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Italy
Health system review

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PREFACE

The Health Systems in Transition (HiT) series consists of country-based reviews that provide a detailed description of a health system and of reform and policy initiatives in progress or under development in a specific country. Each review is produced by country experts in collaboration with the Observatory's staff. In order to facilitate comparisons between countries, reviews are based on a template prepared by the European Observatory, which is revised periodically. The template provides detailed guidelines and specific questions, definitions and examples needed to compile a report.

HiTs seek to provide relevant information to support policy-makers and analysts in the development of health systems in Europe and other countries.

They are building blocks that can be used to:

- learn in detail about different approaches to the organization; financing and delivery of health services, and the role of the main actors in health systems;
- describe the institutional framework, process, content and implementation of health care reform programmes;
- highlight challenges and areas that require more in-depth analysis;
- provide a tool for the dissemination of information on health systems and the exchange of experiences of reform strategies between policy-makers and analysts in different countries; and
- assist other researchers in more in-depth comparative health policy analysis.

Compiling the reviews poses a number of methodological problems. In many countries there is relatively little information available on the health system and the impact of reforms. Due to the lack of a uniform data source, quantitative data on health services are based on a number of different sources, including data from national statistical offices, the Organisation for Economic Co-operation and Development (OECD), the International Monetary Fund (IMF), the World Bank's World Development Indicators and any other

relevant sources considered useful by the authors. Data collection methods and definitions sometimes vary, but typically are consistent within each separate review.

A standardized review has certain disadvantages because the financing and delivery of health care differ across countries. However, it also offers advantages because it raises similar issues and questions. HiTs can be used to inform policy-makers about experiences in other countries that may be relevant to their own national situations. They can also be used to inform comparative analysis of health systems. This series is an ongoing initiative and material is updated at regular intervals.

Comments and suggestions for the further development and improvement of the HiT series are most welcome and can be sent to contact@obs.who.int.

HiTs and HiT summaries are available on the Observatory's website (https://eurohealthobservatory.who.int).

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The HSPM is an international network that works with the Observatory on Country Monitoring. It is made up of national counterparts that are highly regarded at national and international level and have particular strengths in the areas of health systems, health services, public health and health management research. They draw on their own extensive networks in the health field and their track record of successful collaboration with the Observatory to develop and update the HiT.

This 2022 edition was written by Antonio Giulio de Belvis (Università Cattolica del Sacro Cuore), Michela Meregaglia (CERGAS, Università Bocconi), Alisha Morsella (Università Cattolica del Sacro Cuore), Andrea Adduci (Università Cattolica del Sacro Cuore), Alessio Perilli (Università Cattolica del Sacro Cuore), Fidelia Cascini (Università Cattolica del Sacro Cuore), Alessandro Solipaca (Osservasalute/Università Cattolica del Sacro Cuore), Giovanni Fattore (CERGAS, Università Bocconi) and Walter Ricciardi (Università Cattolica del Sacro Cuore). It was edited by Anna Maresso and Giada Scarpetti (European Observatory on Health Systems and Policies). The basis for this edition was the previous HiT on Italy, which was published in 2014 and written by Francesca Ferrè, Antonio Giulio de Belvis, Luca Valerio, Silvia Longhi, Agnese Lazzari, Giovanni Fattore, Walter Ricciardi and Anna Maresso.

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The European Observatory on Health Systems and Policies is a partnership, hosted by the WHO Regional Office for Europe that includes the Governments of Austria, Belgium, Finland, Ireland, Norway, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the Veneto Region of Italy (with AGENAS); the French National Union of Health Insurance Funds (UNCAM); the Health Foundation; the European Commission; the World Bank; the London School of Economics and Political Science (LSE); and the London School of Hygiene & Tropical Medicine (LSHTM).

The Observatory is composed of a Steering Committee, core management team, research policy group and staff. Its Secretariat is based in Brussels and it has offices in London at LSE and LSHTM and in Germany at the Berlin University of Technology. The Observatory team working on HiTs is led by Josep Figueras, Director; Elias Mossialos, Martin McKee, Reinhard Busse (Co-directors); Ewout van Ginneken and Suszy Lessof. The Country Monitoring Programme of the Observatory and the HiT series are coordinated by Anna Maresso. The production and copy-editing process was coordinated by Jonathan North, with support from Lucie Jackson, Andrea Kay (copy-editing) and Steve Still (typesetting).

LIST OF ABBREVIATIONS

Abbreviation	English term	Italian term
AGENAS	National Agency for Regional Health Services	*Agenzia Nazionale per i Servizi Sanitari Regionali*
AIFA	Italian Medicines Agency	*Agenzia Italiana del Farmaco*
ANAC	National Anticorruption Authority	*Autorità Nazionale Anticorruzione*
ANVUR	National Agency for the Evaluation of Universities and Research Institutes	*Agenzia Nazionale di valutazione del sistema universitario e della ricerca*
AD	scheduled home care	*Assistenza Domiciliare*
ADI	integrated home care	*Assistenza Domiciliare Integrata*
AO	hospital enterprise (public hospital); also referred to as hospital trusts in English	*Azienda ospedaliere*
ASL	local health authority	*Azienda sanitaria locale*
CCM	National Centre for Disease Prevention and Control	*Centro Nazionale per la Prevenzione e il Controllo delle Malattie*
CCNL	National Collective Labour Agreement	–
CHE	current health expenditure	–
CME	continuous medical education	–
COPD	chronic obstructive pulmonary disease	–
COVID-19	coronavirus disease 2019	–
CT	computerized tomography	–
CUP	single appointment centres	*Centri Unici di Prenotazione*
DDD	defined daily dose	–
DEA	first-level emergency-urgency department	*Dimpartimento di emergenza-urgenza accettazione*
DRG	diagnosis-related group	–
EEA	European Economic Area	–
EHR	electronic health record	–
EMA	European Medicines Agency	–
EU	European Union	–
EU-27	The 27 EU Member States from 1 February 2021	–
EU-28	The 28 EU Member States prior to 1 February 2021	–

FCP	Palliative Care Federation	*Federazione Cure Palliative*
FESR	European Fund for Regional Development	*Fondo Europeo di Sviluppo Regionale*
FOB	faecal occult blood test	–
FSE	Electronic Health Files	*Fascicolo Sanitario Elettronico*
GDP	gross domestic product	–
GP	general practitioner	–
HPV	human papillomavirus	–
HTA	health technology assessment	–
ICU	intensive care unit	–
IMF	International Monetary Fund	–
IRCCS	Institutes for Care and Scientific Research	*Istituti di Ricovero e Cura a Carattere Scientifico*
IRAP	an earmarked corporate tax	*Imposta regionale sulle attività produttive*
IRPEF	personal income tax	*Imposta sul reddito delle persone fisiche*
INAIL	National Institute for Insurance against Accidents at Work	*Istituto Nazionale Assicurazione contro gli Infortuni sul Lavoro*
ISS	National Institute of Health	*Istituto Superiore di Sanità*
ISTAT	National Institute of Statistics	*Istituto Nazionale di Statistica*
IT	information technology	–
LEA	nationally defined health benefits package	*Livelli essenziali di Assistenza*
MOH	Ministry of Health	–
MRI	magnetic resonance imaging	–
NGO	nongovernmental organization	–
NSG	New Guarantee System	*Nuovo Sistema di Garanzia*
NSIS	New Health Information System	*Nuovo Sistema Informativo Sanitario*
NRRP	National Recovery and Resilience Plan	*Piano Nazionale di Ripresa e Resilienza*
PNPV	National Vaccine Prevention Plan	*Piano Nazionale Prevenzione Vaccinale*
OECD	Organisation for Economic Co-operation and Development	–
ONFMS	National Observatory for the Education of Medical Specialists	*Osservatorio Nazionale per la Formazione Medica Specialistica*
ONS	National Screening Observatory	*Osservatorio Nazionale Screening*
OOP	out-of-pocket	–
OPV	oral poliovirus vaccine	–
OTC	over-the-counter	–

PAL	local implementation plan	*Piani Attuativi Locali*
PET	positron emission tomography	–
PNA	National Anticorruption Plan	*Piano Nazionale Anticorruzione*
PNE	National Outcomes Programme	*Programma Nazionale Esiti*
PNGLA	National Waiting Lists Plan	*Piano Nazionale Governo Liste d'Attesa*
PNHTADM	National Health Technology Assessment Plan	*Piano Nazionale Health Technology Assessment Dispositivi Medici*
PPP	purchasing power parity	–
R&D	research and development	–
REACT-EU	Recovery Assistance Package for Cohesion and European Territories	–
RRF	Recovery and Resilience Facility	–
RSA	residential health facilities	*Residenze Sanitarie Assistenziali*
SDO	Hospital Discharge Charts	*Schede Dimissione Ospedaliera*
SSN	National Health Service	*Servizio Sanitario Nazionale*
TUC	compensation of interregional mobility	*Tariffa unica convenzionale*
UPC	Unique Regional Purchasing Centre	–
USCA	Special Continuity-of-Care Unit	*Unità Speciale di Continuità Assistenziale*
UN	United Nations	–
VAT	Value Added Tax	–
VHI	voluntary health insurance	–
WHO	World Health Organization	–

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ABSTRACT

This analysis of the Italian health system reviews recent developments in organization and governance, health financing, health care provision, health reforms and health system performance. Italy has a regionalized National Health Service (SSN) that provides universal coverage largely free of charge at the point of delivery, though certain services and goods require a co-payment.

Life expectancy in Italy is historically among the highest in the EU. However, regional differences in health indicators are marked, as well as in per capita spending, distribution of health professionals and in the quality of health services. Overall, Italy's health spending per capita is lower than the EU average and is among the lowest in western European countries. Private spending has increased in recent years, although this trend was halted in 2020 during the coronavirus disease 2019 (COVID-19) pandemic.

A key focus of health policies in recent decades was to promote a shift away from unnecessary inpatient care, with a considerable reduction of acute hospital beds and stagnating overall growth in health personnel. However, this was not counterbalanced by a sufficient strengthening of community services in order to cope with the ageing population's needs and related chronic conditions burden. This had important repercussions during the COVID-19 emergency, as the health system felt the impact of previous reductions in hospital beds and capacity and underinvestment in community-based care. Reorganizing hospital and community care will require a strong alignment between central and regional authorities. The COVID-19 crisis also highlighted several issues pre-dating the pandemic that need to be addressed to improve the sustainability and resilience of the SSN. The main outstanding challenges for the health system are linked to addressing historic underinvestment in the health workforce, modernizing outdated infrastructure and equipment, and enhancing information infrastructure. Italy's National Recovery and Resilience Plan, underwritten by the Next Generation EU budget to assist with economic recovery from the COVID-19 pandemic, contains specific health sector priorities, such as strengthening the country's primary and community care, boosting capital investment and funding the digitalization of the health care system.

EXECUTIVE SUMMARY

Italy's life expectancy at birth is one of the highest in the European Union (EU)

The average life expectancy at birth in Italy has increased consistently over the past 25 years, rising to 83.6 years in 2019, when it was the second highest in Europe. In 2020, as a result of the significant number of deaths due to COVID-19, it decreased back to 82.4 years. Italy's leading causes of death are cardiovascular diseases, cancer and, since 2020, infectious respiratory disorders. The health care system faces significant obstacles from multimorbidity and chronic diseases in the older population. Risk factors for health, in particular tobacco consumption and unhealthy diets, are major drivers of mortality in Italy, responsible for about one third of all deaths in 2019. Despite the significant improvements in health status, there are still regional disparities in lifestyle factors, health issues and the availability and overall quality of health care services, especially between northern/central regions and southern regions.

The National Health Service in Italy is highly decentralized, with regions responsible for health care delivery and organization

The Italian National Health Service (*Servizio Sanitario Nazionale*, SSN), was founded in 1978 and provides universal coverage to all citizens and legal foreign residents. The national benefits package is established by the central government, which also oversees and allocates funding for regional health systems. The regions, through local health authorities, are in charge of financing, planning and provision of services at the local level. The 3-year health plans and the pacts between regions and the national government, as

well as national programmes addressing particular health challenges, are the key planning tools at the national level. Planning is also shaped by guaranteeing the delivery of the national benefits package through a monitoring system and budget allocations. The financing and distribution of funds among the local health authorities, as well as the adaptation of national goals to local socio-epidemiological contexts, form the foundation of regional planning. During the COVID-19 pandemic, the national government played a central role in directing the health system's response to the crisis through re-centralizing coordination and accelerating decision-making at the national level with flexible guidelines for the regions.

Italy spends less on health care than most other EU countries

The Italian health care system spends less than many other western EU countries both per capita and as a percentage of GDP. In 2019, health expenditure represented 8.7% of GDP. This spending equates to approximately US$ PPP 3 998 per capita, somewhat below the average for EU/European Economic Area (EEA) countries and the United Kingdom (US$ PPP 4 347). In 2019, current health care expenditure was equal to EUR 154.8 billion, of which EUR 114.8 billion (about 74%) was funded by the SSN and the remaining EUR 40 billion (26%) came from private sources. The share of private health spending has grown over the last 10 years and is mostly (89%) driven by out-of-pocket (OOP) payments by households. However, public spending on health increased sharply in 2020 in response to the COVID-19 pandemic.

Per capita public expenditure by the regional health care systems varies due to funding (northern regions, with older populations, tend to receive more resources) and because some regions are able to deliver services beyond those covered by the national benefits package if they have sufficient resources available. Moreover, there is significant interregional mobility in terms of patients seeking care outside their region of residence, which also shapes regional differences in per capita health spending.

A shortage of physicians is expected in the near future, in addition to the ongoing acute lack of nurses

The density of physicians in Italy is above the EU average (412 practising doctors per 100 000 inhabitants compared with 397) but the number of doctors practising in public hospitals and within primary care is declining. The number of nurses per 100 000 inhabitants in Italy is considerably lower than the EU average (626 compared with 835). In addition to shortages, there are also regional imbalances in the numbers of health care workers across the country. One of the issues behind the shortage of health care professionals is the rigid turnover schemes that historically have been in place as cost-saving measures, especially in SSN facilities, not allowing new hiring.

During the COVID-19 pandemic, Italy took a series of measures to increase the number of necessary staff and to ensure the retention of current health workers. Extrabudgetary resources were allocated to hire health care professionals and remunerate staff for overtime. Other measures included the authorization of health care facilities to delay the retirement of staff; offering retired doctors and nurses the opportunity to volunteer to practice once again; temporarily enrolling doctors and nurses from the armed forces into the SSN; converting precarious work contracts to open-ended employment contracts; and increasing the number of medical residency contracts.

There is considerable variation in the distribution of health care facilities

Similar to the imbalances in the geographical distribution of human resources, there are large regional differences in the capacity of health care infrastructure. In 2017, approximately 52% of health care facilities were public, while accredited private facilities accounted for the remaining 48%, with a high concentration in the regions of Lazio, Lombardy, Campania and Sicily. Overall, the number of acute beds in Italy has decreased over the last two decades, falling from 422 per 100 000 people in 2000 to 260 in 2019, in line with trends in Organisation for Economic Co-operation and Development (OECD) and EU countries. The government has increasingly incentivized the provision of outpatient care in an effort to move away from inpatient care across all regions. Hospital planning plays a pivotal role, with detailed specifications

on the number of beds, minimum volumes of care, hospital networks as well as on human resources and technological standards. Overall, Italy is planning to reduce its bed stock by 0.3 beds per 1 000 inhabitants compared with its current number: these standards do not include beds in long-term institutions with social care activities (e.g. residential health facilities or retirement homes). However, in 2020, the declining trend in hospital beds was (temporarily) reversed as the number of ICU beds virtually doubled in a few months due to the COVID-19 crisis.

Public health and primary care are well established, and efforts to promote the integration of care are underway

Public health policies are set by the Ministry of Health and implemented by the regions. The main areas of focus include communicable disease control programmes, occupational health and screening programmes. Italy launched a vaccination campaign in December 2020 in response to the COVID-19 pandemic, starting with priority populations before expanding to the entire public for primary and booster shots in 2021–2022. Utilizing a variety of facilities, including designated vaccination centres, the vaccination plan has been carried out under the supervision of the regions and the COVID-19 Emergency Commissioner. It is being administered by GPs, nurses, paediatricians and other specialists, dentists and pharmacists who have received the necessary training.

Primary care is generally well developed, though underresourced, and in recent years has experienced a reorganization. It aims to strengthen the role of GPs and paediatricians (who act as gatekeepers to specialist care), promote the integration of care between GPs and other professionals through advanced information technology, and foster the involvement of primary care in preventive activities, including personalizing health interventions based on patients' risk profiles and being more proactive with healthy individuals. Despite this progress, most GPs still work in solo practices with limited opportunities to share knowledge with other colleagues and no access to diagnostic technologies. Attempts to incentivize different forms of group practice have only taken hold in a handful of regions. Moreover, because of retirements and limited new hirings, the number of GPs has declined over time and a major shortage is expected in the years to come.

Primary care played a key role in the pandemic response through the establishment of "special continuity-of-care units", created to assist COVID-19 patients in home isolation. These units provided telephone and video consultations, and home visits to patients who did not require hospitalization or who were recently discharged from the hospital.

Hospital care is being reorganized into acute care networks

Hospital and outpatient specialist care is provided by SSN organizations (independent hospitals or local health authorities) and private-accredited providers (which are mainly for-profit organizations). Patients are free to choose providers and there is a high level of cross-regional mobility, mainly from patients residing in southern regions seeking care in central and northern regions. Legislation in 2015 set out new standards to reorganize hospital care as well as to promote greater integration and continuity of care. The reorganization of acute care hospital networks into three different types (levels) and, according to the hub and spoke model, means that the most expensive technologies and most complex care services are centralized in "second-level" hospitals while the less complex technologies and interventions are reallocated to the "basic" hospitals. Implementation is not yet homogenous across the country: in 2021, some regions were fully compliant with most of the provisions while others were far from the standards.

The use of day hospitalizations, including day surgery for specific scheduled procedures, has been promoted over the past few decades and has seen sharp increases. The average length of stay in hospitals in 2019 (7.04 days) increased slightly from the level in 2013, while it decreased in about half of the EU Member States. This increase may be due to more patients requiring low-intensity care being treated through ambulatory care; and hence, the remaining inpatient cases are likely to require more complex care and longer stays. Despite significant improvements in the emergency care system over the last 30 years, there has been a progressive increase in emergency admissions, many of which are due to inappropriate use by patients, i.e. for minor illnesses or conditions that could be treated within primary care, thus contributing to driving up costs and increasing inefficiencies, such as longer waiting times.

Recent health reforms have focused on prevention, hospital care and redefining the national benefits package, while major investments are planned to strengthen the resilience of the Italian SSN post-COVID-19

Over the past 15 years, while the SSN's essential structure has not undergone significant changes, most regional health systems have consolidated their governance, planning and delivery systems. However, the government has made substantial adjustments at the national level in the areas of prevention and hospital care, as well as rationalization of the national benefits programme and monitoring. For prevention, the Ministry of Health released a plan to expand vaccination coverage and target populations, increase the number of vaccines to be offered as part of the benefits package and set up an online vaccination registry, as well as enhance measures to improve patient safety.

For hospital care, the Ministry issued a decree that sets specific standards for both SSN facilities and private-accredited hospitals and their activities, and introduces hospital networks (see above). However, the degree of implementation varies among regions. In terms of redefining the benefits basket, a thorough revision and update were actioned in 2017, with some new services and health devices added. Special attention has also been given to financial probity, with the introduction of 'recovery plans' for regions that exceed their health budget and/or do not deliver the guaranteed core services of the national benefits package. Regions undergoing recovery plans fall into a region-specific cost-reduction regime, which applies to all SSN organizations and private-accredited providers. In 2022, seven regions are still running under such recovery plans. In addition, preliminary data on the financial situation of regions in 2022 signal that some of them are likely to incur important deficits that will need to be covered with regional resources and/or national ones.

The COVID-19 pandemic exposed several issues that require attention, such as the need for further investment in the digitalization of the SSN, as well as addressing sustainability and health system resilience. In response, the Italian Government adopted the EU-funded Recovery and Resilience Plan in June 2021. The funding for the health components of the Plan, which provides EUR 15.6 billion for the period 2021–2026, aims at strengthening primary and community care by investing in facilities, and improving the SSN digital infrastructure, as well as investing in upgrading medical equipment and training for human capital.

The Italian health system provides high-quality care at a relatively low cost, although sizeable disparities exist in access to care across regions

The national policy agenda has become increasingly aware of the importance of performance monitoring and accountability, implementing several initiatives in these areas, including improving existing information systems and making data available to the public. Health system performance measurement strongly relies on both the National Outcomes Programme (PNE) and the New Guarantee System (NGS), which is complemented by quarterly monitoring and evaluation of the adequate delivery of the national benefits package.

Given its level of health expenditure, which is significantly below the EU average, the Italian SSN has shown to be generally efficient in delivering access to high-quality treatment at a reasonably low cost, albeit with major variability among regions. However, years of cost-cutting measures have resulted in a large rise in OOP expenses, increased wait times and underinvestment in health infrastructure and technologies.

Accessibility of services is generally high, and although the level of unmet needs is similar to the EU average, citizens from poorer regions in the south of Italy are more likely to report unmet medical care needs than those living in wealthier regions in the north, due to financial reasons, waiting times or travel distances. The health system faces some difficulties in protecting citizens from financial hardship. In 2019, a high proportion of Italian households experienced catastrophic health expenditure (9.4%). Excessive waiting times are one of the reasons citizens use their savings or incur debts to cover private health care expenses.

Key indicators of the quality of primary care, such as avoidable hospital admissions for chronic conditions, including chronic obstructive pulmonary disease (COPD), congestive heart failure, diabetes and asthma, show good results for Italy. The country also performs well in terms of the effectiveness of secondary care, with 30-day mortality after admission from acute myocardial infarction among the lowest in Europe. Prior to the COVID-19 pandemic, Italy's rates of mortality from preventable and treatable causes were among the lowest in the EU, which reflects the effectiveness of the health system. Strong public health measures that were put into place in the early 2000s (such as the indoor smoking ban) can also be used to explain, at least partly, Italy's low rate of preventable deaths.

1

Introduction[1]

Chapter summary

- With a population of approximately 60 million (2021), Italy is the fourth most populous country in Europe. The country is made up of 20 regions (with one region divided into two autonomous provinces). The Italian regions are extremely varied, differing in size, population and levels of economic development. Regions have considerable powers, particularly in health care financing and delivery, especially since the early 1990s.

- Until the coronavirus disease 2019 (COVID-19) pandemic started in 2020, the Italian population's health had been improving over several decades. Average life expectancy at birth reached 83.6 years in 2019, the second highest in Europe, and decreased temporarily back to 82.4 years in 2020 due to COVID-19 and high numbers of COVID-19-related deaths.

- Italy has one of the lowest total fertility rates in the world: in 2021 it was 1.3 births per woman. The population growth rate is negative (–0.15% in 2020), one of the lowest in the EU, with immigration no longer being able to compensate for the negative natural trend.

- In almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic and social imbalance between the north and south of the country.

1 The majority of the text in this section is based on, and updates, Chapter 1 of the previous *Health System Review* on Italy (see Ferrè et al.,2014).

- The main diseases affecting the population are cardiovascular diseases, cancers and, as a result of the COVID-19 pandemic in 2020, also infectious respiratory diseases. Multimorbidity and chronic diseases in the older population are major challenges for the health care system.

1.1 Geography and sociodemography

Italy is situated in southern Europe, with a population of about 60 million in 2021 (ISTAT, 2021a), making it the fourth most populous country in Europe (Eurostat, 2022a). The country covers 302 073 km^2 and extends from the north, where it borders France, Switzerland, Austria and Slovenia, to the south, where it includes the Mediterranean islands of Sardinia and Sicily and a cluster of other smaller islands.

The country is made up of 20 regions. The region of Trentino-Alto Adige/Südtirol is composed of the Autonomous Province of Trento and the Autonomous Province of Bolzano. Five out of the 20 regions (Friuli-Venezia Giulia, Sardinia, Sicily, Trentino-Alto Adige/Südtirol, with its two autonomous provinces, and Valle d'Aosta) are special status regions with autonomous statutes. They are granted home rule in relation to legislation, administration and finance in order to account for cultural differences and protect linguistic minorities. In addition, enclaves within mainland Italy include the countries of San Marino and the Holy See, a papal state enclosed by Rome, Italy's capital (Fig. 1.1). About 77% of the country is mountainous or hilly and 23% is forested. Population density on average is 196 inhabitants per km^2 and most of the population clusters around metropolitan areas and along the coasts (rural population accounts for only 17% of the total population) (Il Sole 24 Ore – Info Data, 2020).

Italian is the major language throughout the country, although there are small areas in which German (in Alto Adige/Südtirol), French (in Valle d'Aosta) and Slovene (in Trieste and the area around Gorizia) are spoken. The most widespread religion is Roman Catholicism but the Constitution guarantees freedom of worship to other religions, which are primarily Protestantism, Islam and Judaism.

The structure of the population has been changing since the 1990s (see Table 1.1), with low fertility rates and a rapidly ageing population. The continuously low total fertility rate over the last 35 years is a major matter of concern in Italy. In 2020, the fertility level was 1.3 live births per woman (Table 1.1), well below the 2.1 replacement level. The reasons behind this process are complex and could be explained by the delay in transition to adulthood, the difficulties experienced by Italian women in combining work and raising children (Rosina & Caltabiano, 2012), the lack of effective family policies and the postponement of getting married to later ages, in a country where having children is tightly linked to marriage (Kertzer et al., 2009). The population growth rate is negative (–0.15% in 2020), one of the lowest in the EU, with immigration no longer being able to compensate for the negative natural trend. At the beginning of 2020, foreign residents accounted for 8.4% of the Italian population (Tuttitalia, 2021). The number of legally documented immigrants is still on a growing trend and varies across the country with higher numbers in northern and central regions and smaller numbers in the south. The largest foreign communities, for both genders, are represented by Romanians, Albanians and Ukrainians.

TABLE 1.1 Trends in population/demographic indicators, selected years

	1995	2000	2005	2010	2015	2020
Total population (millions) measured on 31 December of each year	56.8	56.9	58.8	60.6	60.7	59.6
Population aged 0–14 (% of total)	14.9	14.3	14.1	14.1	13.8	13
Population aged 65 and above (% of total)	16.7	18.3	19.6	20.4	21.7	23.2
Population density (people per km^2)	194	193	198	202	206	206
Population growth (average annual growth rate, %)	–0.07	0.06	0.57	0.37	0.28	–0.15
Fertility rate, total (live births per woman)	1.2	1.3	1.3	1.4	1.4	1.3
Distribution of population (rural/urban) (expressed as urban population over total population, %)	67	68	68	69	68	69

Sources: Ferrè et al., 2014; ISTAT, 2021a, 2022a, 2022b; Statista, 2021a; Worldometer, 2020, 2021a, 2021b.

FIG. 1.1 Map of Italy

Source: Authors

1.2 Economic context

Italy has a market economy, is a founding member of the EU and is in the Eurozone. It is also a member of major multilateral economic organizations such as the Group of Seven Industrialized Countries (G-7), the Group of Eight (G-8), the Group of Twenty (G-20), the Organisation for Economic Co-operation and Development (OECD), the World Trade Organization and the International Monetary Fund (IMF). In 2021, Italy was the eighth-largest economy in the world and the fourth-largest in Europe in terms of nominal gross domestic product (GDP) (IMF, 2022). Its annual GDP (in current prices) accounts for 11% of the European Union's (EU's) total GDP (RGS, 2019). In 2020, gross national income (GNI) per capita was $US 31 714 (Table 1.2). In 2021, southern Italy was the poorest and least developed area with a family poverty incidence of 9.9%, against a value of 7.5% in the north and 5.4% in the centre (ISTAT, 2021b). In the last two decades, in terms of GDP annual growth rate, the Italian economy has underperformed and was heavily impacted by an 8.9 % decline in 2020 as a result of the COVID-19 pandemic lockdown measures and a drastic fall in internal demand (MEF, 2020); the average decrease across EU members states was 6.2%. Likewise, government gross debt rose to 183.5% of GDP in 2020, against an OECD average of 94% (OECD, 2022a). After a sharp rebound of 6.6% in 2021, a snapshot of the Italian economy in June 2022 forecasts a growth rate of 2.5% in 2022, supported by strong base effects, new incentives for the private sector and the National Recovery and Resilience Plan (NRRP) (*Piano Nazionale di Ripresa e Resilienza*) (OECD, 2022b). However, at the time of writing (September 2022) it is clear that this outlook will be negatively impacted by the persistent inflationary pressures connected to the current war in Ukraine, the increase of oil and gas prices, and a domestic political crisis which led to new elections at the end of September 2022. Uncertainty will impede household consumption and investment, slowing the recovery of services.

TABLE 1.2 Macroeconomic indicators, selected years

	1995	2000	2005	2010	2015	2020
GDP per capita (current US$)	20 664.5	20 087.6	32 043.1	36 000.5	30 230.2	31 714.2
GDP per capita, purchasing power parity (current international US$)	22 382.9	27 072.4	30 130.6	35 158.4	36 899.4	41 828.5
GDP annual growth rate (%)	2.9	3.8	0.8	1.7	0.8	–8.9
Public expenditure (government expenditure as % of GDP)	51.6	46.5	47.2	49.9	50.3	57.3
Government deficit/surplus (% of GDP)	–7.2	–2.4	–4.1	–4.2	–2.6	–9.6
General government gross debt (% of GDP)	118.7	118.4	117.2	124.3	156.9	183.5
Unemployment, total (% of labour force)	11.7	10.8	7.7	8.4	11.9	9.2
Poverty rate (people at risk of poverty or social exclusion as % of total population)	n.a.	n.a.	25.6	25.0	28.7	25.6[a]
Income inequality (Gini coefficient of disposable income)	n.a.	n.a.	n.a.	31.7	32.4	32.8[a]

Notes: [a] Latest data available: 2019. n.a.: not available.

Sources: Eurostat, 2022b; IMF, 2021; OECD, 2022a, 2022b; World Bank, 2020, 2022.

The Italian economy is based on a large service sector (public and private) and manufacturing goods, primarily in small and medium-sized firms. Italy has few natural resources and most of its energy requirements have to be imported (78.6% compared with 47.3% in France, 64% in Germany and 76.3% in Spain). In 2019, the agricultural sector employed 3.89% of the workforce; the secondary sector employed 25.87% of the population, whereas the services sector employed 70.24 % of the population (Statista, 2022). As for the contribution of the productive sectors to GDP, in 2020, the agricultural sector accounted for only 1.9% of GDP; the secondary sector provided for 21.6% of GDP and the services sector 66.7% (Statista, 2021b).

From 1992, economic policies were launched to tackle the fiscal and monetary imbalances that had developed over the previous years, aiming to contain public debt, stabilize the currency (up to the introduction of the Euro) and keep interest rates low (Ferrè et al., 2014). Since the late 1990s, one of the specific weaknesses of Italy's economy has been the labour market structure. By the end of 2021, the unemployment rate was 9% and the youth unemployment rate was 26.8% (ISTAT, 2022c). Temporary jobs continue to play an increasingly important role within Italy's economy, primarily in

the south. Women account for 42.2% of the workforce (Censis, 2019), one of the lowest rates among EU countries, which sharply declines moving up the career ladder. Furthermore, with the pandemic, the majority of those who lost their jobs were women (FSCdL, 2020). Italy also has a major underground economy that accounts for an estimated 11% of GDP – EUR 192 billion (ISTAT, 2020a). This includes many nominally unemployed people, as well as undocumented immigrants, often in harsh agricultural working conditions in the rural south, informal carers and domestic workers.

In the 2000s, policy priorities included a fiscal reform, revamping of communication systems, reducing pollution in major industrial centres and aligning with the economic integration and expansion of the EU (Lo Scalzo et al., 2009). In early 2009, Italy went into recession as a result of the global economic crisis of 2008 and has been struggling ever since. The following decade's policy priorities included reversing sharp decreases in investment and export markets, tackling rising unemployment and implementing cut back measures in the public sector to manage a widening public debt. With an already stagnating economy and very little evidence of growth, the COVID-19 pandemic arrived as the most severe shock to Italy's economy in contemporary history and affected all economic sectors. In 2020 the Italian Government released more than EUR 100 billion to address the impact of the crisis (BdI – Eurosystem, 2020).

1.3 Political context

The Italian state is a parliamentary, democratic republic with a multi-party political system. Italy has been a democratic republic since 2 June 1946, when the monarchy was abolished by a popular referendum. The basic principles of the Republic are stated in the Constitution enacted in 1948. Article 32 of the Constitution is dedicated to health and health care as it states that "The Republic protects health as a fundamental individual right and societal interest, and ensures free care to indigent people". It also adds that "Nobody can be administered a compulsory health treatment unless based on the law".

The main elements of the Italian political system are as follows:

- The President of the Republic, who is the head of state, and is elected for 7 years by the Parliament and representatives of the regions.

- The Chamber of Deputies and Senate, which form the bicameral parliament and whose members (400 and 200, respectively) are directly elected for 5 years by universal suffrage. They exercise legislative power.
- The Prime Minister and the Cabinet, who exercise executive powers. They are appointed by the President of the Republic and must be endorsed by both the Chamber of Deputies and the Senate.
- The judiciary system, which is independent of the executive and the legislative branches.

Since the foundation of the Republic, Italian politics have been characterized by high rates of government turnover, with 67 governments since 1946 (as of 2022).

Italy's regions are extremely varied. They differ in size (Piedmont is 25 000 km^2, while Valle d'Aosta is only 3 000 km^2), population (Lombardy has 15% of the total population, whereas Molise has less than 1%) and levels of economic development. Each region is governed by a Regional Council and its President, both of which are democratically elected every 5 years. The regions have exclusive legislative power over specific issues designated to them while, for several other issues, authority is "concurrent" with the central government (Italian Constitution art. 117). However, regions' financial autonomy is quite modest: they hold 20% of all levied taxes, mostly used to finance the regionally based health care systems. The fiscal system is centralized. Cooperation between the activities of the central government and those of the regions is organized through a permanent body, the Standing Conference of the State, Regions and Autonomous Provinces (or the State-Regions Conferences, for short).

The regions are subdivided into 86 provinces (UPI, 2019) that used to be governed by democratically elected councils but in 2014 were transformed into administrative bodies with limited competencies, with Provincial Presidents (executive power) and Councillors (legislative power) elected by mayors and councillors of the municipalities of the province (Law 56/2014). However, provincial districts are still important because for each of them the national government appoints a prefect who acts as a delegate, representing the central government on a number of matters in each province. The basic unit of local government is the municipality (*comune*), which may range in size from a small

village with less than 100 inhabitants to a large city such as Rome. Italy has about 8 100 municipalities, and only 8% have over 15 000 inhabitants. A mayor and a council are elected for a 5-year term to govern each municipality.

1.4 Health status

The majority of the Italian population has a high standard of living and quality of life resulting, in part, from well-established health policies and welfare measures. Prior to the outbreak of the COVID-19 pandemic, well-being and sustainability indicators showed a generally positive performance, although geographical inequalities and a gender gap in life expectancy continue to be significant. Average life expectancy at birth in Italy had been growing steadily over the last two and a half decades, reaching 83.6 years in 2019, then the second highest in Europe. It decreased temporarily back to 82.4 years in 2020 due to the impact of the high numbers of COVID-19-related deaths (Table 1.3). Even so, in 2020 Italy had the third-highest total life expectancy at birth among EU countries.

Cardiovascular diseases (CVDs) are the main cause of death in Italy, along with cancer and, since 2020, infectious respiratory diseases, moving neurological diseases down to fourth place (The European House – Ambrosetti, 2021). In 2020, the year of the COVID-19 pandemic outbreak, total deaths from all causes were the highest recorded since the Second World War: 746 146 deaths, which is more than 100 000 extra deaths compared with the 2015–2019 average (equal to an excess mortality rate of 15.6%) (ISTAT – ISS, 2021). Multimorbidity and chronic diseases in the older population are major challenges for the health care system.

The most common diseases in the elderly, for both genders, are osteoarthritis (47.6%), hypertension (47%), lumbar disease (31.5%), cervical diseases (28.7%), hyperlipidaemia (24.7%), heart disease (19.3%) and diabetes (16.8%) (ISTAT, 2021c).

Italy has among the lowest infant and neonatal mortality rates in the EU (2.5 deaths per 1 000 live births, compared with the EU average of 3.2 in 2020), explained by effective preventive measures and skilled assistance during pregnancy and at delivery.

TABLE 1.3 Mortality and health indicators, 2020 or latest available year

	1995	2000	2005	2010	2015	2020
LIFE EXPECTANCY (YEARS)						
Life expectancy at birth, total	78.3	79.9	80.9	82.2	82.7	82.4[a]
Life expectancy at birth, male	75	76.9	78.1	79.5	80.3	80.1[a]
Life expectancy at birth, female	81.5	82.8	83.6	84.7	84.9	84.7[a]
Life expectancy at 65 years, male	15.8	16.7	17.3	18.3	18.9	18.5[a]
Life expectancy at 65 years, female	19.9	20.7	21.1	22.1	22.2	21.8[a]
MORTALITY						
Mortality, SDR per 100 000 population						
Circulatory diseases	278	238	202	160	152	142[b]
Malignant neoplasms	192	180	168	157	146	142[b]
Communicable diseases	3.6	5.8	7.7	8.6	11.8	9.7[b]
External causes of death	39	34	30	25	23	23[b]
All causes	680.78	603.61	549.84	478.11	467.98	452.92[b]
Infant mortality rate (per 1 000)	6.1	4.3	3.3	3	2.9	2.5[c]
Maternal mortality rate (per 1 000)	3.2	3	2.6	2.9	3.4	2.5[d]

Note: [a] 2020, estimate, provisional; [b] 2017; [c] 2019; [d] 2018.

Sources: Eurostat, 2022c; OECD, 2022c; WHO Regional Office for Europe, 2021a.

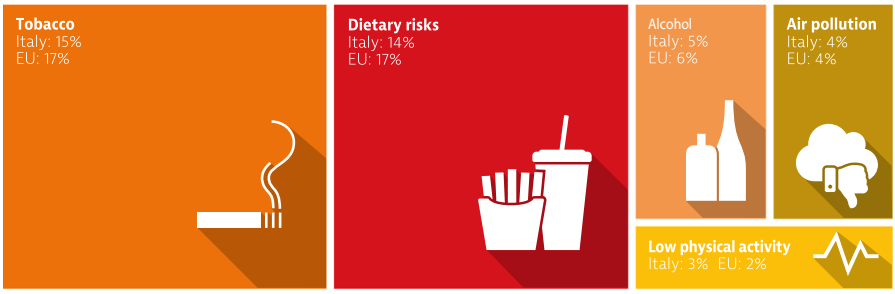
Population risk factors such as tobacco consumption, unhealthy diets and alcohol can be attributed to around one third of all deaths in Italy in 2019. In particular, tobacco and dietary risks are major contributors to mortality (Fig. 1.2). In 2020, 46.1% of the adult population was overweight, while 10.8% was obese (IBDO Foundation, 2020), with a higher prevalence registered in the southern regions. Moreover, the proportion of overweight or obese people increases proportionally with age, reaching a peak in the 65–74 age group before declining slightly among the very elderly (IBDO Foundation, 2020). Childhood overweight and obesity rates in Italy are also comparatively high:

the European HBSC survey records that almost 19% of 15-year-olds were overweight or obese in 2018 while a national survey of primary school children highlights that 30% of 8- and 9-year-olds were either overweight or obese in 2019 (OECD/European Observatory on Health Systems and Policies, 2021).

According to national data, the proportion of smokers among the adult population in April 2020 was 21.9% down from 23.8% in 2003, when Law 3/2003 banned smoking in public spaces. But this rate grew throughout the pandemic to 24% in November 2020 and again to 26.2% in May 2021 (ISS, 2022). Smoking cigarettes is more common in young adults and more prevalent among men than women. In 2020, 66.4% of the population consumed alcohol during the year, with 20.6% drinking alcohol every day (Ministero della Salute, 2021a).

Notwithstanding the important results gained in health status, geographical differences remain in terms of health conditions and lifestyles, as well as in the supply and quality of health services. Southern regions score lower in life expectancy, lifestyles, access to care and quality of services. These data underscore how the tenuous balance between centralized and regional and local control is shifting over time, impacting population health outcomes, and resulting in, arguably, as many as 20 different health care systems within Italy (Ricciardi & Tarricone, 2021).

FIG. 1.2 Risk factors affecting health status in Italy



Note: Data are estimates for 2019 based on the IHME Global Health Data Exchange, 2020.

Source: OECD/European Observatory on Health systems and Policies, 2021.

2

Organization and governance

Chapter summary

- The Italian National Health Service, the *Servizio Sanitario Nazionale* (SSN), was founded in 1978. Over the last few decades, it has undergone a process of decentralization which is now one of the main characteristics of its structure.

- The SSN provides universal coverage, guaranteed to all. The central government is in charge of establishing the national benefits package (known as the *Livelli Essenziali di Assistenza*, LEA), equalizing allocations to regional health systems and stewardship. Regions are responsible for financing, planning and providing services at the local level, through local health authorities.

- Hospital and specialist ambulatory services can be provided by the local health authorities through directly-managed hospitals, semi-independent public hospitals ("hospital trusts") or accredited private providers.

- General practitioners (GPs) and paediatricians, who are independent contractors, act as gatekeepers to higher levels of care.

- At the national level, the main planning instruments include 3-year health plans, pacts between regions/autonomous provinces and the central government, and national programmes addressing

specific health issues (i.e. the National Chronic Conditions Plan). Guaranteeing the national benefits package and funding allocations also serves to shape planning. At the regional level, planning is based on specific regional health plans, financing and allocation of funds among the local health authorities and adapting national goals to local socio-epidemiological contexts.

- The COVID-19 pandemic highlighted the need for further investment in the digitalization of the SSN, and for addressing sustainability and health system resilience.

2.1 Historical background

The SSN was established in 1978, with universal health care coverage, human dignity, health needs and solidarity as its guiding principles. For the first few decades, the central government was responsible for financing and distributing funds within the SSN to progressively reduce regional imbalances, and was responsible for planning through 3-year national health plans (*Piano Sanitario Nazionale*, PSN). Although the first national health plan was due by 1980, a draft version was approved by parliament only in 1994, demonstrating the procedural and political difficulties that impeded the implementation of planning actions. Regional authorities followed national objectives through local planning, organization and management of health care services, via providers and local health units (*Unità Sanitarie Locali*, USL). However, unclear responsibilities, fragmented planning and the separation between central financing and local spending powers increased health care expenditure (Fattore, 1999). The reaction was a series of decrees in the 1990s (502/1992, 517/1993 and 229/1999) that devolved powers to the regions and started the so-called managerialization process. Local health units were transformed into local health authorities (*Aziende Sanitarie Locali*, ASL), which in turn were divided into health districts. Most large and/or specialized public hospitals became semi-independent hospital trusts (*Aziende Ospedaliere*, AO). Both local health authorities and hospital trusts were made directly accountable to their regions.

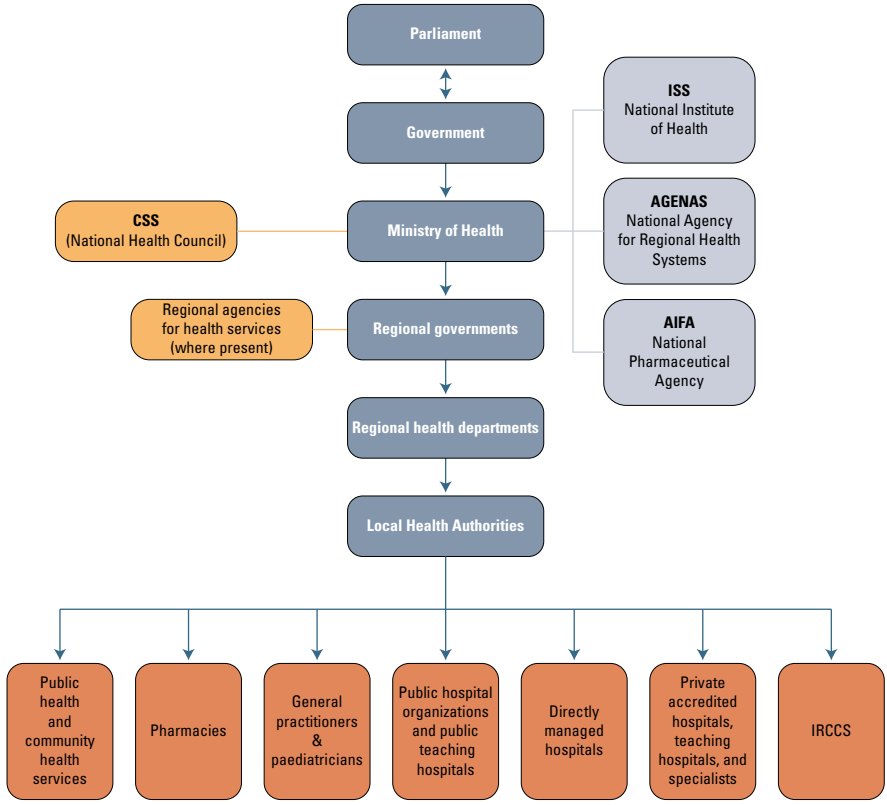
This decentralization process peaked with the 2001 Constitutional reform (Constitutional Law 18 October 2001), which redesigned the competencies between the central government, which was granted a stewardship function and some central powers, such as defining the national benefits package (known as the *Livelli Essenziali di Assistenza*, LEA), and the regions, which were tasked with financing, regulating, organizing and delivering health care. National health plans were gradually replaced by Health Pacts between the central government and the regions.

During this period, improvements in the population's health status, low fertility rates and socioeconomic changes accelerated the ageing of the population and broadened the SSN's strategic focus to embrace prevention and health promotion in addition to providing care: in 2001 the Ministry of Health Care was renamed the Ministry of Health. Such changes, progress in medicine and market pressure required even more attention to be paid to health care expenditure, which led to defining the national benefits package as a broad positive list in 2001. The list was not to be updated until much later – in 2017. Regional "recovery plans" were also established and supervised by the central government (see Chapter 3). In the past decade, with the share of public health expenditure increasing less than the inflation rate, and a reduction of hospital beds above the OECD average in favour of outpatient care, policy-makers have prioritized cost-containment and efficiency of the health system. In 2020, the COVID-19 pandemic brought a health system shock of unprecedented scale, redirecting the focus of Italian decision-makers towards sustainability and health system resilience (Cicchetti et al., 2021).

2.2 Organization

Italy's SSN is regionally based and organized into three levels: national, regional and local. Figure 2.1 summarizes the main organizational actors and the relationships between them.

FIG. 2.1 Overview of the Italian health system



Note: IRCCS: Institutes for Care and Scientific Research.

Source: Authors, adapted from Ferrè et al., 2014.

The national level steers the health system, setting general objectives, the national benefits package, per capita funding and fundamental principles. Through yearly Budget Bills, the national government and parliament agree on expenditures, projected revenues and target priority areas. The Ministry of Health leads health care planning by defining the national benefits package (see section 2.4), setting long-term goals, monitoring the SSN, equalizing fund allocation, and co-governing with regions and the Institutes for Care and Scientific Research (IRCCSs).

Since 2014, the Ministry of Health has had 12 General Directorates on:

1. preventive services;
2. health planning;
3. health professions and human resources;
4. medical devices and pharmaceutical services;
5. health research and innovation;
6. supervision of institutions and health care safety;
7. animal health and veterinary drugs;
8. food hygiene, safety and nutrition;
9. digitilization of the health information system and statistics;
10. health protection collegiate bodies;
11. communication and European and international relations;
12. personnel, organization and budget.

Additionally, a Mission Unit was recently introduced to specifically pursue the health-related goals within Italy's NRRP (Governo Italiano, 2021).

The most relevant consultative body to the Ministry of Health is the Superior Health Council (*Consiglio Superiore di Sanità*, CSS). It consists of 50 members and one president, bringing together representatives of national government agencies, scientists, physicians and other recognized professions.

Furthermore, the Ministry is supported by several government agencies (ISS, 2018):

- The National Institute of Health (*Istituto Superiore di Sanità*, ISS) has an advisory role, directs scientific research, disease surveillance and promotion of public health, and knowledge dissemination;
- The National Agency for Regional Health Services (*Agenzia Nazionale per i Servizi Sanitari Regionali*, AGENAS) is the research and decisions support interface between the Ministry of Health and regional authorities: it regulates continuous education programmes and, through its activities, contributes to ensuring quality, safety and patient dignity (e.g. "humanization of care") in care delivery;
- The Italian Medicines Agency (*Agenzia Italiana del Farmaco*, AIFA) is the national authority for pharmaceutical regulation (see section 2.7.4);
- The National Institute for Insurance against Accidents at Work (*Istituto Nazionale Assicurazione contro gli Infortuni sul Lavoro*, INAIL), operates in the field of health and safety in the workplace.

The National Centre for Disease Prevention and Control (*Centro Nazionale per la Prevenzione e il Controllo delle Malattie*, CCM) is not a body with legal status. Rather it is a network that liaises with the Ministry of Health and regional governments in surveillance, prevention and health emergency response measures: it also designs evidence-based strategies and programmes in prevention, health promotion and improving equity in access to care.

The Ministry of Health also undertakes governmental functions within:

- the IRCCSs, which are tertiary care and research centres. They can be public or private institutes and receive funding for research from the Ministry of Health;
- the Experimental Zooprophylactic Institutes (*Istituti Zooprofilattici Sperimentali*, IZSs), which regulate animal livestock and food of animal origin.

The national and regional levels of governance of the health care system are strategically and institutionally aligned via 3-year Health Pacts agreed upon by the central and regional governments, and through the State-Regions Conferences. The latter is a permanent political body for consultation and communication between the presidents of the national and regional governments in policy domains where their mandates overlap. Their meetings are held every 15 days.

Regional governments ensure the delivery of the national benefits package by organizing networks of health care providers, made up of local health authorities, hospital trusts and private-accredited providers. Regions' competences were largely broadened in scope with reforms in 1999 (Legislative Decree 229/1999 on reform of the SSN) and 2001 (Title V constitutional reform). They currently include:

- setting the general principles and the organization of regional health care systems;
- defining financing criteria;
- providing technical and managerial guidelines and undertaking health needs assessment activities.

The executive functions of the health systems are undertaken by the regional departments of health. Executive powers include: drafting the 3-year regional health plans which are then developed in further detail within local implementation plans (*Piani Attuativi Locali*, PALs); defining authorization and accreditation criteria for public and private providers and monitoring their quality; coordinating health and social care; and defining providers' geographical boundaries, allocating resources to them and appointing their directors.

Some regions, mainly the northern ones, are aided by regional advisory agencies which support local health authorities and hospitals, both scientifically and technically.

At the local level, the local health authorities provide preventive medicine and public health services, primary care – including mental health, family medicine and community services – and secondary care. The territory of each local health authority is further divided into health districts that directly control the provision of public health and primary care services, manage commissioning and promote integration with social services. In detail, the competences of local health authorities cover:

- preventive medicine and public health services, delivered by local health authorities' departments of prevention;
- community services, including mental health services, primary medical and nursing care, home and residential care for the elderly and the disabled, and hospice care;
- primary care and GP services, coordinating with health districts;
- secondary care delivered directly by directly-managed hospitals;
- accredited private hospitals and specialists;
- social care and social welfare services delivered by municipal authorities, with varying degrees of integration and coordination with local health authorities.

Thus, local health authorities can either deliver health services directly or through a network (commissioning) of private-accredited providers and hospital trusts.

To facilitate the management and monitoring of organizations and to avoid the duplication of resource, regions have been merging local health authorities into larger, more centralized authorities since the 1990s. The objectives, which include economies of scale and scope, rationalizing services, reducing overcapacity and improving clinical quality, have led to a reduction in the number of local health authorities by over 40% – from 180 in 2005 to 102 in 2019 (Mariani, Acampora & Damiani, 2017). Various models have been adopted (Table 2.1). Some regions (Veneto, Liguria, Marche, Tuscany) have established the so-called Authorities Zero[2] (*Aziende Zero*) which centralize financial planning and purchasing, determine local objectives, establish investment priorities, define and monitor costs and manage both IT and cash flows. Authorities Zero have been established to facilitate the concentration of activities and to allow their employees to work under SSN labour contracts (employees of regional departments of health have a different contract that is less attractive, especially for medical doctors).

2.3 Centralization and decentralization

The SSN is highly decentralized, with most of the legislative and executive powers assigned to the regional level of governance with the central government taking on a stewardship role. Historically, based on the long-standing principle of cooperation, the once prevailing top-down approach based on the national health plans has gradually been substituted, starting from the 1990s, by agreements between the national government and the regions known as Health Pacts. Legislative and executive powers have, in fact, been devolved substantially to the regions throughout the years. The most decisive shift occurred in 2001, when a constitutional reform (Title V) largely broadened the scope of regional competences and, simultaneously, circumscribed national ones. This substantially reconfigured the governance structure, de facto shifting the organization and management of health

2 An "Authority Zero" is a Health Authority that has lost its connotation of being *local* and is the single body orchestrating an entire regional health system as an intermediate governance level between the regional health systems and local facilities. Its areas of competence involve purchasing, tenders and procurement to exploit economies of scale. An Authority Zero results from a process which gradually merges all previously existing local health authorities – each covering an area of the region – which, in Italy, are typically labelled numerically (i.e. Local Health Authority 1, Local Health Authority 2 etc.).

services to the regions. The process of regionalization has created 21 different health systems.[3] Nevertheless, during the COVID-19 pandemic the national government maintained a centralized role in coordinating the health system's response to the crisis (Box 2.1).

TABLE 2.1 Main types of health system governance arrangements adopted by the regions

TYPE	DESCRIPTION	TYPICAL IN REGIONS
Residual or incremental model	Strictly following Law 833/78, this model is characterized by a hierarchical relationship between the region and local health authorities. Governance is traditional and bureaucratic. Managerial governance and negotiations between the payer and providers do not feature.	Campania, Puglia, Sardinia
Centralized model	Generally suitable for regions with relatively high levels of resources, this "system approach" comprises vertical and horizontal cooperation between all actors (including private providers). The region controls growth through centralized strategic planning and local implementation, budgeting and outcome monitoring with shared financial and fiscal responsibility.	Veneto, Lazio, Basilicata
Contractual model	As the purest expression of the 1999 SSN Reform, this model is based on joint decision-making between regions and local health authorities. Regions must have strong strategic capacity and managerial competences to programme, monitor and conduct performance assessment and budgeting.	Emilia-Romagna, Tuscany
Governance model in the Lombardy Region [a]	Characterized by a clear division between planning and purchasing, and management, where the former is assigned to "health protection agencies" (the name given to local health authorities) and the latter to hospital trusts known as Local Social and Health Care Authorities (ASST), with the intent of grouping all managerial functions at the local level into one body responsible for both hospital and territorial services.	Lombardy

Note: [a] This fourth category is not part of the Mapelli (2007) classification. Its formation is the result of Regional Law 23/2015.

Source: Adapted from Mapelli, 2007.

The central government is responsible for defining health policy strategies, the national benefits package and the per capita budget, although this decision-making process is undertaken in collaboration with the regions. It maintains a stewardship function to monitor expenditure and reduce geographical inequalities. In addition, it supports financially underperforming regions through financial "recovery plans" (*piani di rientro* – see section 3.1). These have proven to be effective in reducing expenditure, although in terms of

3 The region of Trentino-Alto Adige/Südtirol contains two autonomous provinces, each with its own health system.

health outcome impacts, one study recorded a slight increase in avoidable mortality in the regions under these plans (Arcà, Principe & Van Doorslaer, 2020). The governance reach of central government was further enhanced in 2016 when financial recovery plans were extended from regions to hospital trusts (hospital recovery plans) and, in 2017, to local health authorities. This means that facilities experiencing budgetary deficits are directly targeted by the central government, giving its General Director 3 years to restore the organization's financial situation to acceptable levels. Evaluations are based on volume, quality and outcome parameters (see sections 2.6 and 7.1).

Regional differences in policies and financing have contributed to substantial differences in quality of care among regions and local health authorities, with best performers found mostly in the northern part of the country. For example, the degree of integration between social care providers (municipalities) and local health authorities varies throughout the country and is mostly incomplete.

2.4 Planning

The SSN planning system occurs through both national and regional programming. Historically, the most important national programming tool was the National Health Plan (NHP) describing the fundamental principles and values of the health system, the SSN's general goals and strategic directions for quality improvement and research, and efficiency and efficacy evaluations. Its most important feature is the national benefits package (LEA), which is central to planning, priority-setting and ensuring equity.

BOX 2.1 SSN governance during the COVID-19 pandemic

The COVID-19 pandemic placed enormous pressure on the governance system for health care. The chosen solution was to recentralize coordination and accelerate decision-making at the national level while providing flexible guidelines to the regions, which are responsible for delivering health care. Traditional legal frameworks, comprising parliamentary procedures, were bypassed in favour of government decrees and administrative processes. A COVID-19 Emergency Commissioner was appointed and granted unprecedented powers. Moreover, the Council of Ministers entrusted the Head of the Department of Civil Protection to create a Technical and Scientific Committee, composed of experts and representatives of state authorities and administrations, which carried out an advisory role to support decision-making bodies such as the Ministry of Health. Medical device procurement, surveillance systems and funding allocations were organized at national level.

Regions operated different pandemic response models which often led to a struggle between the central and regional levels of government (Ricciardi & Tarricone, 2021). Some regions implemented the solutions communicated by the central government and others proceeded independently in the ways they implemented testing or managed COVID-positive patients. Mirroring the heterogeneity in regional preparedness, this led to the creation of different approaches: the national, the hospital or the "mixed" approaches, depending on the care setting that different regions used most to manage patients (Cicchetti et al., 2021). Initial evidence suggests that the pandemic seems to have worsened inequalities across the country and models that were organized around outpatient networks were better prepared. Based on the pandemic emergency experience, policy commentators have noted that strengthening and clarifying cooperation procedures between governance and care levels ought to be a priority for better preparedness in the future (Cicchetti et al., 2021).

More recently, however, following the progressive process of decentralization (see section. 2.3), Italian policy-makers have gradually given way to planning tools that allow for more integrated governance between the central and regional levels. In fact, whereas current legislation still recalls the 2006–2008 NHP (the last that was released), national Health Pacts are now formulated in the State-Regions Conferences after identifying shared strategies and common guidelines, as part of a broader plan to promote regional autonomy. Plans and programmes of national scope, instead, are left to narrower and more focused areas (i.e. the National Vaccination Plan, the

National Chronic Conditions Plan, etc.). Regional health plans, however, detail strategic interventions to meet population needs, with the participation of local authorities. Examples include bed distribution in secondary, emergency and long-term care, size and location of hospitals, integration between health and social care and measures for the continuous improvement of quality. Regional planning approaches vary widely as some regularly issue plans while others rarely adopt formal planning for their health system (see Box 2.2).

BOX 2.2 Is there sufficient capacity for policy development and implementation?

The COVID-19 pandemic has been instructive in highlighting the existing challenges for policy capacity within the health system. The crisis required a timely and massive response from the SSN and the adoption of extraordinary measures at national level to tackle health system overload and to slow down infection rates. A similar effort was required to define and implement the COVID-19 vaccination campaign, which took a few months before gaining full pace. Future developments in policy capacity-building might be partly shaped by the funding that will be released via the NRRP (EUR 15.6 billion), which includes investment in policy capacity, as well as investments in primary care, telemedicine, health care innovation, research and digitilization (Ricciardi & Tarricone, 2021). Overall, two issues, in particular, call for further attention.

- The relationship between the central government and the regions, and the processes for coordination, should be strengthened as this performed poorly during the pandemic and requires a specific constitutional reform to improve it.
- Policy capacity-building in prevention and crisis preparedness needs to be strengthened, especially in southern regions.

Despite great intra- and interregional variations, local health authorities release "local implementation plans" at three levels: Managing Board, Department Director and single professional. The Managing Board performs long-term strategic planning and monitoring by:

- defining long-term institutional goals;
- analysing the external and internal environments (the former refers to population needs and demand for services, indications from regional and national planning and features of other organizations with similar mandates);
- defining critical success factors;
- formulating strategies, specific goals and implementation plans;
- monitoring and evaluation.

The department directors draft medium term budgets, by:

- assigning resources and accountabilities to specific sub-goals;
- reporting on periodic comparisons between set goals and actual achievements.

Lastly, health care managers conduct short-term operational planning and monitoring.

2.5 Intersectorality

Compared with similar institutions in other countries, the Italian Ministry of Health has broader "horizontal" administrative competences. In addition to health financing and planning, its mandate includes protecting citizens' health through preventive oversight within industry (e.g. biotechnologies, health and safety at work) and agriculture (e.g. veterinary public health and food safety) and the exchange of specific categories of goods (e.g. manufacturing and marketing of medicines, medical devices and cosmetics). Moreover, enforcement of certain environmental health standards (e.g. air and water quality) also fall within the remit of the Ministry, as does the monitoring of their implementation through SSN structures. Furthermore, the Ministry of Health has close links with the Ministry of Economy and Finance, especially with regard to setting the health care budget, and the Ministry of Labour and

Social Policies for the coordination of social services with SSN infrastructure (Ferrè et al., 2014). The integration of social and health services has been a policy target with an increasing number of interventions: currently, some regions (e.g. Basilicata, Emilia-Romagna, Tuscany, Lombardy) utilize planning approaches that promote the integration of health, social and socio-health care programmes. However, we do not have a clear picture of the actual level of integration between social and health care across the country due to the absence of a social service information system and discharge charts from semi-residential facilities.

Policy attention to develop an even broader concept of intersectorality began in 2007, when the CCM (see section 2.2) adopted the World Health Organization's (WHO's) Health in All Policies (HiAP) evaluation tool (WHO Regional Office for Europe, 2021b) which included mobility and transport, work and the identification of social and environmental determinants of health. Despite attempts, the central and regional governments did not systematically apply these principles. As in many other areas, the COVID-19 pandemic has reiterated the need for a holistic vision of the links between environment–animal–human ecosystems, taking into consideration the United Nations (UN) Sustainable Developments 2030 Agenda, the Millennium Development Goals, and the One Health approach. Some of these elements are included in the 2020–2025 National Prevention Plan (PNP) (see Chapter 7).

2.6 Health information systems

The management of data in the SSN and data on citizens' health status falls under the competence of the Ministry of Health's General Directorate of Health Care Statistics. The New Health Information System (*Nuovo sistema informativo sanitario*, NSIS), with its various elements, was introduced in 2003 and is the primary tool for measuring quality, efficiency and appropriateness of care, supporting national and regional governance, monitoring expenditure and guaranteeing the uniform provision of the national benefits package (LEA) (Table 2.2). The NSIS is managed, coordinated and quality-controlled by an intergovernmental body (under the State-Regions Conferences) known as the Control Room. The NSIS has introduced compatibility and coordination among the SSN's IT systems and records process, as well as managerial aspects and citizens' health. Today, its information base covers 85% of the services included in the national benefits package. Already incorporated into legislation

in 2011, e-prescriptions are now widely adopted for pharmaceuticals but are less utilized for referrals for outpatient visits. Through e-prescriptions, citizens can obtain pharmaceuticals in any pharmacy in Italy. In the first year of the COVID-19 pandemic, to reduce in-person visits to doctors' offices, the Ministry of Economy and Finance and the Ministry of Health agreed to extend the validity of e-prescriptions also to medicines not covered by public funds and to psychotropic drugs (Ministero della Salute, 2021b).

TABLE 2.2 New Health Information System

		NAME	AREA
NSIS	Databases/Information for SSN governance	SIISI	Integration of individual health information
		NSIS indicator package	Hospital and ambulatory care, pharmaceutical expenditure, health care personnel
		MRA	Care network monitoring
		SIMES	Error monitoring
		SIAD	Domiciliary care
		SIND	Addictions
		FAR	Residential and semi-residential care
		EMUR	Emergency care
		SISM	Mental health
		OPIS	Public Investments Observatory
		HOSPICE	Hospice care
	Information systems for patient care	CUP	Online booking centre
		Online sick leave certificates and certificates of good health	
		Telemedicine	
		e-Prescriptions	
		Electronic Health Record	

Notes: CUP: single appointment centres; NSIS: New Health Information System; SSN: National Health Service.

Source: Authors.

For the past decade, Italy has been working on the implementation of electronic medical records (*Cartella Clinica Elettronica*), which are the equivalent to inpatient or outpatient medical records, and on Electronic Health Files (*Fascicolo Sanitario Elettronico*, FSE) which include all clinical records, preventive diagnostic assessments and all elements of a patient's health history (Camera dei Deputati, 2018). Implementation, however, remains fragmented for both, despite all regions being actively engaged in their development. Furthermore, jointly with 11 other EU Member States, Italy is part of a project funded by the European Commission for the interoperability of the FSE known as the "Deployment of generic cross-border eHealth services in Italy".

The information system receives data from various sources. For example, local health authorities collect some data from GPs and their various departments and send them to regions, which forward them to the Statistics Office.[4] Hospitals feed data to the national database on hospitalizations which is based on Hospital Discharge Charts (*Schede Dimissione Ospedaliera*, SDO) classifying diseases according to the International Classification of Diseases codes. Implementing EU Directive 24/2011, Legislative Decree 261/2016 extended the amount of information included in SDOs to add, among other things, patients' level of education, patients' access according to priority categories, the name of the chief surgeon (to reinforce the accountability of the surgical team), hospital transfers and pain detection details, with the latter measured according to the Ministry of Health's 2001 guidelines on the so-called Painless Hospital (Ministero della Salute, 2001). The Infectious Diseases Information System – which is not part of the NSIS – rapidly collects alerts on 47 infectious diseases notified by doctors. Local health authorities forward them to regional health departments which warn the Ministry of Health, who may notify international organizations (EU, WHO). An annual Epidemiological Bulletin collects and reports data (broken down by month). The collection of infectious disease data was crucial during the COVID-19 pandemic (see Box 2.3). A similar data flow exists for occupational hazards and work-related accidents. Other notable data flows are on accidents and emergencies, the Childbirth Certificates Registry and the organ donations and transplants register collected by the National Transplants Centre. General

4 It is noted that information collected from GPs is very limited – e.g. the NSIS and regions are not able to collect information on patient–GP encounters (length, frequency, diagnosis, prescriptions, etc.).

demographic health statistics are produced by the National Institute of Statistics (*Istituto nazionale di statistica*, ISTAT). Financial and organizational data are also collected by the General State Accountant.

In 2012, the Ministry of Health and AGENAS developed the National Outcomes Programme (*Programma Nazionale Esiti*, PNE). It assesses the effectiveness, equity, safety and appropriateness of hospital care, cross-linking the discharge data of over 1 300 hospitals with other health indicators and census data through 177 metrics, evaluating outcomes, volumes and hospitalization rates in 11 clinical areas and clinical pathways. Gathered data are published on the AGENAS website, stratified by region and facility. In 2018, the National Vaccination Registry was introduced to track vaccinations, vaccinated people, those to vaccinate, doses and administration times, side-effects and exempted individuals. Data on vaccination against COVID-19 are integrated within this registry.

Given the importance of information and data for timely evidence-based policy-making, Italy's NRRP has allocated EUR 8.63 billion to boost SSN digitalization, which includes modernizing and strengthening technological infrastructure for collection, processing, data analysis and simulation and developing the digital skills of health personnel.

BOX 2.3 The COVID-19 Surveillance System

With the outbreak of the COVID-19 pandemic in early 2020, two national surveillance systems – one coordinated by the National Institute of Health (ISS) and the other by the Department of Civil Protection – were activated to gather national and regional COVID-19 data daily and to publish updated infographics. They reported on the spread of the disease across the country and briefly described infected cases, supporting real-time decision-making and promoting awareness on the emergency situation. In the following months, the country was risk-stratified into three levels, each with its own restriction measures, based on 21 process and outcome indicators. Regions were required to record pertinent data via a platform developed by the ISS. Decisions were taken on a weekly basis according to the probability of infection spread, disease impact and the region's response capacities.

2.7 Regulation

2.7.1 *Regulation and governance of third-party payers*

Until 1992, only the central government could raise taxes and allocate funds to the regions, while the regions funded the local health authorities and their hospitals. Funding was based on past spending; local health authorities lacked cost-containment incentives and overspent their budgets, and the central government habitually covered their deficits. Subsequently, a series of reforms was introduced, underpinned by principles of managerialism, regionalization and managed competition (Fattore, 1999). Managerialism gave local health authorities greater independence but required improvements in performance and encouraged governance techniques resembling those of private companies (Cantù, Ferrè & Sicilia, 2010). Hospitals were allowed to become independent from local health authorities by becoming "hospital enterprises" (hospital trusts), with their own managing board. Reimbursements to providers were based on activity-related funding: diagnosis-related groups (DRGs) for hospitals, capitation for GPs and paediatricians, and fee-for-service for private outpatient specialists (see Chapter 3). More recently, new value-based mechanisms are being introduced for innovative therapies (i.e. for CAR-T therapy, in 2019).

Regions collect their own taxes and user charges (with a national equalization fund compensating for differences in regions' fiscal capacities) and may choose to transfer the purchasing role to the local health authority. As a result, different purchasing models have been experimented with (Anessi et al., 2004).

- Most regions use a "local health authority-centred model", where local health authorities act both as service providers and (limitedly) as purchasers of hospital trusts' services. This model partly resembles a quasi-market, as when residents from one local health authority select a provider from another local health authority, the former must reimburse the latter.
- Some smaller regions in northern and central Italy adopt a "region-centred model", where most purchasing is regional, while local health authorities are mostly providers. These regions directly control most public providers and accredit few private ones.

- Lombardy alone has selected a complete purchaser–provider split. All specialist care is delivered by hospitals that are independent hospital trusts; local health authorities have been replaced by health protection agencies which purchase services from public and private providers, while the region has a regulatory role.

2.7.2 *Regulation and governance of provision*

Health care providers can be both public and private. Public health care providers may be regulated by their local health authority or independent organizations (hospital trusts, university hospitals and the IRCCSs), under regional regulation (see Table 2.3). Both for-profit and not-for-profit private providers cooperate with local health authorities and regional authorities to ensure the supply of services. Structural, organizational and operational standards are mainly assured through the following procedures.

- *Authorization* procedures are regional and grant permission to deliver health care services, according to the structural, technological and organizational criteria required under Italian law. Authorization applies to any subject practising in Italy – from professionals to facilities – even if services are delivered outside the SSN.
- *SSN accreditation* is the public licensing necessary to provide health care services on behalf of the SSN, considering more extensive quality criteria. The accreditation period lasts 5 years and may be renewed upon request by the provider. It encompasses management of human and technical resources, coherence with regional planning and evaluation of activities and outcomes. Currently, accreditation criteria and procedures are established regionally. While accreditation is compulsory for all organizations, it is the main policy tool used to govern the private sector. It can be complemented with additional accreditations (e.g. the Joint Commission International (for accreditation) or the International Organization for Standardization).
- The final step to operate under the SSN is to agree on financing conditions with regional and local authorities through *contracts*, which detail operational and financial information (Cantù, Ferrè & Sicilia, 2010) (see Chapter 3).

In addition, Ministerial Decree 70/2015 sets structural, technological, quality and performance standards for hospital services. The two main quality monitoring systems are the PNE (see section 2.6) and the New Guarantee System (*Nuovo Sistema di Garanzia*, NSG) which, introduced in 2020, gathers information from the NSIS to verify equity, effectiveness and appropriateness in the delivery of the national benefits packages, through 88 indicators (of which 22 are considered "core") for prevention and public health, district (community) care, hospital care, care pathways, health needs assessment and social equity. The NSG is reinforced by Ministerial Decree 77/2022 which, for the first time, sets structural standards for community and primary care (see Chapter 6). As for incentives, an additional funding of 3% is granted to regions that fully comply with the benefits package indicators of the NGS, testing how well regions deliver such services (2%, where compliance has been limited to the last 3 years) (Law 135/2012).

TABLE 2.3 Overview of the regulation of providers

	LEGISLATION	PLANNING	LICENSING/ ACCREDITATION	PRICING/ TARIFF SETTING	QUALITY ASSURANCE	PURCHASING/ FINANCING
Public health services	National and regional, in agreement with State-Regions Conference	National Prevention Plan issued by State-Regions Conference Regions	Regions – following the Policy Document for the revision of accreditation legislation, issued by State-Regions Conference	Central government and regional councils	New Guarantee System (16 indicators on collective prevention and public health)	Mainly regions (IRAP and IRPEF regional supplement) State budget through VAT and National Health Fund Out-of-pocket through fixed tariffs
Ambulatory care (primary and in secondary care)	National level, in agreement with State-Regions Conference (district care within LEA includes ambulatory care) Region	Health Pacts (State-Regions Conference) National Chronic Conditions Plan (State-Regions Conference) National Plan for the Governance of Waiting Lists (State-Regions Conference) Regional health plans Local health plans	Regions – in line with the Policy Document for the revision of accreditation legislation, issued by State-Regions Conference	National tariffs are set by the ministries of health and the economy, supported by the Permanent Commission for Tariffs Regional tariffs are set by regional health departments	New Guarantee System (33 district care indicators) National Outcomes Programme (hospitalization indicators)	Mainly regions (IRAP and IRPEF regional supplement) State budget through VAT and National Health Fund SSN entities' income (co-payments and intramoenia activities)
Inpatient care	National level, in agreement with State-Regions Conference (hospital care LEA) Regions	Health Pacts (State-Regions Conference) National Plan for Governance of Waiting Lists (State-Regions Conference) Regional health plans Local health plans	Regions – in line with the Policy Document for the revision of accreditation legislation, issued by State-Regions Conference	National tariffs are set by the ministries of health and the economy, supported by the Permanent Commission for Tariffs Regional DRG tariffs are set by regional health departments Tariffs for interregional mobility	New Guarantee System (24 hospital care indicators) National Outcomes Programme	Mainly regions (IRAP and IRPEF regional Supplement) State budget through VAT and National Health Fund SSN entities' income (private medical treatment)

	LEGISLATION	PLANNING	LICENSING/ ACCREDITATION	PRICING/ TARIFF SETTING	QUALITY ASSURANCE	PURCHASING/ FINANCING
Dental care	National level, in agreement with State-Regions Conference Regions	Regional health plans, covering only certain vulnerable populations Local health plans, covering only certain vulnerable populations	Regions – in line with the Policy Document for the revision of accreditation legislation, issued by State-Regions Conference	National tariffs are set by the ministries of health and the economy, supported by the Permanent Commission for Tariffs. Regional tariffs are set by Regional Health Departments Out-of-pocket tariffs set by local health authorities	NA	Mainly regions (IRAP and IRPEF regional supplement) State budget through VAT and National Health Fund SSN entities' income (co-payments, intramoenia activities and local health authority tariffs)
Pharma-ceuticals (ambulatory)	National level (AIFA) Regions	Health Pacts (State-Regions Conference) Regional health plans	AIFA	AIFA, in compliance with the 2015 Stability Law	AIFA	Mainly regions (IRAP and IRPEF regional Supplement) State budget through VAT and National Health Fund Co-payments set by each region
Long-term care	National level, in agreement with State-Regions Conference (health and social care LEA) Regions	Health Pacts (State-Regions Conference) Regional health plans Local health plans	Regions – in line with the Policy Document for the revision of accreditation legislation, issued by State-Regions Conference	Regional councils	New Guarantee System (a few long-term care indicators are included in district care indicators)	Mainly regions (IRAP and IRPEF regional Supplement) State budget through VAT and National Health Fund Out-of-pocket (the hospitality share of the tariff is charged to the patient)

	LEGISLATION	PLANNING	LICENSING/ ACCREDITATION	PRICING/ TARIFF SETTING	QUALITY ASSURANCE	PURCHASING/ FINANCING
University education of personnel	National level, supported by several government agencies (general norms and LEA) Regions	Ministry of University and Research Regional plans on university education rights	Ministry of Health, Ministry of University and Research, National Observatory for Medical Specialist Education ANVUR (Italian National Agency for the Evaluation of Universities and Research Institutes), AGENAS (medical residency programmes) Ministry of University and Research, in agreement with ANVUR (medical schools)	Largely publicly financed, while tuition fees are autonomously set by each university	ANVUR AGENAS ONFMS	Mainly national funds Regional funds

Notes: AGENAS: National Agency for Regional Health Services; AIFA: Italian Medicines Agency; ANVUR: National Agency for the Evaluation of Universities and Research Institutes; DRG: diagnosis-related group; IRPEF: personal income tax; IRAP: an earmarked corporate tax; ONFMS: National Observatory for the Education of Medical Specialists; VAT: Value Added Tax. LEA refers to the national benefits package; State-Regions Conference refers to the Conference of the Regions and Autonomous Provinces.

Source: Authors.

2.7.3 *Regulation of services and goods*

NATIONAL BENEFITS PACKAGE – THE LEA

The list of services in the national benefits package is set, modified and updated by the National Commission for the Update of the LEAs and for the Promotion of Appropriateness of Care in the SSN, established in 2017. Chaired by the Minister of Health, the commission includes representatives from the regions, the ISS, AIFA, the Ministry of Economy and Finance and AGENAS. Amendments also may be requested by citizen and patient organizations, health facilities, scientific and professional associations and the IRCCSs. The commission prioritizes requests according to expected impacts, health priorities and available evidence on efficacy.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

An HTA was nationally endorsed in the 2006–2008 NHP, and AGENAS started supporting regions to develop HTA activities. The 2016 Stability Law initiated work on a National HTA Plan (*Piano Nazionale Health Technology Assessment Dispositivi Medici*, PNHTADM), which launched ministerial working groups and developed recommendations as well as the methodology of the national programme that was later released in 2019. Since then, the PNHTADM has been awaiting effective implementation (Tarricone et al., 2021). Despite the efforts of policy-makers to conduct an HTA nationally, more coordinated governance is needed. Currently, AGENAS is still responsible for the assessment of medical devices while AIFA undertakes assessments for pharmaceuticals in parallel to the ISS's National Center for HTA, established in January 2017. Some regions have launched their own initiatives, thus increasing fragmentation. An opportunity to address disparities among regions is presented by implementing the proposed EU HTA Regulation (European Union, 2021) and Next Generation EU, whose expected benefits would include reduced inequalities in pricing and reimbursement and improved access to new technologies across the 21 regions. Furthermore, the system would benefit from a centrally monitored dissemination and evidence-gathering function (Tarricone et al., 2021).

2.7.4 *Regulation and governance of pharmaceuticals*

Italian law distinguishes between branded and generic, or equivalent, pharmaceuticals (see Box 2.4). AIFA regulates pharmaceuticals, approving those that can be produced, used and marketed in Italy, and authorizes clinical trials. While the European Medicines Agency (EMA) evaluates the efficacy, safety and quality of medicines, AIFA analyses pharmaceuticals within the Italian context, evaluating their cost–effectiveness and sustainability for the SSN. After acknowledging the EMA's decisions, the national authorization procedure starts with AIFA verifying the medicine's documentation submitted by the pharmaceutical company, to check compliance with national requirements. Subsequently, a Technical and Scientific Committee and the ISS support safety and efficacy evaluations.

Pharmaceuticals are divided into the following reimbursement categories.

- Class A: reimbursed by the SSN and distributed by community or hospital pharmacies. Regions may impose co-payments and must do so if they are under recovery plans. Co-payment exemption criteria apply and are based on income, age, employment status and the presence of chronic conditions (see Chapter 3).
- Class H: fully reimbursed pharmaceuticals only distributable by (or used within) hospitals.
- Class C: entirely paid for by patients, unless regional provisions state otherwise; some may require a medical prescription.

Off-label pharmaceutical use – purchasing a pharmaceutical for a therapeutic indication that is different to AIFA's specifications – is strictly regulated and only allowed when no alternative exists and enough scientific evidence on its efficacy is available. Negotiations between AIFA and producers determine Class A and H prices. Among other criteria, producers must provide cost–effectiveness evidence (AIFA, 2020b) or demonstrate the benefits for the SSN. Producers determine Class C prices with the consideration that the price must be uniform across the country; the price can be increased every 2 years as long as it does not surpass expected inflation. AIFA monitors compliance with these conditions.

BOX 2.4 Branded and generic – equivalent – pharmaceuticals

Branded pharmaceuticals are sold with specific names and packages, either within patent validity or once it has expired. Generics are not patented but have the same composition, pharmaceutical form and dosing as the branded equivalents. They can be produced and sold following market access procedures and their price must be, at a minimum, 20% lower than that of the matching branded – and previously patented – pharmaceutical. Reimbursement of non-patented pharmaceuticals – with an expired patent or a generic – is regulated nationally. National provisions specify minimum price reductions, leaving regions free to set their reimbursement price to that of the cheapest matching generic available under regional distribution.

To encourage the use of generic medicines, pharmacists must ask patients whether they wish to replace a patented pharmaceutical with the cheapest equivalent. Patients pay the difference between the prescribed pharmaceutical's price and the price of the matching generic if they refuse the replacement, either if specified by the doctor or due to patient preferences. Recently, further cost-containment measures have been introduced. AIFA sets maximum reimbursement prices for equivalent Class A pharmaceuticals, based on current prices in the EU, also taking into account predefined yearly regional budgets.

On average, European citizens access a new medicine after 426 days from EMA's approval (IQViA, 2019). Italy's average is shorter (402 days), especially for oncology medicines (368 days). Orphan drugs, however, take on average 428 days. However, Italy can rely on many regulatory tools to shorten market access times to medicines approved in Europe; for instance, through Managed Entry Agreements, "Compassionate use" (Ministerial Decree, 7 September 2017), off-label prescriptions or special funds (Panteli et al., 2016).

Pharmaceutical distribution in Italy is one of the most complex in Europe and encompasses various actors:

- the manufacturer/marketing authorization holder, i.e. the company that produces the medicine and/or holds its marketing authorization;
- the carriers who are in charge of transport;
- the depositaries, logistic third parties who do not own the medicines they manage (and therefore do not bear the related business risk);

- the intermediate distributors, i.e. the wholesalers who own the pharmaceuticals they distribute and who have a legal obligation to fulfil the order within 12 hours; for this reason, they invest heavily in automation, innovation and technology;
- the dispensing points, which are the places where patients can pick up/buy the medicines, i.e. pharmacies, para-pharmacies, pharma corners in retail outlets such as supermarkets (introduced by Legislative Decree 223/2006, the so-called "Bersani Decree", which liberalized the over-the-counter (OTC) medicines market), as well as local health authorities and hospitals.

Dispensing points for medicines (classes A and H covered by the SSN) are structured in three different ways:

- Direct distribution (DD): the SSN purchases the medicines directly from the industry and then distributes them to patients through its facilities; for example, hospitals or local health authorities. This is supposed to lead to savings for local health authorities, although a parliamentary inquiry on the matter is currently underway (Camera dei Deputati, 2022b).
- Distribution on behalf of the SSN (DPC): the SSN buys the medicines, trying to obtain more advantageous discounts than those imposed by law on pharmacies, and then has it dispensed by local pharmacies, agreeing on a set fee for this service (on average EUR 5 per pack). In this way, patients avoid logistical inconveniences (hospitals and local health authorities are often located far away and have limited opening hours) and widespread distribution is guaranteed.
- Distribution in partnership with SSN (DC): in this well-established model, the pharmacist buys the medicine and sells it to customers, subsequently reimbursed by the SSN (based on a percentage of the medicine's price).

2.7.5 *Regulation of medical devices and aids*

Regulation of medical devices and aids falls under the competence of the Ministry of Health's General Directorate for Medical Devices, Pharmaceutical Services and Care Safety. Its duties include surveillance of the production, commercialization and use of medical devices within the SSN, in line with Italian and European regulations. It manages malfunction alerts or accidents related to medical devices. Its information system, which monitors all medical devices provided by public facilities, is connected to the NSIS (see section 2.6).

Procurement procedures have been undergoing a centralization process since 2012, but with regional variations. Some regions centrally manage public tenders based on local needs while others have established groups of purchasers on a territorial basis. A widespread procurement system is based on public tenders that start with regions asking their health facilities to estimate their annual budget, assess needs, plan expenses and monitor the appropriateness of purchasing choices. Data are recorded into Regional Observatories that send the information to Unique Regional Purchasing Centres (UPCs) to manage negotiations with facilities. Following the centralization trend, UPCs have increased their involvement in the procurement processes, which, however, can still be performed by individual facilities (or groups of facilities aiming at economies of scale). A National Purchasing Centre (CONSIP, the central purchasing body for the Italian public administration) can also be used by SSN organizations, to complement regional procurement avenues (CONSIP, 2021).

Regions establish Commissions for Tender Evaluations and also release guidelines and reports to support decision-making at local level. Calls for tenders privilege the most economically gainful offer according to quality/price ratios. In addition, the establishment of Authorities Zero (see section 2.2) aims to further centralize and cut costs in the procuring and purchasing of medical devices.

2.8 Person-centred care

2.8.1 *Patient information*

The Health Services Charter, adopted by all providers, safeguards patients' rights to information. With regionally produced guidelines, the charter grants citizens the right to consult health planning documents at all levels and includes the activities, timing and structures of health care services. Since 2021, data from the PNE indicators have been published on the AGENAS website (https://pne.agenas.it) (see section 2.6). The Ministry of Health's website communicates general information about the SSN, whereas regionally managed websites contain details on service provision. Table 2.4 summarizes the availability of various types of information for patients.

TABLE 2.4 Patient information

TYPE OF INFORMATION	IS IT EASILY AVAILABLE?	COMMENTS
Information about statutory benefits	Yes, on the Ministry of Health's website	More detailed information is available from the webpage of the Chamber of Deputies
Comparative information about the quality of providers (for example, GPs)	For some services through the National Outcomes Programme website	There are also parallel private initiatives (i.e. https://www.doveecomemicuro.it/)
Patient access to own medical record	Yes, after following specific identification steps	–
Interactive web or 24/7 telephone information	Fragmented among and within regions	National COVID-19 hotline added in January 2020
Information on patient satisfaction collected (systematically or occasionally)	No	–
Information on medical errors	Mainly through private initiatives	–
Information on hospital clinical outcomes	Yes, on the National Outcomes Programme website	There are also parallel private initiatives (i.e. https://www.doveecomemicuro.it/)
Information on hospital waiting times	Only in some regions, through ad hoc observatories	–

Source: Authors.

2.8.2 *Patient choice*

The fundamental right to self-determination, the liberty to dispose of one's body and the right to health and patient safety are explicitly referenced and underpinned in legislation (Bellandi et al., 2017). The Health Charter also recognizes citizens' right to choose among SSN providers. Patients may seek health care from any public or private-accredited provider and freely choose GPs and paediatricians among those working in the municipality (*comune*) where they reside, only limited by capacity constraints. Concerning specialized and secondary health care providers, patients are free to choose the facility but not the specialist unless they pay privately.

Currently, despite patients' and caregivers' engagement initiatives being promoted by public and private actors, and policy efforts recognizing the importance of shared decision-making, there is still room for improvement (Bottacini et al., 2017). Table 2.5 outlines the extent of patient choice in the Italian health care system.

2.8.3 *Patient rights*

The 2002 European Charter of Patients' Rights, still in force today, was drafted under the auspices of the Italian nongovernmental organization (NGO) CittadinanzAttiva ("Active Citizenship") and recognizes 14 patient rights: the right to preventive measures; access; information; consent; free choice; privacy and confidentiality; respect for patients' time; observance of quality standards; safety; innovation; avoidance of unnecessary suffering and pain; personalized treatment; the right to complain; and to receive compensation (CittadinanzAttiva, 2002).

Privacy and data protection are legally regulated by the Code on Personal Data Protection, which specifies informed consent criteria and terms to use data on personal health status, including genetic data. The Authority for Protection of Personal Data is authorized to monitor its implementation.

TABLE 2.5 Patient choice

TYPE OF CHOICE	IS IT AVAILABLE?	DO PEOPLE EXERCISE CHOICE? ARE THERE ANY CONSTRAINTS?
CHOICES AROUND COVERAGE		
Choice of being covered or not	No	Coverage is universal and automatic
Choice of public or private coverage	No	Private coverage is always complementary
Choice of purchasing organization	Yes	–
CHOICES OF PROVIDER		
Choice of primary care practitioner	Yes	Among those in the patient's municipality
Direct access to specialists	No	With GP prescriptions, patients have free choice of provider, a specific hospital, for instance, but not the individual specialist. Privately, patients can also choose their specialist
Choice of hospital	Yes	–
Choice to have treatment abroad	Yes	Directive 2011/24/EU
CHOICES OF TREATMENT		
Participation in treatment decisions	Yes	Implementation into routine clinical practice is ongoing
Right to informed consent	Yes	–
Right to request a second opinion	Yes	–
Right to information about alternative treatment options	Yes	–

Source: Authors.

Currently, patients and citizen organizations are not formally involved in pricing and reimbursement decision-making; however, they may participate in public consultations for specific concept and position papers issued by AIFA (see https://www.aifa.gov.it/consultazioni-pubbliche). Moreover, citizen and patient associations and facilities can suggest amendments to the national benefit packages to the Ministry of Health (see section 2.7.3). Indeed, the Secretary General of CittadinanzAttiva is among the Ministry's nominated delegates to the National Commission for the Update of the LEA and for

the Promotion of Appropriateness of Care in the SSN. Some regions (i.e. Lombardy and Emilia-Romagna) include patient association delegates in their HTA commissions. Table 2.6 summarizes some of the main areas of patient rights.

TABLE 2.6 Patient rights

	Y/N	COMMENTS
PROTECTION OF PATIENT RIGHTS		
Does a formal definition of patient rights exist at national level?	Yes	Charter of Patients' Rights, CittadinanzAttiva. Law 24/2017
Are patient rights included in legislation?	Yes	Laws 219/2017 and Law 24/2017
Does the legislation conform with WHO's patient rights framework?	Yes	Law 24/2017 and Sustainable Development Goals 2030 adoption (Budget Law 2016)
PATIENT COMPLAINTS AVENUES		
Are hospitals required to have a designated desk responsible for collecting and resolving patients' complaints?	Yes	Art. 11 Legislative Decree 165/2001
Is a health-specific Ombudsman responsible for investigating and resolving patients' complaints about health services?	Yes	Art. 2, Law 24/2017, at regional level
Are there other complaint avenues?	–	–
LIABILITY/COMPENSATION		
Is liability insurance required for physicians and/or other medical professionals?	Yes	–
Can legal redress be sought through the courts in the case of medical error?	Yes	–
Is there a basis for no-fault compensation?	Yes	Limited to compensation programmes for vaccine injuries
If a tort system exists, can patients obtain damage awards for economic and non-economic losses?	Yes	–
Can class action suits be taken against health care providers, pharmaceutical companies, etc.?	Yes	–

Source: Authors.

2.8.4 *Patients and cross-border health care*

Italy has converted EU Directive 2011/24 on cross-border health care into national law. The procedure is as follows: 1) eligible Italian patients seeking health care abroad should directly contact health providers; 2) the patients' local health authority of residence issues the required documentation; 3) health care is delivered according to the Directive scheme; 4) in the case of third-party payment arrangements, the Italian Ministry of Health pays the foreign providers and charges the patient's local health authority; and 5) the balance between each local health authority's international debts and credits is considered when assigning resources to the regions.

With Legislative Decree 38/2014, the Italian Government also established the National Contact Point for cross-border health care, responsible for communicating with patients from other EU Member States. It provides guidance on health care providers, as well as information on patients' rights, complaint procedures and protection mechanisms.

3

Financing

Chapter summary

- Based on national statistics, current health care expenditure in 2019 was equal to EUR 154.8 billion, of which EUR 114.8 billion (approximately 74%) was funded by the SSN and the remaining EUR 40 billion (26%) came from private sources.

- The Italian health care system spends less than most EU countries per capita: in 2019, health expenditure stood at 8.7% of GDP which translates to approximately US$ PPP 3 998 per capita.

- The share of private health spending had been growing over the last decade, reaching just over 26% of current health expenditure in 2019. This trend was interrupted in 2020 during the COVID-19 pandemic.

- The largest share of private expenditure (around 89%) was represented by out-of-pocket (OOP) expenses (including both co-payments and direct payments by households), mainly spent on dental care, OTC medicines and specialist outpatient services.

- The national allocation system ensures homogenous per capita funding between the regions but the mobility of patients seeking care outside their region of residence transfers financial resources from the south of the country to the north.

- Providers are paid according to a mix of methods; fee-for-service and DRGs are the main methods of paying independent providers (both public and private accredited) while local health authorities are mainly paid according to capitation formulae that vary region by region. Primary care physicians are mainly paid according to capitation in all regions.

3.1 Health expenditure

According to national ISTAT data, current health expenditure in 2019 was equal to EUR 154.8 billion, of which EUR 114.8 billion was publicly funded and the remaining EUR 40 billion was incurred by families and other private entities (Del Vecchio et al., 2020; 2021). Preliminary estimates for 2020 showed a significant increase in public spending (EUR 122.4 billion) and a reduction in private expenditure (EUR 38.1 billion) (Del Vecchio et al., 2021). The COVID-19 pandemic required additional public expenditure to cope with the emergency, while private health care expenditure decreased due to the suspension of non-urgent services and patients' reluctance to visit health care facilities.

Based on data from the Global Health Expenditure Database in 2019, Italy's health spending represented 8.7% of GDP (Table 3.1 and Fig. 3.1).[5] The share of GDP for health care grew steadily from 7.6% in 2000 to 8.9% in 2010, then declined slightly to 8.7% in 2019. Although this is a little above the EU average (8.5%), Italy remains the lowest spender when compared with countries such as Spain, France, the United Kingdom, and Germany (Fig. 3.2). In 2019, per capita health expenditure stood at US$ 3 998 (adjusted for differences in purchasing power). While this is above the average across the WHO European Region it is somewhat below the average for EU/European Economic Area (EEA) countries and the United Kingdom (Fig. 3.3).

Over the last two decades, public expenditure on health has fluctuated. It grew by an average annual growth rate of 4.1% from 2000 to 2010, and by only 0.9% from 2011 to 2019. Instead, private expenditure has shown a more constant pattern (about 2.1% average annual increase). The government

5 National data from ISTAT diverge marginally from Global Health Expenditure Database (GHED) data due to methodological differences but these differences are minor. In this chapter we mainly use GHED data when discussing the component parts of health expenditure.

share of current health care expenditure decreased significantly from 78.5% in 2010 to 73.9% in 2019 (Table 3.1). Both public and private health expenditure suffered from the country's modest GDP annual growth which averaged 2.4% between 2001 and 2010 and only 1.1% between 2011 and 2019. This left little room to increase the share of GDP dedicated to the SSN, given Italy's very high public debt/GDP ratio. In addition, private expenditure on health did expand despite a weak economy that increased the disposable income of families only modestly.

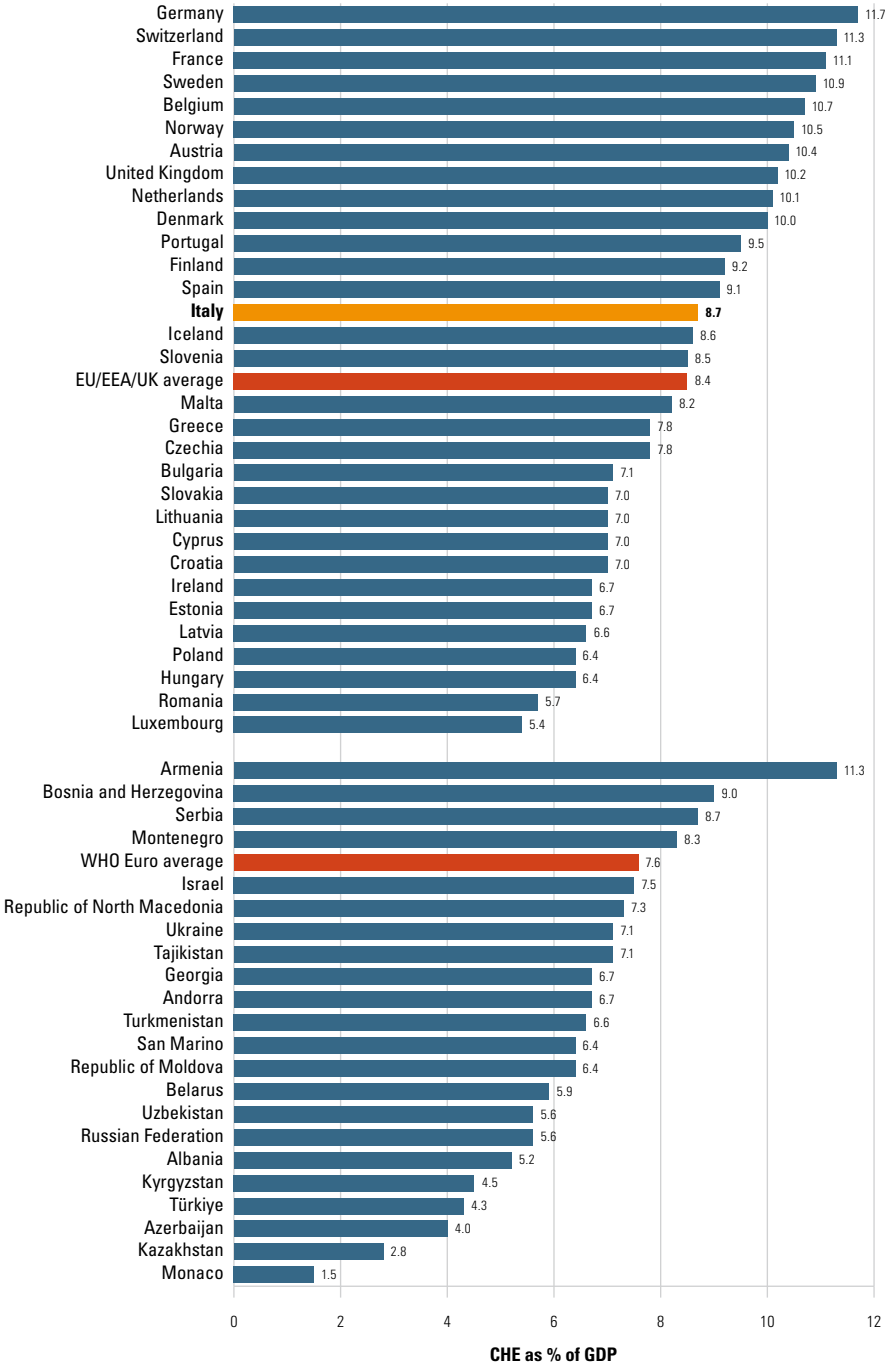
TABLE 3.1 Trends in health expenditure, 2000–2019

EXPENDITURE	2000	2005	2010	2015	2018	2019
Current health expenditure per capita (US$ PPP)	2 050	2 517	3 142	3 265	3 855	3 998
Current health expenditure as % of GDP	7.6	8.3	8.9	8.9	8.7	8.7
Public expenditure on health as % of total expenditure on health	72.6	77.5	78.5	74.4	73.8	73.9
Public expenditure on health per capita (US$ PPP)	1 489	1950	2 465	2 430	2 847	2 955
Private expenditure on health as % of total expenditure on health	27.4	22.5	21.5	25.6	26.2	26.1
Public expenditure on health as % of general government expenditure	11.8	13.7	14.0	13.1	13.2	13.2
Government health spending as % of GDP	5.5	6.5	7.0	6.6	6.4	6.4
OOP payments as % of total expenditure on health	26.5	21.6	20.5	23.5	23.6	23.3
VHI as % of total expenditure on health	0.9	0.9	1.0	1.5	1.9	2.1

Note: GDP: gross domestic product; OOP: out of pocket; PPP: purchasing power parity; VHI: voluntary health insurance.

Source: WHO, 2022a.

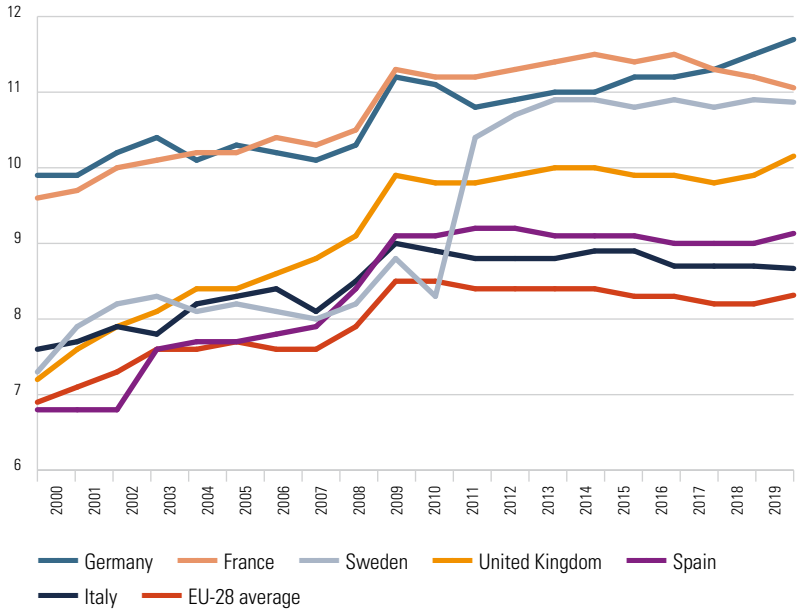
FIG. 3.1 Current health expenditure as a share (%) of GDP in the WHO European Region, 2019



Note: Data for Albania are from 2018. CHE: current health expenditure; EEA: European Economic Area; EU: European Union; GDP: gross domestic product; UK: United Kingdom; WHO: World Health Organization.

Source: WHO, 2022a.

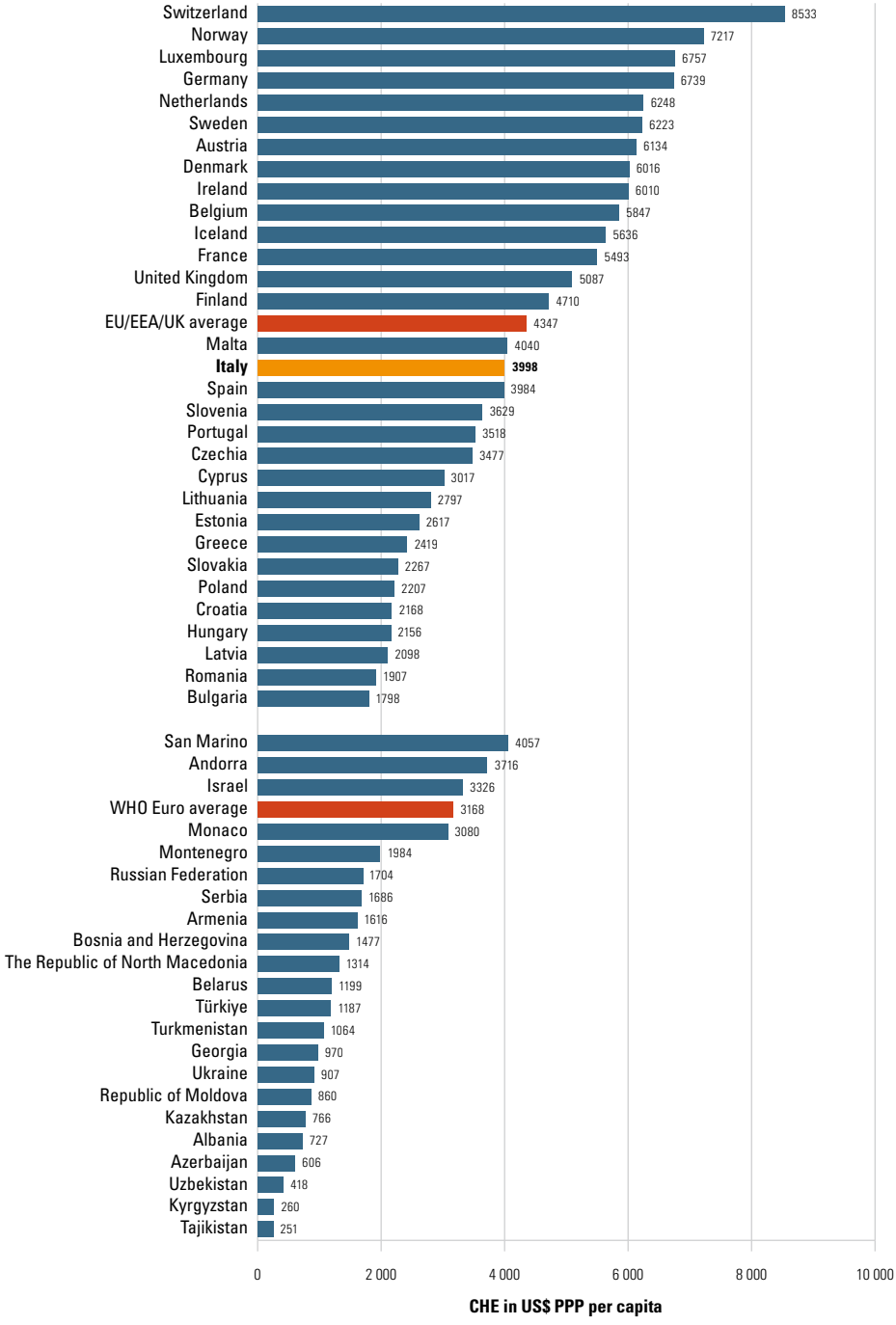
FIG. 3.2 Trends in current health expenditure as a share (%) of GDP in Italy and selected countries, 2000–2019



CHE: current health expenditure; EU-28: The 28 EU Member States prior to 1 February 2021; GDP: gross domestic product.

Source: WHO, 2022a.

FIG. 3.3 Current health expenditure in US$ PPP per capita in the WHO European Region, 2019



Note: Data for Albania are from 2018. CHE: current health expenditure; EEA: European Economic Area; EU: European Union; PPP: purchasing power parity; UK: United Kingdom; WHO: World Health Organization.

Source: WHO Global health expenditure database, 2022.

National data highlights that in 2019, per capita public expenditure by the regional health care systems ranged from EUR 1 845 in Campania and EUR 1 909 in Sicily (southern Italy) to EUR 2 476 in Molise (southern Italy) and EUR 2 457 in the Autonomous Province of Bolzano (northern Italy) (Table 3.2). Differences are mainly due to funding – northern regions tend to receive more resources due to an older population – and to regions being able to deliver services beyond those guaranteed under the national benefits package (LEA). It is worth noting that the financial flows due to the mobility of patients seeking care outside their region of residence also impacts on regional differences in per capita health spending. These flows tend to go from the southern to northern regions given that public and private-accredited hospitals in northern regions (mainly in Lombardy and Emilia-Romagna) attract patients from southern regions (mainly from Calabria and Campania) (Fattore, Petrarca & Torbica, 2014; Brenna & Spandonaro, 2015). The private share of per capita expenditure shows much greater variation across the country ranging, from a minimum of EUR 423 in Campania to a maximum of EUR 899 in the Valle d'Aosta. These data suggest that private expenditure is mainly related to families' disposable income (higher in the northern regions) rather than to the performance of public regional health systems (Del Vecchio et al., 2020).

TABLE 3.2 Per capita health expenditure in the Italian Regions, 2019

REGION	GOVERNMENT PER CAPITA HEALTH EXPENDITURE (EUR) 2019	PRIVATE PER CAPITA HEALTH EXPENDITURE (EUR MEAN VALUES), 2017–2019
NORTHERN ITALY		
Piemonte	2 011	666
Valle d'Aosta	2 169	899
Lombardia (Lombardy)	2 049	753
Trentino – Alto –Adige: AP Bolzano	2 457	672
Trentino – Alto –Adige: AP Trento	2 297	628
Veneto	1 997	708
Friuli-Venezia Giulia	2 199	694
Liguria	2 170	666
Emilia-Romagna	2 133	716
CENTRAL ITALY		
Toscana (Tuscany)	2 095	633
Umbria	2 031	498
Marche	1 953	470
Lazio	1 934	671
SOUTHERN ITALY		
Abruzzo	1 958	477
Molise	2 476	496
Campania	1 845	423
Puglia	1 916	459
Basilicata	1 928	536
Calabria	1 912	537
Sicilia (Sicily)	1 909	519
Sardegna (Sardinia)	2 079	463

Note: AP: Autonomous Province; SSN: National Health Service. Data do not include forgone revenues due to fiscal deductions (20% of expenditure) for goods/services paid outside the coverage of the SSN.

Source: Armeni et al., 2021; Del Vecchio et al., 2020.

According to national disaggregated data on health expenditure by function and financing scheme (Table 3.3), the main areas of health expenditure in 2019 were inpatient care for public (government) expenditure, and outpatient care and pharmaceuticals for private expenditure.

TABLE 3.3 Breakdown of expenditure on health according to function and type of financing, %, 2019

	INPATIENT CARE	PRIMARY CARE	OUTPATIENT CARE	PHARMACEUTICALS	DENTAL CARE	PUBLIC HEALTH	OTHER SERVICES	TOTAL
Public expenditure	44%	7%	13%	12%	n.a.	5%	19%	100%
Private expenditure	5%	Negligible	22%	22%	21%	n.a.	30%	100%

Note: Public expenditure data come from the National Health Information System; most values refer to the binding allocation of resources to regions to provide the national benefits package, rather than to an actual expenditure. Private expenditure data come from different sources. The category of "other services" includes long-term care and devices (e.g. spectacles).

Source: Armeni et al., 2020; Del Vecchio et al., 2020

Overall, the last decade (before the COVID-19 pandemic) was dominated by an aggressive cost-containment strategy adopted at the national level and implemented by regions and SSN organizations. This strategy was based on two main types of measures. The first, directed at regions, forced them to adopt regional and local cost-containment measures. For example, the ceiling on pharmaceutical expenditure was expected to activate regional policies to reduce waste and to improve cost-conscious prescribing. In this respect, some regions (mainly in the north and centre) have been more active than others. In 2007, the government introduced a special regime for overspending regions that required the adoption and implementation of formal regional "recovery plans" (*piani di rientro*). Since then, 10 out of the 21 regional health systems had to adopt these plans, which included actions to address the structural determinants of costs. Currently (2022) seven regions follow these plans. The overall effect of these recovery plans has been a drastic decrease in the yearly level of overspending. In 2019, the overall deficit of the SSN (SSN expenditure minus SSN funding) was close to zero. While these plans were effective in regaining control over expenditure, they also created concern

about their negative impact on the quantity and quality of services delivered to citizens. While a few studies found ambiguous evidence about the impact of recovery plans on health (see Bobini et al., 2019), a recent and very rigorous study by Arcà et al. (2020) found that regions that adopted recovery plans had worse outcomes in terms of amenable mortality. The second type of measure targeted SSN organizations directly. Here, the focus was on national personnel contracts, setting caps on the increase of specific expenditure items (e.g. for goods and services) and on containing prices of pharmaceuticals that are set at the at national level.

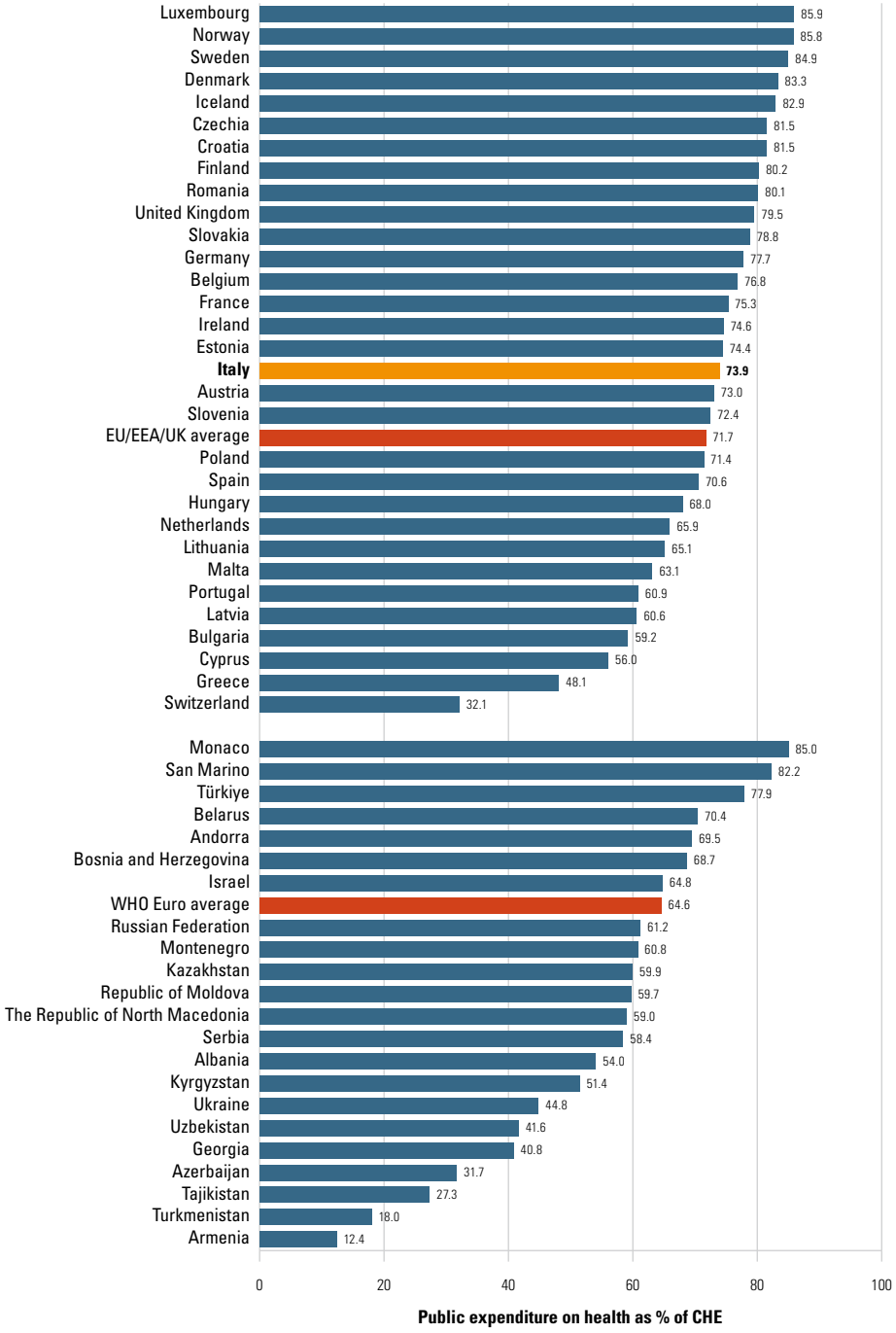
From March 2020, the Italian Government increased SSN funding to address the COVID-19 emergency. Compared with what was originally planned before the pandemic, overall funding for 2020 was increased by more than EUR 5 billion (approximately 4% of the total SSN budget). Additional resources were made available by the government through the Civil Protection Department and the COVID-19 Emergency Commissioner. For example, an important share of the expenses for masks and other protective devices used by SSN personnel, and for ventilators, were directly purchased by these agencies. Most of these expenditures were also incurred in 2021 – in May 2022 total additional national funding for the SSN was recorded as EUR 121.4 million (Camera dei Deputati, 2022a). Also, preliminary data on the financial situation of regions in 2022 signal that some of them are likely to incur important deficits that will need to be covered with regional resources and/or national ones.

3.2 Sources of revenue and financial flows

Figure 3.4 shows that the majority of health funding in the WHO European Region comes from public sources (on average 71.7% in 2019). Based on this data, in 2019, public funding for health in Italy was above the EU average with 73.9%. The remainder was funded privately, mainly through OOP spending (23.3%), as voluntary health insurance(VHI) only plays a minor role (2.1%).[6] The growing trend of total private expenditure and its main components over the period 2012–2019 is reported in Table 3.4. Total private expenditure in Italy was approximately EUR 40 billion in 2019 (Del Vecchio et al., 2020). Of this, EUR 35.8 billion were OOP expenditure (including both co-payments and direct payments), while the remaining EUR 4.3 billion were for VHI, occupational medicine (paid by companies) and services offered by non-profit institutions (e.g. Italian Red Cross). The latter consist of non-compulsory financing arrangements and programmes that are based on donations from the general public, the government or corporations. In 2020, only OOP expenditure was significantly reduced (to EUR 33.9 billion), while other components remained almost stable.

6 This value includes VHI by companies for their employees but excludes the fiscal cost of tax subsidies for private health care expenditure, estimated at about EUR 4.7 billion (Del Vecchio et al., 2020).

FIG. 3.4 Public expenditure on health as a share (%) of current health expenditure in the WHO European Region, 2019



Note: Data for Albania are from 2018. CHE: current health expenditure; EEA: European Economic Area; EU: European Union; UK: United Kingdom.

Source: WHO, 2022a.

TABLE 3.4 Composition of private health expenditure by source of financing (EUR, billions), 2012–2019

YEAR	OUT OF POCKET	VHI	PRIVATE ENTERPRISES	NON-PROFIT INSTITUTIONS	TOTAL
2012	31.5	2.3	0.5	0.2	34.4
2013	31.5	2.2	0.5	0.2	34.3
2014	32.6	2.2	0.6	0.2	35.5
2015	34.4	2.3	0.6	0.2	37.5
2016	34.5	2.5	0.7	0.2	37.9
2017	35.9	2.7	0.7	0.3	39.6
2018	36.1	2.9	0.7	0.3	40.0
2019	35.8	3.3	0.7	0.3	40.0
2020	33.9	3.2	0.7	0.3	38.1

Note: VHI: voluntary health insurance.

Source: Del Vecchio et al., 2020.

Figure 3.5 presents a snapshot of the financial flows of the Italian SSN. The central government retains both a regulatory and funding role. It sets the national benefits package (LEA) and ensures that the regions have adequate resources to deliver them. In practice, however, the central government defines the total amount of public resources assigned to the health system mainly based on the general macroeconomic framework. The national Ministry of Health manages a modest part of this amount for national programmes (*fondi vincolati*) and assigns the rest to the regions. Each region's share is calculated based on a capitation formula that considers the age structure of the population and other epidemiological indicators (Ferrario & Zanardi, 2011). The specific formula to be used is agreed annually between the central government and the regions in the State-Regions Conference.

Thereafter, the central government estimates the amount of revenues that each region is expected to raise from two regional taxes:

- The first regional tax is the IRAP (*imposta regionale sulle attività produttive*), which is an earmarked corporate tax on the value-added of companies (i.e. the difference between operating revenues and costs) and on the salaries paid to public sector employees. The tax base is set at 3.9% but regions are allowed to top up with another 0.92%, depending on the industry, thus leading to interregional differences in the corporate tax base.

- The other tax is a regional surcharge on the national income tax (*Addizionale* IRPEF). The surcharge is applied differently by each region. For example, some regions apply a flat rate while others apply a sliding scale rate according to the personal income bracket.

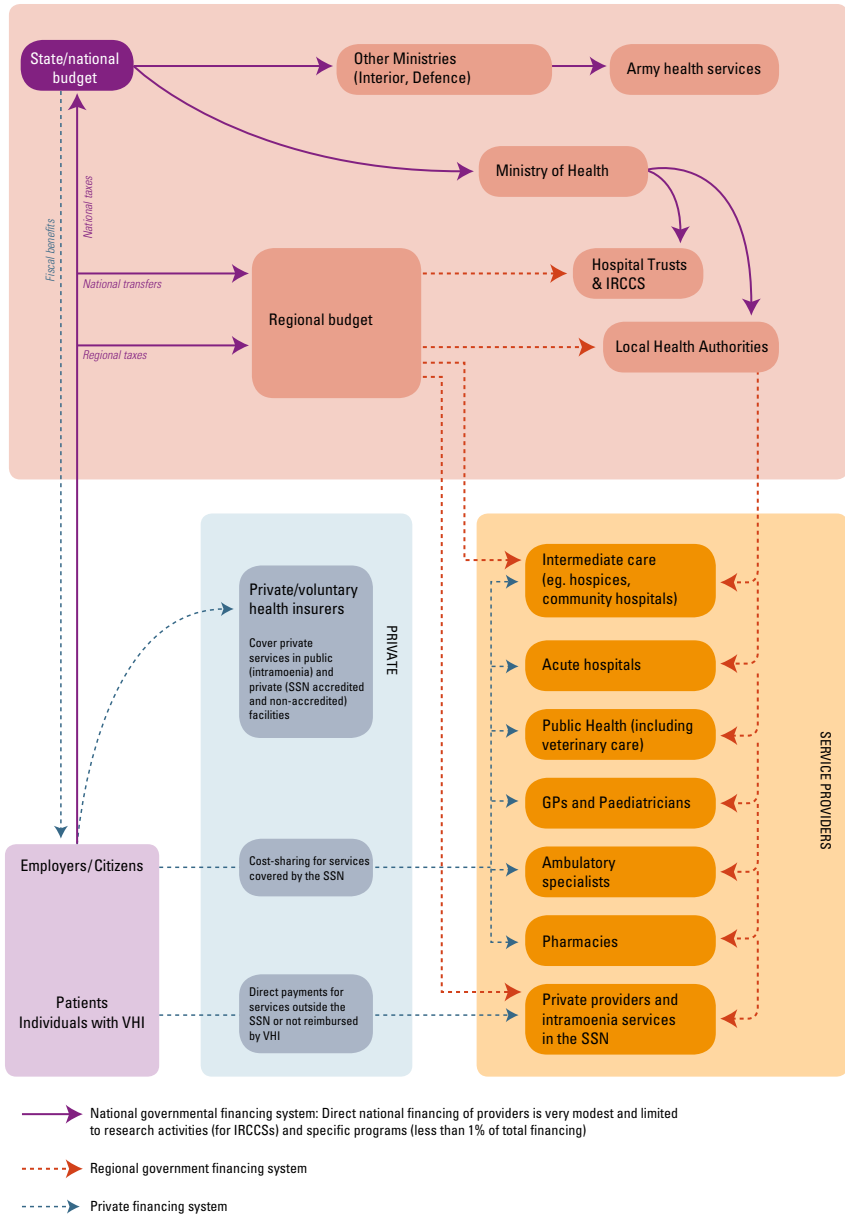
The amount of these regional revenues, augmented by estimates of patient co-payments (received by SSN organizations and accredited private providers) defines the amount of resources that are available in each region from their own sources. For each region the difference between their "financial need" and this amount determines the financial gap that ought to be covered by the central government. This gap is covered through the "equalization fund" which contains resources collected through the national Value Added Tax (VAT).

There are different rules for the five autonomous regions (i.e. Valle d'Aosta, Trentino-Alto Adige, Friuli-Venezia Giulia, Sicily, Sardinia) since they are directly entitled to a share of tax revenues raised by the national government and are expected to provide the national benefits package with their own resources. Rules are also different for "Recovery Plan" regions, where both IRAP and *Addizionale* IRPEF can be higher to generate additional revenues to cover overspending.

Overall, the funding mechanisms comprise a mix of national and regional taxes. While national taxes play a major equalization role, regional taxation systems create an uneven playing field. Richer northern regions, with higher GDPs, have a large taxation base and thus can top up the "financial need" set by the central government, while the poorest regions in the south have a smaller taxation base and thus little space to raise additional funds for their public health care systems. Different regional taxation rules also create different business opportunities across regions and, therefore, may exacerbate regional differentials in socioeconomic development.

Outside the SSN, private funding mainly consists of OOP payments by households and voluntary private insurance, the latter mainly sponsored by employers or professional associations (see sections 3.4 and 3.5).

FIG. 3.5 Financial flows in the Italian health care system



Note: GP: general practitioner; IRCCS: Institutes for Care and Scientific Research; SSN: National Health Service; VHI: voluntary health insurance.

Source: Authors

3.3 Overview of the statutory financing system

3.3.1 *Coverage*

The SSN covers all citizens and ordinarily resident foreign nationals. Population coverage is automatic and universal. Undocumented migrants are entitled to access only urgent and essential services. Health care for prisoners, which was previously delivered through the Ministry of Justice, was integrated into the SSN in 1999; moreover, prisoners are usually excluded from having to pay co-payments.

In terms of the scope of coverage, the SSN guarantees the provision of health services included in the national benefits package (LEA) across the entire country. These are delivered through the activities of public providers (i.e. regional and local health care authorities, independent public hospitals (known as "hospital trusts"), university hospital trusts, the tertiary care and research centres (IRCCSs) and private-accredited providers (see Chapter 2). Regions can choose to offer non-LEA services but must finance these themselves. Health care services provided within the SSN (i.e. the LEA) are identified by positive and negative lists using criteria related to medical necessity, effectiveness, human dignity, appropriateness and efficiency in delivery (Lo Scalzo et al., 2009).

Positive lists exist for community care services (primary care, emergency care, pharmaceuticals, specialist outpatient care, integrated care, prosthesis care, ambulatory and home care, residential and semi-residential care, and thermal therapy), public health and occupational health services (Torbica & Fattore, 2005). For the latter, there is a list of general community and individual levels of preventive services that are covered, including hygiene and public health, immunization and early diagnosis tools. Hospital services are not specifically defined. Dental care – specifically orthodontics and dental prostheses – is generally not covered and is paid for out of pocket or reimbursed through policies offered by private for-profit and not-for-profit insurance companies (see Box 3.1 and section 3.4).

Negative lists include ineffective services; services that are covered only on a case-by-case basis, such as orthodontics and laser eye surgery; and inpatient services for which ordinary hospital admissions are likely to be potentially inappropriate (e.g. cataract surgery and carpal tunnel release). For the latter

category, regions should provide substitute treatment at other levels of the health care delivery system, such as day hospital and ambulatory care.

In 2017, the national benefits package was thoroughly revised and updated; in particular new vaccines, services for outpatient care, diagnostic services, neonatal care and health devices were added. It also included a list of rare disease to be covered by the SSN. Of note, Italy is probably the only country in Europe to introduce a voucher system to subsidize food for patients with coeliac disease.

BOX 3.1 What are the key gaps in coverage?

The main coverage gap within the Italian SSN is dental care, which is provided only to some segments of the population (e.g. children under 14 years) and excludes orthodontic prosthesis. In addition, all psychotherapeutic services to patients whose conditions are not severe are generally unavailable, as are smoking cessation interventions. For several services explicitly covered by the SSN access can be hampered by long waiting lists or lack of local availability in some rural and mountain areas. In fact, waiting lists vary a great deal across regions and even within regions. Co-payments for outpatient care are substantial (EUR 36.15 per prescription).

3.3.2 *Collection*

The main source of financing for the Italian SSN is a mix of taxes applied at both regional and national level (see section 3.2). Thus, collection is performed partially at national and partially at regional level, although pooling of funds is managed at national level.

3.3.3 *Pooling and allocation of funds*

Each year the SSN's health care funding is broadly allocated to three different areas of care that coincide with the main structural pillars of the national benefits package (LEA). In 2019, 5% of funding was allocated to prevention and public health services, 44% of funding was dedicated to hospital care and the remaining 51% to community care, which is further divided into primary

care (7%), community pharmaceutical care (11.6%), specialist outpatient care (13.3%) and other district (community) health care (19.1%) (Table 3.3) (Armeni et al., 2021). These values are used to allocate funding to the regions without, however, binding them to maintain such allocations. Regions are, in fact, free to reallocate the funds received within different programmes and to assign spending duties to local health authorities (as long as they adhere to delivering the national benefits package). In fact, while the central government regulates the national benefits package for citizens and controls the distribution of tax revenue, each region is individually responsible for the organization and delivery of services within its jurisdiction.

Each region has its institutional and organizational structure and thus determines the flow of resources within the system. The most common arrangement entails two main types of SSN organizations: local health authorities and hospital trusts (see Chapter 2). Local health authorities are generally funded according to a capitation formula while independent public hospitals and private-accredited providers can be funded either directly by the region or by local health authorities according to a mix of per-case payments (Italian DRGs), fee-for-service (outpatient specialist care) and budget lines (fixed amounts of resources for specific duties or activities such as emergency care or organ transplantation services).

3.3.4 *Purchasing and purchaser–provider relations*

Regions differ in the purchasing models they implement. Some regions operate mainly integrated models (with hardly any purchaser/provider split) while others lean towards a more de-integrated model, with the extreme case of Lombardy where local health authorities (called health protection agencies, ATS) almost exclusively are purchasing organizations. Here we briefly discuss two examples in northern and affluent regions – Veneto (capital: Venice) and Lombardy (capital: Milan) – which operate integrated and contracting models respectively (Garattini et al., 2021; Bobini et al., 2020; Fattore, Numerato & Salvatore, 2022).

The Veneto regional health system serves around 5 million people and is structured into nine local health authorities which are divided into districts (26) where all community care services are delivered to patients. All but three SSN hospitals are run by local health authorities: the two largest general teaching hospitals and a specialized oncology hospital are independent organizations

with their own senior managers. Hospital care is organized according to three tiers (hub, spoke and nodes), with the aim of ensuring continuity of care and promoting integration among different services. Administratively, the Veneto Region has consolidated several functions into a central operating agency to achieve economies of scale (Authorities Zero). Its activities include public procurement, regional labour contracts, HTA, capital planning, negotiations with private providers and clinical governance initiatives. Regional DRGs and fee-for-service schedules are used to allocate budgets within the local health authorities and to fund the three independent SSN hospitals as well as the few private-accredited providers operating in the region. The Veneto Region's health system has been defined as "hierarchical" and benefits from the high level of technical and policy expertise of its bureaucracy (Bobini et al., 2020).

Since the late 1990s, the Lombardy Region has adopted a quasi-market approach for the delivery of hospital and outpatient care. In 1997 a major reform created a clear purchaser–provider split, strengthened patient's freedom of choice of providers and fostered market competition, especially between public and private-accredited providers (Garattini et al., 2021). Currently the regional health system serves about 10 million people. It consists of nine health protection agencies that are in charge of purchasing virtually all services from 27 SSN delivery organizations, each one with its own territorial jurisdiction, three IRCCSs, 29 accredited private hospitals and several accredited providers for community care. While the region is acknowledged as having an excellent hospital network, also evidenced by the high number of patients from other regions admitted to Lombardy's private and public hospitals, the health system has also come under scrutiny by the central government for some features of its model that depart from national legislation. Moreover, a report released by AGENAS highlighted the excessive fragmentation of the governance system and recommended that the Lombardy Region strengthen the district organization of community care, clarify the roles of health protection agencies and reduce the number of SSN organizations acting in the system.

The reform of the regional health system was approved in December 2022 (Regional Law 22/2021). It transposes some of AGENAS recommendations, mainly to strengthen the role of community care, but leaves the fundamentals of the system substantially unchanged. In Lombardy's regional health system, DRGs, fee-for-service schedules, and other mechanisms of funding related to sets of activities or care volumes play a larger role than in the Veneto Region due to the purchaser–provider split which is virtually complete in Lombardy

and exists only to a modest extent in Veneto.[7] In addition, in Lombardy a higher share of the market is taken by private-accredited providers and the region emphasizes the role of patients' choice. Nevertheless, over time the health protection agencies have increasingly engaged in targeted negotiations with both public and private-accredited providers over payments.

3.4 Out-of-pocket payments

As noted in section 3.1, in 2019, the public share of funding for health care was 73.9%, with the remaining 26.1% of health spending coming from private sources.[8] Of the share of private expenditure, OOP expenditure (i.e. cost sharing and direct payments) accounted for 23.3%, with the rest coming from VHI (2.1%), payments made by companies (e.g. occupational medicine, 0.5%), and services offered by non-profit entities (e.g. health care for undocumented migrants, 0.2%).

Until 2019, private expenditure had grown over time, both in absolute terms (from EUR 34.4 billion in 2012 to EUR 40 billion in 2019) and in relation to total health expenditure (from 21.5% in 2010 to 26.1% in 2019). In particular, OOP expenditure steadily increased from EUR 31.5 billion in 2012 to EUR 35.8 billion in 2019, reaching a peak of 36.1 billion in 2018. This growing trend was interrupted in 2020, when OOP expenditure by households dropped to EUR 33.9 billion (Del Vecchio et al., 2021).

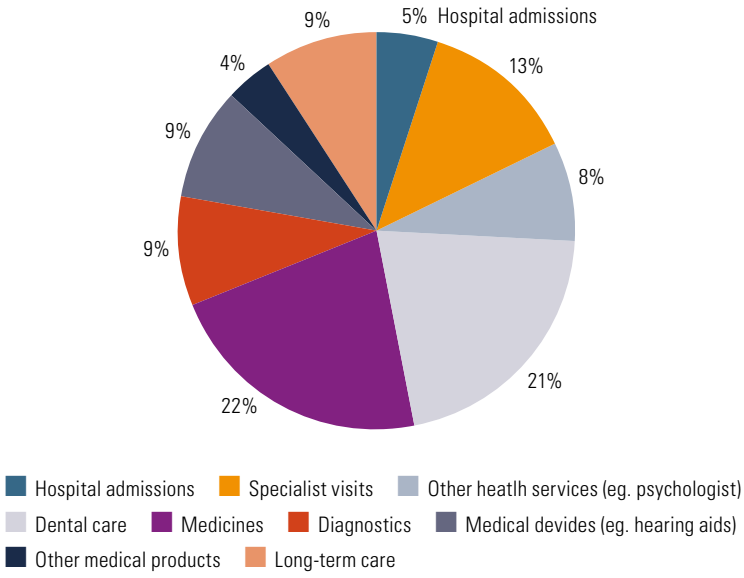
Tax deductions may be an incentive for people to use services that incur OOP payments, since 19% of medical expenses exceeding the ceiling of EUR 129.11 incurred in the previous year can be deducted from personal income tax (IRPEF). In 2019, 46% of taxpayers benefited from tax deductions related to health care costs (Del Vecchio et al., 2020). However, it is also worth noting that in Italy OOP expenditure is mainly borne by households directly rather than through other forms of expenditure brokered by third-party payers – for example, VHI purchased by individuals or companies for their employees (see section 3.5).

7 In Lombardy DRGs are the main source of funding of providers while in Veneto DRGs are only used to fund the three independent SNN hospitals and accredited providers, as well as to compensate for the mobility of patients across jurisdictions.

8 Due to methodological differences, national data for 2019 report slightly different figures of 74.2% and 25.8%, respectively.

Figure 3.6 provides a more detailed breakdown of private health expenditure by function. Total private health expenditure (in 2019) was made up of 65% of spending on services, divided between hospital services (14.3%, including hospital admissions and long-term care) and outpatient services (50.7%), of which dental care represents the predominant component (21.2%), followed by specialist visits (13.2%). The remaining 35% is devoted instead to health care goods: medicines (22%), therapeutic equipment (9%, of which eyeglasses, contact lenses and hearing aids make up the bulk) and other medical products (4%). All these components showed a reduction in 2020 (–9% for hospital service, –6% for outpatient services, –1% for health care goods) (Del Vecchio et al., 2021).

FIG. 3.6 Composition of private health expenditure by expense item, 2019



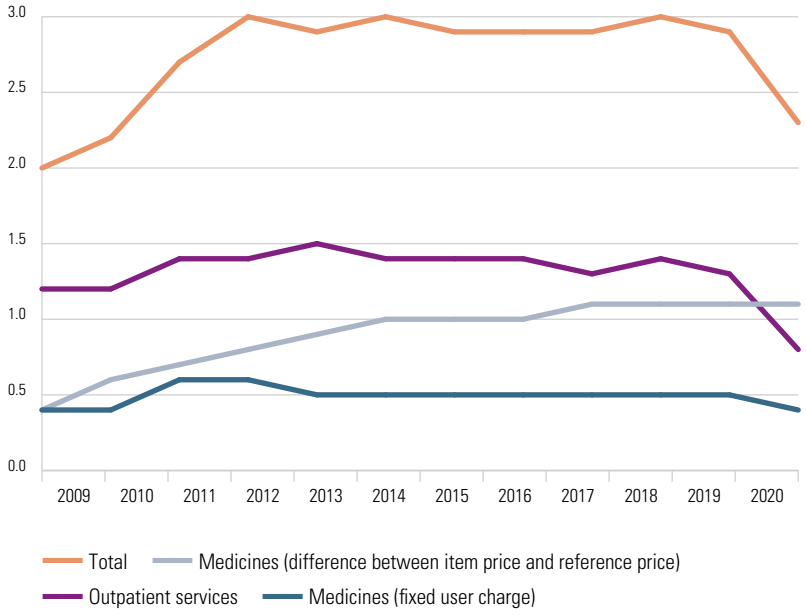
Source: Del Vecchio et al., 2020.

3.4.1 *Cost sharing (user charges)*

In Italy, co-payments are made up of two broad categories: 1) co-payments for *goods* (i.e. medicines) and 2) co-payments for *services* (e.g. outpatient specialist services, some laboratory and diagnostic tests, and non-urgent access to emergency care). The cost sharing for medicines is further divided into: 1) a fixed amount user charge (known as the "ticket") per package, which is set by regions, and 2) the difference between the market price and the reimbursement price for off-patent medicines (i.e. internal reference pricing). There are several exemption categories (e.g. by age or income level) but no overall annual cap on co-payment spending or other major financial protection mechanisms. Primary and inpatient care are totally free at the point of use for everyone (Table 3.3).

In 2019, the level of co-payment spending was estimated at EUR 2.9 billion and has been stable both in absolute terms and as a percentage of household consumption expenditure between 2009 and 2019, despite the introduction of an additional user fee of EUR 10 (with regional variations) charged on specialist outpatient services between 2011 and September 2020 (known as the "super ticket"). The only relevant growth concerned the revenues deriving from internal reference pricing differences, which increased from EUR 0.4 billion in 2009 to EUR 1.1 billion to 2017 (Del Vecchio et al., 2020). This data suggests that policies aiming to incentivize the prescription and use of generics were not so effective in deterring the consumption of branded drugs, with a consequent increase in the financial burden on households. In 2020, the level of co-payment spending dropped to EUR 2.3 billion. This was particularly evident for outpatient services (from EUR 1.3 billion in 2019 to EUR 0.8 billion in 2020), and in line with the overall trend of the other private expenditure components (Del Vecchio et al., 2021) (Fig. 3.7).

FIG. 3.7 Cost sharing expenditure in Italy, 2009–2020



Source: Del Vecchio et al., 2020; 2021.

COST SHARING FOR REIMBURSABLE MEDICINES

Cost sharing for reimbursable medicines (Class A) includes two different forms of payment. The first component ("ticket") is a fixed user charge per package (or per prescription) set by the regions. In 2000, all forms of patient contributions to pharmaceutical expenditure were abolished at the national level, so medicines are categorized as either totally free (Class A) or paid for in full (Class C). However, most regions introduced a user charge system for Class A medicine purchases, which generally consists of a fixed amount per package, although variations do occur. For example, in some regions, the amount of the user charge per pack increases according to family income, while in others it is adjusted to the cost of the medicine and whether the generic (lower cost) or the branded medicine (higher cost) is prescribed. Some regions also apply a fixed amount to be paid per prescription which is added to the amount per package (e.g. Basilicata) or a maximum amount to be paid for each prescription (e.g. Lombardy), or both (e.g. Puglia). Regions also specify

exempted categories; in some cases, these categories also pay a user charge, but a lower amount (partial exemption). Lastly, there are regions that do not apply any user charges on medicines or have progressively reduced or abandoned them. For example, in 2019, Emilia-Romagna abolished the "super ticket" for households with income below EUR 100 000 and also abolished co-payments on first visits for families with two or more children; similarly, Piedmonte abolished the "ticket" following other regions, such as Friuli-Venezia Giulia, Marche and Sardinia.

The second component of cost sharing for medicines is internal reference pricing, which consists of asking the patient to pay the difference between the branded medicine price and the lowest price among all the equivalent drugs available in the regional market. The defining feature of this type of cost sharing is that the payment derives from consumer choice, in cases where individuals prefer to buy a branded drug, or from physician choice, in cases where the doctor indicates that the medicine should not be substituted on the prescription. A few regions (Liguria, Veneto, Bolzano, Molise, Calabria, Sicily) have also established restricted exemption categories (e.g. war invalids, victims of terrorism) which do not pay the price differential.

COST SHARING FOR OUTPATIENT SERVICES

The services for which co-payments are required are: 1) specialist visits, and diagnostic and laboratory exams provided by public and private providers; 2) non-urgent access to emergency rooms (known as "white codes"), only if the attendance is not followed by hospital admission; and 3) thermal therapies (See also Table 3.5).

Conversely, cost sharing is not applied to: 1) diagnostic and laboratory exams included in early diagnosis and collective prevention programmes organized by regions (e.g. HPV testing for cervical cancer screening); 2) diagnostic and laboratory exams performed during epidemics to protect collective health (e.g. nasal swabs for the diagnosis of COVID-19); 3) GP and paediatrician visits and examinations; 4) treatments provided during a hospital stay, including admissions to rehabilitation wards or post-acute long-term care facilities, and the examinations strictly and directly connected to the planned hospitalization and previously provided by the same hospital (e.g. visit with the anaesthetist, electrocardiogram, etc.).

Moreover, co-payments are not levied on services provided in situations of particular social interest, such as: 1) maternity care; 2) preventing the spread of HIV, limited to ascertaining the state of infection in individuals belonging to categories at risk; 3) promotion of blood, organ and tissue donations, limited to services related to the donation activity; 4) protection of individuals injured by irreversible complications due to compulsory vaccinations, transfusions and administration of blood products; and 5) vaccinations included in the National Vaccine Prevention Plan for individuals identified as recipients.

In the area of cancer prevention, the following examinations can be received without co-payment: mammography, every 2 years, for women aged between 45 and 69 years; cervical-vaginal cytological examination (Pap smear), every 3 years, for women aged between 25 and 65 years; colonoscopy, every 5 years, for the population aged over 45 years. In addition, HIV tests are anonymous and free in public facilities.

TABLE 3.5 User charges for health services, 2022

HEALTH SERVICE	TYPE OF USER CHARGE IN PLACE	EXEMPTIONS AND/OR REDUCED RATES	CAP ON OOP SPENDING	OTHER PROTECTION MECHANISMS
Primary care	None	N/A	No	N/A
Outpatient specialist visits and selected diagnostic services	Fixed regional co-payment per prescription	Full exemptions: children over 6 or adults over 65 in households with low income (<EUR 36 000). Partial exemption: chronic or rare diseases, invalidity, other special situations (e.g. pregnancy)	Co-payment is equal to the service fee, up to the maximum limit of EUR 36.15 per prescription	Up to eight different services within the same specialist branch can be included in a single prescription, except for physiotherapy services
	Laboratory and diagnostic services	Full exemptions: children over 6 or adults over 65 in households with low income (<EUR 36 000). Partial exemption: chronic or rare diseases, invalidity, other special situations (e.g. pregnancy)	Co-payment is equal to the service fee, up to the maximum limit of EUR 36.15 per prescription	Not applied to services related to prevention or screening, public health emergencies, tests related to primary care or hospital care, or for certain social priorities (supporting pregnancy, organ donation etc.)
	Non-urgent access in emergency care	Exemptions: • all those listed above plus children under 14 • admissions for acute cases	No	Only in cases with no subsequent hospital admission
Outpatient prescription medicines	Fixed regional user charge per prescription or package	Regional rules. Not all regions apply co-payments	No	–
	Internal reference pricing	None	No	–
Inpatient stay	None	N/A	N/A	N/A
Dental care	Fixed regional co-payment per prescription	Exemptions: children over 6 or adults over 65, low income, chronic or rare diseases, invalidity, other special situations (e.g. pregnancy)	No	–
Medical devices	None	N/A	N/A	N/A

Note: N/A: not applicable; OOP: out of pocket.

Source: Authors' compilation

In general, for all health services that do require a co-payment, patients are entitled to an exemption (for some or all services) in the following cases: 1) particular income situations associated with age or social condition; 2) people affected by certain chronic or rare conditions; 3) recognized disability status; and 4) other (e.g. pregnancy, early diagnosis of some cancers, HIV detection) (Ministero della Salute, 2021c). These are summarized in Table 3.6.

TABLE 3.6 Exemption categories for user charges

EXEMPTION CATEGORY	GROUPS	APPLICATION
1) Income situation	(1a) children under 6 and adults over 65	Family income below EUR 36 151.98 (EUR 38 500 in Lombardy)
	(1b) unemployed and their family members	Family income below EUR 8 263.31
	(1c) social pension recipients and their family members	–
	1d) minimum pension recipients aged over 60 and their family members	Family income below EUR 8 263.31
2) Chronic or rare conditions	For rare diseases, includes more than 110 individual or group diseases	All services aimed at diagnosis, treatment and monitoring of the rare disease, as well as genetic examinations on family members
	For chronic conditions, six additional pathologies were added in 2017: chronic obstructive pulmonary disease, chronic osteomyelitis, chronic kidney disease, autosomal dominant polycystic kidney, endometriosis, thalidomide syndrome	For most conditions, a series of specific services which are deemed appropriate and effective for the purpose of monitoring the evolution of the disease and its complications
3) Disability status	Four categories, each including various subcategories or degrees of invalidity: (3a) war disability (3b) work disability (3c) public service invalids (only for army, police and fire brigade); (3d) civil invalids (also including children under 18; people who are blind, deaf or mute; victims of terrorism and organized crime and their family members)	–
4) Other	Various, including services related to pregnancy, early diagnosis of some cancers, HIV detection	–

Source: Authors' compilation.

COST SHARING FOR NON-URGENT EMERGENCY CARE

Co-payments (of varying amounts depending on the region) are levied for interventions provided by emergency rooms to patients classified as "white codes" (i.e. non-urgent services, patients with non-critical conditions) not followed by hospitalization. For this co-payment the same exemption rules as outpatient specialist services apply with the addition of children under 14 years (Table 3.5).

3.4.2 *Direct payments*

Direct payments refer to payments by users to purchase health care services and OTC medicines that are not covered by the SSN. Given that in 2019, the level of co-payment spending was estimated at EUR 2.9 billion, out of a total OOP expenditure (i.e. co-payments and direct payments) of EUR 35.8 billion (section 3.4.1), it is clear that the overwhelming majority (92%) of OOP spending in Italy is attributable to direct payments (EUR 32.9 billion).

3.4.3 *Informal payments*

There is no evidence of informal payments in Italy.

3.5 Voluntary health insurance

Based on ISTAT estimates, expenditure on VHI was about EUR 3.3 billion in 2019, up from EUR 2.9 billion in 2018. However, only 58% of this value (EUR 1.9 billion) directly financed the health care system, as the remaining EUR 1.4 billion went to profits and administration (e.g. collection of contributions, selection and bargaining with suppliers, reimbursement procedures) (Del Vecchio et al., 2020). The estimates for 2020 (EUR 3.2 billion) remained almost unchanged (Del Vecchio et al., 2021).

Over 20% of Italians are covered by an insurance scheme or a company fund. However, the percentage of health care goods and services paid through VHI reimbursement is still marginal (around 2%) but growing over time (e.g. in 2018, 6% of specialist visits were covered by VHI, versus 3% in 2013).

Consequently, the average private health insurance policy has limited scope (Del Vecchio et al., 2020).

In Italy, there is no option to opt out of the public, universal scheme of health coverage; therefore, substitutive insurance schemes do not exist (as in Germany, for example). Instead, there are entities providing financial coverage for a series of services that are not covered by the public system (complementary insurance) or offering better conditions of access to the services offered by the SSN (supplementary insurance). These entities can be classified into three main types:

1. for-profit insurance companies operating in the health sector and offering individual (individually-based) or collective (employment/group-based) health care policies based on individual or group risk rating;
2. Supplementary Health Funds of the SSN (defined by Legislative Decree 502/1992 and subsequent Legislative Decree 229/1999), the so-called DOC Funds, which operate based on non-selection of risks, non-discrimination in premiums and non-competition with the SSN (but can reimburse *intramoenia* services)[9];
3. Complementary Health Funds and mutual aid companies: these are entities similar to the Supplementary Health Funds in group 2 with the main difference being that they receive fiscal benefits only if they offer at least 20% of non-LEA services.

The formal distinction between these main types of VHI is not clear-cut, since over half of the assistance funds (category 3) perform their function by purchasing collective policies from insurance companies. In the insurance health sector, collective policies account for 75% of total premiums, of which 82% are related to the reimbursement of medical expenses. In addition to collective policies, there are also premiums for individual policies, which do not enjoy tax benefits (unless the policy also covers the risk of accidents) (Del Vecchio et al., 2020).

Italian legislation provides three forms of fiscal support for supplementary health care. The first allows contributions paid to SSN Supplementary Health Funds to be deducted from total taxable income, up to a ceiling of EUR 3 615.20. The second states that contributions paid by workers or

9 *"Intramoenia"* refers to services provided outside normal working hours by hospital doctors, who use the hospital's outpatient and diagnostic facilities and receive payment by the patient.

employees to entities and funds with exclusive health assistance purposes do not add to income from employment, up to a limit of EUR 3 615.20. The third allows the tax deduction of 19% of contributions paid by companies to mutual aid companies up to a maximum of EUR 1 300. In 2019, resources collected in the form of direct premiums (for collective and individual policies) amounted to EUR 3.1 billion (National Association of Insurance Companies – ANIA data). The health sector has the highest loss ratio (i.e. ratio between claims and premiums) in the insurance industry, with 70% of resources collected though premiums which resulted in reimbursements of various types in 2019, and up to 79% for reimbursements of medical expenses (Del Vecchio et al., 2020).

3.6 Other financing

In Italy, there are only a few additional sources of financing, mainly for the military (public), for delivering care to undocumented migrants (private and public – funded by the Ministry of the Interior) and for investments (mainly EU and national funds).

3.6.1 *Parallel health systems*

There is no parallel health system providing services for certain categories of employees and public officials. The only exception is the military health care system (Military Health), which provides care to the military or civil personnel in training and operations of the Ministry of Defence, their families, and, occasionally, also to the general community. In particular, Military Health is in charge of prevention, diagnosis and treatment of diseases, trauma, injuries and neuropsychiatric disorders related to the military profession. The process of rationalizing and reducing the costs of military health care started in 2012 and is still in progress. The number of employees and costs (especially for the army) has gradually decreased. In the near future, the system is expected to implement other reforms, including more collaboration and synergies with the SSN (Corte dei Conti, 2022).

3.6.2 *External sources of funds*

Minimal external funding comes from bilateral/multilateral organizations or donations, mainly for providing services to undocumented immigrants. Italian regions can apply for European Structural Funds for capital investments, human development and cross-border cooperation within the health care sector. For example, the European Fund for Regional Development (FESR), among other purposes, aims to integrate migrants and asylum seekers through investments in social care, health care, education, housing and childcare. In the period 2014–2020, Italy obtained EUR 34.45 billion from the FESR, of which EUR 22.47 billion was the EU contribution and EUR 11.98 billion the national one (Ministero dell'Economia e delle Finanze, 2020). Moreover, Italy attracts some (competitive) international grants from the European Commission (e.g. from the research and innovation funding programme Horizon 2020) for specific research projects in health care.

3.6.3 *Other sources of financing*

While in the past private donations were an important funding source for the construction of hospitals and other health care facilities, they are no longer very common. However, the SSN and private organizations may receive cash or in-kind assets from individuals, mainly through bequests, or from private companies, as donations. As the SSN does not cover primary care and other services for undocumented migrants, a few private non-profit organizations (e.g. the Italian Red Cross) do so. These organizations are funded from external sources (e.g. the general public, corporations) and the government, mainly through taxpayers choosing to allocate a small share of their taxes to specific organizations (known as the *5 per mille*).

3.7 Payment mechanisms

3.7.1 *Paying for health services*

In Italy, different payment mechanisms apply to different health care activities, as summarized in Table 3.7. The regions or local health authorities pay for all providers' services, with few exceptions. For example, the research activity of IRCCSs is financed by the Ministry of Health. The remuneration system follows the rules established at regional level within the regulatory framework defined at national level to ensure homogeneity. The system was initially established by the health care reform of 1992, which introduced prospective payment based on fee-for service schedules and DRGs.

As a general rule, there are three main types of payment methods to fund SSN organizations and accredited providers. The first type is per capita funding that is used for local health authorities. Depending on regional policies, per capita funding can be adjusted depending on population age structure and other criteria, like population density or altitude. The second type of payment method is volume-based. Different fee-for-service, DRGs and day rates (for example for health services in nursing homes or rehabilitation units) are used to compensate providers (see Table 3.7). Finally, SSN organizations and, to a lesser extent, private-accredited providers, receive funds according to several specific budget lines. This latter funding type is generally used to compensate providers for specific activities that are not well captured by the fee-for-service and DRG models (e.g. ambulance services). They are also used to adjust funding according to past expenses and other policy objectives (e.g. to fund innovative projects). SSN organizations and private-accredited providers are also fully reimbursed for very expensive drugs with no caps used for hospitalized patients or directly delivered to patients by their own pharmacies (this line of expenditure is called *file F*).

TABLE 3.7 Provider payment mechanisms

PROVIDERS	PAYERS AND PAYMENT MECHANISMS	
	Ministry of Health	Regional health service and/ or Local Health Authority
GPs	–	C + FFS
Specialist ambulatory care	–	FFS + BL
Other ambulatory care	–	FFS + BL
Acute hospitals	–	Case payment (DRG) + BL
Other hospitals [a]	IRCCs (for research)	PD +BL
Hospital outpatient	–	FFS + BL
Dentists	–	FFS
Pharmacies	–	Margins proportional to the selling price
Public health services	–	C + BL
Social care	–	PD (only for health component)

Notes: BL: budget lines; C: capitation; DRG: diagnosis-related group; FFS: fee-for-service; GP: general practitioner; IRCC: Institutes for Care and Scientific Research; PD: per diem.
[a] Non-acute care hospitals (e.g. community hospital, rehabilitation units).

Source: Authors' own compilation.

The 1992 national health reform legislation strengthened patients' free choice of providers, including private-accredited ones, and introduced per-case and per-unit-of-service funding for hospital care and outpatient care, respectively. To sum up, all-inclusive tariffs are predetermined for each individual service. There are three types of tariffs:

1. National tariffs, established periodically by the Ministry of Health together with the Ministry of Economy and Finance with the support of the Permanent Commission for Tariffs, made up of representatives of said ministries, the State-Regions Conference, as well as AGENAS.
2. Regional tariffs, established periodically by the regional health departments according to their own policies, in line with the national regulatory framework. Regional tariffs cannot be higher than national ones. If regions adopt higher tariffs than those reported in the national nomenclatures (i.e. comprehensive lists of possible services with their relative tariffs), the difference is charged to regional budgets. Regional tariffs can be divided

into classes of providers (e.g. public versus private providers or entities with or without emergency departments) defined on the basis of organizational and activity characteristics, modulated to promote the appropriateness of services and de-hospitalization processes; they can also provide additional remuneration for the costs associated with the use of specific high-performance devices;

3. For hospital activities only, since July 2003, tariffs used for the "compensation of interregional mobility" (known as TUC tariffs) are agreed annually in the State-Regions Conference. Given the high flow of patients across regions (Fattore, Petrarca & Torbica, 2014), the 2014–2016 Health Pact states that regions should make bilateral agreements to regulate interregional mobility in order to reduce it for activities that can be delivered in the patient's region of residency.

The criteria for determining tariffs are defined by law at national and regional level and are required to reflect costs according to adequate efficiency levels and comply with the constraints dictated by the overall financing levels of the SSN. In addition to tariffs, local health authorities, SSN hospitals and private-accredited providers are funded according to specific budget lines. These may apply to a variety of services, including running emergency departments, tissue and organ banks, and specific projects. In general, providers, especially government-owned ones, receive an important share of resources from specific lines of funding that are not volume-related and are often justified, implicitly or explicitly, based on past costs (Fattore & Torbica, 2006).

The health services for which tariffs are determined at national level, in order to ensure homogeneity between regions, are: 1) acute hospital care (DRG system); 2) outpatient specialist services; and 3) prostheses (Ministero della Salute, 2020a).

TARIFFS FOR INPATIENT CARE (DRG SYSTEM)

In 1995 the central government introduced the use of a prospective per-case financing of hospitals. The legislation adopted the diagnosis-related group (DRG) system used by Medicare in the United States to classify hospitalizations and identify tariffs for ordinary admissions, day hospital and day surgery

(Fattore & Torbica, 2006). Since 1 January 2009, version 24.0 of the Medicare DRG system has been used for acute hospital care provided by public and private-accredited hospitals. This version includes 538 valid groups; of these, 44% are surgical. DRGs groupings and tariffs are sporadically updated at national level and more frequently at regional level (Ministero della Salute, 2020b).

The tariff is an all-inclusive remuneration of the treatment profile, on average associated with a type of hospitalization, and may also reflect health planning policies aimed at encouraging the therapeutic and/or organizational methods considered most effective and appropriate (e.g. day hospital) and at discouraging those deemed inappropriate. Current inpatient tariffs were defined based on: the results of the 2011 national study on the costs of DRGs and the level of complexity and severity of the cases treated in the 41 hospitals included; health planning guidelines which promote a significant reduction of inappropriate hospital admissions; the need to ensure compliance with budget constraints and the current macroeconomic situation; OECD data indicating room for improvement in production efficiency in SSN hospitals; and the tariff values in force at regional and interregional level.

Each region and autonomous province are required to determine its own tariffs, within the maximum tariffs established by the Ministry of Health. The objective is to reduce interregional variability. The regions establish their tariffs based on the costs incurred by a sample of regional public and private providers with acceptable levels of efficiency. The TUC tariffs are used for the compensation of interregional hospital mobility. These tariffs are DRG-specific and are established at national level (Fattore, Petrarca & Torbica, 2014).

TARIFFS FOR OUTPATIENT SPECIALIST CARE

Reimbursement for outpatient specialist care, diagnostic imaging and laboratory exams is based on tariffs defined by the unit of service. The first nomenclature of outpatient specialist care, dated 1996, reported a list of specialist outpatient services provided by the SSN. This nomenclature is not revised on a regular basis. The following one (introduced in 2012) reported the corresponding national tariffs based on a full costing approach. The new nomenclature, introduced in 2017, eliminated services that were obsolete, and included new ones and added services that, due to technological advancements, are now safely deliverable in outpatients settings. The most relevant additions

were medically assisted reproduction, genetic counselling and interventions with high technological content (e.g. hadrotherapy). However, tariffs to be paid to (public and private) providers for these services have yet to be published.

TARIFFS FOR PROSTHESES

As for outpatient care, the new nomenclature for prosthetic assistance services, introduced in 2017, replaced the nomenclature that was in place since 1999; however, tariffs are still being defined. The SSN guarantees the provision of prostheses, orthoses and technological aids to persons recognized as disabled or awaiting recognition of disability. The main changes introduced in 2017 by the Italian Government (Consiglio dei Ministri, 2017) include: expanding the list of new recipients (i.e. people suffering from some rare diseases and those assisted in integrated home care); adding new devices (e.g. digital technology hearing aids); stressing the importance of quality (the descriptions of the aids include innovative components and construction quality criteria); and less bureaucracy (simplified language in identifying aids and streamlined supply procedures).

OTHER HEALTH CARE SERVICES

Tariffs for services provided by intermediate care facilities (e.g. community hospitals, hospices and rehabilitation centres) are still to be defined in agreement with central government, regions, and the Permanent Commission for Tariffs (Presidenza del Consiglio dei Ministri, 2020). Currently, regional tariffs are applied (for example, in Veneto, an all-inclusive daily tariff of EUR 145 is paid to virtually any provider) (Regione Veneto, 2019).

Paying for long-term care and residential or semi-residential services, where health care and rehabilitation are provided, is based on cost sharing between the patient and the municipality of residence with important variations across regions and even municipalities. For long-term care there is a universal cash benefit scheme (of EUR 522 per month in 2021) for disabled people, called the *Indennità di accompagnamento*, along with regional funds (with large differences) and municipality contributions. The level of cost sharing is generally determined by patient income. The health share is fully covered

by regional or local health care authorities and is defined on a daily basis (see also section 5.8). The Italian National Recovery and Resilience Plan commits the country to establishing a national long-term universal scheme that re-composes all the fragmented sources of funding for social care.

REMUNERATION OF PHARMACIES

The remuneration of community pharmacies (for medicines reimbursed by the SSN) is based on proportional margins in relation to the selling price. According to the latest legislation (Law 122/2010), margins for wholesalers and pharmacists are equal to 3.00% and 30.35%, respectively. Moreover, since 1997, there has been a progressive discount ranging from 3.75% to 19.00% according to the drug price bracket. There is also a further discount on the final price of the medicine, which has been equal to 2.25% since 2012 (Law 135/2012).

Law 122/2010 also provided for a radical reform of the remuneration of pharmacies, establishing that it should be based on a fixed amount in addition to a reduced percentage of the drug's reference price. An agreement between the Italian Medicines Agency (AIFA) and pharmacies associations was stipulated in October 2012 but not approved by the national government, and the deadline for the introduction of the new remuneration system has been postponed several times. At the time of writing, almost a decade later, there is no permanent agreement in place.

An additional remuneration for pharmacists, equal to EUR 50 million for the year 2021 and EUR 150 million for 2022, was introduced on an experimental basis, starting from 1 September 2021 (Legislative Decree 41/2021). The new remuneration system should progressively enhance the professional role of pharmacists, based on the services provided to citizens and only partially linked to medicine prices. Indeed, the decree has introduced an extra fixed remuneration of EUR 0.08 for each medicine package (EUR 0.12 for generics).

3.7.2 *Paying health workers*

PRIMARY CARE DOCTORS

General practitioners (GPs, or *medici di medicina generale*) and family paediatricians (*pediatri di libera scelta*) are independent professionals with a special contract with the SSN to provide basic health care for adults and children under 14 years of age, respectively. Their remuneration is mainly based on capitation. The maximum number of patients on each doctor's list is 1 500 for GPs and 800 for paediatricians, but many doctors exceed these numbers. Fee-for-service remuneration also applies for some services (e.g. home visits).

Remuneration of GPs is divided into the following (ACN, 2022):

- A per capita amount, defined and negotiated at national level. It is an annual flat-rate fee (EUR 41.32) paid to GPs for each patient. For each patient under 14 or over 75, an additional flat-rate fee is paid (of EUR 18.95 and EUR 31.09, respectively).
- A variable amount (defined at national level and negotiated at regional level) aimed at carrying out specific activity programmes for the promotion of clinical governance, the development of initiative medicine and the care of patients suffering from chronic disease.
- A fee-for-service (mainly home care, *Assistenza Domiciliare Integrata* and *Assistenza Domiciliare Programmata*), defined at national level and negotiated at regional level.
- A share of the corporate fund for production factors (defined at national level and negotiated at regional level) including fees for associative activities and allowances for IT, the employment of a study collaborator and nursing staff or other health professionals.
- A fee for further activities and services (defined and negotiated at regional level), such as essential levels of assistance other than primary assistance, as well as for carrying out the activity in areas identified by the regions as extremely disadvantaged or disadvantaged.

Currently, the annual mean gross salary of GPs is about EUR 105 000 (approximately EUR 4 600 net per month), 197% higher than the average monthly salary in Italy. Of course, salary is higher for GPs with more patients on their lists.

The remuneration of paediatricians is structured in the same way. The per patient amount is EUR 86.31. An additional fee (EUR 17.93) is paid for each child under the age of 6 because of the additional workload related to early childhood programmes (neonatal and paediatric patient pathways).

HOSPITAL DOCTORS

All health care professionals working in public facilities are remunerated according to the National Collective Labour Agreement (CCNL) – Health, negotiated between trade unions and the government, and reviewed every 3 years (the latest refers to the 3-year period 2016–2018). The CCNL defines monthly salaries, performance-related payments, extra fees (e.g. for night duty or risk indemnity), annual leave, other permitted leave (e.g. for family reasons), illness, resignation and dismissal. The average gross salary of a physician is about EUR 75 000 per year (approximately EUR 3 400 net per month), 119% higher than the average monthly salary in Italy. Annual salary significantly increases according to seniority (from EUR 24 000 during the training period to over EUR 100 000 for chief physicians) (Jobbydoo, 2021).

Physicians working in the public sector are also allowed to practice privately, earning extra-income on a fee-for-service bais. The freelance work performed within the hospital of employment (also called intramural or *intramoenia* activity), is regulated by law and refers to services provided outside normal working hours by using the hospital's facilities, and receiving payment from patients, with a fee withheld by the hospital. Law 189/2012 promoted *intramoenia* activity through the creation of ad hoc facilities within public hospitals, the activation of telematic network infrastructure, the setting of adequate tariffs to remunerate professionals and support staff (defined at local level), setting pro-rata costs for depreciation and maintenance of equipment and to ensure the coverage of all direct and indirect costs incurred (Ministero della Salute, 2021d).

OTHER HEALTH PROFESSIONALS

Most personnel working in the SSN (administrative staff, nurses, pharmacists, psychologists) are employees paid on a salary basis with contracts similar to those for physicians. Their remuneration tends to be lower than those of medical doctors. For example, nurses' average gross salary is about EUR 26 400 per year (approximately EUR 1 450 net per month). Higher compensation (up to EUR 2 300 net per month) applies if they are at the end of their career and/or hold a position of higher responsibility (e.g. nursing coordinator).

Most dentists work in the private sector (i.e. clinics or practices), with variable but generally high profits depending on seniority and job title. For example, a freelance dentist working in a dental practice earns up to EUR 4 000 net per month. Conversely, dentists working in the public sector have salaries that are comparable to those of physicians (about EUR 3 000 net per month).

Some medical specialists (so-called *Sumaisti*) have a particular contract with the SSN. They are independent professionals who operate in SSN outpatient facilities and are paid according to the actual number of hours they work.

PROFESSIONALS AND OTHER WORKERS IN THE PRIVATE SECTOR

Doctors and other health professionals working for private organizations have their own contracts. Typically, there is a larger variation in remuneration, with some doctors (especially surgeons) being paid at much higher salaries than in the SSN. A free labour market applies to these personnel; contracts are regulated by agreements between trade unions and industry representatives.

SENIOR MANAGERS

Depending on regional legislation, the General Director of a SSN organization has a temporary private contract that is renewable every 3 to 5 years. Average compensation is about EUR 150 000 gross per year plus a pay-for-performance (P4P) element of about 20%. The General Director appoints the medical director, the administrative director and, depending on the region, the director for the integration between social and health care; and, in some regions, the director of health professionals (Direttore Assistenziale) who has the role of coordinating the activities of nurses and other health personnel (excluding medical doctors). They generally earn about EUR 130 000 gross per year plus about 20% P4P.

4

Physical and human resources

Chapter summary

- After a decade of substantial financing cuts, increasing investments in construction, technological modernization and training of health care professionals have been prioritized since 2018. Despite geographical imbalances, investments have been allocated to technological and scientific improvements driving quality of care, mostly for tangible assets and equipment.

- In 2019, Italy had 260 acute hospital beds per 100 000 inhabitants, with significant differences across regions. Since 2015, the national government has encouraged regions to rationalize and decrease the number of hospital facilities and in parallel increase outpatient facilities.

- The number of magnetic resonance imaging (MRI) units, computerized tomography (CT) scanners and positron emission tomography (PET) units has increased over the last decade, and Italy ranks among the countries with the highest number of units per capita in the EU.

- The shift to digital health care was greatly accelerated by the COVID-19 pandemic through governmental and private initiatives and is focused on telemedicine services.

- Overall numbers of health care professionals have only modestly increased, resulting from cost-containment choices over the past decade. With 412 practising doctors per 100 000 inhabitants, Italy's ratio is above the EU average of 393 but there are growing shortages of doctors practising in public hospitals and within primary care. With 626 nurses per 100 000 inhabitants, the density of nurses in Italy is considerably lower than the EU average (835), especially in lower-income regions.

- In terms of health worker mobility, the country has witnessed an increase in outflows, especially among young practitioners. Simultaneously, there has been an increase in inflows for certain categories of health professionals (nurses and, to a greater extent, less qualified health professional profiles) accompanied by attempts to ease the entry process to respond to workforce shortages.

4.1 Physical resources

4.1.1 *Infrastructure, capital stock and investments*

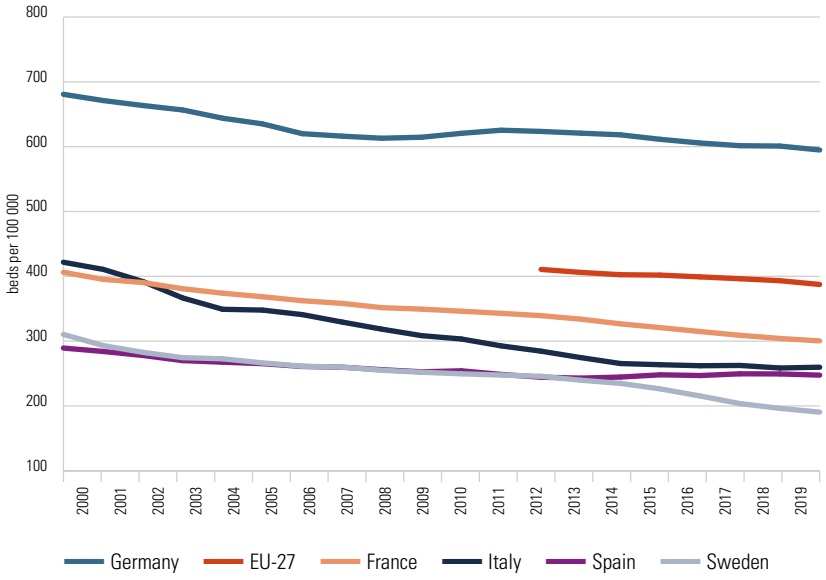
INFRASTRUCTURE

In Italy in 2017, 51.8% of health care facilities were public, while accredited private facilities accounted for the remaining 48.2%, with a high concentration in the regions of Lazio, Lombardy, Campania and Sicily (ANAAO-ASSOMED, 2020).

In 2019, the SSN had almost 190 000 ordinary hospital beds, 21.4% of which were in accredited private facilities. In addition to these, there were 12 173 day hospital beds, which are almost entirely public (83.8%), and 8 389 day surgery beds, which are mostly public (76.2%). At the national level, 0.6 beds per 1 000 inhabitants were allocated to rehabilitation and long-term care, with considerable regional variability. Following similar trends in OECD and EU countries, the number of acute beds in Italy has decreased, falling by 39% since 2000 (from 422 per 100 000 people to 260 in 2019) (Fig. 4.1; see also Table 5.1).

Such numbers result from a progressive reorganization of the hospital network in response to rising financial constraints and the search for quality improvements. With Ministerial Decree 70/2015, which set targets based on "catchment areas" and regulated hospital care standards, the government entrusted regions to identify hospitals or wards to be closed and incentivized the provision of outpatient care (see Chapter 6). However these efforts to reinforce outpatient networks of care were heterogeneous among the regions. In 2020, the declining trend in hospital beds was reversed as the number of intensive care unit (ICU) beds almost doubled in a few months due to the COVID-19 emergency.

FIG. 4.1 Beds in acute hospitals per 100 000 population in Italy and selected countries, 2000–2019



Note: Data for the United Kingdom are not available.

Source: Eurostat, 2022d.

CURRENT CAPITAL STOCK

In 2019, Italy's health care infrastructure comprised 995 hospitals, 8 801 outpatient centres, 1 145 rehabilitation facilities, and 16 270 residential and semi-residential establishments. Hospitals and outpatient care facilities are

mostly public (51.8% and 87%, respectively) whereas establishments that provide residential, semi-residential and rehabilitation assistance are mostly private for-profit and not for-profit accredited organizations (Ministero della Salute, 2020c).

Italian hospitals have a mean age of 70 years (de Belvis et al., 2012), and their sizes are as follows: 39% of inpatient facilities have less than 120 beds and only 13% have over 600 beds, with the largest hospitals exceeding 1 500 beds, mainly located in the large metropolitan areas of Rome and Milan (see Table 4.1 and Box 4.1). Generally, the smallest hospitals cover less than 14 specialties, whereas the largest ones cover at least 15 specialties.

Local health authorities provide inpatient care through their own hospitals in most cases. The rest are autonomous hospitals that may also be connected to a university (known as policlinics). Italian legislation also distinguishes 40 scientific and research institutes, Institutes for Care and Scientific Research (IRCCSs) nominated by the Ministry of Health if they meet standards of excellence in services and biomedical research (see Chapter 2). These entities, which can include hospitals, are entitled to special public funding earmarked for research. With Ministerial Decree 70/2015, Italy's health care facilities were reorganized to integrate services and reinforce networks as a means of enhancing appropriateness, effectiveness, efficiency, quality and safety of care (Box 4.1).

TABLE 4.1 Distribution of hospital facilities in Italy

TYPE OF CARE	CENTRE–NORTHERN REGIONS (per 1 000 population)	SOUTHERN REGIONS (per 1 000 population)	OUTLIER REGIONS (per 1 000 population)
Inpatient care (acute, day surgery)	From 2 to 3.4 beds	2.8 beds	–
Residential and semi-residential care (including rehabilitation)	7.3 beds	2.2 beds	1 in Sicily and 1.4 in Campania

Source: Bianchi, 2019.

BOX 4.1 The distribution of health facilities: the hub-and-spoke hospital network in Italy

Ever since Ministerial Decree 70/2015, hospitals have been arranged in hub-and-spoke networks, where 43 hubs (hospitals with over 802 beds and large catchment areas) provide the full assortment of services, with part of their patient inflow deriving from 112 spokes (hospitals with 382 to 802 beds), which are secondary settings with fewer specialties. Both hub and spoke hospitals are distributed across the country, with the majority being found in northern Italy.

REGULATION OF CAPITAL INVESTMENT

Since 2018, a new unit within the Ministry of Health dedicated to the Evaluation and Verification of Public Investments has been responsible for evaluating compliance of capital investment with national health policies and their sustainability in relation to regional economic–financial contexts. Moreover, regional autonomy allows for other sources of funding for health infrastructures, such as using ad hoc regional funds, EU funds and self-financing through hospitals or local health authorities. Health capital spending decreased significantly from 2010 to 2019, but the 2019 Budget Law and the 2019–2021 Health Pact reversed this trend by allocating EUR 4 billion for construction and technological modernization programmes.

INVESTMENT FUNDING

Public capital investment funds are assigned in the annual health budget. In 2016, Italian legislators began simplifying tendering procedures to facilitate renovation and innovation initiatives. During 2020 and 2021, the necessity to respond promptly to the demands of the COVID-19 pandemic led to procurement processes (for example, for PPE, medicines, medical devices to be used in ICUs, and vaccines) being radically shortened; this experience may lead to a permanent simplification of the system. Between 2009 and 2018,

the health care sector was also reliant on private–public partnerships to fund capital investment, with a slight decrease in this trend more recently.

Starting from 2021, the country's capital investment, infrastructural modernization and digitalization funds for the health care system are being complemented by the designated Next Generation EU budget. Reflecting stated policy priorities, the aim will be to strengthen primary and specialist outpatient services, community care and telemedicine services. Additional efforts are also being made towards the energy efficiency of public health care infrastructure with the support of EU funds, the funding under the Kyoto Protocol Convention[10] and private initiatives.

4.1.2 *Medical equipment*

The use of technical-biomedical equipment is increasing in the public sector, and Italy now ranks among the EU countries with the highest volume of MRI units, CT scanners and PET units per capita. For example, together with Cyprus and Belgium, Italy had the most imaging equipment of all EU Member States in 2018, well above the EU average (Table 4.2).

TABLE 4.2 Items of functioning diagnostic imaging technologies (MRI units, CT scanners) per 100 000 population, 2018

	ITALY	EU AVERAGE
MRI units	2.9	1.5
CT scanners	3.5	2.4

Source: ECHI, 2018.

Since 2015, the medical devices procurement process can be launched individually by facilities or via a more centralized procedure carried out by the UPCs, under regional guidelines and their decision-making support. Regions' medical devices procurement databases feed into the Regional Observatories that send the information to UPCs to manage negotiations with facilities

10 The Kyoto Protocol operationalizes the United Nations Framework Convention on Climate Change by committing industrialized countries and economies in transition to limit and reduce greenhouse gases (GHG) emissions in accordance with agreed individual targets.

(see also section 2.7.5). When awarding the call for tenders, the criteria provide for the evaluation of both quantitative (price) and qualitative elements attributable to the entire life-cycle of the equipment; the most economically valid offer is prioritized. The ongoing centralization process has been shown to hasten procurement processes, especially with larger medical devices, and to contain expenditure. However, purchasing choices appear to be more focused on price considerations than on the quality of the services or clinical benefits (Vecchi et al., 2019). Since 2014, the expenditure cap for medical devices has been set at 4.4% of a region's annual health care funding.

4.1.3 *Information technology and e-Health*

The NSIS is the SSN's primary information system to support national and regional governance, health expenditure monitoring and to guarantee the uniform application of the national benefits package (LEA) (see Chapters 2 and 6). In Italy, the services that traditionally fall under this category are single appointment centres (CUPs), which enable patients to book appointments online and by telephone; electronic health records (EHRs), electronic medical certificates, e-Prescriptions and telemedicine. Online booking and payments connected to regional platforms and EHRs are present in over 75% of facilities. Through the EHRs, citizens can trace and consult their entire health history and share it with health professionals; however, only a minority of people have heard of them. The information in each citizen's EHR is provided and managed by the regions. It is currently active in all the regions, yet its full potential still needs to be operationalized as only 21% of the population actually use it.

The National Waiting Lists Plan 2019–2021 (*Piano Nazionale Governo Liste d'Attesa*, PNGLA) requests regional CUPs, which centrally manage the timetabling of appointments of all SSN facilities, to provide online services allowing people to view and cancel appointments, pay for services, print memos and also view waiting lists in real time. In addition, IT supports over 60% of health facility activities, mostly for diagnostic imaging – particularly for radiology, tests and surgical operating rooms. Digital treatments to remotely monitor adherence to therapy are mostly used for the management of chronic diseases such as diabetes and heart failure (Sanità Digitale, 2019).

In recent years, digital health spending for electronic medical records in health care facilities has been growing (by 2% in 2017 and 7% in 2018), with the largest share being sustained by facilities and regions. Until 2019, digital innovation expenditure mostly focused on the aforementioned services, with the rest funding pilot projects. With the COVID-19 outbreak, legislative changes inserted telehealth services into the list of reimbursable services, with new codes and tariffs being issued to formally integrate remote services into the SSN. Nevertheless, the pace of innovation in this area generally has been slow (Sanità Digitale, 2019). Although the number of tenders for digital innovations has been increasing since 2016, health care companies have found the process difficult, mainly due to the rigid structure of the tendering framework and complex legislation. At the EU level, the significant resources invested with the Next Generation EU budget present an opportunity to drive the digitalization of health care processes and e-Health, with room for policy development also offered by the NRRP. The latter channels investments into the digitalization of care, further promoting the development of EHRs and telemedicine in both health care and preventive services. Box 4.2 outlines some of the barriers to innovation in this area.

BOX 4.2 Barriers to implementing innovation in the digitalization of health services

- Lack of interoperability among different regional and national systems
- Compliance with privacy and the General Data Protection Regulation (GDPR)
- Limited resources, complex implementation
- Scarce knowledge about clinical safety and effectiveness
- Scarce know-how of health care professionals (also given high average age) and patients
- Difficulty in understanding available options
- Heterogeneity in regional reimbursement schemes for telemedicine in health care
- Scarcity of managerial and governance tools (i.e. dedicated pathways, accountability, monitoring)

Source: Adapted from Agenda Digitale, 2022.

From the consumers' point of view, access to digital services, including apps and wearables, has significantly increased despite such data seldom being communicated to doctors. While Italian citizens increasingly resort to the Internet and digital tools to find health information, the opinions of GPs are still considered to be fundamental when choosing a specialist, followed by those of relatives and friends. When it comes to information on institutional websites, online opinions and reviews are considered not to be relevant (Sanità Digitale, 2019). Since the COVID-19 pandemic (2020), use of the Internet for information on pharmaceuticals/therapy, health issues, diagnoses based on symptoms and healthy lifestyles has increased, mainly extracted from institutional websites and medical portals. Apps, blogs and social networks are used mainly for information on lifestyles and nutrition.

4.2 Human resources

4.2.1 *Planning and registration of human resources*

Since 2015, the health system has strengthened the flexibility of its health workforce capacity by allowing yearly modifications to the "3-year needs assessment plans" developed by SSN providers based on their capacity, organizational models, volumes and performance goals. However, changes are conditional on them remaining budget-neutral. There is no longer-term planning within the system.

The number of students allowed to enter the courses in Medicine and Surgery, and other health professions' graduate programmes, is calculated nationally at the State-Regions Conference, based on an assessment of social and productivity needs and the capacity communicated by each university. The number of residency vacancies, in contrast, is determined every 3 years first by the regions, taking into account the employment scenario and their populations' health needs and communicated to the Ministry of Universities and Research and to the Ministry of Health. The final number is then determined by these ministries in agreement with the Ministry of the Economy and Finance, according to the SSN's capacity and that of the health facilities included in the training network by the National Observatory of Specialist Medical Training.

With funds from the NRRP, the number of medical specialization contracts for a full cycle of studies (5 years) has increased by approximately 4 200 since the academic year 2020/2021. In October 2021, the Council of Ministers approved the 2022 Budget Law, which provides for a progressive increase in the funds allocated to the contracts of doctors in specialist training. In particular, an additional expenditure of over EUR 2 billion by 2027 is forecast.

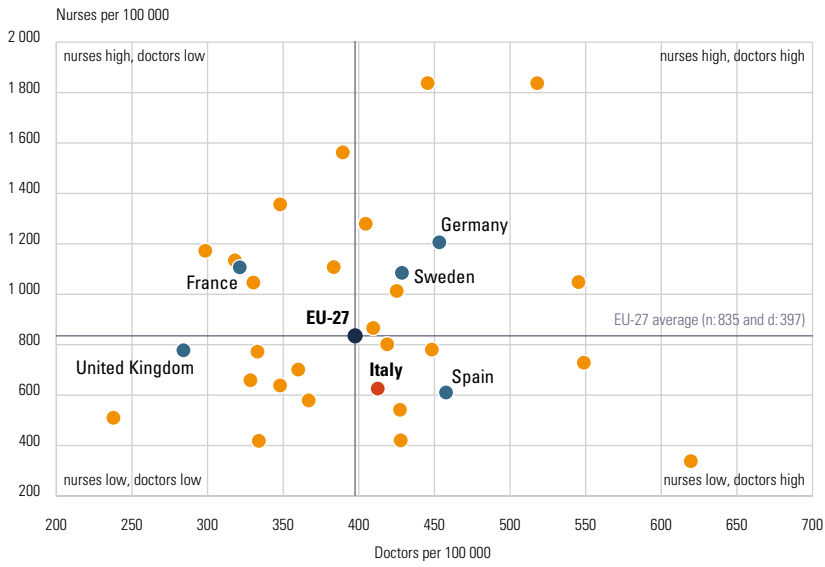
Overall, Italy has not been able to undertake comprehensive planning for the training of health professionals, especially doctors and nurses. For doctors, the main problem is the presence of inadequate planning across specialties, in some cases due to an insufficient level of training capacity (e.g. in anaesthesiology). For GPs, where the future shortage appears to be dramatic in most regions, the main problem is that they are not trained through a university specialty programme, but rather by programmes administered by each region. These programmes are not attractive due to the quality of the curricula and the lack of interest in family medicine. The latter is probably due to the status of GPs in the SSN and, more generally, to professional arrangements that are deemed inadequate to face technological and social changes (e.g. most GPs work in solo practice with scarce IT infrastructure and medical equipment, and limited professional interactions) (Fattore et al., 2009). The shortage of nurses is difficult to justify in a country with a high unemployment rate. Here, professional status and level of compensation contribute to insufficient applications to nursing programmes. To overcome these problems, substantial changes in the distribution of tasks between doctors and nurses and better salaries are the solution. Furthermore, the resources provided through the NRRP to community care will open up more opportunities for GPs and community paediatricians to benefit from greater integration, multidisciplinarity and digitalization.

All qualified professionals are obliged to register with their professional registry in order to be licensed to practice. As provided for by EU Directive 2005/36/EC, health professionals wishing to have their title recognized in another EU country must obtain approval from the Ministry of Health.

4.2.2 *Trends in the health workforce*

National data show that in 2018, the SSN employed over 600 000 workers (almost 50 000 less than in 2010) of which 72% were health professionals, 17.4% technicians, 10.4% in administrative roles and 0.2% engineers, lawyers, architects and other graduates (Ministero della Salute, 2020c). Generally speaking, Italy has a relatively high number of doctors but a scarcity of nurses (Fig. 4.2). The ratio of nurses to doctors is 2.5:1 (see also Chapter 7). The geographical distribution of health personnel is uneven, reflecting the locations of health facilities across the country and also the budgetary constraints that have been impacting the health sector (Box 4.3). In 2020 and 2021, the COVID-19 pandemic necessitated measures to rapidly increase the recruitment of medical and other support staff to meet the needs of the emergency (Box 4.4).

FIG. 4.2 Practising nurses and physicians per 100 000 population, 2021

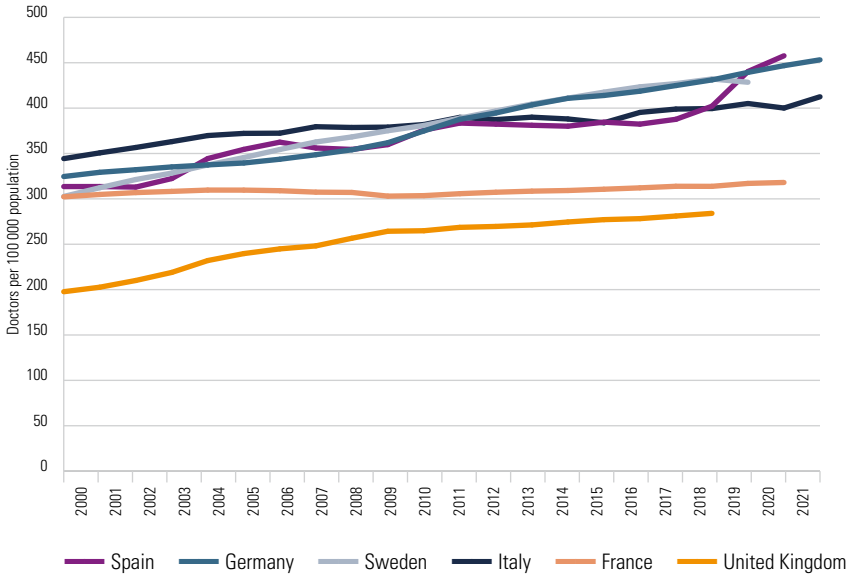


Notes: EU27: The 27 EU Member States from 1 February 2021; UK: United Kingdom. Data on doctors are for 2021 or latest available year. For Slovakia data refer to professionally active physicians; data for Greece and Portugal refer to doctors who are licensed to practice, which leads to an overestimation. Data on nurses are for 2021 or latest available year. For France, Ireland, Portugal and Slovakia data refer to professionally active nurses.

Source: Eurostat, 2022d.

On average, Italy has a higher number of doctors than the EU average (Fig. 4.2). The number of practising physicians has grown steadily since the 2000s, reaching 412 per 100 000 population in 2021 (Fig. 4.3) which is above the EU average of 397. However, the number of public hospital physicians and GPs is now decreasing, potentially causing future shortages. It is noteworthy that more than half of the doctors working in the public system are aged over 55, which is among the highest figures in the EU. In 2019 there was a total of 42 428 GPs working in Italy, (the equivalent of one for every 1 409 inhabitants, compared with the EU average of 1 430) and representing 17.5% of the total number of physicians (ISTAT, 2019). Alongside the crucial role they play in primary care, a major function of GPs is to be gatekeepers to higher levels of care and SSN services: they are responsible for patient referrals, and also play an essential role in ensuring continuity of care, prevention, early detection of diseases and monitoring (see Chapter 5).

FIG. 4.3 Practising physicians per 100 000 population in Italy and selected countries, 2000–2021



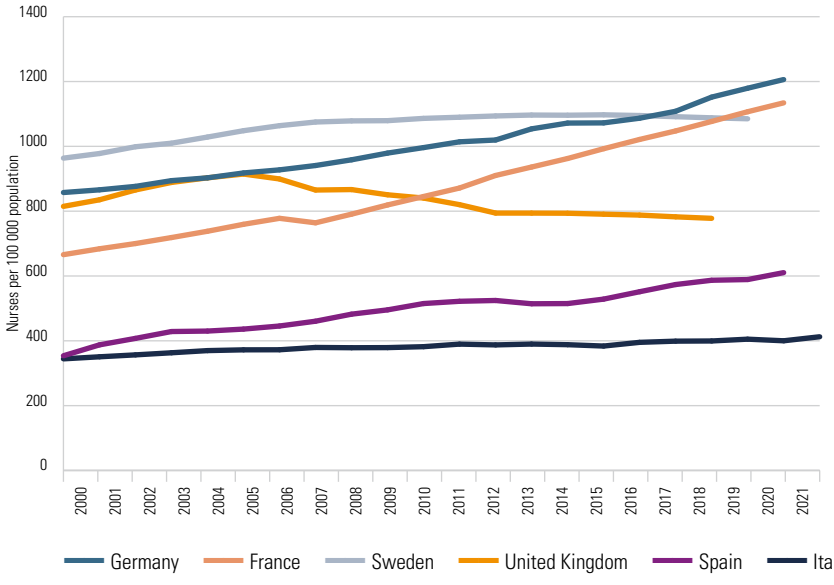
Note: Data are for 2021 or latest available year.

Source: Eurostat, 2022d.

In contrast, the density of nurses per 100 000 population is among the lowest in EU Member States – 626 per 100 000 in 2021 (Fig. 4.4) compared with the EU average of 835 – despite the nursing profession experiencing an expansion of its tasks, especially with regard to the management of patients with chronic conditions. In 2019, there were 17 253 midwives and 367 684 nurses working in Italy (ISTAT, 2020b), placing Italy 15th in the EU ranking for the proportion of nurses and midwives in the total workforce, with a value of 1.8% (against 2.2% EU average). The number of nurses and midwives has increased by only 15 000 over the last decade, which contrasts with much larger increases in Germany and France (147 000 and 125 000 respectively) (Eurostat, 2020a).

Most of the SSN's employees are women (68%). Whereas 78% of nurses are women, female physicians constitute less than half of their category and only a minority are directors of health facilities or hospitals. Notably, however, 60% of physicians under the age of 40 are women. With women earning 24% less than men, Italy ranks eighth among the worst EU countries for overall working conditions of female health professionals and is far from achieving gender equality (Lenstore, 2020).

FIG. 4.4 Practising nurses per 100 000 population in Italy and selected countries, 2000–2021



Notes: Data for Italy, Germany, Spain, Sweden and the United Kingdom refer to practising nurses and, for France, to professionally active nurses. Data are for 2021 or latest available year.

Source: Eurostat, 2022d

In terms of other health professionals, the number of practising dentists in 2021 was 86 per 100 000 inhabitants, increasing from 78 in 2013. Similarly, the number of pharmacists rose from 114 in 2013 to 124 per 100 000 inhabitants in 2021 (Eurostat, 2022d).

BOX 4.3 The distribution of health workers

Substantial heterogeneity persists among regions in terms of the availability of health professionals. For example, in 2017 the number of health workers in regions under recovery plans ranged from 81–108 health workers per 10 000 inhabitants while among the other regions, the number ranged from 119 to a maximum of 148 in some of the autonomous regions. Such differences, however, are not as critical for physicians as they are for nurses. Italy is experiencing an acute shortage of nurses. The causes are most likely related to declining investment in health personnel, which has been decreasing since 2010, alongside a reduction in the overall number of health workers, including physicians and nurses and a deterioration of working conditions, particularly in regions under recovery plans. While the NRRP aims to expand SSN capacity through a massive investment in new facilities, it remains unclear how these facilities will be staffed, given the shortage of health professionals and the constraints on current expenditure.

Source: Ufficio Parlamentare Bilancio, 2019.

4.2.3 *Professional mobility of health workers*

In Italy, the mobility of health professionals is regulated by EU Directive 2005/36/EC. There are not many data sources at the national level that map outflows and inflows of health workers especially for those working outside hospital settings; however, existing evidence suggests that there has been an increase in outflows, especially among young practitioners.

The country is home to 77 500 qualified foreign health professionals, mostly nurses; however, only 10% of these health workers are employed by the SSN, with the remaining working in the private sector. Rigid turnover schemes, particularly in SSN facilities, that impede new hirings, accentuate the difficulty for both foreign and domestically trained foreign professionals to find stable employment.

BOX 4.4 Increasing health workforce capacity during the COVID-19 pandemic

The SSN was required to undertake an unprecedented mobilization of the health workforce to address the exigencies of the COVID-19 pandemic. A series of fast track decrees allocated extrabudgetary resources to hire health care professionals and remunerate staff for overtime. Other measures included: authorizing health care facilities to delay the retirement of staff; offering retired doctors and nurses the opportunity to volunteer to practice once again; temporarily enrolling doctors and nurses from the armed forces into the SSN; and switching precarious work contracts to open-ended employment contracts. In addition, freelance contracts for doctors and nurses were permitted for those who had not yet registered to practice in the relevant medical register and temporary practice in Italy was permitted for those who had been practising abroad. The Department of Civil Protection also issued online calls for volunteers to establish Specialist Medical Units and Technical-Nursing Units; these health professionals were sent to the most affected areas around the country. Several European countries sent additional health workforce reinforcements in solidarity.

A large number of distance training initiatives were launched for health professionals, alongside the first remote graduation examinations for medical and nursing undergraduates. Moreover, following the advice of the Scientific and Technical Committee, INAIL established collaborations with the National Council of the Order of Psychologists (Cnop) to provide psychological support and stress management services to health personnel in an attempt to prevent burnout. Health organizations were advised to set up task forces of psychologists to provide services, even through distance counselling.

In 2021, the COVID-19 Extraordinary Commissioner called for the recruitment of 15 000 health care professionals, including non-EU residents and retired workers, to support Italy's vaccination campaign.

Source: EOHSP, 2021.

Between 2016 and 2020, Italian doctors who requested to practice abroad (numbering more than 5 000) came from regions all over the country. They were pensioners, active physicians or from cooperatives and networks of NGOs or not-for-profit associations that work in international aid. In the same period, requests from foreign doctors who wish to practice in Italy increased, alongside attempts to ease entry processes, especially in relation to rapidly addressing workforce shortages during the COVID-19 pandemic (Box 4.4).

In 2012 (the latest data available), foreign nurses constituted 10% of the total nursing workforce and mostly worked in the northern and central regions (Fortunato et al., 2012). The majority were from eastern European countries, India, Brazil, Peru, Germany and Switzerland. Nursing shortages in Italy have contributed to high inflows, especially in care and nursing homes. The share of foreigners for less qualified health professions, such as social and health care workers (*Operatori Socio-Sanitari*, OSS), who provide basic personal and auxiliary care, is much larger, although not officially documented. Social care, and to a certain extent, basic nursing care are also delivered by personnel who do not have specific qualifications, often working without regular contracts in patients' homes. The number of these workers, by definition difficult to track, is estimated to be about three times the number of nurses (Chaloff, 2008). Bilateral international agreements have been flourishing at the regional and local levels. Regions and health care providers have bilateral programmes with foreign nursing institutes, especially with eastern European partners, to guarantee the recruitment of qualified professionals (e.g. through distance learning programmes). Legislation has sought to regularize care workers' immigration status – which also is a means of recognizing the importance of long-term care.

4.2.4 *Training of health personnel*

For physicians, the 6-year Medicine and Surgery degree, provided primarily by public universities, consists of preclinical/basic science studies followed by clinical rotation. Graduates are effectively considered medical doctors but must enrol in the National Register to be licensed to practice. Postgraduate study and training cover 51 specialties, but until very recently have not included general practice or family medicine as a specialization.[11] Postgraduate specialization schools are supervised by the Ministry of Universities and Research and by the National Observatory of Specialist Medical Training and Regional Observatories which, in 2017, introduced accreditation standards, requirements and indicators to monitor and evaluate the quality of medical schools. Training for GPs is offered by the regional health authorities. Training lasts 3 years and includes internship periods in health care facilities.

11 Some universities are starting to offer Family and Community Medicine as a specialization.

To be qualified as a nurse, a 3-year nursing university degree alternates compulsory in-class activities with practicums and internships. Graduates are required to pass a state examination to be enrolled in the National Registry of Nurses. As for doctors and other personnel, nurses must pass a public competition to be employed by the SSN, whereas private organizations autonomously organize recruitment. Some nurses may specialize in public health, paediatrics, mental health and psychiatry and geriatrics through 2-year Master of Science programmes. The education of nurses is delivered by medical schools. Ancillary staff are generally trained through specialized courses delivered by professional schools.

Medical qualifications are mutually recognized if earned in other EU Member States, Switzerland, Norway, Iceland and Liechtenstein.

All health care professionals are required to participate in lifelong continuous medical education (CME) programmes, collecting at least 150 CME credits every 3 years. Such credits are awarded by course providers based on the educational activity's level and the amount of time dedicated (e.g. participation of the health professional in meetings/congresses/seminars or conferences allows the acquisition of training credits: 0.3 credits per hour (not divisible) up to a maximum of 6 credits). Training programmes are managed by the National Commission for Continuous Training (CNFC), whereas health care professionals' credits are overseen by the Health Professions Management Consortium (COGEAPS).

4.2.5 *Physicians' career paths*

A Technical Council set up by the General Director of each health care facility evaluates health care professionals' activities, results and participation in CMEs on an annual basis. A positive evaluation in training outcomes is linked to salary and determines whether physicians can maintain their positions in the health facility or hospital. Doctors employed by the SSN can be appointed to three different management positions: Head of Simple Units, Head of Complex Units, and Head of Department/Medical Directors (Box 4.5).

BOX 4.5 The managerial levels in a physician's career path

- Heads of Simple Units are selected from among SSN physicians by the General Director (GD) after consulting the Head of Department or Director of the Complex Unit to which the Simple Unit belongs.
- The directors of Complex Units can be appointed after 10 years of work experience in the related field (or 7 years plus the relevant specialization). To select a Complex Unit Director, a committee composed of the hospital's medical director and three complex unit directors in related specialties, identifies candidates to propose to the GD, who makes the final choice (in agreement with the University rector in the case of policlinics).
- Heads of department/medical directors are appointed by GDs whether in hospitals or ambulatory settings, following a public announcement and selection process based on an interview – conducted by a committee appointed by the region – and the candidate's qualifications. Candidates must be under 65, possess a public health specialization (except for single-specialty facilities) and have a minimum of 5 years of managerial experience.
- District directors may be selected among doctors who were employed by the SSN for a minimum of 10 years, managers of the local health authorities who acquired significant experience in primary care management or GPs/paediatricians.

4.2.6 *Other health workers' career paths*

NURSES

Nurses may become experts within an area of care and be considered reference points and teachers in related training. These nurses are also assigned the most complex clinical cases. Coordinating nurses, a position gained through a public competition, manage human resources and equipment, synchronizing all functions within their department. Today, nurses are covering more managerial positions involving increasing responsibilities. Such positions are accessible after a Master's in Management and Coordination of Health Professions and public competition.

DENTISTS

The main career prospects of a dentist involve specializing. Dentists can opt for managerial roles in dental practices or clinics.

PHARMACISTS

After a 5-year degree in pharmacy or chemistry and pharmaceutical technology, pharmacists can work in hospitals or local (community) pharmacies. To be employed in community pharmacies it is necessary to follow a 2-year seniority pathway, which comes with slight wage increases. Hospital pharmacists have a very slow career path and may eventually become directors of the hospital's pharmacy.

5

Provision of services

Chapter summary

- Public health in Italy is well established as part of SSN activities through local health authorities. It includes interventions in the fields of prevention of communicable diseases, occupational health, cancer screening and tobacco control.

- Patients obtain access to health services through their GPs and paediatricians who act as gatekeepers. Emergency departments, almost exclusively managed by SSN organizations, are the alternative for urgent and critical situations but are often overutilized by patients who wish to access care outside the normal working hours of primary care and for minor conditions. For an increasing number of conditions, SSN clinical pathways have been established to increase the homogeneity and appropriateness of patient care.

- Hospital and outpatient specialist care is provided by SSN organizations (independent hospitals or local health authorities) and private-accredited providers (mainly for-profit organizations). Patients are free to choose providers and Italy experiences high levels of cross-regional mobility, mainly from patients residing in southern regions seeking care in central and northern regions.

- Hospital planning plays a pivotal role, with detailed specifications on the number of beds, minimum volumes of care, hospital networks as well as on human resources and technological standards. Italy

has set a target to lower the number of hospital beds from 4.0 to 3.7 per million inhabitants.

- In 1978, Italy was the first country in Europe to close psychiatric hospitals to manage acute patients in psychiatric wards within general hospitals and within various other community-based facilities. Psychiatric care is delivered by multi-professional units with defined catchment areas.

- Pharmaceuticals are mainly delivered by community retail pharmacies (mostly private). Expensive drugs are often provided by hospitals, even for therapies to be administered in patients' homes.

- Publicly funded dental care is very limited and patients mostly rely on their own resources to receive services from private dentists, increasingly organized in multi-professional networks.

5.1 Public health

The Ministry of Health is the main institution responsible for public health at the national level. It undertakes a stewardship role and sets the general policies targeting health improvement and prevention. Public health policies are implemented by the regions through their departments of health and local health authorities, the remits of which include protection of the population's health, health promotion, preventing diseases and/or disability and improving quality of life. The main areas of activity are public hygiene, occupational health, food and nutrition, and veterinary health care.

5.1.1 *Communicable diseases control programmes: vaccinations*

The reduction or elimination of the burden of vaccine-preventable diseases is considered a priority of the public health service. The routine immunization programme includes diphtheria, tetanus (DT) and poliovirus (oral poliovirus vaccine, OPV) vaccinations, which have been mandatory by law since the early 1960s for all infants under 24 months. The hepatitis B vaccine was added in 1991, introducing universal vaccination of infants and children up to

12 years of age. In July 2017, a national law added vaccinations against pertussis, *haemophilus influenzae* type b1, measles, rubella, mumps and chickenpox, to make a total of 10 compulsory vaccines (D'Ancona et al., 2019). All compulsory vaccinations are fully covered by the SSN.

In Italy, regions oversee the organization and implementation of their own vaccination strategy based on the National Vaccine Prevention Plan (*Piano Nazionale Prevenzione Vaccinale*, PNPV) (Ministero della Salute, 2017a). The latest PNPV was published in 2017 and was originally valid until 2019, but its validity was extended to the end of 2021 due to the COVID-19 pandemic.[12] This plan aims to reduce/eliminate vaccine-preventable diseases by identifying effective and homogeneous strategies to be implemented on a national scale. The PNPV was designed taking into consideration the European Vaccine Action Plan 2015–2020, which constitutes a response to the Global Vaccine Action Plan 2011–2020 developed by WHO. Local health authorities and the Ministry of Health are responsible for the implementation of activities outlined in the plan. In Italy, childhood vaccinations are routinely provided through a well-established and organized network of public facilities and are usually administered by specific departments within local health authorities. Moreover, primary care paediatricians are the key contacts for counselling and information regarding vaccines; they verify that children have received vaccinations and can administer vaccines themselves.

To evaluate the efficacy of vaccination programmes, national and sentinel surveillance systems are used to collect data and provide information on the incidence of infectious diseases and vaccination coverage. For this purpose, a National Vaccine Registry was created in September 2018. It ensures the correct evaluation of vaccine coverage, monitoring nationally consistent vaccine implementation and providing information to national and international bodies.

Despite remarkable progress in terms of coverage rates for some compulsory vaccinations (reaching an average of 95% and meeting the target of 95% set by the National Vaccination Prevention Plan), some challenges persist, as measles–mumps–rubella (MMR) coverage still remains half a point below the 95% threshold recommended by WHO (although it increased 5 percentage points between 2011–2017). Further, a certain degree of heterogeneity is still present for different vaccines both at the regional and local levels. For example, coverage for the OPV vaccine in Abruzzo is 97.4%, while it is 91.1%

12 At the time of writing in September 2022, a new PNPV had not been published.

in Sicily and 81.1% in the Autonomous Province of Bolzano (Ministero della Salute, 2020d).

In response to the COVID-19 pandemic, Italy rolled out a vaccination campaign from December 2020, first for priority groups such as health workers and the elderly, and then extending to the general population for primary and booster inoculations throughout 2021–2022. The vaccination plan has been carried out under the supervision of the regions and the COVID-19 Emergency Commissioner (see Chapter 2) utilizing a range of facilities, including designated vaccination centres and administered by GPs, nurses, paediatricians and other specialists, dentists and pharmacists who have undergone the necessary training.

5.1.2 *Occupational health*

Driven by European Commission Directives, the occupational health sector has made significant progress since the introduction of the Italian Occupational Health and Safety Act 2008 which provides the legal framework, setting out the rights and duties of all parties in the workplace and harmonizing previous legislation. The Ministry of Labour and Social Policies is the responsible national authority for health and safety at work. Other institutions also collaborate with the Ministry. These include INAIL, which aims to reduce workplace injuries, protect workers performing hazardous jobs, insure workers, facilitate the return to work of people injured at the workplace, and the National Labour Inspectorate, established in 2015 with the overall responsibility for monitoring compliance of health and safety laws. Additionally, the Standing Advisory Committee for Health and Safety at Work evaluates issues concerning health and safety at work, validates good practice, and establishes standard risk assessment procedures (Ministero del Lavoro e delle Politiche Sociali, 2022).

Funding for occupational health in Italy is achieved primarily through central public funds, along with additional finance which can be provided by the regions and the European Commission. According to INAIL data, the social costs directly associated with work-related accidents in Italy account for EUR 45 billion every year, with more than 700 000 work-related accidents reported yearly, 900 of which are fatal. In all workplaces where workers can be exposed to specific risks, an occupational health specialist must be appointed by law for medical check-ups of employees and education information activities.

5.1.3 *Screening programmes*

Since 2001, the government has adopted a series of measures to promote the widespread and uniform adoption of screening policies and guiding principles at the national level. Among these, secondary cancer prevention has been included in the national benefits package (LEAs). The National Screening Observatory (*Osservatorio Nazionale Screening*, ONS), founded in 2001, currently offers cervical Pap tests, mammography and colorectal screening free of charge for the target populations.

To improve screening coverage, and following the EU's recommendation on cancer screening in December 2003, several plans were developed with the aim of strengthening the diffusion of active programmes: these include the NHP (2003–2005), National Screening Plans (2004–2006 and 2007–2009) and the National Prevention Plan (2005–2007). In addition, Law 138/2004 was introduced, containing a commitment to reduce the gap between the target and the screened population, allocating EUR 50 million for this purpose.

Screening programmes are regulated and organized at the regional level through the local health authorities, which actively invite the target population (mammography, Pap test, faecal occult blood test (FOB)). Participation in screening programmes is voluntary and several indicators are calculated to monitor screening invitations and uptake, which impacts the efficacy of programmes in reducing cancer mortality. The National Centre for Screening Monitoring (managed by the *Osservatorio Nazionale Screening*) was created in 2002 and was charged by the Ministry of Health with monitoring and promoting screening programmes nationwide. According to its report in 2019, the development of organized screening programmes continues, even if gaps still exist between the central, northern and southern regions. Data also shows that screening has increased in absolute numbers from 2017 to 2018, with more than 14 million invitations, 6.3 million tests, and between 80–90% of the Italian population of target age being invited for mammography and cervical screening, as well as 75% for colorectal cancer (Osservatorio Nazionale Screening, 2019).

Breast cancer is the most prevalent cancer among women in Italy, and mammography screening reached a coverage rate of 84% between 2008 and 2018 for women between 50–69 years old. However, there is still a large difference (40 percentage points) between the southern and northern regions.

Mammography screening is offered every 2 years to women aged 50–69, while some regions are piloting tests for a wider age group, between 45–74 years old (Ministero della Salute, 2021e).

Cancer of the colon and rectum have the second- and third-highest cancer prevalence rates, respectively, in both women and men. Current guidelines recommend two colorectal cancer screening tests: most programmes use the FOB in subjects aged either 50–69 or 50–74, while others (mainly those in the Piemonte and Veneto regions) have adopted flexible sigmoidoscopy (FS) once in a lifetime (or with a frequency of at least 10 years) in patients aged 58 or 60 (Zorzi et al., 2015; Ministero della Salute, 2021f). In 2018, nearly 6 million citizens aged 50–69 years were invited for the FOB test; 68 893 aged 58 years for the FS test; and 214 679 between the ages of 70 and 74 years for the FOB. However, data points to differences between regions in terms of target population being invited to screening tests. North-central regions were well above 80% in 2018, while southern regions stood at just above 40% (Osservatorio Nazionale Screening, 2020).

The coverage for cervical cancer screening has grown overall between 2011 and 2018, mainly due to the increase of invitations for human papillomavirus (HPV) screening, while Pap tests have decreased. For cervical cancer, the Pap test is offered every 3 years to women aged 25–30, and the papillomavirus test (HPV-DNA test) is offered every 5 years to women aged 30–64 years. Regional differences are still present, but they are less stark (Ministero della Salute, 2021g).

5.1.4 *Tobacco control*

CIGARETTES

In January 2003, a law to ban smoking indoors was introduced, with exceptions for: 1) private dwellings which are not open to the public; and 2) places reserved for smokers and marked as such. The ban also extended to all education and training establishments, as well as hospitals and scientific research laboratories (Law 3/2003, art. 51). After the law came into force in January 2005, Italy became the first country in the EU to ban indoor smoking to improve the health of the population (Laurendi et al., 2007), setting up a model for this effective public health intervention (see Box 5.1). Recent data show that

nationally: 1) the number of daily smokers aged 14 years and over decreased from 23.8% in 2005 to 19% in 2020; 2) sales of tobacco products decreased by 32% between 2004 and 2018; and 3) the perception of compliance with the smoking ban in 2020 was 91.9% for public places and 93.9% for workplaces. However, smoking rates among 15-year-old boys and girls, who are under the legal age for smoking, remain high (24.8% in boys, 31.9% in girls) (Ministero della Salute, 2020e).

Other measures related to smoking are now also being addressed by cities, as in the case of Milan, which in January 2021 introduced a new smoking ban in the city to stop cigarette smoking in outdoor spaces, including public transport stops, parks, dog walking areas and cemeteries. The fines for those who do not comply range from EUR 40 to 240 (Il Sole 24 ORE, 2021).

BOX 5.1 Are public health interventions making a difference?

Price rises are one of the most effective measures that can be imposed to reduce consumption of tobacco products (WHO Regional Office for Europe, 2017a). In Italy, over the period 1970–2001, a rise of 1% in the price of cigarettes, led to a –0.30% decline in smoking prevalence and –0.43% in cigarette consumption. It has been estimated that if an increase of +10% in price takes place in the future, a decrease in consumption ranging from 2.5% to 5% could be achieved (Gallus et al., 2003). In addition, smoking rates have fallen over the last 15 years, in part attributable to the variety of tobacco control policies in place.

Total adult (15 years and older) per capita alcohol consumption fell from 12.4 litres to 7.7 litres between 1990 and 2019 (WHO, 2022b). Among the policies introduced during this period were a minimum legal buying age of 18 years, legal blood alcohol concentrations for drink–driving, legal regulations on alcohol sponsorship and sales promotion (WHO Regional Office for Europe, 2017b), and the creation of a national alcohol and health plan starting in 2007 (Ministero della Salute, 2007).

Food labelling has proven to be one of the most cost-effective measures to tackle unhealthy eating and obesity both in the short and long term. One study reports that food labelling, relative to no intervention, was estimated to increase the average number of people making a healthier food choice by about 18% (Goryakin et al., 2017).

ELECTRONIC CIGARETTES

Electronic cigarettes and a new generation of inhalation-without-combustion ("heat-not-burn") products are classified in Italy as tobacco-related products and are regulated. Manufacturers or importers must also submit an annual report to the competent authority. The cross-border sale of e-cigarettes is prohibited, as is the sale to minors (under 18 years). According to an European School Survey Project on Alcohol and Other Drugs (ESPAD) poll, e-cigarette use has grown in popularity among teenagers, with 13% of 15- and 16-year-olds reporting using them in 2019. This percentage is similar to the EU average (14%) (OECD/European Observatory on Health Systems and Policies, 2021). E-cigarette advertising is currently prohibited in the country (LD 6/2016).

Starting from 1 January 2021, the tax duty on products containing e-liquids with nicotine was raised to 15%, with subsequent increases of 5 percentage points each year until 2023 (rising to 20% in 2022 and 25% in 2023). Nicotine-free e-liquids are also subject to a new tax of 10% in 2021, 15% in 2022, and 20% in 2023. As of December 2020, the Customs and Monopoly Agency in Italy reported 19 569 notified e-cigarette products in the country (Camera dei Deputati, 2020; ECigIntelligence, 2021).

5.2 Patient pathways

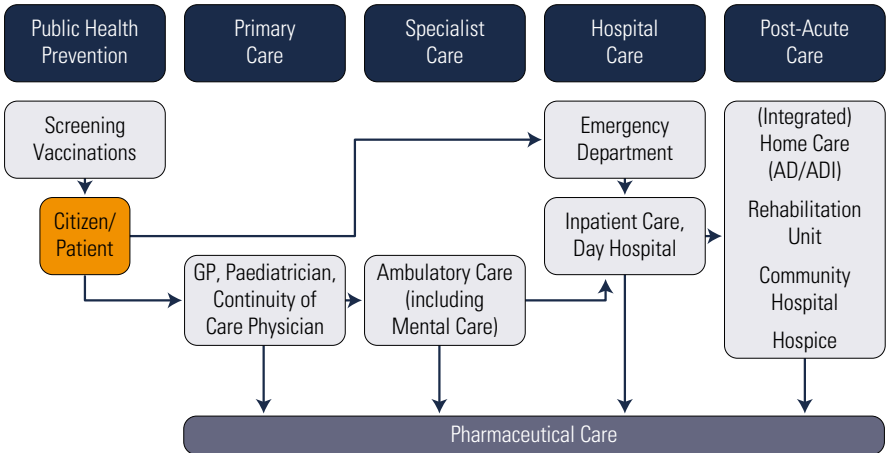
Italy's typical patient pathway is represented in Figure 5.1. For non-urgent needs, the first point of contact with the health care system is the GP (for adults) or the family paediatrician (for children). Both offer an office-based service that is available on weekdays (from Monday to Friday) in predefined time slots (usually either morning or afternoon). In case of out-of-hours non-urgent care, assistance is provided by continuity-of-care physicians (*Medici di Continuità Assistenziale*) via telephone consultations and/or ambulatory or home visits. In tourist areas, a medical service is available during holiday periods (i.e. summer and Christmas time). For urgent needs, remote assistance and free ambulance services to the nearest hospital are provided by calling the emergency number (112). Italy is planning to introduce the 116 117 European number that will provide first contact with the SSN and sort patients to access the most appropriate level of care. In practice, emergency departments, which

should receive only genuinely acute cases, are often the first point of physical contact with the SSN at night, during weekends and even during regular working hours (see section 5.5).

GPs act as gatekeepers, referring patients to specialized care (e.g. appointments with ambulatory specialists or diagnostics). Bookings are made by patients themselves, through a local or regional telephone number, or at dedicated points such as single appointment centres (*Centri Unici di Prenotazione*, CUP) or community pharmacies. CUPs offer several options in terms of type of provider (public or private accredited) and waiting times; therefore, patients can choose where to be treated although they cannot generally choose the specialist providing care. This refers to patients under SSN coverage. Patients who opt out of the SSN can bypass their GP (or the family paediatrician) and book and pay for a private ambulatory appointment independently; in such cases, the specialist can be chosen, and the waiting time is much shorter.

If acute care is required, the GP, the specialist or the emergency department doctor can recommend hospital admission. Hospitals are distinguished according to the type of provider (public or private accredited), teaching status (university hospital or not), and level of specialization (general or specialized hospital). Further, Italy has a number of research hospitals that, in addition to normal funding, directly receive additional resources from the Ministry of Health (IRCCSs). The admission can be for an overnight stay (ordinary admission) or just for a day (day hospital or day surgery). Once discharged, patients usually return home, possibly with assistance through integrated home care or other institutions. Rehabilitation is generally offered by specialized institutions. In cases where the patient is frail, and/or in the absence of caregivers, patients can be transferred to an intermediate care facility such as a community hospital for a short-term stay, and/or to a retirement home (e.g. *Residenze Sanitarie Assistenziali*, RSA) for long-term care.

FIG. 5.1 Typical patient pathways within the SSN



Note: GP: general practitioner.

Source: Authors.

5.3 **Primary care**

Primary care is provided by GPs for adults and by paediatricians for children under 6 years of age (and up to 14 if parents request it, with a possible extension to 16 for disabled or chronically ill children). Patients are entitled to choose GPs/paediatricians among the physicians operating in the patient's municipality (covered by the local health authority). GPs must complete a 3-year postgraduate regional education programme in general medicine, while paediatricians hold a 5-year specialization in paediatrics. GPs provide ambulatory or home visits, prescriptions for medications, referrals to specialists, as well as for laboratory or diagnostic tests. They can recommend routine screening procedures based on risk factors and calendars formulated by regional health authorities. Moreover, they provide health certificates (e.g. for sport activities and readmission to school or workplace). Similarly, paediatricians provide the same services for their patients.

GPs and paediatricians work as independent professionals under the SSN and are mainly paid on a capitation basis with additional payment for home visits, other extraordinary interventions (e.g. minor surgeries) and for participating in screening programmes (see Chapter 3). They are also

financially incentivized to work in groups. Except for special circumstances, GPs and paediatricians should not have more than 1 500 and 800 patients, respectively. De facto, in some areas several professionals exceed these ceilings due to insufficient supply. The situation is likely to worsen in the future given the large number of GPs and paediatricians who will retire (see section 4.2).

Three main interrelated trends have characterized primary care organization in Italy during the last decade. First, there have been attempts to strengthen the role of GPs and paediatricians through the creation of aggregate forms of primary care and integration with other professionals working in the area. In fact, the National Collective Agreement for General Medicine (29 July 2009) stated that GPs should form functional group practices and operate within a specific Primary Care Complex Unit (UCCP). For example, the Community Health Centres (*Case della comunità*), which were defined as "multi-functional structures in charge of delivering primary care, continuity of care and prevention activities" (Ministerial Decreee 10 July 2007), are the most popular model for organizing the delivery of primary care in the regions of Emilia-Romagna, Tuscany and Marche. Second, the use of more advanced IT has allowed for more integration of care between GPs with other professionals through data and knowledge sharing. Since 2010, GPs have transmitted "patient summary" data within the health system, through regional electronic networks. Thirdly, central and regional governments have promoted more involvement of primary care in preventive activities, including tailoring health interventions on the basis of patients' risk profiles and being more proactive with healthy patients. These three trends show different paths across regions. For example, while in some regions more than half of GPs work in group practices and patient data are recorded electronically, there are still regions where group practices are rare, and the digitalization of information is not complete (Box 5.2). Overall, up to 2020, investment and progress in strengthening community services, particularly to address the needs of older patients and a growing burden of chronic diseases, has been uneven across the country with under-resourcing in some regions. This is set to change: plans to strengthen the provision of primary and community care are an important part of Italy's NRRP, which earmarks significant funding to support the creation of a wide network of infrastructure (buildings, technologies, digital infrastructure), including facilities to provide community-based services and telemedicine amenities (see Chapter 6).

The COVID-19 pandemic saw an expanded role for GPs who contributed to testing and contact tracing as well as monitoring and treating patients post infection. Italy also introduced special units dedicated to providing continuity of primary care for COVID-positive patients who did not require hospitalization (Box 5.3).

BOX 5.2 What are the key strengths and weaknesses of primary care?

Strengths: Over the last decades, the closure or reconversion of several hospitals has enhanced the role of primary care in Italy. GPs and family paediatricians are the backbone of primary care – 74% of Italians attend their clinics at least once a year – and are an easy-to-contact entry point to the SSN. Currently, the average age of physicians is around 56, and 60% of doctors attending the general medicine programme (future GPs) are women. There is an established and well-organized CME programme for primary care doctors. Organizationally, there is a gradual, although uneven, switch from the traditional single practice model to group practice. There has also been progress towards achieving greater horizontal and vertical integration of care involving other health care professionals, which is expected to improve accessibility and patient's satisfaction and to lower admissions to emergency rooms.

Weaknesses: Progress towards integrated models of care is still slow and heterogeneous, due to the lack of implementation at the regional and local levels. Resistance to change is common and often justified on the basis of reduced proximity for patients. Despite progress, most GPs in many regions still work in solo practices with limited opportunities to share knowledge with other colleagues and no access to diagnostic technologies. Moreover, there are no formal assessments of clinical outcomes achieved in primary care. Because of several retirements and few hirings, the number of GPs has declined over time – from 94 per 100 000 inhabitants in 2009 to 88 in 2018 – and a major shortage is expected in the years to come (see also Chapter 4). Furthermore, GPs' workloads are growing due to population ageing, increased prevalence of chronic conditions, and consequent burdens on caregivers, who increasingly are seeking assistance from GPs for psychological disorders.

BOX 5.3 The role of special continuity-of-care units during the COVID-19 pandemic

Primary care played a crucial role in the pandemic response: one innovation was the establishment of special continuity-of-care units (*Unità Speciale di Continuità Assistenziale*, USCA), in 2020 to assist COVID-19 patients in home isolation within 48 hours of a GP's request. At least one USCA had to be established for every 50 000 people. Each unit could be composed of continuity-of-care physicians, young physicians enrolled in the general medicine training programme, and, in some cases, medical graduates and nurses. USCAs operated 7 days a week, from 8 am to 8 pm. At the height of the pandemic USCAs provided telephone and video consultations, and home visits to patients who did not require hospitalization or who were recently discharged from hospital. In some regions, they also carried out nasal swabs at home for patients who could not reach testing centres. They are still active in some regions.

5.4 Specialized care

Outpatient specialized care can be delivered by doctors under three different regimes. In the first, SSN doctors, who are generally based in hospitals, have ambulatories for outpatients. This work is part of their normal working duties. However, under dual practice arrangements they are allowed to see private patients outside working hours according to detailed national and regional rules (e.g. fees are determined by their SSN facility). In the second regime, independent professionals operate within SSN facilities and are paid hourly rates. The amount of time they work is defined by each SSN organization within the framework of a national agreement. These doctors have no major restrictions on the care they provide for private, paying patients. Finally, patients can receive ambulatory care in private-accredited facilities. In such cases, visits are charged on a fee-for-service basis.

5.4.1 *Specialized ambulatory care*

The outpatient care provided by the SSN can be divided into two categories (Ministero della Salute, 2019a):

1. clinical activity, comprising specialist visits (first visits and check-ups), therapeutics (e.g. radiotherapy, psychotherapy, medications) and rehabilitation (e.g. motor skills, speech or cardio-pulmonary re-education); and
2. diagnostics which include instrumental diagnostics (e.g. echography, radiography, gastroscopy) and laboratory tests (e.g. virology, microbiology, genetics).

The provision of outpatient services can occur in hospitals, clinics or polyclinics, either public or private-accredited facilities. Access usually occurs through a GP's referral, but specialist doctors can directly prescribe additional interventions where more detailed examinations are needed. The prescription can include up to eight interventions within the same specialist area. Patients can also book services in a different region to the one they reside in. However, access to specialized ambulatory care is often hampered by long waiting lists, despite a national law which established a maximum of 30 days for visits and 60 days for diagnostics between booking time and service provision. Under the NGLA (Ministero della Salute, 2019b), four priority categories were introduced and could be indicated on a GP's referral:

- U (urgent), the service must be booked within 48 hours and provided within 72 hours;
- B (short), to be provided within 10 days;
- D (deferrable), to be provided within 30 days for visits and 60 days for diagnostic tests;
- P (programmable); for example, check-ups, to be provided within 120 days.

Alternatively, patients can book these services privately to avoid waiting lists or choose their preferred provider. For example, the average waiting time for an orthopaedic consultation was 56 days in an SSN facility, 27 days for a private-accredited provider, and only 6 for a private specialist (CREA Sanità, 2017). For specialized ambulatory care, a co-payment is required (except for exempted patients) (see section 3.4.1).

5.4.2 *Day care*

Day care includes a variety of hospital services (e.g. diagnostics, specialist visits, complex therapies) that are provided during the daytime without an overnight stay. The day hospital model was first introduced with national Law 595/1985 following a series of measures oriented towards reorganizing and reducing the number of hospital beds. "Daily hospitalizations" cannot be urgent care and therefore take place only on a scheduled basis. Specifically, day care usually includes multidisciplinary services, requires the use of professional and technological resources that can be found only in a hospital setting and an adequate period of observation that cannot be guaranteed with outpatient care. These include complex diagnostics (e.g. preoperative examinations), therapeutics (e.g. administering long intravenous drug therapies such as chemotherapy) and rehabilitation (e.g. post-surgery cardio-pulmonary re-education). "Day surgery" is a particular type of day care which includes minor or mini-invasive surgical procedures (e.g. cataract surgery, tonsillectomies, hernia repair) or invasive diagnostic or therapeutic procedures which do not require a long postoperative observational period. Interventions are performed in the morning and patients are discharged in the evening with a prescription for medicines and follow-up visits (Ministero della Salute, 2019c; 2019d; 2019e). As for almost every EU Member State, in Italy the share of cataract surgery carried out in inpatient settings fell from 3.8% in 2013 to 2.9% in 2018 (Eurostat, 2020b). There is recent evidence that for some services (e.g. cataract or oncology treatments) there has been a shift from day care to outpatient care. While for the latter a co-payment is required, both "day hospital" and "day surgery" are free of charge as they are considered hospital admissions.

The supply of non-urgent hospital-based services during the COVID-19 pandemic was disrupted, as inevitably, hospitals came under huge stress and had to redeploy wards to cope with the high numbers of COVID-positive patients who required hospitalization, particularly at the beginning of the emergency in early 2020 (Box 5.4). The COVID-19 crisis found Italy largely ill-prepared due to the already depleted hospital front, and the sometimes limited availability of community-based care.

BOX 5.4 Outpatient hospital services and implementation of telemedicine during the COVID-19 pandemic

The COVID-19 emergency in Italy required the concentration of hospital resources on COVID-19 patients and avoiding overcrowding in hospitals. National and local efforts focused reorganizing services to maintain the provision of care through the prompt expansion of hospital capacity for ordinary and intensive care, the establishment of USCAs (see Box 5.3), as well as a dramatic increase in the use of telemedicine. In April 2020, the ISS published a document (Gabbrielli et al., 2020) which provided support for the implementation of telemedicine services, offering indications, identifying operational problems and proposing solutions supported by evidence. The recommendations were collected in a general reference model but could be used in different ways to provide health services and psychological support, to proactively monitor the health conditions of people in quarantine, in isolation or after hospital discharge, or isolated at home because of social distancing rules but in need of continuity of care, even if they did not have COVID-19. The pandemic caused interruptions (or reduction) of routine, non-urgent health services, especially during the first wave in 2020, with knock on effects thereafter. Indeed, the waiting time for specialist visits and scheduled interventions have increased. The backlog of treatments is severe and will take a long time to be absorbed.

5.4.3 *Inpatient care*

Inpatient care is provided through a network of public and private hospitals. In 2015, a minimum threshold of 60 acute beds was introduced for the accreditation of private hospitals. Since then, a trend towards the accreditation of bigger facilities has been observed: in 2014 there were 553 private-accredited hospitals with less than 60 beds, dropping to 531 in 2016, and 477 in 2019 (Ministero della Salute, 2021h). Requests for hospital admissions can be formulated by a GP, paediatrician or an emergency department doctor. Altogether, in 2019 there were 316 ordinary hospital beds per 100 000 inhabitants,[13] totalling 209 157 beds: of these, almost 10% are dedicated to day hospital care (Table 5.1) (Ministero della Salute, 2021h).

13 The ratio of acute hospital beds in Italy is 260 per 100 000 inhabitants in 2019 (see Fig. 4.1).

TABLE 5.1 Number of hospital beds by region and hospitalization regimen in Italy

REGION	ORDINARY HOSPITALIZATION	DAY HOSPITAL	DAY SURGERY	TOTAL
Valle d'Aosta	444	26	15	485
Piedmont	14 572	1 079	862	16 513
Liguria	5 056	390	277	5 723
Lombardy	35 451	928	1 438	37 817
Veneto	16 114	623	735	17 472
Bolzano	1 730	95	87	1 912
Trento	1 887	135	118	2 140
Friuli-V. Giulia	3 854	401	64	4 319
Emilia-Romagna	16 398	507	403	17 308
Marche	4 642	366	227	5 235
Tuscany	10 491	935	598	12 024
Lazio	18 460	1 597	761	20 818
Umbria	2 849	179	206	3 234
Abruzzo	3 931	217	213	4 361
Molise	1 037	67	59	1 163
Campania	14 636	1 642	882	17 160
Puglia	11 595	584	233	12 412
Basilicata	1 628	145	79	1 852
Calabria	4 856	540	217	5 613
Sicily	14 128	1 188	738	16 054
Sardinia	4 836	529	177	5 542
Italy	**188 595**	**12 173**	**8 389**	**209 157**

Note: Data are for 2019.

Source: Ministero della Salute, 2021h.

National law (Ministerial Decree 70/2015) sets out a new standard to reorganize hospital care as well as to promote greater integration and continuity of care (Box 5.5) by aiming to reach 3.7 beds per 1 000 inhabitants, 3.0 for acute care and 0.7 for rehabilitation. Overall, Italy is planning to reduce its bed stock by 0.3 beds per 1 000 inhabitants compared with its current number. These standards do not include beds in long-term institutions with social care activities (e.g. residential health facilities or retirement homes – see section 5.7).

BOX 5.5 Are efforts to improve integration of care working?

Technological progress achieved in the last decade has increased the quality of diagnostic–therapeutic interventions. In addition, it highlighted the need for a rationalization of the health system's resources, reinforcing the awareness that hospital-centric care models are destined to evolve towards a dynamic system integrated with networks of local services. Ministerial Decree 70/2015 proposed a reorganization of the acute hospital model, aiming for hospital services to work in synergy with primary care, community medicine and social service. The decree makes direct reference to the need to ensure the provision of care in conditions of appropriateness, effectiveness, efficiency, quality and safety in a context of limited resources.

In the new model, hospital activities should focus on pathologies with acute onset and/or significant functional impairment, or elective services that are more technologically and organizationally complex. The reorganization of acute care hospital networks according to the hub and spoke model (see Box 4.1) means that the most expensive technologies and most complex care services are centralized in second-level hospitals while the less complex technologies and interventions are reallocated to the basic hospitals. In turn, the hospital network has been integrated with local outpatient facilities following guidelines for the integrated management of clinical or critical pathways (CPs) and supported patient discharge protocols. Organizational guidelines and recommendations have been defined for oncological care, other time-dependent conditions and integrated inpatient acute and outpatient post-acute care.

Hospitals are categorized into three types (Salute Internazionale, 2015). The first two categories include district hospitals managed by local health authorities, while the latter includes hospital trusts (AOs), University Hospital Trusts and some IRCCSs:

- **Basic hospital facilities** (catchment area 80 000–150 000 inhabitants), equipped with emergency departments and the following specialties: internal medicine, general surgery, orthopaedics, anaesthesia, and 24h on-call service and/or availability of radiology, laboratory and blood banks, and "brief intensive observation" beds.

- **First-level hospitals** (catchment area 150 000–300 000 inhabitants), providing first-level emergency-urgency departments (*Dimpartimento di emergenza-urgenza accettazione*, DEA) and the following specialties, in addition to those of basic hospitals: obstetrics and gynaecology (if required by number of births/year), paediatrics, cardiology with ICU cardiology (UTIC), neurology, psychiatry, oncology, ophthalmology, otolaryngology and urology.
- **Second-level hospitals** (catchment area 600 000–1 200 000 inhabitants), equipped with second-level DEAs and structures that also offer more complex care. In addition to the services available in second-level hospitals, they have more specialized units such as cardio-surgery, haemodynamics, paediatric and neonatal resuscitation. Radiology, radiotherapy, and immune-transfusion services are available 24/7.

The standards set by the government are detailed and stringent although their implementation at regional level is not homogenous, given the different starting points in terms of bed supply and interregional mobility of patients. In 2021, some regions were fully compliant with most of the provisions while others were far from the standards set. This mainly occurs in the requirements for small hospitals and the minimum volumes of care for specific services (e.g. births, breast cancer surgical interventions) (Table 5.2). Nevertheless, the Italian SSN has recently endorsed a very active and detailed hospital planning regime, aiming at improving clinical effectiveness, appropriateness, patients' safety and efficiency (Ministerial Decree 70/2015).

Hospital care falls into eight areas of activity: 1) emergency; 2) ordinary acute hospital admission; 3) day surgery; 4) day hospital; 5) rehabilitation and post-acute long-term care; 6) transfusions; 7) transplantation of cells, organs, and tissues; and 8) poison control centres. For each activity area, the national benefits package reports the type of interventions covered by the SSN. The revised national benefits package (2017) includes some additional inpatient services, such as epidural analgesia in facilities that exceed 1 000 deliveries per year. Overall, the national benefits package does not set any major limitation to the supply of hospital services if they are deemed effective and appropriate. The only major exception is cosmetic surgery, covered by the SSN only if needed after accidents, medical-surgical procedures and congenital or acquired malformations.

TABLE 5.2 Thresholds for minimum volumes of care per year for hospitals

INTERVENTION	NUMBER OF INTERVENTIONS/CASES
Surgical intervention for breast cancer	150 incident cases per department
Laparoscopic cholecystectomy	100 interventions per department
Surgical intervention for hip fracture	75 interventions per department
Acute myocardial infarction	100 cases for first admission per hospital
Coronary artery bypass graft	200 interventions per department
Percutaneous coronary angioplasty	250 interventions with at least 30% angioplasties for AMI-STEMI
Maternal care	500 deliveries for the most basic units; higher volumes for more specialized obstetrics and neonatology units (*Accordo Stato Regione*, 16 December 2010)

Note: AMI-STEMI: acute myocardial infarction in patients with ST-segment elevation.

Source: Ministerial Decree 70/2015. Ministero della Salute, 2021h.

The average length of stay in 2019 (7.04 days) in Italy increased slightly from the level in 2013, while it decreased in about half of the EU Member States (Eurostat, 2022f). This increase may be due to more patients requiring low-intensity care being treated through ambulatory care (see Chapter 7). Hence, the remaining inpatient cases are likely to require more complex care and longer stays. The evidence on the quality of services as perceived by patients is heterogeneous but overall positive (Box 5.6).

BOX 5.6 What do patients think of the care they receive?

A survey conducted by Eurobarometer in November 2013 on 1 019 Italian citizens indicated that the overall quality of health care was perceived as "good" by 56% of responders, and "bad" by 42%. The quality of health care compared with other EU countries was considered "better" by 12% of responders, "the same" by 37%, and "worse" by 35%. Moreover, 57% thought it is likely that patients could be harmed by hospital and non-hospital care, and 13% reported that the patient or a family member had experienced an adverse event in receiving health care (European Commission, 2014).

In 2017, ***Forum Ania Consumatori*** and ***Federconsumatori*** published the results of an online survey that asked 1 500 people to report on their satisfaction levels with health care interventions provided by the SSN. Overall, services satisfied 71% of respondents, with percentages higher than 80% regarding the professionalism of doctors, nurses and of administrative staff. The main reasons for dissatisfaction were related to waiting times (44% of cases), followed by costs, considered to be excessive by 24% of dissatisfied respondents (Federconsumatori & Forum Ania Consumatori, 2017).

5.5 Urgent and emergency care

Emergency care is provided free of charge to everyone, except in cases where it is deemed that the use of such care is not justified as an emergency (see section 3.4.1). Despite significant improvements in the emergency care system over the last 30 years, there has been a progressive increase in emergency admissions, many of which are due to inappropriate use by patients, i.e. for minor illnesses or conditions that could be treated within primary care, and has contributed to driving up costs and increasing inefficiencies, such as longer waiting times.

In 2001, a 24-hour nurse-led triage system was introduced to evaluate the patient's level of urgency, with assessment resulting in the assignment of a priority code (Table 5.3). Since 2019, the transition from colour codes to numerical codes (i.e. 1, 2, 3, 4, 5) has been gradually introduced (Ministero della Salute, 2019f).

TABLE 5.3 Priority codes under the emergency triage system [14]

CODE	TREATMENT ACCESS
1. Red code "emergency"	Immediate access to a medical intervention
2. Yellow code "urgent"	Access to treatment within 10–15 minutes (never more than 20 minutes)
3. Blue code "deferrable urgency"	Access to treatment within 60 minutes
4. Green code "minor urgency"	Access to treatment within 120 minutes
5. White code "non-urgent"	Waiting time over 120 minutes

Source: Ministero della Salute, 2012.

The patient's pathway through the health emergency system starts with the health alarm system, equipped with a short, free, and universal access telephone number 112, in connection with 76 operational centres throughout the country, which ensures the coordination of all interventions in the reference area and activates the hospital's response 24 hours a day.

The rescue system, consisting of rescue vehicles distributed throughout the country use basic rescue vehicles (with rescuers), advanced rescue vehicles (with doctors and/or nurses), and air ambulances. Emergency facilities that are available include (Ministero della Salute, 2021i):

- first aid points, fixed or mobile, organized in tourist seasons and locations, and during major sporting, religious, or cultural events;
- emergency rooms (*Pronto Soccorso*, PS), which provide diagnostic tests and any other interventions required to complete treatment, or in more complex cases, to guarantee the patient's stabilization and organize their transport to a specialized hospital;
- DEAs which have all necessary operating units and ensure a quick and complete response. DEAs are categorized into two levels of complexity (i.e. Level 1 and Level 2), based on their number of operational units, and can be either generic or specialized (e.g. paediatrics, obstetrics, orthopaedics).

Regions adopt different organizational models for emergency care. For example, Lombardy has one dedicated authority for its entire territory while most other regions follow more decentralized models (e.g. each local health

14 A co-payment is payable if a white code patient is not subsequently hospitalized; see Chapter 3.

authority manages emergency care independently). More centralization is likely in the future, partly due to the introduction of the new European first-contact emergency number (116 117), which provide patients with an initial telephone or digital reference to receive directions on how to access care.

5.6 Pharmaceutical care

In Italy, the pharmaceutical industry is a solid, profitable and expanding sector. Its main strengths are manufacturing and exports, mainly to middle-income countries. Research and development (R&D) activities are important and well developed. The number of firms operating in the sector grew from 15 637 in 2018 to 18 363 in 2020 (data include pharmacies that are about 60% of the total). In 2020, the value of pharmaceutical production increased to EUR 34.3 billion, particularly thanks to the growth in exports (+3.8% compared with 2019) (Filodiritto, 2022). Most pharmaceutical companies (including pharmacies) are concentrated in the Lombardy (19%), Lazio (10%) and Campania (10%) regions.

Italy has the highest number of small and medium-sized pharmaceutical companies in Europe (37% of them have only up to two employees) (Cribis, undated). Recently, emerging international trends are challenging Italy's pharma sector, including the growth of the life science industry, the technological revolution based on digital tools and genomics, the cost of developing therapeutic innovations, and the need to ensure the sustainability and equity of health systems. To face these challenges, Italy is expected to invest in human resources, know-how, R&D, digitalization and partnerships (BancaIfis, 2019).

Overall, and with the exception of direct distribution (see section 2.7.4), pharmaceutical services are mainly provided through local pharmacies, which can be urban (if located in municipalities with more than 5 000 inhabitants) or rural (with less than 5 000 inhabitants). Further, a considerable share of medicines (mainly of Class H, used in hospitals or prescribed to patients admitted to day hospital) is distributed through hospital pharmacies and/or the pharmaceutical service of local health authorities. The prevailing criterion for establishing the number of pharmacies in each municipality is demographic, i.e. one pharmacy for every 3 300 inhabitants (Law 27/2012). In 2019, the density of pharmacies per inhabitants in Italy (one for every 3 129 inhabitants) was in line with the European average (one every 3 275

inhabitants) (Federfarma, 2019). Following recent extraordinary tenders, leading to more new pharmacies opening, the density of pharmacies per inhabitant is expected to increase. In terms of ownership, pharmacies can be divided into private (the larger share) and public, owned by the municipality where they are located. A major change was brought by Law 124/2017, which allowed joint stock companies to become pharmacy owners, even without pharmacist members in the company (but with a pharmacist remaining in charge of the pharmacy's management).

The role of pharmacies was enhanced in 2010 when they were authorized to provide additional services beyond distribution, such as first-level tests (e.g. blood glucose, cholesterol and triglyceride tests) and second-level services (such as non-invasive measurement of blood pressure and testing lung capacity by auto-spirometry) (Ministerial Decree 16 December 2010). The decree also regulated activities that can be provided by nurses and physiotherapists in pharmacies, such as medication and intramuscular injection cycles (by nurses) and functional re-education of motor, psycho-motor disabilities (by physiotherapists). In 2011, pharmacies were allowed to be equipped with a dedicated workstation to operate as access channels to the CUP to book specialist outpatient services at accredited public and private health facilities, pay co-payment fees and collect the related reports (Ministero della Salute, 2013). In reality, the implementation of these activities is still sporadic, due to the reluctance of other health care professionals and facilities to delegate part of their activities to pharmacies and to the limited regional resources available to remunerate pharmacies for such extra services.

In 2021 the Legislative Decree *"Sostegni"* (41/2021) allowed pharmacies to vaccinate individuals against COVID-19 and receive extra remuneration for distribution of medicines on behalf of the SSN (see section 2.7.4), as an acknowledgement of the key role played by pharmacies during the pandemic. In 2019, over 40 million people (around two thirds of the total population), of which 55% were women, received at least one pharmaceutical prescription corresponding to per capita expenditure of EUR 197 and a consumption ratio of 1 029 defined daily doses (DDD) per 1 000 inhabitants per day, suggesting that, on average, every Italian citizen received one dose of medication every day of the year. Total pharmaceutical expenditure – both public and private – amounted to EUR 30.8 billion, of which 76.4% was reimbursed by the SSN. OOP expenditure amounted to EUR 7.3 million and was mainly composed of Class C prescriptions (Table 5.4) (AIFA, 2020a).

TABLE 5.4 Pharmaceutical expenditure, 2019

	EUR (MILLION)	% OF TOTAL
Outpatient SSN expenditure (including vaccines and Class C medicines reimbursed)	10 034	32.6
Oxygen	55	0.2
Class A medicines by DD and DPC	4 481	14.5
Local health authorities, hospitals, health care residences and prisons (including vaccines and oxygen and net of DD/DPC of Class A)	8 980	29.1
Total public expenditure	**23 550**	**76.4**
Class A drugs (private purchase)	1 544	5.0
Class C with prescription	3 066	9.9
Class C without prescription	2 392	7.8
Retail	259	0.9
Total private expenditure	**7 261**	**23.6**
Total expenditure	**30 811**	**100.0**

Note: DD: direct distribution; DPC: distribution on behalf of SSN; SSN: National Health Service.

Source: AIFA, 2020a.

Equivalent (or generic) medicines prices should be at least 20% lower than reference medicines (AIFA, 2020b). According to Law 405/2001, off-patent drugs with the same active ingredients as well as pharmaceutical form, route of administration, method of release, number of dosage units and equal unit doses, are reimbursed to the pharmacist by the SSN up to the lowest price of the corresponding generic drug available in the normal regional distribution cycle. After informing the consumer, the pharmacist provides the medicine with the lowest price, unless the doctor has explicitly expressed that the prescribed medicine is not substitutable or the consumer refuses the generic. In these cases, the difference between the price of the generic and of the prescribed drug is borne by the customer (with the exception of war pensioners who are entitled to life pensions). Moreover, Law 135/2012 states that physicians treating a patient for a chronic disease for the first time, or for a new episode of a non-chronic disease, for which more than one equivalent medicine is available, must indicate only the name of the active ingredient of a drug in SSN prescriptions. Despite these measures, the utilization of generics in Italy is still relatively low (Box 5.7).

BOX 5.7 Is there waste in pharmaceutical spending?

Despite a significant increase in consumption (from 7% in 2005 to 25% in volume in 2017), the use of generic medicines in Italy is still significantly lower than the EU average (almost 50% less, and up to 80% compared with some countries such as the United Kingdom), especially in southern regions. There are a number of possible reasons. Firstly, although the pharmacist is required to offer the customer any available cheaper generic, doctors can still specify the prescribed medicine as "non-replaceable". Secondly, customers can still decide to purchase the branded medicine, paying out of pocket for the difference between the generic and the prescribed medicine. Despite TV information campaigns (e.g. Health For All 2012), many patients do not fully understand how the system works or prefer to rely on branded drugs which are well known in the market. Thirdly, pharmacy staff often do not help patients to choose between branded and generics as they have no financial incentives to do so (European Commission, 2019).

5.7 Rehabilitation/intermediate care

According to the 1998 Guidelines and the 2011 Rehabilitation Policy Plan, rehabilitation can be provided in three types of settings:

1. hospitalization settings, whether ordinary or day hospital;
2. outpatient/day service specialist settings and rehabilitation clinics;
3. home, outpatient, residential or semi-residential care.

Rehabilitation in residential and semi-residential facilities is for clinically stable patients with disabilities due to diseases and who need adequate assistance for 24 hours (residential care) or shorter periods (semi-residential care). Access to physical and psychosocial rehabilitative treatment should be preceded by a multidimensional assessment of the patient's rehabilitation and care needs, carried out by multidisciplinary evaluation units (*Unità Valutativa Multidisciplinare*, UVM), and authorized by the local health authority.

To strengthen their role in guaranteeing continuity of care, offering alternative post-acute care and preventing inappropriate hospitalization, over the last two decades a few regions have introduced residential primary care facilities, called community hospitals. These are low-intensity care hospitals, often managed by nurses and under a GP's (or paediatrician's) clinical supervision; they have a limited number of beds (15–20) and a length of stay

of 15–20 days. Community hospitals were formally recognized through the 2014–2016 Health Pact between the central government and the regions. Subsequently, in February 2020, the State-Regions Conference defined the minimum structural, technological, and organizational requirements of these facilities based on the 2014 agreement and Ministerial Decree 70/2015. The presence and features of intermediate care are today very diverse throughout the country. A recent mapping study (Fattore, Meda & Meregaglia, 2021) identified around 180 facilities, mainly concentrated in the regions of Veneto, Emilia-Romagna, Toscana and Puglia.

5.8 Long-term care

In 2050, one in three Italians are expected to be over 65 years old. Socioeconomic developments (e.g. decrease in multi-generational family units and an increase in female participation in the labour market) have contributed to reducing the availability of family caregivers to provide care and assistance to the elderly. Therefore, residential health facilities or retirement homes (*Residenze Sanitarie Assistenziali*, RSA) have been subject to a rapid, demand-driven expansion in the last two decades. Currently, there are 18.6 available RSA beds for every 1 000 older residents in Italy, well below the OECD average of 43.8, and these are mainly in central and northern Italy. It is difficult, however, to provide precise estimates since Italian regions use different denominations and organizational models, encompassing retirement homes, geriatric rehabilitation institutes, etc. Overall, RSAs are open-ended or temporary residence facilities. The Ministry of Health has indicated that they should be integrated within the existing urban fabric, in areas well connected by public transport, to avoid isolation. Their capacity can vary from 20 to 120 places, divided into modules of 20 residents each. One quarter of the available modules should be reserved for residents with dementia. Some RSAs have an "Alzheimer's Nucleus", an area dedicated to patients with cognitive and behavioural disorders.

RSAs are mainly private. Local health authorities or social services regulate access to public or accredited RSAs upon GP's or hospital doctor's request, organize visits to the geriatric evaluation unit, and manage waiting lists. Only health service costs are borne by the SSN and vary according to the level of assistance provided. The remaining costs are borne by patients, municipalities and, indirectly, by the National Institute for Social Security (*Istituto nazionale della previdenza sociale*, INPS). Italy does not offer insurance

for long-term care; however, a universal national allowance (*Indennità di accompagnamento*; EUR 525 per month in 2022) is granted by Law 18/1980, irrespective of income status, to non-self-sufficient individuals. Large regional variations exist with regard to the additional resources topped up by other government entities (regions, municipalities).

Similar facilities exist for disabled people, with different denominations and types, such as socio-rehabilitation communities or centres for the disabled (*Centri Diurni per Disabili*, CDD). Long-term care for elderly, cognitively or physically disabled people also can be provided in semi-residential settings, such as day centres. These centres provide social, health, rehabilitation, and educational services to people usually aged 18–65 years (although younger people can also be admitted) on the basis of individual projects (Ministero della Salute, undated). Similarly, integrated day centres (*Centri Diurni Integrati*, CDI) offer social and health care and services to people over 60.

Lastly, the SSN guarantees home care, i.e. assistance in one's own home, to non-self-sufficient people or those in a frail condition. Home care services are included in the national benefits package and thus are entirely paid by the SSN, upon a preliminary multidisciplinary evaluation of the patient's health and social condition. Home care is divided into "scheduled home care" (*Assistenza Domiciliare*, AD) that provides medical, nursing and/or rehabilitation health services limited to the episode of illness in progress, and "integrated home care" (*Assistenza Domiciliare Integrata*, ADI) that consists of an integrated set of health and social treatments, delivered in a coordinated and continuous manner. Moreover, "home hospitalization" is a service characterized by diagnostic, therapeutic and rehabilitative services of high complexity and defined duration, provided by a specialist team usually recruited from hospitals.

5.9 Services for informal carers

The large majority of caregiving in Italy is provided by families and friends. There are over 8.5 million caregivers (17.4% of the total population, the majority being women), of which 7.3 million are family caregivers. In total, 30% are under the age of 45, and 60% are not employed (ISTAT, 2017). Law 104/1992 grants 3 days of paid leave each month for employed people who assist family members with disabilities, and an extraordinary leave of up to 2 years. To benefit, two conditions must be satisfied: 1) the assisted person is recognized to have a serious disability; and 2) the assisted person is not hospitalized full time.

The government established a national fund of EUR 20 million per year over the period 2018–2020 to support family caregivers. This funding, however, has not yet been used as the parliamentary approval process is still pending. In 2020, due to the challenges posed to caregivers by the COVID-19 pandemic, some resources were allocated to the regions with the condition of prioritizing caregivers of people with very serious disabilities and who had no access to residential facilities due to the emergency. More recently, the Ministry of Labour established a new fund for the recognition of the social and economic value of non-professional care activities, with a budget allocation of EUR 30 million for each of the years from 2021 to 2023. These funds are available from different ministries and are not part of the national health budget. Informal caregiving is a critical issue which is still low in the political agenda. There is a lack of policies to guarantee a basic level of support for caregivers, such as providing certification of services performed, training and psychological support. In this respect, the needs of patients' relatives and friends are largely neglected.

5.10 Palliative care

In Italy, the regulation of palliative care was first introduced with Law 38/2010, which defines it as a set of interventions for a person suffering from a disease with an unfavourable prognosis and no longer responding to specific treatments. The law guarantees access to palliative care and pain therapy to all citizens. Palliative care can be provided in inpatient, outpatient or home settings (Ministero della Salute, 2021j).

In 1999, national legislation introduced a new type of residential facility, called a "hospice", which is an alternative to, or complementary to, home care and dedicated to terminally ill (mainly oncological) patients and their families (Ministero della Salute, 2017b). There are about 240 hospices in Italy, with a total of 2 777 beds and over 42 000 admissions per year. Among the regions, Lombardy has the highest number of hospice beds per 100 000 inhabitants (8.3), followed by Lazio (6.9) and Emilia-Romagna (6.5) (VIDAS, 2017). Admission is planned by health care professionals in agreement with patients and their families. Around 5 000 volunteers work in hospices every year. They belong to different voluntary organizations coordinated by the Palliative Care Federation (*Federazione Cure Palliative*, FCP). Volunteers follow specific training, defined by FCP in the volume "Training courses and core curriculum

for volunteers in palliative care". The document distinguishes two types of volunteering: "one dedicated to organizational support, fundraising, awareness raising and dissemination activities", and the other closer to the patient and the family, which requires careful selection, training and support from psychologists. The training follows three phases: basic training, internships of a minimum of 20 hours and continuous training. A FCP survey (2015) showed that volunteers are mainly women (76%), over 50 (63%) and with at least a high school diploma in 54% of cases.

In very recent years, Italy reached two milestones in the area of palliative care. The first was the approval of the "End of Life" law (Law 219/2017), also known as "living will" law, which came into force in January 2018. The law has introduced the "advance treatment statement" (known as the DAT, in Italian), which is a document in which a person specifies what future medical treatments they would like if they were no longer able to make such decisions themselves due to illness or incapacity. They can also state certain treatments they do not want (e.g. artificial feeding and hydration). The second was the introduction of the School of Specialization in Medicine and Palliative Care and of a compulsory course in palliative care at the School of Specialization in Paediatrics for the first time in the Italian university system.

5.11 Mental health care

In 1978, with Law 180/1978 (*"Legge Basaglia"*), Italy was the first country in Europe to abolish mental hospitals (or asylums) (around 100 were active at that time) and compulsory mental treatments on psychiatric patients, establishing the basis for a new mental health care and philosophical model (Fattore et al., 2000). The inspiring principle was that mentally ill people should have the same rights as other patients and be integrated into the community, instead of admitting them and coercively treating them in isolated facilities. Compulsory health treatment (*Trattamento Sanitario Obbligatorio*, TSO) became acceptable only in cases of clinical urgency or under justified circumstances, and as an exception to the constitutional principle (art. 32) that no one should be treated against their will. Mental hospitals were gradually replaced by domiciliary assistance, outpatient mental health centres, hospital psychiatric wards, long-term psychiatric residential structures, and residences for the implementation of security measures (*Residenza Sanitaria per l'Esecuzione delle Misure di Sicurezza*,

REMS), the latter dedicated to mentally ill offenders. Two different medical specializations are available in the mental health area: "psychiatry" for adult patients and "child neuropsychiatry" for paediatric patients, which also deals with neurological disorders.

Italy's hospitalization rate for psychiatric disorders decreased steadily from 2001 to 2018, in line with the trend for all hospitalizations, and with the objective of shifting the management of mental disorders mostly to community care. Uneven distribution of mental care services and the lack of a standardized monitoring system account for some level of regional variability in this hospitalization rate. Further, services for individuals with addiction (*Servizi per Dipendenze*, SERT or SERD) are multidisciplinary outpatient services dedicated to the treatment, prevention and rehabilitation of people abusing narcotic substances (drugs or alcohol) or affected by other types of addictions (e.g. gambling, compulsive shopping, social media, food). SERT/SERD are multi-professional organizational units within local health authorities led by a clinician (often a psychiatrist). In the context of the COVID-19 pandemic, research and policy initiatives were promoted in the mental health area (Box 5.8).

BOX 5.8 COVID-19 and mental health

COVID-19 had a dramatic effect on the mental health of Italians, mainly due to the restrictions imposed on people's normal lives. As in the rest of Europe, Italians suffered from complete and partial lockdowns that limited working and social life such as forced confinement at home, disruption of school activities and reduced opportunities for sport and recreation. There is evidence that all these restrictions impacted on mental health, especially in the younger segments of the population (OECD, 2021a). The impact has been investigated since the beginning of the pandemic. For example, the National Twin Registry (RNG), managed by the ISS, surveyed the twin population. About 2 700 adult twins (average age 45 years, 64% women) and 878 families with non-adult twins (average age 9 years) participated. Overall, depression and stress symptoms were observed in 11% and 14% of the sample, respectively, while anxiety levels were beyond the normal range in about half of the participants. In twins aged 11–17 years, 16% slept worse during the lockdown period, 13% felt sad quite often and 11% felt alone quite often.

Two interventions were promoted during the pandemic period: a programme to manage the impact of the epidemic on mental health in high-risk individuals, and an intervention programme for the management of anxiety and perinatal depression in emergency and post-emergency COVID-19 patients (Epicentro, 2020).

5.12 **Dental care**

Dental care is almost exclusively provided by private clinics, with most dental treatments purchased privately, either out of pocket or through private insurance. The SSN only covers costs for children aged 0–14 years, and clinically or socially vulnerable people. The services in the national benefits package include the treatment of caries and monitoring of malocclusions as well as treatment of severe orthodontic pathologies. The eligibility criteria for qualifying as a part of a vulnerable group are defined on the basis of an "ascending criterion", which considers conditions more frequently associated with dental complications (e.g. cleft lip and palate, some rare diseases), or a "descending criterion", which considers patients affected by severe illness (e.g. pre-, or post-transplant, severe immunodeficiency, congenital cardiopathy) that could be worsened by a dental pathology. Although citizens are eligible for urgent interventions; for example, for acute pain, use of SSN dental services by the population is limited due to a mix of factors, including poor reputation, lack of supply, long waiting times and consolidated use of private services (Ministero della Salute, 2017c).

6

Principal health reforms

Chapter summary

- No major structural reforms have been approved by the Italian Parliament in the last 15 years. The fundamental features of the SSN have not changed and most regional health care systems have been consolidating.

- However, the government has brought about important changes through specific measures in prevention and hospital care. It has also redefined the national benefits package and introduced a special regime for regions that overshoot their budget and/or do not deliver on the benefits package.

- The NRRP adopted in 2021 offers an opportunity for changes to the SSN. Many of these changes will depend on the institutional capacities of the central government, regional governments and SSN organizations.

6.1 Analysis of health reforms

Table 6.1 gives an overview of the most recent health reforms from 2005 to 2022. Details on other past reform measures can be found in Ferrè et al. (2014). While no major reforms have changed the fundamental structure of the SSN over the last 15 years, most regional health systems have been consolidating their governance, planning and delivery mechanisms. At the national level, the government has brought about important changes in the

areas of prevention and hospital care as well as in rationalizing the national benefits package (LEA). Specific attention has also focused on financial probity, with the introduction of a special regime for regions that overshoot their health budget and/or do not deliver the guaranteed core services of the national benefits package.

TABLE 6.1 Most recent health reforms in Italy

YEAR	REFORM	FOCUS
2005	Recovery plans for underperforming regional health systems	Financing: addressing overspending and guaranteeing the national benefits package
2015	Ministerial Decree 70/2015	Planning for hospital care
2017	Law 24/2017 "Gelli Law"	Prevention and patient safety
2017–2019	National Vaccination Plan	Prevention
2022	Ministerial Decree 77/2022	Primary care, intermediate care, digitalization, research and innovation

Source: Authors.

6.1.1 *Prevention*

The Ministry of Health released a National Vaccination Plan for 2017–2019 to expand vaccination coverage and targeted populations, increase the number of vaccines to be offered to the population and set up an online vaccination registry. In the last decade, in fact, Italy had been experiencing a decline in coverage of children's vaccination (Ricciardi, Boccia & Siliquini, 2018). In 2017, national legislation increased the number of compulsory vaccines from four to 10 (see section 5.1.1), with an additional four recommended and free of charge. The government's decision was contested by a tiny minority of the population and, initially, by a major political movement (*Movimento 5 Stelle*), but a large majority of the Italian Parliament voted in favour to re-introduce compulsory vaccination. In hindsight, it appears that the policy was effective in increasing coverage (Ricciardi, Boccia & Siliquini, 2018).

Through Law 24/2017, also known as the "Gelli Law", the Italian Government enhanced the preventive role of patient safety, as endorsed by scientific bodies and patient associations. In addition, while recognizing safety as a right for everyone accessing health services, the new law also protects

health care professionals from being sued if guidelines and safe practices accepted by the ISS have been followed, even in cases of adverse outcomes. In fact, professionals can be prosecuted only in cases of wilful misconduct or gross negligence (Bellandi et al., 2017).

6.1.2 *Hospital care*

A Ministerial Decree targeting hospital care was issued by the Ministry of Health in 2015 (Ministerial Decree 70/2015). This major and ambitious planning document took a long period to develop, during which time there was no detailed planning of the hospital system. The document sets standards for the main characteristics of SSN and private-accredited hospitals and their activities; for example, it sets a minimum number of beds each hospital should have and classifies hospitals into different categories. It indicates that regions should aim for 90% hospital bed occupancy rates, 160 admissions per 1 000 patients and 3.7 hospital beds per 1 000 inhabitants: 3.0 for acute care and 0.7 for rehabilitation or medical long-term care. These figures are calculated using detailed standards for each specialty, using national experience and international evidence. These standards aim to incentivize the use of ambulatory care for appropriate treatments (e.g. for cataract surgery) and reduce inappropriate admissions (e.g. those of frail patients without an acute episode who should be cared for in other settings). The most innovative element of Ministerial Decree 70/2015 relates to the use of volume standards for planning hospitals' sizes and their reconfiguration (see below). Based on systematic reviews on the relationship between volumes and outcomes, the Ministerial Decree sets minimum standards for specific surgical procedures, generally expressed as a number of cases per year (e.g. for cardiology at least 100 and 200 cases per year should be treated for acute myocardial infarction and coronary artery bypass graft, respectively).

These provisions face two major constraints, one institutional and the other geographical. The difference in population size among regions limits the full implementation of the decree without formal agreements between regions for the different categories of hospitals (see Chapter 5 and section 4.3). Moreover, the decentralized nature of the SSN makes these agreements sometimes difficult: the geographical constraints mean that some villages can be more than a 45 minutes drive away from the closest hospital, very often with limited means of public transport. It is not surprising, then, that

reorganizing hospital care for these communities is challenging and that Ministerial Decree 70/2015 faces strong resistance from the population and their political representatives as hospitals are staffed with local people and they are important political and social symbols for local communities (Healy & McKee, 2002). For this reason, the decree also leaves open the option of maintaining small hospitals that do not comply with the targets presented above (e.g. because they are in the minor islands or mountain areas) and envisions the development of community hospitals, i.e. small facilities providing low and medium intensity care with no more than 40 beds.

Another important innovation of the decree is the introduction of hospital networks. These are inter-organizational arrangements aimed at coordinating different levels of care and facilitating the movement of patients to appropriate clinical and organizational settings. The decree identifies 10 networks, including oncology, acute myocardial infarction, stroke, paediatrics, traumatology and rare diseases (see Box 5.5) with defined catchment areas. Special attention is paid to conditions for which the timing of the intervention is essential to ensure clinical results.

While the decree sets national standards, it leaves regions a degree of flexibility for implementation (e.g. which hospitals had to be closed), taking into account their spatial specificities. In this respect, the degree of compliance is very heterogeneous with some regions being very active in reorganizing their hospital systems (e.g. Emilia-Romagna and Veneto) and others progressing at a slower pace (e.g. Calabria and Campania). This diversity in the transposition of national directives into regional legislation and implementation stems from the diversity of socioeconomic contexts, political attitudes and institutional capacities available within regions. For example, in southern regions, where the unemployment rate is very high (in some areas above 20%), SSN organizations are often the largest employers and are often primarily regarded by the population as an opportunity for jobs rather than providers of services. Moreover, certain medical professionals needed to re-design health services are particularly lacking in some regions due to unfavourable employment conditions in regional departments of health (the employees of regions have different contracts from those offered by the SSN).

6.1.3 *Recovery plans*

Legislation in 1992 and the 2001 constitutional reform transferred some legislative and administrative power in the area of health and health care from the central government to the regions. As a result, the SSN was largely decentralized and health care became the main government function held by regions (in some regions over 80% of the budget is for health care) (Longo, 2016). The first years of implementation of these new arrangements (2007–2010) led to large budgetary deficits in several regions (about 10 out of 20, mainly in the south). This prompted the central government to partially recentralize the SSN through a new institutional and policy framework. Initially, the central government made it mandatory for regions in financial deficit to agree on a set of measures of recovery (these were referred to as internal "stability pacts"). These pacts envisioned that regions have to cover their deficit, information systems had to be strengthened to monitor financial performance and the central government had to bear part of the extra costs provided that the regions acted according to agreed interventions. In 2005, legislation transformed these pacts into recovery plans (*piani di rientro*), which were implemented from 2007; they have had a profound impact on the SSN (Bobini et al., 2019) (see also Chapter 3).

Recovery plans are intergovernmental arrangements targeted towards regions that overspend and/or fail to deliver the guaranteed services in the national benefits package to their residents. Regions fall into this region-specific regime when they overspend more than 5% of their health budget or in the case of deficits under 5%, if automatic budgetary mechanisms that are triggered are not sufficient to balance the books. The automatic mechanisms consist of: 1) raising IRAP (the earmarked regional corporate tax and the regional components of personal income taxes; 2) not replacing employees who retire; and 3) banning any discretional expenditure for services that are not strictly related to the national benefits package. Regions have to submit a recovery plan (a formal document) that needs to be approved by the Council of Ministers on the proposal of the Ministry of the Economy and Finance. These plans should report all main actions aimed at balancing budgets. The implementation of the plans is a precondition to receiving funding from the government to cover the budgetary imbalance and are monitored on a quarterly basis (*Tavoli di Monitoraggio*) through a sophisticated information system. In the most severe situations, all political prerogatives are taken by the President

of the Region who acts as a commissioner (*Commissario ad acta*). If, despite this, the region's financial situation remains critical, the national government can appoint an extraordinary commissioner who centralizes all regional political power (in short, authority is taken away from the regional parliament and government). In addition, the top managers of the entire regional health care system are dismissed and replaced by national government appointees. Finally, the regions which are put under the authority of an extraordinary commissioner are subject to significant fiscal penalties.

Recovery plans, which apply to all SSN organizations and private-accredited providers, target cost reduction in six areas (Ministero dell'Economia e delle Finanze, 2009; Arcà, Principe & Van Doorslaer, 2020):

1. hospital care: reduction of the number of beds and hospitals, more use of day hospitals and ambulatory care to substitute for ordinary admissions;
2. pharmaceutical care: direct distribution by hospital pharmacies to non-hospitalized patients, electronic monitoring of prescribing behaviour;
3. personnel: suspension of hiring unless in exceptional situations, freeze on staff turnover;
4. private-accredited providers: caps on their SSN budgets;
5. purchasing: centralization of purchasing and better monitoring of tenders;
6. appropriateness of pharmaceutical prescriptions made by GPs and specialists.

This major policy has reshaped the governance of the SSN in two ways. First, at the central level it redistributed power in favour of the Ministry of the Economy and Finance, which has developed the internal capacity to govern the economic side of the system and has taken a leading role in the processes of recovery plans (e.g. in managing the discussion with the regions). The Ministry of Health plays a secondary role when discussing financial issues. In this respect, it is significant that no Ministry of Health division has the word "economics" or "finance" in its name. Second, this re-centralization has been asymmetric as it relates to some regions only. Despite national attempts to have a greater grip over all regional systems, centralization of budgetary control has occurred only in regions that were subjected to recovery plans. The other regions have maintained administrative, organizational and financial autonomy

to a much larger extent. As of September 2022, seven regions (Abruzzo, Calabria, Campania, Lazio, Molise, Puglia, Sicily) are still functioning under recovery plans (Ministero della Salute, 2022).

On paper, regions should be monitored for both their financial performance and the performance of the health system in terms of population health outcomes and the delivery of services. However, financial concerns dominate. The delivery of the national benefits package is indeed monitored (see Chapter 7) but, so far, plans have included few interventions aimed at improving the performance of the SSN. This is not only due to the dominance of cost-containment objectives, but also to the difficulties in identifying adequate metrics to monitor the delivery of services and health improvement. Despite these difficulties, however, Italy has made important progress in establishing a national system to monitor the regions and their organizations with a number of indicators that are collected robustly and reliably. This monitoring system, called the New System of Guarantees (*Nuovo Sistema di Garanzia*), consists of 88 indicators. They are built on the basis of data collected by the SSN, ISTAT and other institutions. For the first time, with this system, the SSN includes equity indicators to monitor its performance (e.g. in addition to mean regional values, intraregional variability indicators are used) (see Chapter 7). Overall, the available evidence shows that recovery plans have contained health care expenditure, mainly through cuts of hospital beds and freezing of personnel hiring, and thus have contributed to the financial stability of the SSN. However, some of this evidence, but not all, also shows that citizens living in regions under recovery plans (mainly in the south) experienced worse health outcomes (Aimone Gigio et al., 2018; Depalo, 2019; Arcà, Principe & Van Doorslaer, 2020, 2020; Bordignon et al., 2020).

The 2016 National Budget Bill (*Legge di Stabilità 2016*) extended the requirement of financial recovery plans to the SSN's public hospital trusts with budget deficits and, in 2017, to local health authorities. In cases where there is a deficit equal to 10% of the difference between costs and revenues or, in absolute values, greater than EUR 10 million, general directors have 3 years to rectify the deficit or risk being replaced. Specifically, for hospitals, the recovery criteria also include non-compliance with certain parameters of quality and outcomes of care (Mauro, Maresso & Gugliemo, 2017). Furthermore, all SSN facilities are required to publicly post their financial statements on their website and activate quality monitoring systems (de Belvis, 2016).

6.2 Future developments

In the framework of the EU Budget 2021–2027, the European Commission has introduced the Next Generation EU as an instrument for post-crisis economic recovery from the COVID-19 shock, for a total amount of EUR 750 billion, of which EUR 390 are grants and EUR 360 loans. In absolute value, Italy is the first beneficiary of the two main instruments of the Next Generation EU: the Recovery and Resilience Facility (RRF) and the Recovery Assistance Package for Cohesion and European Territories (REACT-EU). The RRF alone guarantees resources of EUR 191.5 billion, to be deployed over the period 2021–2026. Italy also intends to make full use of its financing capacity through RRF loans, estimated at EUR 122.6 billion.

The RRF Facility requires Member States to present a package of investments and reforms: the NRRP. The Italian plan for recovery has six missions: 1) digitalization, innovation, competitiveness, culture, and tourism; 2) green revolution and ecological transition; 3) infrastructure for sustainable mobility; 4) education and research; 5) inclusion and cohesion; and 6) health.

Mission 6, Health, has a budget of approximately EUR 15.63 billion. It is made up of two components: 1) proximity networks, facilities and telemedicine for community care; and 2) innovation, research and digitalization of the SSN.

The aim of the first component is to strengthen primary and community care by creating a vast and widespread infrastructure of facilities. For this, the NRRP has budgeted EUR 2 billion for new facilities hosting community services, EUR 4 billion for telemedicine and the creation of digital infrastructure to care for and treat patients in their homes, and EUR 1 billion for buildings and technology dedicated to community hospitals, which are facilities without emergency care and surgical activities (20–40 beds). The investment in this component of the NRRP, along with the recognition of important shortcomings in primary care experienced during the pandemic, has prompted a lively policy discussion about the present organization of primary care in Italy. In short, the model of solo-practice GPs, which is still the most prevalent in the majority of Italian regions, is deemed inadequate to ensure the quality of clinical care, integration across providers and efficiency. Two decades of attempts to promote group practice through voluntary associations among GPs and multidisciplinary teams have not been successful, with only some exceptions such as the regions of Emilia-Romagna, Tuscany and Veneto. Now, many policy-makers advocate for a radical reform, e.g. proposing the

transformation of GPs from independent providers to SSN employees. This, it is argued, would facilitate their integration into the system and would facilitate the management of GPs according to patients' needs.

More generally, the NRRP (component 1 of mission 6) calls for a major overhaul of primary and community care to provide patients with more human and accessible care where they live, reserving the role of hospitals only for acute care, where sophisticated and expensive technologies and professional expertise need to be concentrated to benefit from clinical and organizational learning curves and economies of scale. These new facilities require staff and other resources to become operational. However, the NRRP does not provide any extra funding for this as it only funds capital expenditure (buildings, technologies, digital infrastructure). One major challenge for the future of the SSN is the need for extra personnel. It will be difficult to staff new facilities due to the shortage of doctors (mainly GPs and specialists in some areas) and, to a much larger extent, nurses (see Chapter 4). The only viable strategy, although difficult to implement due to resistance from most professionals, is to transfer part of the staff working in acute hospitals to these new facilities.

Implementing the NRRP has also opened a new discussion that was taboo for decades: task-shifting. The Italian regulatory framework on the division of tasks among health professions (e.g. doctors, nurses, pharmacists) is obsolete and does not reflect changes in technologies and professional training. This regulation needs to be updated, learning from the best international experiences (such as the Netherlands and the United Kingdom). For example, task-shifting would allow doctors to concentrate more on diagnostic and clinical activities, thus spending less time on administrative activities, while nurses could focus on care (e.g. patients' education to promote compliance). This shift would also increase the appeal of nursing as a profession, which is still low in Italy, and would generate savings for the SSN given the differences in salaries between nurses and doctors.

The second component of the NRRP aims to upgrade the technological assets of the SSN and benefits from EUR 9.6 billion from 2022 to 2026. Here, the focus is on digital health, medical equipment and biomedical research. The NRRP funds are expected to replace obsolete equipment and improve hospital earthquake safety, as well as facilitate the exploration of the potential of big data for clinical, organizational and government activities. The NRRP funds will also be used to invest in human capital (training) and to establish a new national centre on epidemics. Related to this second component, another

planned reform aims to strengthen the role of public and private IRCCSs in the SSN through new funding mechanisms and governance arrangements.

The deadline for the conclusion of projects related to the NRRP is 2026. The conditions are such that even if just one of the projects agreed upon with the European Commission is not implemented by that deadline Italy would lose part of the funding. These circumstances probably triggered the central government to use a top-down approach; for component 1, the main planning document (Ministerial Decree 77/2022) was drafted by the central government and then negotiated with the regions in the State-Regions Conference. It took months to be finally approved in May 2022. Compared with the NRRP, this new decree further details standards and targets for community care and tries to impose them in all the regions homogenously, despite their different starting points and institutional capacities. Although detailed, national planning leaves a great deal of room to design regional models such as deciding what types of services should be offered in retirement homes for long-term care or where to locate community hospitals (e.g. as stand-alone facilities to decentralize care or as a specific ward in general hospitals run by nurses).

Given the unprecedented situation, the NRRP is a testing ground for the SSN. After a decade of cost-containment policies, there is now an opportunity to implement important investments and bring about major changes. Overall, it has been argued that investing in the health system and the health sector helps to promote socioeconomic development (WHO Regional Office for Europe/ European Observatory on Health Systems and Policies, 2022). However, using EU funds, and in general, investment funds, presents challenges, particularly as the technical capacities to design and implement sound projects are lacking, especially in southern regions. Investing in these capacities is essential for success (Anessi Pessina et al., 2021).

Even if the NRRP proves to be successful, two major concerns are likely to continue for the Italian health system in the years to come. The first concern is financial: will Italy increase public resources for the SSN to cope with increasing needs and expand the potential supply of services due to the NRRP and other investments? Will gains in efficiency unlock additional resources? The Italian public debt is so high that additional funding can be obtained only through an exceptional growth of GDP and/or a change of societal priorities. Without these conditions, any large increase in SSN financial resources appears unlikely and will undermine the SSN's ambitious principle of complete and equitable universal coverage.

The second concern is the widening gap between geographical areas. The concentration of hospital care in fewer facilities with high volumes has increased the transregional mobility of patients and reduced access to care for populations living in decentralized areas (mainly in mountain areas). The ambition of the NRRP is to close, or at least reduce, these gaps but the plan lacks practical guidance. Many policy-makers and advisors have highlighted that the new (and long overdue) financial resources under the NRRP could give the Italian Government an opportunity to tackle geographical inequalities through some form of re-centralization of governance. However, it is unclear whether the central government has (or can quickly acquire) all the competencies to effectively recentralize the SSN. It is also unlikely that regions, whose health budgets represent about 80% of their total financing, would accept relinquishing their powers in this area.

7

Assessment of the health system[15]

Chapter summary

- **Governance:** The national policy agenda has become increasingly focused on the importance of performance monitoring and accountability, directing legislative efforts in both areas. Governance choices have been oriented towards the centralization of specific competencies (such as medical device procurement) to reduce costs and increase transparency. Several interventions also have been directed at improving existing information systems, monitoring of health system performance and making data available to the public.

- **Accessibility:** Nearly all Italian residents are covered by the SSN, which covers most of the medical costs in hospitals and consultations with doctors. Unmet needs for medical care are equal to the EU average. Only 1.8% of the population reported unmet needs for medical care in 2019, driven mainly by financial hardship and waiting times, which contribute to relatively high levels of catastrophic spending among households.

- **Quality:** Some of the key indicators show that overall the quality of the SSN is improving. Although indicators of hospital care outcomes have improved, there is variability among regional facilities. As a measure of the effectiveness of primary care, at the national level, the rate of avoidable hospital admissions for several

15 This chapter was co-authored with Dr Andrea Adduci and Dr Alessio Perilli.

ambulatory-sensitive conditions has also been improving in recent years. In contrast, while national screening programmes have been expanded, indicators on screening uptake show that rates in Italy are still below EU averages in some cases.

- **Outcomes:** Avoidable mortality rates in Italy are, historically, among the lowest in Europe. Moreover, the life expectancy of Italians is one of the highest in the world, and their mortality profile is comparable to that of other high-income countries. However, the impact of deaths due to the COVID-19 pandemic reduced average life expectancy by 1.2 years in 2020. In terms of inequalities in health status, there are geographical differences, also linked to socioeconomic status, which disadvantage mostly the poorer southern regions and the main islands. In addition, almost half of the older population lives with severe limitations or with multiple chronic conditions.

- **Efficiency:** Given its level of health expenditure, which is significantly below the EU average, the SSN has proven to be generally efficient and capable of providing good access to high-quality care at a relatively low cost, although there are significant variations across regions. Decades of cost-containment policies have, however, implied a significant increase in OOP expenditure, longer waiting times and underinvestment in new facilities and technologies.

7.1 Health system governance

In terms of the Corruption Perceptions Index, Italy ranks 42nd out of 180 (Transparency International, 2022). Accounting for 13% of corruption cases (ANAC, 2019), the health sector is known to be particularly exposed to the risk of corruption, due to the large amount of public resources at its disposal and its network of national distribution channels, with an estimated loss of EUR 23.6 billion every year due to health expenditure waste, inefficiencies and corruption (the impact of the latter amounts to EUR 6.4 billion) (ISPE Sanità, 2014). According to the ISPE Sanità report, the main areas involved are medicine supplies, medical equipment and cleaning services.

Thus, the Ministry of Health's 3-year plans for prevention of corruption and transparency (the latest one released for 2021–2023) identify interventions aimed at preventing corruption risk factors, on the basis of the National Anticorruption Plan (*Piano Nazionale Anticorruzione*, PNA). According to the Plan, the main areas at risk are workforce recruitment, career progressions of health personnel, the assignment of public tenders, inspection of facilities, administrative surveillance and monitoring (Ministero della Salute, 2021k). Furthermore, the National Anticorruption Authority (*Autorità Nazionale Anticorruzione*, ANAC), the Ministry of Health and AGENAS have developed a monitoring system and a detailed roadmap to promote transparency in health care to reinforce the PNA. Specifically, the collaboration between AGENAS and ANAC has led to the establishment of a transparency portal, in which transparency indicators will be incorporated into the PNE which serves as one of Italy's health system performance measurement programmes (see below) (AGENAS, 2017).

Moreover, to safeguard citizens, if citizens (even a European citizen accessing Italian health care facilities according to EU Directive 24/11) are unsatisfied with the quality and safety of the treatment received, they can file a complaint directly with the facility's Public Relations Office (URP) and consult the Health Service Charter that each health facility is required to have (Ministero della Salute, 2019g). In addition, there are Consultative and Conciliatory Commissions (*Commissioni miste conciliative*) (Natangelo, 2006) and Ombudsmen at regional level (*Garante per il diritto alla salute*) introduced by the Gelli Law. However, these authorities have only a role in steering health care facilities with weak advocacy powers.

Some policy measures that already have been implemented, such as simplifying bureaucracy and centralizing the procurement of medical devices or public tenders, also seek to increase transparency and accountability as well as to avoid duplication of tasks and reduce waste. The main example here is the concentration of purchasing activities in regional or supra-organizational entities through the establishment of UPCs, the enlargement of several local health authorities or the establishment of a new authority, an Authorities Zero, in charge of a number of administrative tasks, including central purchasing (see Chapter 2).

Finally, the national policy agenda has become increasingly aware of the importance of performance monitoring and accountability, implementing several initiatives in these areas, including improving existing information systems and making data available to the public. Health system performance

measurement strongly relies on the PNE and on the NGS (see also Chapter 2) which is complemented by quarterly monitoring and evaluation of the adequate delivery of the national benefits package (LEA).

7.1.1 *Monitoring and evaluating the delivery of the national benefits package*

The Permanent LEA Committee, known as the National Commission for the Update of the LEAs and for the Promotion of Appropriateness of Care in the SSN, is composed of:

- four representatives of the Ministry of Health (one of whom is the coordinator);
- two representatives of the Ministry of Economy and Finance;
- one representative of the Department for Regional Affairs of the Council of Ministers;
- seven representatives of the regions.

The Committee's activities, technically supported by AGENAS, comprise the verification of the provision of the LEAs, their appropriateness and efficiency in the use of resources in delivering the benefits package in each region. Once the LEA Committee certifies the level of compliance of the regions, a technical evaluation board at the Ministry of Economy and Finance provides the final assessment. Such assessments then allow regions to access a premium quota of the National Health Service Budget.

The assessment is performed through the NGS, which was introduced on 1 January 2020 (Ministero della Salute, 2019h), updating the previous Guarantee System from 2000. The NGS is the tool that, with the multidimensional data available through the NSIS (see Chapter 2), evaluates the dimensions of equity, effectiveness and appropriateness of the care received by all Italian citizens through 88 indicators, including social, well-being and integrated care indicators as outlined in Table 7.1.

In order for regions to be compliant, each area of care, separately assessed, must score at least 60 out of 100. For underperformers, recovery plans are launched (see Chapter 3). Within each LEA it is possible to identify critical areas where performance is not meeting the required standards, time trends and, if significant, local deviations.

TABLE 7.1 New Guarantee System indicators

NATIONAL BENEFITS PACKAGE (LEA) AREAS	DOMAINS	NUMBER OF INDICATORS	EXAMPLES OF INDICATORS
Prevention and public health	• Vaccination and screening • Veterinary care • Lifestyle	16	1) Pneumococcal vaccination coverage 2) Chemical safety – surveillance in the production, import, market placement, use and distribution stages of chemical products 3) Proportion of people undergoing first-level uterine cervix, breast, colorectal cancer screening tests, within an organized campaign
District/community care (primary care), including integrated care	• Community care aimed at preventable hospitalization • Pharmaceutical care • Home care, nursing homes and intermediate care (e.g. community hospitals)	33	1) The standardized hospitalization rate in adults (≥18 years) for complications of diabetes, chronic obstructive pulmonary disease and heart failure 2) The standardized hospitalization rate for children and adolescents (<18 years) for asthma and gastroenteritis 3) Antibiotics consumption per 1 000 inhabitants 4) Long-term care: the number of non-self-sufficient older people aged ≥75 years in socio-health residential facilities per 1 000 inhabitants, and the rate of patients treated within ADI
Hospital care	• Outcomes of hospital care (e.g. hospital mortality) • Effectiveness and appropriateness (e.g. postoperative length of stay, waiting times) • Safety (e.g. hospital infection rate)	24	Seven of the 22 core indicators are in this domain: 1) standardized (daily and ordinary) hospitalization rate per 1 000 inhabitants 2) proportion of interventions for breast cancer performed in wards with a volume of activity greater than 135 interventions per year 3) ratio between hospitalizations attributed to DRG at high risk of inappropriateness and hospitalizations attributed to DRG not at risk of inappropriateness 4) proportion of laparoscopic cholecystectomies with a hospital stay of less than 3 days 5) percentage of patients (age ≥65) diagnosed with femoral neck fracture operated within 2 days in ordinary regimen 6) percentage of primary caesarean deliveries in facilities with less than 1 000 deliveries per year 7) percentage of primary caesarean deliveries in facilities with 1 000 deliveries or more per year
All	Context indicators on equity and for estimating population needs	5	1) Self-perceived health status 2) Chronic disease index 3) Forgone medical care due to organizational inappropriateness in services supply and/or service costs
All	Clinical appropriateness (diagnostic and therapeutical care pathways)	10	Percentage of patients with heart failure having undergone an adequate number of echocardiograms as indicated by guidelines

Note: ADI: integrated home care; DRG: diagnosis-related group.

Source: Authors.

In the context of monitoring important areas of regional performance, since 2007, recovery plans have been used as tools to maintain a balance between regional health care expenditure and quality of services (see Chapter 3). At present, there are seven regions subject to recovery plans (Abruzzo, Calabria, Campania, Lazio, Molise, Apulia and Sicily), two of which are under the supervision of a national-level Extraordinary Commissioner (Molise and Calabria) (see Chapter 6). Such plans have been effective in decreasing regional financial deficits: now very few regions exceed budgets and deficits are modest. However, cost-containment measures have mainly been driven by reductions in workforce capacity, cuts in the number of beds and, in some cases, an increased role for private sector providers. There is also some evidence that these policies had adverse effects on health outcomes (Arcà, Principe & Van Doorslaer, 2020).

7.1.2 *National Outcomes Programme*

The National Outcome Programme (PNE) is a parallel system managed by AGENAS aimed at measuring the clinical performance of SSN organizations and private-accredited providers. It provides a comparison at the national, regional and provider levels by assessing effectiveness, equity, appropriateness and safety. It makes available indicators using micro-data (at patient level) and risk adjustment procedures (for example, adjusted mortality at 30 days for acute myocardial infarction, re-hospitalization rates after hip replacement and caesarean section rates) (see section 7.4).

7.2 **Accessibility**

As mentioned in Chapter 3, population coverage for health services in Italy is universal and automatic for all citizens and those who are ordinarily residents. There are, however, some gaps in coverage in that undocumented migrants are only entitled to access urgent and essential services free of charge. The regions must also ensure that the services listed in the national benefits package (LEA) are delivered across the country, and systems are in place to monitor delivery (see section 7.1).

In 2017, the SSN updated the national benefits package, increasing the number of covered services, including in the areas of rare and chronic diseases, vaccinations, screening tests, medically assisted procreation and prosthetics assistance. However, many regions lack the financial and professional capacity to provide these additional benefits. In fact, the interregional mobility of patients seeking treatments outside of their region of residence has been growing, from 7% in 2001 to 8.5% in 2016 (OECD/European Observatory on Health Systems and Policies, 2019).

In 2019, 1.8% of the Italian population reported unmet needs for medical care (Fig. 7.1) which, given the broad range of services covered by public funds, is likely imputable to longer waiting times and to patient's co-payment/OOP payments (OECD/European Observatory on Health Systems and Policies, 2021). While this average rate of unmet needs is equal to the EU average, rates are higher for the population in the lowest income group (3.8%) and in less prosperous regions. In the southern part of the country, the likelihood of experiencing unmet needs for medical care is almost twice as high as that of richer northern regions, due to waiting times and longer distances to be covered to access services. In 2019, 44% of Italians went directly to the private sector to obtain at least one health care service, without even trying to book in the public system. This happened to 38% of people with low income and 50.7% of those with high income (RBM-CENSIS, 2021).

Similarly to several other national health systems, waiting times represent a long-standing issue for the SSN, and have been the subject of many debates and political initiatives. Comparable data at the EU level is available only for elective procedures and, with regard to other EU countries, Italy records good results for cataract removal (25 median waiting days) and hip replacement (50 median waiting days) (OECD, 2021a), despite interregional variation. For cardiological visits, however, the average waiting time is 49 days, for gynaecological visits it is 33 days and 75 days for colonoscopies (RBM-CENSIS, 2021). The effects of these long waiting times include patients turning to hospital emergency departments for non-emergency issues, and over 13 million admitting to having jumped waiting lists by resorting to favours or family/friend relationships (CENSIS-ANIA, 2016).

In 2019, the government adopted a national plan to reduce waiting times (*Piano national governo liste di attesa 2019–2021*; see also Chapter 5) and is currently launching a National Observatory on waiting times. In the meantime, the country is also having to address the consequences of the COVID-19 pandemic which caused the suspension and delay of numerous scheduled

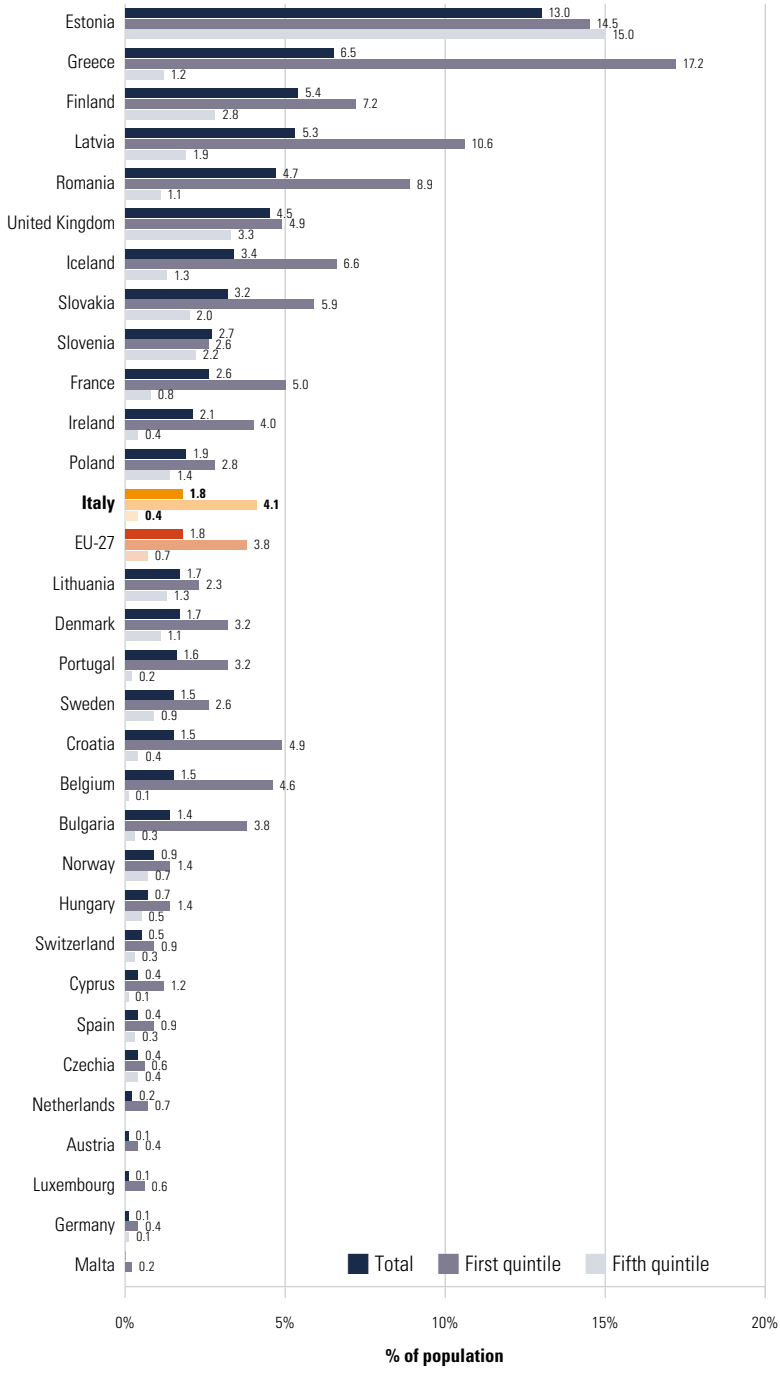
activities of non-urgent medical care. At the national level, AGENAS is in charge of monitoring and publishing waiting times as required by the *Piano Nazionale governo liste di attesa*. Moreover, in compliance with the EU cross-border health care directive (2011/24), individual health care facilities also publish waiting times on their websites.

7.3 Financial protection

Total health expenditure was 8.7% of GDP in 2019, below the EU average (9.9%). Overall, Italy spends much less on health care than comparator countries such as Germany, France and the United Kingdom. In 2019, per capita health expenditure was US$ PPP 3 998 (or EUR 2 525) which is below the EU average (OECD/European Observatory on Health Systems and Policies, 2021), with higher values in all central and northern regions (except Umbria and Marche) and lower in the southern regions and islands. The public share of health spending was 74% in 2019 – lower than the EU average (80%) – with most of private expenditure being almost entirely composed of OOP payments, which have been increasing over recent years. VHI plays a very small role in health financing (see Chapter 3).

Household expenditure on health care is quite high: this source of financing started increasing after the economic crisis in 2009; in 2019, OOP spending constituted 23% of total health expenditure, which is well above the EU average of 15%. A large proportion of OOP payments in Italy are spent on outpatient medical care (10.5% of total health expenditure) and on pharmaceuticals (6.9%). Italy is among the countries with a high percentage of households that experienced catastrophic health expenditure in 2019 (9.4%) (Fig. 7.2). Other national evidence points to the health system facing difficulties in protecting citizens from financial hardship. Due to excessive waiting times, it has been estimated that nearly 8 million people used all their savings on private health care or indebted themselves to cover health expenses. Additionally, 1.8 million people fell below the poverty line and now belong to the category of the population that has been "impoverished by health expenses" (RBM-CENSIS, 2017).

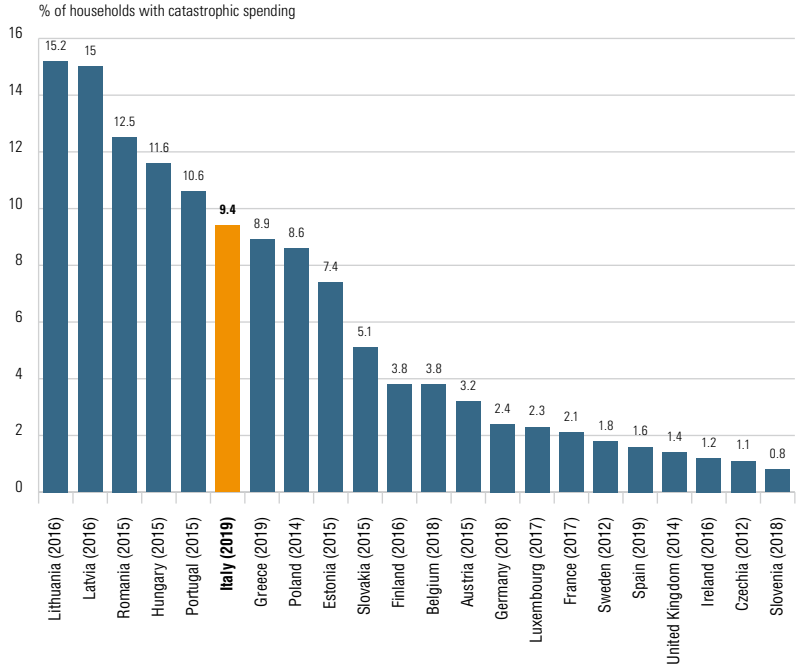
FIG. 7.1 Unmet needs for a medical examination (due to cost, waiting time, or travel distance), by income quintile, EU/EEA countries, 2020 or nearest available year



Notes: Data for Italy are for 2019; data from Iceland and United Kingdom are for 2018.

Source: Eurostat, 2022d.

FIG. 7.2 Share of households that experienced catastrophic health expenditure, latest year for all countries with data available



Source: WHO Regional Office for Europe, 2021b.

Overall it seems that in terms of financing, the SSN has adapted to ever tighter financial constraints brought about by increasingly complex population needs (population ageing, increased prevalence of chronic diseases), higher costs of technological innovation and weaker socioeconomic conditions after the financial crisis. However, as echoed during the COVID-19 emergency, keeping up with the demand for services has involved an increasingly important role for the private sector, with collateral impacts on direct household spending on health.

7.4 Health care quality

Italy reports good results for many but not all of the indicators that investigate the quality of care. In primary care, the country has low prescription volumes of opioids and benzodiazepines compared with the rest of Europe, as

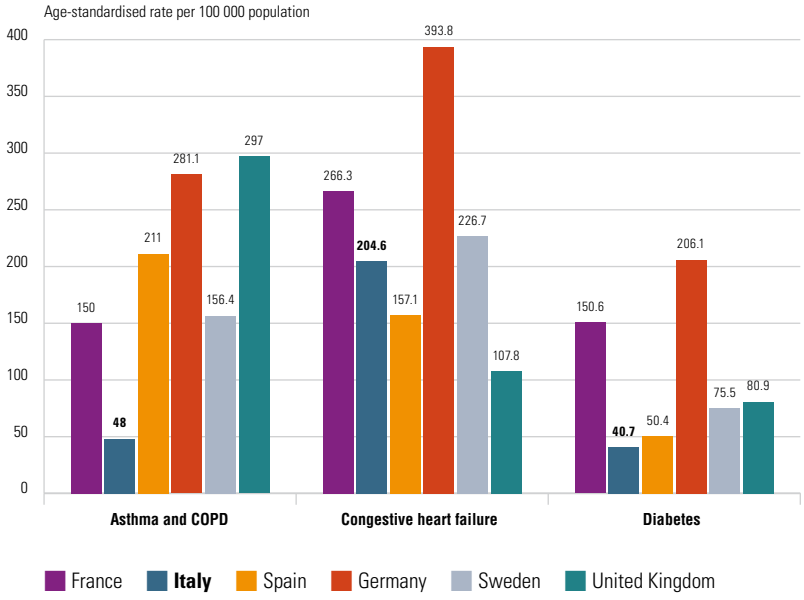
appropriateness in prescription may also be imputable to reimbursement and prescribing procedures and guidelines (OECD/EU, 2020). In contrast, policies need to be put in place to fight the spread of antimicrobial resistance. In 2017, patients were prescribed 28 defined diurnal dosages of antibiotics per 1 000 people in primary care in comparison to a median of 18 doses among OECD countries in 2017, ranking Italy the second highest in terms of antibiotic use (OECD, 2021b). More recent data shows that Italy was among the top five consumers of antibiotics among EU countries in 2020 (ECDC, 2022).

Indicators of avoidable hospitalization for ambulatory-sensitive conditions have been improving in recent years. These are defined as admissions for medical problems that are potentially avoidable if they are effectively managed in outpatient settings. In general, with reference to the standardized (daily and ordinary) hospitalization rate per 1 000 inhabitants, the overall hospitalization rate in 2019 was 129.8 per 1 000, lower than the established national benchmark. In 2019, 12.3 daily and ordinary hospitalizations per 1 000 were potentially inappropriate, as defined by the Prime Ministerial Decree of 12 January 2017, with the trend during 2016–2019 showing noteworthy improvements.

Italy has among the lowest hospitalization rates in the EU for diabetes, and for asthma and chronic obstructive pulmonary disease (COPD) (OECD, 2021b) (Fig. 7.3). For example, the hospitalization rate in adults for complications due to diabetes has shown a slight reduction, going from 0.42% in 2016 to 0.38% in 2019. Despite variability among regions, this value does not go above 0.6% (AGENAS, 2020) and observed differences have no geographically defined patterns, probably partly reflecting different prevalence of the disease among the Italian regions.

The 2019 standardized hospitalization rate for children (under 18 years) for asthma was 0.40 per 1 000 people (11% lower than in 2018) while for gastroenteritis, it was 1.64 per 1 000 people (2% higher as compared with 2018) (ONSRI, 2020). An above-average rate was detected in a few regions, thus highlighting regional disparities. A declining trend has been seen for COPD in adults: the hospitalization rate for this clinical condition reduced from 2.35% in 2012 (AGENAS, 2020) to 1.07% in 2020 (AGENAS, 2021). In this case, though, a moderate inter- and intraregional variability is still noticeable. Of course, the possibility of these measures being linked to differences in prevalence in more polluted areas must be taken into consideration. Less favourable results are recorded for congestive heart failure.

FIG. 7.3 Avoidable hospital admission rates for asthma and chronic obstructive pulmonary disease, congestive heart failure and diabetes-related complications, 2019

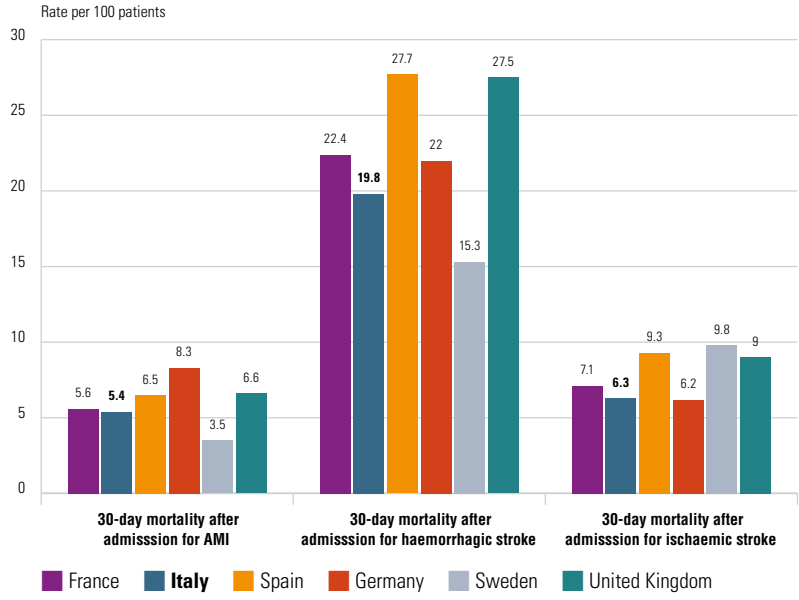


Note: Data for France refer to 2015.

Source: OECD Health Statistics 2022d.

In terms of the effectiveness of secondary care, 30-day mortality after admission from acute myocardial infarction (AMI) is a measure of the quality of hospital care for life-threatening conditions. In Italy, this mortality rate has improved over the past decade and compares well with other EU countries, with rates that are among the lowest in Europe, along with countries such as France, Germany and Spain (Fig. 7.4).

FIG. 7.4 In-hospital mortality rates (deaths within 30 days of admission) for admissions following acute myocardial infarction, haemorrhagic stroke and ischaemic stroke, Italy and selected countries, 2019



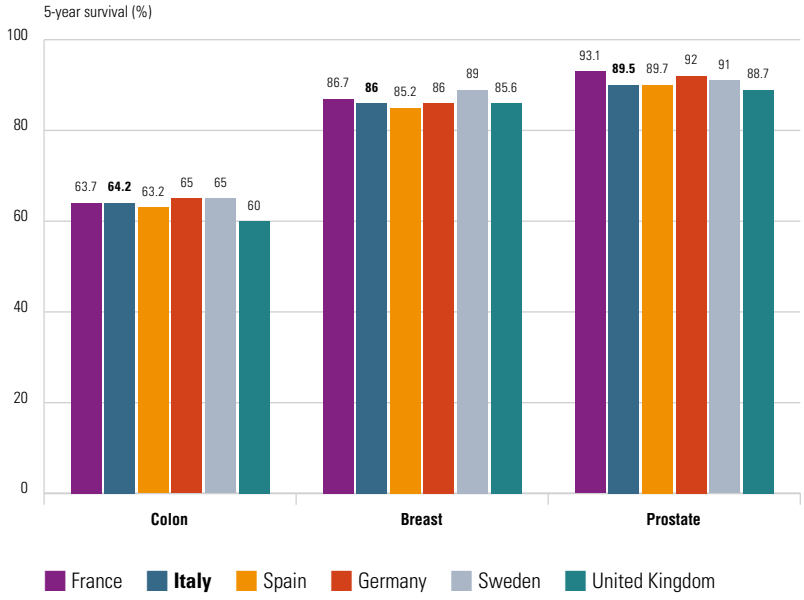
Notes: Data are for 2019 except for France and Italy which are for 2015.

Source: OECD Statistics, 2022d.

Shedding light on the effectiveness and quality of preventive care, several national screening plans were put in place over the last decade to promote screening for common types of cancer such as breast, cervical and colorectal cancers. Although these programmes are offered free of charge for their respective target populations, coverage remains limited. Only about 61% of women in the target age group of those aged 50–69 were screened for breast cancer over the 2 years leading up to 2019, which is slightly above the EU average of 59% but considerably lower than, for example, the Nordic countries where breast cancer screening rates are over 80%. Screening rates for cervical cancer are much lower, with only 39% of women aged 20–69 screened over the past 3 years, compared with the EU average of 58 %. The COVID-19 pandemic saw the temporary suspension and delays in cancer screening programmes, with an impact on uptake rates in 2020 compared with 2019: early evidence suggests that screening rates for breast cancer fell by 38%, while those for cervical and colorectal cancer also fell by 43% and 48%, respectively.

Despite relatively low screening rates, 5-year survival rates following diagnosis for these and other cancers are similar to other EU countries (Fig. 7.5), suggesting that the health system is generally able to provide effective and timely treatments for patients with the most common forms of cancer. However, caution is needed in interpreting these results due to the time lag in the data – the most recent available cancer survival rates cover the years 2000–2014.

FIG. 7.5 5-year cancer survival rates for colon, breast (among women) and prostate (among men) cancer in 2010–2014



Source: Allemani et al., 2018.

7.5 Health system outcomes

Amenable mortality (also called mortality from treatable causes) refers to deaths in people under 75 years old which should not occur if people have access to timely and effective health care interventions, including secondary prevention and treatment. Preventable mortality is broader and includes deaths in those under 75 which could have been avoided through public health interventions focusing on the wider determinants of public health, such as behaviour and lifestyle factors, socioeconomic status and environmental factors. Low and decreasing rates of preventable and amenable mortality reflect the effectiveness of Italy's health system (see also ISTAT, 2020d) (Fig. 7.6).

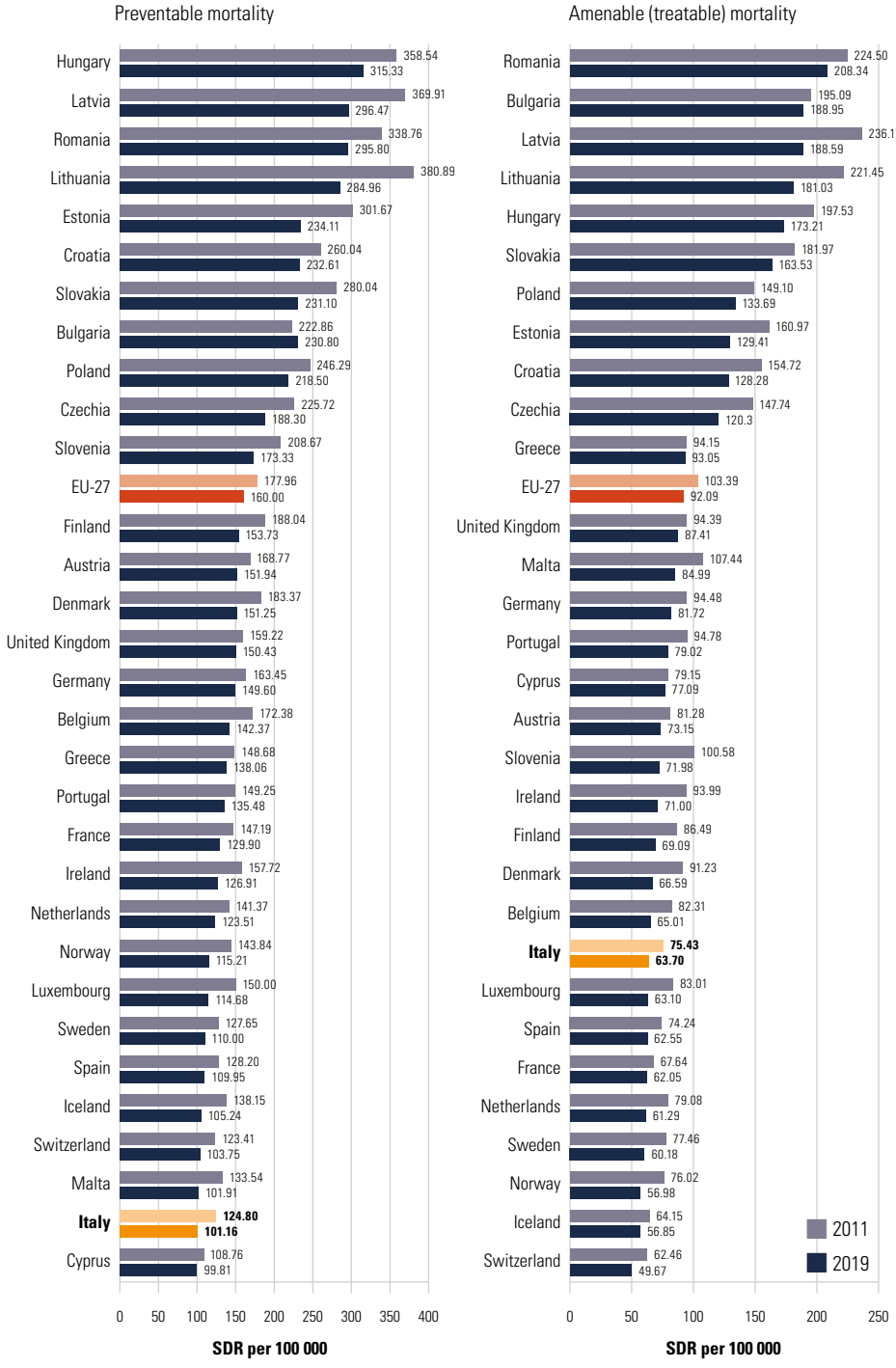
Since 2011, amenable mortality rates have been among the lowest in Europe, and in 2019, Italy had the sixth lowest rate among EU countries. In the Italian regions, the best performers are all located in the centre-north. In 70% of cases, amenable mortality rates have been linked to colon and rectal cancers (19.09%), cerebrovascular diseases (18.23%), ischaemic heart disease (17.06%), and breast cancer (16.66%) (ONSRI, 2020).[16] In the past 30 years, death rates for cardiovascular diseases have decreased by more than half and for neoplasms by almost a third. However, in parallel, dementia and Alzheimer's diseases are increasing along with chronic respiratory diseases, hypertension, influenza and pneumonia (Monasta et al., 2019). Behavioural risk factors and demographic changes seem to play an important role in these trends.

Following reductions between 2011 and 2019 in ischaemic heart disease,[17] lung cancer, accidental deaths, suicide and alcohol-related diseases, preventable mortality values also are all well below the EU average, given the lower prevalence of risk factors, effective treatments and lower incidence of these health conditions.

16 Separate data from the international Global Burden of Disease Healthcare Access and Quality Index (HAQI), corroborate the decline in amenable mortality, from 81.54 in 1990 to 94.9 in 2016, ranking Italy ninth in the world in 2016 (Our World in Data, 2017).

17 Ischaemic heart disease is considered to be both amenable and preventable; the overall rate is divided between the two indicators.

FIG. 7.6 Preventable and amenable mortality, 2011 and 2019



Note: Data are for 2011 and 2019 or latest available year.
Data for France are from 2017; and data for Malta and the United Kingdom are from 2018.

Source: Eurostat, 2022d.

Italy's low levels of preventable deaths can also be explained, at least in part, by solid public health policies that have been implemented from the early 2000s. A nationwide indoor smoking ban in public places and workplaces was implemented in 2005 (Mele & Compagni, 2010), and increases in cigarette prices were subsequently enforced although they remain low compared with other European countries. In 2013, stricter rules on tobacco access among young people were also introduced: the minimum purchase age was raised to 18 years; higher fines were imposed on tobacco retailers who sold cigarettes to minors; automatic age-detection systems were installed in tobacco vending machines; a smoking ban was extended to the outdoor premises of schools; and a ban on sales of electronic cigarettes to minors was implemented. In addition, in 2016, a new law regulated the combination of images and warnings on cigarette packs and introduced a smoking ban in cars (in the presence of pregnant women and minors) and in the outdoor premises of hospitals. However, it is worth noting that according to national data, the number of daily smokers grew steadily during the COVID-19 pandemic, rising from 22% of the adult population in April 2020 to 24% in November 2020, a value that then increased by more than 1 million people from November 2020 to May 2021 (26.2%), which is equivalent to a rise of over two percentage points in the share of the Italian population smoking regularly (ISS, 2022).

Alcohol consumption – people (aged 11 and over) having at least one alcoholic drink during the year – was stable from 2019 to 2020 (66.8% and 66.4% of the population, respectively) (ISTAT, 2020e); a similar trend is found for daily consumption, while consumption out of meal times continues to increase. Year-over-year alcohol consumption is strongest in the north-eastern part of the country. Among over-25 year olds, the percentage of alcoholic beverage consumers increases as the level of education increases. This is the case especially for women: in 2020, among those with an elementary school qualification, 41.6% consume alcohol at least once a year, a quota that rises to 74.3% among university graduates (Ministero della Salute, 2021a).

7.5.1 *Equity of outcomes*

Despite a decline of more than 1 year due to the impact of the COVID-19 pandemic, in 2020, average life expectancy at birth in Italy was 82.4 years, the fifth highest (along with Spain) in Europe, after Norway, Iceland, Ireland and Malta. Disaggregated by sex, in 2020, life expectancy was estimated

at 80.1 years for males and 84.7 for females. Umbria, in central Italy, now shows the highest values for both men and women (1.4 and 1.2 years above the national average, respectively). The most disadvantaged regions for both sexes are Campania (in the south) and Valle d'Aosta (in the north). Lombardy, one of the hardest hit regions during the pandemic, went from having above national average values to below national average values as both males and females have suffered the greatest decreases in life expectancy at birth in the period 2016–2020 (–2.1 years and –0.9 years below the national averages respectively) (ONSRI, 2020).

Heterogeneity in mortality rates is more accentuated for cardiovascular disease, respiratory diseases and accidents, whereas mortality rates due to cancer are more uniform. Inequalities due to social determinants are a constant for all regions, but are more marked in the poorer regions of the south. Specifically, for education level inequalities, there is a 3-year difference in life expectancy between men with high education and those with low education (ISTAT, 2018). Furthermore, the pandemic had a strong impact on the older population: the share of over 75-year-olds with severe limitations or with multi-chronic conditions (suffering from three or more chronic conditions) is 48.8%, with higher values in the south and in people with lower levels of education (ISTAT, 2020c). In general, geographical differences in mortality are relevant regardless of age and socioeconomic status. Moreover, the poorer southern regions generally record lower health status, while regions along the Adriatic coast are the healthiest. A lower education level explains a considerable proportion of mortality risk, although with different effects by geographical area and cause of death.

These variations are also carried through into healthy life years (HLY) i.e. in 2020, the average life expectancy without health limitations and/or disability was 62.8 years, with important differences among regions. Specifically, Umbria has the highest value (67.5 years), followed by the autonomous provinces of Trento and Bolzano (66.9 and 66.5 years respectively). In contrast, Calabria in the south of the country presents the lowest value with 58.1 years (The European House – Ambrosetti, 2021).

In terms of morbidity, generally, in Italy people in lower-income groups tend to suffer from poor health more often and register lower life expectancy compared with other European countries. This inequality peaks among middle-aged individuals, when mortality is considered avoidable, and has

been further accentuated with the COVID-19 pandemic (ONSRI, 2020). In terms of mortality, however, compared with other European countries, inequalities in Italy are less prominent, probably due to lifestyle factors such as the Mediterranean diet, the presence of family support networks and a universal health care system.

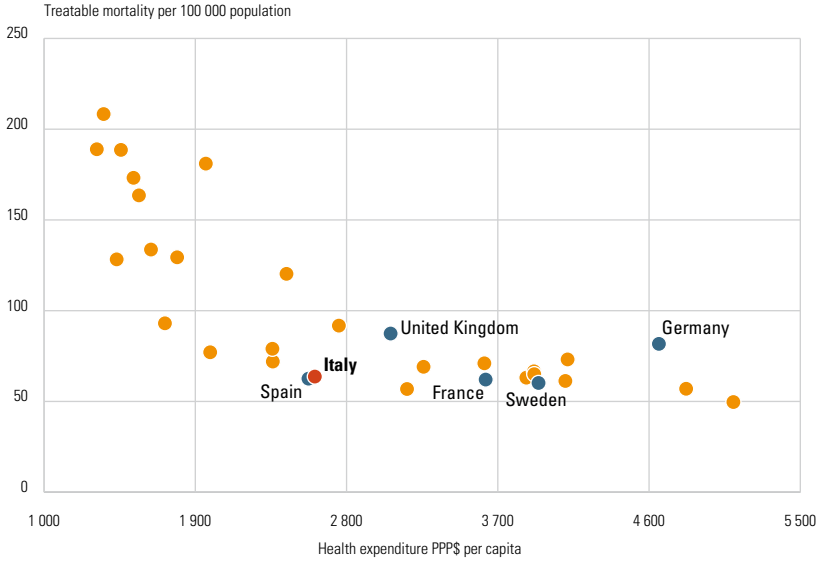
7.6 Health system efficiency

Given its level of health expenditure, which is significantly below the EU average, the Italian SSN has proven to be generally efficient and capable of providing good access to high-quality care at a relatively low cost, albeit with significant variations across regions.[18] Decades of cost-containment policies have, however, entailed a significant increase in OOP expenditure, longer waiting time and underinvestment in new facilities and technologies (see Chapters 3 and 4).

One way to provide a very cursory illustration of how the health system is performing in terms of input costs and outcomes is to plot current expenditure on health against the amendable mortality rate. Although we must be mindful that it is not possible to effectively disentangle the role of health behaviours and other determinants of the health care system in influencing the level of amenable mortality, Figure 7.7 provides a useful entry point for discussion. As mentioned in section 7.5, Italy's amendable mortality rate has been decreasing and is among the lowest in Europe. In addition, the country recorded a health expenditure level in 2019 that was lower than half of the other EU Member States. These basic results suggest that given its expenditure levels, Italy has been able to secure very good outcomes on this metric.

18 Health spending as a percentage of GDP increased from 8.7% in 2019 to 9.7% in 2020 (compared with an average of 0.9 points increase among OECD countries), but this new growth was also due to a fall in GDP (OECD, 2021a).

FIG. 7.7 Amenable mortality per 100 000 population versus health expenditure per capita in Italy and selected countries, 2019



Note: PPP: purchasing power parity. Data are for 2019 except for France (2017), Malta (2018) and United Kingdom (2018).

Source: Eurostat, 2022d.

7.6.1 *Allocative efficiency*

Allocative efficiency indicates the extent to which limited funds are directed towards purchasing an appropriate mix of health services or interventions that maximize health improvements. Health resources are allocated by adjusting regional populations by seniority and gender (age profiles) with poor consideration of socioeconomic differences (OCPI, 2020). Regional health care expenditure originates from both regional taxes and transfers from central funds. The latter are distributed based on criteria that have varied significantly over the last 20 years, and allocation combines regional need and the supply of different health services. Formally, today's allocation system, according to Legislative Decree 68/2011, is based on standard costs per capita incurred yearly by the three "best performing" regions in providing the national benefits package (Parlamento italiano, 2011; Caruso & Dirindin, 2011). These regions

are selected at the intergovernmental State-Regions Conferences from a pool of five regions selected by the Ministry of Health that have demonstrated that they have appropriately and efficiently delivered the LEA with the ordinary resources allocated nationally. The overall costs borne by such regions in the delivery of the national benefits package are broken down into per capita expenditure benchmarks.

Law Decree 68/2011 also requires regions to allocate 5% of health spending to prevention activities and programmes, 51% to primary and community care (known as district care) and 44% to hospital care. These quotas, however, are not binding (see also Chapter 3). In 2019, government schemes and compulsory contributory health care financing schemes provided a total of EUR 114 759 billion allocated mainly to curative and rehabilitative care (EUR 67 105 billion), long-term care (EUR 12 345 billion) and preventive care services (EUR 6 493 billion) (ISTAT, 2021d).

Different formulae are used to calculate the specific amount of each of these shares for each region. Since 2011, the share for prevention activities has been based on the regional population; the share for hospital care based partly on absolute population and partly on absolute population weighted by age; within primary and community care, the funds for family medicine and other community care have been based on absolute population; those for specialist care on age-weighted population, and those for pharmaceutical care on a region-specific expenditure cap related to the absolute population. As a result, 59% of total funds are assigned to regions on a pure capitation basis, while 41% is based on variable age-weighted capitation scores. Despite its orographic characteristics there is no adjustment according to population density or altitude (to take into account access difficulties for people living in mountain areas).

Since 2005, when it emerged that several regions suffered from severe financial deficits, the allocation of funds to regions has also been heavily influenced by financial recovery plans, agreed upon by central government and regional administrations, and which set conditions for budgetary discipline and stricter monitoring of the LEA.

Today, the three allocation components of national health care expenditure seem to reflect the objectives and directions undertaken by health policy: regions are generally complying with spending requirements at the three macro-levels (prevention, district care and hospital care), despite some lower

spendings levels in prevention. From 2008 to 2018, national spending on prevention has been lower than the target of 5% (around 4.4%), with only Valle d'Aosta, Calabria, Campania and Sardinia exceeding the threshold without, though, maintaining constant values. In parallel, we can generally observe the reallocation of resources from inpatient to outpatient care. Regional disparities persist, however; in particular, in southern Italy more traditional functions still absorb many resources making the development of community care challenging. In the north-west (particularly in Lombardy), primary care is underdeveloped, but much attention is paid to social-health assistance (IRS, 2020).

7.6.2 *Technical efficiency*

Technical efficiency indicates the extent to which a health system is securing the minimum levels of inputs for a given output (or the maximum level of output in relation to its given inputs). A number of policies have been implemented within the health system with the objective of enhancing efficiency; some of which are discussed below.

In recent years, hospital capacity has been reduced and incentives have been put in place to promote appropriateness of care. In line with the trend observed in almost all EU countries, between 2000 and 2019 the overall number of hospital beds per capita in Italy decreased by over 30%, reaching 260 acute care beds per 100 000 inhabitants, a figure well below the EU average (387 acute beds per 100 000). The total number of hospital discharges also decreased, while the average length of stay (ALOS) underwent a slight increase, due at least in part to the hospitalization of patients with more serious diseases and to the greater use of outpatient care for less severe cases.

Regions have improved efficiency in terms of appropriate hospitalizations, and length of stay; however, those undergoing recovery plans demonstrate greater fragmentation in their supply networks and experience difficulties in concurrently enhancing outpatient services. Heterogeneity is also found among facilities within the same region. In the Recovery Plan regions, bed occupancy rates remain low, likely due to highly specialized services still being provided mainly by large hospitals in the northern regions and large cities, stimulating cross-regional mobility of patients.

Since 2010, major initiatives have been launched to improve government purchasing, operational efficiency and appropriateness of care in hospital. Some progress has been achieved in reducing low-value care and unnecessary interventions. Ministerial Decree 70/2015 set new standards that require minimum capacity volumes of care for hospitals, forcing regions to close some small hospital and to implement mergers.

Day surgery has seen a sharp increase, although further progress is possible. The development of day surgery interventions has been a priority in recent decades, to reduce avoidable overutilization of hospital resources as well as to meet the preference of the majority of patients to return home as soon as possible. In Italy, the percentages of cataract, inguinal hernia and tonsillectomy operations performed in day surgery have recorded a considerable increase since 2000, reaching, if not even exceeding, the EU average. However, there is still room for improvement to reach the levels of the best performing countries, such as the Scandinavian group of countries and the United Kingdom. Case-mix indexes show that the complexity of cases treated varies greatly among regions with both basic departments and specialist units treating complex cases mostly in the north and rarely in the south; this is also due to patients from the south seeking care in the north for more complex diseases (Marino & Quattrone, 2019).

Pharmaceutical expenditure in Italy is a major component of public spending on health. Regulatory measures, such as spending caps, have been introduced to contain pharmaceutical expenditure outside hospitals and in hospitals, with mixed success. However, very expensive hospital drugs are subjected to a cost-recovery funding system (File F) that may discourage cost-conscious prescribing and appropriateness. Limits for reimbursable pharmaceutical spending in retail pharmacies were first introduced in 2001. These were initially capped at 13% of total health expenditure per year at both national and regional levels, then reduced to 11% in 2013 and to 8% in 2017. In 2003, spending caps were also introduced for medicines delivered by hospital pharmacies for inpatients and outpatients. The maximum hospital pharmaceutical expenditure was initially set at 2.4% of total health expenditure, but then increased to 3.5% in 2013 and 6.9% in 2017. Over the past 7 years, expenditure on oncology drugs has increased by approximately 87%, with an average annual increase of 11%. Hospital spending on these drugs in 2020 amounted to EUR 3.9 billion (OsMed, 2021).

To avoid overspending, some agreements between industry, regions and the SSN have been established. If the cap on community pharmacy expenditure is exceeded, the industry (manufacturers and distributors) is liable to refund the excess spending to the SSN – a mechanism known as a claw-back. If the hospital inpatient expenditure cap is exceeded, the regions and manufacturers are liable to refund 50% each of the excess expenditure to the SSN. In order to monitor the dynamics of pharmaceutical expenditure and GP prescriptions, a comprehensive information system called *Sistema Tessera sanitaria* has been implemented, which keeps track of e-Prescriptions and other health data at the patient level.

8

Conclusions

Italy's health expenditure is lower than the EU average. Nevertheless, the SSN provides services that are universal, highly specialized and of good quality. The main issue with the Italian National Health Service is the increase in private expenditure that is challenging equity principles. The increasing challenges for fair access to timely diagnostic, elective and outpatient services, and the shift towards paying for services out of pocket, are also having an impact on the health system's affordability.

In terms of basic indicators of health outcomes, Italy has one of the highest life expectancies in Europe, although it did decline – at least temporarily – in 2020 due to the impact of high numbers of COVID-19 deaths. Moreover, important gains have been achieved in health status over the last two decades, albeit with clear geographical differences that are contrary to the basic principles of the SSN.

The COVID-19 pandemic has shown significant structural flaws in the Italian health care system, often resulting from years of underinvestment in the health workforce, building stock and equipment, and information infrastructure. These critical issues, most of them pre-dating the COVID-19 pandemic, have a profound impact on the SSN, putting its long-term sustainability under strain. They are both demand-side issues, given the progressive ageing of the population and the growing burden of chronic diseases, and supply-side issues, such as fragmented primary care, poor integration between care levels (hospital, intermediate facilities, community and primary care), technological underdevelopment and the lack of HTA and priority-setting. These issues affect Italy's highly heterogeneous, regionalized health care system, not only in relation to the level of supply and quality of services across regions but also in terms of organizational capacities and infrastructural endowments within the regions.

The last 30 years have been characterized by health policies aimed at the "de-hospitalization" of non-acute patients, a direct consequence of the period of the so-called epidemiological transition earlier in the century. In Italy, de-hospitalization began in the 1980s and 1990s and was favoured by technological progress and active policies to improve appropriateness of care. Together with the rationalization of expenditure, these policies have led to the progressive closure of hospitals with fewer than 120 beds, a decline in bed numbers, and very modest overall increases in health personnel. The new organizational configuration of hospital services should have been accompanied by the strengthening of community services, quantitatively and qualitatively appropriate to the needs of the population, and capable of preventing avoidable hospitalizations and guaranteeing a sustainable path on the whole continuum of care. However, in most parts of the country, this did not happen: in the context of health policy choices made in conditions of limited financial resources, particularly following the global financial crisis after 2008, local services and, in particular, primary, ambulatory, intermediate and home care services, were heavily penalized, alongside the abatement in hospital supply.

When the COVID-19 emergency broke out, the country generally found itself under-equipped, both on the hospital front and in terms of mobilizing community-based care. The hope now is that more resources will be channelled into primary care so that the role of community services can be effectively reorganized and strengthened, in the decentralized context of the SSN's organization. In fact, Italy's regions have dealt with the emergency in different ways, not always complying with the directives of the central government, and achieving different performance outcomes in coping with the various waves of the epidemic. In some cases, community care – including testing, contact tracing, isolation and home treatment of new cases – proved ineffective and the strategies used for monitoring and managing the crisis were not uniform. In addition, as the spread of the virus was uneven across communities, regions and health care providers have increased the variety of the organizational responses to the pandemic. Nevertheless, overall, the SSN managed to cope with the pandemic and in some areas, such as vaccination coverage, compares very well internationally. The high mortality rate that Italy experienced during the early phase of the pandemic was most likely due to the higher proportion of older and fragile population and the weaknesses of care homes, rather than

to the capacity of the SSN. Especially in some of the northern regions at the epicentre of the outbreak, the system was under exceptional strain due to the high incidence of COVID-19, high hospitalization rates of frail patients and a lack of sufficient hospital capacity of regular beds and intensive care units.

The pandemic has highlighted the responsibility of the SSN to provide more holistic care to meet the needs of citizens, particularly the frail and patients with comorbidities. The crisis has called for a reprioritization of the human, financial and physical resources that sustain the SSN, in an effort to put an end to the past "season of austerity" characterized by the prevailing goal of containing costs. Furthermore, it has also highlighted the importance of active personnel policies, bolstering the number of nurses and doctors, investing in training and innovating the division of labour (e.g. between nurses and doctors). Policy-makers have argued that the resources earmarked for health care should not be regarded merely as costs but, rather, investments aimed at improving people's quality of life and at promoting socioeconomic development. From this perspective, the increase in available resources should not only be adequate to guarantee care under normal conditions but should also be such as to create a reserve or endowment to be activated in any future emergencies.

The challenge of the COVID-19 pandemic, therefore, calls for action to strengthen the SSN, increasing its resilience, seeking ways to overcome the fragmentation in governance, optimizing coordination between central and regional authorities and aiming to reorganize both hospital and community care in a coordinated way. In the wake of the pandemic, Italy's NRRP represents a unique opportunity to address the new and growing challenges of the SSN and will shape the health care of the future, offering the chance to turn the crisis into an opportunity for revitalization. With this goal in mind, it is critical to address the need to eliminate geographical disparities, especially in terms of preventive policies and care; to build more effective links between research and care, promote long-term sustainability and ensure equitable accessibility. In this respect, the SSN would benefit from leveraging the most advanced technologies and push towards increased digitalization.

Another key challenge for the future will be to adopt a One Health approach, which means to promote an effective integration of human medicine, veterinary medicine and environmental protection, given the impact of climate change on societies and the high proportion of emerging infectious diseases

originating from animals. Finally, a sustained focus on strengthening the resilience of the health system will also help to deal with other unexpected emergencies that potentially loom on the horizon, such as the increase in mental health morbidity, antibiotic resistance, post-pandemic economic uncertainties and the dramatic increase of displaced people (for example, from Ukraine), who require urgent measures to ensure their safety and to restore their physical and mental health.

9

Appendices

9.1 References

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9.2 Main legislation and decrees

9.2.1 *Laws*

Law 833/1978: Legge 23 dicembre 1978, n. 833. Istituzione del servizio sanitario nazionale.

Law 180/1978: Legge 13 maggio 1978, n. 180. Accertamenti e trattamenti sanitari volontari e obbligatori.

Law 18/1980: Legge 11 febbraio 1980, n. 18. Indennità di accompagnamento agli invalidi civili totalmente inabili.

Law 595/1985: Legge 23 ottobre 1985, n. 595. Norme per la programmazione sanitaria e per il piano sanitario triennale 1986–88.

Law 104/1992: Legge 5 febbraio 1992, n. 104. Legge-quadro per l'assistenza, l'integrazione sociale e i diritti delle persone handicappate.

Law 405/2001: Legge 16 novembre 2001, n. 405. Conversione in legge, con modificazioni, del decreto-legge 18 settembre 2001, n. 347, recante interventi urgenti in materia di spesa sanitaria.

Law 3/2003: Legge 16 gennaio 2003, n. 3. Disposizioni ordinamentali in materia di pubblica amministrazione. art. 51 (Tutela della salute dei non fumatori).

Law 138/2004: Legge 26 maggio 2004, n. 138. Conversione in legge, con modificazioni, del decreto-legge 29 marzo 2004, n. 81, recante interventi urgenti per fronteggiare situazioni di pericolo per la salute pubblica.

Law 38/2010: Legge 15 marzo 2010, n. 38. Disposizioni per garantire l'accesso alle cure palliative e alla terapia del dolore.

Law 122/2010: Legge 30 luglio 2010, n. 122. Conversione in legge, con modificazioni, del decreto-legge 31 maggio 2010, n. 78, recante misure urgenti in materia di stabilizzazione finanziaria e di competitività economica.

Law 27/2012: Legge 24 marzo 2012, n. 27. Conversione in legge, con modificazioni, del decreto-legge 24 gennaio 2012, n. 1, recante disposizioni urgenti per la concorrenza, lo sviluppo delle infrastrutture e la competitività.

Law 135/2012: Legge 7 agosto 2012, n. 135. Conversione in legge, con modificazioni, del decreto-legge 6 luglio 2012, n. 95, recante disposizioni urgenti per la revisione della spesa pubblica con invarianza dei servizi ai cittadini.

Law 189/2012: Legge 8 novembre 2012, n. 189. Conversione in legge, con modificazioni, del decreto-legge 13 settembre 2012, n. 158, recante disposizioni urgenti per promuovere lo sviluppo del Paese mediante un più alto livello di tutela della salute.

Law 24/2017: Legge 8 marzo 2017, n. 24. Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie.

Law 124/2017: Legge 4 agosto 2017, n. 124. Legge annuale per il mercato e la concorrenza.

Law 219/2017: Legge 22 dicembre 2017, n. 219. Norme in materia di consenso informato e di disposizioni anticipate di trattamento.

Regional Law 23/2015: Regione Lombardia, Legge regionale 11 agosto 2015, n. 23. Evoluzione del sistema sociosanitario lombardo: modifiche al Titolo I e al Titolo II della legge regionale 30 dicembre 2009, n. 33 (Testo unico delle leggi regionali in materia di sanità).

Regional Law 22/2021: Regione Lombardia, Legge regionale, https://www.ats-brianza.it/images/consigliosindaci/LR_23_2015_Evoluzione_sistema_socio_sanitario.pdf, 14 dicembre 2021. Modifiche al Titolo I e al Titolo VII delle L.R. 33/2009 (Testo unico delle leggi regionali in materia sanitaria).

9.2.2 *Legislative decrees*

Legislative Decree 502/1992: Decreto Legislativo 30 dicembre 1992, n. 502. Riordino della disciplina in materia sanitaria, a norma dell'articolo 1 della legge 23 ottobre 1992, n. 421.

Legislative Decree 517/1993: Decreto Legislativo 7 dicembre 1993, n. 517. Modificazioni al decreto legislativo 30 dicembre 1992, n. 502, recante riordino della disciplina in materia sanitaria, a norma dell'articolo 1 della legge 23 ottobre 1992, n. 421.

Legislative Decree 229/1999: Decreto Legislativo 19 giugno 1999, n. 229. Norme per la razionalizzazione del Servizio sanitario nazionale, a norma dell'articolo 1 della legge 30 novembre 1998, n. 419.

Legislative Decree 165/2001: Decreto legge 30 marzo 2001, n. 165. Norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche.

Legislative Decree 223/2006: Decreto Legge 4 luglio 2006, n. 223. I misure urgenti per lo sviluppo, crescita e la promozione della concorrenza e della competitività, per la tutela dei consumatori e per la liberalizzazione di settori produttivi.

Legislative Decree 68/2011: Decreto Legislativo 6 maggio 2011, n. 68. Disposizioni in materia di autonomia de entrata delle regioni a statuto ordinario e delle province, nonché di determinazione dei costi e dei fabbisogni standard nel settore sanitaria.

Legislative Decree 38/2014: Decreto Legislativo 4 marzo 2014, n. 38. Attuazione della direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera, nonche' della direttiva 2012/52/UE, comportante misure destinate ad agevolare il riconoscimento delle ricette mediche emesse in un altro stato membro.

Legislative Decree 6/2016: Decreto Legislativo 12 gennaio 2016, n. 6. Recepimento della direttiva 2014/40/UE sul ravvicinamento delle disposizioni legislative, regolamentari e amministrative degli Stati membri relative alla lavorazione, alla presentazione e alla vendita dei prodotti del tabacco e dei prodotti correlati e che abroga la direttiva 2001/37/CE.

Legislative Decree 261/2016: Decreto Legislativo 7 dicembre 2016, n. 261. Regolamento recante modifiche ed integrazioni del decreto 27 ottobre 2000, n. 380 e successive modificazioni, concernente la scheda di dimissione ospedaliera.

Legislative Decree 41/2021: Decreto Legislativo 22 marzo 2021 n. 41. Misure urgenti in materia di sostegno alle imprese e agli operatori economici, di lavoro, salute e servizi territoriali, connesse all'emergenza da COVID-19.

9.2.3 *Ministerial decrees*

Decreto Ministeriale 10 luglio 2007. Progetti attuativi del Piano sanitario nazionale – Linee guida per l'accesso al cofinanziamento alle regioni e alle province autonome di Trento e Bolzano.

Decreto Ministeriale 16 dicembre 2010. Erogazione da parte delle farmacie di specifiche prestazioni professionali.

Decreto Ministeriale 2 aprile 2015, n. 70. Regolamento recante definizione degli standard qualitativi, strutturali, tecnologici e quantitativi relativi all'assistenza ospedaliera.

Decreto Ministeriale 7 settembre 2017. Disciplina dell'uso terapeutico di medicinale sottoposto a sperimentazione clinica.

Decreto Ministeriale 23 maggio 2022, n. 77. Regolamento recante la definizione di modelli e standard per lo sviluppo dell'assistenza territoriale nel Servizio sanitario nazionale.

9.3 Useful websites

Ministry of Health – http://www.salute.gov.it
National Institute of Health (Istituto Superiore di Sanità, ISS) – http://www.iss.it
National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali, AGENAS) – https://www.agenas.gov.it
Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) – https://www.aifa.gov.it
National Institute of Statistics (Istituto Nazionale di Statistica, ISTAT) – https://www.istat.it
National Center for Disease Prevention and Health Promotion (Centro Nazionale per la Prevenzione delle Malattie e la Promozione della Salute) – https://www.iss.it/centro-nazionale-per-la-prevenzione-delle-malattie-e-la-promozione-della-salute
National Association of Pharmaceutical Companies (Farmindustria) – https://www.farmindustria.it
Observatory on Healthcare Organizations and Policies in Italy (OASI) – https://cergas.unibocconi.eu/observatories/oasi
Italian Observatory on Health among the Italian Regions (Osservasalute) – https://osservatoriosullasalute.it/

9.4 HiT methodology and production process

HiTs are produced by country experts in collaboration with the Observatory's research directors and staff. They are based on a template that, revised periodically, provides detailed guidelines and specific questions, definitions, suggestions for data sources and examples needed to compile reviews. While the template offers a comprehensive set of questions, it is intended to be used in a flexible way to allow authors and editors to adapt it to their particular national context. The latest version of the template (2019) is available on the Observatory website at https://eurohealthobservatory.who.int/publications/i/health-systems-in-transition-template-for-authors.

Authors draw on multiple data sources for the compilation of HiTs, ranging from national statistics, national and regional policy documents, to published literature. Furthermore, international data sources may be incorporated, such as those of the OECD and the World Bank. The OECD Health Data contain over 1200 indicators for the 34 OECD countries. Data are drawn from information collected by national statistical bureaux and health ministries. The World Bank provides World Development Indicators, which also rely on official sources.

In addition to the information and data provided by the country experts, the Observatory supplies quantitative data in the form of a set of standard comparative figures for each country, drawing on the European Health for All database. The Health for All database contains more than 600 indicators defined by the WHO Regional Office for Europe for the purpose of monitoring Health in All Policies in Europe. It is updated for distribution twice a year from various sources, relying largely upon official figures provided by governments, as well as health statistics collected by the technical units of the WHO Regional Office for Europe. The standard Health for All data have been officially approved by national governments.

HiT authors are encouraged to discuss the data in the text in detail, including the standard figures prepared by the Observatory staff, especially if there are concerns about discrepancies between the data available from different sources.

A typical HiT consists of nine chapters.

1. Introduction: outlines the broader context of the health system, including geography and sociodemography, economic and political context, and population health.

2. Organization and governance: provides an overview of how the health system in the country is organized, governed, planned and regulated, as well as the historical background of the system; outlines the main actors and their decision-making powers; and describes the level of patient empowerment in the areas of information, choice, rights and cross-border health care.
3. Financing: provides information on the level of expenditure and the distribution of health spending across different service areas, sources of revenue, how resources are pooled and allocated, who is covered, what benefits are covered, the extent of user charges and other out-of-pocket payments, voluntary health insurance and how providers and health workers are paid.
4. Physical and human resources: deals with the planning and distribution of capital stock and investments, infrastructure and medical equipment; the context in which IT systems operate; and human resource input into the health system, including information on workforce trends, professional mobility, training and career paths.
5. Provision of services: concentrates on the organization and delivery of services and patient flows, addressing public health, primary care, secondary and tertiary care, day care, emergency care, pharmaceutical care, rehabilitation, long-term care, services for informal carers, palliative care, mental health care and dental care.
6. Principal health reforms: reviews reforms, policies and organizational changes; and provides an overview of future developments.
7. Assessment of the health system: provides an assessment of systems for monitoring health system performance, the impact of the health system on population health, access to health services, financial protection, health system efficiency, health care quality and safety, and transparency and accountability.
8. Conclusions: identifies key findings, highlights the lessons learned from health system changes; and summarizes remaining challenges and future prospects.
9. Appendices: includes references and useful websites.

The quality of HiTs is of real importance since they inform policy-making and meta-analysis. HiTs are the subject of wide consultation throughout the writing and editing process, which involves multiple iterations. They are then subject to the following.

- A rigorous review process.
- There are further efforts to ensure quality while the report is finalized that focus on copy-editing and proofreading.
- HiTs are disseminated (hard copies, electronic publication, translations and launches).

The editor supports the authors throughout the production process and in close consultation with the authors ensures that all stages of the process are taken forward as effectively as possible.

One of the authors is also a member of the Observatory staff team and they are responsible for supporting the other authors throughout the writing and production process. They consult closely with one another to ensure that all stages of the process are as effective as possible and that HiTs meet the series standard and can support both national decision-making and comparisons across countries.

9.5 The review process

This consists of three stages. Initially the text of the HiT is checked, reviewed and approved by the series editors of the European Observatory. It is then sent for review to two independent academic experts, and their comments and amendments are incorporated into the text, and modifications are made accordingly. The text is then submitted to the relevant ministry of health or appropriate authority, and policy-makers within those bodies are restricted to checking for factual errors within the HiT.

9.6 About the authors

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