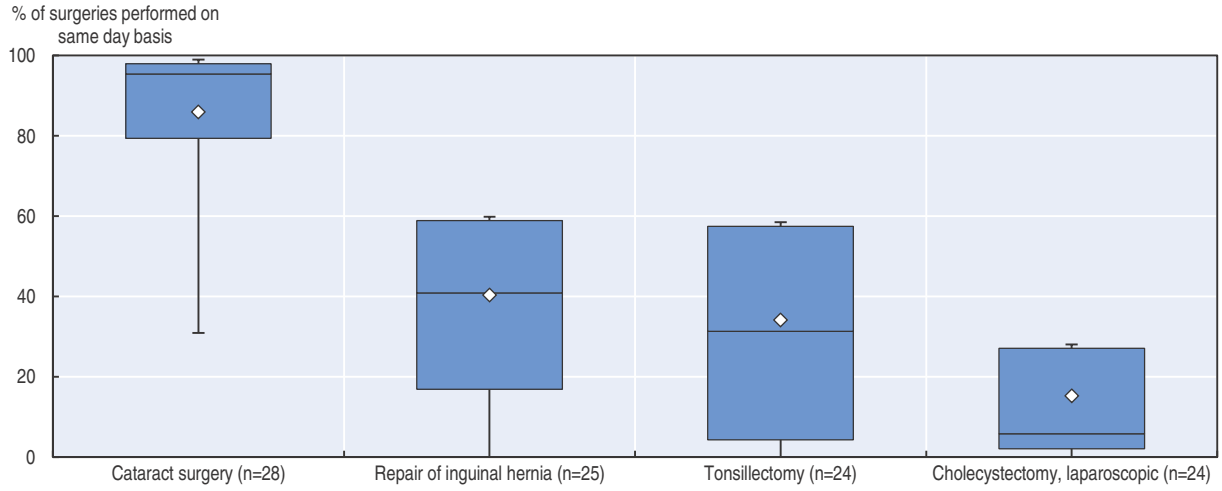
Data from OECD countries show wide variation in the share of minor surgeries delivered on a same-day basis, both across countries and for different types of minor surgery. For instance, while on average 86% of cataract surgeries are provided on a same-day basis, the rate varied from 31% to 100% across OECD countries (with an interquartile range of 79-98%). Average rates of same-day surgery for the repair of inguinal hernia (40%), tonsillectomy (34%) and laparoscopic cholecystectomy (15%) were considerably lower than for cataracts, with variation across countries particularly large for tonsillectomy (Figure 5.4).

Over time, the share of minor surgeries provided on a same-day basis increased in most countries. This reflects a number of factors, including improved surgical procedures and follow-up care, changing attitudes of health personnel, and the pressure from long waiting lists to speed up care. For example, for cataracts, same-day surgery in 2014 was higher than in 2000 for 22 of the 23 countries with available data, with increases particularly marked in Austria and Portugal. Nevertheless, same-day surgery rates remain relatively low in Poland, Hungary and Turkey (Figure 5.5). Similar patterns over time are observed for repair of inguinal hernia, tonsillectomy and cholecystectomy.

1.3. Delays in discharging patients from hospital are costly

Keeping people in hospital is expensive. In England, the Department of Health estimated the cost to National Health Service (NHS) England of each "excess bed day" – when someone is kept in hospital for an extra day without receiving further treatment – as GBP 303 in 2014-15 (Department of Health, 2015). Sometimes it is clinically necessary for people to stay in hospital, for example if they need to be monitored for a period before they can safely return home. When additional time in hospital does not help to improve outcomes, though, better value for money in the health care system could be gained by reducing excess bed days.

Figure 5.4. **Share of four minor surgeries carried out as ambulatory cases: Boxplots of OECD countries for 2014 (or nearest year)**



Note: Boxes represent the interquartile range, internal black lines the median, and white dots the mean, with outer lines minimum and maximum values.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

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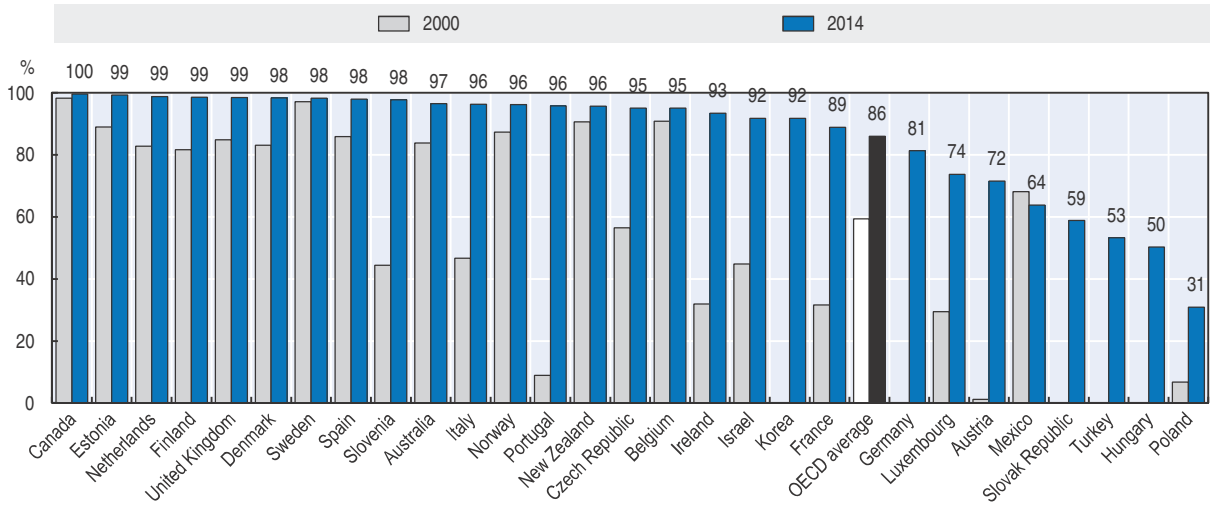
Figure 5.5. **Share of cataract surgeries carried out as ambulatory cases, 2000 and 2014 (or nearest years)**

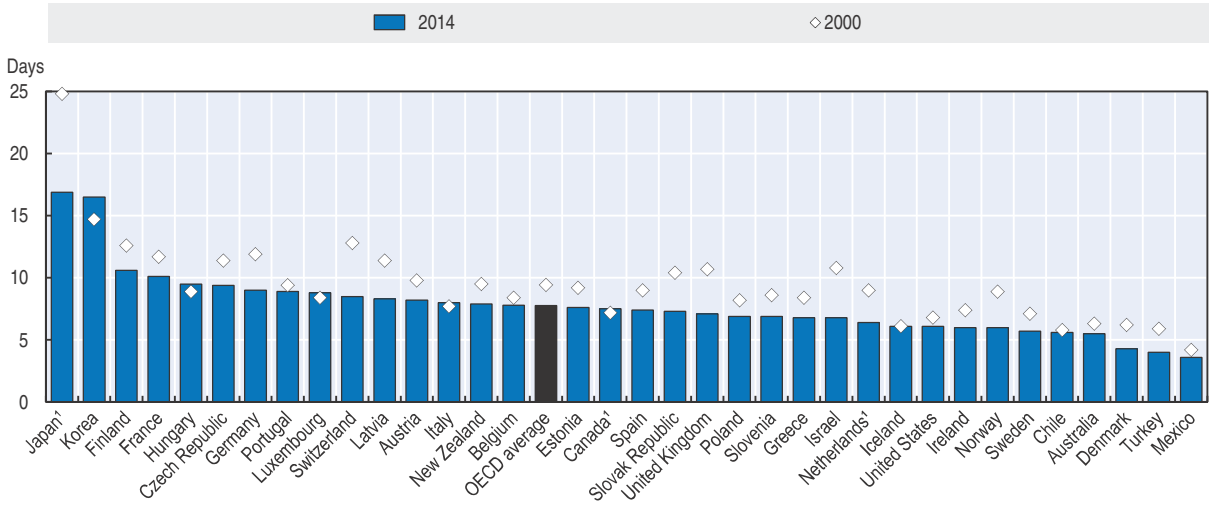


Note: The OECD average includes 28 countries.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444202

All OECD countries monitor the average length of stay (ALOS) of people admitted to hospital (Figure 5.6), and significant cross-country variation emerges. Patients admitted to hospital in Japan or Korea can expect to stay for more than 15 days, while those in Denmark, Turkey and Mexico stay on average fewer than 5 days. Variations in length of stay can be driven by a number of factors. Some of these are indicative of poor-value care: processes in the hospital may be inefficient, leading to delays in providing treatment; errors and poor-quality care may leave patients needing further treatment or recovery

Figure 5.6. **Average length of stay in hospital, 2000 and 2014 (or nearest year)**



1. Date refer to average length of stay for curative (acute) care (resulting in an under-estimation).
Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

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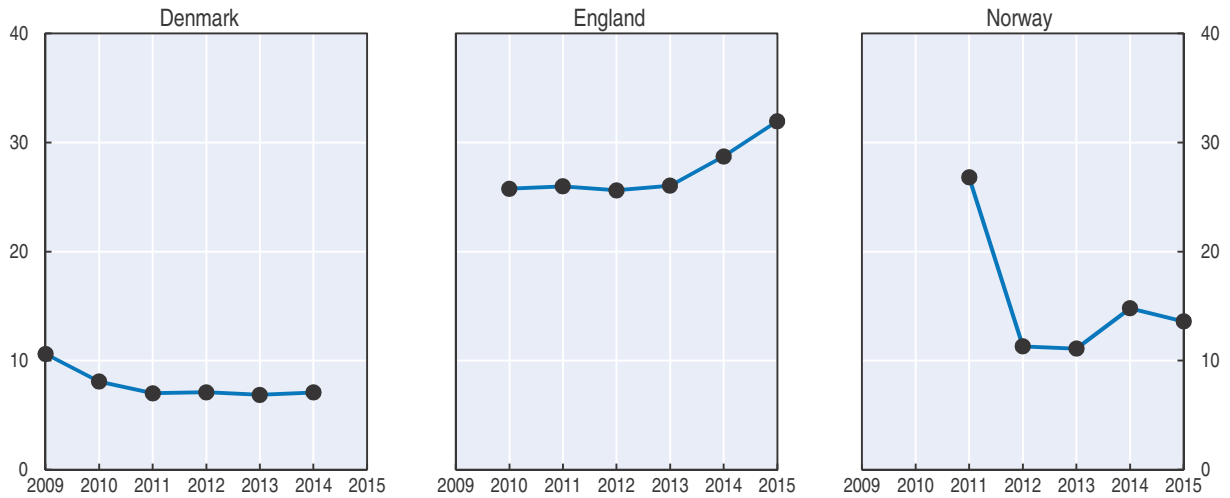
time; or poor co-ordination between different parts of the health care system may leave people stuck in hospital waiting for ongoing care to be arranged. Addressing these issues would save money through shorter hospital stays while potentially improving outcomes.

Shorter hospital stays may not always indicate more efficient use of resources. Some people may be discharged too early, when staying in hospital longer could have improved their outcomes or reduced their chances of re-admission at a later date. A better understanding of value for money per bed day could be reached by looking at data on outcomes alongside data on utilisation, but most outcomes can be affected by a range of factors and it is difficult to attribute them to differences in length of stay.

To get around these difficulties, some OECD countries (e.g. Canada, Denmark, Norway, Sweden and the United Kingdom) began to collect data on delayed discharges, one situation that clearly offers opportunities to improve efficiency. Once their treatment is complete, many people stay in hospital longer than is clinically necessary, for example because poor co-ordination between different parts of the health care system leads to delays in arranging ongoing health or social care services. By collecting data on delayed discharges, or delayed transfers of care – that is, by counting the number of days that people stay in hospital after a doctor declares them ready to be discharged – countries are able to isolate a use of hospital resources that has no clinical rationale and does not improve patient outcomes (Figure 5.7).

These data appear to show significant differences between countries: Denmark reports around 10 additional bed days per 1 000 population in 2014, while the equivalent figure for England is more than 30. Data may not be comparable across countries due to differences in how the indicators are defined. Changes over time within individual countries are more reliable and show some significant changes in recent years: Norway saw a sharp drop in delayed transfers between 2011 and 2012, while England saw a significant increase after 2013. Possible reasons for these patterns are discussed later in this chapter.

Figure 5.7. **Delays in transferring patients from hospitals in three OECD countries (total number of days per year per 1 000 population), 2009 to 2015**



Source: OECD analysis of data from NHS England, the Norwegian Directorate of Health and the Danish Ministry of Health. Please note that data from different countries may not be comparable.

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2. Drivers of hospital overuse

The drivers of wasteful use of hospital care are complex and interlinked. They range from behavioural factors for clinicians and patients to financial incentives misaligned with system objectives, and shortcomings in organisation and co-ordination. Specific factors include a lack of alternatives to hospital care (such as primary or community care); failures of co-ordination of care between hospitals and other settings; and patient preferences for hospital services over primary care.

2.1. Lack of access to alternative options is a key driver of unnecessary hospital use

Good accessibility is essential for primary care services to be an effective first contact point for individuals with the health care system. Yet timely access to primary care is not always the norm. Lack of access to primary care services is a key driver of unnecessary hospital use since it can result in patients rationally choosing to bypass primary care services.

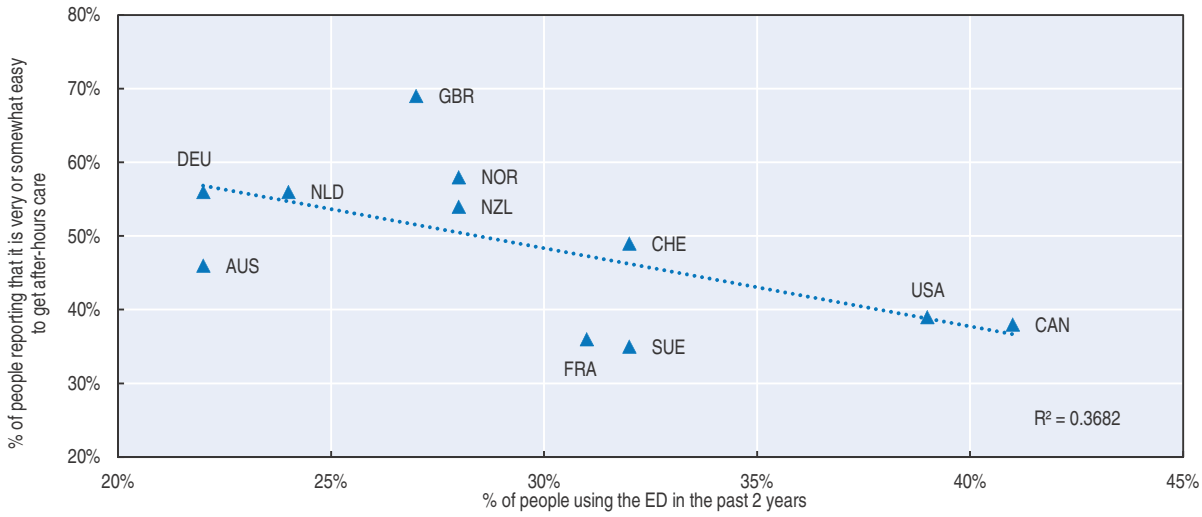
Having timely access to care means that primary care services can respond to patient needs 24 hours a day, 7 days a week. However, this is rarely the case. Recent OECD analysis shows that a significant proportion of patients in OECD countries face barriers to accessing their PCP either because of a lack of out-of-hours (OOH) services or because of long waiting times during normal office hours (Berchet, 2015; Berchet and Nader, 2016).

Such barriers not only lead to delays in care (and a consequent greater risk of health complications), but also higher ED visits and avoidable hospital admissions. Evidence suggests an inverse relationship between the ability of patients to access their PCP quickly and the likelihood of reporting an avoidable hospital admission. Indeed, access to primary care can reduce avoidable hospitalisation for chronic conditions (Ansari et al., 2006; Rizza et al., 2007). Conversely, poor availability to PCPs outside normal hours is the main cause of hospitalisation for ACSCs (Freund et al., 2013). A recent systematic review based on

49 studies shows that having a continuously accessible primary care system seemed to be more important in reducing avoidable hospitalisations than how primary care delivery is organised (van Loenen et al., 2014).

Timely access to primary care also seems to affect the use of EDs. Analysis of Commonwealth Fund data shows a negative association between access to OOH options for primary care and the use of EDs. For example, Germany and the Netherlands, where more people report easy access to after-hours care, have relatively fewer ED visits. In contrast, Canada and the United States display the highest number of ED visits and some of the lowest proportions of people reporting easy access to after-hours care (Figure 5.8).

Figure 5.8. **Comparing ease of access to after-hours care and the use of emergency departments**



Source: Based on data from the 2013 and 2014 Commonwealth Funds International Health Policy Survey.

StatLink http://dx.doi.org/10.1787/888933444232

Several other studies confirm this negative association. In Canada, 57% of patients presenting to an ED stated they would have consulted their PCP if one had been available at the time (Wong et al., 2009). In England, Cowling et al. (2014) found that 26.5% of unplanned hospital emergency visits in England were due to an inability to obtain a GP appointment. In France, Boisguerin and Valdelièvre (2014) showed that visits to EDs were the most appropriate solution for 11% of patients because usual sources of care were not available. In the United States, Gindi et al. (2012) concluded that about 80% of adults who visited an ED in the past 12 months did so because they lacked access to other providers.

Geography is another key driver of primary care access, with long travelling times costly and inconvenient for patients. Geographical access barriers are more common in rural and remote areas, particularly for OOH services. For example, evidence from Scotland and England found that patients in rural areas had fewer contacts and consultations with OOH primary care services compared to patients in urban areas (Campbell et al., 2006; Turnbull et al., 2008). Similarly, increased travel distance was associated with lower use of OOH services in Norway, even for the most acute cases (Raknes et al., 2013). Geographical barriers to accessing primary care have been associated with excess hospital admissions (Cunningham and Cornelius, 1995; Shah et al., 2003; Cloutier-Fisher et al., 2006), where sparsely distributed populations have higher admissions rates for ACSCs compared to their urban counterparts.

2.2. Poor co-ordination between hospitals and other settings can leave people stuck in hospital

A large proportion of delays in discharging people from hospital occur because ongoing health or social care services are not ready to receive them. In England, this accounts for around 60% of the additional bed days used as a result of delayed discharges (NHS England).[4] Delays in arranging ongoing care can arise for two reasons: either the necessary services do not exist or they are insufficiently co-ordinated with hospitals.

Many people – particularly older patients with more complex needs – require additional health care after leaving hospital to make a full recovery. Others need to be discharged into a residential long-term care facility, or may be able to return home safely only after community long-term services are arranged. This is only possible when the right types of services are available, and when these services have sufficient capacity to arrange care promptly when it is required. Committing insufficient resources to these types of services may lead to additional costs in hospitals: for example, a major driver of the rise in delayed transfers from hospitals in England is an increase in the number of people waiting for social care services, which have seen significant funding reductions.

Even when the right types and quantities of services are available, delays can occur when services are not well co-ordinated with hospital care. Poor co-ordination can be a cultural or institutional problem, but it is a particular risk when financial incentives are not aligned between providers. In many countries, hospitals bear the cost of any additional bed days resulting from delays, but efforts to reduce these costs rely on community health care and social care providers.

2.3. Inadequate quality of primary care services leads to excess hospital use

Inappropriate ED visits and avoidable hospital admissions are not just a question of access to primary care, but also relate to the quality of health services delivered within primary care settings. High-quality primary care services not only prevent the onset of disease, they can also control an acute episodic illness and effectively manage chronic conditions. The evidence is particularly marked for chronic conditions, where suboptimal monitoring has been shown to be a cause of preventable hospitalisation (AHRQ, 2001; FitzGerald and Gibson, 2006; Freund et al., 2013).

Indeed, the number of individuals living with multiple chronic conditions has increased in most OECD countries (OECD, 2011). Increased prevalence of chronic disease and higher levels of morbidity are positively associated with high rates of emergency inpatient admissions (Purdy, 2010). That is, more and more people have complex health needs that require more resource-intensive evaluation, which may not always be sufficiently available in primary care settings.

Yet appropriate ambulatory services that can be safely provided by a PCP or broader primary care team are underused. This results in deterioration of patients' health and increases the need for much more expensive acute care. For example, AHRQ (2001) shows that high-quality management of diabetic patients at the primary care level leads to reductions in almost all types of serious hospitalisations. Similarly, FitzGerald and Gibson (2006) found that optimal strategies to reduce hospital admission for asthma exacerbation include early introduction of anti-inflammatory treatment at the primary care level, coupled with a structured education programme that entails information, self-monitoring, regular medical review and a written action plan.

2.4. Individual preferences shape decisions to seek care at hospitals

Financial and non-financial demand-side factors contribute to explaining inappropriate use of hospitals. Demand for hospital services partly reflects the inadequate supply of alternative care, namely quality primary care services. In particular, patient preferences for seeking emergency care were traditionally high because a full range of medical services was often freely accessible 24 hours a day, 7 days a week (Durand et al., 2012). Availability of resources including medication, laboratory tests and radiography, access to technical facilities, and the opportunity to carry out specialist tests in one location, often without charge, are all rational reasons for patients to visit EDs rather than PCPs.

In addition, prices of hospital services may create incentives to direct patients towards one type of care over another. For example, co-payments for outpatient care create incentives to seek free care in EDs. This occurs in Greece and Portugal, where low-income populations bypass primary care in favour of emergency services, since hospitals are more likely to waive co-payments than primary health care clinics (Eurofound, 2014). More generally, Kringos et al. (2015) noted that co-payments are collected for PCP visits in 13 European countries (Belgium, Bulgaria, the Czech Republic, Finland, France, Iceland, Ireland, Latvia, Malta, Luxembourg, Norway, Portugal and Sweden), which could affect patient decisions on where to first seek care, although most PCPs apply exemptions for co-payments.

Socio-economic circumstances are another important demand-side factor. Poverty, minority status, low educational attainment and lack of social support are positively associated with excess hospital admissions and ED visits (Purdy, 2010; Purdy and Huntley, 2013; He et al., 2011; Uscher-Pines et al., 2013; Nishino et al., 2015). This relationship may be partly explained by the fact that poorer populations have higher levels of chronic illness, tend to engage in more risky health behaviours, and are less likely to have a regular PCP. Households facing difficulties in paying medical bills may also delay or forgo needed health care, which increases the risk of health complications and the need for more expensive secondary care. In England, for instance, people living in the most deprived fifth of neighbourhoods suffer nearly two-and-a-half times as many preventable emergency hospitalisations as people living in the least deprived fifth (CHE, 2016). These estimates indicate that social inequality was associated with almost 160 000 preventable emergency hospitalisations in England in 2011.

3. Policy levers to reduce hospital overuse

Many of the policy levers introduced by countries to reduce hospital overuse are about better organisation of services. Promising initiatives include policies that develop suitable alternative care, or aim to improve care co-ordination. Revisiting the role of health care professionals can also produce cost-savings, though such policies may require more transformative changes to how health care is organised. Alongside organisational reform, provider payment innovations, removal of financial barriers for patients in accessing primary care, and behavioural change through non-financial means show promise in encouraging better use of hospital resources. This section discusses these policies, focusing mainly on those that are more incremental in scope, rather than more transformative policies around system redesign.

3.1. Many actions can contribute to effective organisational change

Ensure alternative care options are available, especially through better access to primary care

Invest in out-of-hours primary care services. To limit inappropriate ED visits and avoidable inpatient hospital admissions, primary care services ought to be available at times that suit the population and for emergencies outside normal working hours. Investing in OOH primary care is an important way to achieve this. Due to the lower costs (both fixed and recurrent) of primary care centres compared with hospitals, such investments can save money as well as improve access.

Several models of OOH primary care exist in OECD countries, ranging from practice-based services and rota groups to deputising[5] services (Berchet and Nader, 2016). Recent OECD analysis shows a current tendency to shift OOH primary care towards large-scale organisations, such as general practice co-operatives and larger primary care centres. These service delivery models have been shown to improve timely access to appropriate primary care services and limit the inappropriate use of hospital care, while increasing patient and physician satisfaction (e.g. van Uden and Crebolder, 2004; van Uden et al., 2005, 2006; Giesen et al., 2011).

In Norway larger primary care centres act as intermediate care facilities ("Distriksmedisinsk senter" or "Sykesture" in Norwegian). Acting as a primary care emergency unit or a post-acute care unit, these facilities deliver non-urgent care and a mix of post-acute, rehabilitation and nursing care on a 24-hour, 7-day a week basis. They were specially established to strengthen primary care and curb hospital care costs by reducing unnecessary admissions (OECD, 2014). It is important to note that in some countries (Estonia, for example), small hospitals already operate as intermediate facilities. Another innovative primary care delivery model is the SOS Médecin network in France, which provides services for unplanned care, non-life threatening emergencies and medical assistance outside normal office hours. Created in 1966, the network has played an increasingly prominent role in recent decades. The association gathers volunteer PCPs and has its own telephone-based service. In most cases, it consists of home consultations by mobile physicians, but health facilities were recently developed. It is cost-effective for non-urgent conditions: the cost associated with a visit to a hospital ED (including transportation) is between five and ten times higher than the cost of a home visit from SOS Médecin (Guerin, 2012).

The United Kingdom is piloting seven-day opening of GP practices to improve primary care access for patients, especially during OOH periods. Recent results from Dolton and Pathania (2016) show that seven-day GP opening reduced ED visits, with a significantly larger drop on weekends. The reduction in ED visits is mainly concentrated in cases of moderate severity, and among elderly patients, with potentially significant cost-savings. Another recent study shows that offering seven-day extended access (including evening and weekend opening) to serve both urgent and routine appointments is associated with a reduction in ED visits in England (Whittaker et al., 2016).

Develop community care services. Community care centres (also called community health centres, health care homes, or rapid access clinics) provide an important source of primary care services for vulnerable populations, including frail elderly, those with chronic conditions, and people with low incomes. Evidence from various countries – Australia, Ireland, Italy and the United States –shows that community care centres successfully reduce ED visits and limit avoidable hospitalisation (Choudhry et al., 2007; Rust et al., 2009;

Purdy et al., 2012; Lippi Bruni et al., 2013). This reflects community care centres' focus on prevention, rehabilitation and chronic disease management. Developing community care services is also an important strategy for long-term care services (Box 5.2).

In Australia, 31 Primary Health Networks (PHNs) were established to better target the use of hospital care and reduce hospital overuse. PHNs improve interfaces between acute and primary care to: i) reduce potentially preventable hospitalisations and re-admissions and unnecessary use of EDs; and ii) improve care in the community. PHNs work with local hospital networks to develop better patient risk stratification tools to identify those requiring more comprehensive care. The overarching objective is to improve management of chronic diseases, including self-management and care pathways to reduce unnecessary referrals or duplication of services. The Australian government is also establishing Health Care Homes (HCH) to improve co-ordination of care for people with complex and chronic diseases.

Looking more closely at the United States' experience, patients visiting one of the 5 000 community care centres across the country saw improvements in health outcomes and were less likely to visit an ED. For example, in New York State users of community care centres had nearly 50% fewer ED visits than non-users. Overall, community care centres were estimated to generate a potential 30% saving per Medicaid patient by preventing avoidable ED visits (Choudhry et al., 2007). Patients served were typically low-income populations, uninsured individuals and ethnic minorities. The reduction of ED visits related to establishment of community health centres was particularly strong for uninsured patients (Rust et al., 2009).

Implement hospital at home. Hospital at home is an innovative initiative that offers patients the option of receiving hospital-level care at home for conditions that can be safely treated there. Hospital at home can act as a full substitute for acute hospital care or as a complement to hospitalisation after hospital discharge. It generally entails a multidisciplinary health care team (with nurses, social workers, physiotherapists, psychologists and other allied health professionals) with one care co-ordinator. Hospital at home is an effective alternative to inpatient care for a selected group of patients for whom a home environment can support treatment. It has the potential to reduce costs for patients requiring hospitalisation for conditions with well-defined treatment protocols, while improving patient safety, quality and satisfaction. New dialysis technology offers the opportunity for patients to receive haemodialysis at home, for example. With appropriate patient-training times and adequate support, home haemodialysis is a more patient-centred strategy to provide treatment than centre-based dialysis. Evidence also suggests that home haemodialysis offers cost-effective advantages compared with centre-based haemodialysis (Klarenbach et al., 2014).

Hospital at home is already largely developed in the United States. Evidence shows that providing hospital at home is not only cheaper but also leads to improved health outcomes, reduced mortality rates and increased satisfaction rates. Hospital at home patients have fewer re-admissions, lower mortality, reduced falls, lower costs and reduced spending compared to hospitalised patients with similar health conditions (Klein et al., 2016). France also took steps to develop hospital at home. Since 2005, the proportion of hospital at home patients has increased 160%. Implementing hospital at home is considered a national priority; development of home-based dialysis is an important objective of France's 2015-17 health strategy. By 2018, the share of hospital at home is expected to reach 1.2% of the total volume of hospitalisation.

Box 5.2. **Reducing the overuse of expensive long-term care settings**

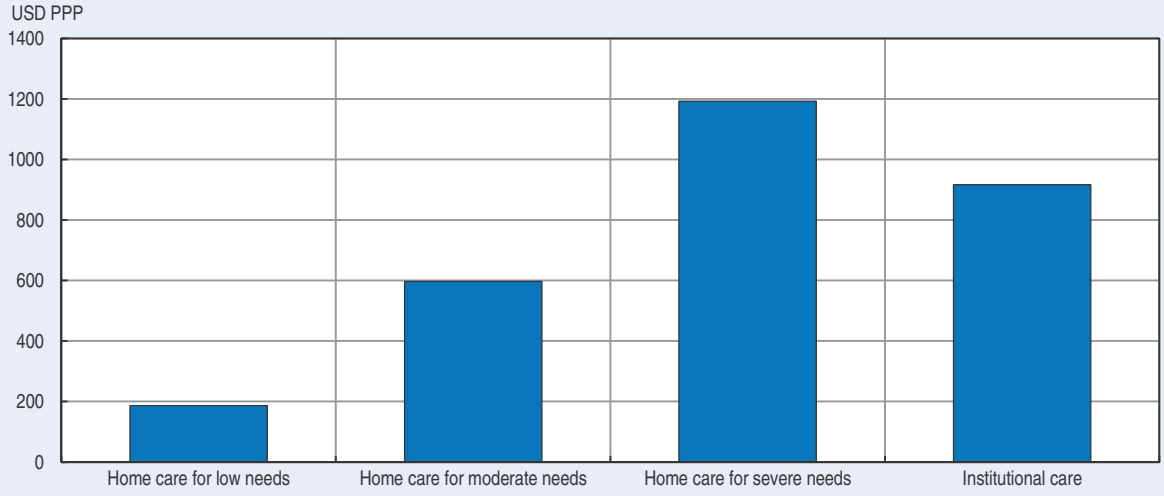
People in OECD countries are living longer than ever. In 1970 a 65-year-old could expect to live for another 14 years (on average across OECD countries) but by 2013 this rose to nearly 20. This has led to a sharp increase in the number of older people in society. While longer lives are a cause for celebration, they also present challenges. In particular, some illnesses become much more common with age: for example, nearly 45% of people aged over 90 in OECD countries have dementia (OECD, 2015a). Illness or disability can lead to dependency and the need for long-term care (LTC).

With demand for LTC services expected to increase, and with current pressures on government spending exacerbating concerns about the long-term impact of growing public expenditure on LTC, delivering these services in the most efficient way is an increasingly important issue for OECD countries. LTC is a labour-intensive service and opportunities to improve efficiency by reducing labour inputs – especially in a way that does not affect the quality of care – are limited. Technology may present opportunities in the future, but evidence on the cost-effectiveness of these approaches is often lacking and take-up remains low in many countries.

Opportunities to save money may arise in the provision of LTC by ensuring that people are cared for in the most appropriate setting, and in particular that people are not cared for in expensive institutional settings when cheaper options are available that would allow them to live more independent lives. Many OECD countries explicitly aim to move care out of institutions into the community, and in the vast majority of countries the proportion of LTC users living in the community increased in recent years.

The motivation for moving care into the community is primarily about achieving better outcomes, and in particular allowing people to live independently and remain a part of their local community for longer, but cost implications arise. For people with severe needs, community care can be more resource-intensive than institutional care (Figure 5.9). Economies of scale are sacrificed and staff may have to travel to care for people in different locations. People receiving LTC in the community are also more likely to be hospitalised, increasing health care system costs (Bardsley et al., 2012).

Figure 5.9. **The weekly cost of meeting LTC needs through formal care services only, 2014 (USD PPP, average of 15 OECD countries)**



Note: Low, moderate and severe needs correspond to 6.00, 22.50 and 41.25 hours of care per week. All scenarios assume that no care is provided informally, so needs must be met in full by a professional carer. Institutional care costs include accommodation and food, so will be inflated relative to home care costs. PPP = purchasing power parity.
Source: OECD (forthcoming), "Quantifying Social Protection for Long-term Care", OECD Publishing, Paris.

StatLink http://dx.doi.org/10.1787/888933444246

Box 5.2. **Reducing the overuse of expensive long-term care settings** *(cont.)*

In reality, it is rare for community care to be provided entirely by professional carers, and much of the work of caring is done by unpaid, informal carers such as families, friends and neighbours. By pooling the results of a large number of studies, researchers in the United Kingdom found that although community care for people with severe dementia was more resource-intensive, around three-quarters of that care was provided informally, leaving the direct financial costs significantly lower than for institutional care (Prince et al., 2014).

In most OECD countries, informal carers are not paid for the time they spend caring, although they may receive some cash and in-kind benefits (Colombo et al., 2011). As such, the direct cost of informal care to government budgets is small and community care could be seen as saving money while improving outcomes. However, this analysis neglects the indirect costs that informal care imposes on the carer, society and government budgets. The time that someone spends caring is an opportunity cost, and if it prevents people from working, informal care can lead to lower productivity in the economy and lower tax revenues. The net effect is difficult to assess, but it should not be assumed that institutions provide low-value care simply because they have a higher direct financial cost.

Nonetheless, scenarios arise where institutional care would appear to be neither the best way to meet the needs of the individual nor the cheapest. As Figure 5.9 shows, people with low to moderate needs can be cared for in the community more cheaply than in a care home. Failing to care for these people in the most appropriate setting could be considered low-value care, and though most countries aim to keep people in the community for longer, evidence suggests that gaps in social protection for community care might make this difficult. Improving social protection for community care may thus help to reduce the inappropriate, and expensive, use of institutional care.

Integrate primary care services within hospitals. Along with better services in health clinics and other facilities at the primary care level, offering better primary care services within hospitals is an important policy option. This is particularly relevant for hospital ED visits, where integrating primary care services can help redirect non-urgent patients to primary care settings or speed up discharge for non-urgent cases. More specifically, the use of fast-track systems or involving PCPs at hospital EDs are two policies used for this purpose.

Fast-track systems involve treating patients with non-urgent conditions in a dedicated area by professionals with the competencies to make discharge decisions. Patients are assessed by less expensive health care providers such as residents, nurse practitioners (NPs) and physician assistants who are specifically dedicated to fast-track patients. Patients are then either treated on site, or if not requiring emergency care, discharged to appropriate primary care services or clinics. These programmes apply for stable patients who do not require medical imaging or laboratory tests. The introduction of fast-track systems in Canada, France, the United Kingdom and the United States led to a reduction in inappropriate ED use by using less resource-intensive inputs than in more traditional ED set-ups (Cour des Comptes, 2014; Sanchez et al., 2006; Rogers et al., 2004; Yoon, 2003).

Another approach is to involve PCPs within EDs. In this context, PCPs are placed at the front of the ED to act as a filter to redirect patients with non-urgent problems away from costly ED treatments. By seeing non-urgent patients quickly and redirecting them to ambulatory settings, the involvement of PCPs can reduce inappropriate use of emergency resources and improve appropriateness of care. The impact of this policy has been more mixed than that of fast-track systems. For example, in the Netherlands and Switzerland the strategy was cost-effective as it lowered the use of emergency services (Boeke et al., 2010; Thijssen et al., 2013; Wang et al., 2013). But in England concerns persist that the

strategy actually increased the number of inappropriate ED visits by increasing the number of primary care attendance to EDs (Carson et al., 2010). Similarly, a recent review of 20 studies found evidence of increased demand for emergency care services when primary care doctors and nurses were co-located with or adjacent to a hospital ED (Ramlakhan et al., 2016). Such a strategy is found to lead to patient confusion and lower staff satisfaction. Box 5.3 provides details on the Netherlands experience.

Box 5.3. **Primary care integrated within emergency departments in the Netherlands**

Some regions in the Netherlands have a model that integrates primary care services into hospital EDs. In these regions, one triage point determines which service patients attend, with self-referred patients no longer able to bypass the PCP. Depending on their triage outcome, patients either receive a scheduled appointment at a general practice co-operative (a primary care facility) or are directly referred to the ED (Thijssen et al., 2013). As well as increasing patient satisfaction, strong evidence shows that these integrated models are associated with a reduction in patient self-referrals to hospital EDs.

For example, after creation of this integrated model, the number of consultations with primary care services increased by 27% and the proportion of patients who self-referred to a hospital ED fell from 62% to 46% (Kool et al., 2008). Similarly, the proportion of patients using OOH emergency care decreased by 53%, patients using OOH primary care increased by 25%, and patient self-referrals to EDs fell from 68% to 16% (van Uden et al., 2005). There were also fewer hospital admissions, and fewer subsequent referrals to the patient's own PCP and medical specialists. Van Uden et al. (2003) found significantly lower patient ED self-referrals in patients attending a PCP-integrated model compared with patients attending a standalone ED. A more recent study found that after six years of an integrated model's operation, almost no ED patients self-referred (Thijssen et al., 2013).

Improve the internal efficiency of hospitals by standardising processes

Hospitals are complex organisations within which many inefficiencies can arise, whether through poorly designed processes with unnecessary steps, a lack of communication between different parts of the hospital or different professions, or unavailability of equipment and staff when needed. Although each hospital may have different issues, standardised approaches have proved effective in addressing these issues and delivering more efficient care.

One such approach is "Lean Management", a set of principles based on the production philosophy developed by the car manufacturer Toyota to improve efficiency within its factories. Lean Management has been applied in many sectors of the economy and has recently seen use in health care settings. It comprises a set of tools and methods that aim to understand and improve the processes within an organisation and to help staff identify and solve problems. Commonly used approaches include guidance and checklists to standardise procedures and "just-in-time" stock replenishment, whereby feedback systems ensure that technicians know exactly which equipment has been used and needs replacing. Importantly, Lean Management aims to develop a team approach to problem solving and a culture of continual improvement.

Lean Management is implemented in individual hospitals in many OECD countries, although it has not been applied on a system-wide level in any country. Evaluations show promising results, with many reporting reductions in staff time and errors and improved

productivity (Mazzocato et al., 2010; D'Andreamatteo et al., 2015). For example, one hospital in Australia reduced waiting times and improved the efficiency of its ED by redesigning processes to improve patient flow (Kelly et al., 2007). Similarly, in a New Zealand hospital, Lean Management principles were used to better plan radiology services, improving report turnaround times and reducing unreported cases (MacDonald et al., 2013).

Improve care co-ordination

Manage hospital discharges better. When people require more care after a stay in hospital, ensuring the right services are available when they are needed – and that they are well co-ordinated with hospital care – can improve outcomes and reduce the overuse of expensive hospital beds.

Making the right services available means investing in: i) the community health services that people need to help them recover from a stay in hospital; and ii) the social care services and institutions required to provide day-to-day support to people who can no longer live fully independently. In addition to this, some countries have sought to develop new types of care settings that bridge the gap between hospital and community care, providing short-term care for people who have been discharged from hospital or who would otherwise require a hospital admission. These services can take various forms – such as community hospitals, hospital at home, rehabilitation centres and nurse-led units – and are often referred to as "intermediate care". As discussed earlier, intermediate care services in Norway seem to have been successful, with evidence suggesting benefits to patients and cost savings to the health care system (Garåsen et al., 2007).

Experiences elsewhere are more mixed. Intermediate care services in the United Kingdom and the Netherlands have existed since 2001 and 2006, respectively. In both countries, definitions of intermediate care were initially unclear, leading to a fragmented set of providers that varied widely in their composition and service models. Coupled with a lack of national standards for monitoring, this has made it difficult to evaluate the impact of intermediate care (OECD, 2014). Moreover, although these services are supposed to act as a link between hospitals and community care, they are sometimes undermined by a lack of co-ordination with these other services. Evaluations in the Netherlands highlighted a lack of information-sharing between intermediate care units, hospitals and long-term care facilities (Mur-Veeman and Govers, 2011) and poorly organised transitions between services, leading to unnecessarily long hospital stays (Plochg et al., 2005).

Transitions between services are not only a challenge for intermediate care. Poorly co-ordinated transitions from hospital to community health or social care services can lead to overuse of hospital beds and worse patient outcomes. As a result, some OECD countries implemented policies targeted at the point of discharge from hospital. For example, German hospitals are entitled to prescribe medications, assistive devices and care services for up to seven days after discharge, meaning that people in need of more care can go home while they wait for a more permanent arrangement to be established. Some hospitals in England established multidisciplinary teams of health and social care workers focused on improving discharges for complex patients. The results of this approach seem promising – for example, University Hospitals Birmingham saw the number of delayed discharges cut in half within a year of establishing a multidisciplinary discharge team – but more evaluation is needed to see whether and how this can be scaled up to a national level. A similar approach is planned in Israel, where dedicated staff based in Health Maintenance

Organisations (HMOs) will co-ordinate appointments for complex patients who are discharged from hospital. In France a specific programme was developed to assist patients after inpatient admissions and to reduce delayed hospital discharges. Known as *Programme d'Accompagnement du Retour à Domicile* (PRADO), the programme started in 2010 in maternity care, and was later extended to orthopaedics and heart failure. A care co-ordinator is responsible for organising the transition between hospital and community-based services.

Manage pathways of care in the rest of the health care system. While hospital discharges are one important point where a lack of co-ordination can lead to poor-value care, many OECD countries seek to improve co-ordination across the whole system, in particular for patients with more complex needs. In many countries, responsibility for care co-ordination falls naturally on primary care doctors, who are the main entry point to the health care system. However, experiences in Sweden suggest that unless this role is formalised, the lack of clarity around responsibilities can undermine the co-ordination of care (OECD, 2013). Other countries have dedicated case managers working particularly with people with complex needs. In Germany, for example, *AGnES zwei* nurses provide case management mostly for older, multimorbidity patients.

Some countries introduced disease management programmes – standardised pathways of care covering multiple organisations, often targeted at complex or life-threatening diseases. In Demark, for example, heart and cancer care is delivered in standardised packages that detail the specific care a person should receive and when, from diagnosis through to treatment. Norway recently introduced standardised cancer care, based on the Danish experience, and plans to standardise care for mental health disorders and substance abuse.

Evidence on the impact of case management programmes is mixed. For example, an evaluation of 16 "integrated care pilots" in England found that although more patients had a care plan, they actually felt less involved in decisions about their care. Reducing emergency hospital admissions was a key goal of the pilots, but admissions actually rose by 9% – although significant reductions in elective care meant that overall inpatient and outpatient costs were reduced (Roland et al., 2012). More broadly, a recent review of the economic impact of care co-ordination policies found very limited evidence of cost-effectiveness (Nolte and Pitchforth, 2014).

Revisit how health care professionals are used

Extend the scope of practice for non-physicians. Some countries are re-examining the traditional functions of health professionals. For example, about half of OECD member countries expanded the scope of practice for non-physicians between 2007 and 2012. In particular, many countries took steps to introduce or expand the roles of non-physician providers, such as NPs or pharmacists. In Canada, the Netherlands and the United States, student intakes in advanced education programmes for NPs are increasing the supply of these "mid-level" providers (OECD, 2016a).

Such changes to the staff mix within and beyond hospitals can produce cost-savings with no adverse effects on quality of care. Indeed, evaluations show that NPs with proper training can improve access to primary care services, and manage and deliver the same quality of care as GPs for many types of patients, particularly those with chronic conditions requiring routine follow-up (Delamaire and Lafortune, 2010). NPs could also potentially play a central role in improving care co-ordination (as discussed earlier).

It should be noted that such policies can take time to implement effectively. In particular, the introduction or expansion of such non-physician roles often needs to overcome initial opposition from medical professionals, and may depend in part on the future supply of physicians. It also requires legislative and regulatory support.

Make better use of specialists through telehealth. Giving greater responsibilities to NPs and other non-physicians has the added benefit of allowing physicians to focus more on their areas of expertise. Similarly, ensuring adequate numbers of administrative staff helps minimise the time both physician and non-physician providers have to spend on non-clinical activities – an issue discussed in Chapter 6. Alongside such policies on health workforce mix, policy makers have explored telehealth as a way to make the best use of highly specialised personnel. Successful examples of this innovative service delivery model can be found in Brazil, India and Mexico.

In Brazil, a state-wide telehealth system linked cardiologists and other specialists virtually to primary care professionals. About 33 000 teleconsultations and 825 000 electrocardiograms were performed from June 2006 to October 2011 in Minas Gerais state. Survey results showed that 81% of the teleconsultations averted a referral. The average telehealth activity cost was estimated at USD 6, much lower than the average cost per patient referral of USD 64. Conservative estimates suggest savings to the public health care system of USD 20 million over the five-year period (Alkim et al., 2012). It should be noted that this policy was driven by access concerns, responding to a shortage of specialists in more remote areas. But such use of telehealth could equally be understood as an efficiency-enhancing policy, by maximising the output of highly specialised clinicians.

In India, the Apollo Telemedicine Networking Foundation makes secondary and tertiary medical expertise available to rural areas using information and communications technology (ICT). From 2000 to 2009, more than 57 000 teleconsultations were provided, with the majority case reviews (Ganapathy and Ravindra, 2009). In Mexico, telehealth is used for direct consultations between providers and patients. The start-up Medicall allows people to consult a medical professional on demand by phone for a low monthly fee. Telephone advisers are able to triage patients so that callers can speak to suitable specialists. This system takes up less of a health worker's time as compared with traditional in-person care, with just over 60% of calls managed on the phone without medical attendance (Oldham et al., 2012).

3.2. Financial incentives can be used to change behaviour

Policies targeting health providers: Reform provider payments

Incentivise same-day surgery. Financial incentives may affect the extent to which minor surgeries are conducted on a same-day basis. For example, Hungary's budget caps for same-day surgery financially discouraged the practice. A recent policy change to abolish this budget cap is expected to increase the rates of same-day surgeries for cataracts and other minor surgeries (OECD, 2015a). More generally, increasing payments for same-day surgery and/or reducing payments for inpatient admissions for minor surgeries can be used to incentivise greater uptake. Belgium, France and the United Kingdom provide interesting examples of how payment systems can introduce incentives for investing in same-day surgery.

In Belgium, two lists were created in 2002 to finance day-care surgery: i) list A, surgical procedures for which the hospital received additional funding when performed in day care; and ii) list B, surgical interventions for which the hospital received exactly the same budget irrespective of being performed on a day-care or inpatient basis. That is, list A introduced financial incentives for performing same-day surgery, while under list B, hospitals are financially penalised for performing an intervention in an inpatient setting. Evidence shows that the reform led to some shifts from inpatient to day care for a number of interventions including arthroscopic meniscectomy, laparoscopic follicle aspiration, inguinal hernia repair, and subcutaneous portal system. Day-care surgery for arthroscopic meniscectomy, for example, increased by 67.6% between 2000 and 2010, while inpatient surgery for the same condition decreased by 73.3% over the same period (KCE, 2012).

Denmark and France provide examples of how diagnostic-related group (DRG) systems are used to incentivise same-day surgery (2016 OECD Waste Survey). A specific classification for same-day surgery procedures called the Danish Ambulatory Grouping System (DAGS) was introduced within the general Danish DRG system. A "grey area rate" exists within both classification systems for procedures that can be carried out both as a conventional hospitalisation or as same-day surgery. This system ensures that the tariff is identical no matter how patients are treated. This financing system is expected to increase rates of same-day surgeries. Likewise in France, the prices of day-case stays are aligned with non-complicated overnight stays for most common procedures to encourage hospitals to invest in day-case surgery. Paying same-day surgery above its production cost can be a powerful incentive to promote its increase (HAS, 2014). Subsequently, the proportion of same-day surgery in France increased by 1.8 percentage points per year on average between 2010 and 2014, reaching around 50% of all elective surgery. The new 2015-20 national programme for same-day surgery set a target for 66.2% of all elective surgery to be performed as day cases by 2020.

The United Kingdom took a step further with the introduction of a day-care best practice tariff (BPT) for a selection of surgical procedures in 2010. The British Association of Day Surgery (BADS) and the Department of Health identified key procedures where a financial incentive of approximately GBP 300 per case would be awarded if the patient was booked and managed on a day-case basis. At present, the range of procedures linked to a same-day surgery BPT includes breast surgery, gynaecology surgery, urology, hernia and orthopaedic surgical procedures. Evidence shows that introducing the BPT increased the proportion of patients treated with same-day laparoscopic surgery for cholecystectomy, without adverse effects on patient selection and care quality (Allen et al., 2012). Concerns were raised that the tariff incentives did not produce efficiency gains, however, as they led to higher tariffs for same-day surgery compared with their actual cost to the hospital (HAS, 2014).

Align financial incentives to promote care co-ordination. Delivering patient-centred, co-ordinated care often relies on at least two health care providers or payers, but if the financial incentives faced by these organisations are not aligned, it can be more difficult for them to work together effectively. One specific example is around hospital discharges. Some patients need more health or social care after a spell in hospital, which in most countries is arranged by a different care provider, and often funded by a different payer or level of government. If discharge is poorly co-ordinated, delays and longer stays in hospital

can result, costing the health care system money. Although co-ordination relies equally on the provider of ongoing care, these costs fall entirely on the hospital. The provider of ongoing care may actually save some money by leaving the patient in hospital for longer.

This misalignment of financial incentives is recognised as a barrier to improving hospital discharge in some OECD countries, and implemented policies seek to redress the balance. In Denmark and Norway, different health services are financed by different levels of government. While regions operate hospitals, community health and long-term care are the responsibility of municipalities. Both countries implemented a system of "municipal co-financing" whereby municipalities share in the cost of any delayed discharges. In Norway, this policy was introduced from 2012 to 2015 as part of a wide-ranging co-ordination reform in 2012. Financial sanctions were imposed on local authorities in case of delays in discharging patients from hospitals. This policy was followed by a significant reduction in delayed discharges (Figure 5.7). This may be attributable to other aspects of the reforms and research to evaluate the impact of municipal co-financing is ongoing.

A similar policy was implemented in England, where local authorities – who are responsible for social care – share in the cost of delayed discharges. In this case, the local authority is only charged when the delay is considered to be caused by social care services. A steady fall in delays caused by social care between 2010 and 2013 – despite increases in delays caused by health providers – seemed to indicate that the policy was effective. But delays caused by social care rose sharply between 2013 and 2015, suggesting that the incentives are no longer sufficient to overcome other problems with service capacity and co-ordination.

Policies to align financial incentives between care providers, and thereby promote care co-ordination, extend beyond the point of hospital discharge. For example, German insurance funds are able to contract for "integrated care" across multiple providers. This involves a group of providers sharing a single payment from the insurer in return for delivering a co-ordinated pathway of care, with providers able to keep any savings that this delivers. The benefits of financially integrating providers remain unclear; a recent review of financial integration of health and social care services found mixed evidence on the effect on hospital utilisation (Mason et al., 2014). Sweden introduced bundle payments to improve care co-ordination between providers across different care settings. Bundle payments for an episode of care (known as SVEUS) target patients requiring spine surgery. The tariffs reflect clinical guidelines and can also include follow-up, warranty payment and outcome information (OECD, 2016b). Evidence shows a positive impact of reduced ALOS, cost per patient and complication rates (OECD, 2016b).

Encouraging more appropriate admissions and discharges

Financial rewards or penalties can nudge health providers into providing the most cost-effective care and patients into seeking care at the appropriate level within a health care system. On the supply side, some traditional provider payment methods incentivise overprovision of expensive hospital services (fee-for-service/FFS) or unduly long admissions (per diem payments). New provider payment innovations or adjustments to traditional payment mechanisms can help. For example, in Japan, additional fees are provided to hospital EDs to encourage patient discharge to primary care clinics (Japanese Ministry of Health, Labour and Welfare, 2014). In Australia, Activity Based Funding was implemented for public hospitals. This included incentives to reduce length of stay when clinically appropriate. In England, a "quality premium" for clinical commissioning groups

(CCGs) was recently introduced to reduce avoidable emergency admissions (Morse, 2013). CCGs receive additional funding if they achieve specific targets such as reducing avoidable emergency admissions for long-term and chronic conditions (Box 5.4). In the United States, a pilot pay-for-performance (P4P) programme was implemented to reduce asthma-related emergency admissions for children. The programme pays the community health workforce for providing a range of preventive interventions, including, for example, home-based support (Galloway, 2014).

Box 5.4. **Incentivising providers to reduce avoidable emergency admissions: The quality premium in England**

In England, the "quality premium" is intended to reward clinical commissioning groups (CCGs) for improvements in the quality of services they commission and for associated improvements in health outcomes and reduced inequalities. In 2015/16 the premium was paid to CCGs based on six measures that cover a combination of national and local priorities, including reducing avoidable emergency admissions. A quarter (25%) of the quality premium relates to avoidable emergency admissions for Ambulatory Care Sensitive Conditions (ACSCs), based on:

- unplanned hospitalisations for chronic ACSCs (all ages)
- unplanned hospitalisations for asthma, diabetes and epilepsy in children
- emergency admissions for acute conditions that should not usually require hospital admission (all ages)
- emergency admissions for children with lower respiratory tract infection.

To earn this portion of the quality premium, CCGs need to demonstrate: i) a reduction, or 0% change, in emergency admissions for these conditions for a CCG population between 2013/14 and 2014/15; or ii) the Indirectly Standardised Rate of admissions in 2014/15 being less than 1 000 per 100 000 population.

Source: NHS England (2014), "Quality Premium: 2014/15 Guidance for Clinical Commissioning Groups", 13 March 2014, available at *www.england.nhs.uk/*.

Policies targeting patients: Revise cost-sharing policies

On the demand side, careful changes to cost-sharing policies can encourage patients to seek care at the right level. First, removing payments at the point of care for outpatient primary care visits gives patients easier access to primary care services. It also removes incentives to seek free and unnecessary care in EDs. This is the policy in Canada, Denmark, Italy, the Netherlands, Poland, Spain, the United Kingdom and for most cases in Germany. Steps in this direction are underway in France, where the new National Health Strategy plans to remove payments at the point of care for ambulatory care services by 2017, thereby helping reduce inappropriate referrals to emergency care (Berchet, 2015).

At the same time, introducing cost-sharing for patients seeking hospital care without a PCP referral could in principle reduce the bypassing of primary care facilities. Cost-sharing for non-urgent visits to EDs applies in Belgium, Finland, Italy, Ireland, the Netherlands, Portugal and the United States. However, little evidence is available to support the effectiveness of this policy. In Belgium, for example, self-referred patients attending an ED have incurred a financial charge since 2007, but the strategy has not

effectively reduced ED visits (De Wolf and Vanoverloop, 2011). Similarly, recent increases in co-payments for ED visits in Portugal have not significantly impacted the use of emergency services (Ramos and Almeida, 2014).

3.3. Behaviour change can be achieved by non-financial means

Policies targeting health providers: Develop suitable training and monitoring systems

Evidence-based clinical practice guidelines help health care professionals meet defined standards, thereby making better clinical decisions and reducing unwarranted variation in care (as discussed in Chapter 2). But a large body of evidence shows that provider variation from evidence-based care guidelines is associated with increased patient complication rates and inpatient admissions at hospitals, and ultimately less-than-optimal patient health outcomes. This is particularly important for chronic conditions, where appropriate adherence by primary care providers to clinical practice guidelines for asthma, COPD or diabetes management is associated with lower admission rates (AHRQ, 2001).

Improving adherence to clinical practice guidelines by PCPs is therefore an important way to reduce inappropriate hospital use. Improving provider knowledge and awareness through formal education programmes and practice sessions is an important step, but is not enough by itself. Establishing a consistent framework to monitor adherence to clinical practice guidelines is fundamental, and appropriate incentives (financial or non-financial) to stimulate guideline uptake should also be considered. Experience from the United Kingdom shows that introducing financial incentives had favourable effects on PCPs' compliance with clinical practice guidelines, improving diabetes outcomes (Latham and Marshall, 2015).

Training health professionals on effective communication of complex information is also important. That is, providers need to be able to explain complex health diagnoses and treatment approaches to patients in a user-friendly, easily understood manner. Improving communication skills for health professionals has potential to encourage greater shared decision making, and is therefore beneficial. Training health professionals on effective communication of complex information includes methods to assist patients to problem solve and interpret their symptoms, and increasing health professionals' awareness of the impact of patient self-management on health outcomes (Yank et al., 2013).

Policies targeting patients: Improve patient self-management

Unnecessary hospital admissions can be avoided when patients take a more pro-active role in managing their health and well-being. This is because self-management prevents health complications and reduces adverse events. It is particularly important for chronic ailments, for which most of the care must be managed directly by the patient. Evidence demonstrates that improving patients' self-management reduces physician visits, ED visits and avoidable admissions for chronic conditions (e.g. for COPD patients and adults with asthma) and improves patients' health outcomes (FitzGerald and Gibson, 2006; Holman and Lorig, 2004; Purdy, 2010).

Develop patient education programmes and counselling sessions. Patient education programmes and counselling sessions are a fruitful way to improve patient self-management. Such interventions help patients develop a better understanding of how their conditions affect their lives and how to cope with their symptoms. These give them the

tools, skills and support they need to improve their own well-being and quality of life (Purdy, 2010; Yank et al., 2013). Interventions can also improve patient compliance with treatment, thereby reducing hospitalisation for many chronic conditions. A fundamental element in patient education programmes is to establish action plans where competencies are broken down into smaller tasks. For example, FitzGerald and Gibson (2006) show that asthma education programmes (including information, self-monitoring, regular medical review and a written action plan) reduce the proportion of patients having an asthma exacerbation requiring a hospital admission, an ED visit or an unscheduled visit to the doctor.

A number of countries introduced education programmes specifically designed to support better patient self-management. In Israel, for example, patient education is provided through patient training courses and counselling sessions organised by health funds. Such programmes intend to improve lifestyle habits and self-management skills for those with complex needs (OECD, 2012). Australia adopted a national approach to health literacy in 2014[6] that focuses on education for patients and health care providers, among other areas (OECD, 2015c).

Use telehealth to help patients monitor long-term (chronic) conditions. Alongside education programmes, careful use of telehealth can improve patients' self-management, especially for those with chronic conditions. Studies have shown that telemedicine is associated with fewer ED attendances and fewer hospital admissions for heart disease, diabetes and hypertension (Purdy, 2010; McLean et al., 2012; Steventon et al., 2012; Bashur et al., 2014). For example, a three-year randomised controlled trial in England found that telehealth could reduce emergency admissions by 20% and emergency attendance by 15% for patients with long-term conditions, including diabetes, COPD and heart failure (Steventon et al., 2012). In this trial, telemedicine involved monitoring systems (e.g. a pulse oximeter for COPD, a glucometer for diabetes, weighing scales for heart failure). It also managed patients' questions about symptoms and allowed educational messages to be sent to participants via a telehealth base unit or a box connected to a television.

3.4. Better information is needed to identify hospital overuse

Many of the reforms described above require better information on the nature and extent of hospital overuse. A good information system is crucial to assure that health care is effective and to make optimal use of available resources. Robust reporting information systems are needed to detect, measure and learn from inappropriate hospital admissions and poor primary care quality. Investing in a rich information system can be costly, but it forms the basis to achieve a good understanding of how, where or why hospital overuse exists. Such transparency is a necessary prerequisite to turn measurement into actions that lead to efficiency gains.

Equally important is an information-sharing system between health care facilities and providers to support provision of the most appropriate care and to improve care co-ordination. Many countries are working towards implementation of full electronic health records (EHRs) that will contain information on patients' medical history, medications and other relevant characteristics. Leading countries include Canada, Denmark, Finland, Israel, Korea, New Zealand, Singapore, Sweden and the United Kingdom. In several health care systems, however, EHRs are not portable across health care settings or between providers, which hampers the possibility of improving quality, safety and efficiency of health care. This was noted in the Czech Republic, Israel, Italy, Korea, Norway, Sweden and Turkey, for

instance (OECD, 2017). By contrast, the United States has already taken steps to improve interoperability of information infrastructure systems through its Nationwide Interoperability Roadmap.

Another approach taken by countries to improve care co-ordination is schemes targeted at medications (such as electronic medication records) or specific diseases (such as diseases registries). In Denmark, information on medications for each patient is recorded on a joint Medicine Card that all care workers can access and update. Germany introduced a medication record for anyone taking more than three medications. Such medication record systems are expected to reduce the likelihood of inappropriate prescribing (see Chapter 2) through improved care co-ordination. In a similar vein, disease registries are information schemes targeted at specific conditions. They provide opportunities for health professionals to provide better care for the same cost. Sweden is advanced in developing and maintaining disease registries. The Swedish dementia registry (SveDem), for example, holds information on over 40 000 people with dementia, including test results and the medical and social care they have received. This information, available to providers and patients themselves, has potential to reduce care fragmentation and hospital overuse.

Conclusion

This chapter focused on a key manifestation of operational waste: the use of costly hospital resources when alternative options could offer the same (or better) quality health care at lower cost. Unwarranted ED visits, hospital admissions for chronic conditions, avoidable inpatient stays for minor surgeries and delays in discharging patients from hospital are important examples where hospital resources are unnecessarily used across several OECD countries.

Such unwarranted use of hospital care is the result of a number of interlinked factors. Lack of access to alternative options, in particular primary and community care, is a key driver. This is compounded by inadequate quality of primary care services, particularly for chronic conditions where suboptimal monitoring is a cause of preventable hospitalisation. Even when alternative services do exist, poor communication and co-ordination between hospitals and other care settings can leave people stuck in hospital. On the demand side, patients' preferences, driven in part by socio-economic circumstance as well as their specific health needs, can drive unwarranted use of hospital care.

Country experiences demonstrate a number of tractable policy solutions to hospital overuse. Policy options with the greatest potential for immediate change include the following:

- Make sure that primary and community care options are available in the right place at the right time. Offering OOH services is particularly important, with several models demonstrating success, such as general practice co-operatives and larger primary care services (as seen in the Netherlands, Norway and the United States).
- Offer better primary care services within hospitals, particularly in EDs. Fast-track systems help to redirect non-urgent ED patients to more appropriate ambulatory settings (as seen in Canada, France, the United Kingdom and the United States).
- Improve care co-ordination between hospitals and primary or social care services for complex cases by using dedicated health professionals (such as a multidisciplinary discharge team or case manager). This policy option, implemented in Israel, England and Germany, is a particularly promising way for reducing delayed discharges from hospital.

- Carefully design financial incentives to encourage better use of hospital services. For example, on the supply side, additional payments to hospital EDs to encourage patient discharge to primary care clinics have had some success (e.g. Japan). Similarly, aligning the prices of same-day surgery with those of inpatient surgery can encourage more of the former (e.g. France and Denmark). Shared financial sanctions across providers have improved care co-ordination with subsequently less delayed discharges (e.g. Denmark, England and Norway). On the demand side, removing co-payments at the point of care for outpatient primary care visits has improved patients' access to primary care (as seen in Canada, Denmark, Germany, Italy, Poland, Spain and the United Kingdom).

Alongside these financial incentives, non-financial policy levers have a role in changing behaviours. For clinicians, evidence-based clinical practice guidelines can support clinical decisions, improve management of chronic conditions, and reduce avoidable hospitalisations. For patients, improving self-management through education programmes and counselling can help them develop a better understanding of their own health conditions, and the appropriate place to seek care.

These and other policy options analysed in the chapter are incremental, and should be achievable – assuming strong political commitment – in a relatively short timeframe. Such policies can be crucial early steps to a more fundamental transformation of health care systems in the longer term, where there is a general reorientation of services away from hospitals and towards more patient-centric, primary care-based approaches, as well as greater investment in health promotion.

Notes

1. Based on other evidence (Wise, 2014), the College of Emergency Medicine in England estimated that 15% of patients attending hospital EDs could have been seen by a GP in the community without the need for an ED assessment.
2. Unjustified bed days in some hospital departments have also been observed. In France, a pilot study conducted in a Parisian hospital between September and December 2015 suggested that avoidable hospitalisations in cardiology and rheumatology could reach 69% and 93%, respectively. Among these avoidable hospitalisations, 31% and 46% of patients were stable and ready to be discharged (Trosini-Désert, 2016).
3. For a minority of patients same-day surgery will not be a suitable option. Eligibility criteria include physical and mental stability, availability by phone, and guaranteed access to follow-up care at home. Therefore, achieving 100% same-day surgery shares may not be feasible even for minor surgeries.
4. *www.england.nhs.uk/statistics/statistical-work-areas/delayed-transfers-of-care/*.
5. Deputising services are commercial companies that employ doctors and nurses to take over a GP's provision of OOH care through an outsourcing or contracting arrangement.
6. "The National Statement on Health Literacy: Taking Action to Improve Safety and Quality."

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PART III

Governance-related waste in health care systems

Governance-related waste pertains to use of resources that do not directly contribute to patient care, either because they are meant to support the administration and management of the health care system and its various components, or because they are diverted from their intended purpose through fraud, abuse and corruption.

In Part III of the report, Chapter 6 looks into administrative tasks and related costs. Many of these tasks are vital to ensure access, equity and quality of health care provision at all levels of the system. Other activities may be of limited use, adding no value for patients, and are thus considered wasteful. Chapter 7 focuses on the significance and consequences of fraud, abuse and corruption in OECD health systems.

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PART III

Chapter 6

Administrative spending in OECD health care systems: Where is the fat and can it be trimmed?

by
Michael Mueller, Luc Hagenaars *and* David Morgan

Administrative tasks are essential at all levels of the health care system, from ministries and insurers to health providers. Many tasks are vital to ensure access, equity and quality of health care provision. Other activities may be of limited use, adding no value for patients.

This chapter looks into differences in administrative costs at the level of the health care system, for both health care facilities and individual health workers. Some differences are related to the way health care is financed. Many countries see the need to tackle inefficiencies in health care administration. The most promising strategies to increase efficiency are centred on simplifying procedures – partly by making better use of ICT – and optimising the size of administrative bodies to generate economies of scale. Additionally, regulatory changes can have an enormous and immediate effect on administrative costs and the administrative workload of health providers.

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Introduction

Spending on administration comprises a rather modest share of overall health expenditure – only around 3% on average in OECD countries in 2014 – but it is often perceived as a soft target when it comes to cutting waste in the health care system. Indeed, when austerity measures have to be implemented, the resources that go into administration are often the first to be considered, while the more politically sensitive provision of frontline medical services remains largely exempt from cuts. This was certainly true during the recent financial and economic crisis, when administrative spending was seen as a clear target for cost-saving measures in a number of countries. In addition to the widespread view that bureaucracy can be cut when times are hard, the extra workload pushed onto providers simply to satisfy administrative requirements is often perceived as inappropriate or inefficient (Maarse et al., 2005; Morra et al., 2011; Cutler et al., 2012).

But are administrative costs higher in health compared to other sectors? A comparison with other governmental functions may shed light on this. In Germany, for example, administrative costs for public pension funds are around 1.4% of total expenses (mainly pension payments) while accounting for almost 5% of total spending of public health insurance funds. But many of the health sector's resource-intense activities such as purchasing or co-ordination of service delivery are not required in most pension schemes.

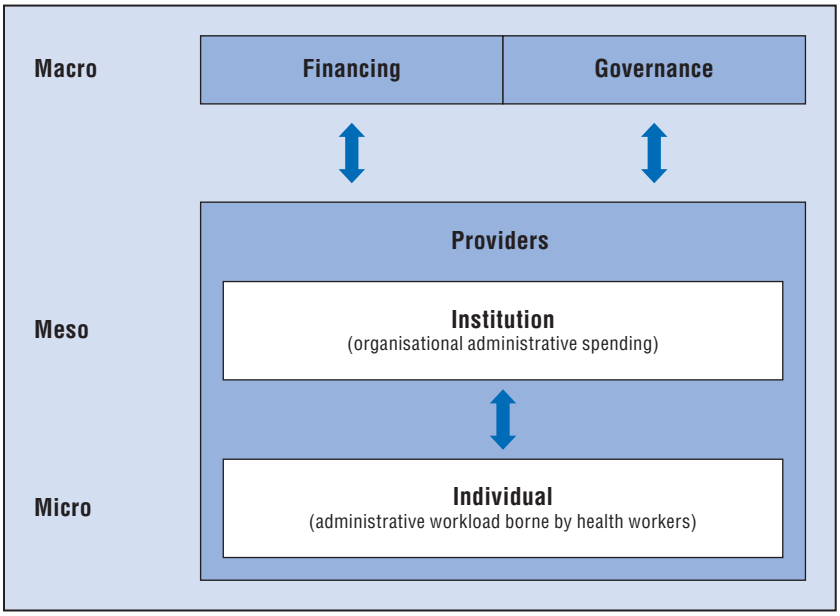
Spending on administrative activities should not be seen as "bad" *per se*: administration has its costs but provides core public health functions such as ensuring patient safety. And the range of administrative functions has multiplied over the years as important health policy objectives such as improving equity, access and efficiency came to the fore. For example, elaborate mechanisms are put in place – both at the provider and financing level – to avoid risk-selection and meet the goal of universal health care coverage. Secular trends such as the increased autonomy of providers, which must be harnessed by proper mechanisms to ensure accountability, or innovations such as pay-for-performance (P4P) induce a higher administrative burden for providers and payers alike as they typically involve the reporting and analysis of additional data to evaluate progress towards improved quality of care (OECD and WHO, 2014). In fact, by increasing the efficiency and responsiveness of care delivery and patient safety, administrative efforts can even generate savings down the line. So a certain level of administration is both necessary and vital in any modern health care system. Indeed, the role of administration is likely to grow even more as countries implement strategies encouraging value for money in health care delivery, further complicating governance and financing activities (Mathauer and Nicolle, 2011).

Thus it is clearly inappropriate to equate all administrative costs with waste. Wasteful administrative spending – in line with the general definition of waste in this report – refers to:

- administrative outputs that add little or no value
- administrative processes that are inefficient and could be carried out at lower cost.

The framework in Chapter 6 refers to administrative waste generated at the level of the regulator, but it can also be a concern at the provider level. In fact, the more refined analysis herein looks at three different levels of administration and their interactions, as shown in Figure 6.1.[1] The first – the macro (or system) level relates to health financing (collection and pooling of resources, and reimbursement of providers) on one hand, and governance activities, such as health care system planning and regulation, on the other. But administrative costs are not only incurred at the level of ministries and insurance funds. Health care providers likewise allocate a certain amount of their resources to administrative functions. They do so at two levels: i) the meso level, which captures the financial resources health care facilities spend on administration, ranging from overall planning and accounting to documenting care delivery; and ii) the micro level, which covers the time spent by health care workers performing administrative duties rather than providing clinical services.

Figure 6.1. **Levels of administrative inputs in health care systems**



Source: Authors' analysis.

Administrative costs and benefits across these three levels are clearly interconnected: easing the administrative burden on one level may impact a different level within the system if institutional arrangements remain similar. For instance, if the size of a hospital's administrative staff involved with coding, reporting and billing (meso) is reduced, more of the administrative workload may be pushed onto health workers within this institution (micro).

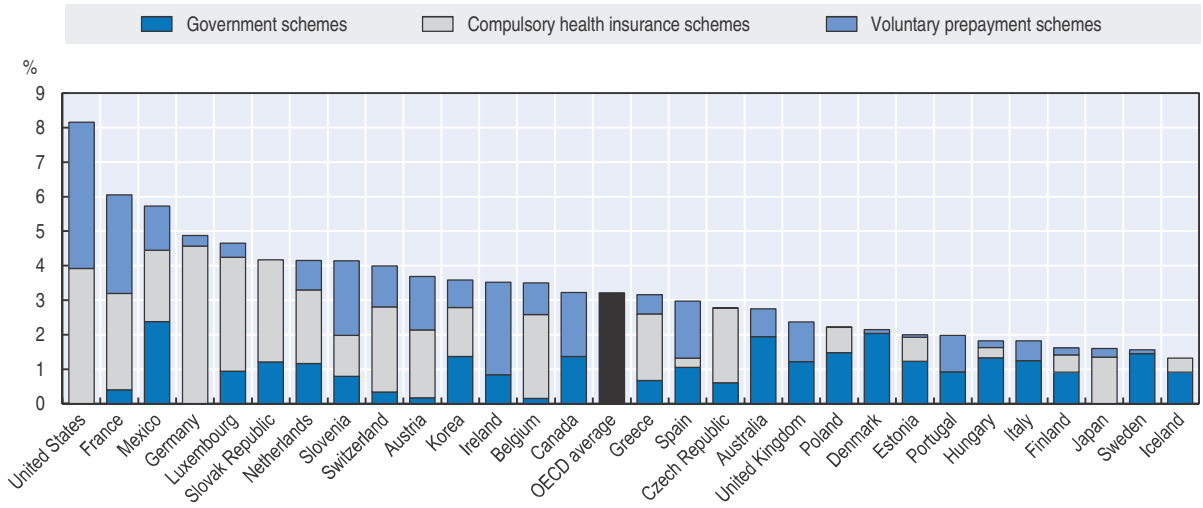
Administrative costs at the macro level are seldom studied and discussed in depth. The first section of this chapter uses internationally comparable health expenditure data to scale country differences in the administrative expenditure of bodies that finance and govern health care systems and to shed light on their determinants. The second section focuses on administrative costs incurred at the level of both health care providers and individual health workers. The third section summarises recent measures taken in OECD countries to address administrative waste across different parts of the health care system, followed by a set of recommendations on how best to identify and tackle low-value administrative output and inefficiencies.

1. At the macro level: Wide variation in spending on governance and administration

1.1. Administrative costs are influenced by the type of financing system

The resources that countries allocate to administrative activities at the system level vary substantially. While the OECD average was around 3% of health spending in 2014, it was double that level in France and higher still in the United States (Figure 6.2). On the other hand, a number of countries report administrative expenditures of less than half that level.

Figure 6.2. **Administration as a share of current health expenditure by financing scheme, 2014 (or nearest year)**



Note: Compulsory health insurance schemes predominantly refer to social health insurance (SHI) funds but can also refer to compulsory health insurance provided by private insurers. Voluntary prepayment schemes mainly refer to voluntary health insurance schemes. The OECD average includes 30 countries.

Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444250

While establishing completely comparable data remains a challenge (Box 6.1), a number of factors undoubtedly play a role in explaining the differences. For example, the costs involved in collecting revenues may be higher in countries with inefficient tax collection systems, large informal economic sectors, or a geographically scattered population. Skills can impact the efficiency of administration: a shortage of skilled workforce and low staff productivity due to insufficient information and communications technology (ICT) support will have an upward effect on costs. Cultural factors such as acceptance of schemes or the level of corruption within a country may impact the cost of regulation and monitoring (Nicolle and Mathauer, 2010). Finally, the legal culture and risk of litigation, with the resulting level of premiums and claims, can affect administrative costs. While differences in the size and scope of planning and management of health care systems can lead to some variations in overall costs, the way that health care is financed in a country – whether mainly tax-based, by social health insurance (SHI) funds, or by private insurance –appears to play a more pivotal role.

Indeed, Figure 6.2 suggests that financing schemes organised around SHI funds or some kind of compulsory insurance generally feature higher administrative expenditure than those managed by general governments (covering both central and regional/state-level governments). Frequently offered by for-profit corporations, voluntary private

Box 6.1. **Administration services in the System of Health Accounts**

The System of Health Accounts (SHA) provides an international framework for the definition, demarcation and categorisation of health expenditure. The SHA proposes a tri-axial accounting approach, classifying transactions used in the consumption of health care goods and services around the core dimensions of financing (who pays), provision (who provides) and function (what is the purpose). One of the health care functions refers to governance, health care system and financing administration.

While progress in recent years improved the comprehensiveness and comparability of international health spending data, comparability issues remain in some areas. One such area is the accounting of administrative activity. A 2013 study found that approaches in the estimation and valuation of administrative spending differ considerably across countries, potentially affecting the comparability of data (OECD, 2013). Common accounting issues relate to:

- underestimation of spending by governance agencies of all different layers of government (central, regional and local) due to lack of data
- overestimation of administrative spending that should methodologically be considered as spending on prevention due to inclusion of agencies concerned with public health issues
- differences in cost items (e.g. depreciation) considered administrative spending
- valuation of administrative expenditure of private health insurance as the sum of costs instead of following the recommended accounting practice of including profits and brokerage fees
- general differences in the use of data sources.

Source: OECD/WHO/Eurostat (2011), *A System of Health Accounts: 2011 Edition*, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264116016-en*.

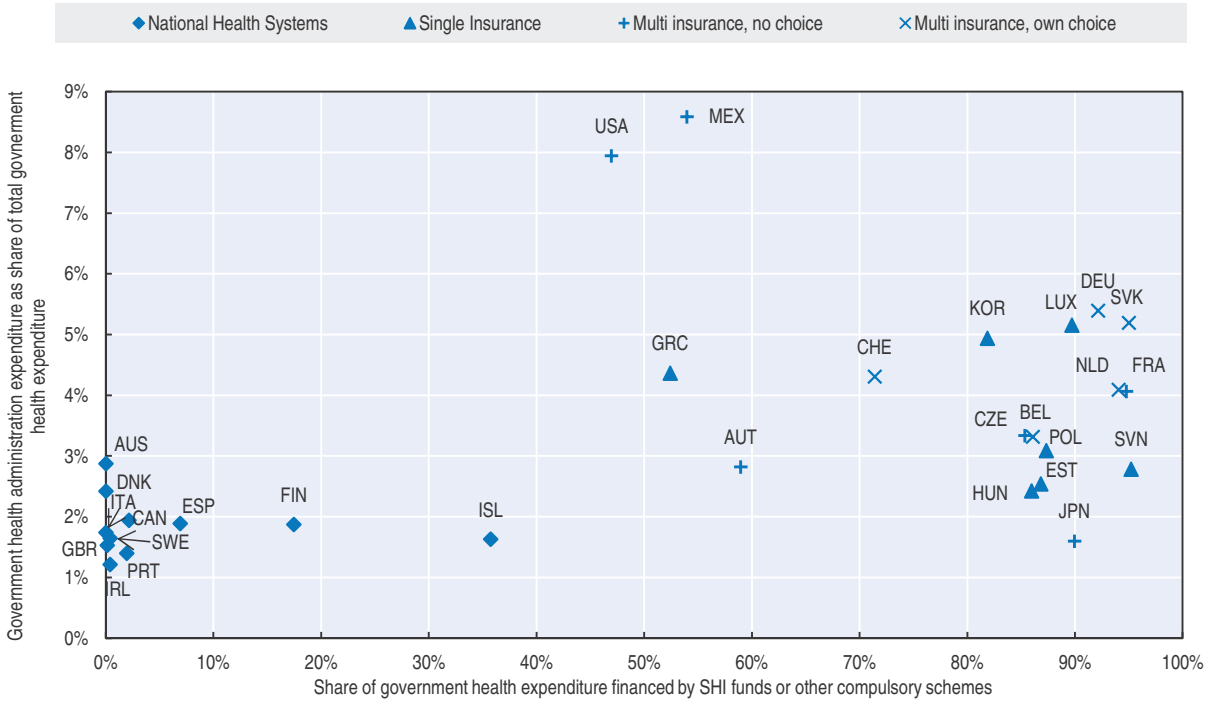
insurance incurs a relatively high share of total administrative expenditure, albeit accounting for a comparably low share of overall health spending. Thus systems featuring a high proportion of health care financing via SHI funds and/or private insurance generally demonstrate a higher share of administrative spending overall. The following sections explore in more detail the institutional characteristics that lead to these differences.

1.2. The multiplication of funds has a significant impact on administrative costs

The high cost of administration is often cited as one of the main disadvantages of (multi-payer) insurance-based, public health financing compared with health care systems where coverage is based on residency and that are mainly financed through taxes (Saltman et al., 2004). Figure 6.3 shows that those systems with a more predominant SHI scheme tend to have higher administrative costs. On average, in countries where social security spending constitutes less than 40% of public health expenditure, administrative costs accounted for less than 2% of public spending on health in 2014, whereas it was more than double that in countries where social security funds accounted for the bulk of public health spending.

Interestingly, while administrative costs appear similar for systems with residence-based entitlements, a much larger spread occurs across insurance-based health care systems. Ultimately, this variation reflects the number of different funding pools and the presence of competition, ranging from single-payer to multi-payer systems either with automatic affiliation or with a choice of insurers. Generally, countries with a single SHI

Figure 6.3. **Government health administration expenditure related to share of total government expenditure financed by SHI or other compulsory schemes, 2014 (or nearest year)**



Note: The US Government health financing system was categorised as a multi-insurance system with no choice of insurer due to entitled persons' direct affiliation with either Medicare or Medicaid.
Source: *OECD Health Statistics* (2016), *http://dx.doi.org/10.1787/health-data-en*.

StatLink http://dx.doi.org/10.1787/888933444262

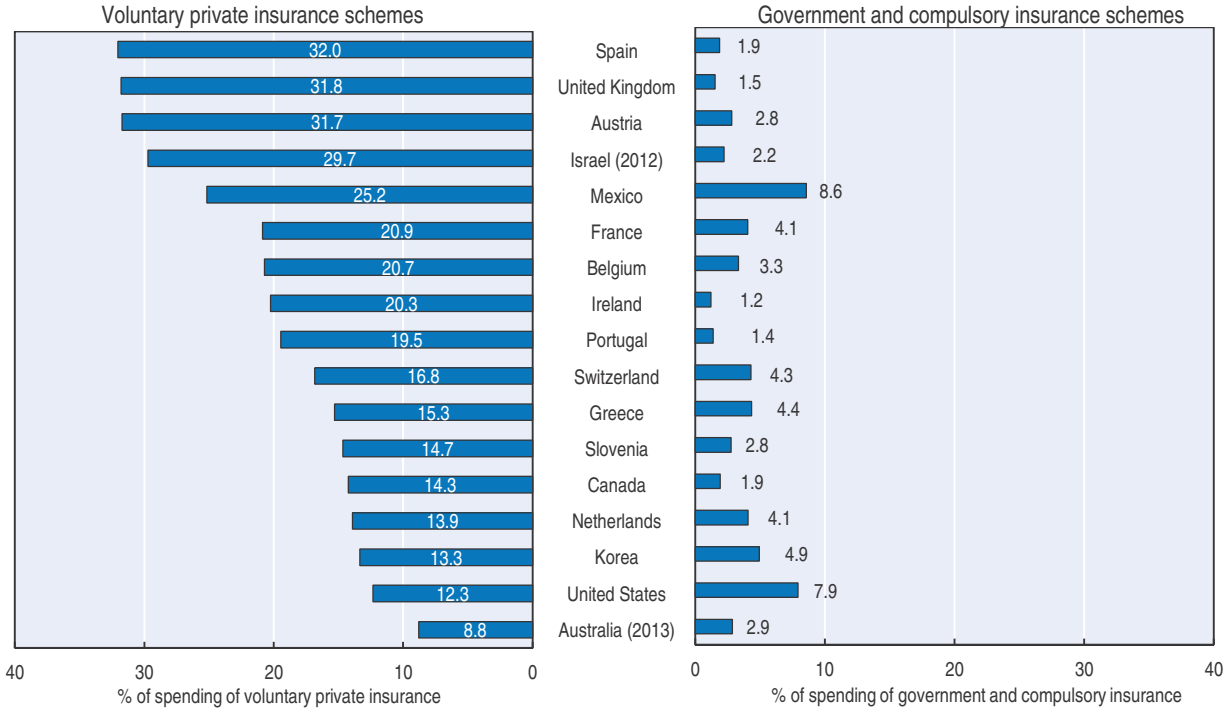
fund (e.g. Hungary, Poland and Slovenia) show lower levels of administrative spending; indeed, levels are similar to those seen in health care systems with residence-based entitlement, such as Australia and Denmark.

While administrative costs are higher in multi-payer systems, the distinction between those with choice and those with automatic affiliation is less clear-cut. For example, in the Czech Republic, Germany and the Netherlands, people can choose between competing insurers; the resulting administrative costs range from 3.3% of public health spending in the Czech Republic to more than 5% in Germany. In Austria, Belgium, France and Japan, multiple insurance funds also exist, but affiliation with a specific insurer is generally linked to a profession and not a matter of individual choice. While Austria and particularly Japan report administrative cost levels below those in countries where insurers do compete, Belgium and France have government administrative costs at a similar level. The United States and Mexico have notably higher government administrative costs – pointing to other inherent organisational and cultural factors. The litigious environment, but also scrutiny from regulatory bodies and efforts devoted to utilisation management and quality improvement, may partially explain why administrative costs in the United States are so high (Kahn et al., 2005). In Mexico, distinct health financing systems exist for different sections of the population, creating many administrative duplications (OECD, 2016).

1.3. Administrative costs for private insurance are much higher than for public schemes

Not surprisingly, given that profits more often than not play an integral role, administrative costs associated with the private health insurance (PHI) market are significantly higher than those in public systems, albeit they generally cover less people and purchase fewer services. Across the OECD, administrative costs of PHI schemes range from 9% of spending in Australia to more than 30% in Spain, the United Kingdom and Austria (Figure 6.4). Administrative costs in public schemes represent at the most 9% of health spending in any country. This is in line with the analysis of Mathauer and Nicolle (2011), who stipulated that administrative costs are about three times higher in PHI schemes compared to their public counterparts globally, with large variations across and within countries.

Figure 6.4. **Health administration expenditure as a share of financing schemes' total health spending, 2014 (or nearest year)**



Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink *http://dx.doi.org/10.1787/888933444271*

In summary, analysis of the existing data suggests that:

- Little difference arises in governments' administrative costs between tax-based systems with residence-based entitlement and single-payer, insurance-based systems.
- Single-payer systems have lower administrative costs than multi-payer systems.
- Multi-payer systems with free choice of insurer tend to have higher administrative costs than multi-payer systems with automatic affiliation.
- Private insurance schemes have much higher administrative costs than any public schemes.

The next section sheds more light on how the range of activities linked to different financing systems can help explain these differences.

1.4. Cost differences relate to the scope of administrative functions associated with different financing schemes

In any health financing environment, the regulator and the entity running the scheme(s) must perform a number of tasks to ensure achievement of system goals and to best operate in their business environment. Table 6.1 lists various tasks related to collection and pooling of funds, purchase of goods and services, and stewardship of the system. It then shows, from a purely conceptual point of view, how these tasks might apply and affect costs across various types of health financing schemes.[2] As mentioned above, the extent to which insurers are permitted to generate profits has a significant impact on total administrative "costs". The rest of the section elaborates on these initial findings and provides a more detailed explanation of structural differences in the level of administrative costs required to operate different financing schemes.

Table 6.1. **Functions of various administrative tasks across health financing systems**

Health financing function	Administrative activities	Residence-based entitlement (mainly tax-financed)	Insurance-based			
			Single payer	Multi payer		
				Social insurance, no choice	Social insurance, own choice	Private insurance
Resource mobilisation	Product communication	0	0	0	+	++
	Member enrolment	0	+	++	++	++
	Collecting contributions	+	+	++	++	++
	Managing exemptions	0	+	++	++	0
Pooling	Underwriting	0	0	0	0	+
	Pooling and resource transfers	+	+	+	+	+
	Managing risk equalisation information	0	0	+	+	0
Purchasing	Purchasing, contracting and provider negotiations	+	+	++	++	++
	Claims processing, provider payment, patient reimbursement	+	+	++	++	++
	Care co-ordination	+	+	++	++	0/++
Stewardship and management	Executive management, HR management, supervision	+	+	++	++	++
	Policy planning incl benefit basket design	+	+	+	++	++
	Surveillance, monitoring, enforcement and appeal	+	+	+	+	++

0 Function not relevant in financing system or only marginally performed.
+ Function performed in financing system.
++ Function performed in financing system with estimated higher costs per unit through lower economies of scale.
Source: Authors' own assessment based on framework of Nicolle and Mathauer (2010), "Administrative Costs of Health Insurance Schemes: Exploring the Reasons for their Variability".

Little difference arises between administrative activities of different single-payer systems

Residence-based entitlement schemes and single-payer insurance systems perform roughly the same services with regard to pooling, purchasing and stewardship. There is therefore reason to assume that similar resources would be required to perform these functions.

Differences can exist in relation to member enrolment and subsequent collection of funds. Coverage in residence-based schemes occurs automatically and revenues are usually collected as part of general taxation. In social insurance systems, where coverage is compulsory or voluntary, additional resources are required to identify, register and enrol

members or to verify entitlements at the point of service (Paris et al., 2010). The management of contributions – and perhaps even their collection – can add a burden to insurance-based schemes. Additionally, in an insurance scheme, if coverage is not universal, specific mechanisms or programmes may have to be put in place to ensure that all citizens have access to care before contributions can be collected.

Multi-payer systems duplicate many of the same activities

Health care systems in which coverage is provided by a single entity generally have lower administrative costs than multi-payer systems, partly because they enjoy more economies of scale (Mossialos et al., 2002). Enrolment, collection of contributions, claims processing, benefits management, sales and marketing, and insurance funds' compliance with government and non-government regulations and accreditation need only a single accounting and processing system in single-payer schemes, whereas multi-payer systems by their nature multiply the same functions (Bentley et al., 2008). The same holds true for purchasing and contracting, which creates an additional burden at the provider level.

Moreover, in multi-payer systems, costly and technically demanding risk-equalisation and resource transfer mechanisms are frequently required to counter issues of patient selection, ensure equal basic benefit packages, or indeed avoid budgetary difficulties of payers. Such systems exist, for instance, in Belgium, the Czech Republic, Germany, Japan, the Netherlands and Switzerland (Paris et al., 2010; van de Ven et al., 2013) but are not required in single-payer systems.

Patient choice can drive up administrative costs

Multiple social insurance funds with free choice of insurer exist in a number of OECD countries, including the Czech Republic, Germany, the Netherlands, the Slovak Republic and Switzerland. Competition among insurers is credited with stimulating innovation and responding better to patient needs (Paris et al., 2010; Saltman et al., 2004; Carrin and Hanvoravongchai, 2002). The complexity of fostering competition in health insurance markets while guaranteeing universal access is nevertheless associated with higher administrative costs.

Competition in the insurance market only works when consumers can make informed decisions. But the need to provide information on benefits, premiums or contribution rates as well as the related advertising and marketing all comes with a cost. Moreover, when switching insurers is an option, such information needs to be up-to-date and communicated regularly to clients (Paris et al., 2010). Naturally, where affiliation is automatic these requirements do not normally apply. Of course, competition can lead to a more efficient organisation of insurers, with costs offset by more streamlined procedures. The sharp decrease in insurers' administrative overheads in the Netherlands from 4.5% in 2006 to 2.9% in 2010, for instance, was linked to the effects of such competition (Jeurissen and Trienekens, 2014). But in many instances, competition in health insurance markets with multiple insurers is limited without leading to any detectable gains in efficiency (Mathauer and Nicolle, 2011).

Competing insurers may also contract selectively with providers. This can lead to a multiplication of transactions, such as contract negotiations and claims management, and may require additional data collection on prices and quality. But again, these additional administrative costs may lead to savings elsewhere in the system. It was hypothesised, for

instance, that the threat of selective contracting and associated negotiations alone put pressure on prices and increased the efficiency of care delivery in the Netherlands (Jeurissen and Trienekens, 2014).

Private health insurance schemes face strong competition but lack economies of scale

PHI can play different roles, for example providing coverage for a basic benefit package when public schemes are absent or for additional services not covered by public schemes. What is common is that in countries where PHI plays a role in health care financing, a high degree of competition is typically present. In contrast to the public system, many administrative functions are less likely to be shared, leading to a duplication of processes and a lack of economies of scale. More resources are therefore required for: distribution of information; registration and enrolment of patients; billing and underwriting of members' insurance policies; and negotiation, contracting and payment of providers. PHI schemes also spend more on marketing and acquisition, product innovation and agents' commissions (OECD, 2004).

One key difference between PHI and SHI is the fact that private insurance may be offered by insurance corporations that are allowed to make a profit from their operations (although limits may exist) while SHI funds are typically not-for-profit entities.

The importance that private insurance plays in financing health expenditure in a country does not appear linked to the level of administrative costs, however. France and Slovenia, for example, both have complementary PHI (mainly reimbursing co-payments) and similar shares of PHI in total health spending (14-15%). But the share of administrative costs in PHI expenditure appears significantly higher in France (21%) than in Slovenia (15%), indicating that country-specific factors, for example related to regulation, play a more pivotal role in determining administrative costs in private insurance (Box 6.2).

1.5. *Administration at the health care system level cannot be equated with waste*

Keeping in mind that macro level administrative cost data have some limitations and that other factors play a role, this analysis indicates that differences for a large part reflect structural choices countries made in the organisation of their health financing system. These choices are made in part because they generate system-level impacts (for instance, higher financial protection in France, or more responsiveness in competitive systems) that cannot be measured. In other words, the "benefit" of administrative activities cannot be captured. A simple comparison of costs, therefore, cannot conclude that one system's administration is more efficient than another's nor can it help much in identifying waste.

2. Unpacking administrative costs at the health care provider level

This section examines the resources allocated to administrative functions at the level of health care provision, in terms of: i) inputs in health facilities (meso level); and ii) the time devoted by health care workers to non-clinical tasks (micro level). At these levels, no comprehensive data are collected with which to identify and compare the costs by health care providers or professionals across countries. Nevertheless, certain consistent relations can be identified between health care system characteristics and administrative inputs at the provider level.

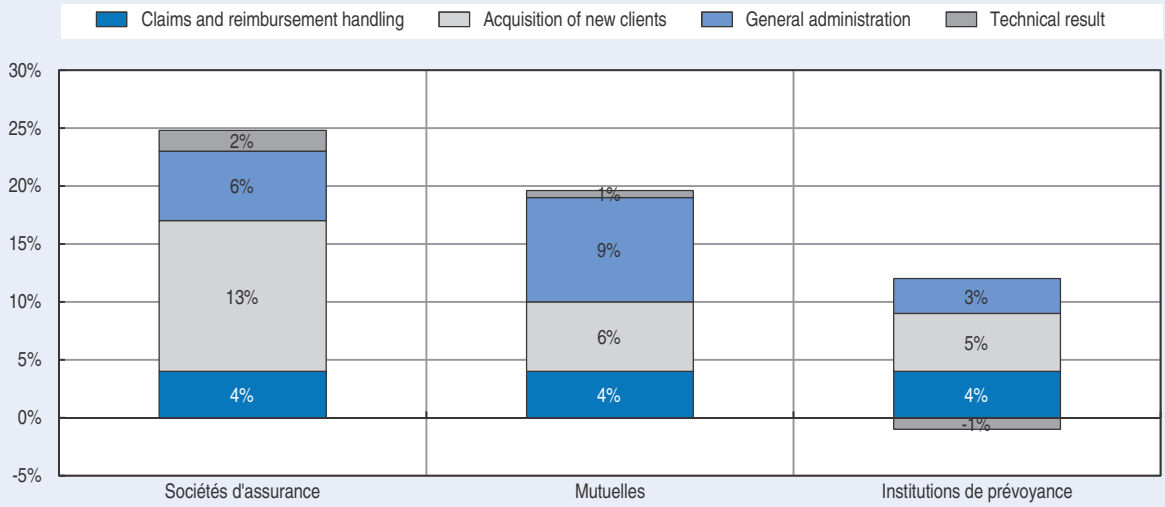
Box 6.2. **Spending on administration by French private and public insurance schemes**

In France, almost the entire population (95%) has complementary PHI ("assurance maladie complémentaire", AMC) to cover cost-sharing in the social security system ("assurance maladie obligatoire", AMO). Three categories of insurers are present in the AMC market:

- The "mutuelles" are not-for-profit entities that aim to achieve solidarity in cost-sharing. Mutuelles mainly focus on health care and make limited use of risk-rating but sometimes adjust premiums according to income. Mutuelles mainly cover people on an individual basis. Their market share stands at 54%.
- The "sociétés d'assurances" are profit-making companies that mainly provide life insurance for groups, and coverage for unemployment, disability, and judicial assistance purchased by individuals. Health care coverage is only a by-product. Sociétés d'assurances make use of a large set of indicators including health status to rate premiums. Their market share is the second highest, at 28%.
- The "institutions de prévoyance" are non-profit-making and focus on collective contracts for companies that have a mandatory enrolment of employees in AMC. Their market share stands at 18%.

Functions related to management of claims and reimbursements are similar across all types of AMC, but levels of administrative spending differ between them. Total administrative costs are highest in sociétés d'assurance, because of higher profits and higher acquisition costs for clients. Institutions de prévoyance have the lowest administrative spending as they mainly offer group contracts and therefore enjoy economies of scale, reflected in lower spending on general administration (Figure 6.5). Mutuelles, which focus on the individual market, have relatively high general administrative costs.

Figure 6.5. **Administrative spending including profits among complementary PHI schemes in France, 2013**



Source: Adapted from Montaut, A. (2015), *Rapport 2014 : La situation financière des organismes complémentaires assurant une couverture santé*, Direction de la recherche, des études, de l'évaluation et des statistiques (DREES), Paris; and DREES (2015), *Les dépenses de santé en 2014*, Direction de la recherche, des études, de l'évaluation et des statistiques, Paris.

StatLink http://dx.doi.org/10.1787/888933444288

One additional factor explaining France's relatively high administrative costs (recall Figure 6.2) is the duplication of transactions: for example, patients can pay some medical costs upfront before filing two reimbursement requests, first to the SHI and then to their PHI to cover part of the co-payments.

2.1. Meso level: Administrative overheads can be considerable in health care organisations

Generally, organisations that provide health care must allocate a certain amount of resources to manage, finance, organise and document health care delivery. This section gives an overview of the multiple administrative tasks health providers have to perform and why this may differ between providers and across countries.

A clear demarcation of administrative costs is challenging because many tasks performed across health facilities can serve both an administrative and a clinical purpose; for instance, documenting care delivery. It is therefore almost impossible to clearly define what entails "administrative overheads", let alone compare it across settings or countries. Table 6.2 categorises some of the main tasks on a continuum from purely administrative functions to those that also have a more clinical purpose. Beyond looking into administrative tasks, a number of costs (such as for site maintenance, utilities, depreciation and interest payment) are frequently classified as "administrative" in nature and also affect administrative costs of health care facilities.

Table 6.2. **Conceptual overview of administrative activities in health care settings**

Administrative activities			Primary care providers	Hospital
Purely administrative	Boards and strategic governance		0/+	++
	Financing	Payrolls	0/+	++
		Accounting and auditing	+	++
		Billing and insurance related	+	++
	Organisational	HR management	0/+	++
		Planning and scheduling	+	++
		Material purchasing, distribution, administration	+	++
	Clinical governance		0/+	++
Mixed administrative and clinical	Care delivery documentation	Patient admission and discharge co-ordination	+	++
		Quality and risk data processing	+	++
		Medical records	+	++

Note: For Primary Care Providers intensity of administrative activities varies depending whether it refers to a solo GP practice or primary care clinic.
0 Not relevant or activity is only marginally performed in this health care setting.
+ Activity performed in this health care setting.
++ Activity performed more extensively in this health care setting.
Source: Authors' own assessment.

In principle, two main institutional factors appear to explain variation in resources allocated to administration across different health care facilities within and across countries:

- Complex and large health care organisations like hospitals have higher administrative costs than smaller and less complex facilities.
- Administrative costs incurred by health care facilities are higher in countries with high data-reporting demands, activity-based payment mechanisms and multi-payer systems.

While this may seem rather obvious, a number of other factors also contribute to differences in administrative costs, such as the size of separate medical groups within a facility, its legal status (public, private, for-profit, not for-profit), the quality of management, the uptake of ICT in facilities, and regional aspects such as differences in wages and other costs.

Complex health care organisations are likely to have higher administrative costs

Costs in health care facilities related to administrative tasks differ across levels of care (e.g. primary care, hospital care, long-term care). The more complex health care delivery becomes (i.e. longer episodes of care delivery, higher variety of diagnostics and treatments used, more diverse workforce composition), the more resources are necessary to perform these functions and consequently, more administrative overheads are required to monitor the provision of care. Costs for maintenance and equipment are also higher in more complex settings.

Health care system characteristics affect administrative costs of health care provision and higher administrative spending may lead to benefits elsewhere in the system

The administrative costs borne by health care facilities depend on aspects of the health financing and governance systems in which they operate. For instance, activity-based payment systems such as fee-for-service (FFS) and diagnosis-related groups (DRGs) are likely to lead to a greater administrative burden for providers compared with global budgets. Individual case billing may require additional staff to code and translate medical records into billing forms and to monitor reimbursements. That said, these payment systems may come with other potential benefits or cost-savings elsewhere in the system. DRG-based payment systems, for example, are associated with reduced average length of stay (ALOS) in hospitals, thus increasing technical efficiency. In the Netherlands, they contributed to a reduction in cost per care episode (Westert and Klazinga, 2011). Similarly, multi-payer systems can increase the administrative burden at the provider level with their duplicative contracting and billing activities.

Other country-specific factors are related to reporting requirements of regulatory bodies, public or professional demands in relation to the reporting of quality measures or data processing, the autonomy of medical professionals and their culture in co-operating with administrators and boards, and the reporting requirements for different financing agents. But higher regulatory requirements may, too, come with certain benefits. Resource-intensive and costly pretreatment authorisation requirements, for instance, can increase the appropriateness and quality of care (Hussey and Anderson, 2003).

Despite differences in accounting standards and definitions, some research compares administrative costs across countries, even if it is mainly limited to hospitals (Himmelstein et al., 2014; Table 6.3).

Of the countries where comparison was limited to *central* administrative costs, Canada reported a share of hospital costs (7.4%) less than half that of the United States. When expanding the analysis to total hospital administrative costs, Scotland reported the lowest figure (11.6%). In the United States, this figure was, again, more than twice as high. Procurement and co-ordination of facilities, supplies and personnel were found to be the core tasks of hospital administrators, as they constitute about 12% of total hospital expenditure in countries where administrators have few responsibilities beyond such logistics.

As mentioned, differences in the way hospitals generate financial income may explain why hospital administrative overheads are considerably higher in some nations. Countries with case-based (DRG-type) hospital billing systems (England, France, Germany, the Netherlands and the United States) exhibit higher administrative costs than countries where hospitals receive global budgets (Canada, Scotland and Wales). Additionally, the way

Table 6.3. **Hospital administrative costs and spending in eight nations, 2010**

	USA	CAN	FRA	DEU	NLD	UK		
						ENG	SCO	WAL
Total hospital expenditure								
Per capita, (USD PPP)	2 634	1 271	1 357	1 245	1 631	1 458	1 416	1 482
Share of GDP (%)	5.63	3.25	3.98	3.33	3.87	4.09	4.39	4.60
Central administration								
Share of hospital costs (%)	15.51	7.40	8.77	9.00	10.85	..	..	..
Hospital administration								
Share of hospital costs (%)	25.32	12.42	..	..	19.79	15.45	11.59	14.27

Note: Hospital costs data of these nations were classified under clinical and administrative functions (including IT) using the Medicare hospital costs reporting format. Mixed costs like plant maintenance and repairs and capital costs were apportioned between clinical and administrative costs. Research and teaching costs were excluded. Central administration costs excludes IT costs and administrative work on wards or otherclinical locations.
Source: Adapted from Himmelstein, D. et al. (2014), "A Comparison Of Hospital Administrative Costs In Eight Nations: US Costs Exceed All Others by Far", *Health Affairs*, Vol. 33, No. 9, pp. 1586-1594.

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hospital investments are financed seems to affect administrative costs. Countries where investments are largely generated out of operational revenues (the Netherlands, the United States and increasingly England) show higher administrative costs than countries where direct capital transfers from the central or regional governments account for a substantial share of hospital investment (Canada, France, Germany, Scotland and Wales). In countries where capital investment is funded out of hospitals' revenues, additional activity appears to be required to identify opportunities to generate profits. Higher administrative cost may also be related to the extent to which capital investment is financed out of loans and their subsequent interest payments.

Interpreting the data, Himmelstein et al. (2014) highlight a positive correlation between the role of market mechanisms in a country's health system and the share of administrative costs. Analysing data for the United States in more detail they find a higher share of administrative spending in for-profit hospitals than in non-profit or public hospitals. But they admit that other factors such as the higher intensity of care in US hospitals or the heavier regulatory burden in the United States and the Netherlands may partly explain the higher administrative costs in those countries.

Higher administrative costs at the provider level in the United States are confirmed in several other studies comparing the United States to Canada (Evans, 2013; Berwick and Hackbarth, 2012; Bentley et al., 2008). One study found that extra administrative expenses accounted for the largest share (39%) of the spending difference for physicians and hospitals (Pozen and Cutler, 2010). The high overheads of providers in the United States can also be linked to the need to claim reimbursements from multiple payers that have little incentive to synchronise their communication with providers (Bentley et al., 2008; Berwick and Hackbarth, 2012; Cutler et al., 2012). A study that investigated this in more detail compared the resources allocated to "Billing and Insurance Related" (BIR) functions in US health facilities with Canada to estimate the "added BIR costs". It found that BIR costs in the US health care system represented 13% of US national health spending on physician practices, 8.5% on hospitals, and 10% on other health services and supplies. Around three-quarters of these costs were considered "added" due to complexities associated with the US multi-payer system (Jiwani et al., 2014).

Differences in administrative costs at the provider level within a country suggest inefficiencies

Differences in administrative costs at the provider level across countries cannot automatically be considered wasteful. As mentioned, some administrative activities may come with other potential benefits or may save costs elsewhere in the system.

A large variation in administrative costs for similar health providers within a country, however, may hint at inefficient use of resources in some facilities. A recent report analysing variations in productivity and performance across National Health Service (NHS) acute hospitals in England found huge variations for clinical and non-clinical resources, highlighting the potential for substantive efficiency gains (Department of Health of the United Kingdom, 2016). Between the cheapest and most expensive 5% of NHS trusts, procurement costs varied by 100%; the difference for facility running costs was almost three-fold, and more than double for cleaning costs and food costs per meal. Even corporate and administrative staff costs were almost 50% higher. For the latter, the variation across NHS trusts was equivalent to between 6-11% of the trusts' income. Large staffing differences were also found. The ratio of administrative staff to managers ranged from 5:1 to more than 25:1 among the different NHS trusts, while the clinical to administrative staff ratio ranged from 2.3:1 to 7.9:1. Overall, estimated efficiency gains of around GBP 2 billion could be achieved in the areas of procurement, facilities and administrative costs by reducing unexplainable cost variation. Improving the quality of management is one possible lever to increase health facilities' performance.

Related to this are missed managerial opportunities to optimise the use of human resources. This extends the notion of "administrative waste" somewhat but it, too, concerns management capacity at the health provider level. One element is staff absenteeism, which can be a source of considerable inefficiency. Of course, this issue is relevant in all industries but seems to be more pronounced in the health sector. For instance, across NHS trusts in England, the average rate of sickness absence is around 4%, higher than both the public (2.9%) and private (1.8%) sector averages. Moreover, an unexplained variation arises across NHS providers, with those displaying the highest sickness absence rates at 1.6 times those with the lowest absence rates. Variations in staff absence also exist between professions, ranging from 1.2% for medical and dental staff to 5.6% for clinical support staff (Department of Health of the United Kingdom, 2016). This difference is observed in other countries; for example in public health facilities in France, sickness-related absence of medical staff (3.4%) is less than half that of non-medical staff (Agence Technique de l'Information sur l'Hospitalisation, 2016). Reducing sickness rates could potentially generate huge savings. For NHS trusts in England, a 1% improvement in sickness absence equates with GBP 280 million in staff costs (Department of Health of the United Kingdom, 2016). That said, reasons for sickness absence and in particular its variation across professions and providers must be better understood. High staff absence can hint at poor organisational management without a coherent strategy to address work conditions. A recent report in England made a number of recommendations both at the national and regional level mainly centred on improvement in staff health and well-being (NHS Employers, 2014).

Although efforts to reduce administrative costs at the level of health providers may be welcome, it needs to be stressed that these costs are a necessary part of all industries. A look beyond the health sector may give a clue as to whether administrative spending in health care facilities is exceptionally high. But again, data to make comparisons are scarce.

In other service-oriented industries such as the banking sector, overhead costs as a share of total assets averaged at just above 3% in OECD countries in 2009 (Beck and Demirgüç-Kunt, 2009). Profits aside, it is expected that banks would incur lower overheads than most health care settings, as delivery of financial products is much more standardised and less complex than the provision of health care services, and less labour-intensive. But industries with high administrative costs are not necessarily inefficient. Analysing the UK manufacturing sector's performance by comparing enterprises' skill mix and gross value added, Barnes and Haskel (2001) found a positive correlation between the ratio of administrative costs for operative workers and productivity.

2.2. Micro level: Time spent by health care workers on non-clinical administrative tasks is non-trivial

Concerns persist that health workers have seen an increase in administrative duties in recent years in many countries, thereby reducing the time available for patient treatment and care provision. This can be traced to the same causes that increase administrative activities at the macro and meso levels: increasingly complex health care systems and rising reporting and data demands.

From a conceptual point of view, the list of administrative tasks performed by health workers is similar to those at the facility level,[3] with the same discussion about what is "purely" administrative (Table 6.4). The extent to which these administrative activities are carried out by health workers depends on the different professions but employment status has an impact. The administrative workloads of various health professionals can also be very country-specific, as for some professions (e.g. nurses) a wide variety of different profiles exists across countries, associated with more or less autonomy and responsibility.

Table 6.4. **Conceptual overview of functions contributing to administrative workload borne by health workers**

Administrative activities			Salaried	Self-employed
Purely administrative	Financing	Accounting and auditing	0	+
		Claims, billing and insurance related	0	+
	Organisational	Planning and scheduling	0	+
		HR management	0	+
	Clinical documentation	Medical records	+	+
		Other data reporting (e.g. quality)	+	+
		Medication administration	+	+
Mixed administrative and clinical		Patient correspondence, discharge letters and documents	+	+

0 Activity not relevant or only marginally performed by health workers.
+ Activity performed by health workers.
Source: Authors' own analysis.

Three main factors explain variations in the administrative workload borne by different health workers within and between countries:

- Self-employed health workers in solo practices are likely to have a higher administrative workload than those working in group practices and much more than salaried health workers.

- High-skilled health workers may spend less time on administrative tasks than less qualified categories of health workers.
- The administrative workload across countries differs due to the organisation and financing of the health care system and other contextual factors such as labour market characteristics.

Self-employed health workers typically have higher administrative workloads

A large difference is present in the individual administrative workload of self-employed health professionals working in their own practice compared with salaried employees working in larger health care facilities. While the overall amount of time spent on administrative activities in larger structures certainly exceeds that in solo practices, it is usually distributed among several health workers or delegated to other non-clinical staff, hence unburdening health professionals. For instance, physicians employed by a hospital can often depend on non-clinical staff to take care of a number of administrative tasks, such as billing procedures. Self-employed general practitioners (GPs) working solo have to spend more time on these activities themselves. A French study found that GPs working in group practices are more likely to have secretarial assistants and help with bookkeeping (Box 6.3). The study suggested that the time spent on administrative activity depends on the level of clinical activity and hence on income and opportunity costs.

Box 6.3. **Organisation of administration by independent French physicians**

A study that surveyed how French GPs spent their time showed large variation in the administration of practices. Forty-four per cent of GPs reported conducting secretarial tasks themselves, such as scheduling and reception duties. Bookkeeping was done by GPs in 22% of cases, while 14% even reported cleaning their own practice. A significant difference arises between GPs working in solo versus group practices, though. While three-quarters of GPs in group practices had a secretariat, this was true for only a third of those working in solo practices. The share of GPs doing their own bookkeeping was also higher for those in solo practices than in group practices.

GPs with high levels of clinical activity tend to perform administrative tasks less frequently themselves. Among those GPs with more than 4 000 consultations per year, 63% had a secretariat and 16% did their accounting themselves. For less active GPs the shares stood at 43% and 32%, respectively. Age and region seem to be two other factors that influence the administrative workload among GPs.

Source: Jakoubovitch, S. et al. (2012), "Les emplois du temps des médécines généralistes", *Études et résultats*, No. 797, Direction de la recherche, des études, de l'évaluation et des statistiques, Paris.

High-skilled clinicians spend considerable time on administrative tasks

Measuring the time spent on administrative tasks by health workers is difficult. In addition to the problem of definition and distinguishing such tasks from clinical activities, issues around study design can impact results and comparability. Quantification based on self-reporting can be heavily biased, while observational studies in which the use of health workers' time is monitored and documented by a third party are costly and

resource-intensive. That said, observational studies conducted across different settings in different countries found the following:

- Time spent by physicians on "documentation" ranged from 8% to 27%. Austrian inpatient physicians were found to spend more than a quarter of their time on documentation, although much was defined as "clinical" with the rest purely administrative (Ammenwerth and Spötl, 2009). An Australian study conducted among emergency department specialists found even higher figures, although these are overestimated because they contain activities related to indirect patient care that could not be reclassified (Kee et al., 2012). Finally, a German study found that cardiologists dedicate 15% of their time on documentation (Mache et al., 2011).
- Other health workers devote a significant proportion of their time to administrative tasks: Australian clinical dieticians were found to spend 13.5% on "documentation" (Milosavljevic et al., 2011). For personal carers in Australian residential aged care facilities, the share was reported to be 10% of working hours (Munyisia et al., 2013). Pharmacists in geriatric hospitals in Malta were found to spend more than a quarter of their time on documentation (Wirth et al., 2009). Finally, a US study reported that intensive care unit nurses dedicated around 17% of their time to documentation (Dwibedi et al., 2011).

For the limited number of studies comparing across several professions, it appears that less-skilled workers devote more time on administrative activity than high-skilled health workers:

- Two studies conducted in Australian teaching hospitals found that the time spent on documentation ranged from 8% for registrars to 13% for residents and indicated that interns bore the brunt of the administrative workload (27%) (Westbrook et al., 2008; Arabadzhiyska et al., 2013).
- A study that surveyed physicians, nurses and clerical staff on their time spent on interactions with payers in the United States and Canada found that lower-skilled health workers take up more administrative tasks. Physicians reported interacting 3.4 hours (the United States) and 2.2 hours (Canada) per week on average with payers, whereas American and Canadian nurses spent 20.6 and 2.5 hours for the same tasks, respectively. In both countries, these tasks were predominantly done by clerical staff who spent 53.1 hours (the United States) and 15.9 hours (Canada) hours per week on them (Morra et al., 2011).

A division of labour where highly specialised physicians can concentrate on the treatment of patients makes economic sense, as purely administrative activities without clinical aspect can be performed by health workers with a lower skill set.

Health care financing systems can impact health professionals' administrative workload

As with health care facilities, variations across countries in the time spent by health workers on administration may reflect cultural differences, such as the autonomy of health workers or the extent to which regulatory bodies influence daily clinical practice. How health care delivery is organised may play a role. Finally, how health care is financed appears to be important as well. Studies comparing time spent by physicians, nurses and administrative staff interacting with payers show that this is significantly higher in a multi-payer system such as the United States than in Canada (a single-payer system). This

is partly because more time is spent on managing claims and billing activities in a multi-payer system but is also caused by additional interactions with payers in the US health care system, such as obtaining prior authorisations for many services under managed care programmes (Morra et al., 2011; Cutler et al., 2012).

Lack of data obscures health professionals' actual administrative burden

The limited amount of available evidence on health professionals' administrative burden makes it difficult to confirm the hypotheses made at the conceptual level. Efforts to quantify time spent by health workers on non-clinical tasks should be strengthened to give policy makers a better idea to what extent skill mismatches exist and to see whether complaints by health workers are justified. At the same time, any analysis should take into account the subjective burden of administrative tasks, which can impact job satisfaction. A survey conducted among US physicians, for instance, found that physicians who reported to be very satisfied with their work spent 16% of their time on administration, compared to 21% for those who reported to be very dissatisfied (Woolhandler and Himmelstein, 2014). Careful monitoring can help pinpoint inefficient administrative processes or outputs that add little value. Within that context, the most obvious case occurs when relatively simple administrative tasks are performed by highly skilled staff who could use their time for more valuable activities.

Going beyond administrative activities, the question about the right skill mix and whether all health workers are employed to the best of their abilities is also relevant to the managerial level of health providers. As in the case of sickness absence, suboptimal use of the available workforce can cause considerable inefficiency. In England, a recent report showed that nurses in acute and general medicine wards and community midwives only spend between 41% and 55% of their work time on direct patient care (McKinsey, 2009). Better organisation and staff planning at the provider level could increase health workers' face-time with patients. Related to this are discussions about changes in the scope of practice in health professions, but any changes in the skill set of that kind cannot be influenced by managers. These reforms are much more transformative in nature, requiring commitment for change at the policy level, and go beyond the scope of this report.

In an ideal scenario, administrative tasks should only be conducted at the macro and meso level, with health workers spending all of their time on patient care. Such a scenario is unrealistic, however. Quality indicators, for instance, are unlikely to offer meaningful information for health providers if information collected at the macro and meso level does not relate to what happens at the micro level. This linkage cannot occur without health workers' involvement (OECD, 2010a). But not all clinical data collected appear to add value. For NHS England, the time spent on the collection, recording and validation of data by clinical staff ranges from two to ten hours per week but only 65% of it is considered useful and relevant for patient care (NHS Confederation, 2013). It is therefore a matter of finding the right balance in the use of health workers' time, such that the benefits of administrative tasks exceed their costs and do not outweigh the value of core clinical work.

3. Policies targeted at reducing administrative costs

During the recent economic crisis, many OECD countries targeted a reduction in administrative spending as public finances were tightened. For example, in the Czech Republic the Ministry of Health budget was reduced by 30% between 2008 and 2010 (OECD, 2014). In Ireland, staff numbers at the Health Services Executive were cut by 6 000

in 2010, following a commitment to reduce administration, management and advertising costs by at least 3%. In Switzerland, staff costs in the health administration were lowered (by up to 10%) from 2008 onwards (European Observatory on Health Systems and Policies, 2015). Finally, in Greece, austerity measures included a 50% reduction in administrative staff at the central social security fund (Karanikolos et al., 2013). While an effective tool to contain administrative spending in the short term, cutting salaries or reducing the workforce does not necessarily tackle waste and can affect the provision of vital services. That said, such measures can potentially increase efficiency if it is seen that the remaining workforce delivers the same or even higher administrative output, or if cuts are concentrated in areas that add little value.

3.1. Best practices can identify wasteful spending

A prerequisite to avoid indiscriminate and across-the-board spending cuts in health care administration is identification of areas where wasteful spending actually occurs. Promising approaches in pinpointing and quantifying such areas or activities include an in-depth stocktaking of the administrative burden of health care providers or a comprehensive functional analysis of organisations. Development of subsequent strategies often results from these smaller- or larger-scale investigations of administrative activities.

Systematic reviews of administrative burden can help identify output that is not value for money

One method to identify wasteful administrative spending is a systematic review to assess the administrative burden of enterprises due to government regulation. A framework for these types of evaluations was developed with the Standard Cost Model (SCM). Developed in the Netherlands, the SCM (Box 6.4) measures the costs of administration imposed on business by governments and allows for comprehensive measurement and comparison of administrative costs across industries. This approach is limited to an assessment of administrative costs related to governmental regulation, and only shows the costs, not the benefits, of different administrative tasks. Nonetheless, the model contributes to the discussion by identifying activities that represent no value for money; as such, it helps streamline administrative activities.

Using this approach, a German review identified and costed the administrative burden on physicians, psychotherapists and dentists affiliated with the SHI system. The review was the basis of a German multistakeholder approach to identify low-value activities related to reporting, documentation and other administrative tasks of these health care providers (Statistisches Bundesamt, 2015). The discussions brought together the federal associations of doctors, dentists and public health insurers, the Ministry of Health and a task force at the Federal Chancellery concerned with reductions in bureaucracy. The measurement of administrative costs was carried out by the Federal Statistical Office. The results showed that provider groups' administrative workload due to reporting obligations, data requests and other administrative requirements amounted to EUR 4.3 billion per year. EUR 2.2 billion was due to obligations defined by physicians' self-governing institutions, EUR 1.1 billion by dentists' self-governing institutions, and EUR 1 billion to requirements set out by the Ministry of Health. The costs translated into 14 million days per year spent by physicians, psychotherapists and dentists on various information-reporting requirements, or 96 days per year for an average physician practice.

Box 6.4. **Methodology of the Standard Cost Model**

The Standard Cost Model (SCM) is a method to measure administrative costs imposed on business by government regulation. It applies a pragmatic approach to measurement and provides estimates that are consistent across policy areas. Costs can either be measured directly or determined through interviews and observations. The process to measure costs caused by government regulation requires the following steps:

1. The SCM breaks down regulation into manageable components that can be measured: information obligations,[1] data requirements[2] and administrative activities.[3]
2. The SCM then estimates the costs of completing each activity on the basis of a couple of basic cost parameters:
   - Price: price consists of a tariff, wage costs, plus overheads for administrative activities done internally or hourly costs for external services.
   - Time: the amount of time required to complete the administrative activity.
   - Quantity: quantity comprises the size of the population of businesses affected and the frequency with which the activity must be carried out each year.
3. The combination of these elements gives the basic SCM formula:
   Cost per administrative activity = Price × Time × Quantity

1. Information obligations are obligations to provide information and data to the public sector or third parties (e.g. energy labelling of domestic appliances).
2. A data requirement is each element of information that must be provided in complying with an information obligation. Each information obligation consists of one or more data requirements (e.g. statement of business's equity, identity of business).
3. To provide information for each data requirement, a number of specific administrative activities must be carried out. These may be done internally or outsourced. They can be measured (e.g. performing relevant calculations, submitting information, archiving information).

Source: International SCM Network to Reduce Administrative Burdens (2009), "International Standard Cost Model Manual", *www.oecd.org/gov/regulatory-policy/34227698.pdf*.

Based on this review, the various stakeholders jointly recommended 20 very detailed, sector-specific actionable measures to improve efficiency; many of them related to lifting regulations (Box 6.5). Taken individually, some of the detailed suggestions might seem to be of limited effect as they probably take up only a small portion of health workers' time, but taken together such small changes might eventually account for significant reductions in bureaucracy.

Quantification of potential savings is also possible with other approaches. In France, identification of wasteful spending, its quantification and development of strategies to achieve efficiency gains were part of a report of the financial and social affairs inspectorates (Box 6.6).

Wasteful administrative spending can be identified with other bottom-up and top-down approaches

In other countries, a combination of approaches is used to identify wasteful administrative costs. In the Netherlands, a working group comprising doctors, insurers, the government and patient representative bodies was set up to identify unnecessary administrative requirements for GPs, focusing on both short- and long-term solutions for key problems. As a result, a limit in reporting requirements through a reduction in forms requested by health insurance companies was signalled for action in 2016. This multistakeholder approach inspired six other sectors in primary care (district nurse, dental

Box 6.5. **Twenty recommendations following the in-depth investigation of administrative processes and requirements among physicians, psychotherapists and dentists in Germany**

ICT-related

- Adoption of electronic application and approval procedures for dental treatment plans.
- Digitalisation and simplification of archiving requirements to reduce physical space necessary for documents and dentistry models.
- The filling of forms by physicians can be done more efficiently by implementing easy-to-understand guidelines in the supporting software.

Optimisation of forms

- The current form to prescribe patient transport should be improved and simplified. Currently, it is generally considered confusing for physicians, leading to unnecessary additional communication between providers and sickness funds.
- Standardisation and merging of medical certificates for incapacity for work (for employers/sickness funds) and sick pay (sickness funds) that would allow for automatic processing. Currently, sick pay certificates are not standardised among sickness funds and physicians have to fill them out by hand.
- Duplication of certain forms related to medical rehabilitation could be avoided, for instance by transferring the responsibility to fill certain forms to insurers.
- Periodical reviews and standardisation of particular reporting forms, ideally using telematic infrastructures, to make them easier to understand and use for physicians.

Optimisation of procedures

- Adaptation of guidelines for internal quality management in outpatient care facilities to clarify that quality management should be jointly implemented by all physicians working within a facility across all care delivery processes.
- Simplification of procedures for physicians in prescribing long-term therapy (e.g. physiotherapy, ergotherapy, speech therapy) for certain chronic conditions. Some sickness funds still insist on approving some standard cases individually, requiring additional documentation by physicians.
- More flexibility regarding mandatory professional training could save dentists time, for instance by allowing online courses for the use of X-ray machines.
- Simplification of procedures to prescribe narcotics by adopting a system that allows for the use of regular laser printers. Currently, narcotics require special prescription forms for enhanced safety requirements, for which a special printer is needed.

Duplication of documentation or collection of data

- Streamlining the use of X-ray machines by centralisation of registration requirements for dental practices.
- Abandoning in-practice inspection of the efficacy of medical devices that have already been officially approved.
- Joint inspections of dental practices by different supervisory bodies to decrease the associated burden.
- Certain authorisation requirements related to software used for the printing of forms that require special safety paper should be abolished because whether practices use required software can be assessed from other data submissions.

Box 6.5. **Twenty recommendations following the in-depth investigation of administrative processes and requirements among physicians, psychotherapists and dentists in Germany** *(cont.)*

Reducing bureaucracy

- To test administrative alternatives that aim to reduce the bureaucratic burden for physicians, a standardised method to assess the effects of such alternatives in pilot-settings is proposed.
- Certain processes to assess the level of *ex ante* remunerations of administrative costs imposed on physicians and dentists following new legislation might be conducted more efficiently when information is collected from providers early in the assessment process.
- Simplification of the documentation of using medical instruments. Currently dentists (and physicians) need to document every step taken in using medical instruments to maximise hygienic use. Given the routine use of these products, the proposal is to only document exceptions in the use of medical instruments, at the end of a working day ("Negativdokumentation").
- Procedures for declarations of chronic illness could be streamlined and the form should be simplified. This declaration is required to limit co-payments for chronic patients and has to be signed by the treating physicians. Sickness funds should prefill the form with all available patient information to limit the burden of physicians.
- Streamline approval procedures for psychotherapy. Currently, an independent expert evaluation can be required. It is proposed to abolish this evaluation for short-term psychotherapy and additionally reduce paper documentation that is already available electronically.

Source: Statistisches Bundesamt (2015), *Mehr Zeit für Behandlung. Vereinfachung von Verfahren und Prozessen in Arzt- und Zahnarztpraxen*, Statistisches Bundesamt, im Auftrag des Nationalen Normenkontrollrates, Wiesbaden.

Box 6.6. **Menu of reform options in French health insurance**

In 2013, the French financial and social affairs inspectorates investigated potential approaches to save costs in social and private health insurance. Generally, the investigators pointed to the strict institutional separation between AMO ("assurance maladie obligatoire") and AMC ("assurance maladie complémentaire") and the lack of economies of scale due to the multi-payer system as reasons for high administrative costs. Strategies mentioned for improvement and their savings potential include:

- automating claims processing and file administration using ICT (estimated to save AMOs at least EUR 542 million per year)
- detecting and tackling differences in administrative performance across different insurers managing AMO (with a savings potential of between EUR 425-EUR 730 million)
- structural re-organisation of the operation of AMO by reducing the number of insurers managing AMO (with a savings potential of around EUR 440 million)
- integrating administrative processes between AMO and AMC by adopting a tele-transmission system ("Norme Ouverte d'Echanges Maladie") that exchanges reimbursement information between payers (with a savings potential of EUR 191 million for insurers managing AMC)
- increasing transparency on administrative costs of insurers managing AMC, including profits, which could put downward pressure on administrative costs in general.

Source: Inspection générale des finances and Inspection générale des affaires sociales (2013), *Les coûts de gestion de l'assurance maladie*, Inspection générale des finances and Inspection générales des affaires sociales, *www.igas.gouv.fr/IMG/pdf/RM2013-146P_2_.pdf*.

care, paramedics, mental health care, pharmacies and obstetrics) to constructively scrutinise their administrative relationship with health insurers. In the hospital sector, the *Kafka-Project* was supported by the Ministry of Health to identify and tackle bureaucratic bottlenecks preventing high-quality and efficient care, all seen from the perspective of the patient. Apart from these more bottom-up approaches, the Ministry of Health takes a leading role in exploring possibilities to reduce bureaucracy. For example, the Ministry develops strategies based on a survey that asks health care professionals to identify which pieces of legislation and regulation they perceive as adding no value and to put forward possible alternative solutions requiring less bureaucracy.

Bottom-up initiatives to find low-value administrative tasks exist in other countries as well, such as the *Administrative Simplification Initiative* set up by the American Medical Association. This platform advocates administrative simplification in the US health care system but also serves as a practical tool for health workers to point out a diverse array of support systems for clinical practices (AMA, 2015).

Generally, recommendations to curb administrative waste are more effective when they are a result of wide stakeholder consultations and ideally have wide stakeholder support. Of course, providers and payers frequently disagree about the usefulness of administrative tasks and their output, but both sides generally feel that the process of their interaction could improve (Morra et al., 2011; Micheau and Molière, 2010). This reality should be incentive enough in itself to bring stakeholders together to discuss administrative simplifications.

Functional reviews of governance activities on a macro level ask "Are we doing the right things?"

In a number of countries, governments have started to ask a more fundamental question. In addition to analysing how they can deliver services more efficiently they wonder whether they concentrate on the essential services in the first place. "Functional reviews" can help governments assess whether their administration is fit for purpose. Such reviews evaluate the effectiveness and efficiency of a governmental entity in its operations, programmes and administration. They also analyse whether the functions performed are in line with governmental objectives. In that sense, the term "function" refers to "a self-contained body of work likely to be at the sub-programme level, and includes all areas in which the government employs staffing or resources to achieve an output. This may include functions that contribute to service delivery, policy development or functions that support activities such as corporate functions" (Australian Department of Finance, 2016).

Australia, for example, conducted a functional review of the Commonwealth Department of Health as part of a broader assessment of the entire governmental activity. The *Efficiency through Contestability Programme* was introduced in 2014 to identify "the most efficient and effective way of designing and delivering government policies, programmes and services" (Australian Department of Finance, 2016). The programme has three components:

- Portfolio stocktakes assess all functions performed at the portfolio level across all entities within the portfolio and identify those functions that could be provided more efficiently through alternative means (e.g. by other organisations inside or outside the government).

- Contestability reviews analyse in detail specific functions identified in portfolio stocktakes and review the most efficient alternative means to provide them (including an implementation plan).
- Functional and efficiency reviews analyse for specific entities whether their current functions are aligned with government priorities, and identify those functions where efficiency in delivery could be improved and ways to achieve this (alternative means, operational improvements or additional efficiencies).

The objective of the Australian functional and efficiency review was to realign administrative functions to better position the Department to provide national leadership in the health care system. The review identified efficiency gains of around AUD 106 million in the Department's operations, partly by removing duplication of administrative activities.

3.2. Organisation and co-ordination are main areas in which to rein in administrative waste

Coming back to the initial framework set out in Chapter 1, the detailed analysis presented here suggests that the main drivers of wasteful administrative spending are problems in organisation and co-ordination. The solutions are therefore typically organisational in nature but may also require regulatory interventions. In many cases, these two policy levers overlap; large re-organisations of administrative functions must be based on legal changes. The key recommendations with regard to organisational changes emerging from more or less comprehensive reviews are typically country- and system-specific and range from smaller adjustments to re-organisation of regulatory functions. They can be broadly clustered into the following categories:

- making better use of ICT in communications between payers and providers
- simplifying administrative procedures
- finding the right size of administrative bodies.

Frequently, actions taken are accompanied by measures to generate and publicise information on administrative costs or the administrative workload to increase transparency. In many instances, measures introduced that affect administrative spending do not only tackle administrative waste, but also relate to operational or clinical waste. This refers, for example, to overall budget targets for public insurers that require them to find efficiency gains at all levels of service delivery and operations. Finally, some of the measures taken to combat administrative waste are not health-specific but relate to the entire public sector, and are thus much larger in scope.

In addition to action taken by governments, other public bodies or private payers, health providers themselves try to reduce administrative activity by streamlining their operations without the involvement of payers or the regulator – just like any other industry. Depending on the managerial autonomy of health providers this may refer to leaner management structures and more flexibility in staff numbers or better organisation of hospital management. Improving overall management quality and capacity can also be an aim. In England, for example, hospitals are encouraged to apply management strategies borrowed from the manufacturing industry, such as "Lean" or "Six Sigma" (NHS Institute for Innovation and Improvement, 2005). Whereas "'Lean" strives to improve the flow in the value stream and eliminate waste in companies' operations, "Six Sigma" is a framework to understand and limit variations in the quality of products. As seen in the previous section, better management of human resources at the provider level is an important strategy to

boost provider performance, albeit going beyond addressing only "administrative" inefficiency. Relying on e-solutions to optimise hospital staff planning can save money by limiting the use of additional temporary staff. To address costly staff absenteeism, a recent report in England made a number of recommendations mainly centred on improvement in staff health and well-being (NHS Employers, 2014). For the NHS trusts at the local level, the report recommended, for example, to embed staff health and well-being into the organisational culture, to develop further support for mental health issues for both staff and managers, and to encourage staff to be personally responsible for their own health and well-being.

Organisational changes can make administration more efficient

Make better use of ICT in communication between payer and provider. Generally, ICT solutions are seen as important to reduce paperwork, particularly in the interaction between payers and providers. Measures of this kind have been taken or are currently under development in many countries, including Belgium, France, Norway, Slovenia, Switzerland and Estonia (Box 6.7). This can refer to electronic support in a wide range of domains such as electronic reporting of performance measurement, implementation of e-prescription and/or e-referrals, development of electronic health records (EHRs), or more generally using a digital platform to exchange information between providers and payers. Such platforms, for example, are used in France where practitioners can submit electronically some of the compulsory declarations (e.g. sick leave for employees or pregnancies) to the social security and other authorities. ICT solutions are also developed for billing purposes: standardisation of electronic health care claims was the aim of two initiatives in the United States in recent decades (Box 6.8).

Box 6.7. **Estonia's use of e-prescription**

Estonia embarked on a comprehensive e-health strategy, with e-prescription as one element to improve efficiency. Launched in 2010, e-prescription is integrated in a platform that also incorporates EHRs, a digital image archive, a patient portal, an e-laboratory and e-emergency care solutions.

All e-prescriptions issued by physicians are sent to a national database that can be accessed by pharmacies, other physicians and the health insurance fund. Patients can pick up their medication at any pharmacy by identifying themselves with their ID card. Repeat prescriptions can be issued by physicians after an email or a phone call, no longer requiring physical visits to the doctor. Digitalisation reduced the administrative workload of pharmacists; the health insurance fund gained better information about the pharmaceutical market and can now monitor prescription habits more effectively. It also improved efficiency for the Estonian health insurance fund: staff costs related to administering incorrect prescriptions reduced by more than 90% between 2009 and 2015. The database can provide an overview of all prescriptions issued for a patient and help signal possible interactions between different pharmaceuticals. By May 2011, 84% of all prescriptions were issued digitally and over 95% of pharmacies were ready to process e-prescriptions. Over 90% of patients are satisfied with these services.

Source: Estonian Health Insurance Fund (2016), Information on Digital Prescription, *www.haigekassa.ee/en/digital-prescription*.

Box 6.8. **A history of health care claim simplification strategies in the United States**

The 1996 Health Insurance Portability and Accountability Act (HIPAA) introduced mandatory standards for electronic health care claims in the United States, but the eventual regulations were criticised as being relatively vague. HIPAA was also criticised for failing to take into account the different data needs of insurance companies, and for lacking payer and provider incentives for investment in technology needed to support electronic transactions. As part of the reform a single claim form was developed, but payers and providers never agreed on a truly common standard in filling the standardised form. This resulted in publication of more than a thousand instruction guides (Bentley et al., 2008).

A second standardisation attempt that, so far, seems more successful was included in the Affordable Care Act (ACA). There, the rules for processing administrative interactions are more detailed, leaving less room for disagreement between providers and payers, and are accompanied by financial penalties for health plans that do not adopt the standardised procedures (Cutler et al., 2012). Furthermore, the ACA represents a much wider health care reform that may be more conducive to administrative simplification strategies than the HIPAA, which can be characterised more as a stand-alone initiative.

In many cases where increased use of ICT at the provider level is proposed, higher-quality data and improved patient safety are additional important aims. Generally, moving towards electronic recording and reporting is associated with high up-front development and implementation costs, but in the long run these measures may generate savings for governmental oversight bodies, insurers and health providers alike.

The potential for ICT uses in health care is extensively documented but privacy concerns and the lack of common standards and co-ordination across systems remain and can be barriers to ICT adoption (OECD, 2009, 2010b). The final jury on their cost-effectiveness is still out for most ICT services in health care. At the same time, promising tools appear to be electronic transaction systems for billing and insurance-related tasks, and for integration of administrative and clinical health care systems. In the United States, adopting electronic transactions for the electronic processing of claim submissions, eligibility inquires and requests, claim status requests, and payment and remittance transactions is estimated to save providers USD 11 billion annually, with another USD 2 billion potential saved when administrative and clinical health systems are integrated (Cutler et al., 2012). Wide adoption of these initiatives could also benefit payers including the US federal government. However, these savings often remain untapped because providers lack incentives to invest in supporting technology (Bentley et al., 2008). In health care, this is a general issue. Experience with the introduction of ICT shows that providers frequently bear most of the costs and yet gain little of the benefits (OECD, 2010b). To overcome this problem, since 2011, health providers in the United States that successfully demonstrate "meaningful use" of certified EHR technology can benefit from financial support under the Medicare and Medicaid EHR incentive programmes. Under these programmes, "meaningful use" refers to the use of EHR to exchange health information or to submit quality measures, or to the use of EHR in another meaningful manner, such as for e-prescription. In 2015, financial penalties were introduced for those eligible providers not participating in the programmes. Despite

disbursement of significant funding under these programmes, physicians remain critical of the extent to which EHR improves efficiency. Three out of four believe that it increases costs and does not save time. Seven out of ten nevertheless think EHR provides useful analytics and 60% are convinced EHR contributes to value-based care (Deloitte, 2014).

At any rate, a careful implementation strategy needs to be planned, including extensive training of providers but also addressing patients' data security concerns from the outset if countries start moving towards better use of ICT for administrative purposes in health care.

Simplify administrative procedures. Regulatory processes – not directly related to treatment – can be simplified with the help of ICT, as was the case for accreditations for professionals and providers in Denmark (changes in hospital accreditation) and Israel. In Israel, the move towards digitalised procedures for medical graduates to receive their medical licenses and to apply for compulsory clinical internships helped speed up these processes considerably. It also led to a better matching of hospitals and interns, who are now more likely to work in the hospital of their choice. Other simplification measures include streamlining forms used by physicians for billing purposes or prescription forms.

Billing was simplified in Germany in 2013 when it abolished a EUR 10 co-payment per quarter for GP and specialist consultations. Between 2004 and 2012, patients made the co-payment to the doctor while insurers directly financed the rest of the services for publicly insured patients. Removal of the co-payment is estimated to have saved GPs and specialists around EUR 330 million annually in administrative costs associated with the collection and documentation of co-payments. Physicians' total revenues were not affected as insurers covered the foregone co-payments. Also in Germany, some recommendations from multistakeholder consultations related to simplifying and lifting regulations, such as allowing online courses for mandatory professional training in radiation protection for dentists using X-ray apparatus, or scrapping special prescription forms for narcotic prescription that would permit the use of regular laser printers (Statistisches Bundesamt, 2015).

Find the right size of administrative bodies to generate economies of scale. Finally, many recommendations to improve administrative efficiency with organisational changes are around redefining the size of governmental bodies and redesigning the portfolio and operations of health administration entities. The overall aim is to find the optimal size of an administrative entity to achieve efficiency gains without compromising responsiveness. These changes can be part of a major system overhaul or refer to smaller organisational changes and include the mergers of previously separate administrative entities, or in other cases, their separation.

For example, Korea's move from a multi-payer to a single-payer health insurance system considerably reduced resources devoted to administration. This move facilitated a more standardised use of ICT and a standardisation of processes, and is generally associated with greater economies of scale in purchasing, but also in performing administrative tasks. Merging insurers resulted in a reduction of health insurance staff by about a third. The share of administrative costs in total SHI spending went down, from 8.5% in 1997 to 2.4% in 2008 (Jeong, 2010). In Iceland, the Ministry of Health merged with the Ministry of Social Affairs in 2008, while in the Slovak Republic two state-owned insurance companies joined forces with insurance companies in 2010, reducing their number of staff by 10% between 2010

and 2011. As part of the rescue financing deal with the European Commission, the European Central Bank and the International Monetary Fund, Greece merged the health divisions of the four main social insurance funds into one health insurer – the National Organization for Healthcare Services Provision (EOPYY) – and limited its role to purchasing services. Previously separate administrative bodies were also merged in Belgium. In Denmark, however, organisational change referred to the separation of institutions; in this case the Medicines Agency was separated from the National Health Authority to better streamline procedures to license new medicines. Whether agencies are merged or separated depends on the country-specific context but generally countries try to find the most appropriate organisational size to achieve efficiency gains. Consolidation of administrative activities of public insurers or governmental departments can be the result of efficiency targets striving to improve operations within administrative institutions, as was done in France and Australia. These consolidation efforts typically result in a reduction of administrative staff. Again, improvements in the processes of governmental operations can be facilitated by better use of ICT, as seen for example in Korea and Slovenia.

Consolidation and separation initiatives typically involve regulators, while the finer organisational changes can also concern managers, and to a certain degree, physicians.

Some countries have introduced regulatory controls over administrative burdens

Most of the organisational changes described above already involve the regulator to a certain extent. This section covers strategies applied in countries that use regulatory levers to improve administrative efficiency on a broader scale. These tools can vary a lot in their scope, from very broadly defined measures of legislative principles to different approaches to impose budget ceilings.

Many countries aim at simplifying procedures for providers and governance bodies or payers through regulatory changes in different areas of the health care system:

- With the introduction of the *Protection Universelle Maladie* in 2016, France amended its legislation to ensure continuity of insurance coverage to the entire resident population. Previously, entitlement to public insurance was linked to personal circumstances (in particular, employment status). The insured had to prove that they were entitled when circumstances changed and to meet specific criteria in each case. This measure reduced the administrative burden associated with enrolment for the insured and insurers alike.
- Simplification also stretches to legislative procedures. The Netherlands became more flexible in terms of legislation for innovative health providers. If a piece of legislation is perceived as an obstacle to potentially successful alternative care models, part of the legislation can be temporarily deactivated under certain conditions for innovative providers. If these experiments are successful, the Ministry of Health will scrutinise and, if necessary, remove the legislation altogether.

Other regulatory measures try to limit administrative burden or administrative spending, directly or indirectly:

- Germany introduced “a one-in one-out” rule for administrative reporting requirements, aiming to limit red tape for businesses in 2015. This means that for each additional legislated administrative burden an equivalent existing burden needs to be removed. This measure is not health-specific but is applicable to health care-related legislation. In 2013, the Australian government committed to reduce or eliminate regulatory burden on business, community groups and individuals by AUD 1 billion per year. In 2015, the

Commonwealth Department of Health's contribution to this regulation was a reduction of around AUD 97 million (Commonwealth of Australia, 2015). Part of this broader initiative to cut red tape in Australia includes strengthening regulatory capabilities by measuring regulators' performance. This is expected to highlight areas for regulatory improvement, which can potentially reduce compliance costs for business in all sectors including health care. Legislation to reduce paperwork for companies was introduced on a broader scale also in the United States and other countries.

- Adoption of international standards and risk assessment can reduce duplication of and delays in regulatory approvals. This principle is currently implemented in Australia: if a system, service or product is approved under a trusted international standard or risk assessment, national authorities should not impose any Australian-specific requirement unless good reasons exist to maintain country-specific standards. In practice, this has been applied, for example, by the Therapeutic Goods Administration (TGA) co-operating with a range of international bodies to develop international standards and risk assessments in the field of medical devices (Commonwealth of Australia, 2015).
- To limit private and public payers' administrative costs, some countries defined upper limits for administrative costs, implicitly or explicitly. As the oversight body for statutory health insurance, the Swiss Office of Public Health (FOPH), which has to approve annually all premiums charged by insurers for public coverage, surveys the financial records of health insurance companies and requires insurers to reduce their administrative costs below a defined limit if they are deemed excessive. In the United States, the Affordable Care Act (ACA) stipulates a Medical Loss Ratio requiring insurers to spend at least 80-85% of premiums on medical claims and quality improvement. If insurers do not meet this minimum standard they are required to issue rebates to enrolees. Since its introduction in 2011, the share of non-medical overhead costs in net premiums decreased slightly, resulting in accumulated savings of USD 3.7 billion by 2013. It remains unclear to what extent these savings can be attributed to the new regulation (McCue and Hall, 2015). On an aggregate level, however, introduction of the ACA is believed to have increased administrative costs, as coverage for those previously uninsured is supposed to be provided by private insurers. One alternative, extension of the Medicare programme to people without insurance coverage, would have resulted in lower total administrative costs, according to one study (Himmelstein and Woolhandler, 2016).
- Without immediate consequences for administrative costs some countries reformed budget setting procedures or introduced automatic efficiency targets in budgets to reduce waste. Denmark introduced changes to strengthen the governance of public expenditure (including health) by defining mid-term spending ceilings. These ceilings are also relevant for the annual budget negotiations between the central government and regions and municipalities, requiring the autonomous regions to stay within their budgets. Related to overall budget ceilings, efficiency targets are set in other countries to limit spending growth. In France, budget ceilings are defined in the agreements between the Ministry of Health and the main public insurer (CNAMTS), the "Conventions d'objectifs et de gestion". These agreements already incorporate projected annual efficiency gains that have to be realised by CNAMTS. For NHS England, an estimated total of GBP 22 billion in efficiency savings needs to be generated by 2020 to close the NHS funding gap. That said, many of the efficiency gains may have to be found outside of the administration and are more related to reducing clinical or operational waste.

Generation and publication of information will increase transparency

All OECD countries have some level of transparency for public administrative costs in place. At the very minimum, annual budget procedures require governments to publish past and projected costs and staff employed in Ministries of Health and other relevant public health administration bodies. Additionally, most OECD countries report their administrative spending on an aggregate level as part of international data collections on health expenditure and financing or publish administrative costs in other formats.

But governments can, of course, engage more actively in generating and publishing information for increased transparency of administrative costs. One measure that falls into that category is the legal requirement to estimate any additional administrative burden associated with each piece of new legislation discussed in parliament. This tool is not health-specific but can raise awareness of administrative burden and increases transparency of administrative costs. Germany and the Netherlands are among the countries that have adopted this principle. In Australia, any proposed regulation must undergo an assessment of regulatory impact in the private sector but this could possibly be expanded to include impact on government administrative burden. Other, more health-specific measures that highlight administrative costs can be related to the obligation for public health bodies to publish the salaries of their chief executive officers or to make private health insurers disclose their brokerage fees and operational costs.

Conclusion

Administrative tasks must be carried out at all levels of the health care system: at the macro level related to the financing, governance and organisation of the system as a whole, as well as at the provider level, where health care facilities and professionals must perform a number of administrative activities related to the organisation of health care delivery. At the macro level, large differences in administrative spending between countries can be observed, some of which can be explained by the way health care is financed in countries. Countries with multi-payer systems exhibit higher administrative costs than countries with a single payer. Private insurers' administrative costs are generally higher than those of public schemes. This difference in financing can also affect the administrative burden of providers and professionals.

But more resources going to administration is not necessarily a bad thing – they can be related to measures increasing quality of care or enhancing patient choice or lead to efficiency gains in care delivery. But if waste in health administration can be detected it should not be tolerated.

Many examples of addressing administrative spending in health care are relatively simple. Reducing staff, decreasing wages, or implementing a policy of non-replacement of staff reaching retirement age can be done to control spending on administration but across-the-board cuts are not the most efficient solution to address administrative waste. Better strategies to tackle waste basically involve a two-step approach:

- identification and quantification of administrative outputs that add little value or could be done more efficiently, and
- finding the right measures to optimise administration.

The most promising strategies to increase efficiency are centred on simplification of procedures – partly by making better use of ICT – and optimising the size of administrative bodies to generate economies of scale. Additionally, regulatory changes can have an enormous and immediate effect on administrative costs or on providers' administrative workload.

Over and above this broad set of recommendations to cut wasteful administrative spending, it is difficult to find more universally applicable best practices. What administrative services to cut or which administrative bodies to reform depends primarily on the nature of the health care system and the scope and autonomy of the different providers and health professionals. Cultural aspects also play a role, such as how societies determine the balance between comprehensive regulation and risk management on the one hand and flexibility in their health care systems on the other. As mentioned throughout this chapter, the separate levels of administration are interconnected and administrative changes in one level may have repercussions on others – this should be borne in mind in all administrative reform.

At the system level, limiting the discussion to making health care administration more efficient may be somewhat short-sighted. Broader analysis of administration in general as a key government function would be desirable. The health sector may benefit from broader initiatives, be it more effective budgeting procedures, streamlined communication between public bodies and citizens, or identification of spill-over effects between administrative bodies of health and social care. More potential for efficiency gains may lie untapped in this field.

While this chapter shows that much potential remains to drive up administrative efficiency theoretically, administrative simplification might be more difficult in practice. A recent OECD report highlights that administrative simplification is not that easy given that societal pressure for risk management is increasing, as is demand for more decentralised governments that nevertheless need to create effective regulatory environments to address market failures and foster technological innovations (OECD, 2010c). Very much in line with the recommendations in this chapter, the OECD report finds that:

- Simplification projects should focus on a broad range of actors and costs and should be integrated with other regulatory reforms.
- Administrative burdens and targets for their reduction need to be quantified based on their value for money.
- Simplification strategies need an environment of communication and trust between those affected and those that have the means to change an existing situation.

One difference that sets health care apart from many other governmental functions is the much higher reporting burden imposed on service providers related to accreditation and licensing, the measurement of performance, and the need to warrant patient safety, all of which contribute to health care systems' complexity. Policy makers need to find a balance between the potential benefits of additional data and the burden to provide them. A decisive factor in this discussion should be what matters to patients.

More generally and going beyond reporting requirements, policy makers should aim to find a "balance in complexity" in health care systems. The benefits of any health policy that increases complexity should be weighed carefully against its associated administrative costs. Some trends, such as the increasing number of multimorbid patients, are already projected to make health care management more resource-intensive in the future.

Moving away from governance-related or governance-induced administration, potential exists to strengthen the management of health care providers to divert less money from patient care. Cost variations for administrative activities within countries should be monitored closely; strengthened management capacities and more exchange with other industries can help make health care operations more efficient. Health providers should also make the best use of health workers' skills. That means, for example, that clinical staff should be able to devote most of their time to the care and treatment of patients and be unburdened of administrative tasks as much as possible. Going beyond tackling inefficiencies in administrative activities, managers should strive to optimise the use of human resources in health facilities at large. Better optimising staffing plans or addressing absenteeism has huge potential for efficiency gains.

Notes

1. Figure 6.1 could be expanded to include the administrative efforts at patient level, for instance related to co-payments, reimbursement and insurance policies. This level, however, is not included in the analysis.
2. The assessment is very simplified, not taking into account country-specific aspects when performing the various functions, such as degree of centralisation and regulations, both of which will have an impact.
3. In certain cases, e.g. for a self-employed GP working in a solo practice, a distinction between the meso and micro level is unnecessary.

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PART III

Chapter 7

Wasting with intention: Fraud, abuse, corruption and other integrity violations in the health sector

by
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This chapter discusses fraud, abuse, corruption and other integrity violations that divert resources from the health care system and as such are wasteful. The first section explains why the health sector is prone to integrity violations and gathers evidence on the scale of the problem in OECD countries. The second section analyses in more details integrity violations in service delivery and financing and reviews how OECD countries detect, prevent and tackle them. The third section points to the most common inappropriate business practices observed across health care systems and maps some of the regulatory and self-regulatory approaches used by countries to limit such practices.

Julien Daviet conducted the initial bibliographic research and analyses of the Eurobarometer and Transparency International surveys. Valuable comments and insights were provided on earlier drafts by Paul Vincke, Managing Director of the European Healthcare Fraud and Corruption Network; Ruth Lopert, Deputy Director, Pharma Policy & Strategy, Management Sciences for Health; and Sophie Peresson, Director, Pharmaceuticals & Healthcare Programme, Transparency International UK. We thank the respondents to the questionnaire and delegates for their comments on the draft and suggestions, in particular during the expert meeting of 8 April 2016, and the OECD Health Committee meeting of 28-29 June 2016.

The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

Introduction

Situations in which resources are misspent or spent inefficiently reviewed in this report so far are, for the most part, the unintended consequences of the way health care systems are organised and human factors, sometimes driven by poor incentives. In contrast, the behaviours reviewed in this chapter all have in common that the actors engaging in them deliberately divert resources from the health care system in their own self-interest or in the interest of a group they support.

Numerous terms are used to describe these behaviours and their many variations – including fraud, corruption, abuse, collusion and traffic in influence, among others. To avoid a semantic debate, they are simply coined resource-diverting and intentional "integrity violations" here. They prevail in all OECD health care systems and are multifaceted. These behaviours take place in the context of:

- a vast array of transactions involving providers of health services, payers of these services, and/or recipients/consumers
- the procurement and distribution of medical goods and services
- the promotion of corporate/industrial interests in the health sector.

The following section sets out the problem of integrity violations in the health sector. Subsequent ones reflect on the experiences and approaches of OECD countries in dealing with the two main categories of integrity violations in health care systems for which health-specific policies or regulations are in place: integrity violations in financing and delivery as well as inappropriate business practices.

1. Setting the scene: Why worry about fraud, abuse and corruption?

A number of theoretical and ethical considerations explain why the health sector might be prone to fraud, abuse and corruption (Section 1). Despite the challenges inherent to measuring the costs of corruption, existing data suggest that it is prevalent in OECD health care systems (Section 2). To learn from countries' experience in preventing, detecting and tackling fraud, abuse and corruption, a framework is developed to map the various integrity violations that divert resources from their intended use in the health care system (Section 3).

1.1. Why would fraud, abuse or corruption be present in health care systems?

Perhaps more than in other industries or sectors, the nature of the health care system's core objective to improve human health and potentially save lives may create expectations that stakeholders are bound to behave ethically. In reality, a number of theoretical reasons suggest that the sector is particularly vulnerable to corruption, with consequences that are not only financial.

A number of considerations suggest that health care systems are particularly vulnerable to corruption

Savedoff and Hussmann (2006) detail how the high prevalence of uncertainty and asymmetry of information, as well as the number and variety of actors with diverging interests involved in the system, create opportunities for integrity violations in health. Uncertainty is inherent to the health sector, since individuals do not know whether or when they may become ill, or what disease or condition they may develop. Those who develop new treatments do not necessarily know which ones will succeed. Despite health providers' best efforts, permanent risks remain inevitable to a certain extent. Such uncertainty creates the need for risk pooling through an insurance mechanism as part of the system so patients can bear the costs associated with future illness and needed care. But the underlying drivers of health care costs (including technology, but also the possibility of systemic risks such as a pandemic) are much more complex than in other lines of insurance business (e.g. automobile), making health insurance itself a risky endeavour. Apart from that, asymmetry of information characterises most transactions in the health sector. Patients, physicians, insurers (or payers in general) and industries that develop new technologies all possess certain information or expertise that is not always available to others. Health professionals in particular have a double monopoly position with regard to information: towards their patients, who turn to them for advice but expect confidentiality; and towards managers, government and other actors that regulate and may finance their services (Freidson, 2001). Finally, the sector is characterised by a high degree of fragmentation and decentralisation of responsibility among the various actors involved in the delivery of services, financing and regulation.

The combination of uncertainty, asymmetric information and fragmentation makes it difficult to standardise services, monitor behaviour and ensure transparency in the health care system. Many transactions in the health sector result from delegation of responsibilities from one actor to the following (e.g. from patient to physician, from payer to physician, from patient to the regulator, etc.). Economists label these situations "agency relationships": a "principal" who has a direct stake in the result delegates a task to an "agent". These relationships are often imperfect in the sense that agents can choose not to act in the best interests of the principal, attributing suboptimal results to uncertainty or information that the principal cannot verify. While economists primarily see this as a source of inefficiency, the situation paves the way for fraud, abuse and corruption.

Complications arise from the fact that value and quality are particularly difficult to define and measure in health. Prices are not as easily set in health as in sectors where supply and demand for a standardised and observable product of a given quality can be readily captured. In fact, many prices for health goods and services are negotiated, which generates opportunities to extract profits from the system to an extent that is contrary to the general interest.

Finally, the large amount of public money invested in the health sector probably contributes to opportunities for fraudulent behaviours. Indeed, on average in the OECD, 15% of government expenditures are allocated to health (OECD, 2015a). National Health Accounts (NHA) data show that the share of government expenditures on health ranges from 10% to 22% (OECD, 2015b).

The impact of corruption in health is not merely financial

The analysis presented here deliberately focuses on the financial impact of integrity violations in health, which can be direct (money is diverted from the system) and indirect (the risk of corruption requires additional investments in prevention or detection activities). But integrity violations – particularly in the health sector – have far-reaching consequences, direct and indirect, tangible and intangible, in both the short and long term. The 2013 European Commission study on fraud and corruption in the health sector pointed this out. In particular, integrity violations can affect:

- The quality of goods and services provided in the sector. Poor quality can be detrimental to human health, either: i) directly through provision of substandard quality of medicines or equipment or of unnecessary service; or ii) indirectly if, for instance, corruption results in less than adequately qualified providers gaining access to the market. If such problems are frequent, it can even discourage or force honest brokers out of the market and undermine the service delivery system itself. Substandard quality can lead to costly adverse events (see Chapter 2 of this report) and lower health can undermine growth in the longer term.
- Access to care and equity. Corruption, for instance informal payments, can discourage access to care, likely affecting lower-income groups disproportionately.
- Allocative efficiency. On a systemic level, corruption can distort allocations within the health sector and between health and other sectors. OECD (2015c) summarises evidence that more corrupt countries appear to spend less on health.
- Public trust and welfare. Access to health services is required by everyone. Widespread corruption in the sector can thus be very tangible to the population and undermine trust in public systems and society.

1.2. How much fraud, abuse and corruption really exists in the health sector?

Integrity violations in health are notoriously difficult to measure. For one, the understanding of what may constitute fraud, abuse and corruption is not uniform. In addition, the manifestations of integrity violations are so polymorphous that they cannot be summarised in a simple metric or costed out systematically. Other measurement issues include whether the cost of activities aimed at preventing, deterring or fighting corruption should be included in a measure of their burden or whether estimates of negative externalities on health and other societal costs should be factored in. Above all, integrity violations, which are covert – if not criminal – activities by nature, do not lend themselves easily to measurement. In effect, no comprehensive attempt at measuring the impact of fraud, abuse and corruption in health could be identified in any of the OECD countries.[1]

In this context, two types of tools are typically used to capture the importance and cost of integrity violations in the health sector: perception surveys and investigation-based measurements.

Perception surveys show that corruption prevails in the health sector

Perception surveys are one tool commonly used to assess the prevalence of corruption in various sectors (Box 7.1). They focus on eliciting citizens' perceptions of and actual experience with corruption and bring to light the scope of the problem and its relative importance across sectors and countries. The 2013 Eurobarometer survey (European Commission, 2014) and the 2013 Transparency International Global Corruption Barometer provide the most recent

Box 7.1. **Measuring corruption in a given sector: Common tools and their limitations**

Leaving aside country-level corruption indices, two categories of tools are typically used to measure the prevalence and extent of corruption in specific sectors.

Perception surveys

Administered in the general population, perception surveys typically ask respondents to state their perception about the prevalence of corruption or describe their personal experience with corruption (e.g. having to pay a bribe). They are helpful in scoping the problem, particularly when it comes to petty corruption, and in comparing across sectors (e.g. health, police, education, judiciary). At the same time, perception surveys have limitations: they potentially suffer from biases if respondents believe there is a "right way" to respond (by either under- or overstating the extent of the problem) and they typically cannot be used to estimate the financial burden of corruption in the sector.

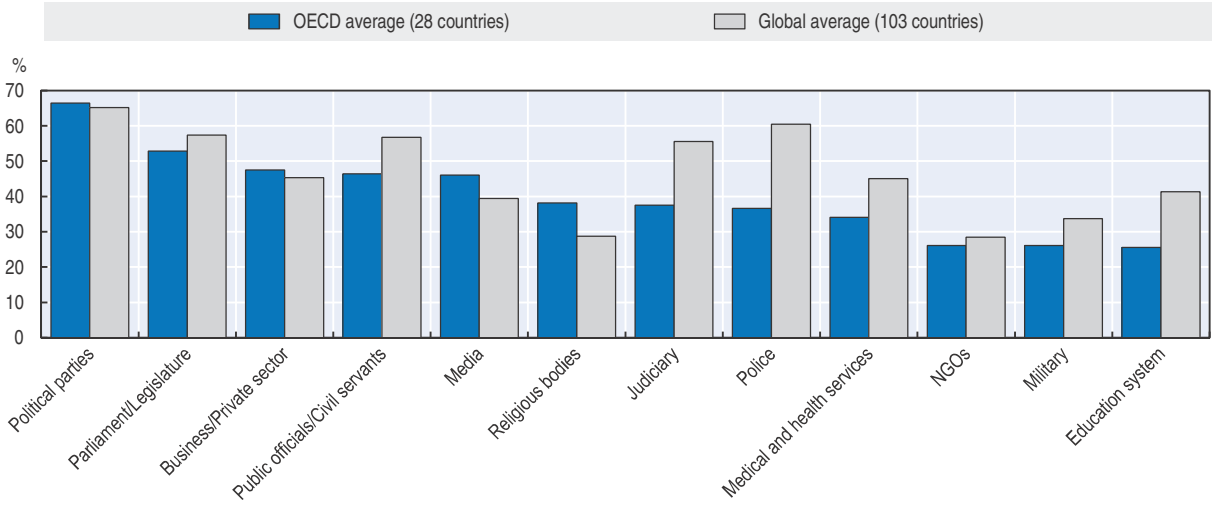
Investigation-based measurements

Investigation-based measurements are typically based on the results of administrative or legal investigations aimed at detecting corruption, including audits, data-mining exercises and systematic price comparisons. The number of incidents of corruption provides an estimate of the prevalence of corrupt behaviours, and the amounts involved or recovered help assess the loss to the system. These measures are a convenient way to scope corruption and a powerful attention-grabber. Still, they only reflect cases that could be detected. They only pertain to the types of behaviour the investigation is set to capture and typically focus on fraud among payers, providers and patients and do not cover other types of integrity violations. The development of "Big Data" and related analytics sometimes allow for comprehensive analysis but in many cases, estimates of fraud are based on samples. The construction of sector-wide estimates of the cost of corruption on their basis thus requires assumptions, which can always be a source of criticism. Importantly, analyses typically capture "suspect" cases. Further and sometimes lengthy investigations are required to establish an intention to divert resources (as opposed to an error or a justified deviation from expected behaviour). Published numbers thus typically bundle error and fraud. Finally, investigation-based measures may reflect the effort to detect corruption rather than the actual level of corruption. Increases in the numbers observed are not bound to represent a rise of corruption but can reflect more intense or more effective detection efforts.

cross-country comparisons of the perceived level of corruption across a range of sectors, including health. Neither survey focused on OECD countries, but both included some of them, providing interesting insights and opportunities for cautious comparisons.[2]

A comparison of OECD and global averages (Figure 7.1) suggests that corruption is less prevalent in OECD countries than globally, especially in the delivery of services that are typically publicly financed or delivered, such as police, judiciary, education and health care. The health sector – in OECD countries – is ranked in the bottom third of corrupt institutions. Nevertheless, a third of respondents deem the sector as corrupt or extremely corrupt (versus 45% globally). In Europe, a similar pattern can be found (Figure 7.2). In the list of 12 institutions and sectors listed, health is in the bottom third for OECD countries. Still, around 35% of citizens in OECD European Union (EU) countries believe that "giving and taking of bribes and the abuse of power for personal gain is widespread" in health. The number is close to 55% in EU countries that are not part of the OECD.

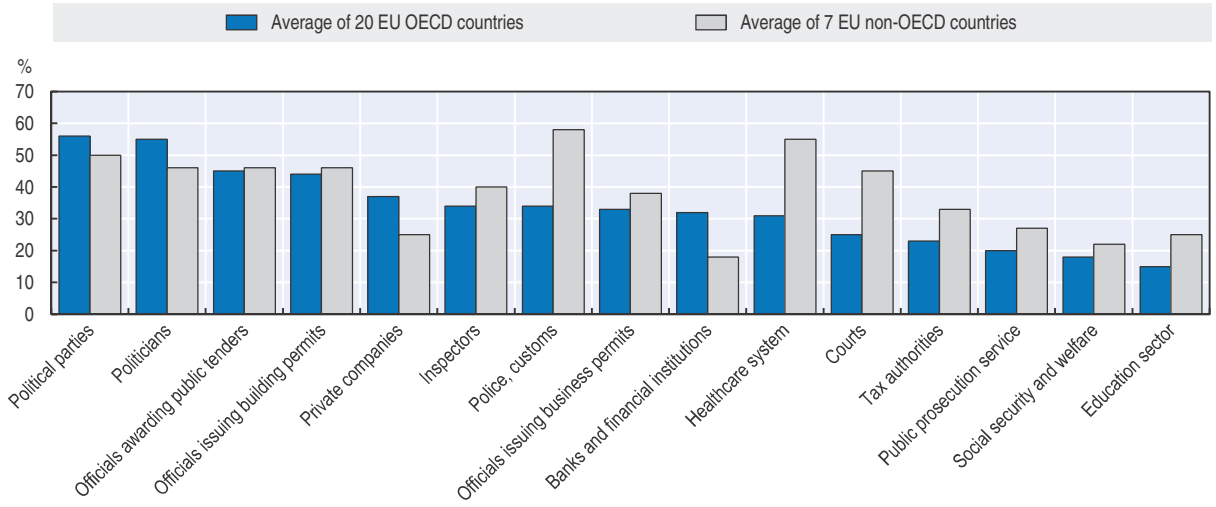
Figure 7.1. **Percentage of global and OECD countries' population that considers various sectors corrupt or extremely corrupt**



Source: Transparency International (2013), *Global Corruption Barometer Report and Data*, *www.transparency.org/gcb2013*.

StatLink http://dx.doi.org/10.1787/888933444296

Figure 7.2. **Corruption perception across sectors in EU OECD countries versus EU non-OECD countries**

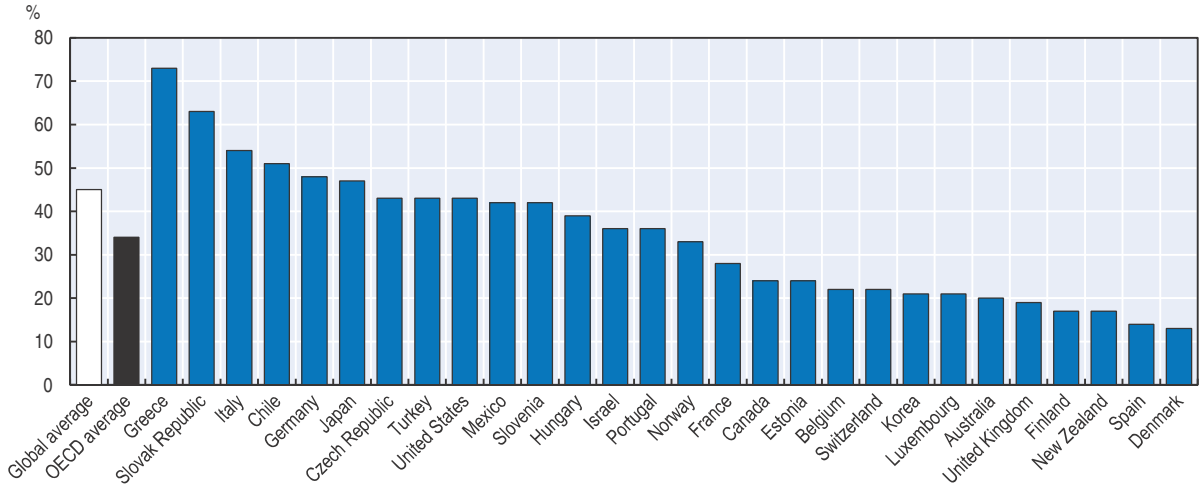


Source: European Commission (2014), *Special Eurobarometer 397: Corruption Report*, Publications Office of the European Union, Luxembourg.

StatLink http://dx.doi.org/10.1787/888933444304

Levels of corruption seem highly variable across OECD countries. Figure 7.3 presents the percentage of the population that believes the health sector to be corrupt or very corrupt for all OECD countries present in the *Transparency International* database. The level of perceived corruption in health within OECD countries varies between 10% and 70%. Perceived corruption seems lower in many Commonwealth nations and Nordic countries of the OECD.

Figure 7.3. **Percentage of the population that considers the health sector corrupt or very corrupt in OECD countries**



Note: The global average includes 103 countries. The OECD average includes 28 countries.
Source: Transparency International (2013), *Global Corruption Barometer Report and Data*, *www.transparency.org/gcb2013*.

StatLink http://dx.doi.org/10.1787/888933444316

Investigation-based measures provide some insight into the cost of fraud in a number of countries

Investigation-based numbers are unlikely to provide a full picture of corruption. As previously highlighted, no reliable way exists to evaluate the overall cost of corruption, if only because of undetected offences (see Box 7.1). Further, if a wrongful transaction is suspected, the determination of whether it constitutes fraud or corruption is generally a lengthy exercise, sometimes only finalised in a court of law. Thus in many cases, published numbers refer to suspicious transactions (including errors). Building sector-level estimates usually requires formulating assumptions, for instance to extrapolate sample data, and may be informed by expert opinion.

Investigation-based numbers published by authorities are typically small, but the return on investment to detect and combat fraud can still be high. A number of institutions regularly publish figures on the extent of fraud detected, based on investigations carried out by authorities. Some examples are displayed in Box 7.2. In instances where it is possible to relate the amounts of fraud detected to the expenditure on the programmes where the investigation took place, the ratios are low: the amounts of fraudulent payment typically represent less than half a percentage point of programme expenditure. This does not mean that the return on investment in fraud detection is negligible. To give an idea, the return on investment of a US detection programme for 2013-15 was estimated at USD 6.1 returned for every USD 1.0 expended (HHS and DOJ 2016). Beyond this, experts believe that having an active programme in place acts as a deterrent in and of itself, helping to reduce the amount of fraud.

Often, however, estimates and investigation-based numbers vary by an order of magnitude, as illustrated by two examples:

- In 2014, USD 2.3 billion was recovered in restitution and recoupment for fraud by Medicare and Medicaid (HHS and DOJ, 2015), representing 0.2% of expenditure on the programme that year. Berwick and Hackbarth (2012) estimated that the cost of fraud to

Box 7.2. **OECD countries' published figures regarding the extent of detected health care fraud**

Based on investigations carried out by authorities, some countries publish numbers regarding the costs associated with integrity violations in health:

- *France's* National Health Insurance Fund (CNAMTS) recovered EUR 200 million lost in health care fraud in 2014, representing 0.1% of health insurance benefits, of which 37% was committed by health care practitioners, 27% by health facilities and a bit less than 20% by insured persons.
- Health insurance companies in the *Netherlands* – which have a legally obligated responsibility to detect health care fraud – discovered wrongful cost claims worth EUR 53 million in 2014, yet were only able to prove actual fraud (illegal and intentional wrongful billing for health care services) worth EUR 18.7 million (NZA, 2016). This corresponds to 0.04% of the total costs covered by health insurers in 2014.
- In the *United Kingdom*, National Health Service (NHS) England reported GBP 11.9 million as the total value of fraud, bribery and corruption identified in 2014-15 (NHS Protect, 2014/2015). This corresponds to 0.01% of NHS England expenditures in 2014-15.
- In the *United States*, the Centers for Medicare & Medicaid Services (CMS) reported that USD 2.3 billion was recovered in restitution and recoupment for fraud in Medicare, Medicaid and the Children's Health Insurance Program in 2014 (HHS and DOJ, 2015), corresponding to 0.2% of the total amount of expenditures on these programmes. Approximately 70% of health care fraud is committed by medical providers, 10% by consumers, and the balance by others, including insurers and their employees (NCSL, 2010).
- *Belgium's* Medical Evaluation and Inspection Department of the National Institute for Health and Disability Insurance (INAMI, *Institut National d'Assurance Maladie-Invalidité*) detected EUR 6.8 million in fraud in 2014.
- In *Germany*, the Association of Health Insurance Funds (GKV-Spitzenverband) reported that fraud was detected for a total amount of EUR 43 million in 2013-14.
- *Greece's* National Organisation for Health Care Provision (EOPYY, *Ethnikos Organismos Paroches Yperesion Ygeias*) established that a total amount of EUR 0.3 million of fraud was detected in 2014.
- *Portugal's* General Inspectorate of Health (IGAS, *Inspeçâo Geral das Actividades em Saúde*) reported EUR 4.6 million of fraud detected in 2014.

these programmes would be at least USD 30 billion, and maybe as high as USD 98 billion. The US Government Accountability Office (GAO) in fact concluded that no reliable baseline estimate of the amount of health care fraud currently exists in the United States (CBO, 2014).

- In the Netherlands, Hasaart (2011) showed that adverse behavioural responses (e.g. overbilling for care) of medical specialists and hospitals linked to the hospital payment system alone could amount up to EUR 1 billion (about 6% of total hospital care and medical specialist care expenditures for the year the estimate was produced). The payment system was subsequently revised in a way that could have reduced the amount but the number is still in sharp contrast to the EUR 18.7 million recovered by all health insurance funds in 2013.

Every year, PKF, an accounting firm, and the Centre for Counter Fraud Studies (CCFS) at the University of Portsmouth jointly publish an assessment of the cost of health care fraud, based on data from 33 organisations in 7 OECD countries (Australia, Belgium, France, New Zealand, the Netherlands, the United Kingdom and the United States). They reportedly only include statistically significant and methodologically sound measurement exercises subjected to external validation. The latest report (Gee and Button, 2015) shows that the loss to fraud and error is an average 6% of related health expenditure. In the majority of cases, this loss ratio lies between 3% and 8%, and in nearly 90% of cases fraud and error represent more than 3% of the expenditure reviewed. Given the recovery ratios available (Box 7.2), it is fair to assume that measures against integrity violations in health within OECD countries could be strengthened.

1.3. Resource-diverting "integrity violations" can be grouped in three broad categories

From a policy perspective, integrity violations in the health sector are best divided into three categories depending on who is involved and the type of "transactions" affected.

Going beyond labels captures a wide range of dishonest behaviours

Deliberately putting aside semantic discussions, this study pragmatically sets out to include all integrity violations that engender private benefit at the expense of the health care system. Corruption, fraud, abuse, regulatory capture, revolving door politics, embezzlement, collusion and nepotism are among the many terms defined by Transparency International's plain language guide on corruption (Transparency International, 2009). These definitions typically describe various facets of the integrity violation itself, for instance whether it includes one or more people (fraud versus corruption), whether a rule is broken or not (abuse versus fraud), or the degree of pressure exerted (from influence to extortion). All of these terms correspond to problems that can take place in the health sector. From a policy perspective, characterising and distinguishing each and every term precisely is not particularly relevant. The present study thus uses "integrity violations" as an umbrella term to capture them all. Integrity violations include the entire spectrum of behaviours that reasonable and well-informed laypersons observing the health care system would – in all likelihood and in most health care systems – consider inappropriate and unethical. The integrity violations included in this analysis further have in common that they increase the costs of goods and activities in the health sector and divert resources from their intended purpose to dishonestly serve the interest of specific individuals or groups.

Integrity violations considered here thus include what most practitioners label corruption: "the abuse of public or private office for personal gain" (OECD, 2008). This commonly used definition already covers a large set of possible integrity violations and hints: i) that corruption may involve a wide diversity of actors, from public officials to individual private medical practitioners; and ii) that the "gain" is not necessarily immediate and monetary but may be intangible and delayed. Indeed, personal gain can come in the form of gifts, honorary titles or recognition, sponsorship (of training, research, events) or future paid or unpaid services (consultancy contracts, jobs, other favours that can be called in). This definition does not explicitly include situations where the dishonest behaviour serves – directly or indirectly – the interest of groups of stakeholders (such as an industry or

a profession).[3] Although it is hard to draw the line between, for instance, lobbying and undue influence on regulation or between strategic marketing and abusive promotion of commercial interests, these questions are certainly relevant in the health sector.

Fraud and abuse are included in the scope of this study. Corruption is generally understood to involve more than one participant, one of whom at least is in a position to abuse his position. Fraud and abuse, in contrast, are more individual in nature. Fraud is generally defined as knowingly and wilfully executing, or attempting to execute, a scheme or artifice to defraud the health care system (adapted from the US Health Insurance Portability and Accountability Act).[4] In that respect, fraud differs from errors, which are unintentional. Anyone in the health care system can commit a fraud, including a patient. From a legal perspective, abuse mostly differs from fraud in that a rule has to be broken for misbehaviour to be labelled fraud. If an investigator cannot establish the act was committed knowingly, wilfully and intentionally, it is perceived as an error (Rudman et al., 2009). From an operational perspective, however, if the objective is to reduce waste, then fraud and abuse are equally important. Detecting and correcting errors is more an administrative task in nature but it can make sense to functionally integrate fraud and error detection. In any case, all forms of integrity violations ultimately lead to waste – even if the cost is not necessarily direct, immediate or even measurable.

In conclusion, it is important to recognise that the boundaries of what constitutes integrity violations cannot be universally defined. Indeed the question of whether a given act should be considered corrupt may find a different response depending on a country's cultural fabric. For instance, giving or accepting a present in the context of a patient-physician relationship may be considered normal in one culture and unacceptable in another (Blind, 2011).[5] Consequently, no consensus exists among countries about which integrity violations should be considered offences in the eyes of the law, although ratification of the OECD Anti-Bribery Convention (which covers the bribery of foreign public officials) by OECD countries in 1997 constituted a first step towards recognition of a common range of potential offenses related to corruption.

For policy purposes, integrity violations are best grouped in three categories

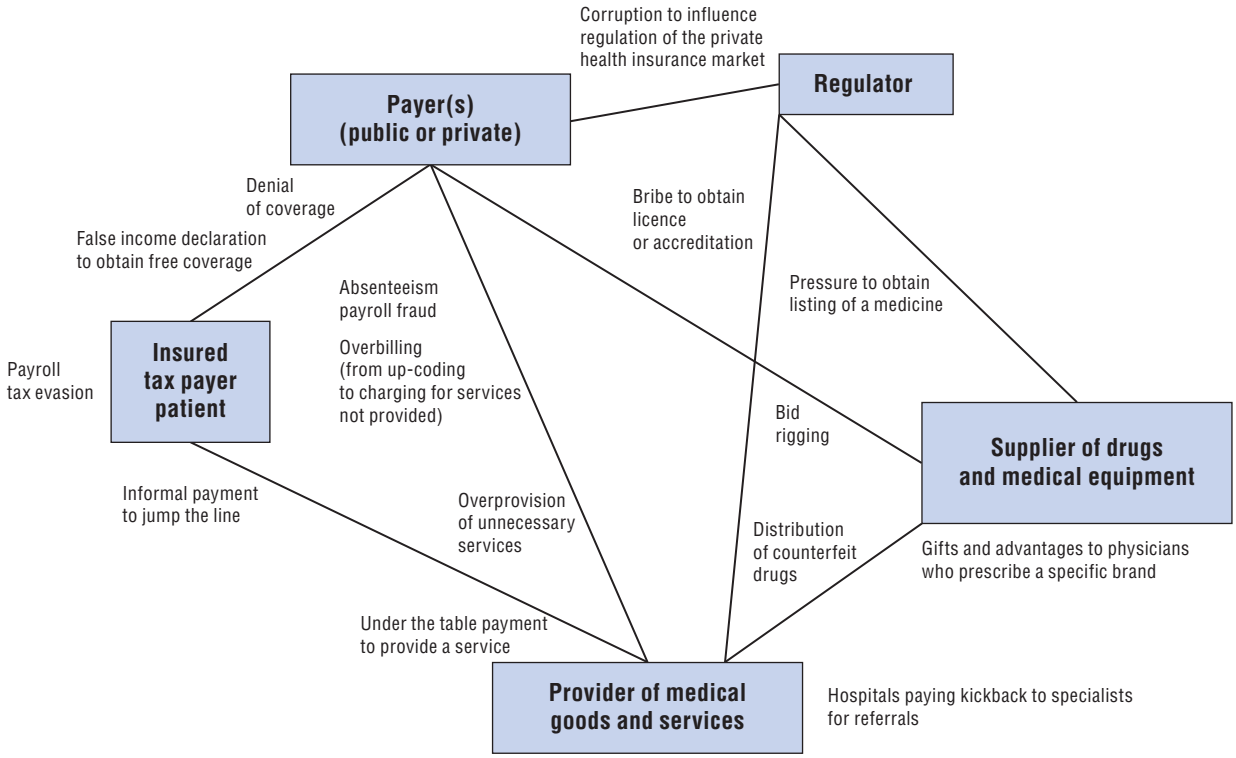
From a policy perspective, grouping integrity violations according to who is involved in the related transactions is proving to be most helpful. Savedoff and Hussmann (2006) first used a stylised representation of the main actors involved in the health care system to illustrate the many ways in which corruption could manifest.[6] In the same spirit, five categories of stakeholders that can perpetrate or be victims of integrity violations are distinguished here:

1. *Providers of medical goods and services*. This category includes individual service providers (physicians, nurses and other health professionals), health facilities and retail pharmacies.
2. *Suppliers or manufacturers of medical goods and services used in the process of delivering care*. These include the manufacturers of goods and services as well as wholesalers that provide pharmaceuticals, medical devices and medical equipment as well as – for instance – health ICT applications.[7]
3. *Payer(s)*. These are entities that pool funds in the health care system and finance care on behalf of all or part of the population. Depending on the country, payers can be public entities or private insurers, single or multiple.

4. *The regulator of the sector.* The regulator represents the government through its ministry and often a number of dedicated agencies as well as the individuals who work for them.
5. *Individuals.* Patients, taxpayers or the insured can either commit or be the victim of fraud.

A few specific examples of integrity violations are mapped to these types of actors in Figure 7.4 for illustrative purposes. These were drawn from examples of corruption described in the literature on fraud abuse and corruption in the health sector and mapped to the stakeholders involved.

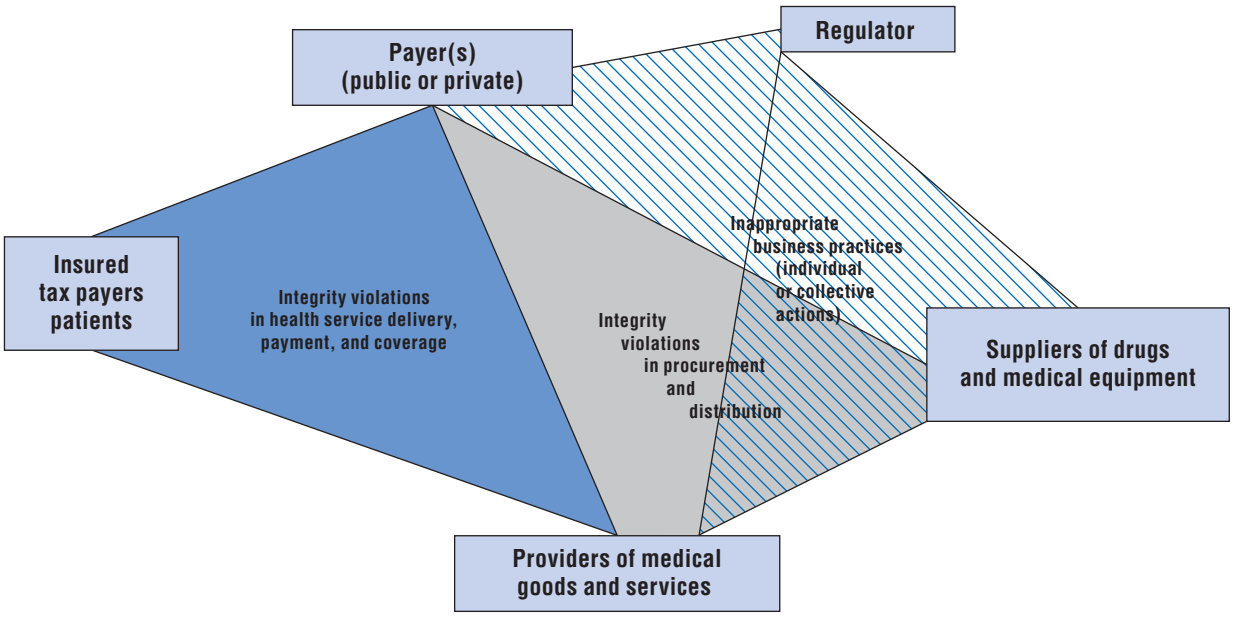
Figure 7.4. **Mapping integrity violations to various actors: A few examples**



From this exercise, three main categories of integrity violations emerge (depicted in Figure 7.5):

- The first category takes place in the context of transactions involving providers of health services, payers of these services, and/or individuals. Depending on the specific situation, each can be perpetrator or victim. These integrity violations are sometimes grouped under the label "health care fraud", particularly in systems where competitive health insurance dominates, but variations of these integrity violations can be found in all health care systems.[8]
- The second category primarily involves suppliers of drugs and medical equipment as perpetrators; (financial) victims are the purchasers of these goods or services, most of which are typically payers or providers themselves (e.g. hospitals). These integrity violations take place in the context of procurement, which includes purchase as well as distribution of drugs and equipment. In the health sector, delivery of substandard or counterfeit drugs or medical devices is of particular concern given the potential safety implications (Box 7.3).

Figure 7.5. **Three main types of integrity violations in health care systems**



Box 7.3. **Counterfeiting of medical goods and products: The MEDICRIME Convention**

Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products are made to appear genuine but are likely to be ineffective or even harmful. They include "products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging" (WHO, 1992, 2009). They can enter the legitimate supply chain or be distributed though illegitimate channels, for instance via unauthorised websites, and pose a threat to public health and the integrity of health care systems. All studies agree that the problem is significant and growing and that while low- and middle-income countries are most affected, OECD systems are not spared (Cockburn et al., 2005; IOM, 2013; Mackey et al., 2015).

OECD countries have policies in place to ensure the safety of the production and distribution of medicinal goods and products, the analysis of which goes beyond the scope of this report. A noteworthy initiative is the MEDICRIME Convention drafted by the Council of Europe, which came into force in January 2016. This international agreement obliges signatories to criminalise the counterfeiting of all medical products and falsification of documents and similar acts and establishes them as international crimes. It provides a basis under international criminal law for national and international co-operation to fight this phenomenon and for co-operation between the competent health, police and customs authorities (Council of Europe, 2015). As of September 2016, 7 had ratified the agreement and an additional 17 had signed it.

- The third category covers a range of inappropriate business practices that ultimately serve to secure more favourable market positions either for individual stakeholders or for their "trade/industry". These integrity violations can be perpetrated by any stakeholder for whom the health sector is a source of revenue. This category includes what is sometimes called "systemic corruption", where representatives of an industry (pharmaceutical companies, private insurers or provider lobbies) exert undue influence on the regulator at the system level. It also covers situations where any of these stakeholders commit fraud, abuse or corruption in their own limited interest (e.g. to gain

market entry for a specific product, to obtain a licence to operate, or to ensure their product is favoured over a competing one). In all these cases, the "victim" of the fraud is generally the regulator and the cost is ultimately borne by the public payer(s).

The remainder of this chapter reviews some of these categories in more detail to learn what health sector policy makers are doing to tackle them in OECD countries. This focus has a number of implications for the scope of the work, as follows:

- Countrywide challenges in public governance are not discussed. As public funding dominates health in most OECD countries and the sector is heavily regulated, the overall quality of governance (particularly in domains such as public finance and budgeting, public financial management, public procurement and civil service management) frames what happens in the health sector. An overall poor level of governance in a given country is likely to permeate the health sector. Conversely, if the civil service or public procurement is corrupt, the health sector is unlikely to be able to address the problem through sector-specific measures alone. Consequently, for instance, issues related to tackling absenteeism in public health facilities or corruption in public procurement in health specifically are not covered as they would necessitate research beyond the scope of this report.[9]
- Another assumption made is that basic checks and balances and fairly solid administrative systems are in place. In other words, in the context of OECD countries, it does not make sense to discuss them in detail.
- With this in mind, the report focuses on two domains where at least some OECD countries have introduced sector-specific interventions to tackle integrity violations: service delivery and financing and inappropriate business practices.

To map, describe and classify integrity violations and policy measures aimed at tackling them, data were retrieved from responses to a survey undertaken for this report. In addition, an extensive review of literature was carried out, covering studies, reports, journal articles and other documents that discuss integrity violations in health.

2. Variable levels of effort by OECD countries to tackle integrity violations in service delivery and financing

The majority of studies on integrity violations in health care focus on the primary process of health care service delivery and financing. Different types of integrity violations related to this primary process are reviewed and the main categories prevalent in OECD countries tentatively identified. Based on this, the rest of the section highlights the variety of institutional set-ups chosen by countries to deal with these integrity violations and the common features of the strategies used, with a focus on the experience of those who responded to the questionnaire.

2.1. Integrity violations in service delivery and financing are varied and most often originate from providers

An extensive review of mainly academic and grey literature identified the various manifestations of integrity violations involving providers, patients and payers. Table 7.1 organises the findings by linking perpetrator (first column) and target (second column). In reality, collusion can take place between those involved in perpetrating integrity violations (for example, both patient and provider can seek to defraud the payer). The table abstracts from system-specific examples but seeks to provide a comprehensive overview.

Table 7.1. **Who commits which type of integrity violation in health care service delivery and financing?**

Who commits the fraud?	In relation to	Type of fraud
Patient	Payer	In the process of obtaining and paying for coverage: • coverage obtained on the basis of a false identify, or misrepresentation of characteristics (e.g. labour status, income, etc.) • fraud to avoid or reduce/avoid insurance premiums, or contributions (or taxes) Wrongful claims (misrepresenting the cost of care, lying to provider to obtain unwarranted benefits, multiple prescription requests) Claiming reimbursements from multiple insurers
	Provider	Bribery (for access to care, referrals, shortening of waiting time, priority on waiting lists, uninsured care, privileged treatment, etc.)
Payer	Patient	Unjustified denial of coverage Unjustified denial of benefits to patients
	Payer	Misuse of resources (embezzlement of funds)[1]
	Provider	Unjustified denial of payments to health providers
Provider	Patient	Informal payments (under-the-table payments, gratuity, "black medicine", "fakelaki")[2]
	Payer	Overprovision/overuse of services Overbilling (upcoding, sidecoding, debundling, double defrayment, billing for higher-qualified personnel than those involved in performing the services) Charging for phantom care (charging for care that is not provided, use of false patient identity) Misuse of resources (embezzlement of funds, pilferage of medicines, misuse of medical equipment, including the use of public equipment for private/commercial use) Absenteeism and other payroll fraud

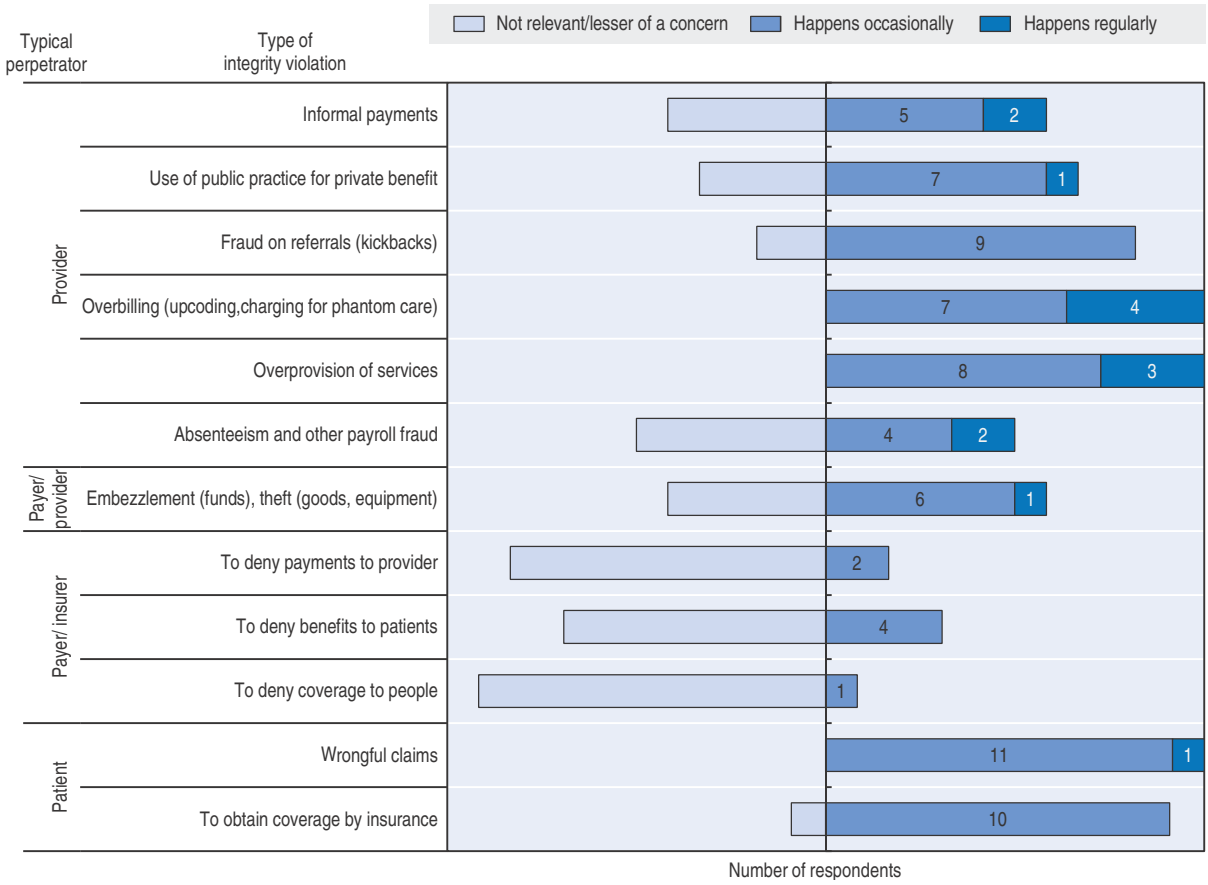
1. The institution that acts as the payer for health services to providers (or staff working for them) can divert resources from their intended purpose. This results in a form of leakage – the diversion of financial resources that were intended for health care.
2. Informal payments can be the result of either the provider asking for the payment or the patient offering it. In the latter case, it is considered bribery.

The table calls for a few remarks:

- It illustrates the point made in the first section regarding the vast range of opportunities for corrupt behaviour in the health sector given the number and diversity of actors and transactions between them. Behind each example above lie specific cases documented in a number of country-specific contexts.
- Not all types of integrity violations described are relevant to all OECD countries, simply due to the various ways in which countries' systems are organised and financed. For example, if access to medical services is not based on a formal insurance mechanism or if insurance coverage is universal, patients have no interest in identity theft to obtain coverage. Similarly, absenteeism or payroll fraud is less of a concern in systems that rely on fee-for-service (FFS) payment than in systems with salaried providers (see also European Commission (2013), which maps how different types are linked to different financing schemes).

A significant proportion of the literature about manifestations of integrity violations in service delivery and financing discusses low-income countries; the question is open as to whether their content applies to OECD countries. To assess which types of integrity violation are most relevant, countries were asked to state their opinion on the relative frequency of specific types of integrity violations in service delivery and financing. Figure 7.6 provides an overview of the results for the 12 countries that responded.[10]

Figure 7.6. **Relative importance of integrity violations in service delivery and financing in 12 OECD countries**



Source: Authors' computations based on country responses to OECD 2016 survey.

StatLink http://dx.doi.org/10.1787/888933444321

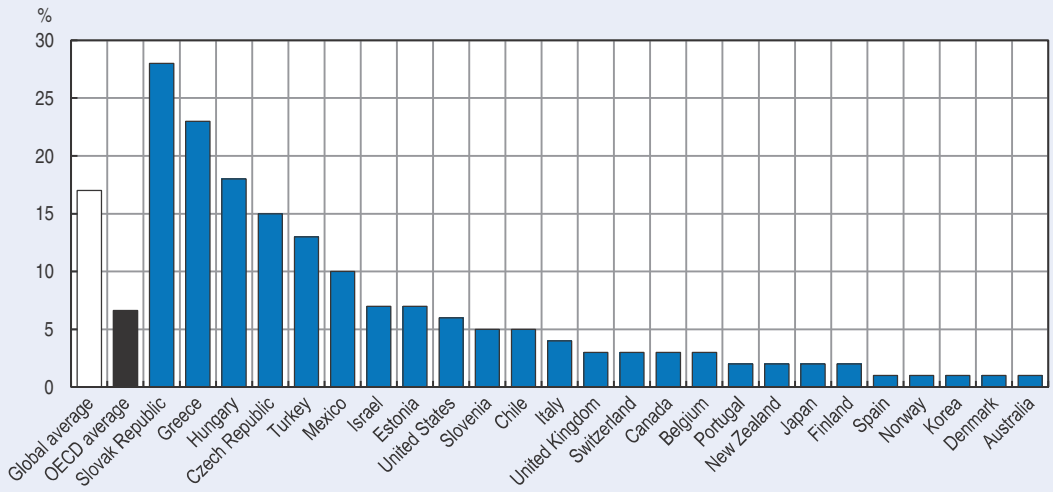
The sample is small, and reflects survey respondents' perceptions, but results suggest that:

- Insurers/payers themselves are less likely to commit fraud towards patients and providers than the reverse. In most sample countries, this is deemed of little or no concern. Patients, on the other hand, appear to cheat the system occasionally everywhere. Providers are the most likely of the three to commit fraud and abuse regularly (this is aligned with the numbers observed in France and the United States, per Box 7.2).
- Overbilling – including upcoding, debundling and charging for phantom care – and overprovision of services (providing more care than necessary) are clearly the most widespread methods providers use to cheat the system.
- Informal payments are of concern in more than a few OECD countries, contrary to intuition perhaps (see Box 7.4 for additional data).
- Absenteeism and embezzlement are relevant in some countries but seldom encountered in others.

Box 7.4. **Informal payments**

Informal payments and their impact on access to services among the poor in public service delivery systems have received considerable attention in developing and transitional economies (Transparency International, 2006). This should not be construed as a sign that they are absent in OECD countries, some of which at least struggle with this issue. For example, "fakelaki" (little envelopes) are an ingrained social institution in Greece (Liaropoulos et al., 2008). In OECD countries, on average, 6% of people declare having had to pay a bribe to obtain a medical service, but the proportion is significantly higher in a number of countries (Figure 7.7). In the 2013 Eurobarometer survey, on average across EU27 countries, 5% of the population reported having paid a bribe and the proportion was at least that in the following OECD countries: France, Germany, Greece, Hungary and the Slovak Republic (European Commission, 2014).

Figure 7.7. **Percentage of population that paid a bribe for a medical service in the past 12 months**



Note: The global average includes 103 countries. The OECD average includes 25 countries.
Source: Transparency International (2013), *Global Corruption Barometer Report and Data*, *www.transparency.org/gcb2013*.
StatLink *http://dx.doi.org/10.1787/888933444336*

Whether or not informal payments – consisting of either money or other valuable goods – are regarded as an integrity violation partially depends on culturally defined norms and habits of each country. In that regard, debates arise about the perfectly legitimate act of gift-giving versus the illegal transaction of bribery (Kurer, 2005).

2.2. Various types of institutions tackle integrity violations in service delivery and financing

Efforts made to tackle integrity violations in service delivery and financing vary greatly across OECD countries. Some countries have dedicated institutions or organisations in place tasked to prevent or tackle integrity violations in health service delivery and financing. Others rely on more ad hoc approaches. Based on the survey results, augmented by analysis of grey literature and experts' input, Table 7.2 describes various countries' approaches.

Table 7.2. **Examples of institutions detecting and responding to integrity violations in health service delivery and financing in OECD countries**

Country's institutions	Description
Health sector-specific institutions	
Centralised institutions (government, government agency or public institute)	
Australia Multiple state and federal bodies, including: the Department of Health; the Department of Human Services; ombudsman and crime and corruption-related state bodies	The Department of Health is responsible for detecting and investigating fraud by providers (it also examine incorrect claims). The Department investigates cases relating to about 2% of providers each year, around 60% of which are ultimately confirmed as fraudulent. The Department of Human Services is in charge of fraud by patients.
Belgium Medical Evaluation and Inspection Department (MEID) at Institut National d'Assurance Maladie Invalidité (INAMI-RIZIV)	INAMI, a public institution, manages the mandatory health insurance. MEID is tasked with the detection of integrity violations. MEID carries out thematic and individual investigations. Individual insurance funds are responsible for prepayment checking of claims.
Portugal Inspeção – Geral das Actividades em Saúde (IGAS)	IGAS's mission is to audit, inspect, supervise and conduct disciplinary actions within the health sector, including to address fraud. The Inspectorate's annual report suggests it investigates cases brought to its attention and it carries out thematic analysis. In 2014/15, EUR 150 000 was recovered.
Switzerland	The Federal Office of Public Health supervises insurance companies, in particular to ensure that patients'/insured rights according to the law are respected. It can conduct audits, issue requests to comply or refer cases to the penal authorities as needed.
United Kingdom National Health Services Protect (NHS Protect) – Department of Health Anti-fraud Unit	NHS Protect is tasked with safeguarding all NHS staff and resources from crime, including economic crimes. Part of this mandate was taken over by the recently created Anti-fraud Unit.
Tasks delegated to payers (public funds or private organisations including health insurers)	
Public institutions	
Germany Health Insurance Funds and Professional Councils	All health insurers are required to have a department in charge of fraud detection. The dental and medical professional councils (public entities) each have "departments for combatting inappropriate behaviours" and can conduct investigations. These institutions do not report or publish data on their results.
France Caisse Nationale d'Assurance Maladie	Public health insurance funds are required to detect and investigate fraud committed by patients and providers. Each fund must produce an annual report on fraud detection activities and results.
Ireland Health Service Executive (HSE)	HSE, responsible for providing public health care services to the population, is formally responsible for tracking fraud and abuse but has no dedicated unit.
Japan Health Insurance Claims Review & Reimbursement Services (HICRRS) and National Health Insurance Federation (NHIF)	HICRRS and NHIF reimburse providers on behalf of the two main insurance regimes in Japan for provided medical care services on the basis of reimbursement claims. They are tasked with checking whether claims are valid, appropriate and in compliance with rules. In 2014, unlawful claims amounted to JPY 13.32 billion.
Norway Helfo's control department	Helfo, Norway's public payer, has a control department that detects fraud based on claims analysis.
Poland Health Insurance Fund (NFZ)	NFZ is tasked with detecting irregularities and reporting them to the competent authorities (Central Anti-Corruption Bureau).
United States Centers for Medicare & Medicaid Services (CMS) HEAT initiative	CMS engages various contractors to detect fraud and errors (for instance Recovery Audit Contractors (RACs) are paid on a contingency fee basis to detect under- and overpayments in publicly funded programmes). ZPICs (Zone Program Integrity Contractors) are specifically responsible for detecting, deterring and preventing Medicare fraud and abuse. As part of the Affordable Care Act (ACA), the Health Care Fraud Prevention and Enforcement Action Team (HEAT) joint initiative of CMS and the Department of Justice (DOJ) reinvigorated the fight against fraud and abuse in public programmes (Medicare, Medicaid). HEAT's key component is the Medicare Fraud Strike Force, a multi-agency team of federal, state and local investigators designed to fight Medicare fraud. CMS and DOJ produce an annual report on their results.
Private institutions	
Netherlands Health insurance companies	Health insurance companies have a legal obligation to detect integrity violations.
Turkey Health insurance companies	Health insurance companies are responsible for paying for service delivery and financing, as well as detecting the corresponding integrity violations.

Table 7.2. **Examples of institutions detecting and responding to integrity violations in health service delivery and financing in OECD countries** *(cont.)*

Country's institutions	Description
General anti-fraud institutions (not health sector-specific but do look into health)	
Austria	Federal Anti-Corruption Bureau Office for Prosecution of Corruption
Greece	Independent Authority for Public Contracts
Slovenia	Commission for the Prevention of Corruption
Countries reporting no anti-fraud institutions or efforts	
No specific effort to detect fraud in service delivery and payments for health reported: Israel. No general antifraud body: Denmark, Hungary.	

Source: Country responses to OECD 2016 survey and authors' research.

Among the more than 20 countries for which the information was availed, countries' institutional set-ups and strategies for dealing with integrity violations in service delivery and financing differ widely. Some countries clearly put more emphasis on the issue than others. Four approaches were identified:

- A number of countries have dedicated departments in a central-level institution – e.g. a ministry (Australia, Belgium, Portugal and the United Kingdom), with some countries further splitting responsibilities depending on who perpetrated the fraud (e.g. frauds committed by patients versus providers are managed by two different entities in Australia).
- Nine countries explicitly delegate the responsibility to detect and address fraud and abuse to payers – public and private. Interestingly, in Germany part of the responsibility for detecting fraud and abuse perpetrated by providers lies with professional councils.
- In some countries, fraud in service delivery and payment falls under the general purview of a specific anti-corruption agency that can and typically does investigate health sector issues.
- Some countries appear to have neither health-specific nor general anti-corruption bodies in place.

Some approaches and insights shared by countries regarding the set-up for fraud detection are worth highlighting:

- Actively detecting and combating fraud and corruption is not necessarily in health care payers' direct interest. Ultimately, the payer is a financial intermediary between patients/clients (who may contribute to financing the system through taxes or premiums) and providers (with which payers have some form of contractual relationship). As such, payers typically have explicit fiduciary responsibilities. Still, fraud detection activities are costly and can be perceived as adversarial by both patients and providers. The benefits, on the other hand, are not necessarily direct. The cost-benefit ratio of fraud detection may not be perceived as high enough, and the "spontaneous" level of effort may be suboptimal. This might explain why in the Netherlands, private health insurance companies (which compete with each other) have a legal obligation to detect integrity violations. Germany also mandates that public health insurance funds have a dedicated department and report fraud to the judicial authorities. In contrast, in Switzerland, it is assumed that private insurers have an inherent incentive to combat fraud.

- The US Centers for Medicare & Medicaid Services (CMS) systematically uses (separate) contactors to detect fraud and errors. Among contractors tasked with detecting errors, Recovery Audit Contractors, whose mission is to deal with improper payments, are incentivised by a contingency fee (a controversial programme). The CMS also contracts Zone Program Integrity Contractors (ZPICs) specifically tasked with detecting (via data analysis, hotlines, or based on reports of other contractors) and investigating instances of fraud.
- Some, but not all, institutions tasked with detecting integrity violations can enforce administrative sanctions. For instance in Belgium, the National Institute for Health and Disability Insurance (INAMI, *Institut National d'Assurance Maladie-Invalidité*) has additional administrative judicial capacities, in the form of administrative courts within the national institution, that can impose administrative fines up to 200% of the amount involved in the integrity violation concerned. Australia can apply administrative penalties (which may be lowered when healthcare providers voluntarily admit wrongdoing), as well as professional sanctions or penalties when the activities are clinically inappropriate.
- Some countries choose to publish data on the results of their efforts at regular intervals (Belgium, France, the Netherlands, the United Kingdom and the United States). In these countries, publication of results creates awareness of counter-fraud activities and is seen as a deterrent of further integrity violations.
- Countries recognise the value of sharing experiences in combatting integrity violations across public and private institutions as well as internationally. In the United States, the National Health Care Anti-Fraud Association created in 1985 comprises nearly 90 private health insurers and those public sector law enforcement and regulatory agencies that have jurisdiction over health care fraud. Some OECD countries are members of the European Healthcare Fraud and Corruption Network (EHFCN)[11] and the Global Health Care Anti-Fraud Network (GHCAFN), which includes Canada, the United Kingdom and the United States.

2.3. Effective detection of integrity violations in service delivery and financing requires data mining and review campaigns; responses must be well graded and credibly enforced

Approaches to detecting fraud and abuse in service delivery and financing can be more or less pro-active. Traditional approaches rely on the investigation of complaints or regular audits and controls. Some, but not all, countries set up tip-off hotlines (e.g. Australia, the United States) to encourage reporting of fraudulent behaviours. The United States developed several toolkits, training opportunities and materials for beneficiaries and providers to identify and reduce fraud. Statistical and data-mining tools are now an integral part of the fraud detection arsenal of many but not all countries.[12] Essentially, data mining can be used to: i) identify patterns[13] and deviations from them; and ii) screen cases that need to be further scrutinised for fraud and abuse. Various types of analysis can be deployed. Ranging from least to most complex:

- Rules-based approaches are the most simple and help identify cases that do not meet specific pre-set criteria. These controls are often automated and carried out prior to settling claims, for instance to verify that all the required information is available, that no major inconsistencies exist, and that the claim complies with formal rules and guidelines (e.g. the provider is duly registered, the number of sessions prescribed does not exceed the allowed limit, etc.).

- Outlier or anomaly detection techniques focus on identifying usual patterns (for instance, typical treatment patterns by diseases), and deviations from them. These methods can lead to identification of geographic variations in medical practices (see Chapter 2).
- Predictive techniques use information about past fraud to flag high-risk fraud candidates.
- Social network analyses identify patterns of transactions between different entities across time and can help identify collusion between perpetrators and networks organised to defraud the system.

In addition to, or as a result of, the detection of specific instances of fraud, agencies typically carry out programmed thematic investigations targeting specific issues. For instance, in 2014, the Belgian INAMI investigated repetition of restorative dental care; France's CNAMTS (*Caisse Nationale de l'Assurance Maladie des Travailleurs Salariés*) investigated home-based hospital care to determine whether services supposed to be included in a lump-sum payment were not also charged on an FFS basis; England's NHS Detect focused on payroll fraud; and Portugal focused on cochlear implants.

To address suspicious patterns that could result from integrity violations, practitioners highlight the importance of a stepwise, graded, comprehensive and credibly enforceable response. This response should – as relevant – incorporate measures to prevent future occurrences of similar problems and engage the community of providers in a constructive dialogue. This is the case when the pattern falls into the category of "abuse" rather than fraud; in other words, when no pre-existing rules are explicitly broken (for instance, overprescription of specific tests, unusual frequency of repeated visits, etc.). In these situations, especially if many providers behave similarly, the nature of the problem does not differ fundamentally from that of the "overtreatment" examined in Chapter 2.

Engaging professional organisations or scientific societies can help generate technical consensus around the fact that certain behaviours are – under most circumstances – inappropriate. Based on this, new and acceptable rules or guidelines can be created. Subsequently, this reduces opportunities to abuse the system and more clearly redefines future outliers as fraudulent. Communication and other soft tools can be used to limit future offences. Sending targeted information, benchmarking data or warnings to all providers or the subset of individuals whose behaviour is unusual can effectively deter future offences (because perpetrators know the behaviour is under observation or because they feel peer pressure). Still, entities involved in detecting fraud and abuse recognise the difficulty they face in building a constructive dialogue with health professionals who are typically – and unsurprisingly – reluctant to engage in a dialogue on fraud and abuse, which they expect to reflect badly on their profession. Putting more emphasis on errors and good practice can be more constructive.

Deeper investigation of specific cases and outliers is warranted. As soon as the investigation process starts though, efforts must go into engaging and communicating with perpetrators (typically health professionals), recognising that errors can happen and that special circumstances can dictate deviations from good practice. As relevant, suspects can be offered the option to correct their "mistakes" and voluntarily repay the amounts due. Investigations often start with formal or material checks and requests for additional information from the parties involved. More rarely, full-scale investigations require forensic techniques and involve inspectors. Because of privacy considerations and

doctor-patient confidentiality, inspectors may need to be specifically trained physicians. They can reach out to all parties involved, for instance patients, to verify their circumstances or the care that they received (ZN, 2011).

The last step is to take – as feasible – administrative and disciplinary sanctions and/or initiate civil or criminal legal proceedings. The Unites States recently expanded the scope or magnitude of sentences and penalties for integrity violations in health service delivery and financing.[14] In addition, the United States and the Netherlands enhanced funding for the prevention and detection of fraud, abuse and corruption in health care. Countries with active programmes (e.g. Belgium, the Netherlands and the United States) highlight the importance of organising and even formalising co-operation between health and judicial authorities. In 2009, the United States created a joint task force for combatting fraud on Medicare between the Department of Health and Human Services (DHHS) and the Department of Justice (DOJ) that is a multi-agency team of federal, states and local investigators.

Integrity violations in service delivery and financing are not rare. Yet large cross-country variation arises in the attention and resources dedicated to the problem. Countries that have stronger institutions and apply more systematic efforts always seem to succeed in detecting significant amounts of fraud. In the end, the amounts recovered remain fairly small compared with total health expenditure. Still, these programmes likely have positive externalities and deter at least some individuals who could be tempted to cheat the system. In recent years, some countries, including France, the Netherlands and the United States, stepped up efforts to combat integrity violations in service delivery and financing. As part of the waste agenda, more countries could consider joining them.

3. Inappropriate business practices: Opening the governance debate

The second category of integrity violations reviewed in this chapter, inappropriate business practices, can potentially be perpetrated by anyone who derives income from selling goods and services in the health sector. This includes individual health care providers, health facilities and a number of industries, notably in the domains of insurance, pharmaceuticals and medical devices. All of these stakeholders are legitimately involved in the health care system and the vast majority conduct their business in entirely appropriate ways. Yet on any day, a story can emerge about an unqualified person delivering services,[15] a hospital group giving a range of inducements to a consultant practice in exchange for referrals (Godlee, 2015), or a pharmaceutical company using unethical marketing practices. Compared with integrity violations in service delivery and financing or procurement, these inappropriate behaviours are less directly linked to the actual process of care and perhaps even less observable. They ultimately target the regulator, understood here as the institutions entrusted with safeguarding the public's interest and safety.

The review of the literature on and actual cases of fraud and corruption in health care systems show that at least some of these inappropriate business practices occur in most OECD countries. The 2013 European Commission report collected 86 examples of corruption occurrences across EU countries, many of which could be categorised as "inappropriate business practice". More recently, the first report of the newly established chapter of Transparency International on Pharmaceuticals and Healthcare Programme covers inappropriate practices in research and development, marketing and registration in the pharmaceutical industry and offers additional examples of inappropriate practices in OECD countries (Transparency International-UK, 2016).

This final section presents a simple framework that captures the various inappropriate business practices mentioned in the documents reviewed and identifies some of the regulatory approaches countries chose to deal with them. The research undertaken for this report and the responses received to the questionnaire highlight that inappropriate business practices are of increasing concern to OECD countries. At the same time, the case for linking this discussion to the waste agenda is perhaps weaker. The issues at stake are equally important, though: patient safety and the transparency, integrity and accountability of decision making in the health sector. Rather than being comprehensive, the following discussion paves the way for future discussion.

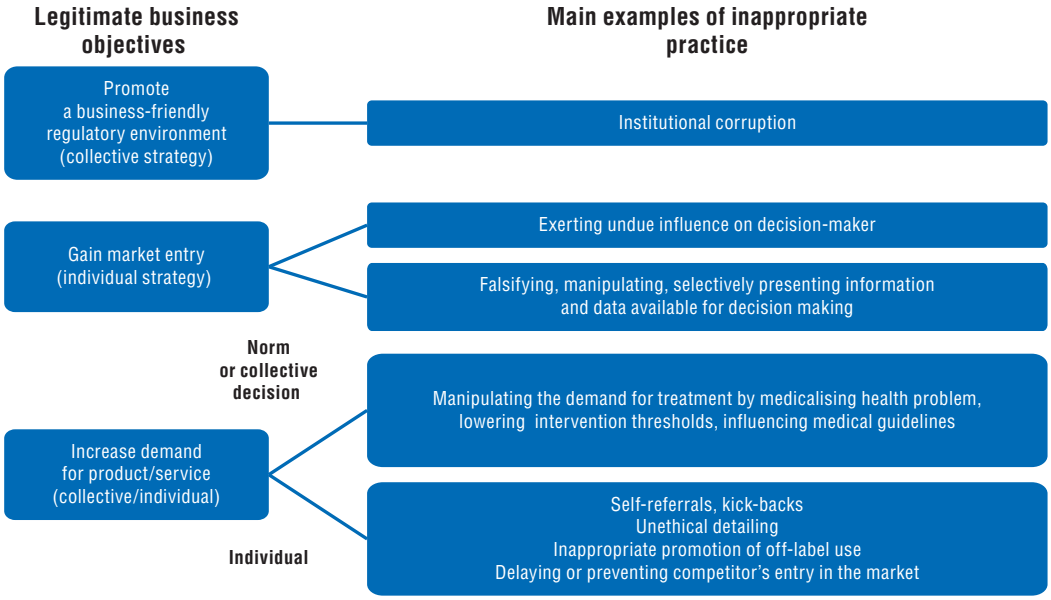
3.1. The pursuit of legitimate business objectives can give rise to inappropriate business practices

The first difficulty lies in identifying what constitutes inappropriate behaviour. If a rule is broken, the case is straightforward: for instance, an entity forges credentials to enter a regulated market. But as previously highlighted, the line between appropriate and inappropriate is drawn at different points in different cultural and policy contexts. In fact, the definition of the term "institutional corruption" highlights that an entity operating in a "legal or even currently ethical way" can still be "corrupt" if its institutional environment was designed under a systematic and strategic influence that weakens its ability to achieve its societal mission (Lessig, 2013). In health, a concern is that some groups of stakeholders (the pharmaceutical industry, the medical lobby, the insurance industry) have the means to – and do – exert such influence. Following the literature, the mapping of inappropriate business practices therefore includes: i) instances when stakeholders act inappropriately to promote their individual business (individual strategy); and ii) situations where the organised action of groups of stakeholders undermines achievement of health care systems' goals (collective strategy[16]).

The framework below links the various inappropriate business practices documented in the literature on integrity violations in health to the pursuit of specific legitimate business objectives, distinguishing individual and collective strategies. To operate and succeed, businesses can legitimately seek to: i) promote a business-friendly environment; ii) gain market entry for their products and services; and iii) take action to increase demand for products or services. Figure 7.8 points to the type of inappropriate business practice that can be traced back to each of these strategic objectives.

The question of whether some industries are able to distort legislation in the health sector is controversial, with some observers arguing that the influence of the pharmaceutical industry in Europe and the United States is excessive. A detailed analysis of the means and funding deployed by pharmaceutical firms and trade associations on lobbying at the European level highlighted that they outstrip the resources spent by civil society organisations registered as working on access to medicines and public health issues (EUR 40 million versus EUR 2.7 million in 2014). Over the last two years, civil society organisations in Europe repeatedly expressed concern that changes in intellectual property regulation and other legal provisions envisaged in the context of the EU-US Transatlantic Trade and Investment Partnership (TTIP) for the pharmaceutical industry could undermine countries' capacity to regulate pharmaceutical prices, generics competition or the transparency of data on clinical trials (CEO, 2015; Commons Network, 2015). In the United States, the Center for Responsive Politics, which compiles data from the Senate Office of Public Records, shows that lobbying expenditure on health is more than USD 480 million a

Figure 7.8. **Linking inappropriate practices to legitimate business objectives**



Source: Authors' elaboration.

year (a virtual tie for first place with the banking, insurance and real estate sector).[17] In 2013, a special issue of the *Journal of Law Medicines and Ethics* contended that institutional corruption has undermined the capacity of the US Food and Drug Administration (FDA) to safeguard public health (Light et al., 2013) and contributes to explaining the content of some legislation (Jorgensen, 2013). Governments' capacity to act as independent regulators – in health or other sectors – warrants constant attention, including in OECD countries (OECD, 2016).

Circumventing regulation to gain entry into the health care market is a second category of documented problem. Entry into the health sector for a professional or a facility providing health care services is always regulated, primarily to protect patients' safety but for other reasons as well.[18] Similarly, medical products are subject to marketing authorisations. Potential entrants into the market might be tempted to bribe, exert pressure on or simply use their influence with the regulator. More indirectly, they can manipulate the regulator by proving misleading information. In this domain, leaving aside the relatively simple case of individuals who might present falsified credentials, the main concern in the literature is the strong conflict of interest (CoI) the pharmaceutical industry faces when presenting the results of clinical trials. As part of their research and development process, firms undertake or fund clinical trials to assess the safety and effectiveness of their own products and present the evidence to the regulator to obtain a marketing authorisation. The information can also be used by the payer to include a product on the positive list or in the price-setting process and to influence drug prescription down the line.

Clinical trials must meet quality criteria and are subject to scrutiny by regulatory authorities, but opportunities exist to manipulate data and exaggerate positive findings, underplay negative outcomes or selectively publish results (Lexchin, 2012). Several analyses show that industry-sponsored clinical trials are more likely to yield positive results for their sponsors and have higher citation impact (for a review, see Transparency

International-UK, 2016), including trials that compare treatments with one another (Flacco et al., 2015). In recent years, re-analyses of evidence from industry-sponsored trials led to questioning of the efficacy of Tamiflu,[19] and to showing that paroxetine, which had been prescribed to adolescents, was not only ineffective but could cause harm (Le Noury et al., 2015). The latter case was part of a USD 3 billion fraud settlement by GlaxoSmithKline (Almashat et al., 2016). Ebrahim et al. (2014) reviewed 37 published re-analyses of randomised clinical trial data and found that more than a third resulted in changing the conclusions drawn from the information available. A new analysis producing concordant results is less likely to be worthy of publication than one that modifies them, so the proportion is probably artificially high. Further, the revised conclusions do not necessarily contradict the initial findings, but this analysis clearly highlights that published results are not necessarily definitive.

A vast range of inappropriate strategies can be used by providers of medical goods and services to increase demand for their product. Rather than systematically listing them, Table 7.3 offers a synthesis. To increase demand for their products and services, businesses need to convince the final decision makers: patients, who "consume"; physicians, who guide or even prescribe use; regulators, who are in a position to set or validate standards and rules; and payers, who define what can be financed from pooled funds (private or public), hereby ensuring that large contingents of patients can afford the goods or services. Each of these stakeholders can be subject to direct influence (for instance, direct-to-consumer advertising targets patients). Businesses can also seek to influence "intermediary" institutions expected to offer independent and objective input to ultimate decision makers (for instance, patients' associations, opinion leaders or scientific societies).

Table 7.3. **Levers, intermediary targets and ultimate targets of inappropriate business practices aimed at increasing demand for medical products or services**

Levers (and how they might be misused)	Intermediary target	Ultimate target
Direct funding Grants and donations leading to financial dependence of beneficiaries to carry out their missions	Patients' associations Specialised or general press	Patients demanding treatment
Financial incentives Stake in commercial success (% of sales, shares, etc.), self-referral, kickbacks, the promise of consultancies or future jobs	Scientific societies	Clinicians who prescribe and guide the choice of treatment
Free-of-charge provision Provision (of equipment, samples, etc.) to create later demand	Research institutions	Regulators involved in standard setting and safeguarding patients' safety
Other gratification (hospitality, gifts)	Scientific journals (and conferences)	
Direct persuasion Misleading use of marketing techniques, advertisement, physician detailing, media; direct marketing to consumer	Opinion leaders	Payers or entities who decide inclusion of treatment on positive list (increases patients' capacity to pay)
Indirect persuasion Manipulation of scientific evidence Inappropriate influence on education curriculum, guidelines and other professional recommendations (disease boundaries, intervention threshold, treatment protocols, indications and off-label use)	Institutions providing initial and continuing education	

The first column of Table 7.3 groups the most common practices documented as leading to abuse. Keeping in mind that inappropriate practices are not necessarily widespread, a few concrete and recent examples help highlight the risk. A final category of inappropriate practice, which consists of delaying or preventing competitors' entry into the market, is discussed subsequently.

- *Direct funding*. Patients' groups, which typically represent the interests of or support people suffering from specific diseases, are perceived by the public to be independent but many are frequently funded by pharmaceutical industries that market drugs used to treat these very diseases. Arie and Mahony (2014) offer some examples of situations where this has created at least the appearance of a CoI.
- *Indirect funding and other gratifications*. In 2015, the *British Medical Journal* reported on a hospital in Chicago that provided kickbacks to referring physicians and a group of UK physicians receiving financial inducements in exchange for referrals to a private hospital group (Godlee, 2015). The European Commission (2013) offered additional examples of pharmaceutical companies remunerating or rewarding physicians who prescribed their brand and a 2016 *New York Times* article shed light on the practice of paying haemophiliac patients in an effort to recruit customers.[20]
- *Direct persuasion*. Firms operating in a competitive environment use marketing techniques to differentiate their products and appeal to more (or better) customers. A classic example is health insurance companies using marketing techniques to attract healthier patients. For instance, two studies showed that advertising was targeted at, and resulted in, enrolling lower-risk Medicare patients by health insurance plans (Mehrotra et al., 2006; Aizawa and Kim, 2015). Pharmaceutical companies spend considerable amounts on a wide range of marketing techniques, including physician detailing, and can also be tempted to breach good marketing practices (Transparency International-UK, 2016; European Commission, 2013). A review of 25 years of settlements by the industry in the United States showed that a quarter of offences were related to "unlawful promotion". Most cases pertained to promoting off-label use (which was restricted)[21] or downplaying information about side effects (Alsmashat et al., 2016).
- *Indirect persuasion*. Indirect persuasion consists of influencing the production of evidence or guidelines that the "ultimate targets" factor into their decision making. The possibility for the industry to influence the dissemination and presentation of clinical trials data was mentioned earlier. Chapter 2 on low-value care discussed the pharmaceutical industry's role in shaping the social construction of disease and medicalising normal human experience, which can ultimately open new markets. The possibility that manufacturers can influence the production of guidelines that are designed to influence prescription patterns has also drawn attention. The financial relationships between the bio-medical industry and the experts or institutions involved in production of clinical guidelines are "pervasive, under-reported, influential in marketing, and uncurbed over time" (Lenzer et al., 2013; Campsall et al., 2016).

Central to many of these examples is the notion of CoI, defined as a set of circumstances that create a risk that the professional judgment or actions of individuals or institution regarding the accomplishment of their core mission could be unduly influenced by their private interest.[22] As highlighted in the comprehensive analysis of CoI by the US Institute of Medicine, the mere existence of the risk creates a CoI, whether the entity is ultimately influenced or not (IOM, 2009). Indeed, relationships between actors with potential or actual

conflicting interests do not necessarily result in inappropriate business practices. In fact, physicians, biomedical researchers and pharmaceutical or medical device companies need to collaborate to develop new treatments that benefit the population. Still, teaching or academic institutions and associated researchers, scientific journals, patients' associations, health care providers, their opinion leaders and scientific societies can all risk appearing conflicted as soon as they enter into a relationship with industries.

The last category of documented inappropriate practice falls more in the domain of breaches in competition policy. Some brand name pharmaceutical companies and generic drug producers engage in strategies to delay or prevent the availability of cheaper generic drugs, thereby increasing the price paid by patients, governments and insurance companies. These practices involve brand name companies paying would-be generics competitors to delay entering the market, securing a longer period of exclusivity and high profits. Alternatively, generics producers can be bought out by brand name companies. Depending on circumstances, such practices infringe competition law and on a number of occasions the involved companies were forced to return the unduly earned profits (Jones et al., 2016). Based on the known cases, in the United States alone, the Federal Trade Commission (FTC) estimated that such practices add at least USD 3.5 billion annually in higher medicine prices. A 2009 EU inquiry estimated that savings due to generics entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity (European Commission 2009, 2016).

Drug companies combine these forms of inappropriate business practice with "product hopping", also called "ever-greening". This involves making minor variations to a drug prior to its patent expiration (for instance, by patenting a slightly different tablet or capsule dose) and obtaining new patent protection without adding any therapeutic advantage. Pay-for-delay in connection to product hopping can mean that by the time a potentially competitive generic drug enters a market, the originator product is transformed such that the substitution is not legally possible (in most countries, a clinician can only substitute a brand name drug with a cheaper generic drug if the latter has exactly the same dosage strength).

3.2. Regulation and emphasis on transparency play an increasing role in tackling inappropriate business practices

No comprehensive information is available about policies aimed at tackling inappropriate business practices across OECD countries. The literature review undertaken to fill the gap as well as the responses received from 15 countries to the OECD 2016 questionnaire give a sense of the policy levers some countries use to discourage inappropriate business practices, but the picture is far from comprehensive. Table 7.4 presents the information collected. This final section highlights the first lessons drawn from the exercise. The overall conclusion is that countries rely primarily on self-regulation to manage inappropriate business practices but many countries do have some regulations in place to ban or limit specific practices. These sector-specific regulations tended to develop over time and many countries are considering introducing them. Finally, pressure to increase the transparency of clinical trials is growing.

Table 7.4. **Levers used to manage inappropriate practices: Examples from OECD countries**

Activity	Banned	Severely restricted	Authorised and regulated	No specific law	Self-regulated
Measures limiting incentives to overprescribe					
Self-referral/financial interest in business with potential to refer	**United States:** 1993 law applying to federal programmes for facilities with which provider has a financial relationship. 34 states' laws mirror and some ban financial ownership			**Germany:** a provision of the Penal Code banning this for self-employed professionals is under discussion	**Canada:** for the most part self-referral is governed by professional associations although some provinces have additional regulations (e.g. a ban in British Columbia) (Beck, 2013)
Kickbacks	**United States:** 1972 law bans kickbacks in the context of federal programmes, 36 state laws and DC typically expand this to all payers (NCSL, 2010) **Poland, Slovenia, Switzerland**				**Canada:** self-regulation by professional associations
Sale of medicine by physicians (of medicines they prescribe)	**Australia, France**	**United Kingdom** (rural areas)	**Switzerland, United States** (44 states), **Japan, Netherlands, Canada**		
Marketing practices					
General framework on marketing practices[1]			**EU Directive** 2001/83 frames marketing practices for medicinal products to encourage industries to comply with code of conduct **Japan, Slovenia:** several laws frame marketing practices		**IFPMA, EFPIA** **Canada:** the Canadian Medical Association provides guidelines for physicians in interaction with industry
Direct-to-consumer advertising for prescription medicines	**All OECD** countries except New Zealand and the United States, EU-wide ban		**New Zealand, United States**		
Advertising to professionals			**Australia** (advertising limited to reimbursed indications), **Canada, United States, Slovenia**	**Japan:** prior approval of material not required	
Promotion of off-label drug use		**United States:** not allowed but companies can distribute peer-reviewed articles and answer physicians' questions			
Physician detailing			**EU Directive** 2001/83/CE: representatives should be adequately trained and provide complete information, including adverse events **Slovenia:** registration of sales representatives		**Australia:** covered by self-regulation **Canada** (provincial variations)

Table 7.4. **Levers used to manage inappropriate practices: Examples from OECD countries** *(cont.)*

Activity	Banned	Severely restricted	Authorised and regulated	No specific law	Self-regulated
Gifts and advantages[2]	**France:** 1993 "Anti-gift" law prohibits health professionals from receiving gift in cash or in kind, direct or indirect (with a few exceptions linked to research activities or attendance of scientific conferences) **Germany** has a similar law	**Japan** (2016 effectiveness) **EU Directive 2001/83/CE:** gifts must be limited to inexpensive and related to the practice of medicine **Norway** (2005), **Sweden** (2004), **Poland, Slovenia** **Switzerland** (2016): Art. 55 of Therapeutic Product Act)		**Japan, Poland, Sweden, United Kingdom**	
Disclosure of financial relationships and transfers of value (Sunshine Act or transparency)[2]			Comprehensive laws: **United States** (2010), **France** (2011 website open to the public), **Portugal** (2013), **Slovak Republic** (2011) Some mandated disclosure (limited): **Australia** (industry-sponsored events), **Belgium, Denmark, Germany, Italy** (hospitality), Slovenia (public servants), **Spain** **Switzerland** (on rebates as of 2016)		**Netherlands** (2012): Health professionals and pharma industries jointly decided to disclose relationships Disclosure by pharma industry required by **EFPIA** (2016) and **Japan's** pharmaceutical association
Sponsorship of individuals to attend medical conferences[3]	**Sweden, United States, Norway**	**Belgium, Greece, Italy, Netherlands, Turkey**	**Japan, Austria, Finland, France, Germany, Switzerland, Slovenia, Hungary, Portugal**	**Czech Republic, Ireland, Poland, Slovak Republic, Slovenia, Spain**	**Canada:** Canadian Medical Association provides guidelines for physicians in interaction with industry
Promotional meetings		EU Directive 2001/83/CE: hospitality limited to event and prescriber			
Relation with education institutions		**Germany** has in place specific rules to ensure neutrality of education and training			
Provision of free samples		Restricted by **EU Directive** 2001/83/CE	**Japan, Canada** (provincial variations)		
Provision of low-value promotional aids	**United States, United Kingdom**		**Japan**		

1. This first line in "marketing practices" points to existence of a general law or self-regulation of marketing practices. The following lines review specific marketing practices. A comparative analysis of the content of the various pharmaceutical laws to assess whether some might be more restrictive than others goes beyond the scope of this chapter. By default all countries that responded having a law are grouped under "authorised and regulated".
2. McDermott et al. (2015), "Snapshot of Sunshine Rules in EU Countries for the Pharmaceutical Industry", *www.lexology.com/library/detail.aspx?g=8d220555-2e13-49cf-8d46-c70b7a1ab3e5*.
3. Arie (2015), "The Device Industry and Payments to Doctors", *British Medical Journal*, *http://dx.doi.org/10.1136/bmj.h6182*.

Source: Multiple sources, including responses to questionnaires.

Most countries rely significantly on self-regulation to prevent inappropriate business practices

Self-regulation is at the core of the strategy used across OECD countries to deter inappropriate business practices. This self-regulation originates either from industry itself in the form of codes of conduct or from institutions or professionals who may face a CoI and adopt CoI policies. In some instances, CoI policies are laid out by governments to cover civil servants or individuals in a position to advise the government.

Codes of conduct are widespread among pharmaceutical associations, but less visible in the medical device industry. Over the years, the pharmaceutical industry's professional associations worldwide developed and encouraged adherence of individual firms to codes of conduct. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) code of conduct, last revised in 2012, includes provisions on interactions with health care professionals, medical institutions and patient organisations (Francer et al., 2014). All member associations are required to adhere to the minimum principles laid out in the code of conduct – provided they are not in contradiction with countries' legal framework and recognising that individual codes can include additional provisions. In turn, individual industries registered with these associations are required to adopt a code of conduct based on these guidelines. Operating along these principles, the European Federation of Pharmaceutical Industries and Associations (EFPIA) – a member of IFPMA – developed its own code of conduct. It contains more stringent requirements and in particular, as of 2016, requires all member companies to disclose transfers of value to health care professionals and health care organisations. All OECD countries follow either a code formally aligned with those of IFPMA or EFPIA or ones seemingly developed independently (in the case of Israel, Luxembourg and New Zealand). For the medical device industry, the practice of encouraging the development of codes of conduct does not seem as well organised. MedTech Europe, an alliance of European medical technology industry associations, developed a new code (combining two previous ones) that will come into force in 2017.

Little is known about the take-up or effectiveness of codes of conduct. Adherence is ultimately a company's decision and no data on the proportion of firms that actually adhere to a code are readily available. Codes of conduct generally provide for the possibility of a complaints mechanism in case of breach but again, little information is available about the frequency of complaints (if any), the sanctions taken or their impact.

Self-regulation is used by all stakeholders at risk of CoI: physicians, experts, advisors to policy makers, academic and research institutions and medical journals. The US Institute of Medicine undertook an in-depth analysis of CoI in medical research, education and practice and in the development of clinical practice guidelines (IOM, 2009). Among its key conclusions, the report highlighted that:

- Preventively dealing with CoI helps protect stakeholders' integrity and increases trust in the institutions they represent.
- Disclosure of financial interest is a critical but insufficient element of a CoI policy; institutions at risk should be mandated to develop explicit CoI policies. As relevant, these policies should include prohibition of specific practices, guidelines for management of specific situations (for instance, individuals who have or may be perceived to have a CoI should not participate in the relevant decision making), and creation of committees to evaluate and manage CoI.
- Mandates to implement CoI policies are not always effective and their content is not always strong enough to achieve their purpose.
- CoI policies can put a significant burden on providers.

CoI policies are not only the domain of self-regulation. In fact, a number of countries put CoI policies in place for civil servants in general (e.g. Australia, Belgium – law of 2002, Poland and the United States) and codes of conduct for professionals (for instance, in German Länders) and/or for people who act in an advisory position to Ministries of Health

or related institutions. Responses to the questionnaire mentioned that disclosure of interest is mandated as follows:

- In Australia, for officials of the National Health and Medical Research Council (which funds research and establishes guidelines); the Department of Health also mandated CoI provisions and policies for all its employees and members of external advisory committees.
- In Belgium, for members of the Commissions and linked Working Parties and Subcommittees competent in the reimbursement of pharmaceuticals and medical devices.[23]
- In Norway, for the Norwegian Medicines Agency.
- In Slovenia, for advisors to the Ministry of Health and board members in public institutions (since 2015); and in Poland, for consultants (physicians operating in an advisory capacity to the government).
- In France, which expanded measures over time; a harmonised disclosure form must now be filled by all individuals working for or advising all health-related administrations since 2011; these declarations are made public.
- In contrast, Germany does not have sector-specific measures in place.

Governments regulate specific practices but not uniformly

Considerable variation arises in the way countries deal with situations, which can generate CoI or inappropriate practices. Table 7.4 highlights the range of approaches used to deal with a list of specific situations and activities. The list was established based on evidence that some countries had explicitly put such measures in place, but the list may not be exhaustive. Potentially inappropriate practices fall into two categories:

- Activities that leave a possibility for a provider's recommendation to a patient regarding a treatment to be overly self-interested, such as:
  - receiving payments for referrals or prescriptions (kickbacks)
  - selling medicines (physicians)
  - having financial ties with an entity that can gain from one's prescription or being allowed to refer to an entity with which one has such ties (e.g. a private hospital).
- Marketing practices. In many – perhaps even all – countries, guidelines frame the marketing of medicinal products. For a start, the pharmaceutical industry's codes of conduct, which exist in all OECD countries, typically cover a common set of core issues, including the obligation to provide truthful and balanced information about marketed products. Marketing practices are probably covered in some form of government regulation in most countries. As part of these, or in addition, a number of practices are identified on which countries clearly put more or less emphasis, in particular (see Table 7.4): direct-to-consumer advertising, advertising to professionals, physician detailing, gifts and advantages, sponsorship of individuals to attend medical conferences, promotional meeting/conference sponsorship, provision of free samples and provision of low-value promotional aids.

The columns of Table 7.4 list regulatory responses in order of decreasing strength:

- Bans. Some countries simply choose to ban specific activities that are at too high a risk of generating inappropriate behaviours. This is the case for dispensing of medicines by physicians (Australia and France) and for sponsorship of health professionals to attend educational events (Norway, Sweden and the United States).
- More or less severe restrictions. The distinction between "severely restricted" and "authorised but regulated" is probably arbitrary but Arie (2015) introduces it when describing across countries the rules surrounding sponsorship of conference attendance. In some countries, the regulation may consist of requesting employers' authorisation to attend, banning the funding of relatives' travel expenses, or setting a limit on the total amount payable for hospitality. In others, all these rules apply simultaneously, which is more restrictive.
- No restrictions. In some instances explicit mention was made that a given practice was not subject to regulation (often in contrast to other countries).
- Self-regulation. Self-regulation may coexist with government-dictated regulation but in some cases it is the only framework governing the activity.

In the last decade, systematic disclosure of transactions by either health professionals or industry became much more frequent. Sunshine Act types of regulations exist in the United States (since 2010), France (since 2011), Portugal (2013) and the Slovak Republic (2011). Another set of countries (including Australia, Belgium, Denmark, Germany, Italy and Spain) has rules on disclosure but these are typically less comprehensive (McDermott et al. 2015). Some countries do not have mandatory disclosure (Poland, Sweden and the United Kingdom). In the Netherlands, the principle of such a law was discussed but a self-regulatory approach was elected: a number of pharmaceutical companies and health professional associations jointly created a national and public registry of transactions. Similarly, in 2016 the Association of the British Pharmaceutical Industry put in place a website disclosing payments, but professionals can decline to be identified. Early results suggest that physicians receiving large payments are more likely to decline identification (Hawkes, 2016).

The scope of Sunshine laws varies across countries. In the United States, industries must report relationships only with physicians and teaching hospitals, whereas in France disclosure covers ties with all health professionals and associations representing them, scientific societies, patients' associations and the press. The type of transaction disclosed is also variable. In the United States, all payments and transfers of value must be reported, as well as ownership or investment interests held by physicians or their immediate family members. Disclosure can be delayed for some payments related to research. In France, fees and honoraria levels are not disclosed. Typically, the information is centralised and made public in more or less user-friendly ways, such as a researchable online database. In the Unites States, datasets can be downloaded and annual summary reports are published. In France, transactions above EUR 10 are reported and available on a public website but the data cannot be downloaded.

Critics of such regulation contend that it may damage providers' reputation, even if they do not act inappropriately, or may reduce funding for innovation or medical education. On balance though, disclosure is gaining momentum and additional countries are considering legislation in that vein. Interestingly, the EFPIA code of conduct requires that companies report all transfers of value to providers as of June 2016.

Mandates to disclose information on clinical trials are slow to bear fruit

Registration of clinical trials is a globally accepted principle, but dissemination of results remains incomplete. Registration of all research study involving human subjects in a publicly accessible database before recruitment of the first subject is a principle laid out in the 1964 World Medical Association Helsinki declaration. Creation of an international registry platform was proposed by WHO's 2005 World Health Assembly declaration and initiated soon after. But a considerable amount of evidence shows that registration and reporting of results remains incomplete (Moorthy et al., 2015), despite the fact that most developed countries mandate this. Miller et al. (2015) reviewed the registration, dissemination and publication of results for 15 drugs approved by the FDA in 2012. Per drug, a median of 57% of trials were registered, with an interquartile range of 32-83%; a median of 65% of results were publicly available (either published or reported) in the national registry. For 3 of the 15 drugs, the results of all studies were made public. Chen et al. (2016) reviewed the dissemination of results of 4 347 registered trials conducted by 51 major academic medical centres due to be completed by 2010. As of July 2014, results were reported for only 66% of the registered trials, and in only 36% of cases did the reporting take place within 24 months following completion. In other words, even if agreement exists in principle that clinical trials data should be registered and results availed, fierce debates still rage about whether raw data should be open to scrutiny. Progress on this front is warranted.

Conclusion

The final category of waste reviewed in this report essentially comprises resources illegitimately and deliberately diverted from health care to serve the self-interest of a few. From the report's perspective, it is easy to conceptualise these integrity violations as wasteful. The chapter reviewed actions taken to reduce fraud and abuse in service delivery and financing as well as strategies put in place by countries to prevent inappropriate business practices in the sector.

Integrity violations in health, as in any sector of the economy, are notoriously difficult to measure and compare across systems. A first reason is lack of a uniform understanding of what may constitute fraud, abuse and corruption. More importantly, since most activities are reprehensible and some at least can be sanctioned, they naturally tend to be covert. Nevertheless:

- A third of OECD citizens deem the sector as corrupt or extremely corrupt (45% globally).
- The loss to fraud and error combined is an average 6% of related health expenditure, with most estimates ranging between 3% and 8%.

Countries differ significantly in the level of effort they put into addressing integrity violations in service delivery and financing.

- The response is primarily organisational in that it involves assigning responsibility for detecting or tackling integrity violations in service delivery and financing to specific institutions and sometimes defining how it will be done.
- Fraud detection activities can be more or less pro-active. They can rely on simple audits, controls and/or the investigation of complaints, and systems may or may not be in place to encourage the reporting of integrity violations – for instance through hotlines. More advanced countries use analytical tools to detect integrity violations, including data mining.

- Practitioners highlight the importance of having a stepwise, comprehensive and credibly enforceable response. Overall, efforts must go into engaging and communicating with health professionals, recognising that errors can happen and that special circumstances can dictate deviations from good practices.

The need to tackle inappropriate business practices in the health sector is gaining increasing attention:

- Responses by countries are typically regulatory in nature and consist of limiting or banning certain practices.
- Little attention is paid to actively detecting these types of integrity violations. Instead, countries rely on whistle-blowers reporting integrity violations or the investigation of and reaction to specific crises, particularly when they have detrimental consequences on health.
- The three main domains where some countries have introduced regulation seek to limit self-interested referrals by health providers and the means by which the pharmaceutical industry is allowed to promote sales – including Sunshine-type regulations. The question of how to ensure the integrity of research, particularly when it comes to clinical trials and CoI, is also gaining traction.
- Self-regulation by industry remains the norm, nonetheless.

Overall, many OECD countries need to strengthen their efforts to curb integrity violations in health, not only to reduce waste and increase efficiency, but to enhance transparency, improve the integrity of the sector and contribute to patient safety as well.

Notes

1. In response to the survey conducted for this report, Denmark, Israel, Japan, Norway, Poland, Slovenia, and Switzerland could not point to recent studies of the risk of fraud, abuse and corruption in health or measurements of its impact.
2. Both surveys list a series of sectors and types of transactions that could be prone to corruption (12 in the TI case, 15 in the Eurobarometer). They ask respondents to give their perception on the relative prevalence of corruption across sectors. Although the questions and the sectors' boundaries are not strictly identical, six sectors are mentioned in both surveys, including health. The TI survey covers 107 countries, 28 of which are OECD members. The Eurobarometer survey covers 27 members of the EU, including 20 OECD members. Sixteen countries are common to the two surveys.
3. The Asian Development Bank's definition is more complete in this respect: "Corruption involves behaviours on the part of officials in the public or private sector in which they improperly and unlawfully enrich themselves and those close to them, or induce others to do so, by misusing the position in which they are placed."
4. *www.govtrack.us/congress/bills/104/hr3103*.
5. To give specific examples, favouritism is largely accepted in France and seen as non-corrupt (Lascoumes and Tomescu-Hatto, 2008). Gift-giving is a common practice in Luxembourg, whereas in other places, this might be considered bribery (European Commission, 2013).
6. Building on this idea, the 2013 European Commission report identified six types of corruption.
7. Many manufacturers of non-medical goods and services, for instance construction companies, are also involved in the health sector and potentially in integrity violations (e.g. bribery, procurement fraud, etc.). However, the tools required to combat these types of integrity violations would not be health-specific and no further reference is made to them for that reason.

8. For instance, a classic form of fraud in an FFS/insurance-based system is for the provider to overbill the "payer". In a system where the provider's salary comes from the payer, this type of fraud would not materialise. On the other hand, the payer would potentially be exposed to payroll fraud and absenteeism. All of these are integrity violations that take place in the context of delivery payment and coverage.
9. Issues related to the efficiency of procurement are discussed in Chapter 4.
10. Australia, Belgium, France, Germany, Israel, Japan, the Netherlands, Norway, Poland, Slovenia, Switzerland and the United States.
11. Belgium, the Czech Republic, France, Germany, Greece, Luxembourg, the Netherlands, Norway, Poland, Portugal and Slovenia.
12. For instance in response to the questionnaire Germany and Switzerland reported the government does not use data mining (insurers still might), and France reported that it has used it for two years.
13. Data-mining techniques are typically classified into supervised and unsupervised methods. Supervised methods incorporate into models information that is already known (e.g. whether specific previous claims are known to be fraudulent or not). Unsupervised methods help identify hidden patterns and structures in cases where no natural or logical grouping exists. Both can be useful and combined in fraud detection activities (Joudaki et al., 2015). Australia recently enhanced funding for data-mining activities, which will result in greater use of unsupervised data mining and social network analyses.
14. The Affordable Care Act (ACA) increased federal sentencing guidelines for health care fraud in the United States by 20-50%, in particular for crimes with losses over USD 1 million.
15. Between 2012 and 2013, a woman who provided a fake diploma to obtain a registration with the order of pharmacists ran a pharmacy in Paris (*www.lemoniteurdespharmacies.fr/actu/actualites/actus-socio-professionnelles/151231-escroqueries-en-series-pharmacienne-parisienne-sans-diplome.html*).
16. Collective strategy or action here means that an organised group of stakeholders joins forces to achieve the same objective. This could be a professional association, a lobbying firm paid by several firms, etc.
17. *www.opensecrets.org/*. The pharmaceutical industry alone is the one that spends most on lobbying (USD 230 million per year or more since 2009, nearly 50% more than the second industry – insurance).
18. For instance, opening a facility in a given location may be conditional on certification of need.
19. Goldacre (2014) and Silverman (2015) present the debate that surrounded the case.
20. Andrew Pollack, *New York Times*, 14 January 2016, p. B1 "The Patient's Sales Pitch", online version: *www.nytimes.com/2016/01/14/business/hemophilia-patient-or-drug-seller-dual-role-creates-ethical-quandary.html?_r=0*.
21. Off-label use is the prescription of a medicine outside of approved indications, dosage or patient populations that have not been approved by the authorities. Off-label use expands the market for a given product. Off-label use is not illegal and can provide needed access to some patients (for instance children, who are less likely to be included in clinical trial studies). But it also raises concerns, particularly about the lack of evidence of safety and effectiveness (Wittich et al., 2012).
22. Definition adapted from IOM (2009) and TI (2009).
23. A similar provision for all committees related to public health and social security included in a 2013 law awaits a Royal Decree.

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