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Italy

Health system review

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European
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Preface

The Health Systems in Transition (HiT) profiles are country-based reports 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 profile is produced by country experts in collaboration with the Observatory's research directors and staff. In order to facilitate comparisons between countries, the profiles are based on a template, which is revised periodically. The template provides detailed guidelines and specific questions, definitions and examples needed to compile a profile.

HiT profiles seek to provide relevant information to support policy-makers and analysts in the development of health systems in Europe. 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;
- to describe the institutional framework, the process, content and implementation of health care reform programmes;
- to highlight challenges and areas that require more in-depth analysis; and
- to 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.

Compiling the profiles poses a number of methodological problems. In many countries, there is relatively little information available on the health system and the impact of reforms. Because of the lack of a uniform data source, quantitative data on health services are based on a number of different sources, including the World Health Organization (WHO) Regional Office for Europe Health for All database, national statistical offices, Eurostat, the Organisation for Economic Co-operation and Development (OECD) Health

Data, the International Monetary Fund (IMF), the World Bank and any other relevant sources considered useful by the authors. Data collection methods and definitions sometimes vary but typically are consistent within each separate series.

A standardized profile 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. The HiT profiles can be used to inform policy-makers about experiences in other countries that may be relevant to their own national situation. 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: info@obs.euro.who.int. HiT profiles and HiT summaries are available on the Observatory's web site at www.euro.who.int/observatory. A glossary of terms used in the profiles can be found at the following web page: www.euro.who.int/observatory/glossary/toppage.

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The current series of HiT profiles has been prepared by the staff of the European Observatory on Health Systems and Policies. The European Observatory on Health Systems and Policies is a partnership between the WHO Regional Office for Europe, the Governments of Belgium, Finland, Norway, Slovenia, Spain and Sweden, the Veneto Region of Italy, the European

Investment Bank, the World Bank, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

The Observatory team working on the HiT profiles is led by Josep Figueras, Director, and Elias Mossialos, Co-Director, and by Martin McKee, Richard Saltman and Reinhard Busse, heads of research hubs. Technical coordination and production is led by Jonathan North, assisted by Caroline White and Aki Hedigan.

Special thanks are extended to the OECD for the data on health services. Thanks are also due to national statistical offices that have provided data. This report reflects data available up to 2009.

List of abbreviations

ADI	Assistenza domiciliare integrata (integrated home care)
AEP	Average European price
AIFA	Agenzia Italiana del Farmaco (Italian Medicines Agency)
AO	Azienda ospedaliera (‘hospital enterprises’ (public hospital))
ASL	Azienda sanitaria locale (local health enterprise)
ASSR	Agenzia per i Servizi Sanitari Regionali (Agency for Regional Health Care Services) (since 2007, AGENAS (National Agency for Regional Healthcare))
BMI	Body mass index
CAM	Complementary and alternative medicine
CARK	Central Asian republics and Kazakhstan
CCM	Centro Nazionale per la Prevenzione e il Controllo delle Malattie (National Centre for Disease Prevention and Control)
CCRQ	Comitato Consultivo Regionale per la Qualità dal lato del Cittadino (Advisory Committee for Quality from the Citizen’s Perspective)
CdS	La Casa della Salute (‘health house’)
CIS	Commonwealth of Independent States
CNAQ	National Committee for Quality and Accreditation
CRS	Regional Services Card
CUP	Centro unico di prenotazione (central booking point)
DALE	Disability-adjusted life expectancy
DDD	Defined daily dose
DRG	Diagnosis-related group
ECM	Educazione continua in medicina (continuing education in medicine)

ENPAS	Ente Nazionale Previdenza e Assistenza Dipendenti Statali (National Institute for Civil Servants)
ESTAV	Ente per i Servizi Tecnico-amministrativi di Area Vasta (*wider area organizations*)
EU	European Union
EU12	Countries that joined the EU in May 2004 and in January 2007
EU15	Countries belonging to the EU before May 2004
GDP	Gross domestic product
GP	General practitioner
HALE	Health-adjusted life expectancy
HiT	Health Systems in Transition
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
HTA	Health technology assessment
ICT	Information and communication technology
IMF	International Monetary Fund
INADEL	Istituto Nazionale Assistenza Dipendenti Enti Locali (National Institute for Local Authority Employees)
INAM	Istituto Nazionale per l'Assicurazione Contro le Malattie (National Institute for Disease Control)
IRAP	Imposta Regionale sulle Attività Produttive (regional business tax)
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico (National Institutes for Scientific Research)
IRPEF	Imposta sui Redditi delle Persone Fisiche (personal income tax)
ISPESL	Istituto Superiore Prevenzione e Sicurezza sul Lavoro (National Institute for Occupational Safety and Prevention)
ISS	Istituto Superiore di Sanità (National Institute of Health)
ISTAT	Istituto Nazionale di Statistica (National Institute of Statistics)
LEA	Livelli essenziali di assistenza (basic health benefits package)
MOH	Ministry of Health*
NCCED	National Commission on Continuing Education in Medicine
NPCEM	National Programme on Continuing Education in Medicine
NSIS	Nuovo Sistema Informativo Sanitario (New Health Information System)
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-counter

*Note: The Ministry of Health has fallen under a number of different government portfolios over the years. It is currently part of the Ministry of Labour, Social Services and Health.

PNLG	Piano Nazionale Linee Guida (National Programme on Clinical Guidelines)
PPP	Purchasing power parity
RSA	Residenze sanitarie assistenziali (skilled nursing facility)
RSSP	Relazione sullo Stato Sanitario del Paese (National report on health status)
SARS	Severe acute respiratory syndrome
SISS	Health Care Information System
SOP	Senza Obbligo di Prescrizione (drugs that do not require prescription and cannot be advertised)
SSN	Servizio Sanitario Nazionale (National Health Service)
STP	Stranieri temporaneamente presenti (foreigners on temporary stay)
URP	Ufficio Relazioni con il Pubblico (Office for Public Relations)
USL	Unità Sanitaria Locale (Local Health Unit)
VAT	Value-added tax
VHI	Voluntary health insurance
WHO	World Health Organization

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Abstract

The HiT profiles are country-based reports that provide a detailed description of a health system and of policy initiatives in progress or under development. HiTs examine 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 and health care policies; and highlight challenges and areas that require more in-depth analysis.

Various indicators show that the health of the Italian population has improved over the last few decades. Average life expectancy reached 77.6 years for men and 83.2 years for women in 2005, and the mortality rate among adults has fallen significantly, as has the infant mortality rate. However, in almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic imbalance between the north and south of the country. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases, while smoking and rising obesity levels, particularly among young people, remain important public health challenges.

Italy's health care system is a regionally based National Health Service (*Servizio Sanitario Nazionale* (SSN)) that provides universal coverage free of charge at the point of service. The national level is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organizations and public and private accredited hospitals. Again, there is a considerable north–south divide in the quality of health care facilities and services provided to the population, and there are significant cross-regional patient flows, particularly to receive high-level care

in tertiary hospitals. Health care is mainly financed by earmarked central and regional taxes. Each region is free to provide additional health care services if budgets permit, as long as they also deliver the basic package. However, regional budget deficits historically have been a major problem and reform efforts since the 1990s have aimed, in part, to enforce balanced budgets.

The most important state-level reforms from the beginning of the 1990s include: the devolution of health care provision to regional governments and the progressive strengthening of regional powers to deliver and finance health care; a parallel delegation of managerial authority to hospitals and local health enterprises; the establishment of the uniform basic package of health services that should be guaranteed to all citizens; the introduction of a national clinical guidelines programme to enhance the quality of health care; and the development of an electronic patient records system. Future challenges for the devolved Italian health care system include: overcoming the large variability in the quality of health care among regions; providing a national policy for the governance of patient mobility; the reorganization of primary health care; the integration of health care networks for emergency care, transfusions and transplants; and the integration of health, social care and palliative care.

Executive summary

Introduction

Italy is located in southern Europe and is bordered by France, Switzerland, Austria and Slovenia. It has a population of 57.5 million (2004). The 1948 Constitution established the current parliamentary republic, which has a bicameral parliament – the Chamber of Deputies and the Senate. The head of state is the President, who is elected for seven years by a joint session of the Chamber and Senate, while the government is headed by the Prime Minister, who is usually the leader of the party that has the largest representation in the Chamber of Deputies. The country is divided into 20 regions, which are extremely varied, differing in size, population and levels of economic development. Since the early 1990s, considerable powers, particularly in health care financing and delivery, have been devolved to this level of government.

Various indicators show that the health of the Italian population has improved over the last few decades. Average life expectancy reached 77.6 years for men and 83.2 years for women in 2005, and the mortality rate among adults has fallen significantly, as has the infant mortality rate. However, in almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic imbalance between the north and south of the country. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases, while smoking and rising obesity levels, particularly among young people, remain important public health challenges.

Organization

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The catalogue of SSN benefits, the *livelli essenziali di assistenza* (LEAs), is defined in terms of a positive and negative list. The positive list contains the services that the SSN is required to provide uniformly in all regions. Regions are free to provide non-LEA services to their residents but must finance these with own source revenues, and some actually do so. The negative list excludes categories of defined services based on various criteria, including proven clinical ineffectiveness. The SSN also has a positive and a negative drug list in the *National Pharmaceutical Formulary*, outlining which medicines will be reimbursed by the SSN and which need to be paid for in full by patients, respectively.

Financing

Total expenditure on health as a proportion of gross domestic product (GDP) has risen from 7.9% in 1990 to 8.7% in 2007. Public spending on health accounted for 77.0% of the total in 2007, but there has been considerable fluctuation in this figure over the years depending on GDP rates and various co-payment policies implemented by different governments, thus affecting the private share of health care spending. Although Italy has one of the lowest public shares of total health care expenditure among European Union (EU) countries, the volume of public health care expenditure remains an important issue for the Government, both at the national and the regional levels, mainly because of the existence of a large public deficit. Available research on public health care expenditure also shows that differences in regional expenditure are mainly explained by socioeconomic factors, such as differences in GDP, and in the supply of health care.

Health care is mainly financed by earmarked central and regional taxes – a corporation tax that is levied on the value added of companies and on the salaries of public sector employees, and an additional regional income tax. The former tax is collected nationally, but 90% of its revenue is allocated back to the region in which it is levied, thus favouring those regions with a stronger industrial base. This has led to a long-standing debate between the regions and central government over health care funding mechanisms. In 2001, the government introduced a National Solidarity Fund (financed through central government value-added tax (VAT) revenue) to redistribute resources to those regions that are unable to fund the basic package. However, an agreement has not yet been reached over an equitable redistribution formula, which effectively has blocked implementation of the fund.

Nationally, hospital expenditure takes up a considerable proportion of health care spending, accounting for 46% of the total in 2005. Primary care made up a further 46%, while spending on public health stayed stable at only 3.6%. Administrative costs only amounted to 4.3%, which, along with public health, have experienced a decrease in spending over the years, with more money going to primary and community care, where expenditure for drugs has undergone a major and worrying increase.

Inpatient care and primary care are free at the point of use. There are two main types of out-of-pocket payment. The first is cost-sharing: patients pay a co-payment for diagnostic procedures, specialist visits and pharmaceuticals (in those regions that have chosen to levy co-payments on drugs for the purposes of containing rising drug expenditure). Moreover, since 2007, a fixed co-payment has been levied for unwarranted access to hospital emergency departments. The second type of out-of-pocket payment is direct payment by users to purchase private health care services and over-the-counter (OTC) drugs. In 2004, cost-sharing and direct payments by users represented 19.6% of total health care expenditure and 83% of all private health care expenditure. Cost-sharing exemptions exist for various groups, including children under 14 years of age, elderly people over 65 years of age with gross household income less than €36 152 per annum, people with chronic or rare diseases, disabled people, people with HIV, prisoners and pregnant women.

Due to near universal coverage, voluntary health insurance (VHI) does not play a significant role in funding health care in Italy. Spending on VHI, both as a percentage of total expenditure and of private expenditure, is well under 5%. Where it is purchased, complementary insurance policies cover co-payments, non-reimbursed services, dental care and hospital per diems for private rooms while supplementary insurance allows patients to access a wider choice of providers and to have increased access to private providers.

Delivery of services

The number of health care professionals, including general practitioners (GPs), paediatricians, hospital physicians and dentists, has generally increased in Italy over the last two decades. An exception to this trend is hospital nurses, which have been in short supply. Some increases in numbers have occurred since 2005 with the introduction of policies to promote the profession and to allow foreign-trained nurses to practise in the country.

Public health activities are mainly overseen by ASLs, which are responsible for a variety of services, including health promotion and prevention activities, food safety, occupational diseases and accidents, and veterinary medicine.

Primary care is provided by GPs, paediatricians and self-employed and independent physicians working alone under a government contract, who are paid a capitation fee based on the number of people (adults or children) registered on their list. Although primary care physicians are given financial incentives to share clinic premises with their colleagues, they usually work in single practices.

Specialist ambulatory services, including visits and diagnostic activities, are provided either by ASLs or by accredited public and private facilities with which ASLs have agreements and contracts. Services are listed in specific formularies that vary among regions. People are allowed to access specialist care either through a referral by their GP or for some services, by directly booking an appointment themselves through a central booking point (*centro unico di prenotazione* (CUP)).

Currently, hospital care is delivered mainly by 669 public facilities, which provide both outpatient and inpatient services; nevertheless, ASLs also contract out services to 553 private hospitals, especially not-for-profit institutions. Since 1994, major hospitals (highly specialized hospitals with national relevance) have been given financial and technical autonomy, and granted the status of independent hospital enterprises (*aziende ospedaliere*, 'hospital enterprises' (AO)). Other public hospitals are kept under the direct management of ASLs. A reduction in the number of beds, together with policies aimed at promoting the appropriate use of hospital care during the 1990s and after 2000, has resulted in a sharp decrease in the number of hospital admissions, with Italy having one of the lowest admissions levels in the EU. Patients can choose to receive treatment from hospitals within their own ASL or through a provider in another ASL (within the same region or in another region). Thus, ASLs have to pay for the treatment provided to their residents by providers located in other regions or ASLs (outward mobility) and, in turn, they receive payments for the health care provided to patients coming from other regions (inward mobility).

At the national level, dental health care is included in the benefits package for specific populations, such as children (0–16 years old), vulnerable people (the disabled, people with HIV, people with rare diseases) and individuals who need dental health care in some urgency/emergency cases. Other members of the population purchase dental services out of pocket. Tariffs for dental services are centrally regulated by the national formulary. Regions may also carry out their own dental services initiatives; for example, in Lazio, dental care for the elderly has been successfully promoted and implemented.

Medicines are mainly obtained through licensed private or public pharmacies. The former – accounting for 92% of the total – are owned by pharmacists who act as independent contractors under the SSN, while the latter (8%) are managed by pharmacists employed by the municipality in which the pharmacy is located. In addition to selling pharmaceuticals on prescription, both types of pharmacies are licensed to sell commercial products including bandages, contraceptives, personal hygiene items, baby products (such as nappies and infant formula) and cosmetics; some pharmacies also sell homeopathic products. In 2007, the government allowed OTC drugs to be sold outside pharmacies (such as in supermarkets), although it expressly banned the sale of medicine requiring a GP's prescription.

The effective coordination of health and social care to provide long-term care to the elderly and disabled is still in its early stages and has been hampered by the existence of different providers across the spectrum of services. This has prompted some municipalities to delegate responsibility for delivering such care to ASLs. Care is usually provided in residential or semi-residential facilities (RSAs) and through community home care. The RSAs are normally used for patients whose health status requires an intensive use of health care resources, while community home care is often utilized when patients do not have critical health conditions.

A national policy on palliative care has been in place since the end of the 1990s, which has focused attention on this kind of care and contributed to an increase throughout the country of services, such as hospices, day-care centres and palliative care units within hospitals. Although much still needs to be done to ensure the homogeneous diffusion of palliative care services, until 1999 availability was very small, and was concentrated mainly in northern Italy. Much was left to the efforts of voluntary organizations, which still play a crucial role in the delivery of these services.

Italy has experienced a significant change in its mental health sector, with a radical shift from old mental health institutions (before 1978) to new community-based psychiatric services. At present, specific departments of mental health within ASLs, with multidisciplinary teams, are expected to promote and coordinate mental health prevention, care and rehabilitation within defined catchment areas. Services are provided within a variety of settings, including: community mental health centres, general hospital inpatient wards, semi-residential facilities (day hospitals and day-care centres) and residential facilities. Better integration and closer collaboration between different services is now emerging as a leading principle in the mental health sector. A significant proportion of services related to people with mental disorders and learning disabilities are also operated by voluntary organizations.

Reforms and future challenges

The most important state level reforms from the beginning of the 1990s include: the devolution of health care provision to regional governments and the progressive strengthening of regional powers to deliver and finance health care; a parallel delegation of managerial authority to hospitals and ASLs; the establishment of the uniform basic package of health services that should be guaranteed to all citizens; the introduction of a national clinical guidelines programme to enhance the quality of health care; and the development of an electronic patient records system. Future challenges for the devolved Italian health care system include: overcoming the large variability in the quality of health care among regions; providing a national policy for the governance of patient mobility; the reorganization of primary health care; the integration of health care networks for emergency care, transfusions and transplants; and the integration of health, social care and palliative care.

1 Introduction

1.1 Geography and sociodemography

Italy is a parliamentary republic, with a population of 57.5 million in 2004. The territory covers 301 316 km^2, with a population density of 193 inhabitants per km^2. Italy is located in southern Europe and is bordered by France, Switzerland, Austria and Slovenia. Enclaves within mainland Italy include the countries of San Marino and the Holy See, a papal state mostly enclosed by Rome, Italy's capital (Fig. 1.1). In addition to the mainland, Italy includes the Mediterranean islands of Sardinia and Sicily and many smaller islands, making 20 regions in all (Fig. 1.2). About 77% of the country is mountainous or hilly, and 23% is forested. Northern Italy consists of a vast plain with the Alps in the north and is the richest part of the country, with the best farmland and largest industrial centres. Central Italy has great historical and cultural centres, such as Rome and Florence, and a flourishing tourist trade. Southern Italy is the poorest and least developed area.

Italian is the major language, although there are small areas in which German (in parts of the Trentino-Alto Adige region), French (in the Valle d'Aosta region) and Slovene (in the Trieste-Gorizia area) are spoken. Although the Constitution guarantees freedom of worship to religious minorities – which are primarily Protestant, Muslim and Jewish – the dominant religion is Roman Catholicism.

The structure of the population changed significantly between 1970 and 2006 owing to marked declines in fertility rates (from 2.42 to 1.35) and increases in life expectancy. Italy has one of the lowest total fertility rates in the world: in 2006, it was 1.35, far below the replacement level (Table 1.1). The population growth rate is, therefore, very low (0.52), one of the lowest in the EU, and immigration is the source of most of the growth.

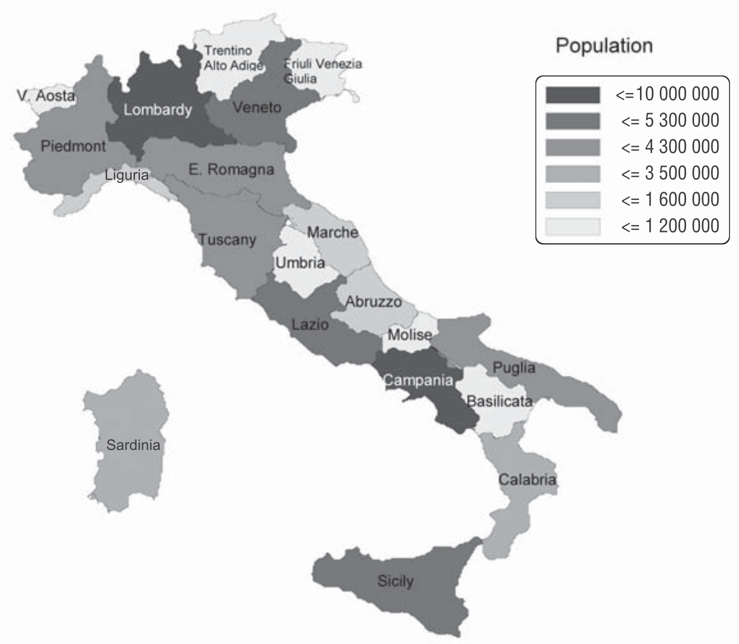
Fig. 1.1 Map of Italy

Source: Central Intelligence Agency, 2007.

1.2 Economic context

Italy has an open economy and is a founding member of the EU. It is also a member of major multilateral economic organizations such as the Group of Eight Industrialized Countries (G8), OECD, the World Trade Organization and the IMF. According to OECD figures, in 2004 Italy's economy was the sixth largest among industrial powers. Its annual gross domestic product (GDP) accounts for 6.6% of the total GDP of the G8 countries and 14.0% of the EU's total GDP. Per capita income, nevertheless, is 28.8% lower than in the United States and nearly 10% lower than the average EU level.

Fig. 1.2 Italy's 20 regions and their populations as of 1 January 2003



Source: WHO Regional Office for Europe, 2007.

The basis of Italy's economy is processing and manufacturing goods, primarily in small and medium-sized firms. Its major industries are precision machinery, industrial machinery and equipment, transportation equipment, motor vehicles, chemicals, pharmaceuticals, electric and electronic equipment, fashion, clothing, leather, jewellery and shoes. Italy has few natural resources, with no substantial deposits of iron, coal or oil. Natural gas reserves are located mainly in the Po Valley and offshore in the Adriatic Sea. Most raw materials for industry and over 75% of energy requirements have to be imported. In 2005, the agricultural sector employed 4.9% of the workforce, although it accounted for only 2.5% of GDP; industry employs 31.8% of the population and represents 26.6% of GDP; the service sector employs 63.3% of the population and comprises 70.9% of GDP. Tourism represents an important part of the economy, with nearly 86 million visitors to tourist facilities in 2004, an increase of 7% with respect to 2000. However, the seasonal nature of tourism and the large numbers of illegal immigrants working in tourism make it difficult to assess its impact on employment.

Since the end of the Second World War, Italy's economic structure has completely changed from being agriculturally based to industrially based,

Table 1.1 Population, demographic indicators, 1970–2006

Indicators	1970	1980	1990	2000	2003	2004	2006
Total population (1000s)	52 771	55 657	56 737	57 189	57 478	57 553	58 435
Population, female (% of total)	51.3	51.3	51.4	51.4	51.4	51.5	51.4
Population aged 0–14 years (% of total)	22.9	20.5	16.5	14.5	14.4	14.3	14.2
Population aged 65 years and over (% of total)	10.5	12.9	14.6	17.7	18.2	19.0	19.6
Population growth (% annual)	0.50	0.21	0.08	0.05	0.78	0.13	0.52
Population density (people/km^2)	178.6	187.3	188.2	189.0	191.2	192.6	–
Fertility rate, total (births per woman aged 15 to 49 years)	2.42	1.64	1.33	1.23	1.26	1.33	1.35
Birth rate, crude (per 1000 people)	17.0	11.7	10.2	9.5	9.4	9.7	9.6
Death rate, crude (per 1000 people)	9.8	9.9	9.6	9.8	10.1	–	9.5
Age dependency ratio[a]	50.3	49.9	45.2	47.4	48.2	49.9	50.9

Source: OECD, 2009b.

Note: [a]The age dependency ratio is the ratio of the combined child population (aged 0–14 years) and the elderly population (aged 65 years and over) to the working age population (aged 15–64 years). This ratio is presented as the number of dependents for every 100 people in the working age population.

with about the same total and per capita output as France and the United Kingdom. Italy experienced its ‘economic miracle’ from 1958 to 1963 when industrial output peaked at over 19% per year, investment levels reached 27% of GDP (in 1963) and the country enjoyed full employment. The country did, however, suffer considerably from the two economic crises of the last quarter of the 20th century. After 1963, the economy slowed down, and after 1973, it experienced a severe downturn. The oil shocks of the 1970s hit Italy’s economy particularly hard, given the reliance on foreign sources of energy. An extended period of high inflation and large budget deficits ensued during the 1980s, as the industrial complex restructured to meet the challenges posed by the new context. In addition, during the international economic crisis of the early 1990s, the rate of GDP growth decreased markedly, unemployment rose and inflation peaked, increasing to more than 6%. Severe financial unrest forced monetary officials to withdraw the lira (its legal tender prior to joining the single European

Table 1.2 Macroeconomic indicators, last 10 available years

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
GDP (billion euros)[a]	1091	1112	1128	1150	1191	1212	1217	1217	1230	1230
GDP, PPP (billion $)	1136	1193	1238	1271	1338	1369	1444	1488	1527	1543
GDP per capita, US$ PPP	22 080	20 930	23 003	24 026	25 245	24 670	26 430	27 119	28 180	28 080
GDP growth (annual %)	2.20	1.92	1.44	1.95	3.56	1.76	0.41	0.00	1.06	0.00
Labour force (1000s)	22 933	22 896	23 094	23 240	23 425	23 593	23 770	23 902	24 128	24 280
Unemployment (% of labour force)	11.2	11.6	12.1	12.2	12.0	11.6	10.7	9.5	9.2	8.9

Source: OECD, 2005.
Notes: GDP: Gross domestic product; PPP: Purchasing power parity; [a]GDP prices for 2000.

currency) from the European monetary system in September 1992 when it came under extreme pressure in currency markets.

From 1992, after learning that Italy might not qualify to join the European Economic and Monetary Union, the authorities made a significant effort to address the most pressing economic issues. Economic policies were launched to tackle the fiscal and monetary imbalances that had developed over the previous years, aiming to re-establish an environment of sound finance, stable currency and low interest rates. The government adopted fairly strict budgets, ended its highly inflationary wage indexing system and started to reduce its social welfare programmes, specifically focusing on pension and health care benefits. In addition, the private sector was increasingly emphasized as the primary engine of growth: to this end, a broad array of deregulation measures was enacted, and from 1994, a massive privatization programme for state-owned enterprises was implemented to reduce the presence of the state, which, at the time, played a major role in the economy by owning large industrial and financial companies. The most significant effect of such initiatives was a progressive, continuous decrease in inflation rates throughout the 1990s. In addition, unemployment declined and GDP growth rates increased substantially during the mid-1990s, although they were somewhat reversed during the late 1990s. Unemployment figures from the OECD show that Italy had an unemployment rate of 8.9% in 2005 (Table 1.2).

Some of the most remarkable, specific weaknesses of Italy's economy in the late 1990s were related to its labour market structure. In 1999, for instance, 32.7% of all unemployed people were younger than 25, one of the highest proportions in the EU, although five years later this decreased to 26%. Women only account for 39% of the workforce, one of the lowest rates among EU countries and, above all, a percentage that sharply declines as one moves up the hierarchical scale, with top positions both in the public and private sectors usually being the domain of the male workforce. In addition, temporary jobs continue to play an increasingly important role within Italy's economy, primarily in the south. There is also a major underground economy that accounts for an estimated 14–20% of GDP. This includes many nominally unemployed people, as well as illegal immigrants, especially in difficult agricultural work in the rural south.

The success of the corrective action undertaken during the 1990s has been highlighted by the participation of Italy in the common European currency, the euro, since its introduction on 1 January 1999. In the 2000s, priorities for the Italian economy include the need to address proposed fiscal reform, revamp its communication system, reduce pollution in major industrial centres and adapt to the new competitive environment related to the ongoing process of economic integration and expansion of the EU. Following the onset of the severe global financial crisis in 2008, Italy's economy went into recession in early 2009. Priorities now include reversing sharp decreases in investment and export markets, tackling rising unemployment and implementing improved spending controls to manage a widening public debt (OECD, 2009a).

1.2.1 The north–south divide

One of the most enduring, crucial problems of Italy's economy since its inception as a unified country has been the marked north–south divide. At the time of unification (1861) certain northern and central regions (Piedmont, Lombardy and Tuscany) had reasonably well-developed industrial enterprises, commerce and agriculture, based on efficient modern structures and plentiful capital. In contrast, the central and southern regions were characterized by underdeveloped agricultural systems, especially the *latifundia* (vast estates and few landowners), while industry, based on state enterprises, was given internal tax protection. The introduction of a free trade system (abolished in 1878) throughout the country, together with adoption of the Piedmont tax system and excise tariffs, contributed to a widening of the economic and social disparity between the north and the south.

Italy's period of greatest economic expansion, which lasted for over a decade (1951–1963), led to a correspondingly radical transformation of life and society, as considerable sections of the population migrated from the southern regions and the less-developed areas of the north towards the industrialized parts of Italy (the Milan–Turin–Genoa triangle) and to other countries in central and western Europe, accentuating the imbalance between north and south. Despite considerable economic development during the second half of the 20th century, the income gap between the north and the south remains one of Italy's most difficult and enduring economic and social problems. At the start of the 21st century, Italy is still divided into a developed industrial north, consisting of a few multinational companies and a large number of small and medium-sized private firms, and an undeveloped agricultural south.

In particular, recorded labour force participation rates are markedly higher for the centre and north (62%) than for the south (52%). The most significant difference between central and northern Italy and southern Italy is the unemployment rate: 27.8% for the south versus 4.6% for the centre and north in 2003. Another important characteristic is the dual economy: 75% of total GDP is produced in the centre and north (Lombardy accounts for 20% of GDP) and only 25% in the south (Table 1.3). Moreover, this proportion has remained almost the same over the last two decades.

Table 1.3 Per capita GDP and percentage of the national average in Italy's regions, 2003

Region	Per capita income (×1000 euros)[a]	Percentage of national average
Piedmont	20.4	115.9
Valle d'Aosta	23.2	131.8
Lombardy	22.7	130.0
Trentino-Alto Adige	23.4	132.9
Veneto	20.8	118.2
Friuli-Venezia-Giulia	20.1	114.2
Liguria	18.9	107.3
Emilia-Romagna	22.5	127.8
Tuscany	19.5	110.8
Umbria	17.2	97.7
Marche	18.1	102.8
Lazio	18.9	107.4
Abruzzo	15.3	86.9
Molise	13.7	77.8
Campania	11.2	63.4
Puglia	11.8	67.1
Basilicata	12.8	72.2
Calabria	10.9	61.9
Sicily	11.6	65.9
Sardinia	13.2	75.0
ITALY	17.6	100.0

Source: Ministero dell'Economia e delle Finanze, 2003.
Notes: GDP: Gross domestic product; [a]1995 GDP prices.

1.3 Political context

Italy's political system is based on the 1948 Constitution. A popular referendum abolished the monarchy in 1946. The Chamber of Deputies and the Senate form the bicameral parliament, whose members are directly elected for a five-year term by universal suffrage. The President of the Republic is elected for seven years by a joint session of the Chamber and Senate. The Prime Minister must be endorsed by, and have the confidence of the Parliament and is nominated by the President. The Prime Minister is usually the leader of the party that has the largest representation in the Chamber of Deputies.

From 1948 until the late 1970s, the Prime Minister was consistently from the Christian Democratic Party. Coalition governments including several of Italy's political parties were in power, consistent with an electoral system based on almost pure proportionality. During 1976–1979, the Communist Party voted in support of the government (which included the Christian Democratic Party, the Socialist Party, the Social Democratic Party and the Republican Party) for the first time, although it did not enter the government coalition. Starting in 1979, a new alliance was formed, also headed by the Christian Democrats. As part of the formation of this government (known as the five-party coalition), the Communist Party ceased to support the government and the minority rightist Liberal Party was incorporated. The Minister for Health was from the Liberal Party during most of the 1980s and until 1993.

During the early 1990s, persistent government instability, mounting economic pressure and especially a series of corruption scandals implicating all governing parties in illegal party financing prompted a profound political crisis. By September 1993, many political leaders were under criminal prosecution by the courts and the five-party government fell. A non-partisan ('technical') government, led by the former president of the Bank of Italy, was put in charge of ruling the country during the transition period, which lasted until March 1994. The proportional electoral system, which had been established in the 1948 Constitution, was reformed into a predominantly majoritarian system, and new parties developed around two poles. The conservative coalition 'Pole of Liberties' was formed by the leading Forza Italia party, the regionalist party Lega Nord (Northern League) and the radical right-wing group Alleanza Nazionale (National Alliance). Several centre-left, leftist and green parties (including the ex-communists) joined to form an alliance initially called the Progressives and later L'Ulivo (the Olive Tree). For nearly 15 years, governments have tended to alternate between these two poles.

The Italian political system underwent another major change when the centre-right government successfully but controversially introduced further changes to the country's electoral system a few months before the general elections of 2006. Since 1994, Italy's electoral system had allocated 25% of parliamentary seats by proportional representation and the rest by a first-past-the-post system based on constituencies. The new rules introduced three separate cut-off thresholds for parties and coalitions. Individual parties obtaining less than 2% of the national vote would not be represented in parliament and their votes would not go towards their coalition's overall tally. Parties obtaining between 2% and 4% of the vote would not be given seats but their votes would contribute to their coalition's tally. Finally, individual coalitions which failed to win at least 10% would not obtain any seats. In the event of a narrow outcome, the coalition with the most votes would be given extra seats to guarantee a parliamentary majority of 340 seats in the 630-seat Chamber and 170 seats in the 315-seat Senate.

The ‘extra seats mechanism’ was first applied in the tightly fought April 2006 elections when the centre-left Ulivo alliance won by a very narrow margin. Further elections were held in the spring of 2008 and Italy’s current government is from the centre-right coalition, with a very strong majority in both chambers.

The Constitution organizes Italy’s territory into 20 regions, which are extremely varied. They differ in size (Piedmont is 25 000 km^2, while Valle d’Aosta is only 3000 km^2), population (Lombardy has 15% of the total population, whereas Molise has less than 1%), and levels of economic development. The regions also differ in population age distribution. For example, an average of 17% of Italy’s population is aged 65 years or older; southern Italy has fewer (15%) and central and northern Italy has more (19%). Each region is governed by an Executive and a Regional Council, both of which are democratically elected. The 20 regions are subdivided into 107 provinces. The provinces are led by a president and a council, both of which are popularly elected. In addition, each province has a prefect who represents – and is appointed by – the national government. The basic unit of local government is a municipality (*comune*), which may range in size from a small village to a large city such as Naples. Italy has about 8107 municipalities, many of which are small villages with an ancient tradition of independent self-government. A council elected for a four-year term by universal suffrage governs each municipality. Mayors of cities and towns with more than 15 000 residents are directly elected.

The constitutional framework distinguishes between ordinary regions and those governed by special statute. Italy has five special regions (Valle d’Aosta, Friuli-Venezia-Giulia, Trentino-Alto Adige, Sicily and Sardinia), one of which, Trentino-Alto Adige, is further divided into two autonomous provinces (Trento and Bolzano), which also enjoy constitutionally based self-government rights. Their special status, based on specific constitutional statutes, derives from the fact that they are border regions with a historically distinctive identity, specific language, and demographic and socioeconomic traits. Italy has 15 ordinary regions, which also have autonomous powers over a more limited number of policy fields (such as urban planning, agriculture, forestry and transport). All regions have some power to allocate funds received from the central government. However, special regions enjoy wider autonomy in this respect and also receive a higher than average share of government funding. In addition, their self-government rights extend to an additional number of policy areas, such as primary and secondary education, arts and culture, and subsidies to industry, commerce and agriculture. Regions, as well as provinces and municipalities, are granted some limited fiscal autonomy within the limits determined by national laws. In addition, they complement their own revenues with state transfers sufficient to carry out their ordinary functions. Besides this, the regions own some health care centres (assigned by law) that are allowed to borrow to finance investment (see Chapter 3).

The process of regional devolution, which started during the 1950s for special regions, was first extended to ordinary regions in the late 1970s. Within health care, regional autonomy was limited to restricted administrative powers over hospital planning and management until the early 1990s, when this autonomy was widened considerably through the 1992 reform legislation (see Chapter 7). Starting in the mid-1990s, broader policy proposals to transform Italy into a federal state were debated and adopted. Significant power was also shifted to the regions before the early 1990s as a result of a series of Constitutional Court judgements that recognized that the regions had wide powers in the organization and administration of health care services (France, 2006: pp. 1–3). A reform passed in 1997 – known as the *Legge Bassanini* – significantly extended the powers transferred to regions through the principle of subsidiarity. In particular, responsibility for regulating, planning and organizing health care delivery has been transferred to the regions, and the central government retains responsibility for such functions as approving the National Health Plan, allocating funding and defining clinical and accreditation guidelines. The gradual devolution of political power during the 1990s runs parallel to the fiscal reform passed in 2000, which grants regions significant autonomy over revenue in the regional budget and complete autonomy over the allocation of funds.

In 2001, a significant constitutional reform was passed by Parliament (Constitutional Law No. 3/2001) and then confirmed by a referendum. Briefly, the more important changes include the direct election of regions' governors, the autonomous approval of regional statutes and a new division of legislative powers between the central government and the regions. The central government can now only appeal against any approved regional laws before the Constitutional Court and no longer exercises control over regional legislation and administration. Moreover, the Constitution now lists the responsibilities reserved for the central government and the legislative powers and responsibilities shared concurrently by both the regions and central government. As a result, regions now can exercise legislative powers without interference from the central government in matters that are not explicitly under the centre's remit.[1] Under the 2001 reform, the central government has legislative jurisdiction over foreign and defence policy, coordination at the European level, citizenship, the justice system, the civil and penal codes, local

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[1] Prior to this, the regions held responsibility only for those matters explicitly listed by the Constitution.

authorities, environmental protection, and protection at the national level of civil and social rights. Concurrent legislative powers are recognized in the areas of infrastructure, welfare, labour policies, and urban and territorial planning (Caravita, 2004).

1.4 Health status

Life expectancy at birth rose substantially during the 1980s and continued to grow to just above the EU average by the late 1990s. The infant mortality rate has remained one of the highest in the EU, although it underwent the second largest decline, and a marked reduction, during the 1990s to reach 4.2 per 1000 live births in 2003. However, data show a slight increase for the year 2005 (Table 1.4).

It should be noted that certain population groups often differ significantly, such as men and women, and overall measures do not detect these differences. For example, in 2005, women's life expectancy at birth was 83.2 years, 6 years longer than men's (77.6 years). The gender gap has widened slightly over the last decade. With regard to perceived health, 59.6% of a sample of Italy's population self-assessed their health status as being good in 2002. In particular, more men claimed to be in good health than women (ISTAT, 2005b).

Cancer is the most frequent cause of death for people under 64, followed by cardiovascular diseases. However, when all ages are considered, cardiovascular diseases cause more deaths than cancer (Table 1.5). Age-specific mortality patterns show that up to 88% of all deaths in each age group have three main

Table 1.4 Mortality and health indicators, 1980, 1990, 2000, 2003, 2005

Indicator	1980	1990	2000	2003	2005
Life expectancy at birth (years)					
Female	77.4	80.1	82.5	82.9	83.2
Male	70.6	73.6	76.6	76.8	77.6
Total	74.0	76.9	79.6	79.7	80.4
Mortality rate					
Female adults (per 10 000 female adults)	67.6	53.7	44.1	41.4[a]	45.0
Male adults (per 10 000 male adults)	115.6	93.0	75.4	71.2[a]	76.1
Infant (per 1000 live births)	14.6	8.2	4.5	4.2	4.7

Sources: [a]WHO Regional Office for Europe, 2002, 2007; OECD, 2009b.

Table 1.5 Main causes of death, 1970–2003

Cause	Standardized death rate (per 100 000 population)					
	1970	1980	1990	2000	2001	2003
Perinatal conditions	26.2	13.7	8.0	4.0	4.2	–
Infectious and parasitic diseases	17.4	5.3	6.0	5.4	4.0	–
Circulatory diseases	465.3	408.5	288.8	218.6	207.6	–
Malignant neoplasm	177.9	187.0	193.6	169.3	169.7	–
Trachea/bronchus/lung cancers	24.7	36.3	40.1	36.0	35.8	–
Mental and behavioural disorders	1.7	1.3	6.6	8.6	8.5	
Respiratory diseases	98.7	61.4	44.2	34.5	29.8	31.3
Digestive diseases	57.0	51.0	38.0	26.1	25.5	–
External causes	54.4	52.6	42.2	32.7	33.3	–

Source: OECD, 2009b.
Note: Data for 2003 only available for respiratory diseases.

causes: accidental or other injuries (by far the main cause until 35 years of age), followed by cancer and cardiovascular diseases. Mortality from breast cancer is at the EU average and mortality caused by cervical cancer is very low, even though standardized death rates for all types of cancer among people aged 0–64 years and for lung cancer are still high.

Given the existing north–south economic imbalance, regional differences in demographic and health indicators are also marked. In 2003, the proportion of the population aged 65 years or older ranged from 14.8% (Campania) to 26.27% (Liguria). In addition, fertility rates ranged from 1.17 (Tuscany) to 1.48 (Campania), while birth rates ranged from 7.3 (Liguria) to 11.4 (Campania) per 1000 population. The highest death rate in 2002 was 13.6 (Liguria) and the lowest 8.0 (Campania) per 1000 population. Infant mortality ranged from 6.9 (Basilicata) to 2.0 (Friuli-Venezia-Giulia) per 1000 live births. In 2003, the highest and lowest regional life expectancy figures differed by 2.7 years for males (75.5 versus 78.2) and by 2.5 for females (81.5 versus 84) (ISTAT, 2000).

The disability-adjusted life expectancy (DALE) index summarizes the expected number of years to be lived in what might be termed the equivalent of “full health” (Table 1.6). The indices at birth in Italy are equal to 71.0 for the total population (69.2 for males and 72.9 for females). To better reflect the inclusion of all states of health in the calculation of healthy life expectancy, the name of the indicator used to measure healthy life expectancy has been changed from disability-adjusted life expectancy to health-adjusted life expectancy (HALE). HALE is based on life expectancy at birth but includes an adjustment for time

Table 1.6 DALE and HALE

	Total population	Male	Female
DALE	71.0	69.2	72.9
HALE	73.1	71.0	75.0

Sources: DALE, WHO, 2001; HALE, WHO, 2002.
Notes: DALE: Disability-adjusted life expectancy; HALE: Health-adjusted life expectancy.

spent in poor health. It is most easily understood as the equivalent number of years in full health that a newborn can expect to live based on current rates of ill health and mortality. In the Italian context, the index is equal to 73.1 for the total population (71.0 for males and 75.0 for females).

Overall, the total number of smokers has declined over the last decade and, in particular, the proportion of the population that smokes has remained stable at about 24% over the last five years (Table 1.7). Men and women have different trends (the women's rate is still growing). Young people are smoking less than before (declining from 17.1% to 9.5% among people between 14 and 17 years of age during the 1990s). However, only the consumption pattern of men seems to reflect that found in other industrialized countries, where the decline in consumption has been led by young people from the higher socioeconomic classes. In contrast, upper-class women are more likely to start smoking and less likely to give up than women from lower social classes. The growing prevalence of obesity and the overweight population in Italy in recent years (42% of the population in 2002), particularly among children, has been related to increased calorie intake due to changing dietary habits, including more snacks and shorter lunchtimes. It is worth pointing out, however, that 2005 data show a marked decrease (-18.5% compared to 2002). Since the 1980s, beer consumption has been increasing in association with a reduction in wine drinkers. Beer is the preferred alcoholic drink of young people, whereas people over 35 mainly drink wine (ISTAT, 2005a).

By the end of 2006, 2 670 514 foreigners were officially registered as residing in Italy; about 53% were non-EU citizens and the rest were from the EU. Some 70% of immigrants are young adults (aged 18–40 years), the age category that usually enjoys the best health status. The most widespread diseases among immigrants are infectious diseases, especially sexually transmitted infections (ISTAT, 2007a). Immigrants usually access the health care system through specific immigrant health offices created inside "local health enterprises" (*aziende sanitarie locali* (ASLs)) and through some voluntary centres delivering health services specifically for immigrants (see Section 6.14).

Table 1.7 Factors affecting health status, 1980, 1990, 2000, 2002, 2003, 2005

Indicators	1980	1990	2000	2002	2003	2005
Alcohol consumption (litres per capita, people aged 15+ years	13.2	10.9	9.0	8.6	8.1	–
Tobacco consumption (daily smokers as % of population)	35.5	27.8	24.4	24.0	24.2	23.4
Overweight or obese (% of total population)[a]	–	38.1[b]	41.1	42.0	42.6	34.7

Sources: OECD, [b]2007.
Note: [a]Body mass index (BMI) > 25 kg/m^2.

Dental diseases offer an example of the likely success of preventive efforts (Table 1.8). Over the last two decades, 12-year-old children in Italy have had decreasing indices of decayed, missing and filled teeth, ranging from 5.5 in 1980 to 1.1 in 2005.

Table 1.8 Decayed, missing or filled teeth at age 12 years

Years	Number
1980	5.5
1985	3.0
1990	4.0
1995	2.2
1996	2.1
2003	1.2
2005	1.1

Source: WHO Regional Office for Europe, 2007.

2 Organizational structure

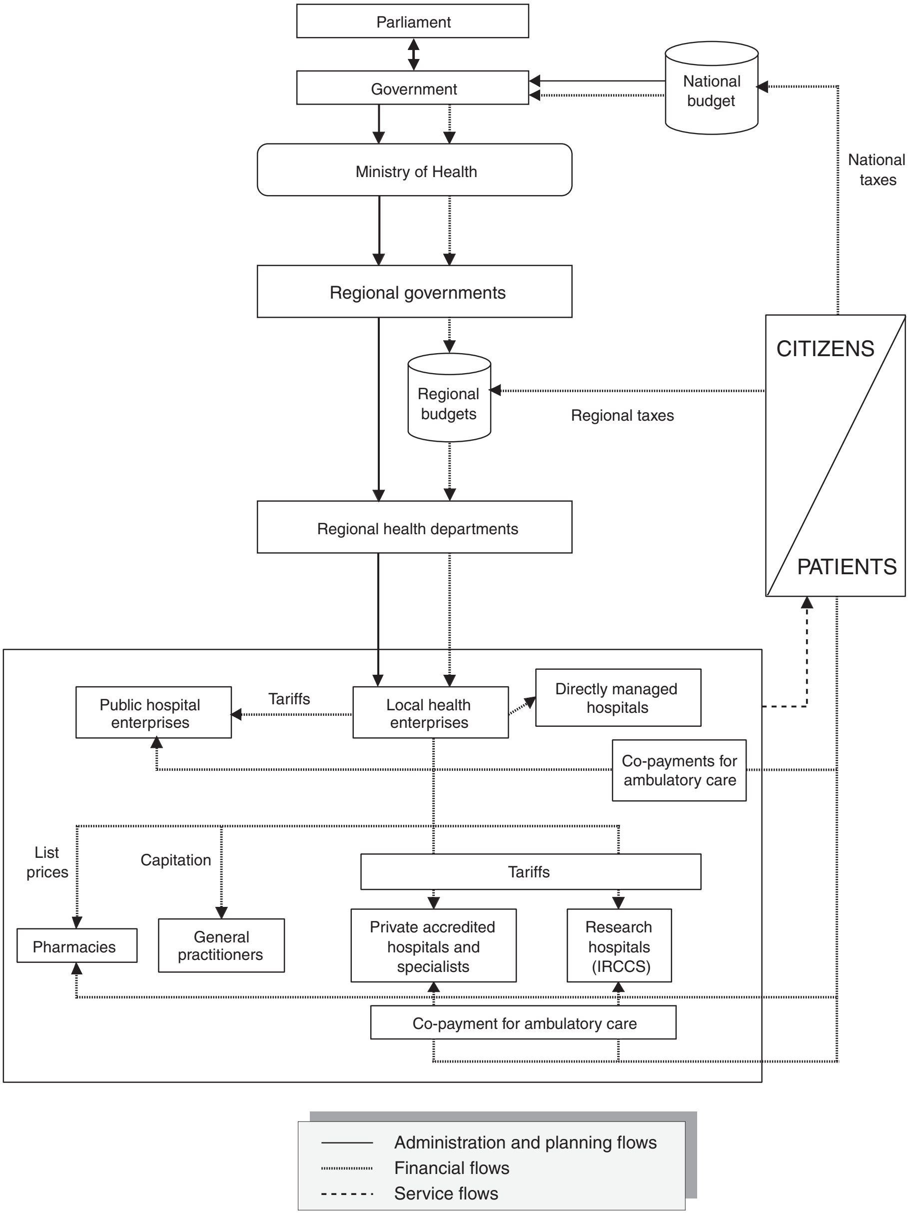
2.1 Overview of the health care system

Italy's health care system is a regionally based National Health Service (*Servizio Sanitario Nazionale* (SSN)) that provides universal coverage free of charge at the point of service. The system is organized into three levels: national, regional and local. The national level is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based ASLs – and public and private accredited hospitals. Figure 2.1 summarizes the main organizational actors, as well as the relationships between them.

2.2 Historical background

During the period between national unification (1861) and the fascist regime in the 1920s, health care in Italy relied on several different structures. Some of them were health care centres sponsored by the Catholic Church, others were old charitable institutions nationalized by the new liberal state. There was also a provincial network for preventive medicine and public health, municipal provisions for economic and social assistance to disabled and needy people, autonomous mutual aid associations for artisans and workers and independent not-for-profit structures. In the 20th century, employers and employees became responsible for financing health care, contributing a percentage of the monthly wage to these voluntary, work-related health insurance funds. The result was a highly fragmented health care structure based on several health insurance

Fig. 2.1 Overview of the Italian health care system



Note: IRCCS: National Institutes for Scientific Research.

funds responsible for covering workers. In 1878, for instance, more than 2000 mutual funds had about 330 000 members. The public sector had a marginal role, restricted to minor prevention programmes and to providing health care for poor people. In 1898, occupational accident insurance was regulated for the first time, and in 1904 it became compulsory for workers in industry and in 1917 for agriculture.

During the fascist regime (1922–1943), several changes to Italy's health care system were pushed forward. Through a 1923 Royal Decree, the right to hospital care for the needy, indigent population was guaranteed for the first time. Several initiatives targeting diseases of perceived social relevance were launched. In 1922, a Royal Decree provided for free treatment of venereal diseases, and in 1926 several centres for cancer diagnosis were created. In 1927, provincial authorities in charge of treating tuberculosis were established and tuberculosis insurance became compulsory. Some steps towards compulsory health care insurance for workers were also taken. In 1925, the National Institute for Local Authority Employees (*Istituto Nazionale Assistenza Dipendenti Enti Locali* (INADEL)) was established as the national body for providing health care for the employees of local authorities. The regulatory framework for the trade union system issued during 1926–1928 included mandatory health care provisions for workers as a prerequisite for collective agreements. Compulsory insurance for occupational disease was introduced in 1929. During the 1930s, health insurance funds became responsible for covering not only workers but also their dependants. In 1942 and 1943, two major institutions for social insurance (including health) were created: the National Institute for Civil Servants (*Ente Nazionale Previdenza e Assistenza Dipendenti Statali* (ENPAS)), the national body in charge of social insurance and health care for public sector employees; and the National Institute for Disease Control (*Istituto Nazionale per l'Assicurazione Contro le Malattie* (INAM)), the national body for private sector employees' health care insurance. During the 1950s, financial solidarity among workers was extended to cover retired people in the same occupational category. In 1958, an independent Ministry of Health was established for the first time and, in 1968, public institutions providing hospital care were established as autonomous entities (*enti ospedalieri*).

By the early 1970s, as a result of these historical developments, Italy had nearly 100 health insurance funds. Each fund had its own regulations and procedures. Some provided direct care through their own facilities and others indirect care, reimbursing patients for the cost of care delivered by private physicians and facilities. Coverage was not only segmented across largely diverse funds but also characterized by important limitations. About 7% of the population was not covered by insurance in the mid-1970s, including many unemployed people (those who had previously worked within the informal economy). In addition, self-employed people were only entitled to use hospital services. More generally, the health care system was affected by serious structural problems, such as organizational fragmentation, compartmentalization across levels of care, unnecessary duplication of services, bureaucratization and rapid growth of expenditure. In addition, the insurance funds' large deficits led to a financial crisis, which prompted the government to intervene. In 1974 and 1975, Laws Nos. 386/1974 and 382/1975 transferred the responsibility for managing hospitals to the regions. Soon after, health insurance funds were abolished and the SSN was established.

The 1978 reform (Law No. 833/1978) that created the SSN introduced universal coverage to Italian citizens and established human dignity, health needs and solidarity as the guiding principles of the system. The main objectives of the reform were to guarantee everyone equal access to uniform levels of health care, irrespective of income or geographical location, to develop disease prevention schemes, to reduce inequality in the geographical distribution of health care, to control health expenditure growth and to guarantee public democratic control (exerted by political parties) over the management of the whole system. A mixed financing scheme was established that combined general taxation and statutory health insurance contributions. The main aim was to move progressively to a fully tax-based system. The new health care system was based on a decentralized organizational structure with national, regional and local administration. The central government was responsible for determining the level of public resources to devote to health care and for planning – every three years – through a National Health Plan. The central government would provide funding to the regions, and the distributional criteria aimed to supply regions with enough financing to provide health care and to progressively reduce regional imbalances. Regional authorities were responsible for local planning according to health objectives specified at the national level, for organizing and managing health care services and for allocating resources to the third tier of the system: 'local health units' (*Unità Sanitaria Locale* (USLs)). USLs were operational agencies responsible for providing services through their own facilities or through contracts with private providers. They were to be run by management committees elected by assemblies of representatives from local governments.

However, the SSN created jurisdictional conflicts among the different levels of authority. Responsibility was not clearly divided and health care was not planned coherently at the national and regional levels. Above all, regional governments considered the resources they received from the central government to be insufficient to satisfy the health care needs of their populations. As a result, regional public deficits mounted, and the central government had to cover the accumulated regional debts. The sharp separation between central financing responsibilities and regional and local spending power was seen as the main cause of constantly rising health care expenditure. However, increased spending was not perceived to lead to a corresponding improvement in the quantity and quality of health care provided. The central government tried to contain costs by setting budget caps, which were regularly surpassed, and by introducing user co-payments. Several attempts were made to increase and extend co-payments from 1983. These were fiercely resisted by trade unions, leading to subsequent reversals in policy. Moreover, health care was markedly different in the north and the south of the country, causing concern about the capacity of the health care system to guarantee equal rights to citizens across Italy's territory. In addition, health care management suffered from excessive politicization, as political party representatives managed USLs according to their electoral strength. In practice, front-line administrators often ended up being peripheral party cadres who lacked the relevant professional skills while cross-cutting party memberships often led to political quarrels among members of local management committees, and sometimes to episodes of corruption and fraud.

Faced with these widespread problems, the government set out new reforms of the health care system. Legislative Decrees Nos. 502/1992 and 517/1993 were the first steps of a progressive pro-competition reform aimed at retaining universal coverage while introducing a financing system that would secure the macro-level objectives of containing costs and promoting equity, and incorporate micro-level incentives for promoting efficiency and enhancing responsiveness to consumers through competition among providers. The 1992 reform introduced managerial principles into the SSN and began concerted efforts to devolve health care powers to the regions. USLs and major hospitals were transformed into autonomous bodies and made more independent of political influence and party-political control. The USLs were thus transformed into public entities, the ASLs, which were directly accountable to the regions. And major hospitals became semi-independent public enterprises – 'hospital enterprises' (*aziende ospedaliere* (AOs)) (see Section 2.4).[2]

In 1998, dissatisfaction with the effects of the 1992–1993 reforms prompted the parliament to authorize the government to completely reorganize the SSN, including the relationships between levels of responsibility and management, the roles played by various actors (such as managers, physicians and local institutions) and the balance between economic constraints and the principles of universalism and equity of access. The resulting reform was launched through Legislative Decree No. 229/1999, which extended the regionalization

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[2] The deliberate use of the term enterprise in renaming these entities reflects the reform's goal of introducing business-like practices into the health care organizations.

process and strengthened the role of municipalities, making clearer the division of responsibilities between levels of government.[3] This reform also softened the previous shift to the market and competition, promoting cooperation among health care providers and partnerships with local authorities for health promotion and community care. Some previously unresolved issues, such as the relationship between health and social services, were taken into account, creating a more integrated organizational framework for delivering health care to disadvantaged people such as the elderly, people with reduced autonomy and poor people.

Enhancing the process of fiscal federalism, a further measure in 2000 (Legislative Decree No. 56/2000) set out a timetable to abolish the National Health Fund (the central government fund used to disperse health care financing to the regions) and to replace it with various regional taxes. Under this legislation, regions that are unable to raise sufficient resources to provide the basic package of health services will receive additional funding from a newly created National Solidarity Fund to be allocated annually based on criteria recommended by the government and the *Conferenza Stato Regioni et Unificata* (Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces).

Table 2.1 summarizes the main historical landmarks in the development of Italy's health care system.

Table 2.1 Italy's health care system: historical background and recent reform trends

Period	Main changes
1861–1920	Autonomous mutual aid associations for artisans and workers; the Catholic Church and charitable institutions established several health care providers. Moreover, provincial and municipal networks provided social assistance to disabled and needy people
1898	Insurance for occupational accidents became compulsory for the first time. In 1904 and 1917, respectively, insurance became compulsory in industry and agriculture
1922	Campaigns to prevent diseases perceived as highly socially relevant were launched
1923	The right to hospital care for the needy, indigent population was guaranteed for the first time
1925	A national body in charge of insurance for the employees of local authorities was created (INADEL)

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[3] Two years earlier, Legislative Decree No. 446/1997 provided some sources of autonomous financing to the regions.

Table 2.1 cont.

1926	Following on from 1922 campaigns, some centres for cancer diagnostic testing were created
1927	The provincial authorities for tuberculosis treatment were created, and tuberculosis insurance became compulsory
1926–1929	Health care provisions for workers became a mandatory prerequisite for the government to approve collective labour force agreements
1942	A national body was created to guarantee social insurance and health care for public sector employees (ENPAS)
1943	A national body for private sector employees' health care insurance was created (INAM)
1958	An independent Ministry of Health was created for the first time
1968	Public institutions providing hospital care were established as autonomous entities (Law 132/1968)
1974–1975	The responsibility for hospital management was transferred to regions (Laws 386/1974 and 382/1975)
1978	A national health service (SSN) was established by Law 833/1978. As a consequence, health insurance funds were abolished
1992–1993	The government approved the first reform of the SSN (Legislative Decrees 502/1992 and 517/1993). This involved the start of a process of devolving health care powers to the regions and a parallel delegation of managerial autonomy to hospitals and local health units. The latter was envisaged within a broader model of internal market reform
1994	The first National Health Plan for 1994–1996 was approved. The plan defined national health targets and established that uniform levels of assistance should be guaranteed to all citizens (LEAs)
1997	Two critical steps were taken towards transforming Italy into a federal state: Law 51/1997 devolved some key political powers to regions, and Legislative Decree 446/1997 initiated the process of fiscal federalism
1998	The second National Health Plan for 1998–2000 was created; it defined national health targets and detailed some of the strategies for achieving them
1999	Legislative Decree 229/1999 launched a new reform package. It deepened the regional devolution process, envisaged the reorientation of the internal market reforms towards strengthening cooperation and regulation, established the initial tools for defining the core benefit package and further regulated the introduction of clinical guidelines to guarantee quality in health care
2000	Legislative Decree 300/2000 prescribed that the Ministry of Health would be replaced by a joint Ministry of Labour, Social Services and Health. Legislative Decree 56/2000 prescribed that the National Health Fund would be replaced with a National Solidarity Fund and mandated that fiscal federalism should be in full operation by the end of 2013
2001	Constitutional Law No. 3, 18 October 2001, modified the second part of the Italian Constitution (Title V), providing regions with more powers
2003	The third National Health Plan, for 2003–2005, was passed
2006	The fourth National Health Plan, for 2006–2008, was passed and in June the Ministry of Health under the newly formed centre-left government outlined the policy programme, *A New Deal for Health*

2.3 Organizational overview

The Italian health care system is regionally based and organized at three levels: national, regional and local. Under the Italian Constitution, responsibility for health care is shared by the state and the 20 regions. The state has exclusive power to set the ‘essential levels of care’ (*livelli essenziali di assistenza* (LEAs)), or basic package, which must be available to all residents throughout the country, and is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regions have virtually exclusive responsibility for the organization and administration of publicly financed health care.

The parliament approves framework legislation, which lays out the general principles for organizing, financing and monitoring the SSN. In particular, the National Health Plan for 1998–2000 prescribes that the whole SSN should be organized according to the following principles.

- *Human dignity*. Every individual must be treated with equal dignity and have equal rights irrespective of his or her personal or social characteristics.
- *Health needs*. Everyone in need has a right to health care, and resources should be allocated with priority given to satisfying the basic needs of the population.
- *Equity*. The SSN resources should be used to eliminate geographical and/or economic barriers that constitute an obstacle to citizens’ demand for appropriate services. Behavioural and information gaps among the population should be reduced to provide the same opportunity for access to health care services.
- *Protection*. The SSN should give highest priority to protecting and promoting citizens’ health status.
- *Solidarity with the most vulnerable people*. Resources should be allocated primarily to the individuals, groups or groups of diseases with the most relevant social, clinical and epidemiological impact.
- *Effectiveness and appropriateness of health interventions*. Resources must be channelled to services with scientifically demonstrated effectiveness and to individuals who can benefit the most from them.
- *Cost–effectiveness*. Services should be provided by the relevant organizations pursuing financial balance through efficient and effective management.

The National Health Plan for 2006–2008 confirms the importance of these general principles for the national health care system.

2.3.1 The central level

The main central institution is the Ministry of Health. Previously, the ministry managed the National Health Fund (consisting of insurance contributions and general taxation) and was in charge of guaranteeing the public resources required to provide health care to all citizens. However, in 2000, the National Health Fund was abolished and replaced by various regional taxes (see Chapter 3).

According to the Budget Law for 2008 (Law No. 244/2007), the Ministry of Health has been replaced by a joint Ministry of Labour, Social Services and Health.

Through its departments and services, it is responsible for five different functions:

- health care planning
- health care financing
- framework regulation
- monitoring
- general governance of the National Institutes for Scientific Research (*Istituto di Ricovero e Cura a Carattere Scientifico* (IRCCS)).

The Ministry is currently structured into four departments, each of which is organized into the following directorates:

- Department of Quality:
  - health care planning, essential levels of care (LEAs) and health system ethics
  - human resources and health professionals
  - information systems
- Department of Innovation:
  - pharmaceuticals and medical devices
  - scientific and technological research
  - personnel, organization and accounting
- Department of Prevention and Communication:
  - health care prevention
  - communication and institutional relationships
  - international relationships
- Department of Veterinary Care and Food Safety:
  - veterinary care and pharmaceuticals
  - food and nutrition safety
  - nutrition risk assessment.

The Department of Quality is responsible for defining the SSN's health targets through the National Health Plan. Through the national health planning process, the Ministry of Labour, Social Services and Health suggests how resources should be allocated among levels of care (hospital care, district and primary health care and community health care) to address the population needs surveyed in the yearly national health status report. The Ministry of Labour, Social Services and Health also participates in the process of allocating resources to regions. Consistent with the emerging federal political system, its role in financing will be restricted to allocating resources from the global national budget and targeting funds towards ensuring uniform availability of resources in the regions. The Ministry is also responsible for technically regulating health care activities in various areas: managing human resources within SSN institutions, optimizing the workforce within the SSN, maintaining disease prevention programmes with a nationwide focus, promoting nutritional health and promoting veterinary health through the general regulation of a network of 10 experimental zooprophylactic institutes. Italy is one of the few countries in the world where the National Health Service manages veterinary care.

The monitoring activities of the Ministry of Labour, Social Services and Health include the market authorization of drugs and research. In 1992, following a series of corruption scandals, the Ministry stopped directly regulating prices and the criteria for inclusion in the list of publicly reimbursed drugs. Instead, its role was progressively delimited by the creation of new bodies. In 1994, an independent, non-partisan National Committee for Pharmaceuticals was created to decide on the specific brands that should be publicly funded and the co-payment schemes that should apply to them. The members of the National Committee for Pharmaceuticals come from the scientific community and are accountable to the Ministry of Labour, Social Services and Health. Also, in 1994, the Interdepartmental Committee on Pharmaceuticals, which was in charge of regulating drug prices, was abolished, and its functions were assumed by the Interministerial Committee on Economic Planning. Finally, in 2003, the Italian Medicines Agency (*Agenzia Italiana del Farmaco* (AIFA)) was established, and is in charge of regulating the market and monitoring the consumption of pharmaceuticals (see Section 6.4 on pharmaceutical care).

In line with the decentralization process occurring within the SSN since 1992, administrative control by the Ministry of Labour, Social Services and Health over the functioning, effectiveness and efficiency of public hospitals and ASLs is becoming less relevant. These activities have increasingly been devolved to the regional health departments and to the ASLs themselves.

The Ministry of Labour, Social Services and Health, through the Directorate for Scientific and Technological Research, is also responsible for generally coordinating the activities of the IRCCS, a network of public and private hospitals of national relevance working to meet research aims (see Chapter 4).

The Ministry of Labour, Social Services and Health draws on the input of a number of other ministries and institutions:

- the Ministry of Social Affairs, to coordinate social services provided within the infrastructure owned by the SSN;
- the Ministry of the Economy and Finance, a critical agent in the process of setting the health care budget and providing technical support and institutional control over financing health care services;
- the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces, set up in 1988 with the presidents of the regions and representatives from the central government as its members, constituting the main consultative body for all the legislative activities with a regional dimension (it can promote collaboration schemes across regions and the central government and propose its own legislation);
- the National Health Council;
- the National Institute of Health (*Istituto Superiore di Sanità* (ISS));
- the National Institute for Occupational Safety and Prevention (*Istituto Superiore Prevenzione e Sicurezza sul Lavoro* (ISPESL));
- the Agency for Regional Health Care Services (*Agenzia per i Servizi Sanitari Regionali* (ASSR)) (since 2007, AGENAS (National Agency for Regional Healthcare)); and
- the AIFA.

The National Health Council provides important technical and consultative support to the SSN. It is structured as a commission with a president and 50 members, including scientists, physicians and other experts with nationwide expertise in health care. The ISS is the main institution for scientific and technical research, control and advice in public health. Founded in 1934, it is under the authority of the Ministry of Labour, Social Services and Health and, since 1978, has become the SSN's main technical and scientific body. The ISPESL is also one of the SSN's technical and scientific bodies, and is responsible for providing information and research on health promotion and healthy conditions in the workplace.

Since 1995, the ASSR has provided support to the SSN by promoting innovation in health care and through comparative analysis of the cost and efficiency of the services offered to the public. The Agency is accountable to the regions and to the Ministry of Labour, Social Services and Health. The Director of the Agency is nominated by the Prime Minister on the basis of Ministry of Labour, Social Services and Health recommendations, and in accordance with the opinion of the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces.

The AIFA, founded in 2003, is the main national institution responsible for coordinating all the activities that concern pharmaceuticals: public research, private company investment in research and development, production, distribution, scientific information, monitoring of consumption, monitoring of adverse effects, pricing and reimbursement policies. The Agency is accountable to the Ministry of Labour, Social Services and Health and to the Ministry of the Economy and Finance.

2.3.2 The regional level

The regions are responsible for ensuring the delivery of a benefit package through a network of population-based ASLs and public and private accredited hospitals. The process of devolving political power and fiscal authority to regions provided the regional health departments with responsibility for legislative and administrative functions, for planning health care activities, for organizing supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided. The regional level has legislative functions, executive functions and technical support, as well as evaluation functions.

Legislative functions

The legislative functions at the regional level are shared between the elected Regional Council and the regional government (the Executive). According to Legislative Decree No. 229/1999, regional legislation should define:

- the principles for organizing health care providers and for providing health care services;
- the criteria for financing all health care organizations (public and private) providing services financed by the regional health departments; and
- the technical and management guidelines for providing services in the regional health departments, including assessing the need for building new hospitals, accreditation schemes and accounting systems.

Legislative Decree No. 229/1999 significantly increases the legislative power devolved to the regions. It is currently being implemented at the national and regional levels.

Executive functions

Regional governments, mainly through their departments of health, outline a three-year regional health plan. Regional governments use this plan, based both on the National Health Plan and on assessed regional health care needs, to establish strategic objectives and initiatives, together with financial and organizational criteria for managing health care organizations. Regional health departments are also responsible for:

- allocating resources to various ASLs and AOs;
- applying national framework rules to define the criteria for authorizing and accrediting public and private health care settings in the region;
- technically coordinating health care activities through a Standing Conference for Regional Health and Social Care Planning;
- monitoring the efficiency, effectiveness and appropriateness of the services provided by accredited public and private organizations;
- defining the geographical boundaries of health districts inside each ASL;
- appointing the general managers of ASLs and AOs; and
- defining a regulatory framework governing how the general directors of hospitals and ASLs exercise autonomy in the strategic planning process.

Technical support and evaluation functions

The regional health departments in some regions provide technical support directly to the ASLs and to public and private hospitals. Other regions have formed a regional agency for health responsible for assessing the quality of local health care and providing technical and scientific support to the regional health departments and to the ASLs. The regional agencies also provide technical support to the regional health departments during the planning process to assess population needs, to define the range of services to be supplied to address these needs and to assess the quality of services provided by providers in the region. Ten regions have created a regional agency for health: Emilia-Romagna (1994), Friuli-Venezia-Giulia (1995), Campania (1996), Marche (1996), Piedmont (1998), Lazio (1999), Abruzzo (established in 1999; active since 2006), Tuscany (2000), Veneto (2001) and Puglia (2001) (see Chapter 4).

2.3.3 The local level

Health services are delivered through a network of population-based ASLs and public and private accredited hospitals (see Section 4.1 and Chapter 6).

2.4 Decentralization and centralization

The decentralization of the health care system has been a key issue in the development of the SSN since its inception in 1978, and especially during the last decade. The 1978 reform defined an integrated, centralized system in which a few specific administrative responsibilities were allocated to the regional and local levels. The central and regional governments had clashed since 1978 about financing and jurisdiction, with the regions still relatively weak vis-à-vis the central government in terms of political power and administrative and technical capacity. Following a process of informal expansion of regional power, Legislative Decree No. 502/1992 started an explicit, formal process of devolving political power and fiscal authority to regions. This process provided the regional health departments with more autonomy in policy-making, health care administration and management, resource allocation and control.

Several legislative measures approved during the period 1997–2000 have further promoted the devolution of political power to the regions. In addition, during this same period, a process of transition towards federal reform of the state ran parallel to the progressive introduction of fiscal federalism, transferring the funding of the SSN from the central to the regional level, thus strengthening the fiscal autonomy of the regional health departments. As a rule, the northern regions have been very assertive in exploiting their independence, while most of the southern regions have been slower in changing their systems. The chief problems have been the shortage of own-source resources for the regions to match their new responsibilities, large interregional differentials in fiscal capacity and conflictual intergovernmental relations, especially over the adequacy of central government funding for the SSN.

In addition, the SSN underwent a process of delegation (*aziendalizzazione*) during the 1990s. All ‘USLs’ as they were then called, as well as tertiary hospitals, were transformed into autonomous bodies (enterprises). Until 1992, the governance committee of USLs, according to Law No. 833/1978, was headed by a president elected by the members of the USL’s management committee, which represented political parties. Since 1992, the delegation process has been oriented towards providing management with autonomy from political influence. As a result, ASLs, as they are now known, and AOs started to be governed by general managers chosen for their technical expertise by the regional health care authorities. Under this new governance model, the ASLs and the AOs were given greater financial and decision-making autonomy. The top management teams were given responsibility for the resources used and the quality of services delivered.

This delegation process was based on a more general set of structural changes aimed at introducing elements of managed competition among public and private (accredited) providers. At the micro level, new private-sector management tools were also introduced to facilitate the sound exercise of the new managerial autonomy conceded to lower-level units and to guarantee their accountability to the regional government tier in charge of controlling their operation. The subsequent 1999 reforms deepened the delegation process and simultaneously reinforced the regulatory and monitoring roles of state authorities (see Chapter 7 on health care reforms for more details).

In the health care sector, in contrast to other traditional state domains (such as utilities), the public sector owns most hospitals and service providers. In addition, no privatization initiatives are under way. Nevertheless, collaboration between private firms and public health care providers is being piloted for some project financing experiments devoted to promoting the renovation (and new construction) of public hospitals with private funding, with a subsequent public–private mix in the management of health care activities.

2.5 Patient rights and empowerment

During the last 15 years, national legislators have devoted increased attention to the issue of patients' rights and empowerment in the health care sector, recognizing these principles in SSN reforms and providing national legislation to ensure their actual implementation.

2.5.1 Patient participation

Patient empowerment and respecting patients' rights can be secured through different mechanisms, ranging from less participative initiatives (e.g. patient satisfaction surveys) to more involved activities (collective or individual involvement of patients/citizens and associations in decision-making processes and assessments of health services). The 1978 law establishing the SSN included the collective involvement of citizens in decision-making processes as one of its most important principles. Nonetheless, in the health care sector, the actual implementation of citizens' direct participation in making decisions remained undeveloped. The right was habitually claimed in principle only, and resulted in the institution of local health authority management committees (*Comitati di Gestione delle USL*), where participation by municipal representatives ended up being the only legitimate channel for citizens' involvement.

The first major reform of the SSN since its establishment (Legislative Decrees Nos. 502/1992 and 517/1993) dedicated a whole article (Art. 14) to citizens' rights, focusing on collective involvement of patients/citizens through voluntary and community group representatives and giving greater attention to the use of patients' satisfaction surveys on providers' services. At the national level, Art. 14 provided that the Ministry of Health, together with patients' and citizens' associations, needed to establish a set of indicators to systematically measure the quality of health services from the patient's point of view. The indicators covered four areas: personalizing and humanizing care, citizens' information rights, quality of hospital accommodation services and disease prevention policies. A further Ministerial Decree published on 15 October 1996 identified 79 patient satisfaction indicators in these areas. The indicators under 'personalized and humanized care' include the ability to book appointments by telephone and the percentage of general practitioners (GPs) who set up out-of-hours services. Citizens' information rights cover the existence of consumer relations offices, the dissemination of leaflets providing information on patients' rights to access inpatient care and the percentage of hospital wards that survey patients and relatives. Examples of indicators under the quality of hospital accommodation services include the ratio of toilets to patients and the percentage of rooms with no more than two beds.

At the regional level, regions have been urged to promote consultation with voluntary and patients' associations in health policy planning and evaluation, and to develop formal channels for their involvement; ASLs and AOs have to establish complaints procedures together with patients associations, and to listen to their voice as a legitimate source of complaints and suggestions. A Health Services Conference has to be arranged each year by the Director Generals of the AOs and the ASL in order to gauge levels of patient satisfaction. Specific training activities for health operators working in direct contact with the public also have to be organized by regions, AOs and ASLs. The reforms of 1999 followed this theme, reinforcing the importance of voluntary and patients–citizens associations in decision-making and assessment.

In 1995, further legislation required that each health care provider in the public sector issue a 'Health Service Chart' (*Carta dei Servizi*) informing the public about the complaints system in place, quality indicators, waiting times and existing programmes to guarantee health care quality (Ministero della Salute, Servizio Centrale della Programmazione Sanitaria, 1995). The Health Service Chart legislation applies to the public sector, but almost all the regions with an accreditation programme have included the Health Services Chart as an accreditation requirement for private providers. The Health Service Charts have to be published annually and dissemination mechanisms are decided by the regions or at the level of the ASLs and AOs. The last national report on Health Service Chart implementation and dissemination (Ministero della Salute, Dipartimento della Qualità, Direzione Generale della Programmazione Sanitaria, dei Livelli di Assistenza e Principi Etici di Sistema, 2005) shows that, after almost ten years, all regions have put in place a manager responsible for Health Service Charts in each ASL and AO: 82% of the responding providers disseminate the Health Service Chart through leaflets, while 72% claim to publish it also on the Internet via their web sites. In 2003, a new law required that all public administration entities set up an Office for Public Relations (*Ufficio Relazioni con il Pubblico* (URP)). In the health care sector, each health care entity needs to have a URP that provides information to citizens and, in many cases, also monitors the quality of services from the citizens' point of view.

With regard to patients' rights at the micro level (within clinical practice and the relationship between patients and physicians), the code of practice for physicians includes informed consent as one of its main requirements (Art. 32), while national legislation in 1998 required the establishment of Ethics Committees, which should also provide guidelines for their institutions (Ministerial Decree18 March 1998). Ethics Committees are independent non-profit bodies with an interdisciplinary membership. Their purpose is to assess both ethical and scientific aspects of pharmaceutical clinical trials, verifying the acceptability and feasibility of experiment protocols and researchers' expertise/ qualifications, and a variety of ethical questions – from informed consent to respecting patients' privacy, safety and health.

The implementation of this national framework on patients' rights and empowerment has not been homogeneous, depending on the level of individual regions' efforts at actual enforcement. Regions such as Emilia-Romagna, Tuscany and Veneto have given systematic attention to this issue. These regions have implemented different models of empowerment: the first two highlight the role of standing committees, which include members from citizens' associations, as an institutional means of patient involvement, while the third emphasizes the importance of systematic patient satisfaction surveys. Since 1994, Emilia-Romagna has provided an Advisory Mixed Committee (*Comitato Consultivo Misto*) in each AO and ASL, which includes members from citizens' associations, with the aim of enhancing and monitoring quality from the citizen's point of view (Regional Law for the Reorganisation of the Regional Healthcare Service of Emilia-Romagna). The *Comitato Consultivo Misto* collaborates with its corresponding URP to undertake patient satisfaction surveys, analyse complaints and suggestions and organize health information and promotion activities. In 2001, an Advisory Committee for Quality from the Citizen's Perspective (*Comitato Consultivo Regionale per la Qualità dal lato del Cittadino* (CCRQ)) was established. It is composed of one representative from each ASL and AO's *Comitato Consultivo Misto* and representatives from the

Istituti Ortopedici Rizzoli, the Regional Ministry of Health and the ASSR. The CCRQ is a standing advisory body whose purpose is to guarantee the protection of citizens' rights by making proposals on health care quality improvement to the regional Ministry of Health and by confirming whether or not the quality of services has been enhanced from the citizen's point of view.

In Tuscany, a Mixed Mediation Committee was established in 1995. This committee is also formed by representatives from ASLs and AOs, and voluntary and citizen–patient associations to undertake mediation for specific complaints. In 2001, the Regional Committee for the Health Service Chart (*Comitato Regionale Carta dei Servizi*) was established and is composed of representatives from the Regional Ministry of Health, ASLs and AOs, the Regional Commission on Bioethics, the ASSR, health professionals, citizens and patients' associations and the voluntary sector, and the Regional Civic Ombudsman. In 2001, a regional government Standing Committee for Citizens' Rights in Health Care (*Forum Permanente per L'esercizio del Diritto alla Salute*) was established. It is formed by the Regional Ministry of Health, which chairs it, and by representatives from citizens' and patients' associations. The Committee discusses problems related to patients' rights and makes proposals to enhance quality from a citizen's perspective.

In 2003, a programme signed by all ASLs and AOs was approved to improve quality from the citizen's point of view and to guarantee citizens' rights. The programme includes initiatives such as telephone information lines on services, expanded visiting hours for inpatient care, providing cultural mediators for foreign patients and a patient satisfaction monitoring plan. In 2004, regional guidelines for defining the Health Service Chart (content, dissemination, assessment instruments, etc.) were introduced. Furthermore, two regional observatories have been instituted in this field: the Regional Observatory for the Health Services Chart (*Osservatorio Regionale Carta dei Servizi Sanitari* (1997)) and the Regional Observatory for Legal Arguments (*Osservatorio Regionale Permanente del Contenzioso* (2004)). The first aims to monitor the implementation of the Service Charts, and the regional legislation on patients' and citizens' empowerment at the level of AOs and ASLs.[4] The second aims to monitor the number of legal cases and their final results, enhance training strategies and provide the best possible organizational and scientific/technical answers to the problems highlighted by the different legal arguments. Finally, every year, each ASL organizes a services conference (*conferenza dei servizi*), aimed at promoting dialogue among stakeholders (health professionals, voluntary associations, citizens) and assessing the quality of services.

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[4] For more information, see the following web site (http://www.salute.toscana.it/parliamodi/cartaservizi/osservatorio-regionale-servizi-sanitari.shtml).

In 2004, the Veneto Region developed a regional project, with the assistance of patient organizations, to assess the quality of health care services from the patient's perspective, based on a standardized set of indicators contained in the *Handbook for the Management of Quality Improvement in the Patient's Experience* (*Manuale del Sistema di Gestione per l'Umanizzazione* (Regione del Veneto, 2005)). The Veneto Region also implemented a regional database to promote best practice. The project provides training programmes on the Handbook indicators to practitioners and professionals in ASLs and AOs.

2.5.2 Citizen satisfaction with the health system

Although Art. 14 (mentioned above) paid particular attention to the issue of patient satisfaction, not all regions have enforced this national directive. In order to guarantee its actual implementation, in 2006 the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces signed the 'National Agreement for Health', approving the implementation of a National Programme for Health Care Quality. This document contains guidelines for the systematic and periodic analysis of citizen satisfaction surveys, which, nevertheless, seem to have increased in the last few years. However, according to a Eurobarometer Survey from 2002 on public satisfaction with the health care system in the then EU15 countries, Italy remained under the EU average (Table 2.2).

In fact, in terms of the percentage of people who thought that the health care system 'runs well', Italy ranked equal 11th, just below the United Kingdom and above Ireland, Greece and Portugal. If compared with data collected by Eurobarometer in 1996 and 1999 (data not shown in Table 2.2) (OECD, 2006) there has been a slight increase in Italian citizens' levels of satisfaction. In fact, Italy ranked lowest among the EU15 countries in 1996, and only around 26% of Italians surveyed in 1999 were very or fairly satisfied with their national health system. The 1999 figure placed Italy slightly above Portugal and Greece, but still far below other countries with a national health service, such as Spain (48%) and United Kingdom (56%). At the regional level, available data on Italian citizens' satisfaction in 2005 (ISTAT, 2007b) show that the regions with the least satisfied respondents are Calabria (35.9%), Puglia (28%) and Sicily (25.6%), while those with the highest levels of satisfaction are Bolzano Province (68.8%), Valle d'Aosta (59.6%), Trento Province (58.8%) and Emilia-Romagna (46.8%) (Table 2.3). Satisfaction differs across the north–south divide, with the northern and central regions consistently obtaining above-average results, whereas all southern regions score under the average.

Table 2.2 **Public satisfaction with the health care system as a percentage, EU15 countries, 2002[a]**

Country	Runs well	Minor changes needed	Fundamental changes needed	Completely rebuild system	Uncertain
Belgium	23.8	41.3	22.7	5.2	7.0
Denmark	16.5	35.1	39.4	6.1	2.8
Germany	15.6	31.5	34.8	11.1	6.9
Greece	2.9	15.9	50.5	27.6	3.1
Spain	13.2	2.4	38.6	12.1	3.7
France	22.0	41.9	25.5	7.0	6.0
Ireland	3.7	16.7	39.3	32.9	7.5
Italy	6.5	24.4	45.6	19.9	3.5
Luxembourg	21.7	46.0	2.4	8.2	3.8
Netherlands	6.5	39.1	46.8	6.8	0.8
Austria	31.8	35.4	23.0	4.3	5.5
Portugal	1.8	12.5	39.0	41.4	5.4
Finland	24.0	48.6	21.0	3.2	3.1
Sweden	11.4	36.3	37.8	1.6	3.8
United Kingdom	8.3	22.9	49.7	15.8	3.3
EU	13.2	3.7	38.2	13.5	4.4

Source: OECD, 2006.

Note: [a]Results are based on the following questions from a 2002 Eurobarometer survey: "Now, I will read you four statements about the way the health care system runs in (*country*). Which one comes closest to your own point of view? (*one answer only*).

1. On the whole, the health care system in (*our country*) runs quite well.
2. There are some good things in the way health care in (*our country*) runs, and only minor changes would make it work better.
3. There are some good things in the way health care in (*our country*) runs, but only fundamental changes would make it work better.
4. Health care system in (*our country*) runs so badly that we need to rebuild it completely."

2.5.3 Patient safety and compensation

A national strategy for patient safety has emerged just in the last few years. In 2003, a National Technical Committee on Clinical Risk was established, while a year later the Working Group for the Assessment of Methodological Approaches for the Evaluation of Clinical Risk was also formed. In February 2006, the two groups merged into the Working Group on Patients Safety. In 2007, the Ministry of Health initiated the National System for Patients Safety

Table 2.3 Satisfaction among Italians with regional health services, 2005[a]

	Percentage population scoring			
Region	**1–4**	**5–6**	**7–10**	**Non-respondents**
Calabria	35.9	42.6	15.3	6.2
Puglia	28.0	43.7	23.8	4.5
Sicily	25.6	48.7	21.5	4.3
Molise	22.4	44.3	30.2	3.1
Campania	22.3	50.4	23.0	4.3
Basilicata	21.1	47.1	26.4	5.4
Sardinia	21.0	45.8	26.7	6.4
Lazio	19.7	48.9	25.0	6.4
Italy	17.2	43.4	34.0	5.4
Umbria	17.0	39.2	36.8	7.0
Abruzzo	16.9	45.5	31.5	6.1
Marche	16.0	42.6	35.7	5.7
Veneto	14.1	39.6	39.9	6.4
Liguria	14.0	49.6	33.9	2.5
Piedmont	13.4	38.9	43.2	4.6
Friuli-Venezia-Giulia	11.5	37.3	42.8	8.5
Emilia-Romagna	11.2	36.9	46.8	5.1
Lombardy	11.0	41.2	42.0	5.8
Tuscany	10.7	45.0	38.9	5.5
A.P[b] Trento	7.3	29.4	58.8	4.5
A.P[b] Bolzano	6.2	17.9	68.8	7.1
Valle d'Aosta	6.2	29.3	59.6	5.0

Source: ISTAT, 2007b.

Note: [a]Respondents were asked to score their satisfaction on a scale of a minimum (1) to a maximum (10) level of satisfaction. [b]A.P: Autonomous Province.

as a two-year pilot project, which also functions as the National Observatory for Patients Safety (*Osservatorio Nazionale per la Sicurezza dei Pazienti*) in collaboration with the Working Group on Patients Safety.

The actual implementation of a risk management policy at the regional level depends on individual regional governments. For example, in 2003, Tuscany was the first region to create a Regional Centre for Clinical Risk and Patient Safety. It also instigated a series of important activities in this field, such as regional campaigns, professional training, and produced therapeutic protocols and guidelines (Nuti, Tartaglia and Niccolai, 2007) within a regional programme, which has led to each hospital having a clinical risk manager, a management working group, a patient safety committee, and facilitators in each department to develop mortality and morbidity reviews, undertake clinical audits and to collaborate with forensic medical doctors and administrators for the purposes of litigation assessments.

In order to implement benchmarking activities among the regions and to encourage homogeneity in results, the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces has authorized the ASSR to coordinate and support regions in the field of clinical risk management and patient safety monitoring systems. At present, it is not yet clear if this new remit will replace that of the national Ministry of Health.

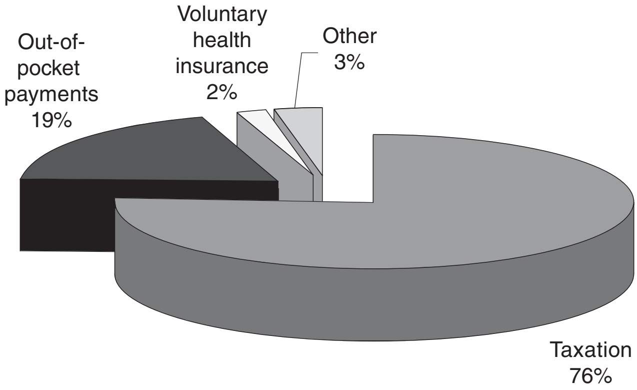
Compensation from a public fund for health care-related harm is regulated by national law (Law No. 210/1992), which recognizes the right to financial compensation for those who have received permanent harm after a mandatory vaccination and transfusion due to contact with infected health professionals. This statutory provision does not prevent patients also taking providers to court for negligence in civil damages suits. Since 1979, public sector health care providers have not been obliged to take out liability insurance for health professionals working for them; however, health professionals can choose to have their own private insurance for this purpose.

3 Financing

The 1978 health reform set up the Italian SSN according to the principles of universal coverage and a fully tax-based public health care system. During the late 1990s, Italy's administrative and institutional settings started to become those of a federal state. The reforms that contributed to this transition included several packages that modified the architecture of health care financing. The progressive move towards fiscal federalism started in 1997 with the abolition of social insurance contributions and the introduction of a regionally collected system of tax financing. General taxation was left to play a complementary role; its main role was now to redistribute resources to regions with a narrower tax base in order to ensure that all residents receive adequate levels of care.

A series of measures passed in 2000 saw the start of a slow and at times difficult approach to fiscal federalism; this process was accompanied by a shift in central health care financing from general revenue to indirect taxes that the state transfers to the regions. Further changes in SSN funding mechanisms are planned within the broader context of significant devolution of revenue-raising powers to the regions. The central government has declared its intention to abolish the IRAP (*Imposta Regionale sulle Attività Produttive*) tax (see Section 3.3.1 for a full definition) but the timing of this change is still uncertain, especially as the overall implications for SSN financing are also unclear (see Chapter 7). Currently, however, taxation is the main pillar of SSN financing, as shown by Fig. 3.1.

Fig. 3.1 **Percentage of total expenditure on health according to source of revenue**



Source: OECD, 2008.

3.1 Health care expenditure

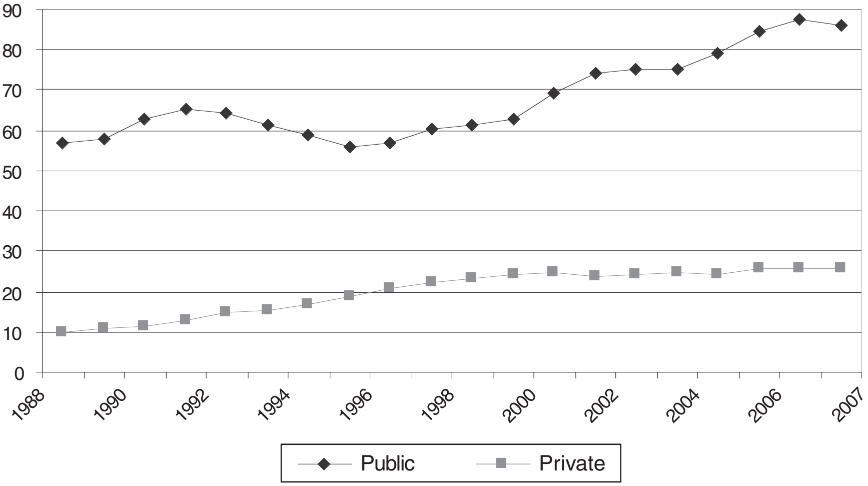
In Italy, as in most OECD countries, health care expenditure has steadily increased over time, making its containment a major issue for successive governments. The existence of a large public deficit and the need to reduce it drastically to comply with the requirements of the European Economic and Monetary Union added further pressure to control health care expenditure. The deficit was primarily the result of a fundamental flaw in the 1978 design, which assigned virtually the entire responsibility for financing the SSN to the central government, which, however, had limited power over how the USL – legally, creatures of the regions and run by the municipal governments – spent these funds. The central government's response to the disconnection between funding responsibility and spending power created a situation of permanent financial crisis. The chronic regional deficits reflected two tendencies of central government policy: to systematically, although not overtly, underestimate the funding needs of the SSN; and to overestimate the savings to be obtained from expenditure containment strategies (France and Taroni, 2005). In recent years, deficits have been the object of heavy intergovernmental negotiation. The central government has tried to limit these deficits by asking regions to underwrite yearly 'Pacts for Health' (*Accordi*), which tie additional resources to the achievement of health care planning and expenditure goals. In addition, regional governors are requested annually to balance the books in health care expenditure; failure to do so might refer the administration of the region to an external commissioner nominated by the regional government. These measures have created an incentive for regions to perform better, with positive results overall: most northern regions have managed to balance their health care expenditure accounts, while some central and southern regions, especially Lazio and Abruzzo, are still struggling to balance their accounts to avoid being administered by an external commissioner.

The latest available data show that total health care expenditure stands at nearly €111 billion (€86 billion in public expenditure and €25 billion in private expenditure) (Fig. 3.2).

Increases in SSN expenditure reached 42% in real terms during 1981–1998; that is, an annual growth rate of 2.1%. In particular, a marked increase in pharmaceutical sales, the renewal of salary negotiations between physicians and the government, and the shift in hospital financing to a diagnosis-related group (DRG) system that rewards activity and citizens' free choice of health care provider have caused a marked increase in health care expenditure since 1995.

When one considers the whole period, considerable fluctuations of GDP growth are easily observed, although in all cases they were inferior to the growth rates for total health care spending, except in 1993, 1994 and 1995 when spending fell in real terms. For example, public expenditure peaked in 1991 at 6.6% of GDP and then fell to a low of 5.3% in 1995. This was partly compensated for by a growth in private spending, and, as a result, total health expenditure dropped by 7.2%. The private share rose from 20.9% in 1990 to 28.1% in 1995, due mainly to a decline in public spending (at an average annual

Fig. 3.2 **Trends in health care expenditure in Italy, 1988–2007 (billion € at 2000 GDP prices)**



Source: OECD, 2008.

rate of 1.5%), but in 1997 a 5.7% increase in SSN funding pushed the private share down again. It is important to highlight the reduction of about €1 billion in private expenditure that followed the abolition of patient co-payments for drugs in 2001: the measure, which was not followed by a transfer of levying power to the regions, came just before the political elections of spring 2001. Although the ruling coalition of the time defended this measure as an attempt to extend universal coverage, it came under strong attack as being an electoral manoeuvre. The share of GDP going to health care increased markedly in 2002 and 2003 due to a virtual halt in GDP growth (+0.3% in 2003) and continued expansion of health care expenditure (see Table 3.1) (France, Taroni and Donatini, 2005). The increase in expenditure was largely the result of increases in spending on drugs: most of this rise was due to the loss of co-payment revenue and the remainder to an increase in consumption (+17.4%), a result of reduced restrictions on prescribing and prescriptions of newer and more expensive drugs (+2.3%).

The national and regional reaction to these rises was somewhat mixed. Nationally, a 7% price cut was applied to pharmaceutical industry sales to the SSN; reference prices were introduced for off-patent drugs; restrictions on drug prescribing were reintroduced; and a ceiling on drug spending was set at 13% of total SSN health care expenditure, with 60% of any overrun to be paid back by the drug industry. In addition, the concept of the relative cost of drugs for treating similar clinical conditions was used to determine the drugs to be included in the formulary. Since 2004, these measures have been coordinated by the new AIFA, an independent body with representatives of the regions on its Board of Trustees (France, Taroni and Donatini, 2005).

At the regional level, co-payments for pharmaceuticals were reintroduced in 2002 in 11 of the 20 regions, either at a flat rate or as a percentage of the price, with an estimated 5% reduction in drug expenditure in the regions that adopted co-payments compared to those that did not (France, Taroni and Donatini, 2005). In addition, regions started distributing drugs directly to patients discharged from hospital or in ambulatory clinics for chronic conditions. This measure allowed an additional cost saving, resulting from the direct purchase of medicines from manufacturers, which by law are obliged to give discounts of 50% of retail prices to the SSN and often make considerably higher reductions. These measures were not enough, however, to contain drug expenditure: although public expenditure fell in 2003, this was accompanied by an increase in private expenditure.

Figure 3.3 shows trends in health care expenditure as a percentage of GDP in selected western European countries during the 1990s and the early 21st century. All the other countries increased or stabilized health care expenditure from 1990 to 2002, while Italy increased slightly until 1993, declined to 7.3% in 1995 and slowly increased again after 1997.

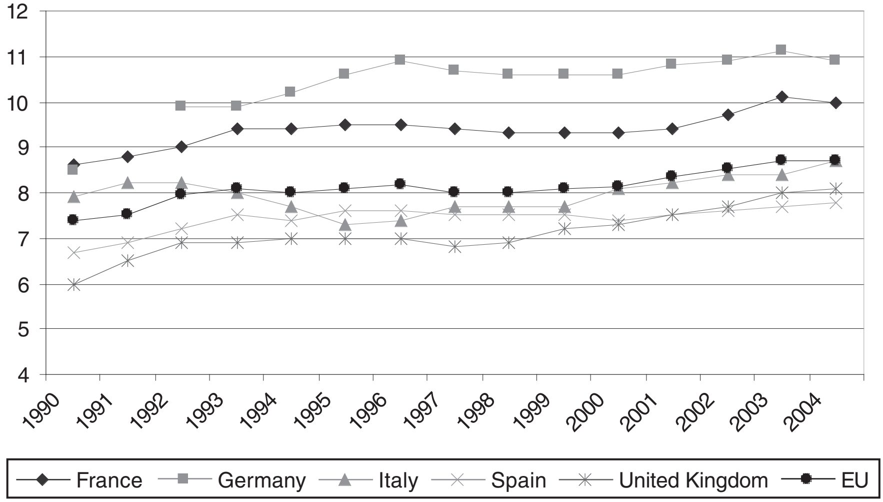
Table 3.1 Trends in health care expenditure in Italy, 1988–2007

Indicators	1988	1990	1995	2000	2003	2004	2006	2007
Total health expenditure (per capita US$ PPP)	1 516	1 689	1 694	2 053	2 162	2 273	2 374	N/A
Total health expenditure (% GDP)	7.7	7.9	7.3	8.1	8.4	8.7	9.0	8.7
Public expenditure on health (% total expenditure)	77.6	79.1	71.9	72.5	74.5	76.0	77.2	77.0
Private expenditure on health (% total expenditure)	22.4	20.9	28.1	27.5	25.5	24.0	22.8	23.0

Source: OECD, 2008.

Notes: GDP: Gross domestic product; N/A: Not available; PPP: Purchasing power parity.

Fig. 3.3 Trends in health care expenditure as a share of GDP (%) in Italy and selected other countries, 1990–2004

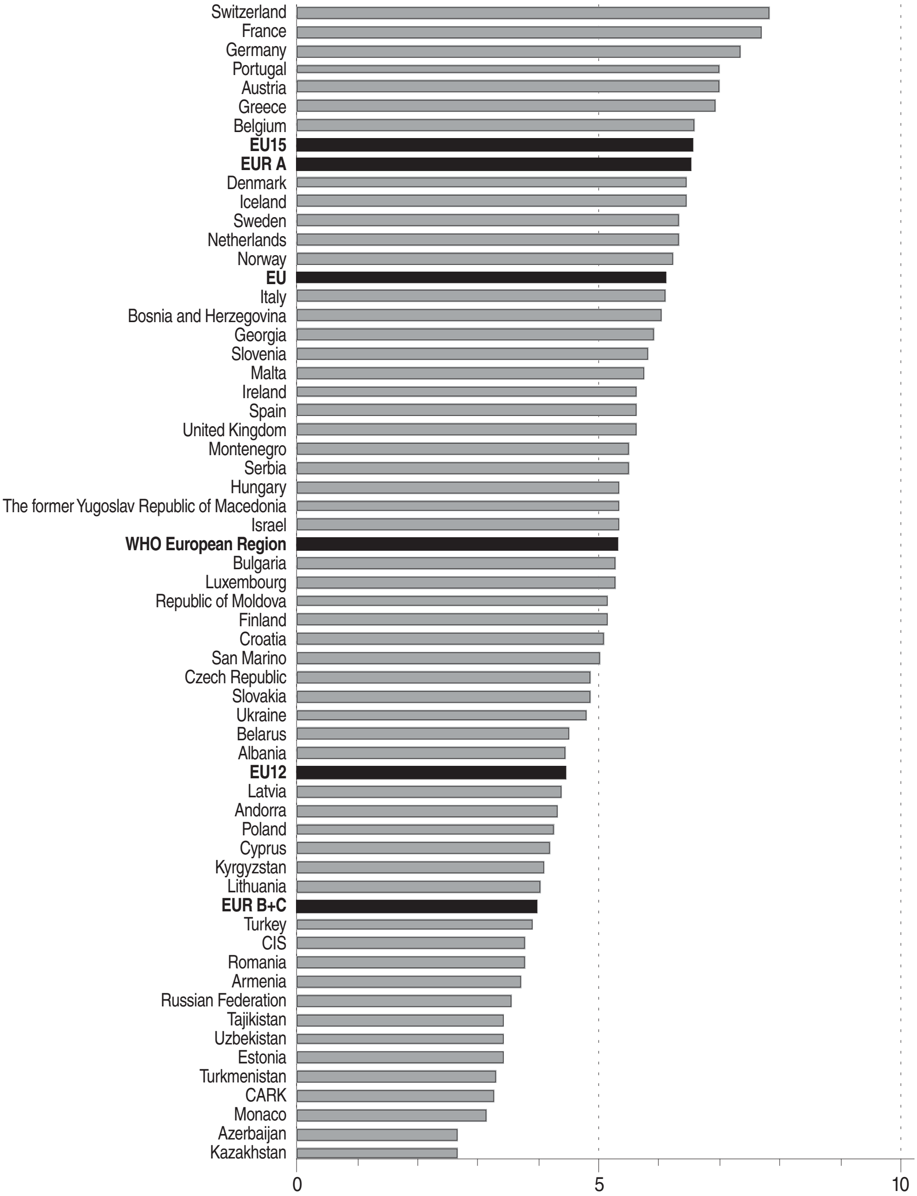


Source: WHO Regional Office for Europe, 2008.

Figure 3.4 shows Italy's position in health care expenditure as a percentage of GDP within the WHO European Region. In 2005, the country's health spending was slightly below the EU average.

Private expenditure played a marginal role during the 1960s and 1970s, but rose steadily during the 1980s and 1990s. The introduction of co-payment schemes for outpatient care and pharmaceuticals, aimed at shifting the burden from the public to the private sector, increased the ratio of private expenditure

Fig. 3.4 **Total health care expenditure as a percentage of GDP in WHO European Region, 2005, WHO estimates.**



Source: WHO Regional Office for Europe, 2008.

Notes: EU: European Union; EU12: Countries that joined the EU in May 2004 and in January 2007; EU15: Countries belonging to the EU before May 2004; EUR A, B, C: Regions as in the WHO list of Member States; CIS: Commonwealth of Independent States; CARK: Central Asian republics and Kazakhstan.

to GDP from its 1960 level of 0.6% to 2.7% in 1997. Similarly, private expenditure was 23.6% of total health expenditure in 2004, one of the highest percentages in Europe. Although Italy has one of the lowest public shares of total health care expenditure among EU countries, the volume of public health care expenditure remains an important issue for the government, both at the national and at the regional levels, mainly because of the existence of a large public deficit (Table 3.1).

3.1.1 The evolution of regional health care expenditure

A main feature of Italy's health care system is the presence of deep regional inequality in health care expenditure and in the supply and utilization of health care services. Table 3.2 shows the evolution of per capita regional health care expenditure since 1981.

From 1981 to 1992, before the start of the second major health reform, real per capita health care expenditure increased by 75%, but this must be seen both in the context of coverage extending to an additional 7% of the population as a result of universalism and of the lack of responsibility for expenditure control placed on regional governments by the central government. Regional growth varied substantially, ranging from 47% in Friuli-Venezia-Giulia to 120% in Valle d'Aosta.

Per capita public health expenditure varied in 1981 between Molise, at 78% of the average, and Friuli-Venezia-Giulia, at 126% of the average. Central and northern regions were above the national average, and southern regions were lowest. By 1997, however, regional differences had narrowed, especially at the bottom, to between 89% and 125% of the national average.

After the 1992–1993 reforms, the rate of growth in health care expenditure slowed substantially. Regional variation around the national average from 1992 to 1997 also narrowed but was still large, ranging between -14.0% in Marche to +10.6% in Bolzano. In fact, econometric analyses on the effects of the 1992 reforms have shown that regional inequality persisted (Giannoni and Hitiris, 1999). Some regions successfully contained costs, but not others. Growth in per capita regional expenditure picked up again after 1997 with an average of 32.2% at the national level and peaks of 57% (Molise). It appears from Table 3.2 that northern regions have been more successful in containing real per capita expenditure growth.

Available research on public health care expenditure shows that differences in regional expenditure are mainly explained by socioeconomic factors, such as differences in GDP, and in the supply of health care.

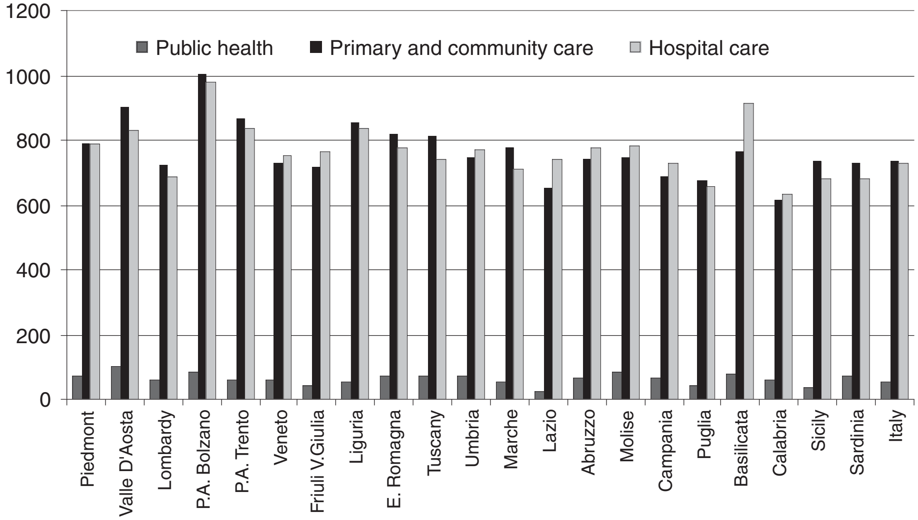
Table 3.2 Per capita public health care expenditure in Italy's regions, 1981–2003

Region	Expenditure (in constant 1998 euros)			Percentage change		
	1981	1997	2003	1981–1992	1992–1997	1997–2003
North						
Piedmont	525	944	1 329	120.0	–6.4	40.8
Valle d'Aosta	511	1 064	1 473	92.3	–5.5	38.4
Lombardy	570	988	1 257	81.3	–4.4	27.2
A.P Bolzano	590	1 216	1 731	81.8	10.6	42.4
A.P Trento	746	1 109	1 487	86.4	–2.1	34.1
Veneto	658	1 002	1 291	64.2	–7.3	28.9
Friuli-Venezia-Giulia	766	1 022	1 311	47.5	–9.6	28.3
Liguria	712	1 104	1 423	72.1	–9.9	28.9
Emilia-Romagna	672	1 118	1 385	92.6	–13.6	23.9
Centre						
Tuscany	666	1 051	1 331	70.5	–7.4	26.7
Umbria	620	1 034	1 377	81.6	–8.2	33.2
Marche	653	1 017	1 263	81.0	–14.0	24.2
Lazio	711	1 022	1 351	57.1	–8.5	32.2
Abruzzo	608	948	1 333	63.7	–4.7	40.6
South						
Molise	472	933	1 469	109.7	–5.8	57.5
Campania	575	866	1 227	72.9	–12.9	41.7
Puglia	577	886	1 167	71.6	–10.6	31.7
Basilicata	495	886	1 168	81.2	–1.3	31.8
Calabria	540	877	1 125	65.0	–1.6	28.3
Sicily	531	871	1 210	87.1	–12.4	38.9
Sardinia	552	929	1 246	92.5	–12.6	34.1
ITALY	607	972	1 285	75.2	–8.7	32.2

Source: Corte dei Conti, 2005.
Note: A.P: Autonomous Province.

Figure 3.5 shows the significant levels of hospital expenditure in the composition of total health care expenditure, amounting to nearly 46% of the total in 2005. When compared with 2000 data, this component shows a decline from 49%, with more funding going to other areas, especially primary and community care, which grew from 40% to 46%. Expenditure for public health is only 3.6% of the total, with no major changes since 2000, when it amounted to 3.3%. Administrative costs only amount to 4.3%. Both areas have, over the

Fig. 3.5 Regional health care expenditure by service category (€) in 2005



Source: Corte dei Conti, 2005.

Note: A.P: Autonomous Province.

years, experienced a decrease in spending, with more money going to primary and community care, where, as discussed above, expenditure for drugs has undergone a major and worrying increase.

When one considers data at the regional level, Lazio, Veneto, Liguria and Campania devote a greater than average amount of resources to hospital care, at 50.7%, 47.4%, 46.1 % and 47.1%, respectively. In contrast, primary and community care are highest in Lombardy (48.1%) and Tuscany (48.2%). Lastly, Valle d’Aosta, with 5.5%, and Molise, with 5.2%, stand out for public health spending.

3.2 Population coverage and entitlement

In terms of coverage, up to the late 1970s, 93% of the population was covered by social health insurance, although under markedly varying conditions. The 1978 reform that created the SSN changed the principle of health care financing: solidarity within professional categories was discarded in favour of intergenerational solidarity, which backed the introduction of universal, free coverage for all Italian citizens. Immigrants were first covered in 1998. Legal immigrants have the same rights as Italian citizens, whereas illegal immigrants only have access to a limited range of free health care services – in particular, urgent specialist and hospital care following an illness or accident, health care schemes for babies and pregnant women, treatment for minors, vaccination programmes and treatments for infectious diseases.

3.2.1 Entitlements, benefits and patient rights

As in most industrialized countries, the definition of the benefit package has always been much debated within Italy's health care system. Trying to establish what types of treatment the SSN should finance and what citizens should pay for sometimes involves pursuing contradictory objectives, including solidarity, social justice, equity and economic efficiency. Reaching a unanimous conclusion can prove to be extremely difficult, as Italy clearly demonstrates.

Up to 1978, the absence of a national health service gave health care a contradictory nature. Health care was indeed provided to all residents but, because of numerous financing bodies, the principle of horizontal equity was not guaranteed. In other words, members of different mutual funds had access to different treatments for the same condition, health care was delivered non-uniformly and risks were not covered in the same manner. For the first time, the 1978 reform introduced the principle of a common package of benefits available to all citizens irrespective of age, social condition or income. This was meant to guarantee equal health care coverage. Although the reform listed the areas in which treatments were to be delivered directly by the USL (as they were then known), it did not define the benefits to be included nor provide detailed specifications, leaving such responsibility to the National Health Plan, a three-year document that was intended to lay out the main guidelines for health care services across the country and to provide recommendations for achieving specific health targets.

Despite the efforts of successive governments, the first National Health Plan was approved only in 1994, 16 years after the SSN was established. The National Health Plan did not specify the benefits to be provided by the ASLs but simply defined six categories of intervention, ranging from hospital care to prevention and from specialist care to primary care. As was long typical in health care systems based on the SSN model, patients de facto received what was medically feasible, what the SSN was able to provide with available resources and what doctors prescribed.

A step forward was taken with the approval of the second National Health Plan for 1998–2000. The Plan stressed the need to explicitly define the content of a homogeneous benefit package that should be met by all regions and to set out the rationing mechanisms in play. In addition, it laid out the general guidelines and initial steps required to define the benefit package. A clear commitment was made to reduce waiting times, which were frequently used as an implicit rationing tool. In 2001, a catalogue of SSN benefits, the LEAs, was defined in terms of a positive and a negative list and based on criteria of necessity, human dignity, effectiveness, appropriateness and efficiency in delivery. The positive list contains the services that the SSN is required to provide uniformly in all regions. This is spelled out in varying degrees of detail, ranging from specific procedures to broad categories of services. Regions are free to provide non-LEA services to their residents, but must finance these with own-source revenues, and some actually do so.

The negative list includes three categories of ambulatory and hospital services. First, a few services are excluded from SSN coverage because of proven clinical ineffectiveness or because they are not considered to fall within the remit of the SSN (e.g. cosmetic surgery, except for malformation and injury, ritual circumcision, non-conventional medicine, medical examinations and vaccinations for employment and vacation purposes, and a few types of physiotherapy). Second, certain diagnostic and therapeutic ambulatory services (e.g. bone density testing, excimer laser surgery and orthodontic services) are included in the entitlement on a case by case basis, if judged appropriate for the clinical condition. Third, there is an indicative list of potentially inappropriate hospital admissions, classified in terms of DRGs, for which the regions are supposed to provide substitute treatment at other levels of the health care delivery system, such as day cases and ambulatory care. Examples of these are carpal tunnel release, cataract surgery and hypertension care. Finally, the SSN has always had a positive and a negative drug list in the *National Pharmaceutical Formulary* (France, Taroni and Donatini, 2005). The current version classifies drugs according to their clinical efficacy and, to an extent, cost–effectiveness under two classes: one prescribed under the SSN and the other containing other drugs, the prices of which are set freely by the manufacturers and paid for in full by patients (see Chapter 6).

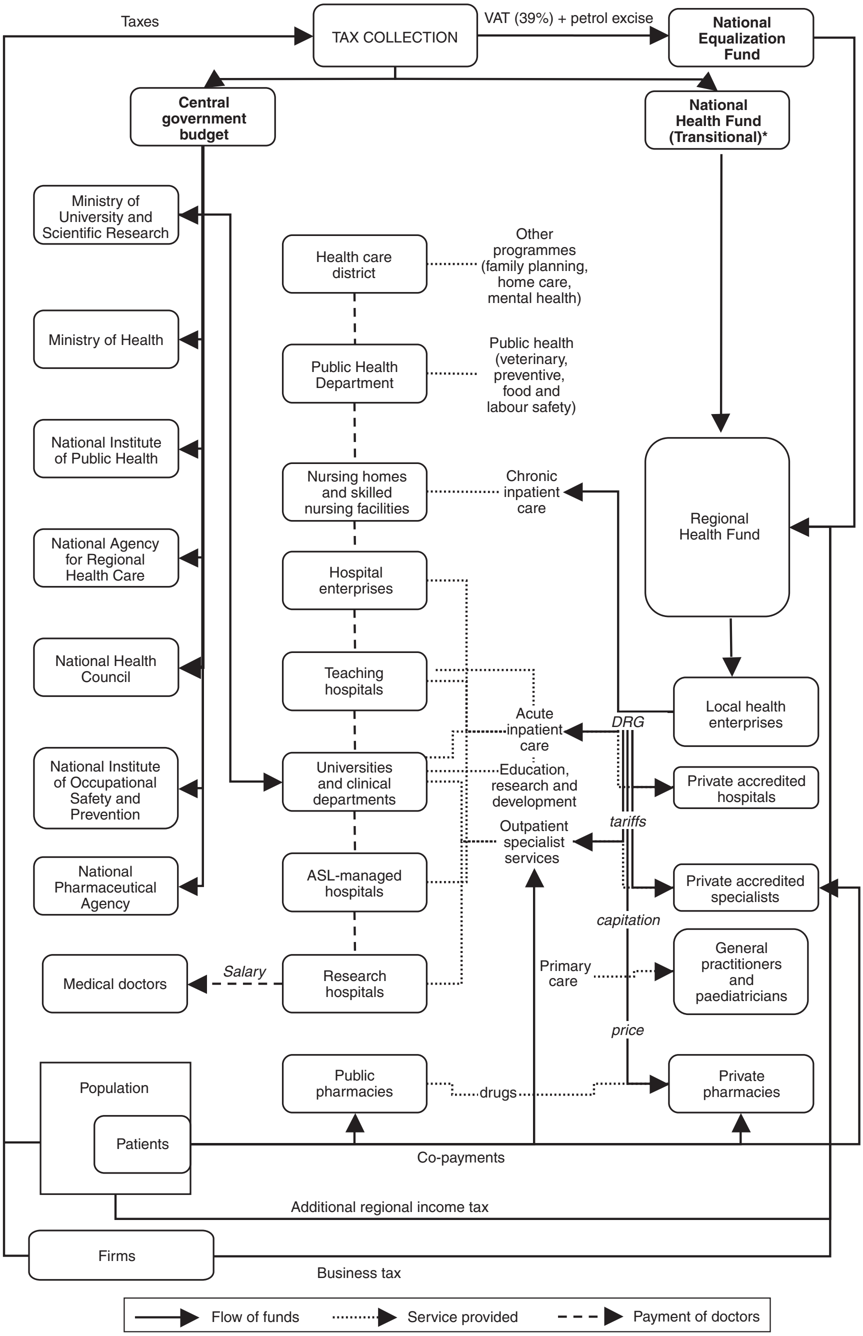
3.3 Revenue collection and sources of funding

Figure 3.6 provides a snapshot of the financial and service flows within the Italian health care system, more detail of which is given in the sections below.

3.3.1 Evolution of the health system funding (1978–1997)

Before 1998, taxation and payroll taxes (social insurance contributions) represented the largest sources of financing for the Italian SSN. As discussed below, the abolition of social insurance contributions in 1998 transformed

Fig. 3.6 Financial and service flows within the SSN



Note: *Abolished in 2000 but still exists as a transitional fund.

taxation into the largest source of income. Out-of-pocket payments, which include both cost-sharing payments and direct payments to private suppliers of health care, represent the second largest source of income.

Before 1978, employers and employees were responsible for financing health care through health insurance funds. The system was fragmented into numerous health insurance funds and lacked unified regulation: there were many different financing methods and contribution rates, and often drastically different benefit packages: employer contributions ranged from 5.2% to 7.5% of gross earnings and employees paid from 1% to 2.2%. The 1978 reform not only granted a homogeneous benefit package to all citizens (although it was not clear what treatments were included in the package) but also rationalized the health insurance system by making contributions more uniform and pooling all resources into a single fund, the National Health Fund. The function of this Fund was to guarantee the public resources required to meet the costs of providing health care to all citizens. The global amount of the National Health Fund was fixed yearly by the central government and came mainly from insurance contributions and general taxation. Additional resources were drawn from other sources, such as regional and local taxes, revenue from services delivered privately by USLs (later called local health enterprises (ASLs)) and hospitals and user co-payments. These various sources of funding were gradually transformed and simplified. Thus, in 1997, before fiscal reforms took place, the main funding sources were as follows.

- *Payroll taxes (social insurance contributions).* These were charged to employers in the public and private sectors and self-employed people with a regressive structure; rates started at 10.6% and 6.6% for the first €20 660 of gross income of employees and self-employed people, respectively, and decreased to 4.6% for both types for gross income between €20 660 and €77 480.
- *Co-payment income of ASLs.* The ASLs received co-payments for pharmaceuticals, diagnostic procedures and specialist visits. It should be noted that co-payments for pharmaceuticals simply reduced the expenditure incurred by ASLs and did not represent an additional source of income as did co-payments for diagnostic procedures and specialist visits. Nevertheless, they were still included as revenue for ASLs.
- *Contributions from regions governed by special statute.* After 1990, the five regions governed by special statute contributed to financing their health care system by using part of their own budgets, as they received higher overall funding than average. In particular, Valle D’Aosta, the Autonomous Provinces of Bolzano and Trento and Friuli-Venezia-Giulia fully financed their own health care systems without support from the

central government. In contrast, Sicily and Sardinia received limited support from the central government.

This system clearly improved the situation in promoting homogeneity in financing but, at the same time, was characterized by the following flaws.

- Significant disparities persisted between the rates paid by wage-earners and those paid by self-employed people and in the resources allocated to each region.
- It seemed inequitable to have a national health care system that addressed the needs of the whole population but was financed mainly by labour income.
- Regions were constantly running budget deficits that had to be covered by revenue from general taxation. The overall deficit for the period 1987–1994 added up to about €6 billion, with wide interregional differences in the size of the deficits, ranging from €620 million for Lazio to a surplus of €2.6 million for Basilicata in 1994.

Tackling such issues was among the objectives of the 1992–1993 SSN reform (Legislative Decrees Nos. 502/1992 and 517/1993) and the 1997 fiscal reform (Legislative Decree No. 446/1997). The latter, in particular, aimed to eliminate the disparity in the payroll tax rates, reduce negative incentives for employment and introduce elements of fiscal decentralization. These changes represented an important breakthrough towards regional financial autonomy and thus, towards genuine regional responsibility for ensuring that the population received a core package of health care services and benefits.

Social insurance contributions were replaced by a business tax, IRAP, which was formally classified as a regional tax, but which, in fact, involved the regions receiving a share of the revenue from a national tax. Revenues from this tax were supplemented by a central grant financed with value-added tax (VAT) revenues, the amount of which was set annually by the national government. The aim was to ensure that all regions had adequate financial resources to provide the LEAs.

3.3.2 Main sources of health financing 1998 to the present

Currently, the main source of finance for the Italian SSN is a mix of hypothecated taxes applied both at the regional and national levels (Table 3.3).[5] Legislative Decree No. 446/1997 replaced the payroll tax and a few local excise taxes with two new types of regional tax:

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[5] Following the approval of the 1997 fiscal reform (Legislative Decree No. 446/1997) and Legislative Decree No. 56/2000, approved in February 2000.

1) The IRAP is a regional corporation tax imposed on the value added of companies (corporations, partnerships and self-employed workers) and on the salaries paid to public sector employees. The value added is defined as the difference between income and production costs; labour costs and financial costs are not counted in the production costs. The companies' value added is taxed at 4.25%, but the tax on public-sector salaries is 8.5%. In both cases, the employer pays the tax. The budget law in 2005 allowed regions to raise the rate by 1% if they were faced with health care expenditure deficits. This provision became compulsory in 2006 and led to the imposition of a 5.25% rate in Abruzzo, Campania, Lazio, Molise and Sicily.

2) A regional tax is imposed on top of the national personal income tax (*Imposta sui Redditi delle Persone Fisiche* (IRPEF)); this piggyback tax is known as the *addizionale IRPEF*. The rate was initially set, for the years 1998 and 1999, at 0.5%. The national income tax rates were reduced by 0.5% to accommodate the new tax.

Legislative Decree No. 56/2000 further pushed the funding system along the path of fiscal federalism. Since 2001, regional financing has come from:

- IRAP, with regions obtaining 90% of IRAP revenue;[6]
- the regional share of IRPEF, now set at 0.9%, with regions allowed to modify the total regional IRPEF rate from 0.9% to 1.4%;
- a set amount (€0.13 per litre) of the petrol excise tax; regions have the right to increase the petrol excise by a further €0.026 per litre; and
- in addition, regions also have revenues from motor vehicle tax and other taxes.

Although Legislative Decree No. 56/2000 formally abolished the National Health Fund, to all intents and purposes a Fund of some sort (often called the National Health Fund in official documents) still operates as a kind of accounting container for monies to be allocated to the regions. The Decree also stated that a fixed proportion of national VAT revenue would be used to build a National Solidarity Fund, to be used to redistribute funds to the regions unable to raise sufficient resources to provide the basic package. The funds transferred to or received from the National Solidarity Fund are determined by the sum of four components devised to take into account the region's share of total VAT revenue, its fiscal capability, its health care financing needs and its non-health care financing needs.

Although these reforms undoubtedly represent progress in financing health care, they have possible drawbacks, mainly related to an unevenly distributed

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[6] The tax is levied nationally but 90% of its revenue is allocated back to the region in which it is levied.

tax base, smaller room for manoeuvre for poorer regions and the need for poorer regions to increase tax rates more than high-income regions, with subsequent negative incentives for business location. These issues and the difficulties in reaching an equitable distribution of the National Solidarity Fund have blocked, in practice, the application of the redistribution formula. Currently the regions and the central government are debating over the application of a revised formula, but no decision has been made yet.

3.3.3 Out-of-pocket payments

Italy currently has two main types of out-of-pocket payments. The first is demand-side cost-sharing: a co-payment for diagnostic procedures, pharmaceuticals and specialist visits. The second is direct payment by users to purchase private health care services and over-the-counter (OTC) drugs. Although no co-payments were envisaged when the SSN was established in 1978, serious concerns over the economic stability of the system led to the introduction of co-payments both for specialist outpatient care and pharmaceuticals just a few years later. No information exists on informal payments, although it may be common, especially in rural areas, to offer non-monetary gifts (usually food) to GPs making home visits as a form of gratitude. In economic terms, demand-side cost-sharing and direct payments by users in 2004 represented 19.6% of total health care expenditure and 83% of all private health care expenditure. The remaining 17% of private financing comprised mutual fund contributions and private insurance premiums.

Co-payments for pharmaceuticals were introduced in 1978 and for specialist visits in 1982; these are regulated by national legislation. Since 1978, both have undergone several extensive changes. Until 1992, co-payments for pharmaceuticals included a percentage of the total cost of the drug and a fixed amount for each prescription. In 1993, a drastic reform classified pharmaceuticals into three categories according to a combination of their relevance (in terms of effectiveness) and cost. The Budget Law for 2001 abolished all co-payments for the first two categories, but there was a sharp impact on health expenditure levels. This led to a change in legislation in October 2001, which allowed regions to choose whether or not to introduce co-payments on drugs, but only for the purpose of containing rising pharmaceutical expenditure. In 11 of the 20 regions, co-payments were applied at a flat rate or a percentage of the price. It is estimated that, in 2002, the first year of its application, this measure reduced drug expenditure by 5% compared with the regions that did not adopt co-payments (France, Taroni and Donatini, 2005).

Understanding the co-payment structure on diagnostic and therapeutic procedures and specialist visits requires a few prior remarks. Procedures and visits can be prescribed either by a GP or by a specialist, with each prescription containing a maximum of eight procedures belonging to the same medical discipline (e.g. a magnetic resonance imaging scan and a laboratory test would go on two separate prescriptions even if prescribed to the same patient during the same visit to a physician). Prior to 1993, all users paid a proportion (from 15% in 1982 to 50% in 1991) of the total cost of each outpatient specialist visit provided, up to a ceiling fixed by law. Since 1993, users have paid for the total cost per visit but always up to a ceiling determined by law. The ceiling has changed several times, rising from €21 in 1982 to €52 in 1993 and declining to the current €36.15 per single prescription. Therefore, a patient who receives two separate prescriptions after a visit has to pay the first €36.15 on each prescription. The Budget Law for 2007 introduced a fixed €10 per prescription, to be added to the €36.15 ceiling. However, the strong debate that followed, with patients complaining about the rising costs of specialty care, led the new government in power to abolish the €10 fixed payment in May 2007. The same Law, in an attempt to curb inappropriate visits to hospital emergency departments, also introduced a co-payment (€25) on non-urgent visits to all emergency departments, which is still in place. Children under 14 are exempt.

Inpatient care and primary care are free at the point of use. Several attempts were made to introduce co-payments in these sectors during the 1990s (in 1989 for hospital stays; in 1993 for GP services, although restricted to higher-income groups), but these had to be abandoned because of popular protest.

Patients with specific health conditions who need particular medical devices (such as absorbent products for urinary incontinence, stoma bags, prostheses, wheelchairs and catheters) can make a formal request to their ASL through their specialist. These devices are free of charge after a specialist's diagnosis; ASLs then grant authorization for delivery. People who are eligible for these devices are patients with urinary incontinence, disabled ex-servicemen, people with work-related injuries and patients admitted to public and private accredited hospitals. Medical devices provided free of charge are listed in the national formulary established by the law.

The issue of cost-sharing exemptions has been hotly debated within the Italian health policy arena. The first criteria, mainly based on income, were established in 1981 and have been modified several times. During 1993, a new legislative measure established a deductible of €52 for those on higher incomes, increased co-payments for the rest of the population and restricted the quantity of free drug prescriptions for the elderly. In 1994, income selectivity was replaced by age selectivity, and children and people over 65 years of age were excluded from the main co-payment schemes, a measure reversed in favour of income criteria in January 1995. Since then, income schemes have been progressively adjusted to take account of age, family and occupation.

Currently, exemptions are established for specific categories of people: elderly people (>65 years old) with gross household income less than €36 152 per annum, people with chronic or rare diseases (as listed in the Decree of the Ministry of Health approved in 1999), disabled people such as disabled ex-servicemen and people with work-related injuries, people with HIV, donors (for health services related to spinal cord donors or organ donors), prisoners and pregnant women (health services are free of charge depending on the gestation week and specific diagnostic protocol).

As an incentive to increase private-sector utilization, and to help families bear the burden of co-payments, fiscal benefits for out-of-pocket payments were reformed in the early 1990s. Co-payments for pharmaceuticals and outpatient care provided by the SSN and direct payments for private health care receive tax benefits: these include a range of services, such as home nursing and physiotherapy. Such tax breaks have been in place since 1973, with private health expenditure fully deductible from taxable income. Since 1991, private expenditure has been eligible for a tax credit; a deductible of €129 is in place, and only 19% of the amount that exceeds the deductible is credited.

3.3.4 Voluntary health insurance

As a result of the near universal coverage, voluntary health insurance (VHI) does not play a significant role in funding health care in Italy (Fig. 3.7). Spending on VHI, both as a percentage of total expenditure and of private expenditure, is well under 5%, in line with other European countries such as Belgium, Greece,

Table 3.3 Sources of revenue as a percentage of total public expenditure on health, 2000–2006

Sources of financing	2000	2001	2002	2003	2004	2005	2006
Taxation	42.8	40.4	43.5	42.4	41.6	43.2	44.4
IRAP and additional IRPEF	47.5	40.1	42.8	42.2	41.2	40.1	39.4
Out-of-pocket payments	9.7	10.0	9.9	10.1	10.9	11.3	11.1
Other	–	9.5	3.8	5.3	6.3	5.4	5.1

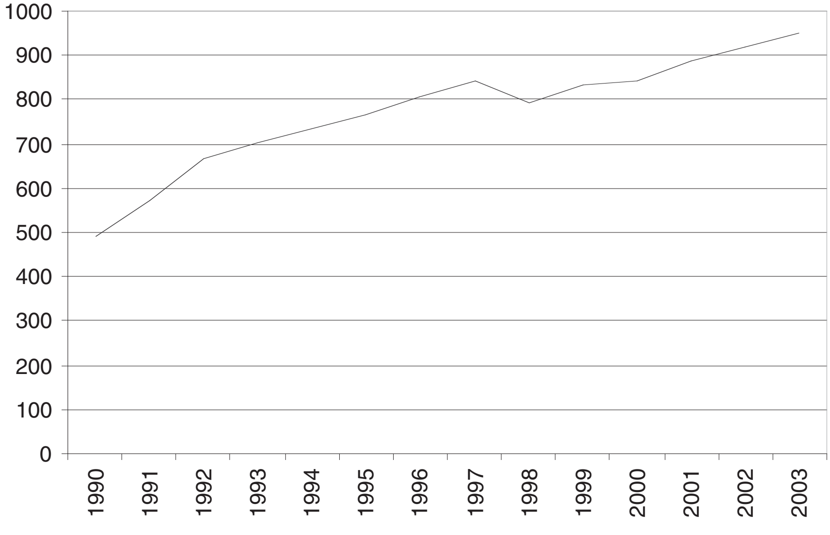
Source: Ministero dell'Economia e delle Finanze (various years).

Notes: IRAP: Regional business tax; IRPEF: Personal income tax.

Portugal, Spain and Sweden. Although, over the years, private expenditure has experienced some growth as a percentage of total expenditure, this has been more the result of increases in cost-sharing rather than an increasing demand for VHI.

Since the Italian SSN does not allow members to opt out of the system and seek only private health care, substitutive insurance does not exist. In terms of levels of coverage, the latest available data show that in 1999, 15.6% of the population was enrolled in complementary and supplementary schemes. In particular, complementary schemes cover co-payments, non-reimbursed services, dental care and hospital per diems for private rooms; supplementary insurance allows patients to access a wider choice of providers and also enables them to have increased access to private providers. The characteristics of subscribers have been well documented by the 2002 *Voluntary health insurance in the European Union* (Mossialos and Thomson, 2002). VHI in Italy is largely purchased by high-earning and highly educated people, with demand varying substantially according to the area of residence and with the age of the head of the family, employment status, education and income. Individual VHI policies sold by commercial, for-profit insurers are bought by people on medium to high incomes, whereas individual policies sold by mutual associations generally have lower premiums and are bought by those on middle to low incomes.

Fig. 3.7 **Voluntary health insurance expenditure (million €) in Italy, 1990–2003**



Source: OECD, 2008.

VHI is provided both by mutual associations (distinguished by their non-profit status) and by commercial companies (with a for-profit status), with very few of them (0.8%) specializing in health care insurance only. Italy, together with France and Spain, has the greatest number of insurance companies (over 100) although the 1990s saw a clear trend towards increased concentration in the market, with numbers falling from 125 in 1997 to 104 in 2000 (Mossialos and Thomson, 2002). Figure 3.8 shows the distribution of policies according to purchasers.

Premium rating policies adopted by commercial insurers depend on the type of purchaser. For individual buyers, premiums are risk rated on the basis of age, sex, health status (determined by means of a medical questionnaire and with exclusions determined by the existence of chronic diseases, mental illness, drug addiction, cosmetic surgery and HIV) and area of residence; groups are rated on the basis of age, sex and area of residence, with less emphasis on health status. Eligibility also depends on age and on the type of insurer/buyer as follows:

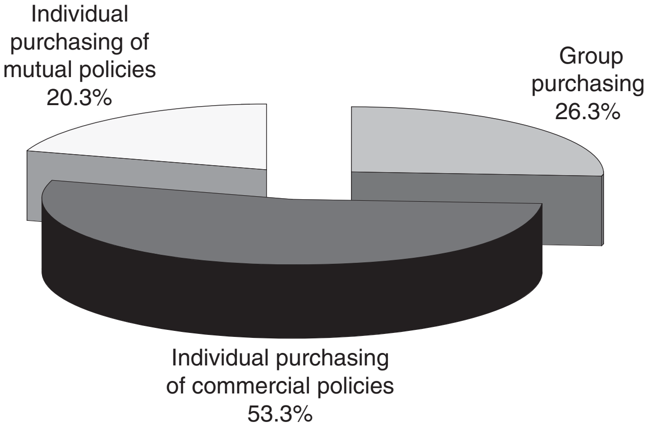
- commercial companies:
  - individual: no eligibility for people over 75 years;
  - groups: access restricted to employees and, sometimes, dependants.
- mutual associations:
  - groups: no age limit, although retired people can continue to be covered if they have been covered up to 10 years;
  - individual: no eligibility for people over 65–75 years.

Until 1992, tax relief on VHI premiums was applied at the marginal tax rate with a regressive effect. In 1992, the government reduced tax relief on commercial group and all mutual VHI premiums from the marginal to the standard tax rate. Currently, VHI premiums for group commercial policies and all mutual policies are deductible from taxable income at the standard rate of tax up to an annual ceiling for all insurance premiums (€1250). In 1999, increased tax relief was established for contributions paid to the funds providing complementary insurance.

3.4 Pooling of funds

The allocation of resources for the SSN has always been a source of friction both between the central government and the regions and between the regions, contributing to delays in assigning each region's annual share of health care resources. It has proven difficult to design an equitable allocation formula in the face of such large geographical differences in levels of economic development,

Fig. 3.8 Distribution of policies according to purchasers



Source: Mossialos and Thomson, 2002.

size and age composition of the population, and availability and utilization of health services. For example, in the central and northern regions, the proportion of the population aged 65 and over exceeds 20% compared with 15% or less in several southern regions. The former have pressed for weighted population formulae, while the latter protest that these unfairly benefit the better-off regions, which are already spending more on health care per capita. In addition, the southern regions point to the inadequacies of their health care systems in terms of facilities and equipment and request additional funding to correct these.

The guidelines used by the central government to allocate financing to the regions have changed frequently over the past two decades, mainly because they have not always been very clear. For example, in 1978, although the reform clearly stated that the Interdepartmental Committee on Economic Planning should allocate resources, the legislation only vaguely described what criteria should be adopted. Indeed, the legislation stated that the criteria should aim to supply regions with an adequate level of financing both for health care and for reducing interregional differences, but it failed to provide the means to do so. The lack of clarity over the criteria meant that the formulas for allocating health care funds were changed several times from 1978 to 1992.

Finally, in 1997, a weighted capitation rate was introduced that took into account demand for health care services and reflected the age structure and health condition of the population as represented by the mortality rate. The capitation rate should, theoretically, represent the resources needed to finance services included in the LEAs. It is also the responsibility of the Ministry of Health to propose the allocation of resources to each region: the proposal is then discussed by the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces, which must approve or reject it.

Under Ministry of Health specifications, health care funding should be allocated to three different health care categories as prescribed below:

- public health services in working and living environments (5%)
- community health care (50%)
- hospital health care (45%).

Regions can then choose how to allocate resources within different programmes. Thus, the percentages fixed by the Ministry of Health can be modulated at the regional level in accordance with regional planning targets. In addition, regions may decide how to allocate resources to the ASLs. Nevertheless, most regions transfer funds to the ASLs based on capitation. Each region sets aside some central funds for special projects and then transfers the remainder to the ASLs.

In some regions, extraordinary financing makes up many of the resources allocated to ASLs. Its main aim is to smooth out the transition from the old financing method, based on historical spending, to the new one, based on capitation. In addition, these funds can help ASLs cover deficits incurred during the year.

Over the years, the central government has followed a policy of first under-financing the SSN and then intervening periodically to fund regional deficits negotiated with each region. Annual funding remained below 1992 levels in constant prices until 1999, with a shortfall regularly occurring between funding granted for the coming fiscal year and the expenditure outcome for the fiscal year just completed. It has been estimated that this shortfall averaged 5% of annual funding over the period 1990–2000 (France, Taroni and Donatini, 2005). It is noteworthy that, during this period, the sheer magnitude of central transfers to cover regional deficits modified quite significantly the distribution of funds initially determined by the allocation formula. Moreover, the *ex post* redistributive effect of supplementary funding was magnified by the fact that the amount a region received was calculated as a uniform and fixed proportion of the absolute value of its deficit.

3.5 Purchasing and purchaser–provider relations

The wide-ranging health care reforms of 1999 introduced measures aimed at regulating the purchasing function, clarifying the boundaries between public and private services within the internal market and reducing the scope of private providers within the public system.

Purchasing was first regulated by Legislative Decree No. 229/1999, which specifies that the comparative evaluation of quality and costs should be used in selecting the providers (public and private) allowed to provide services on behalf of the SSN.

To promote fair competition between providers while simultaneously ensuring the quality of care, the 1999 reform established a four-step process for selecting (inpatient and outpatient care) providers, as follows:

1. Authorization to establish health care structures is only needed to build new facilities or to modify old ones and is granted by municipalities after agreement with the regional health planning unit.
2. Authorization for delivering health care services is granted by the regional health departments once a minimum set of structural, technological and organizational requirements have been satisfied.
3. Regional authorities grant institutional accreditation, conditional on two additional criteria. The first requires regular assessment of the quality of the organizational, managerial and technological infrastructure of health care providers and of the skills and practices of health professionals. The second requires the evaluation of the value added by each newly accredited provider, considering the existing regional health services and the benefit package to be delivered. The state should establish the general criteria for final inclusion or exclusion in collaboration with regions (see below). Institutional accreditation is therefore ultimately a regional responsibility that should be based on specific criteria related to structure, process and outcome, and should be mandatory for contractual agreements. However, accredited status does not automatically confer the right to deliver health care services funded by the SSN.
4. Contractual agreements are the last step in the selection process to be performed by regional and local authorities. Contractual agreements should therefore be negotiated between ASLs and their ‘preferred providers’, themselves in collaboration with regional authorities on a value-for-money basis (that is, through a comparative evaluation of quality and cost) among those accredited by the SSN. Contractual agreements should describe the amount, the price and the quality of the services to be delivered by each provider (with penalties for exceeding agreed-upon volumes), together with

the specification of other relevant details, such as maximum waiting times and health targets to be achieved.

Consistent with the devolution of Italy's health care system, regional governments are in the process of establishing and managing the accreditation process. Nevertheless, all regions will have to follow the general criteria laid out by the Ministry of Health, which will provide them with general guidelines and with the criteria to be used to select providers. The criteria are being laid out to guarantee that all health care providers operate according to common quality criteria (see Chapter 4).

3.6 Payment mechanisms

3.6.1 Paying health care personnel

Physicians

The payment structure for physicians depends on the SSN sector in which they work. GPs and paediatricians delivering primary care and preventive medicine are mainly paid on a capitation basis, and hospital physicians delivering secondary care earn a monthly salary.

General practitioners and paediatricians

Until 1978, GPs and paediatricians were paid fees for services by the patient's mutual fund. Since 1978, both GPs and paediatricians can choose to work full-time or part-time for the SSN, with ASLs paying them on a capitation basis. The payment is therefore determined by multiplying the per capita payment by the number of patients enrolled on the physician's list. ASLs can also pay additional allowances (agreed at the regional level) for the delivery of planned care to specific patients, such as home care for chronically ill and disabled people. Both types of physician can also earn more by treating patients privately and charging fees, provided that the time GPs and paediatricians devote to private treatment does not interfere with the regular provision of primary care services for SSN patients.

The payment levels, duties and responsibilities of GPs are determined in a collective agreement signed every three years by consultation between the central government and the GPs' trade unions. The agreement also fixes the maximum number of patients each physician can have on his or her list. Full-time GPs and paediatricians can have up to 1500 and 800 patients, respectively, and the limits for part-time physicians are 500 and 400. When a GP or paediatrician devotes more than 5 hours per week to private practice, the maximum number of public patients is reduced proportionately by 37.5 patients for each additional hour in private practice above the 5 hours per week. Physicians who have higher limits (1800 for GPs and 1000 for paediatricians) as a result of previous laws and agreements can keep them.

The 1992 and 1999 reforms tried to address some unresolved issues connected with GP activities. First, to overcome the traditional division between GPs and emergency GPs (*guardia medica*), and thus guarantee medical assistance 24 hours a day, seven days a week, the reforms envisaged incentives for GPs to set up medical associations or partnerships. These associations consist of teams that provide continuous care for ordinary activities. Second, to provide an incentive to contain costs and reduce referrals to hospital for specific specialist treatments, the payment system has been split into three parts: fixed, variable and additional parts.

The fixed part is determined on a capitation basis. The collective agreement signed in 2009 introduced a fixed per capita payment equal to €40.05. Each GP receives an additional per capita payment based on the number of patients and on the years elapsed since graduation. The rate is currently between €1.91 for GPs with over 1400 patients and recent graduation and €18.46 for GPs with a small number of patients (less than 500) and over 27 years since graduation. In addition, physicians who set up a joint medical practice receive an additional per capita payment, with additional payments for protecting physicians against risks and for physicians working exclusively within the SSN. The variable part comprises fees for services for specific treatments, including minor surgery, preventive activities, therapies and post-surgery follow-up. The additional part is a reward for effective cost containment: it is a proportion of the positive difference between expected and actual expenditure, including the cost of pharmaceuticals, laboratory tests and therapeutic treatments prescribed by the GP.

The fixed and variable parts are common to all GPs and are established nationally, but each region decides whether to apply expenditure budgets and estimates the budget itself. Historical expenditure, demographic characteristics and epidemiological indicators are proposed as variables to estimate the expected expenditure.

The same payment structure applies to paediatricians, but per capita payments are higher than those of GPs because they have fewer patients: the collective agreement signed in 2009 introduced a fixed per capita payment equal to €83.65. Each paediatrician then receives an additional per capita payment based on the number of patients and the years elapsed since graduation. The rate is currently between €4.14 for physicians with 700 patients and recent graduation, and €37.96 for GPs with fewer patients (less than 250) and over 22 years since graduation.

Hospital physicians

In 1992, the organization of hospital physicians was drastically changed by replacing several professional categories with 'first-level' and 'second-level' physicians.[7] All newly employed physicians started as first-level physicians (*dirigente medico di primo livello*). Physicians at this level provided support and cooperation in clinical duties, as defined by the medical officer in charge of the hospital unit. Second-level physicians (*dirigente medico di secondo livello*) usually had additional duties connected with organizing and managing the hospital unit. Further, they helped to choose the most appropriate therapeutic, diagnostic and preventive treatments for patients.

Up to 1999, all physicians could earn additional income by treating patients privately on a fee-for-service basis. In 1999, the organization and management of hospital physicians were reformed in an attempt to clarify the boundaries between private and public practice and to suppress the perverse incentives associated with dual practice. Therefore, the two-level hierarchical structure established in 1992 was replaced by just one level, with the salary structure dependent on the effective tasks and responsibilities performed. In addition, managerial and directive posts were reserved for physicians who chose to work exclusively for the public sector.

Similarly, the possibility for public hospital physicians to increase their salaries by treating private patients was abolished for all physicians employed after 1998. The physicians employed before 1998 fell into two categories. Some had opted to work only part-time within the public sector, thus receiving lower public wages. Under the reform, they could continue to do so. Such a decision, however, hindered career progression and prevented them from reaching top positions. Many of the remaining physicians who had formally chosen to work full-time for the public sector were also working privately. Legislation forced them to choose, by the end of October 1999, between treating patients privately within public facilities or within the private sector. Physicians choosing the second option were prevented from reaching top management positions.

All public physicians, however, continued to be allowed to conduct private care within public hospitals by paying a proportion of their extra income to the hospital. This provision, introduced in 1992–1993, was further regulated in the late 1990s by prescribing that public hospitals should reserve between

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[7] Prior to 1992, hospitals had multiple-layer hierarchical structures, including such positions as chief medical officers (*primario*) and assistant medical officers (*aiuto primario*).

6% and 12% of their beds for private patients. The strong financial and career incentives, including up to a 20% increase in salary and attractive promotion prospects, led to most (91.6%) doctors and other SSN professionals choosing this option. However, following physicians' pressure, legislation approved in 2004 by the centre-right government reversed this policy and allowed physicians to decide on an annual basis whether to practise privately within SSN facilities and abolished career and remuneration incentives in this regard.

Nurses and other staff

Unlike physicians, nurses in Italy do not constitute a separate professional category but occupy the higher level of a wider hierarchical structure of nonmedical SSN employees that includes technicians, clerks, caretakers and administrative staff. Similar to other public workers, their payment structure is defined by a national collective agreement negotiated every three years by representatives of the trade unions and government.

The organizational structure of nonmedical SSN workers has changed several times, affecting both the hierarchy of the employees and the composition of their income. In particular, the 1998 agreement simplified the structure by reducing the number of levels to four, each characterized by different requirements in terms of skills, duties and training. First-level employees (group A) have simple duties and generally include auxiliary workers and caretakers. Group B includes more skilled workers, such as assistant technicians and administrative staff with little responsibility. The highest levels, groups C and D, comprise mainly nurses together with midwives, dieticians and technicians working in areas such as radiology, orthopaedics and ophthalmology, as well as higher-level administrative staff. Aside from specific professional duties, group D workers (such as ward managers/head nurses) also have decision-making responsibilities and play a significant role in organizing the delivery of health care.

Aside from restructuring the professional hierarchy, changes have also reassessed the payment scheme to stimulate professional motivation by acknowledging and remunerating individual employees' skills. Hence, each nonmedical employee in the SSN (including nurses) receives a basic wage and productivity rewards. The basic wage is determined by the level in the hierarchical structure, taking into account duties, responsibilities and training profile. A seniority allowance is also usually included, as is an allowance for specific duties requested.

Productivity rewards are part of the more general incentive scheme that ties a portion of the wage to the results achieved by the employee. In particular, results are measured both at the individual level and in health care centres, with rewards going to the employees who successfully improve the quality of their performance and contribute to increasing the overall productivity and performance of the health care unit. The medical director and the ‘nurses’ officer’ (where the role exists) evaluate workers’ performance.

3.6.2 Paying for health services

Changes from 1978 to 1991

Hospital care has always represented the largest share of health care expenditure and has often been a source of major concern to the central government. The organization of most hospitals has remained fairly unchanged throughout the years, but reimbursement mechanisms have been altered in an attempt to curb expenditure. Up to 1978, all the structures that delivered hospital care were reimbursed by the mutual health fund to which the patient belonged at a per diem rate: each hospital’s board of directors set the rates, taking into account both the direct and indirect costs incurred in providing hospital care. Bed-day rates were reimbursed without any sort of control over efficiency or the quality of services. This mechanism created strong incentives to push up treatment prices and increase the number of beds and the length of hospital stays. Thus, the severe deficits faced by mutual health funds during the early 1970s were predictable and the government responded in 1974 by shifting hospital management responsibility away from health funds to regional authorities.

In order to reduce the number of beds and contain expenditure, public hospitals and teaching hospitals were no longer paid on a bed-day rate, which was maintained solely for private clinics and for religious hospitals; instead, public facilities were reimbursed on a fixed budget basis. At the same time, regional authorities were made responsible for reaching agreements with all health care suppliers for hospital care. The 1978 reform further enhanced this shift in management by placing hospitals under the direct control of local health authorities: public hospitals were fully integrated into the administrative structure of local health units and were financed through the budget given to the local health units by the regions. The lack of a separate accounting system, however, made tracking expenditure and auditing very difficult. The reform also established that all hospitals that were independent of the USL but had public status (e.g. public teaching hospitals) would be financed on a fixed budget basis, with the annual budget determined by historical expenditure. Private teaching hospitals, private clinics and religious hospitals, in contrast, with which local health units could make agreements, were to be financed on a bed-day rate, negotiated between the central government and the associations of private/ecclesiastical providers with some adjustments at the regional level.

Changes in 1992

Reform measures in 1992 envisaged widespread changes to the structure of hospital care delivery. University hospitals and highly specialized and nationally relevant hospitals were given the status of AOs and therefore were formally separated from ASLs, with considerable financial independence as well as full responsibility for their budgets, financing, management and technical functioning. Public hospitals without AO status remained under the control of the ASLs but were granted some economic and financial autonomy and a separate accounting system within that of the ASL to make auditing and control easier. Private clinics and religious hospitals maintained their previous structures.

Together with the distinction between the two types of public hospital, which aimed to introduce some quasi-market aspects into Italy's health care system, the other important innovation in 1992 was the switch from cost-reimbursement mechanisms (bed-day rates and *ex-post* payments) in the financing of hospital care to prospective payment systems for both inpatient and outpatient procedures. Since January 1995, hospitals and outpatient specialist providers have been reimbursed for services rendered according to rates determined at the national level. Regions are free to redefine the rates according to their own standards, but must take the national rate as the maximum level.

For inpatient care (ordinary and day-hospital treatments), patients are classified according to the DRG scheme, whereas for outpatient care, diagnostic services and specialist treatments, reimbursement is based on fees for services. The only two forms of treatment for which a bed-day rate still applies are for rehabilitation and long-term care. These two types of hospital care have a progressive rate reduction scheme to prevent the unnecessary lengthening of hospital stay. A length-of-stay longer than a set limit (usually 60 days) triggers a 40% reduction in the bed-day rate.

In addition, the reforms specified that regions were allowed to set up specific financing schemes aimed at integrating hospital activities that could be fairly financed by the DRG scheme. In particular, these include: emergency wards; spinal cord units; burn units; organ transplant centres (transport, donor and receiver support and transplant activity coordination); AIDS centres; home-based care; training activities; and teaching and research activities, all of which receive additional funding from the regional government.

A special case is Lombardy, where all hospitals were given AO status from 1998. In this case, ASLs do not manage hospital structures directly and all hospitals are financed by prospective payments. In addition, the smallest regions opted for the regional health department directly negotiating both volume and financing with hospitals (which do not usually hold the status of

AOs). The prospective financing mechanism is slowly being implemented in some southern regions.

Changes in 1999

Finally, reforms in 1999 strengthened the principle of a prospective payment system based on DRGs and redefined the financing schemes for specific activities by stating that all hospitals are to be financed by a predefined overall budget composed of two elements:

- payments for inpatient and outpatient care by means of predetermined rates based on DRGs; and
- payments based on the average production costs for:
  - care for emergencies and accidents and, more generally, care activities with high waiting costs
  - prevention schemes
  - social services
  - transplant activities
  - management of chronic illnesses.

Recent evaluations of the impact of the DRG system in Italy (Falcitelli and Langiano, 2004) have shown that the introduction of a prospective payment system has led to:

- no increased competition, but rather a greater attention to planning and budgeting within public hospitals;
- a move towards specialization in private hospitals;
- increased attention towards organizational appropriateness and volume control; and
- the development of information technology to manage records.

Rather than being just a cost-containment mechanism, DRGs have become one of the most important tools that hospital managers and health policy planners have for:

- managing hospital activity (regional differences)
- analysing and planning hospital activity
- measuring the performance of clinicians.

Without underestimating the importance of this major innovation, the introduction of DRGs and the prospective payment system, as often happens, have left some problems unresolved. In particular, over the years the issue of tariff updates has become one of the most pressing problems: current tariffs do not reflect the underlying cost structure, but in the absence of costing studies and with regions also using tariffs as an overall cost-containment tool, the prospect of seeing a tariff update is not good. In addition to possible budget problems for high specialty hospitals, DRGs have the side-effect of hindering technological innovation as the tariff system is not flexible enough to take into account both rising technological costs and the introduction of new technologies.

Two broad lessons can be drawn. First, the prospective payment system has shown itself to be a robust policy tool, adaptable to differences in the administrative capacity of individual regions and hospitals. DRGs have the merit of being easy to use and require data that are relatively simple and inexpensive to obtain. In fact, the adoption of the prospective payment system involved minimal investment in information technology and human capital. A second lesson is that the effects of introducing prospective payments in a single-payer health care system are highly uncertain. The prospective payment system covers a continuum, ranging from total dependence, that is, complete ownership (hospitals directly managed by ASLs) to semi-independent public hospitals with significant negotiating power (AOs), to complete private ownership of for-profit hospitals with ‘pure’ contractual relationships with purchasers. As a result, incentives associated with the new prospective payment system have become increasingly ‘high powered’ and the objective functions of purchasers and providers ever more divergent (France, Taroni and Donatini, 2005). To manage this uncertainty, the scope of prospective payments has been limited and the hospital sector has been placed under a budget constraint, with the automatic reduction of tariffs when spending ceilings have been surpassed. This has led to significant price flexibility and to published tariffs serving as ceilings.

4 Regulation and planning

4.1 Regulation

4.1.1 Regulation and governance of third party payers

In the Italian SSN, third party payers are represented by the regional governments (with respect to public funding) and private insurance companies (with respect to non-public funding). Public funding accounts for about 70% of total health care expenditure and private insurance companies account for about 11%. Out-of-pocket payments and co-payments account for the remaining part of expenditures (see Chapter 3).

Regions are responsible for delivering a vast range of health care services to the population, regulating, governing and financing a network of population-based ASLs and public and private accredited hospitals. Regions, through this network, are required to guarantee the benefit package to be delivered to the population (LEAs). They are responsible for legislative and administrative functions, planning health care activities, organizing supply in relation to population needs and monitoring the quality, appropriateness and efficiency of the services provided.

Pursuant to Legislative Decree No. 229/1999, and as a consequence of the devolution process that has been occurring within the SSN, Italian regions are fully responsible for governing, regulating, financing and monitoring the health care system. In particular, regional legislation should define:

- the principles for organizing (public and accredited private) health care providers and for providing health care services;
- the criteria for financing all health care organizations (public and private) providing services financed by the regional health departments; and

- the technical and management guidelines for providing services in the regional health departments, including assessing the need to build new hospitals, accreditation schemes and accounting systems.

Through their Departments of Health, regions are also responsible for:

- allocating resources to various ASLs and AOs;
- defining the criteria for authorizing and accrediting public and private health care settings in the region;
- managing the introduction of new health technologies in the territory, applying a health technology assessment (HTA) approach where specific regional laws have been passed (this happens in Emilia-Romagna, Veneto, Tuscany and Lombardy);
- technically coordinating health care activities through a standing conference for regional health and social care planning;
- monitoring the efficiency, effectiveness and appropriateness of the services provided by accredited public and private organizations;
- defining the geographical boundaries of health districts inside each ASL;
- appointing the general managers of ASLs and public hospitals; and
- defining a regulatory framework for how the general directors of hospitals and ASLs exercise autonomy in the strategic planning process.

In view of the greater independence granted to the regions with respect to health policy, there is a great deal of variation in how each region performs its role of 'third party payer' (or purchaser) in the health care system. It is possible to identify four institutional models (Mapelli, 2007):

- *Centralized/integrated*: regions embracing this approach directly control more than 66% of hospital beds;
- *Mixed/semi-integrated*: regions play a direct role in defining region-wide or provider-based purchasing; here the percentage of hospital beds directly managed by regions is between 40 and 66%;
- *Mixed/semi-separated*: the percentage of hospital beds directly managed by regions is between 20 and 40%; and
- *Separated*: the percentage of hospital beds directly managed by regions is <1%; the third party payer function is devolved through the ASLs that purchase services from providers (both public and private).

Seven regions/autonomous provinces form the first group, using an integrated system: Valle d'Aosta, Trento, Bolzano, Abruzzo, Molise, Sardinia and Veneto.

The second group (mixed/semi-integrated) is the biggest and comprises nine regions: Liguria, Umbria, Marche, Basilicata, Calabria, Piedmont, Emilia-Romagna, Tuscany and Puglia.

The mixed/semi-separated group is made up of four regions: Friuli-Venezia-Giulia, Lazio, Campania and Sicily.

Lombardy alone falls into the last category, using a separated system. Only in this region are hospitals completely separated from ASLs and totally autonomous.

The classification of the Italian SSN goes far beyond the identification of the four groups/models described above; according to their composition by region, it seems that the favoured system is the integrated or semi-integrated, accounting for the majority of regions (16 out of 21). However, if the percentage of total national hospital beds directly managed by ASLs is taken into account (39%), the SSN appears to be a mixed/semi-separated system.

In line with the organizational configuration adopted by regional governments, technical support for governing the network of public and private providers, and managing the third-party payer function can be provided either exclusively by the regional departments of health (mainly in the centralized/integrated approach) or, alternatively, sharing this responsibility with specific regional agencies for health. In fact, some regions have formed agencies for health that are responsible for assessing the quality of local health care services and providing technical and scientific support to the regional health departments (again, mainly when a centralized/integrated approach is applied) and to the ASLs (where a mixed approach is adopted). So far, 10 regions have created such an agency:

- Emilia-Romagna (1994; modified in 2000)
- Friuli-Venezia-Giulia (1995)
- Campania (1996)
- Marche (1996)
- Piedmont (1998)
- Lazio (1999)
- Abruzzo (established in 1999; active since 2006)
- Tuscany (2000)
- Veneto (2001)
- Puglia (2001).

The different regional agencies cover various functions in their respective health care systems, including:

- research and development (in coordination with epidemiological observatories), in all agencies with the exception of those in Campania, Abruzzo and Veneto;
- assessment of the quality of services provided by health care providers (hospitals and other health care organizations) in the region;
- technical support for accreditation procedures (with the exception of Veneto);
- technical support to the ASLs and public hospitals for their financial planning and monitoring (in all regions except Lazio, Tuscany and Piedmont);
- technical support to the regional health departments for the definition of financing schemes and resource allocation (with the exception of Tuscany); and
- regulation and management of specific tasks in the regional health care system, such as continuous medical education and coordination of primary prevention (with the exception of Veneto and Abruzzo).

Further specific functions can be devolved by regions to their agencies, such as technical support for the development of regional health planning (Puglia, Tuscany, Campania and Abruzzo), capital investment programmes (Veneto) and the technical support to promote the application of management tools by public providers (Tuscany, Piedmont and Veneto) (ASSR, 2007).

4.1.2 Regulation and governance of providers

The 1978 reform that established the SSN conferred an important role to municipalities, which were given the role of governing the USLs of the time. However, a series of reforms starting in the late 1980s progressively shifted municipal powers to the regional level and transformed the USLs into public enterprises, the current ASLs. Starting in 1992, a network of public and private health care structures and providers began operating at the local level, and these can be divided into four different categories:

- local health enterprises (ASLs)
- public hospital enterprises (AOs)
- National Institutes for Scientific Research (IRCCS)
- private accredited providers.

ASLs

ASLs are geographically based organizations responsible for assessing needs and providing comprehensive care to a defined population. They were created in 1978 (then called USLs) and there were 659 of them before the 1992 reforms, which reduced their number, widened their population base, increased their autonomy and profoundly reshaped their organizational structure and management system. Regions became responsible for determining the size and organization of ASLs and monitoring their operation. As a result, the SSN had 228 ASLs in 1995, with an average catchment population of 250 000 inhabitants. Between 1995 and 2005, the number of ASLs was reduced by the regions further to 197.

ASLs provide care directly through their own facilities or through services supplied by AOs, research hospitals and accredited private providers (acute and long-term hospitals, diagnostic laboratories, nursing homes, outpatient specialists and GPs). A general manager appointed by the regional department of health, based on professional qualifications and technical skills, manages each ASL. General managers are appointed for 5 years, and their results are assessed every 18 months. General managers' contracts include targets to be reached within their five-year mandate, but, if mid-term targets are not met, they may be dismissed. The clarity and precision of targets and assessment procedures are extremely variable across regions. The general manager is responsible for ensuring the sound financial performance of the ASL and for fulfilling the objectives laid out by the regional health plan and by the local planning process. Legislation provides the general manager with substantial autonomy in managing human, financial and technological resources. This autonomy is expressed in a three-year strategic plan in which the general manager defines the organization's mission and goals. The general manager selects a financial manager and a medical director for support. Services are structured under a typical divisional model. Each division has financial autonomy over, and technical responsibility for, one of the three different areas of the health care system.

- Directly managed acute-care and rehabilitation hospitals (*presidi ospedalieri*) provide hospital-based acute inpatient, outpatient and rehabilitation care. These hospitals usually provide only secondary care. Physicians in these hospitals receive salaries directly from the ASL.
- Health districts are geographical units responsible for coordinating and providing primary care, non-hospital-based specialist medicine and residential and semi-residential care to their assigned populations. The number of districts in each ASL depends on its size and on other geographical and demographic characteristics. In 2005, the ASLs operated through 934 districts. The district's physicians provide home care services and preventive services for drug users and people with terminal AIDS. Primary care physicians, paediatricians and other specialists provide these services as independent contractors to the ASLs (see Chapter 6).

- Health promotion divisions are responsible for health promotion, preventing infectious and other diseases, promoting community care and enhancing people's quality of life. These divisions also provide services for controlling environmental hazards, preventing occupational injuries and controlling the production, distribution and consumption of food and beverages.

ASL services are financed under a global budget with a weighted capitation mechanism.[8] The global budget is also adjusted according to historical spending, and additional compensation is given for cross-boundary flows, which vary significantly from region to region and within each region. Hospital providers are paid fees for services based on DRGs for inpatient activities and through various mechanisms for outpatient and other specific health care services, such as intensive care, transplants and chronic patient management (see also Chapter 3).

During the last few years, due to the greater autonomy of the regions, many institutional innovations have been introduced. Different regions have identified new institutional arrangements and governance models for ASLs. In Tuscany, for example, the *Ente per i Servizi Tecnico-amministrativi di Area Vasta* (ESTAV) has been established. Each ESTAV (three in total) integrates three ASLs in the region (nine in total), aiming to better manage specific administrative processes to achieve higher economies of scale. Administrative functions, such as the purchasing of goods and services, health technologies, and technology assessment and management, have been centralized under the ESTAV.

AOs

Legislative Decree No. 502/1992 established public hospital enterprises as quasi-independent public agencies called AOs. AOs provide highly specialized tertiary hospital care (inpatient and outpatient). In 1995, 82 AOs were established by transforming hospitals that previously had been integrated with ASLs. By 2000, the number had risen to 98, mainly due to the increased number of hospitals given this status in the region of Lombardy (from 16 to 27). In 2005, the SSN had 102 AOs.

AOs have a national, or at least interregional, catchment population and were given financial and technical autonomy in 1993.[9] The conditions for obtaining AO status are: a divisional organizational structure; the existence of at least three clinical units considered by Legislative Decree No. 502/1992 to be "highly specialized"; a complete accident and emergency department with an intensive care unit; and a particularly complex case mix. The governing structure of AOs

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[8] In accordance with Legislative Decree No. 229/1999 and Law No. 662/1996.

[9] Pursuant to Legislative Decree No. 502/1992.

mirrors that of ASLs. Legislative Decree No. 229/1999 has provided general managers with more autonomy, which mainly materializes in the power to define a hospital's mission and objectives through a three-year strategic plan, consistent with the recommendations of the regional health plan. Although prospective payment remains the main source of reimbursement, the legislation states that providers are to be paid based on a global budget negotiated yearly by the regional departments of health, ASLs and AOs (see Chapter 3).

A specific group of AOs can be identified in the Teaching Hospital Trusts Network where health care delivery is augmented by research as well as teaching activities.[10] There were 27 teaching hospitals in 9 regions, 25 public and 2 private (both in Rome) in January 2008. Planning and regulation, as well as the governance model, take into account the presence of universities that participate in the appointment of a teaching hospital's general manager. Health care activities are financed on a fee-for-service basis by regions.

IRCCS

The IRCCSs are research-oriented hospitals operating at the local level with competences in research and treatment of important diseases. The IRCCSs represent a national network where basic and translational biomedical research is undertaken in synergy with the delivery of high qualitative health care. In April 2008, 42 IRCCSs, 18 public and 24 private, were distributed among 13 of the regions. The public IRCCSs' governance model is based on the distribution of planning, financing, research, regulative and monitoring competences between the region where the IRCCS is located and the national Ministry of Health. The Ministry of Health is responsible for authorizing hospitals as an IRCCS and for monitoring their scientific activity. It also identifies the Scientific Director of each public IRCCS and provides basic funding for scientific research. Health care activities are mainly financed by the regions on a fee-for-service basis. Legislative Decree No. 288/2003 revised the overall organization of these institutes, transforming them into foundations or reorganizing them according to criteria that conform to research requirements and participation in a national network of centres of excellence. This Decree, among others, modifies the governance model both for public and private IRCCS, foreseeing the establishment of a Board of Trustees that would nominate the general director.

Private accredited providers

Private accredited providers supply ambulatory care, hospital treatment and/or diagnostic services financed by the SSN. The regional departments of

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[10] Pursuant to Legislative Decree No. 517/1999.

health regulate this participation through the authorization and accreditation system. Authorization is required for the construction and operation of the following services:

- acute hospitals providing inpatient and day-hospital care
- ambulatory care settings (including rehabilitation and laboratory diagnostics)
- centres providing residential care and social care.

Authorized private health care organizations are financed by regional departments of health under a DRG payment scheme after having been accredited by the same body. In some regions, such as Lombardy, ASLs contract with private providers for services to be supplied and to determine the level of payment. In other regions, the regional departments of health directly negotiate with private providers (e.g. Abruzzo).

Institutional accreditation is conferred by regional departments of health in order to guarantee the quality of services provided, on the basis of several structural, organizational and technological prerequisites. These prerequisites are defined at the regional level, in order to ensure regional autonomy and respect for local distinctive features. A National Commission for Accreditation and Quality of Care[11] is responsible for defining the general criteria to be used to select providers and for assessing the accreditation model chosen by different regions.

Other additional conditions set by regional departments of health for private accredited providers include:

- formal acceptance of the financing scheme
- formal acceptance of the external system for auditing quality of care
- legitimacy and accuracy of annual reimbursement claims
- availability of quality peer-review programmes
- participation by users in systematically reviewing the quality of services provided
- adoption of ‘health service charts’ (see Chapters 2 and 7)
- acceptance of control based on clinical results.

4.1.3 Regulation and governance of the purchasing process

The 1999 health care reform devolving health care provision to the regions also introduced measures to regulate the purchasing function, clarifying the boundaries between public and private services within the internal market and reducing the scope of private providers within the public system.

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[11] This was established by Legislative Decree No. 229/1999 (Art. 19-*bis*).

Purchasing was first regulated by Legislative Decree No. 229/1999, which specifies that the comparative evaluation of quality and costs should be used in selecting the providers (public and private) allowed to provide services on behalf of, and with funding from, the SSN. To promote fair competition between providers, while simultaneously ensuring the quality of care, the 1999 legislation employs the concept of accreditation and establishes a four-step process for selecting providers, to be applied to both inpatient and outpatient care.[12] The current situation is as follows:

- Authorization to establish health care amenities is only needed to build new facilities or to modify old ones and is granted by municipalities after agreement with the regional health planning unit.
- Authorization for delivering health care services is granted by the regional departments of health once a minimum set of structural, technological and organizational requirements has been satisfied.
- In Italy, the model of accreditation is mandatory or 'regulatory'. This model is characterized by a top-down process, with the introduction of accreditation as a means of regulating the internal market and/or improving and guaranteeing health care quality against explicit standards. A public authority drives the systematic process of monitoring compliance with explicit health care quality standards (unlike Anglo-American models, where health care professional bodies undertake this role). This does not mean that at the professional level there are not any examples of voluntary accreditation, peer review, and so on. They do exist, but as occasional activities, not always based on explicit criteria and which, on their own, are not designed to affect quality of health care as a whole.

Regional departments of health grant institutional accreditation following two criteria.[13] The first requires regular assessment of the quality of the organizational, managerial and technological infrastructure of health care providers and of the skills and practices of health professionals. The second requires the evaluation of the value added by each newly accredited provider, taking into consideration existing regional health services and the benefit package to be delivered in order to control the entry of new providers into the public health market on the basis of planned need.

The central government should establish the general criteria for final inclusion or exclusion in collaboration with regions (as explained below), although not all

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[12] The concept of accreditation was first introduced within national health care legislation in 1992, followed by further legislation in 1994 (Law No. 724/1994), which contained transitional measures whereby regions could enter into agreements with private providers ('temporary accreditation') while deciding on the accreditation procedure to be adopted. However, only in 1999 was this issue addressed systematically.

[13] As laid out by Legislative Decree No. 299/1999.

the regions have followed this national requirement (e.g. Lombardy and Sicily). Institutional accreditation is therefore ultimately a regional responsibility based on specific criteria related to structure, process and outcome, and is mandatory before contractual agreements can be entered into. However, accredited status does not automatically confer the right to deliver health care services funded by the SSN.

- Contractual agreements are the last step in the selection process performed by regional and local authorities. Contractual agreements are therefore negotiated between ASLs and the accredited 'preferred providers', which are chosen by the ASLs in collaboration with regions on a value-for-money basis (that is, through a comparative evaluation of quality and cost). Contractual agreements describe the amount, the price and the quality of the services to be delivered by each provider (with penalties for exceeding agreed-upon volumes), together with the specification of other relevant details, such as maximum waiting times and health targets to be achieved. The length of a contractual agreement is not specified within national law. However, some regions tie this to the annual (regional) financial law, redefining agreements on the basis of available economic resources.

Legislative Decree No. 229/1999 made the regions responsible for organizing and managing the accreditation process. In order to combine regional autonomy and the national government's need to guarantee homogeneous levels of quality, the Decree provided that regional accreditation processes must follow some general criteria and principles issued by the national Ministry of Health via National Policy and Coordinating Act (*Atto di Indirizzo e Coordinamento*).

Several years after its introduction, implementation of the accreditation policy at regional level has been delayed by several problems. Indeed, few regions have passed legislation for mandatory accreditation programmes and yet fewer have actually started to implement accreditation processes (Lombardy, Emilia-Romagna, Marche, Piedmont, Liguria, Tuscany and Friuli-Venezia-Giulia being exceptions). In regions where the accreditation process has not started, regional governments continue to confirm agreements with existing providers. The reasons for this delay are varied: some are related to the central government's intransigence while others spring from the organizational and cultural differences among regions. As yet, the national government has not issued the National Policy and Coordinating Act, which would set national quality criteria, partly due to unresolved constitutional issues associated with the wider devolution process. This seems to have stopped some regions from organizing their accreditation programmes, while others do not acknowledge the constitutional legitimacy of the central government to issue such legislation.

In 2002, a study on 'accreditation implementation problems' in the Italian regions was conducted by the ASSR (ASSR, 2002).[14] Some of the main results of this national survey are presented here. A major problem pointed out by the regions related to the relationship between regional planning and accreditation. The additional step from accreditation to conferring contractual agreements is supposed to imply a selection of providers based on a comparative assessment of quality and costs, together with an evaluation of actual regional health needs. This process can cause friction between regional authorities and different stakeholders, and can also give rise to problems of political consensus, as some of the health care providers, which have always been funded by the SSN, theoretically now could be excluded from public reimbursement.

Moreover, there is sometimes a considerable quality gap between public and private providers, resulting in a problem of equity. The most important health facilities in Italy are public and they do not always fit the quality standards set for both authorization and accreditation. Nevertheless, it is almost impossible for regional authorities to close the internal market to these providers, and this is often due both to stakeholder pressure and/or a lack of alternatives in the catchment area. Some regions reported that they experienced a lack of culture of quality among providers usually depending on health professionals' individual attitudes and sense of initiative. As a result, the key message about accreditation as a means of securing health care quality has been slowly acknowledged, although it still tends to be seen by providers more as a means to control health professionals' independence. Other problems have included the high costs of complying with standards,[15] the long delays due to institutional and administrative problems associated with passing mandatory accreditation legislation, the lack of a National Policy and Coordinating Act setting out general principles and accreditation criteria, and problems with defining and assessing accreditation standards at regional level. It should not be taken for granted that the specific expertise needed to define health care accreditation standards is always available at regional level, above all in those regions where health care provision has never reached high levels of quality (ASSR, 2002).

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[14] The ASSR was commissioned by the National Committee for Quality and Accreditation (CNAQ) to conduct this study on regional accreditation systems. The CNAQ is a national standing committee, whose members are chosen by the national Ministry of Health, tasked with monitoring and assessing the implementation of mandatory accreditation in the regions. The study used a qualitative research method to elicit the main regional stakeholders' points of views on this issue. Twenty-one focus group interviews were run, one for each region and the Autonomous Provinces of Trento and Bolzano. Each group was usually composed of 5–10 participants representing different stakeholder categories (for example, regional officers/public financers, public and private health care providers and citizens' associations). Results of the study are available at http://www.assr.it/monitor/monitor_2002/Monitor_02.pdf.

[15] The higher costs are related to authorization standards and the most difficult structural requirements, particularly as many hospitals are located in old historic buildings.

Among the regions that have implemented accreditation systems, two main models have emerged: one in Emilia-Romagna and the other in Lombardy. In Emilia-Romagna, accreditation is characterized by a strong focus on the professional training of evaluators, the involvement of stakeholders and a linkage between contractual agreements and regional planning. In this model, there is an attempt to use accreditation not only as a means of selecting providers but also as a way to systematize and homogenize the different experiences of quality improvements within AOs and communities. On the other hand, Lombardy has defined a minimum set of quality standards for accreditation and has left the development of quality programmes aimed at excellence to the autonomous initiative of ASLs and AOs. In this model, accreditation is not a means of selecting providers on the basis of regional plans, since all accredited bodies are automatically allowed to provide services for the regional health service. Nonetheless, Lombardy has slightly changed its model by regulating (via the Regional Health Plan 2002–2004)[16] the entrance of new providers into the public market, in accordance with the national standard of 4.5 beds per 1000 inhabitants (ASSR, 2004; Lo Scalzo and Liva, 2004).

The Financial Law for 2007 (Law No. 296/2006) also deals with the issue of institutional accreditation, stating that regions have to complete their accreditation programmes by 2010: temporary accredited providers have to be institutionally accredited by 1 January 2008 (pursuant to regional planning legislation), and new providers that have had a 'tentative accreditation' have to undergo institutional accreditation procedures by 1 January 2010. This law could speed up the process, pushing regions that until now have not passed even framework legislation on regional accreditation procedures or issued a handbook on quality standards to comply with national rules (e.g. the Abruzzo Regional Government quickly passed its accreditation law in February 2007).

4.2 Planning and health information management

The 1978 reform established that the central and regional governments should be in charge of health planning. However, no national health plan was approved before 1992, and only some regions had approved their own plans. Since the early 1990s, Italy's approach to planning and managing health care has changed substantially. Concerns about the sharp increase in health expenditure, inadequate access to health services and overall dissatisfaction with services prompted the 1992 reform, which moved the SSN away from a public integrated

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[16] This is not, technically speaking, 'proper' regional planning based on a needs assessment.

model towards a decentralized, market-oriented one. The main aim of the market-oriented model was to enhance the efficiency, efficacy and quality of all SSN health care services. This shift involved a change in the way the role of the central government was conceived, which was, in principle, to be restricted to establishing and safeguarding the basic principles for health services and controlling global spending through appropriate framework legislation. Moreover, reforms in 1999 implied something of a departure from the market model, and a further shift in the definition of state intervention, by strengthening the planning responsibilities of managing bodies at the regional level.

According to the formal regulatory framework, health care should be planned through the involvement of the relevant actors in central, regional and local government and should aim to fulfil the main objectives of the SSN. The sections below briefly describe what the tasks of the different actors should be, but it should be noted that often these tasks are not all fulfilled to the letter.

The central level

Depending on the resources available (set out in three-year National Financial Plans), public funds are allocated annually to various welfare programmes through the annual national budget. Based on this general framework, the level of resources to be dedicated by the regions for health care services is negotiated annually with the central government. Furthermore, each region, on the basis of regional taxation, annually determines its own-resource budget for its health care system. A National Solidarity Fund has been set up by the central government to transfer money from high income regions to mid- and low-income regions in order to permit all regions to provide LEAs to their population. However, this Fund is not fully operational as yet (see Chapter 3).

According to current legislation, objectives, targets and activities in the National Health Plan should be defined taking into account the proposals set out each year by the regional health departments, based on the health status of their populations and on the supply of services. Each health objective included in the National Health Plan is then further developed into a set of targets – some defined in general terms, and others more precisely – that must be met at the regional level. Each objective is linked to activities that represent an area of priority intervention to be included within regional and local plans.

To make planning effective in implementing change, the National Health Plan includes targeted actions such as national and local regulations, guidelines outlined by experts and measures to make citizens conscious of the main health care issues. The national Ministry of Health is responsible for supporting, monitoring and assessing implementation of the National Health Plan objectives, and an Observatory established within the Ministry's Health Planning

Department monitors implementation and supervises regional departments of health. The Ministry of Health also provides earmarked funding to promote specific priorities defined by the National Health Plan. Lines of action are defined in accordance with the Standing Conference on Relations between the State, the Regions and the Autonomous Provinces.

The regional level

The regional departments of health are responsible for pursuing national objectives at the regional level according to their own political agenda. The Regional Health Plan translates objectives and targets into financing and organizational measures, taking into account regional needs as assessed by specific epidemiological studies. The regional strategic planning process has to be formalized into a regional health plan, and its effective local implementation has to be verified by the Standing Conference on Relations between the State, the Regions and the Autonomous Provinces. The governors of each region and autonomous province are members of the Conference. A General Secretary undertakes the technical coordination of the Conference's activities, while the political coordination and the Chairmanship is assumed by the governor of one of the regions for five years. Tuscany is currently undertaking this role (until 2011).

In theory, regions are accountable to the central government for fulfilling health care targets. Regions have to provide an annual report on the implementation of their regional health plan.[17] This report is aimed at monitoring and ensuring the achievement of the health care targets established by the National Health Plan. The central–regional link in the strategic planning process is further guaranteed by delegating to the regions the task of drawing up proposals for the National Health Plan based on the needs assessment performed at the local level. Finally, other planning-related tasks attributed to regions consist of defining the boundaries of ASLs and health districts, as well as the criteria for controlling the behaviour and performance of the ASLs.

The local level

ASLs are responsible for delivering the benefit package by directly providing services or by funding AOs and private accredited providers. The activities to be performed are defined in the local implementation plan, which should be consistent with the regional health plan. ASLs have to guarantee equal access to services for all citizens, the efficacy of preventive, curative and rehabilitation

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[17] Pursuant to Legislative Decree No. 229/1999.

interventions and efficiency in the production and distribution of services.[18] They are responsible for maintaining the balance between the funding provided by regions and expenditure for services.

ASLs are organized into health districts responsible for ensuring the accessibility, continuity and timeliness of care. Health districts also have the role of encouraging an intersectoral approach to health promotion and ensuring integration between different levels of care and between health services and social services. The health district, therefore, represents both an operational body for providing services and a vehicle for promoting health projects that integrate various operational structures, in accordance with the strategic plans of the region and the ASL. The general manager of the health district is supported by a coordination office to achieve these objectives. This office includes representatives of GPs, paediatricians and other clinical specialists to promote the integration of health care and social services, which is also accomplished by developing and disseminating general organizational guidelines.

4.2.1 Health Technology Assessment

HTA can be undertaken at the macro level (both at the regional and national levels) and at the meso level (that is, by the ASLs and AOs) as an evidence-based tool to rationalize the purchasing process and the introduction of new technologies. No national agency is responsible for conducting, promoting, coordinating and/or financing HTA activities, and few regions have established formal HTA agencies or units (although there are some important HTA experiences at the meso level). Despite the fact that, in recent years, HTA has figured more prominently on political decision-makers' agendas, Italy has not yet formalized its HTA activities in a systematic way.

A survey conducted by the ASSR on the diffusion of HTA in Italy[19] showed that, in 2005, few regions had created a HTA office/unit or a proper HTA agency. However, 59% of the responding public hospitals, and 47% of the responding ASLs stated that they performed some HTA activities. Nonetheless, an analysis of the data highlighted many differences in the definitions of HTA, and in the methodologies, technologies and dimensions assessed. Moreover, standardized procedures for writing HTA reports and guidance were rare. The

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[18] As stipulated by Legislative Decree No. 229/1999 (Art. 3).

[19] The survey was conducted by the ASSR within the framework of a two-year national project (*Promozione di un network di collaborazione per la diffusione delle metodologie di HTA per la gestione delle tecnologie delle Aziende Sanitarie, 2002–2005*) in partnership with several regional health care bodies. The project aimed to promote the creation of a network of local health and AOs involved in HTA and to facilitate the dissemination of HTA principles and practices at the regional and local levels. The results are synthesized in Cerbo, Cicchetti and Morgese, 2005.

survey highlighted that the meso level was more receptive towards HTA than the macro (regional) level (just 8 out of 19 regions answered the questionnaire). Overall, however, HTA seemed to be conceived more as a means of controlling costs than for appraising the overall impact of introducing new technologies (Cerbo, Cicchetti and Morgese, 2005).

The most important HTA activities at the regional level are undertaken by the health agencies of Emilia-Romagna, Friuli-Venezia-Giulia and Veneto. These agencies were created to provide technical support for the planning and evaluation process. In 1989, the Centre for the Assessment of Biomedical Equipment, located in Trieste, was established and became an important embryonic experience in the field of HTA. In 1993, in Veneto, a regional Centre for Technology Assessment and Quality Improvement in Health Care was created, with the aim of carrying out integrated assessments of individual technologies (epidemiological, clinical and economic). It is worth pointing out, however, that the assessments are not mandatory for new or referred technologies.

At the national level, with the Finance Act of 2003, the National Committee for Medical Devices was established. Its main objective is to update and define all medical devices into categories and subcategories, with reference prices. In particular, the aims of the Committee are:

- to make the medical devices market transparent;
- to produce technology assessment reports, highlighting the cost–benefit and risk–benefit ratios of new devices;
- to monitor the medical devices market, consumption and prices; and
- to foster research on medical devices.

The Committee has defined a National Classification of Medical Devices. The list does not include drugs, cosmetics, or human blood and its derivatives. The new classification lists all medical devices – characterized by an alphanumerical code – in 22 categories, 122 groups and types (articulated at five levels). In addition, the network of HTA agencies and units sponsored by the ASSR national project 2003–2005 (see footnote 12, p.79) allowed the publication of a national methodological paper on HTA (Carta di Trento, 2006). This was the first step towards the creation, in 2007, of a scientific society – the Italian Society of Health Technology Assessment (*Società Italiana di HTA*), whose aim is to promote the diffusion of HTA methodologies and best practices. With these crucial steps, HTA began to play a part in the latest National Health Plan, as an important tool in health policy. Late in September 2007, the Standing Conference on Relations between the State, the Regions and the Autonomous Provinces gave the ASSR, in collaboration with the national Ministry of

Health, the remit of appraising technologies and supporting dissemination and implementation of HTA results at the regional level.

4.2.2 Information systems

In February 2001, the Ministry of Labour, Social Services and Health and the Standing Conference on Relations between the State, the Regions and the Autonomous Provinces agreed on the joint development and operation of the New Health Information System (*Nuovo Sistema Informativo Sanitario* (NSIS)) as a governance tool to support, oversee and monitor the LEAs.

The NSIS strategic framework has two primary development objectives:[20]

- To build an integrated system of homogeneous, individual health care information records, where patient information and the care delivery structure are the central information items. The goal is to make information available on the operating facilities at all health care levels, the services delivered, the resources used, and the related costs.
- To contribute significantly to public health authorities' governance principles and capabilities by ensuring that the required analytical data on individual citizen health care is available.

These priorities are based on the following general principles:

- to support the regional devolution process;
- to achieve more cohesion among the SSN's different actors;
- to integrate different information systems that are autonomously managed by regional and local authorities; and
- to improve citizens' knowledge of the information system, integrating each patient's health information.

In particular, the NSIS has seven main objectives that cover different needs:

- developing integrated systems of individual health information in order to establish an electronic patient file;
- monitoring health care providers;
- monitoring the LEAs and the appropriateness of interventions;
- monitoring costs and waiting lists;
- monitoring and safeguarding mental health care;
- monitoring the 'life-cycle' and consumption of pharmaceuticals; and

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[20] See the web site of the Ministry of Labour, Social Services and Health (http://www.mattoni.ministerosalute.it).

- developing an observatory to make data on public investment in health available to the Ministry of Labour, Social Services and Health, regions and ASLs.

A core part of NSIS is represented by a nationwide clinical coding programme, the so-called ‘bricks’ programme, which establishes the semantic toolkit required to ensure a common language to classify and codify concepts in a uniform manner, to share methodologies for measuring quality, efficiency, and appropriateness of services, and to allow an efficient exchange of information between the national level and regional authorities.

The programme is organized into 15 thematic subprojects, with teamwork (guided by a region) responsible for managing each subproject (e.g. Tuscany and Sicily are handling the development of clinical coding for patient records; Lombardy and Molise are developing outpatient performance measures; and Lombardy and Puglia are developing primary care and home care performance measures). Given the complexity of the objectives, an incremental approach has been adopted so that different, progressive levels of achievement have been defined. For example, the development of an integrated system of individual health information has involved several steps (Box 4.1).

Box 4.1	**Development stages for an integrated individual health information system**
Step 1	For each event, to make coded information available on citizens, services and providers
Step 2	For each event, to make information available on outcomes
Step 3	To make information available on clinical pathways and individual health information (patient file)
Step 4	To integrate the monitoring systems for health and social services

Since June 2002, the development of the NSIS has been overseen by the so-called *Cabina di Regia*, bringing together the Ministry of Labour, Social Services and Health, representatives from the Ministry of the Economy and Finances, the Ministry of Innovation and Technologies, the ASSR, along with some regional ministries of health (Emilia-Romagna, Lazio, Lombardy, Tuscany, Umbria and Veneto). The ‘bricks’ programme has been the focus of considerable effort and is one of the most mature elements of Italy’s developing electronic health programme.

4.2.3 Research and development

The aim of the Ministry of Labour, Social Services and Health's research policy is to provide a scientific basis for planning interventions directed at improving the population's health status, through the promotion and funding of high-quality scientific research in biomedicine and health.

There are two main streams of health research.

- *Current research*. This is developed by the IRCCSs in specific branches of biomedicine and public health. IRCCSs are independent hospitals of national relevance working according to standards of excellence to specify research aims (mainly clinical), and which have a direct impact on patient care in the biomedical field, as well as in the organization and management of health services, with special reference to highly specialized hospitalization and health care. The research activity within IRCCS is promoted by the Ministry of Labour, Social Services and Health through a share of the funds available to regions for health care services allocated annually to research, in addition to funds given by regions and other public as well as private bodies. Moreover, in order to improve clinical research, the Ministry has recently promoted the organization of IRCCS networks in some specific fields, such as cancer, stroke and paediatric diseases.
- *Finalized research*. This is directed at meeting the priorities defined by the National Health Plan with regard to health and biomedical research. These research projects are approved by the Ministry of Labour, Social Services and Health, together with the Ministry of Universities and Research, in order to stimulate synergies and coordination, and are developed by regional authorities, the ISS, the ISPESL, the ASSR, the IRCCSs and the Experimental Zooprophylactic Institutes. Universities, other research institutes, private or public companies and the National Research Council can take part in research projects on the basis of specific contracts or agreements. By 2000, managerial research, directed towards the development of new nationally relevant, organizational and managerial models, was included in the research agenda (Legislative Decree No. 229/1999, Art. 12-*bis*).

In 2004, the Ministry of Labour, Social Services and Health introduced the National Commission for Health Care Research to coordinate its research and development policies. The Commission is responsible for:

- defining research priorities and programmes;
- selecting research and clinical trials programmes, monitoring research projects and evaluating and disseminating results; and
- providing consulting services and supporting the Ministry of Labour, Social Services and Health.

Other institutions provide the development of both clinical and managerial research programmes, in particular the AIFA and the regional health agencies.

- *AIFA*. This agency promotes and funds non-profit clinical comparative research to verify the therapeutic efficacy of new pharmaceuticals. In particular, AIFA promotes the production of knowledge in those branches of health that are not commercially relevant and thus risk being marginalized.
- *Regional health agencies* (Section 4.1.1). For example, the Emilia-Romagna Health Agency has invested in technological and organizational innovation by funding research programmes directed at improving knowledge on clinical efficacy and its organizational and economic implications. In particular, funds are directed towards the development of new technologies, assessing their impact (in terms of both efficacy and efficiency), and monitoring technology uptake in order to identify the cultural and organizational conditions that favour effective implementation.

5 Physical and human resources

5.1 Physical resources

5.1.1 Infrastructure

Planning and distribution of infrastructure

Authorization to establish health care structures is only needed to build new facilities or to modify old ones, and is granted by municipalities after agreement with the health planning unit at the regional level.[21] In many cases, the region itself grants financial aid to public plans for setting up new facilities or restructuring old ones. For private structures, no formal planning exists, although authorization is needed.

In 2003, Italy had 265 000 hospital beds: 88% were dedicated to ordinary admissions and 12% to day-hospital activities. Of the 232 000 beds for ordinary admissions, 79.6% were public (versus 81.5% in 1998) and 20.4% were private but accredited by the SSN.

Figure 5.1 shows the trends in the number of beds from 1996 to 2006. In particular, the number of acute beds per 1000 population decreased, from 5.4 in 1996 to 3.3 in 2006, which is below the 4.5 value strongly recommended by the current legislation. The standard was set at 5 beds per 1000 population (including long-term care and rehabilitation beds) by legislation in 2001; a successive agreement signed in 2005 between the regions and the central government lowered the standard to the current 4.5 beds per 1000 population. In the same period, long-term care and rehabilitation beds decreased from 0.9 to 0.2 beds per 1000 population (the legislation recommends 0.5 long-term-care beds).

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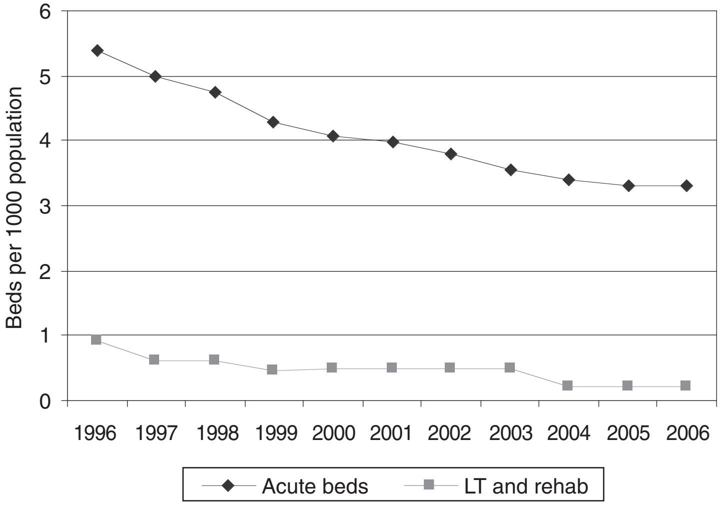
[21] Pursuant to Legislative Decree No. 229/1999.

Fig. 5.1 **Bed mix in acute-care hospitals and long-term-care institutions (LT and rehab) in Italy, 1996–2006**



Source: WHO Regional Office for Europe, European Health for All database (various years).

The changes in bed utilization are an expected result of the initiatives to control health expenditure, foster hospital efficiency and reduce waste (see Chapter 3 for a detailed analysis of the impact of the prospective payment system).

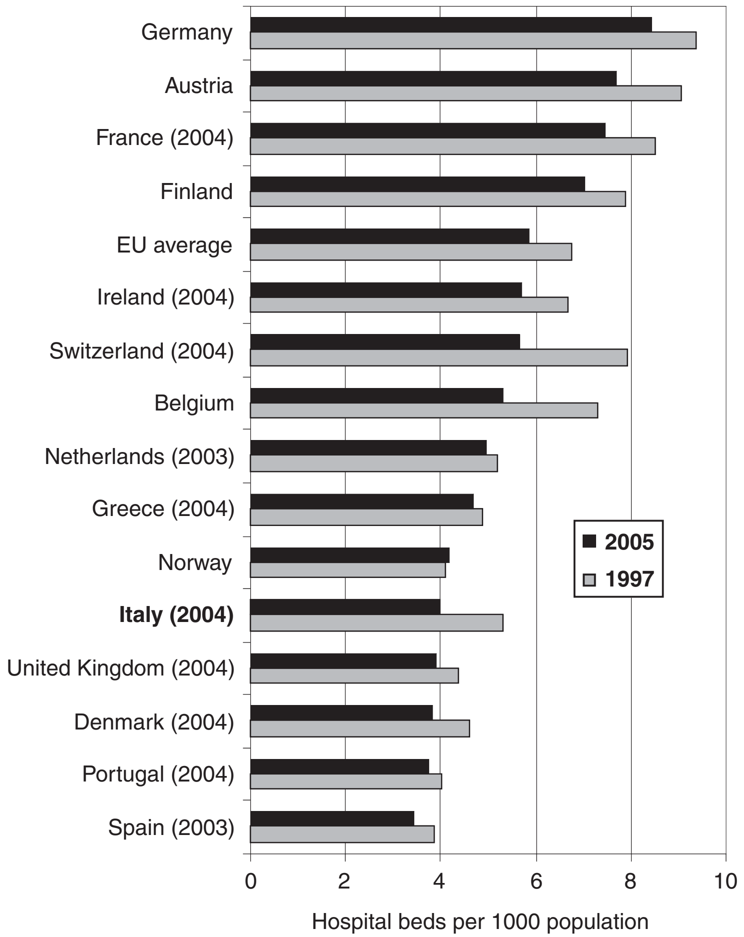
Section 6.3.2 provides information on the number of hospitals delivering care in Italy. In terms of hospital bed numbers, both Fig. 5.2 and Fig. 5.3 clearly show that Italy's hospital bed rate was comparable to the EU15 average in 2005. It was higher than that of the United Kingdom or Spain, but considerably lower than in France and Germany.

5.1.2 Capital investment

From 1980 to 1993, the Ministry of Health allocated a percentage of the National Health Fund to capital investment: new buildings, renovation and new technologies. Resources for different projects and geographical areas were allocated centrally. A national commission established at the Ministry of Health was responsible for selecting the projects to be funded.

Since 1993, funding for renovating existing facilities, building new hospitals and renewing the stock of advanced medical equipment is mainly through a programme approved in 1988 with around €10 billion, while 10% is financed

Fig. 5.2 Beds in acute-care hospitals in western Europe, 1997 and 2005

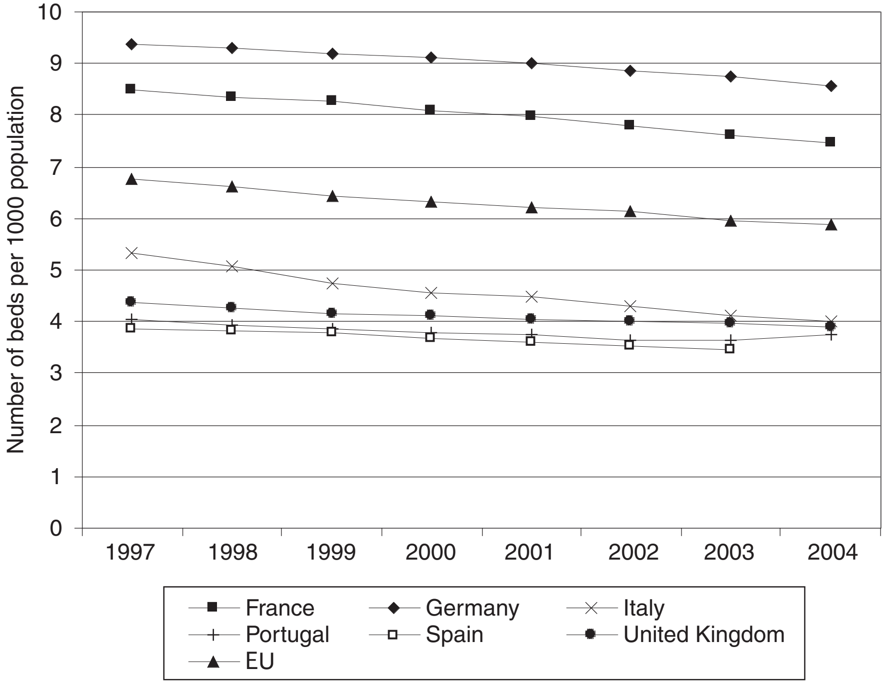


Source: WHO Regional Office for Europe, European Health for All database (various years).

from the current expenditure account. The programme was renewed in 1998 with the approval of new investment plans aimed at significantly improving health care infrastructure. In particular, additional earmarked funds were provided to develop radiotherapy facilities and to build structures reserved for physicians wishing to conduct private care within public hospitals. The 2008 budget further boosted these investments, raising the funds to nearly €20 billion.

Additional capital funding comes from ASLs and AOs, particularly income from property sales or bank loans. Borrowing requires authorization from the regional government and is subject to strict national rules. The scarcity

Fig. 5.3 **Beds in acute-care hospitals per 1000 population in Italy and selected western European countries, 1997–2004**



Source: WHO Regional Office for Europe, European Health for All database (various years).

of funds for investment has had the effect of pushing managers of ASLs and AOs to adopt a more business-like approach to managing their assets. This has meant disposing of surplus land and exploring the potential for commercial exploitation of service sites, as well as searching for public–private partnerships. In the last few years, ASLs and AOs have developed some pilot programmes in public–private financing for specific projects (France, Taroni and Donatini, 2005).

5.1.3 Information technology

Similar to other EU countries, information and communication technology's (ICT) relevance in health care delivery systems is increasing in Italy. ICT services are often used to support health care processes at different levels of care and to enhance accessibility to health care services for the population. Data from the European Information Technology Observatory (2004) shows that Italy – in absolute numbers – ranks third (after the United Kingdom and

Germany) in Europe, and is among the top five countries in the world (after the United States, Japan and the Scandinavian countries) in terms of the number of people with Internet access. According to the National Institute of Statistics (*Istituto Nazionale di Statistica* (ISTAT)), the penetration of Internet use in Italy is 43% of the population compared with an average European penetration of 54% (ISTAT, 2008). People are accessing the Internet on a regular basis and there is a constant increase in use. Nevertheless, according to ISTAT data (2008) the diffusion of the Internet is still insufficient compared to the most advanced countries.

Information technologies have not been introduced into health care organizations in a homogeneous way throughout the country. Unfortunately, there are no surveys performed by the Ministry of Health or other central health care institutions on the diffusion of ICT in hospitals or on ICT expenditures in health care organizations. Available data show that ICT expenditures in Italy amounted to 4.8% of GDP in 2008, compared to an average expenditure of 5.6% in Europe. In the health care sector, investments in ICT grew by 2.1% during 2007–2008 (Assinform, 2009).

A survey undertaken by Confservizi-FIASO-CNR (2002) on the use of ICT in health care organizations identified three clusters of organizations according to the level of ICT spending: the largest number of organizations spend about 0.2% of their budgets on ICT in order to guarantee some minimal administrative functions (e.g. accounting and payroll); most of the organizations spend 0.7% of their budgets on some ICT applications for administrative functions and diagnostic services; very few organizations spend about 3% of their budgets on using ICT as an integrated tool to support health care delivery systems and managerial decision making.

As far as the Internet is concerned, recent research on the diffusion of the use of the Internet in the Italian health care sector shows that on average only 58% of health care organizations have a web site; in northern regions this figure is 68%, 53% for central regions and 51% for southern regions (Forum et al., 2005). Ninety per cent of AOs and ASLs have their own web sites, compared to 41% for private health care providers. The existing web sites provide mainly information about the health care organization and the services offered by the AO or ASL as a one-way communication channel. Nevertheless, the Virtual Transaction Space, which is the web site section dedicated to patient interaction with health care organizations, has a significant diffusion rate (10–30%). Other forms of virtual communication between patients and health care organizations (i.e. clinical information) have very little diffusion (less than 5%).

Many Italian regions launched programmes to create electronic patient records using the Internet to connect patients, GPs, other health care professionals and hospitals. Among the regions, the CRS–SISS (CRS, Regional Services Card; SISS, Health Care Information System) project in Lombardy can be considered, at the moment, to be the most advanced experiment in the creation of an integrated e-health strategy. The 'Healthcare Extranet' represents the core of the project, which links professionals, social services, organizations and citizens, tracking all the events that occur in the patient treatment pathway and providing value-added services. It is based on smart card technologies, granting access to the network to both citizens and health care professionals through their CRS. A CRS allows every citizen to access all public administration services and enables them to access private services. On the other hand, the SISS is the regional network connecting all health and social care players in Lombardy and provides e-health services to ensure continuous care.

5.1.4 Medical equipment, devices and aids

Purchasing of medical aids and devices (gloves, needles, tissues, etc.) must always take place via a tendering process where the ASL or AO issue a call for tender and then choose the best supplier on the basis of the tendering rules set out by the current European directive (Directive No. 18/2004). The procedure for specialized items (such as prostheses) are different in that physicians can indicate their particular requirements and a specific call for tender is issued to select the supplier that best fits the stipulated requirements.

Purchasing unions have been established at the national, regional (Tuscany, Umbria, Marche, Emilia-Romagna, Lombardy) and local levels. In particular, the national purchasing union, CONSIP, mainly deals with office supplies, while regional and local level purchasing unions tend to specialize more on medical aids and devices. Local level purchasing unions are made up of three or more ASLs who join forces to purchase mainly pharmaceuticals for hospital consumption and non-specialized medical aids (needles, gloves, etc.). In some rare cases, specialized items are bought by purchasing unions. Purchasing unions have led to significant cost saving (20–30%) for hospitals and ASLs.

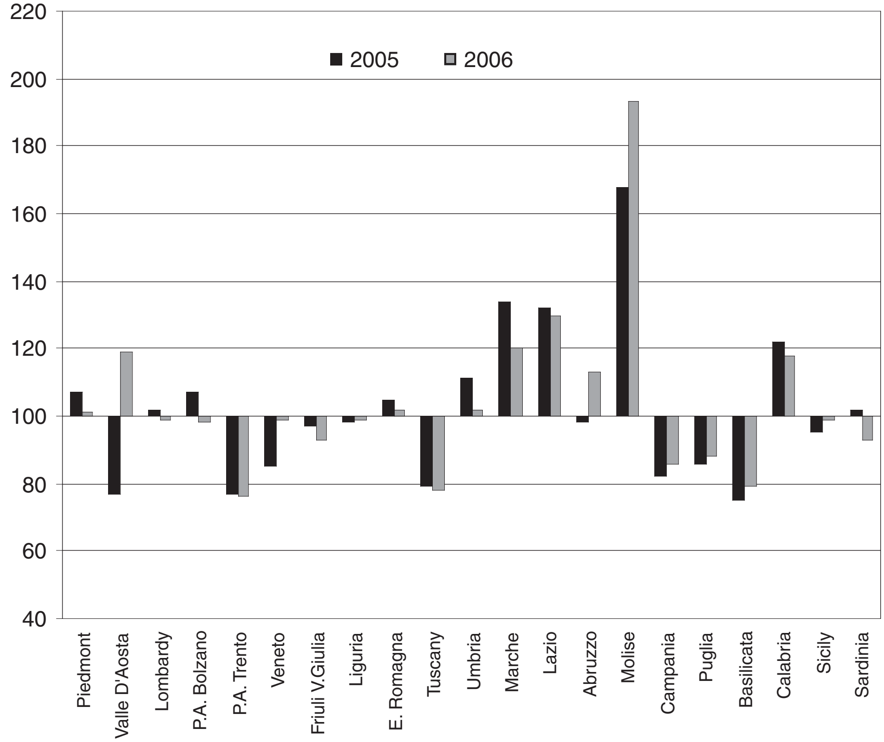
Funding for the major pieces of medical technologies for diagnostic imaging, clinical laboratory services and therapeutic interventions comes from three different sources:

- public funding from the central or regional government;
- public funding from the ASL/AO, which can raise money through bank loans, by selling non-strategic assets or by using money donated by private donors (sometimes private citizens, but in most cases foundations); and
- fund-raising by private citizens.

In most cases, no control exists over the acquisition of big ticket technologies, although for magnetic resonance and positron emission tomography the regional government can impose some form of control to avoid an inequitable allocation of resources. Nevertheless, the lack of central control has meant that big ticket technologies are not uniformly available across the country. Figure 5.4 shows the results of a recent survey of technological resources across the country by region. Values greater than 100 indicate that the levels of technology (magnetic resonance imaging units and computed tomography scanners) per head of population are higher than the national average.

The results in Fig. 5.4 demonstrate how the importance of technology has generally grown between 2005 and 2006, although not uniformly across the country. Alongside regions with a constant level of technology (Lombardy, Trento, Veneto, Lazio), other regions have experienced a significant increase. Nine regions have values in both years greater than the national average, with

Fig. 5.4 **Technology index (magnetic resonance imaging units and computed tomography scanners) in Italy, 2005–2006**



Source: Ministero della Salute, 2006a.

Note: P.A: Autonomous Province.

Molise reaching the highest score (193) in 2006; other such regions are Lazio, Calabria, Valle d'Aosta, Umbria and Marche. A possible explanation for this pattern is related to the willingness of smaller regions (or, in some cases, the strong pressure exerted on them) to offer their populations the latest innovations in diagnostics.

5.2 Human resources

5.2.1 Trends

The number of health care professionals generally increased in Italy from 1990 to 2006 (Table 5.1). Specifically, the number of active physicians grew during the 1990s and early 2000s, with a decline in 2006. The number of dentists also increased over the period.

Physicians

Italy has among the highest number of physicians per 100 000 population compared to other countries in western Europe (Fig. 5.5). In particular, in the early 1990s it had over three times the number of physicians as the United Kingdom and approximately double that of Germany, Portugal and Spain. Since then, numbers have converged somewhat with other comparable countries, reaching a level of 380 per 100 000 population in 2007. It is worth noting that the increase in the number of physicians would seem to be due more to the rise in women entering this professional category, as revealed by the percentages of practising female and male physicians from 1993 to 2005 (Fig. 5.6).

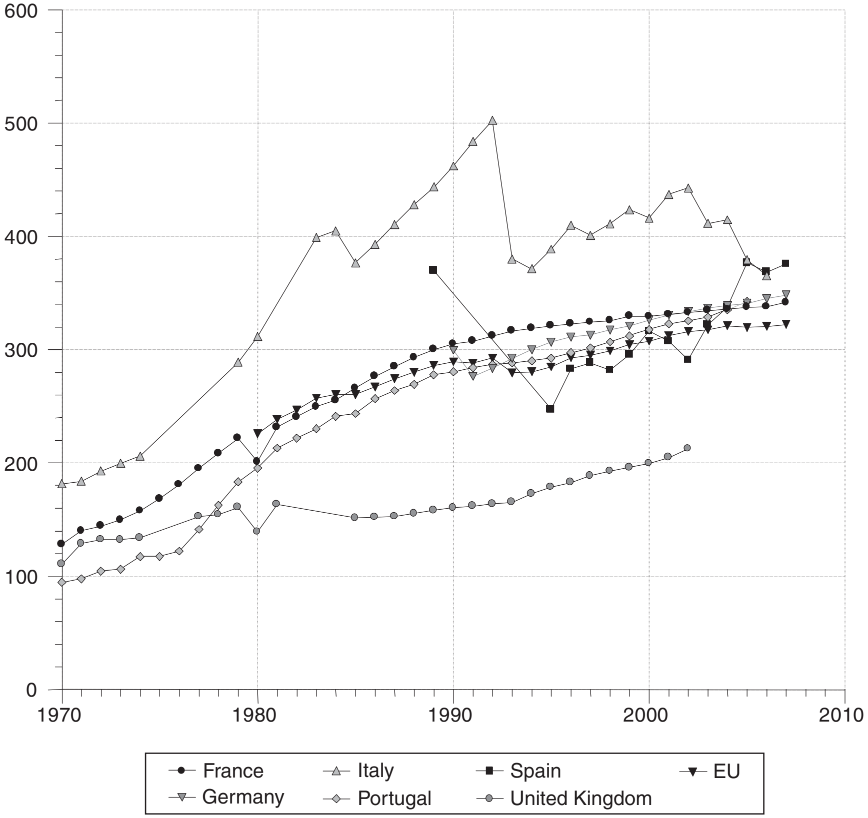
Table 5.1 Health care personnel in Italy per 1000 population, 1990–2006

	1990	1992	1994	1996	1998	2000	2002	2004	2006
Active physicians	–	3.80	3.70	4.10	4.10	4.10	4.40	4.02	3.70
Active dentists	0.20	0.40	0.40	0.50	0.50	0.60	0.50	0.60	0.60
Practising nurses and midwives	–	5.00	5.20	5.20	5.30	5.20	5.40	6.70[a]	7.00
Active pharmacists	1.00	1.00	1.00	1.00	1.10	1.10	1.00	0.09[a]	0.80
Physicians graduating	0.18	0.15	0.12	0.11	0.11	0.11	0.12	0.11	0.10
Nurses graduating	–	–	–	–	–	0.10	0.10	0.16	0.17

Source: OECD, 2009b.

Note: [a]Break in the series.

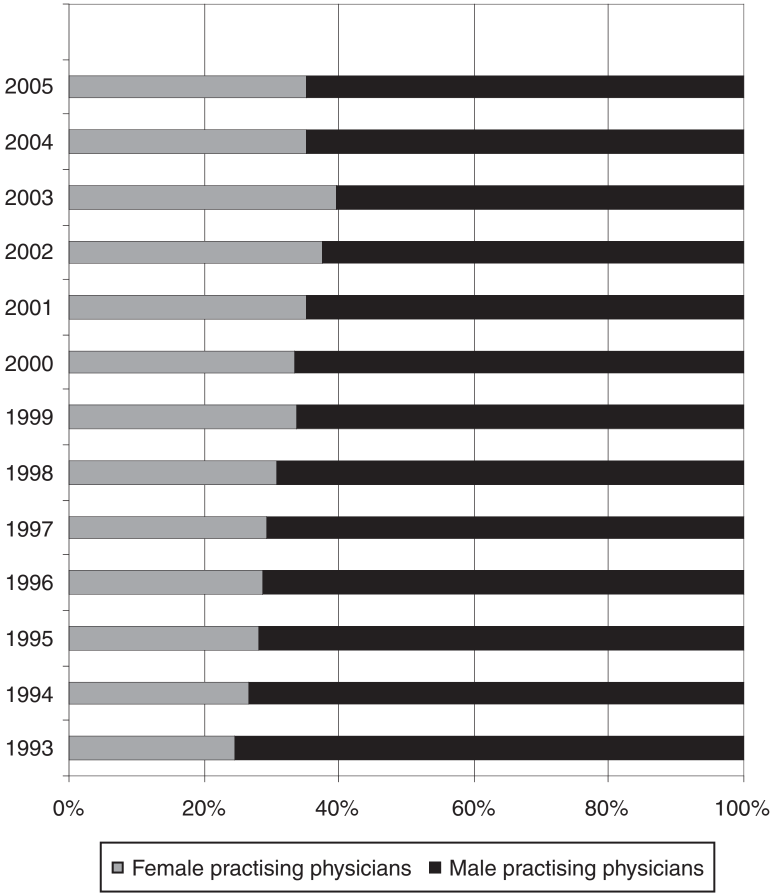
Fig. 5.5 Number of physicians per 100 000 population in Italy and selected EU countries, 1970 and latest available year



Source: WHO Regional Office for Europe, 2009.

The latest available data for 2005 reveal that the average number of GPs per 1000 resident population in Italy is 1.19. The Autonomous Province of Bolzano has the lowest number of GPs per 1000 population (0.77), while Liguria has the highest (1.39) (Table 5.2). Although the number of GPs among regions does not differ dramatically, a slightly higher number of GPs per 1000 population can be noted in central regions. The average number of paediatricians per 1000 resident children is 0.97, ranging from 0.81 paediatricians in Campania, to 1.13 in the Autonomous Province of Trento and Emilia-Romagna. An average of 1.78 doctors per 1000 population, and 3.94 nurses are active in public hospitals (Table 5.2) (Ministero della Salut, 2006a).

Fig. 5.6 Percentage distribution of physicians by gender, 1993–2005



Source: OECD, 2006.

Nurses

In terms of hospital nurses per 100 000 population, Italy has one of the lowest rates among a cohort of comparable EU countries, and is below the EU average. This rate remained fairly stable from the mid-1990s until 2005, when a rise occurred, most probably due to policies aimed at allowing foreign-trained nurses to practise in Italy and other measures to promote the profession (see Section 5.2.2 below).

Table 5.2 **Number of GPs, paediatricians, public hospital doctors and nurses in the regions of Italy, 2005**

Region	GPs per 1000 residents adults[a]	Paediatricians per 1000 resident children[a]	Hospital doctors per 1000 resident population[b]	Hospital nurses per 1000 resident population[b]
Piedmont	1.22	0.83	1.73	3.49
Valle d'Aosta	1.21	0.99	2.06	4.09
Lombardy	1.06	0.90	1.69	4.09
Auto. Prov. Bolzano	0.77	0.67	1.80	5.38
Auto. Prov. Trento	1.18	1.13	1.44	4.00
Veneto	1.11	0.91	1.47	4.05
Friuli-Venezia-Giulia	1.27	0.88	1.89	4.70
Liguria	1.39	1.08	2.17	5.38
Emilia-Romagna	1.21	1.13	1.84	4.61
Tuscany	1.31	1.06	2.00	4.71
Umbria	1.37	1.11	1.92	4.24
Marche	1.25	0.96	1.70	4.30
Lazio	1.32	1.09	2.24	4.36
Abruzzo	1.30	1.14	1.77	4.14
Molise	1.33	0.89	2.32	4.40
Campania	1.13	0.81	1.68	3.14
Puglia	1.19	0.97	1.56	3.35
Basilicata	1.28	0.86	1.47	3.64
Calabria	1.15	0.98	1.60	3.18
Sicily	1.24	1.09	1.84	3.14
Sardinia	1.19	1.16	1.76	3.79
Italy	1.19	0.97	1.78	3.94

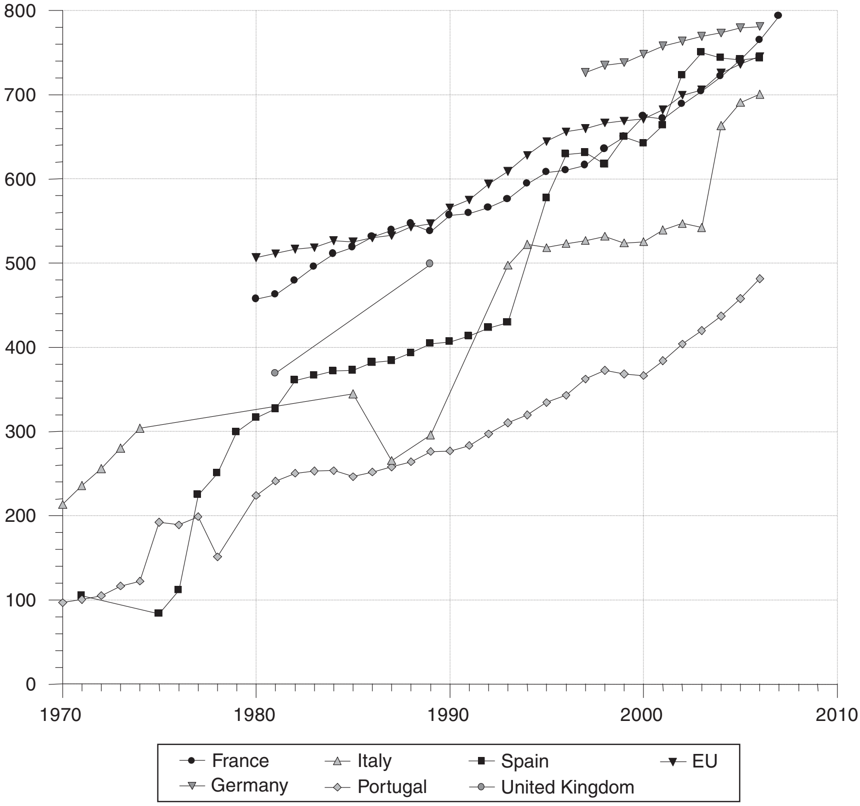
Source: [a]Ministero della Salute, 2005a; [b]ISTAT, 2006.

Note: Auto. Prov.: Autonomous province.

5.2.2 Planning of health care personnel

In Italy, there is a shortage of nurses and the number of new students is not high enough to cover demand from health services. As already mentioned, the number of active nurses per 1000 population between 1990 and 2004 has been consistently below the EU15 average (Fig. 5.7) and it does not seem likely to grow significantly in the future. In order to deal with this shortage, an initial solution has been to rely on foreign-trained nurses. In 2001, the

Fig. 5.7 **Number of active nurses per 100 000 population in Italy and selected EU countries, 1970 to latest available year**



Source: WHO Regional Office for Europe, 2009.

Ministry of Health authorized six regions and the two autonomous provinces (Emilia-Romagna, Valle d'Aosta, Lazio, Lombardy, Umbria, Veneto and the Autonomous Provinces of Trento and Bolzano) to expedite processing of the large number of applications for the recognition of nurses' degrees obtained in non-European countries so that cases could be accelerated and new staff deployed quickly. Other regions, such as Tuscany, are planning to provide financial incentives for people to attend university courses for nursing degrees. The lack of interest in the profession is due to a number of reasons. Although in Italy the role of nurses is changing, and the nurse–physician relationship is moving towards a model of professional collaboration in terms of different types of expertise, the profession nevertheless has not yet been given adequate social recognition. Moreover, salary levels within the profession are low relative to the duties and responsibilities expected. In contrast, the supply of physicians is among the highest in Europe (Fig. 5.5). In order to regulate the entrance into the workforce of this professional category, Law No. 264/1999 imposes a *numerus clausus*, with the number of new students per year to be decided at the national level.

5.2.3 Training of health care personnel

Physicians undergo three different stages in their higher education and training: university education, postgraduate education and continuing professional education.

Physicians have to graduate from a medical faculty at a public or private university. The undergraduate programme lasts six years, during or after which students must work within a hospital ward for at least six months. After university, medical school graduates must take a state examination to be put on a register and be allowed to practise as physicians. They can then choose among various professional paths depending on the kind of postgraduate specialization programme attended.

GPs and hospital physicians have to follow two different career paths. Physicians wishing to become a GP must be registered on a national list. Ranking on the list depends not only on the number of educational and academic qualifications achieved, but also, as of 1 January 1995, on successful participation in a two-year GP training course. Legislative Decree No. 256/1991, which implemented the EU directive on GP training,[22] made participation in this two-year course compulsory to practise family medicine. Moreover, in accordance with Legislative Decrees Nos. 256/1991 and 368/1999, certificates issued by other EU Member States to practise as a GP are equivalent to those issued in Italy and therefore are valid for practice in Italy.

Future hospital doctors and specialists have to attend a medical specialist school at university, whose courses last from four to six years depending on the kind of clinical specialization. Physicians have to take an exam to be admitted to the chosen specialist school, since a *numerus clausus* is in place. Specializing students can benefit from a grant (scholarship) to attend their school and will practise as specialist doctors in hospitals. After specialization, their training will continue under the rules provided by the national Continuing Education in Medicine programme.

In 1992 and 1994, major reforms in the training system for nurses were introduced, which led to the closure of the regional nurse training schools.[23] Prior to the reform, prospective nurses could enrol after just two years of

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[22] Council Directive 86/457/EEC of 15 September 1986 on specific training in general medical practice.

[23] Legislative Decree No. 502/1992 (Art. 6(3)) and Ministerial Decree No. 739/1994.

high school and, upon completing the programme, were awarded a regional certificate by the Ministry of Health. The main aim of legislation for the nursing profession over the last decade has been to provide nurses with a more autonomous and active role and to give them new responsibilities so that this important profession is no longer seen as an auxiliary one. Under the current arrangements, those wishing to be registered as qualified nurses are required to complete a three-year university degree and to take a state examination. Nurses can attend postgraduate programmes in paediatrics, geriatrics, psychiatry, problematic areas and public health care. Complementary training courses are also aimed at training managers and teachers in nursing. In 2000, the role of nurse management was established,[24] with a degree in the nursing sciences for training managers and teachers in nursing. In 2004–2005, a postgraduate two-year nursing specialist degree, which is only available to nurses with a three-year degree, began taking enrolments.

5.2.4 Registration/licensing

As mentioned in Section 5.2.3, physicians wishing to become a GP undergo appropriate training and are registered on a national registry (*Albo Professionale*). Moreover, there is mutual recognition of GP qualifications gained in other EU Member States for the purposes of practising in Italy.

Physicians must also attend a Continuing Medical Education programme that is equivalent to a 're-accreditation system' that is carried out annually.

5.2.5 Continuing Education in Medicine

The National Programme on Continuing Education in Medicine (NPCEM) was launched on 5 July 2000. All health professionals working in private or public facilities were required to undergo continuous education training programmes and earn a minimum of 150 continuing education training credits in three years in order to be accredited. In March 2002, in order to facilitate the start of the programme, it was decided that the 150 credits could be gained over five years instead of three (as in the majority of EU Member States).

The National Commission on Continuing Education in Medicine has established a national database providing information on health professionals' earned credits, but the database needs to be improved (see also Chapter 7).

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[24] Law No. 251/2000.

6 Provision of services

6.1 Public health

ASLs are primarily concerned with protecting and promoting public health and are responsible for achieving the health objectives and targets established by national and regional planning.

Each ASL has a health promotion division with the following activity areas.

- Hygiene and public health, including infectious and parasitic disease prophylaxis, health promotion and education and preventing environmental hazards.
- Food control (production, processing, preservation, commerce and transport), preventing food-related disease and nutritional surveillance (preventing obesity and malnutrition, etc.).
- Preventing occupational diseases and accidents.
- Veterinary medicine (surveillance of animal stock health, hygiene of food production and animal food safety and control). Public veterinary health is pursued through a partnership between the veterinary services of the health promotion division and the activities of the experimental zooprophylactic institutes. These ten interregional research agencies are engaged in laboratory testing, vaccine production activity and research in preventing and treating animal disease.

In 1975, information flows were established from GPs through USLs to regional and national bodies to conduct epidemiological surveillance of communicable diseases. When these information flows were put into place, diseases were divided into five groups according to severity, epidemiological burden, treatment availability and relevance, with a faster pathway and closer attention paid to the most severe diseases, such as poliomyelitis or botulism.

As a result, mild and frequent conditions such as measles and hepatitis A are often not registered, thus generating less accurate statistical reporting that does not reflect the actual burden of disease in the population.

The compulsory vaccination programme includes all children under 24 months, protecting them against diphtheria, poliomyelitis, tetanus and hepatitis B. Other recommended childhood vaccinations are those aimed at protecting children from pertussis, measles and rubella. The regional distribution of average immunization rates shows similar trends for both compulsory and recommended vaccinations: overall coverage is higher in the north than the south. As expected, coverage rates for compulsory vaccinations are higher than for recommended ones throughout Italy.

The actual vaccination calendar of compulsory vaccinations for children established at the central level is shown in Table 6.1.

Table 6.2 presents the incidence rate for diseases such as rubella, measles and tetanus. Data show the effectiveness of immunization campaigns: from 1980 to 2003, pertussis fell at a rate equal to -93.9% and the same occurred for other diseases: -54.3% for measles, -60.6% for tetanus and -77.6% for rubella. Moreover, in 2003 a specific Health Plan for measles and rubella (for the period 2003–2007) was established.

Table 6.1 Calendar of compulsory vaccinations for children

Vaccine	**Age**												
	Birth	**3rd mth**	**4th mth**	**5th mth**	**6th mth**	**11th mth**	**13th mth**	**15th mth**	**2 yr**	**3 yr**	**5–6 yr**	**11–12 yr**	**14–15 yr**
Diphtheria/pertussis/ tetanus		▨		▨		▨	▨				▨	▨	▨
Polio		▨		▨		▨	▨				▨		
Hepatitis B	▨	▨		▨		▨	▨						
Haemophilus influenzae B		▨		▨		▨	▨						
Measles and rubella							▨	▨			▨	▨	▨
Pneumococcal conjugate		▨	▨	▨	▨	▨	▨	▨	▨	▨			
Meningococcal C conjugate		▨	▨	▨	▨	▨	▨	▨	▨				
Chickenpox							▨	▨	▨			▨	▨

Source: Ministero della Salute, 2005b.

Notes: mth: months; yr: years.

Table 6.2 Incidence (per 100 000) for pertussis, measles, tetanus and rubella, selected years

	1980	1985	1990	1995	2000	2001	2002	2003
Pertussis	23.8	26.7	29.5	25.1	4.4	1.8	4.5	1.5
Measles	41.8	123.2	9.1	64.8	2.5	0.9	31.5	19.1
Tetanus	0.3	0.3	0.2	0.2	0.2	0.1	0.1	0.1
Rubella	11.0	99.7	58.2	11.6	4.5	7.7	11.1	2.5

Source: WHO Regional Office for Europe, 2005.

Immunization against specific professional hazards is compulsory for several categories of the labour force. This applies to health workers (hepatitis B and tuberculosis), those preparing or selling food (hepatitis A and salmonella) and people in closed communities such as the army (tuberculosis, meningitis, tetanus, typhoid fever, measles, mumps and rubella).

Until 2004, no national screening programme existed, as regions were responsible for disease prevention activities. Differences in government performance and available resources across regions brought about considerable inequality in access to preventive interventions during the 1990s, one cause of the considerable regional differentials in morbidity and mortality from preventable conditions. Current regional initiatives focus primarily on screening for breast and cervical cancer. For example, Emilia-Romagna's screening programme focuses on these two kinds of cancer, one prevention programme in Friuli-Venezia-Giulia screened for cervical cancer among women, and two prevention programmes for breast and colon rectal cancer were implemented in Lazio.

In 1996, the National Oncology Commission was established to develop an intervention programme to monitor and prevent cancer according to indications contained in the National Health Plan for 1994–1996. Screening guidelines were then produced with the aim of reducing the heterogeneity of interventions and enhancing evidence-based programme planning. The National Health Plan for 1998–2000 highlighted the importance of prevention to achieve the expected targets in reducing mortality and referred to the work of the National Oncology Commission as a landmark. Nevertheless, less than 10% of women were involved in cervical and breast screening programmes that followed the Commission guidelines. Moreover, about 3.5 to 4.0 million pap smears were performed each year, meaning that one in four fertile women underwent such a diagnostic procedure annually, even if they were not included in a screening programme. Pap testing, mammography and colonoscopy were provided free of charge to people in selected age groups beginning in 2001.

Centro Nazionale per la Prevenzione e il Controllo delle Malattie (National Centre for Disease Prevention and Control)

With the passing of Law No. 138/2004 ("Urgent interventions to meet public-health hazards"), the National Centre for Disease Prevention and Control (*Centro Nazionale per la Prevenzione e il Controllo delle Malattie* (CCM)) was established by the Ministry of Health. The CCM's main objective is active prevention through both the promotion of healthy lifestyles and screening, and addressing a variety of health emergencies. CCM was created as a network of existing institutions and a panel of experts, and its activities are coordinated with those of the regional health ministries and institutions, as well as organizations such as the ISS, the ISPESL, the Institute of Zooprophylactic Research, university research centres, the IRCCS, other institutions involved in health care and public and private research, and also military health organizations.

CCM's main duties and responsibilities are:

- analysis of health risks;
- in collaboration with regional governments, coordination of programmes for surveillance and prevention developed by national alert systems and of interventions for rapid responses to public-health situations, including bioterrorism;
- promotion, updating and training for the implementation of yearly programmes at the national and regional levels;
- assessment of annual programmes;
- cooperation with other institutions and analogous organizations in Europe and worldwide; and
- dissemination of results.

The main areas of CCM's activities are as follows.

- *Infectious diseases*. For example avian influenza and severe acute respiratory syndrome (SARS).
- *Vaccines and vaccination*. For example influenza and measles.
- *Health in general and healthy lifestyles:* informing, communicating with and educating the public in preventing diseases related to certain lifestyles (smoking, food, alcohol). These priorities were already clear in 2002, when the Ministry of Health made its first concrete commitment to promoting healthy lifestyles and an extensive and diversified programme of institutional communication on lifestyles and health was created. Health promotion is

mainly carried out through disease prevention (especially immunization). Health education is pursued mainly through television campaigns (e.g. cardiovascular risk, AIDS) and school education programmes managed jointly by teachers and health care professionals working for their own ASL. No information is routinely collected about the dissemination and efficacy of these interventions.

- *The environment and climate*. CCM has included the environment and climatic events among its intervention targets, on the basis that the environment and health are inseparable. As a matter of fact, correlation between environmental pollution and health risks has led to the urgent need for policies that integrate information from a number of sectors, especially public health and the environment.
- *Accidents*. Road accidents, as well as home accidents, represent the third leading cause of death in Italy and, given the high rate of occurrence mainly among young people, result in the greatest number of years of life lost. Prevention can be extremely useful, in that it involves commitments on behalf of a number of different actors: from car manufacturers to road-safety personnel, from building constructors to the manufacturers of the technology used in daily life. The training of specialized personnel and properly educating the public are crucial, as is the continuous revision of existing legislation, such as the law which established the ‘points system’ driving licence, which seems to be producing encouraging results. Moreover, television campaigns on road safety represent another useful prevention measure.
- *Oncological screening*. Approximately 270 000 new cases of cancer and 150 000 cancer-related deaths are reported in Italy each year. Cancer constitutes one of the highest causes of death, and the incidence is constantly increasing with a marked north–south differences in terms of both incidence and mortality. An intensive nationwide screening programme has been launched for breast, cervix–uterine, and colorectal cancer. Table 6.3 outlines these measures.

At present, the National Screening Programme operates with the collaboration of a network based on several screening centres (e.g. the Italian Group for Breast Cancer Screening). Three working groups in the Ministry of Health are responsible for revising the existing guidelines on screening and for promoting nationwide mass screening for breast, cervix–uterine and colorectal cancer. They are also in charge of supervising and promoting screening programmes. Moreover, the Health Information System Unit, in collaboration with the Ministry of Innovation and Technology, has developed information

Table 6.3 Nationwide screening measures in Italy

Legislation	Measures
2001 Finance Act	Established that the following tests would be provided free of charge: • mammography (every 2 years for women between 45 and 69 years of age); • pap test (every 3 years for women between 25 and 65 years of age); • colonoscopy (every 5 years for the general population over 45 years of age and for the population considered to be at risk, according to criteria specified in a Ministry of Health decree)
Decreto del Presidente del Consiglio dei Ministri, 29 November 2001	Included screening for breast, cervix–uterine and colorectal cancer within the LEA
National Health Plan 2003–2005	Focused on prevention, with particular emphasis on the secondary prevention of cancer, including breast, cervix–uterine and colorectal cancer
State–Regions Agreement April 2004	Among the four strategies, one focused on screening for the types of cancer indicated in the resolution of the European Parliament and in the recommendations of the EU Council
Law No. 138/2004	Formalized the commitment to closing the gap between the target population for screening and the population that actually undergoes screening, designating an additional €50 million to reach this goal

systems that will provide information in real time on the status of promotional campaigns and outcomes in terms of their effectiveness.

An agreement (‘Health Pact’) between the state and regions in March 2005 established the National Prevention Plan, aimed at:

- prevention of cardiovascular diseases
- prevention of diabetes complications
- oncological screening
- national vaccination plan
- surveillance and prevention for obesity
- relapse prevention in patients with previous cardiovascular problems
- surveillance and prevention for road accidents
- surveillance and prevention for work accidents
- surveillance and prevention for home accidents.

6.2 Primary/ambulatory care

6.2.1 Primary care

Primary care is provided by GPs, paediatricians and self-employed and independent physicians working alone under a government contract who are paid a capitation fee based on the number of people (adults or children) belonging to their own list. Although primary care physicians are given financial incentives to share clinic premises with their colleagues, they usually work in single practices. However, this attitude has been changing more recently.

Primary care physicians are authorized to work in the SSN after successfully completing a two-year specialization course in general medicine and acquiring clinical experience as temporary staff in SSN facilities. GPs and paediatricians initially assess the patient and are expected to provide most primary care. They act as gatekeepers for access to secondary services. They write pharmaceutical prescriptions and visit patients at home if necessary, as well as vaccinate patients against influenza during the vaccination campaign period. People may choose any physician they prefer at any time, provided that the physician's list has not reached the maximum number of patients allowed (1500 for GPs and 800 for paediatricians).

In 2004, each GP averaged 1107 patients (Ministero della Salute, Servizio Studi e Documentazione, 2008). The regional range of averages ranged from 1015 (Lazio) to 1686 (Province of Bolzano). Each paediatrician averaged 805 children, ranging from 735 in Sardinia to 942 in Bolzano. In some regions, children were mostly on GP lists instead of paediatrician lists, partly because of insufficient paediatricians and partly due to custom.

The major reform in 1999 introduced significant changes in primary health care services by reinforcing group practice, introducing economic incentives for GPs and promoting integration between primary care physicians and district services such as social care, home care, health education and environmental health. In particular, the law allows GPs to work in a team in several ways.

- *Medicina in associazione* (base group practice): from 3 to 10 GPs who keep on working in their own offices but share clinical experiences, adopt guidelines and organize workshops aimed to assess quality and prescribing appropriateness.
- *Medicina in rete* (network group practice): same characteristics as the base group practice but in addition GPs share the patient electronic health record system.

- *Medicina di gruppo* (advanced group practice): 3 to 8 GPs share the same office and the patient electronic health record system. They also provide primary care to patients who do not belong to their catchment area.

  This kind of group practice is still in its early stages and there are no official data about the proportion of GPs working in each of these different types of practice. Primary care is provided free of charge.

6.2.2 Ambulatory care

Specialist ambulatory services, including visits and diagnostic and curative activities, are provided either by ASLs or by accredited public and private facilities with which ASLs have agreements and contracts. Services are listed in specific formularies that vary among regions. People are allowed to access specialist care in two ways.

- Indirect access (referral): after approval by their GP, who is responsible for the referral. Once the GP has authorized the visit or the procedure, people are free to choose their provider among those accredited by the SSN.
- Direct access: patients can obtain an appointment themselves through what is known as the central booking point (*centro unico di prenotazione* (CUP)) (see Section 6.2.3 below) for the following health services: gynaecology, dental care, paediatrics (for those who have decided not to register their children with a designated paediatrician), optometric services and psychiatric services for children. In emergency cases, direct access is allowed for all health services. Urgency is established directly by the doctor.

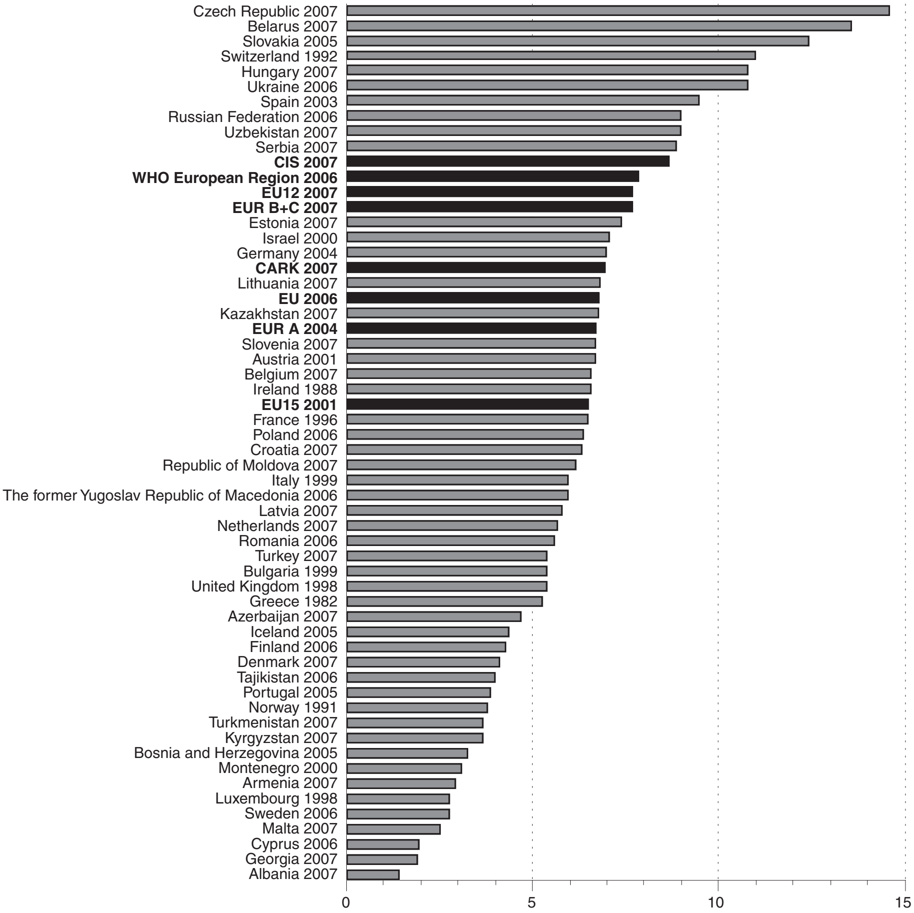
Visits to a specialist and medical devices incur user charges (see Section 3.3.3).

Since waiting lists are very long and the quality of services is not always satisfactory, especially in central and southern regions, many people seek care in private clinics, particularly if they have VHI covering the associated costs. Moreover, people usually seek care outside their own regions, mainly going from the south to the north of Italy.

In terms of available data, the latest report published in 2005 shows the number of outpatient visits in terms of laboratory tests, diagnostic procedures and other ambulatory services per 1000 inhabitants (Ministry of Health, 2005c). For each category, a national parameter has been established as a benchmark. For laboratory tests, Veneto, Lombardy and Tuscany have definitively higher levels of usage than the benchmark (that is, 13 510 tests per 1000 inhabitants), while the Autonomous Provinces of Trento and Bolzano, and the Regions of Abruzzo and Molise have somewhat lower values. In 2001, there was an average of 977 diagnostic services delivered at the national level, with Emilia-Romagna and Tuscany presenting higher levels. As far as other outpatient services are concerned (the parameter is 4214 per 1000 inhabitants), Lazio reported levels that were clearly over this limit (6704 per 1000 inhabitants).

Italy has 6.0 annual outpatient contacts per person (last available data for 1999), a value that is slightly lower than the European average (6.8) (Fig. 6.1). Moreover, it is worth noting that often outpatient visits are delivered inside

Fig. 6.1 **Outpatient contacts per person per year in the WHO European Region based on last available WHO estimates**



Source: WHO Regional Office for Europe, European Health for All database (various years).

Notes: EUR A,B,C: Regions as in the WHO list of Member States; CIS: Commonwealth of Independent States; CARK: Central Asian republics and Kazakhstan; EU: European Union; EU12: Countries that joined the EU in May 2004 and in January 2007; EU15: Countries belonging to the EU before May 2004.

hospitals and therefore the number of contacts is not completely representative of the effective utilization of health services in ambulatory care.

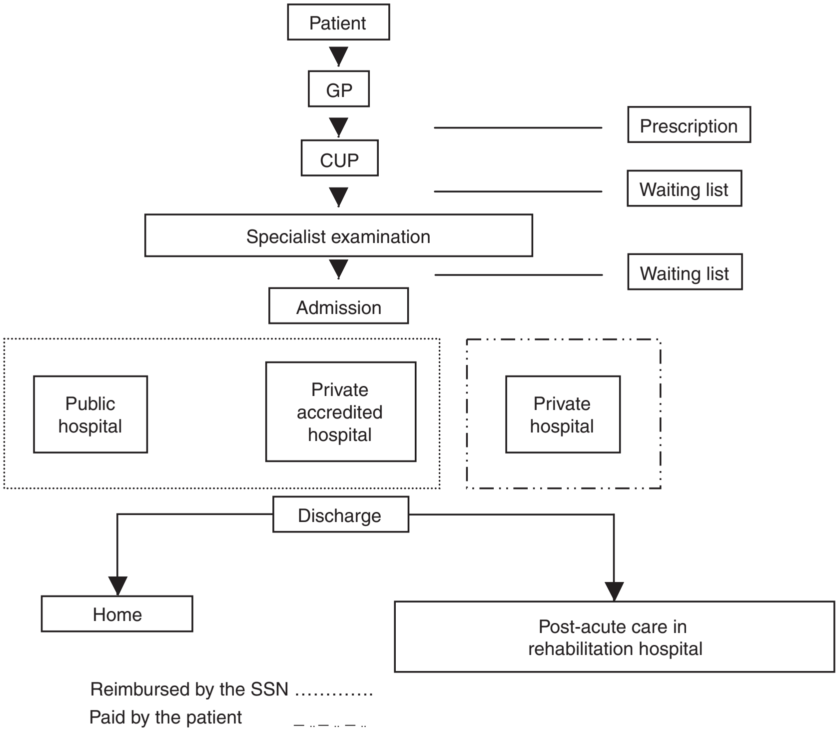
In terms of the geographical distribution of health care facilities, there are no national available data and each region has its own information system monitoring outpatient care. Therefore, it is difficult to provide a national overview.

6.2.3 Patient pathway

In Italy, GPs have a gatekeeping function in the patients' pathway. Figure 6.2 summarizes the pathway followed by a patient who needs a health care intervention.

The first step is represented by a free visit to a GP with whom the patient is registered. The GP then refers the patient to a specific hospital department. The SSN allows a patient to have free access to any public hospital/facility.

Fig. 6.2 Patient pathway



Notes: GP: General practitioner; CUP: Central booking point; SSN: National Health Service.

In some (but not all) regions, patients can then make their own bookings for an intervention: some ASLs use a CUP, which is able to give patients all the relevant information regarding hospitals and their waiting lists. In some regions, patients can book by telephone; however, often, patients or their relatives have to go in person to make a reservation. Information about waiting lists covers both public and private accredited hospitals, while, for the private sector, hospitals have their own information systems.

Patients who do not want to wait can choose to go to a private hospital, where usually waiting lists are much shorter. In that case, there is the option of being referred either to a private clinic (where the patient would pay the total cost of admission without any reimbursement by the SSN) or, alternatively, to a private accredited hospital where interventions are completely reimbursed by the SSN.

After referral, the patient may have to wait for a specific period for an outpatient hospital appointment to be examined by a specialist and, after this, will have to wait for inpatient admission and surgery.

Following surgery and primary rehabilitation at the hospital, the patient goes home, where he or she might need home care (home nurse and/or home assistance). If the patient needs post-acute care, usually the discharging hospital will refer him or her to a specific hospital for rehabilitative care.

In cases of emergency, where patients require an ambulance to be taken to the closest hospital, this service is free of charge. Alternatively, patients can go directly to the nearest emergency department to obtain the necessary treatment. Many regions now apply co-payments in cases of inappropriate use of emergency facilities.

Even though this pathway does not vary much among regions, it is worth highlighting that the management of waiting lists has become one of the crucial issues within the Italian health care system because it varies dramatically from region to region. A key objective is to develop measures to assess patients' relative priority for services for which there are waiting lists. An agreement between the national government and the regions (26 March 2006) sets out a three-year plan to reduce waiting times. Moreover, given the 'cost-containment' environment in which regional governments are accountable for their own health care expenditures, several regions have decided to implement new priority-setting models to promote the rational use of resources (see also Section 6.3.1 below).

Moreover, a north–south imbalance in waiting times still persists, and perhaps has become even more marked since the devolution process. In some central and northern regions, patients are allowed to book outpatient specialist visits directly from a pharmacy; in some others, the CUP covers the whole region and patients may know which specialists or hospitals have the shortest waiting lists, thanks to very good regional information systems. In contrast, this does not happen in the south, where often there are no such facilities and waiting lists are managed manually without any kind of technological support.

6.3 Secondary/inpatient care

The 1978 reform that established the SSN was followed by several legislative acts aimed at improving the quality of hospital care while containing the growth of service utilization.

Despite repeated efforts, the quality of services failed to achieve uniform and acceptable levels and health care costs kept growing. These shortcomings prompted the government to enact reforms (Legislative Decrees Nos. 502/1992 and 517/1993) aimed at promoting efficiency by introducing a limited form of competition between hospital care providers. Accordingly, starting in 1994, ASLs and major hospitals (highly specialized hospitals with national relevance) were given financial and technical autonomy. The major hospitals were given the status of independent AOs. The rest of the public hospitals were kept under the direct management of ASLs. In addition, patients were given the choice of opting for private, contracted-out hospitals that were required to be accredited by the government.

6.3.1 Hospital and bed numbers

Currently, hospital care is delivered mainly by 669 public structures, which provide both outpatient and inpatient services; nevertheless, ASLs also contract out services to 553 private hospitals, especially not-for-profit institutions (Fig. 6.3).

Table 6.4 shows the trends in hospital utilization for 1985–2003. In response to the introduction of the DRG system in the early 1990s, the admission rate initially dropped to 15.5 (per 100 population) in 1990, then peaked at 16.2 in 1995 and finally slowly fell to its lowest level (14.0) in 2003. The pressure to contain per admission costs contributed to decreasing average length of stay by nearly 40% in the period considered, with admissions lasting 12.2 days in 1985 and only 7.4 days in 2007. The occupancy rate for acute care increased from 69.3% in 1990 to 75.8% in 2006. Changes in bed utilization are, together with the reduction in length of stay and in the number of admissions, an expected result of the initiatives to control health expenditure, foster hospital efficiency and reduce waste.

Fig. 6.3 Distribution of hospitals by type, 2005

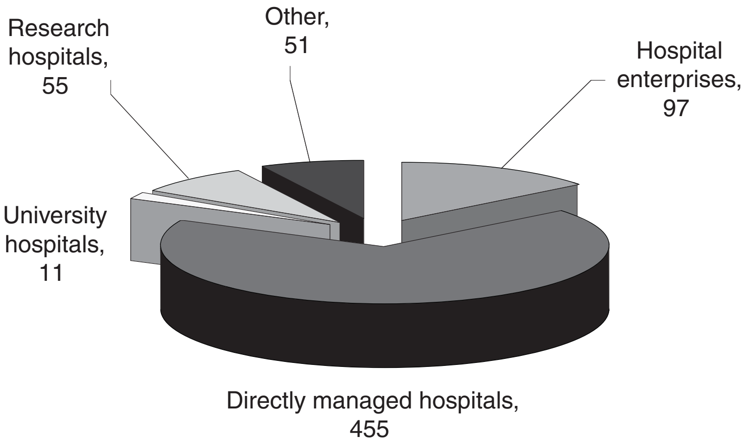


Table 6.4 Trends in hospital utilization in Italy, selected years

	1985	1990	1995	2000	2001	2002	2003	2004	2005	2006
Hospital beds (per 1000 population)	8.3	7.2	6.3	4.7	4.6	4.4	4.2	4.0	4.0	4.0
Inpatient admissions (per 100 population)	17.0	15.5	16.2	15.6	15.2	14.7	14.0	–	–	–
Average length of stay (days)	12.2	11.7	10.1	7.7	7.6	7.3	7.4	7.4	7.4	7.4
Occupancy rate for acute care (%)	67.9	69.3	70.7	75.6	76.0	76.9	76.1	76.4	77.8	77.8

Source: OECD, 2009b.

Reduction in the number of beds, together with the policies aimed at promoting the appropriate use of hospital care, during the 1990s and after 2000, has determined a sharp decrease in the number of hospital admissions. Currently, Italy stands at the lower end of the spectrum, with only Ireland, the Netherlands, Portugal and Spain having fewer admissions per 100 population (Table 6.5).

Table 6.5 Inpatient utilization and performance of inpatient services in acute hospitals in selected European countries, 2005 or latest available year

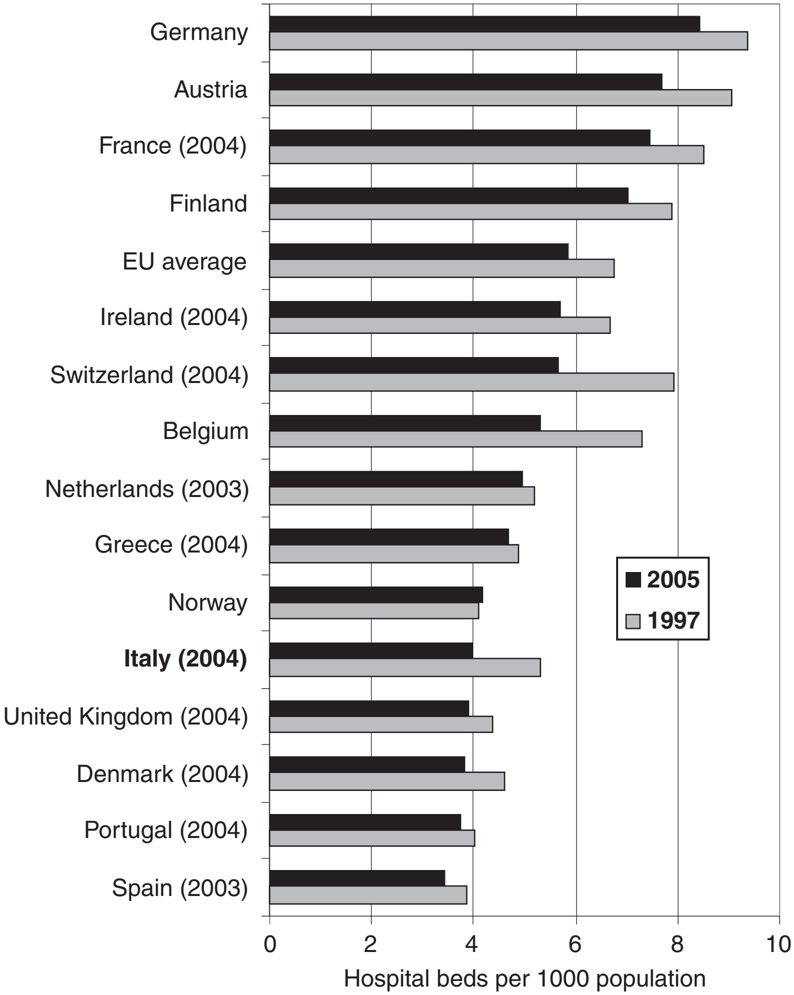
	Hospital beds (per 1000 population)	Inpatient admissions (per 100 population)	Average length of stay (days)	Occupancy rate for acute care (%)
Austria	7.71	31.22[a]	7.97[a]	76.2[b]
Belgium	5.30	16.35[c]	8.7[a]	70.5[a]
Denmark	3.82[c]	22.12[c]	5.0[c]	84.0[d]
Finland	7.03	25.78[c]	10.0[c]	74.0[e]
France	7.48[c]	18.85[c]	11.7[a]	77.1[a]
Germany	8.44	22.60	10.2	75.6
Greece	4.69[c]	16.47[d]	7.9[d]	66.6[f]
Ireland	5.72[c]	14.24	7.6	85.6
Italy	4.00[c]	15.26[a]	7.5[a]	76.1[a]
Netherlands	4.98[a]	9.27[d]	12.5[d]	58.4[d]
Norway	4.19	19.46	7.6	92.5
Portugal	3.75[c]	11.60[c]	8.6[c]	69.8[a]
Spain	3.45[a]	11.83[a]	8.7[a]	79.2[a]
Sweden	5.22[b]	15.60	6.3	77.5[g]
Switzerland	5.67[c]	16.98[f]	12.0[c]	86.3[a]
United Kingdom	3.90[c]	15.33[f]	9.8[g]	80.8[f]

Sources: WHO Regional Office for Europe, European Health for All database. [a]2003, [b]1997, [c]2004, [d]2001, [e]1995, [f]1998, [g]1996.

Figure 6.4 shows the number of hospital beds in acute-care hospitals per 1000 population in some countries in the WHO European Region, and Fig. 6.5 compares Italy's rate from 1997 to 2005 with those in selected western European countries. Both Figures clearly show how Italy's rate is lower than the EU average but higher than that of the United Kingdom or Spain. Although European countries differ in the absolute number of beds per 1000 population, they show, from 1990 to 1996, similar trends in the number of beds, with a general reduction in beds.

Patients' free choice includes either receiving treatment from the structures within their ASL or choosing a provider in another ASL (within the same region or in another region). Thus, ASLs have to pay for the treatment provided to their residents by providers located in other regions or ASLs (outward mobility) and,

Fig. 6.4 **Hospital beds in acute-care hospitals per 1000 population in countries in western Europe, 1997 and 2005 or latest available year (in parentheses)**

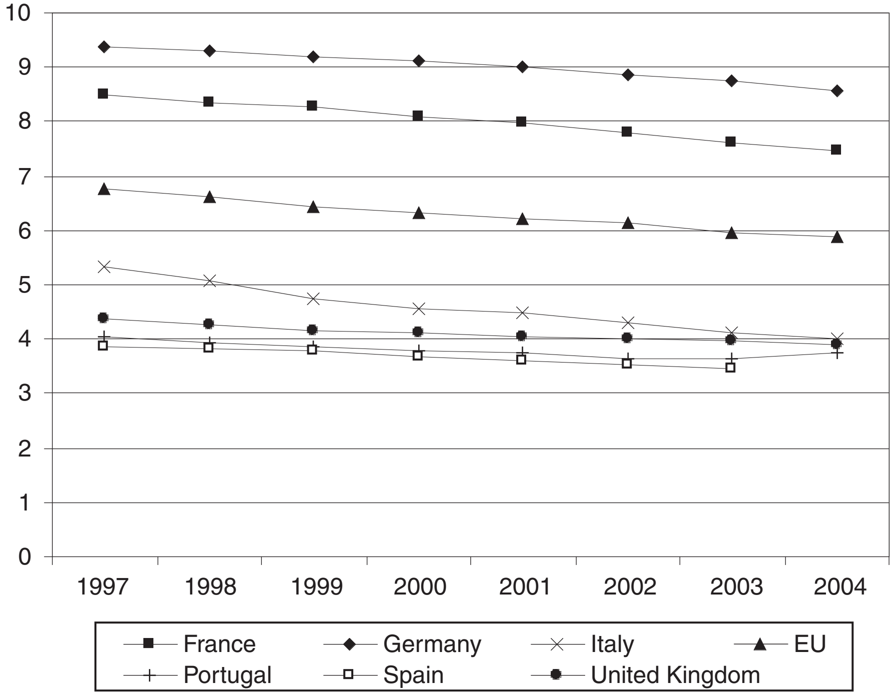


Source: WHO Regional Office for Europe, 2007.

in turn, they receive payments for the health care provided to patients coming from other regions (inward mobility).

The principle of free choice was implemented with the 1978 reform, following which patients were allowed to choose their health care provider. With limited regional responsibility for spending, cross-boundary flows were seen as a tool for compensating for an uneven distribution of providers across regions and for reducing the effects of different levels of per capita health care

Fig. 6.5 **Hospital beds in acute-care hospitals per 1000 population in Italy and selected western European countries and the EU, 1997–2004**

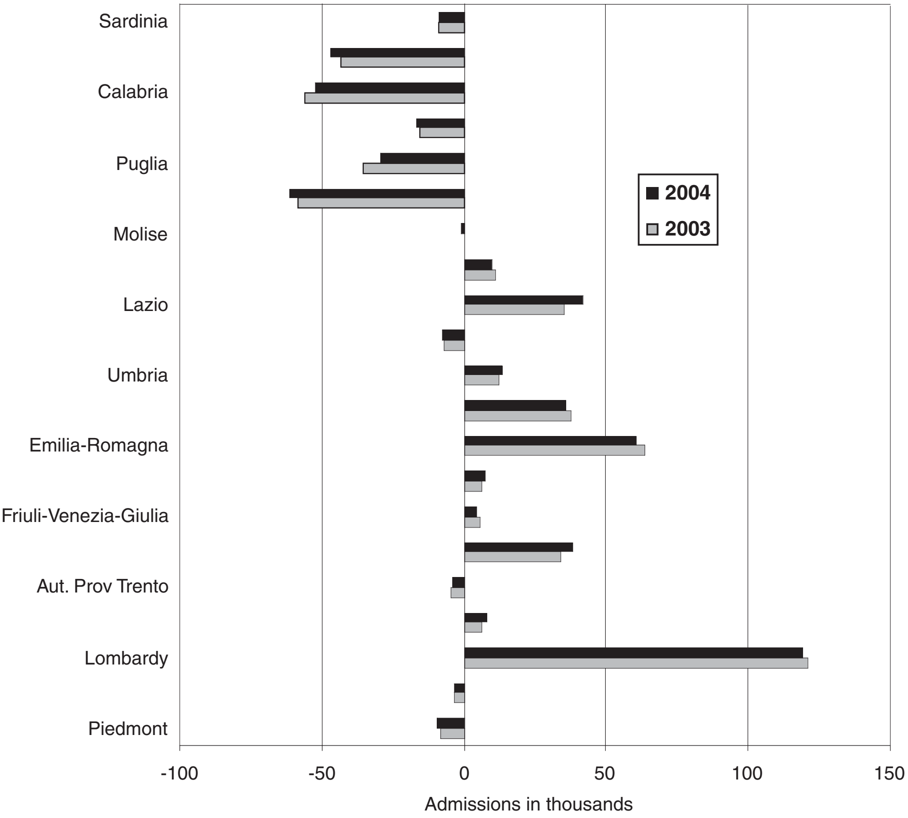


Source: WHO Regional Office for Europe, 2007.

spending in Italy's regions. The 1992–1993 reforms, with the introduction of a prospective payment system and the increased fiscal responsibility of the regions, made mobility a hot issue. Regions were indeed responsible for the deficits that might arise (where outward mobility was greater than inward mobility) and could not rely on state intervention. This also meant that regional health care planners had to concentrate on ways to improve health care services to keep residents within the regional boundaries while attracting patients from other regions. People living in northern Italy tend to obtain health care services in their own or nearby regions. In contrast, most southern patients obtaining services outside their region go to northern regions, in which most tertiary hospitals are concentrated.

Available data show that, in 2004, nearly 890 000 patients received hospital care outside their region of residence. Southern regions (Campania, Calabria, Puglia, Basilicata, Sicily and Sardinia) stand out for high outbound migration, with 343 000 admissions outside the region; Sicily (66 000 admissions), Campania (92 600 admissions) and Calabria (69 400 admissions) represent the regions with the highest levels of patients choosing to be treated elsewhere. Residents of these regions mainly choose hospitals located in Lombardy and Emilia-Romagna, which scored a positive balance of 121 000 and 63 800, respectively. In economic terms, this implies a negative balance of €924 million for southern regions (€260 million for Campania, €195 million for Sicily and €210 million for Calabria, for which the negative balance was approximately equal to 8% of regional health care expenditure). Regions with the highest economic balance were Lombardy (€439 million) and Emilia-Romagna (€270 million). Figure 6.6 shows the positive and negative interregional flows of inpatients according to region.

Fig. 6.6 **Positive and negative interregional flows of patients according to region of residence, per 1000 admissions, 2003–2004**



Sources: Farmindustria, 2005; Ministero della Salute, 2005a.

6.3.2 Appropriateness

The term ‘appropriateness’ became an official term in the Italian health care system with the National Health Plan 1998–2001 and the criterion used to define the LEA entitlement. National and regional policies have mainly concentrated on organizational appropriateness (i.e. on promoting the treatment of patients at the lowest possible level of the health care delivery system that is compatible with the severity and complexity of their specific clinical condition). In most cases, appropriateness was promoted and achieved by creating incentives for health authorities to start treating patients in settings other than ordinary admissions (day-surgery, day-hospital or, where possible, outpatient services). Economic incentives (see Section 3.6.2) were the most frequent choice used to achieve this, with DRG rates for ordinary admissions selectively reduced so as to make the day-surgery option the most appealing. The impact of this policy has been rather positive.

In 2001, 66.4% of admissions included in the list of DRGs for conditions that can safely and effectively be dealt with as day cases or in an ambulatory setting were treated as inpatients. The proportion of those conditions treated as day cases increased between 2001 and 2004 by 7.5% at the national level, while ordinary admissions fell by 28.7%, with values ranging from -61% for Valle d’Aosta to -5.6% for Sardinia (ASSR, 2005). This strategy has contributed to increasing interregional diversity in the supply mix and reflects differences in the regions’ capacity to design and implement policies to reduce the hospital bed stock and to develop alternative forms of care, including home care and residential care for the elderly (France, Taroni and Donatini, 2005).

The ‘Health Pact’ signed in March 2005 by the central government and the regions bound the latter to achieve specific objectives. In particular, heavy emphasis was placed on appropriateness, with the establishment of a National Benefit Package Committee charged with the assessment of the appropriate and efficient delivery of health care services. In addition, regions were requested to adopt all the necessary measures to limit and regulate delivery of services that do not satisfy the principles of organizational appropriateness.

6.4 Pharmaceutical care

The turning point for Italy’s pharmaceutical sector was 1 January 1994, when Law No. 537/1993 came into force. Since 1994, there have been many changes in pharmaceutical policies and these are described below.

In 1994, pressures to contain expenditure and an extraordinary series of scandals favoured the most radical change ever experienced in Italy's pharmaceutical policy (which also had wide-ranging political ramifications; see Chapter 1). Since then, regulatory policies have redefined the positive list, implemented a nationwide drug expenditure cap, created new price-setting models, introduced and promoted generics, created an alternative way of dispensing drugs and attempted to influence the prescribing of GPs. Some of these changes are still ongoing.

The AIFA was set up in 2003 (Law No. 326/2003), replacing a number of predecessors with differing functions. The Agency consists of a president and a general manager, both appointed directly by the Ministry of Health, and has five areas of activity: (a) pharmacovigilance; (b) production; (c) research; (d) pricing and reimbursement; and (e) drug approval.

Among AIFA's many activities, it is particularly involved in: (a) providing drug expenditure governance within the pharmaceutical industry's framework of economic and financial viability and competitiveness; (b) authorizing the marketing of medicinal products through national or EU procedures, according to quality, safety and efficacy criteria set out by European Community legislation; (c) continuously monitoring adverse reactions and the risk–benefit profile of medicinal products through the national network of pharmacovigilance; and, finally, (d) promoting programmes and studies of active pharmacovigilance in agreement with regional authorities and according to training and research plans with health care professionals, scientific associations and academic institutions.

AIFA also promotes non-profit, comparative clinical trials to prove the added therapeutic value of new drugs compared to those already available, fosters research, supervises the implementation of European directives and national regulations in clinical trials, surveys and inspects drug manufacturing sites in order to guarantee the quality of manufacturing of pharmaceutical products and starting materials, and assures the equivalence of the Italian inspection system with those of the other European countries and within mutual recognition agreements with third countries. The scientific authority and autonomy of AIFA is supported by the activities of several technical scientific committees composed of experts with well established experience.

6.4.1 Licensing

The licensing process is run by AIFA, whose task is to verify the completeness of the dossiers presented by the pharmaceutical companies and their consistency with national and European legislation. AIFA makes the final decision and has to provide the Ministry of Health with the evaluation report required by EU rules. All new drugs are assessed according to safety, quality, efficacy and cost–effectiveness criteria.

Traditionally, Italy has experienced long mean licensing times. On average, licensing can take 24 months for a product to be approved via the national system, while the time scale for products going through the EU centralized procedure can be 10 months shorter (although the European legislation provides for a maximum of 210 days). Registration delays, however, are becoming less of a problem as the backlog of applications is cleared (Jommi, 2001).

6.4.2 The pharmaceutical industry

In Italy, there are a total of 262 pharmaceutical companies producing drugs for human use, 23 producing only active ingredients for human use and finally 50 pharmaceutical companies producing drugs for veterinary use (Farmindustria, 2005).

With regard to pharmaceutical products, during 2003 the number of different drugs sold totalled 5019 while the number of packages was 8742. Pharmaceutical companies can deliver drugs in three different ways:

- to pharmacies (direct sale): this represents about 9% of total industrial production and is called ‘sell in’. Pharmacies then provide drugs to the general public (called ‘sell out’);
- to wholesalers (indirect sale): this represents about 80% of total industrial production; and
- to hospitals: this represents about 11% of total industrial production.

Distribution margin rates for pharmaceutical companies and wholesalers are 66.65% and 6.65%, respectively.

6.4.3 Reimbursement of pharmaceutical products

AIFA is also responsible for the drug reimbursement process. At present, drugs are classified into three groups:

- *group A*: drugs for severe and chronic illness that are totally reimbursed by the SSN
- *group C*: drugs that are not reimbursed by the SSN
- *group H*: drugs that are provided only by hospitals.

This list was established according to four criteria: (a) clinical efficacy, documented by evidence-based criteria; (b) the risk–benefit balance of therapy; (c) the acceptability of therapy to patients; and (d) the cost of the therapy.

AIFA also introduced caveats for some drugs (the so called 'AIFA Notes') that can be considered as guidelines for a more appropriate use of pharmaceuticals.

With the Finance Act of 2001, any kind of co-payment on Group A drugs was abolished, even though regions, in order to maintain the national expenditure cap, can introduce some form of cost-sharing (mainly represented by a fixed amount for any drug in the prescription) (see Chapter 3). The pharmaceutical cap is equal to 13% of public health care expenditure. In order to cover possible deficits, regions could: (a) raise local taxes (always according to national law); (b) reintroduce cost-sharing on drugs; and (c) allow hospitals to dispense drugs to outpatients (see also Section 6.4.7 below). The implementation of these measures varies greatly from region to region.

6.4.4 The national drug expenditure cap

In 1998, the government introduced a ceiling on annual public pharmaceutical expenditure to be fixed yearly by the Finance Act. Although, in theory, the drug expenditure budget should be complied with during the year to prevent possible year-end overruns, in practice, budgets have always been exceeded (Table 6.6) (AIFA, 2005).

The ceiling was €5.165 billion for 1994 and €10.639 billion for 2004. Since 1998, private companies, wholesalers and pharmacists were meant to be responsible for paying back 60% of the deficit to control the growth of

Table 6.6 Budgeted and actual public drug expenditure in Italy, 1998–2004

Year	Expenditure (million euros)			Change in annual expenditure (%)
	Budgeted	Actual	Deficit[a]	
1998	6 302	6 802	500	8.7[b]
1999	6 506	7 589	1 083	11.6
2000	7 449	8 753	1 304	15.3
2001	9 856	11 367	1 511	29.9
2002[c]	10 263	11 723	1 460	3.1
2003[c]	9 730	11 095	1 365	5.4
2004[c]	10 639	11 980	1 341	8.0

Source: AIFA, 2005.

Notes: [a]Deficit = Budget – Actual; [b]Actual expenditure for 1997: €6255 million; [c]Drug expenditure budget is equal to 13% of total health expenditure.

pharmaceutical expenditure. However, this kind of clawback system was never applied. In 2004, Legislative Decree No. 156/2004 again established a clawback system, with the amount that should be paid back by the pharmaceutical industry amounting to €495 million.

The Decree also established that in order to contain pharmaceutical expenditure a discount rate equal to 4.12% of drug prices (including VAT) would be applied. The debate over this issue is still very intense, as the pharmaceutical industry obviously does not want to be considered accountable for public pharmaceutical deficits. As a matter of fact, the question is rather thorny because pharmaceutical expenditure depends on several factors, such as the number of prescriptions, drug prices, drug shifting from less expensive drugs to more expensive ones, physicians' attitudes to prescription, regional measures for containing expenditure and so on. Due to the complex mix of all these elements, it is very difficult to establish the impact of the industry's promotional activities, even though an inquiry undertaken by a national consumers' association (*Altroconsumo*) in May 2003 revealed a widespread scandal regarding a well-known pharmaceutical company that was accused of influencing GPs' prescription practices by offering them gifts such as package tours, computers and mobile phones. More recently, in order to address this type of phenomenon, guidelines on pharmaceutical company behaviour were approved. Moreover, in 2008, new national expenditure ceilings at the central and regional levels were again set to help curb pharmaceutical spending: the primary care budget (including patient co-payments and direct distribution of medicines) cannot exceed 14% of overall public health expenditure and, for the hospital (inpatient) budget, pharmaceutical spending cannot exceed 2.4% of overall public health expenditure. Payback mechanisms for individual companies in the case of any overspending also have been introduced (Folino-Gallo et al., 2008).

6.4.5 Pricing

Pricing system for reimbursable drugs

Up to 2003, the laws regulating the prices of reimbursable drugs were different for those introduced into the market using the national procedure and those using the European procedure (mutual recognition). Prices for drugs authorized under the national procedure were set on the basis of the Average European Price (AEP), whose maximum value was determined by the prices of formulations with the same active ingredient in some EU states. For drugs authorized under the European procedure, prices were negotiated by pharmaceutical companies and AIFA and the regions.

Since 1 January 2004, prices for all reimbursed drugs have been determined through a bargaining process between AIFA and pharmaceutical companies, taking into account:

- potential capacity of the drug market
- prices in other countries
- cost–effectiveness ratio
- therapeutic value.

Pricing system for non-reimbursable drugs

In Italy, drugs belonging to Group C (see above) are divided into three categories: (a) the so called 'ethical drugs' that can be delivered only with a GP prescription (such as drugs used in dermatology or drugs for the nervous system); (b) drugs that do not require a prescription and cannot be advertised (*Senza Obbligo di Prescrizione* (SOP)); and (b) OTC drugs that can be advertised (Fattore and Jommi, 1998).

Since 1994, pharmaceutical companies have been free to set prices for Group C drugs. In 1995, prices were temporarily blocked and, in 1996, a 10% cap was introduced for their annual increase. In 1998, the price cap was abolished, even though a surveillance model was introduced (Jommi, 2001), whereby:

- pharmaceutical companies have to report any price increases to the Ministry of Health, AIFA and the pharmacists' association;
- no more than one increase per year is allowed; and
- the Ministry of Health could intervene to prevent unwarranted price increases.

A code of conduct between *Farmindustria* (the pharmaceutical companies' association) and *Assosalute* (the OTC medicines association) was agreed in 1998 due to concerns over excessive price increases. However, it was dropped in 1998 after an investigation by the Antitrust Authority, which ruled that it constituted a cartel.

6.4.6 Generic drugs

Despite all the interest in cost containment, Italy's authorities have not given generic drugs much attention. As a consequence, their use is rather limited. Only during the last few years has this kind of attitude changed slightly.

The 1995 Finance Act introduced the term 'generics' into legislation. The law provided pricing incentives to promote generics, stating that, if the product was marketed at a price at least 20% lower than the equivalent branded product, it would be automatically listed in the same co-payment class. Other incentives came from the financial accountability of regions for overall health care costs and the consequent process of improving management and cost containment within the ASLs (Ministero della Salute, Osservatorio sull'Utilizzo dei Medicinali, 2004).

Because wholesale and pharmacy margins were traditionally set as fixed mark-ups, this has made the distribution of expensive drugs more profitable. From 1997, the pharmacy margin on SSN-reimbursed products became inversely related to the product's price. However, the regressive effect was very slight and did not favour the use of generics. The turning point was the 2001 Finance Act, which established a 'reference price system': the price for drugs with the same active ingredient, route of administration, pharmaceutical form, unit dosage and number of posological units is equal to the lowest price of drugs belonging to the same category. In parallel, some other measures were implemented such as the 'transparency lists', issued by the Ministry of Health and periodically revised, in which all off-patent drugs, grouped by active ingredients, route of administration, pharmaceutical form, unit dosage and number of posological units, are reported. Moreover, in May 2001, the Ministry of Health, in collaboration with the consumers' association *Altroconsumo*, launched an information campaign on generics for doctors, pharmacists and patients, aimed at informing them on the technical and economic characteristics of generics and on the way in which reference pricing works.

The implementation of these measures differed dramatically all over Italy because some regions adopted them completely whereas some others did so only partially. Tuscany was one of the most active regions in this respect, since it advised citizens with a large-scale information campaign, promoted utilization of generics with courses for GPs, adopted transparency lists and set financial targets within primary care budgets in order to encourage physicians to prescribe more generics (Atella, 2000).

Even though these reforms are still in their early stages, it is worth highlighting that, while in 1998 generics accounted for only 3% of all prescribed medicine units sold, the latest data show that generics represent almost 14% of public health expenditure and more than 25% of the consumed defined daily dose (DDD) (Ministry of Health, 2006a). Moreover, recent data from the Ministry of Health (Ministero della Salute, Osservatorio sull'Utilizzo dei Medicinali, 2006) have highlighted that measures for promoting generics are becoming profitable because savings for the year 2004 amounted to €50 million.

6.4.7 Alternative channels for delivering drugs

Law No. 405/2001 established that, in order to contain pharmaceutical expenditure and respect the public health expenditure cap, regions would have recourse to some measures. One of these is the so-called ‘direct delivery’ of drugs through ASLs instead of the usual channel (pharmacies). This is a strategy that could allow great savings in margins for the SSN because drugs bought directly by health authorities (mostly by hospitals) are granted a minimum 50% discount by pharmaceutical companies.

There are specific conditions under which drugs can be delivered directly by ASLs:

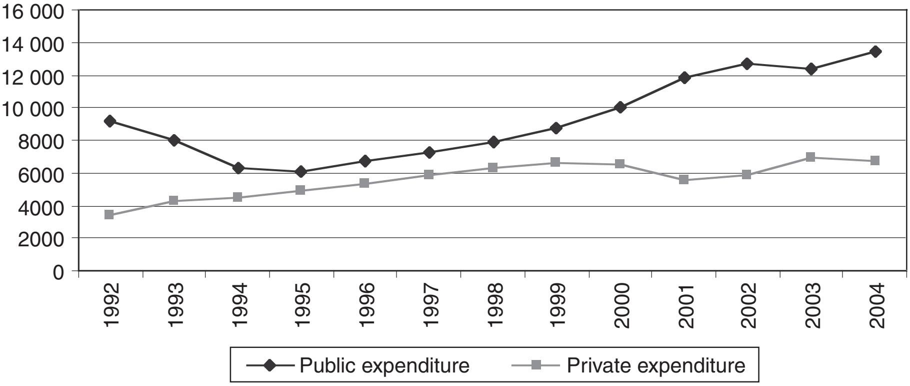
- hospital use drugs: in order to continue pharmacological care after discharge from hospital; applied mainly when the disease requires frequent contact between patient and hospital, due to clinical and management complexity;
- innovative drugs that have not been approved in Italy but are sold in other EU states;
- drugs usually delivered during a day-hospital admission;
- drugs usually delivered during outpatients’ visits;
- drugs for home care patients;
- drugs that are used for specific diseases (e.g. hepatic diseases, transplant recipients); and
- drugs for patients undergoing dialysis.

The implementation of this measure has been initially fragmentary across Italy; however, at present, a regional group with the coordination of the Ministry of Health has created an information system at the national level.

6.4.8 Promoting appropriateness in general practitioners’ prescription practices

GP prescriptions have never been strictly controlled. Only after the series of scandals affecting the whole pharmaceutical system did the 1992–1993 reforms of the SSN create greater incentives and opportunities for making GPs accountable for their prescribing activities, such as establishing an expenditure budget for each GP and incentives to achieve this target. The specific impact of each new regulatory measure is difficult to assess (see Chapter 8), even though the reclassification of drugs substantially affected SSN drug expenditure. In particular, since 1993, the measures described above have had two main effects. First, they dramatically reduced SSN pharmaceutical expenditure from 1993 to 1995. The introduction of guidelines and the introduction of a nationwide drug expenditure budget largely achieved this aim (Fig. 6.7). Second, much of the reduction in SSN pharmaceutical expenditure resulted in shifting costs from the public sector to patients. The demand for drugs is steep: despite an increase in the prices of drugs in Group C, consumption has increased (Table 6.7).

Fig. 6.7 **Public and private expenditure on pharmaceuticals in Italy (million €), 1992–2004**



Source: Ministero della Salute, 2005a.

Table 6.7 **Expenditure on pharmaceuticals in Italy, 1992–2004**

Year	Expenditure (million euros) Total	Public	Private	Expenditure (%) Public	Private
1992	12 580	9 155	3 425	73	27
1993	12 281	8 013	4 268	65	35
1994	10 725	6 282	4 443	59	41
1995	10 983	6 115	4 868	56	44
1996	12 020	6 721	5 299	56	44
1997	13 139	7 288	5 851	55	45
1998	14 201	7 906	6 295	56	44
1999	15 416	8 761	6 655	57	43
2000	16 539	10 036	6 503	61	39
2001	17 451	11 892	5 559	68	32
2002	18 540	12 644	5 896	68	32
2003	19 279	12 355	6 924	64	36
2004	20 224	13 490	6 734	67	33

Sources: Farmindustria, 2005; Ministero della Salute, Osservatorio sull'Utilizzo dei Medicinali, 2006a.

Nevertheless, these cost-containment strategies were not long-term strategies but just emergency measures to stop the never-ending increase in drug expenditure. This could explain why expenditure rapidly increased again from 1996 to 2003.

Italy does not have a standard reporting system for GPs as in other countries such as the United Kingdom. Data on GPs and specialists' prescriptions are managed at the local and regional levels. Hence, the quality and efficiency of the information systems are not uniform all over the country. At present, however, some initial attempts to introduce budgets in some ASLs have begun. These initiatives were firstly targeted at cost-containment: they provide for savings targets, introduce methods to achieve the targets (e.g. guidelines or protocols, lists of cheaper equivalent products, limited lists in critical areas – such as antibiotics or anti-ulcer drugs) and distribute a percentage of the savings to doctors as a 'bonus'.

6.4.9 Drug consumption

Table 6.8 provides some useful macro indicators on drug consumption in Italy during the period 2000–2005.

Drug consumption in 2005 was 807 DDD and this figure highlights an increase of almost 39% compared to 2000. The number of prescriptions and packages, as well as public expenditure, reveal a consistent use of pharmaceutical care. This is not the case for drugs bought by citizens. As a matter of fact, patients' out-of-pocket expenditure in 2003 decreased (-5.5%).

Table 6.8 Drug consumption data in Italy, 2000–2005

	2000	2005	Change from 2000 to 2005 (%)
Number of public packages (millions)	745	899	20.7
Number of prescriptions (millions)	351	478	36.2
DDD/1 000 inhabitants per day	581	807	38.9
Number of private packages (millions)	319	316	-5.5
Total expenditure (public + private) (millions)	15 725	19 459	23.7
Public expenditure as a share of total pharmaceutical expenditure (%)	63.8	68.9	8.0
Public expenditure per capita	174.1	231.6	33.0

Source: Ministero della Salute, Osservatorio sull'Utilizzo dei Medicinali, 2006a.

Note: DDD: Defined daily dose.

Table 6.9 Regional drug consumption, 2005

Regions	Prescriptions (×1 000 DDD)	Packages (×1 000 DDD)	Public expenditure (million euros)	Public expenditure per capita	Packages per capita	DDD/1 000 inhabitants per day	Private expenditure per capita[a]
Piedmont	31 432	891 898	892	195.9	12.1	705.5	111.2
Valle d'Aosta	862	23 419	23	188.6	13.8	757.9	116.2
Lombardy	60 687	1 918 053	1 918	207.3	13.2	722.7	113.5
Trentino-Alto Adige	5 564	162 868	163	177.3	11.8	656.3	102.3
Veneto	30 956	897 498	897	194.5	13.6	749.9	104.7
Friuli-Venezia-Giulia	8 864	245 836	246	191.6	13.7	754.7	97.6
Liguria	14 235	410 382	410	225.0	14.9	791.4	129.5
Emilia-Romagna	33 937	843 382	843	192.2	14.5	791.1	121.3
Tuscany	30 863	719 645	720	186.2	14.6	768.0	120.4
Umbria	8 411	179 439	179	195.5	15.3	810.2	99.8
Marche	13 509	323 717	324	203.4	14.9	776.2	103.6
Lazio	48 587	1 581 638	1 582	306.6	19.0	979.4	110.8
Abruzzo	11 995	297 253	297	225.0	15.6	785.9	95.7
Molise	2 637	72 555	73	217.9	13.9	699.3	75.5
Campania	52 338	1 325 831	1 326	258.1	18.8	889.0	89.7
Puglia	35 196	1 039 805	1 040	274.7	16.7	826.1	86.8
Basilicata	5 458	123 188	123	209.7	15.5	777.9	62.9
Calabria	20 818	530 088	530	277.1	17.8	875.8	81.8
Sicily	47 218	1 432 716	1 424	299.5	18.6	913.1	90.6
Sardinia	14 198	399 127	399	254.7	16.1	849.6	95.5
Italy	477 817	13 409 337	13 409	231.6	15.5	806.9	104.5

Source: Ministero della Salute, Osservatorio sull'Utilizzo dei Medicinali, 2006a.

Notes: DDD: Defined daily dose; [a]This includes private expenditure for A class drugs, C class drugs and OTC drugs.

Table 6.9 reports detailed figures on regional drug consumption expressed in DDDs. The table highlights a profound regional variability; drug utilization ranges from a minimum of 656.3 DDD in Trentino-Alto Adige to a maximum of 979.4 per 1000 inhabitants in Lazio. This variability also has significant repercussions in terms of per capita public expenditure (from €177 to €306). Per capita values are obtained by dividing by a weighted population, taking into account the age and sex of citizens: at the national level, in fact, the Ministry of Health has established precise weights for different health settings (pharmaceutical care, hospital care, ambulatory care). Table 6.10 shows national weights.

Table 6.10 National weights for calculating weighted population

	Age (years)							
	0	**1–4**	**5–14**	**15–44 (M)**	**15–44 (F)**	**45–64**	**65–74**	**>75**
Pharmaceutical care	1.000	0.969	0.695	0.693	0.771	2.104	4.176	4.290
Hospital care	2.348	0.380	0.289	0.418	0.596	1.045	2.575	–
Ambulatory care	0.0518 (ages 0–14)			0.0534 (M+F aged 15–44)		0.0580	0.0850	0.0640

Source: Ministero della Salute, Osservatorio sull’Utilizzo dei Medicinali, 2006a.

6.4.10 Pharmacies

Pharmacies can be classified into two main categories (Law No. 221/1968): urban pharmacies, located in areas with more than 5000 citizens; and rural pharmacies, located in areas with less than 5000 citizens. Both urban and rural pharmacies can be either private or public. The former – accounting for 92% of the total (Table 6.11) – are owned by pharmacists who act as independent contractors under the SSN, while the latter (8%), mainly municipal, are managed by pharmacists employed by the municipality in which the pharmacy is located. Urban and rural pharmacies are basically the same except for some aspects such as: (a) the opportunity for rural pharmacies to obtain compensation (paid by the government) in villages with less than 3000 citizens for the inconvenience of working in these rural areas; and (b) different discount rates (see Table 6.12) based on overall drug prices before VAT (Federfarma, 2005). There are more than 6000 rural pharmacies, which have an important social function, since they often represent the only health ‘reference point’ in such areas.

Although legislation requires that there be at least one pharmacy per 4000 citizens in areas with more than 12 500 inhabitants and one per

Table 6.11 Distribution of public and private pharmacies in Italy, 2005

Region	Number of pharmacies			Percentage		Inhabitants[a]	Inhabitants per pharmacy
	Total	Private	Public	Private	Public		
Molise	162	156	6	96.3	3.7	321 697	1 986
Abruzzo	493	470	23	95.3	4.7	1 285 896	2 608
Valle d'Aosta	47	40	7	85.1	14.9	122 040	2 597
Calabria	757	756	1	99.9	0.1	2 011 338	2 657
Liguria	590	568	22	96.3	3.7	1 577 474	2 674
Piedmont	1 523	1 425	98	93.6	6.4	4 270 215	2 804
Marche	494	428	66	86.6	13.4	1 504 827	3 046
Basilicata	197	195	2	99.0	1.0	597 000	3 030
Sardinia	538	531	7	98.7	1.3	1 643 096	3 054
Umbria	266	216	50	81.2	18.8	848 022	3 188
Province of Trento	162	136	26	84.0	16.0	490 829	3 030
Friuli-Venezia-Giulia	361	345	16	95.6	4.4	1 198 187	3 319
Tuscany	1 073	871	202	81.2	18.8	3 566 071	3 323
Emilia-Romagna	1 195	1 009	186	84.4	15.6	4 080 479	3 415
Sicily	1 410	1 404	6	99.6	0.4	5 003 262	3 548
Lazio	1 439	1 305	134	90.7	9.3	5 205 139	3 617
Lombardy	2 714	2 330	384	85.9	14.1	9 246 796	3 407
Veneto	1 278	1 197	81	93.7	6.3	4 642 899	3 633
Puglia	1 041	1 020	21	98.0	2.0	4 040 990	3 882
Campania	1 506	1 479	27	98.2	1.8	5 760 353	3 825
Province of Bolzano	106	106	0	100.0	0.0	471 635	4 449
ITALY	17 352	15 987	1 365	92.1	7.9	57 888 245	3 336

Source: Federfarma, 2005.
Note: [a]Population at 1 January 2003 (ISTAT, 2003).

5000 citizens in areas with less than 12 500 inhabitants,[25] in fact in almost all regions the proportion of pharmacies to inhabitants is lower. As a matter of fact, at the national level, a single pharmacy serves, on average, 3336 inhabitants (Table 6.11). The law permits some (additional) dispensations on the basis

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[25] Law No. 362/1991.

of geographical characteristics, such as particularly mountainous areas. For example, the Autonomous Province of Bolzano has a higher pharmacy-to-inhabitants ratio precisely because of its mountainous characteristics. Principles and rules for opening a new pharmacy are regulated by a national law (Law No. 475/1968) that defines the number of pharmacies in Italy by means of a list called the *Pianta Organica*. With this tool, the national territory is divided into areas on the basis of inhabitants, so that the whole population can have the same access to pharmaceutical care. The law also requires that the list has to be formally revised every two years. The number of pharmacies in Italy is shown in Table 6.11.

Both types of pharmacy are licensed to sell commercial products and, on behalf of the ASLs, pharmaceuticals. Commercial goods mainly include bandages, contraceptives, personal hygiene items, baby products (such as diapers and infant formula) and cosmetics, while some pharmacies also sell homeopathic products. Pharmaceuticals include drugs and dietary goods and can only be sold if consumers have a prescription. In 2007, the government allowed OTC drugs to be sold outside pharmacies (such as in supermarkets), even though it expressly banned the sale of medicine requiring a GP's prescription.

6.4.11 Pharmacy distribution margins and discount rates

All revenue goes directly to the pharmacy owner: to the pharmacist, if the pharmacy is private, to the municipality, if the pharmacy is municipal, which then pays a salary to the pharmacist running the pharmacy.

Pharmacies' revenue is a percentage, set by law (usually the Finance Law), of the overall price before VAT. In particular, distribution margins were traditionally set as a fixed mark-up on ex-factory prices and have not varied much during the last 15 years. In the period 1981–1997 the wholesale margin changed from 8.0% to 6.65% and the pharmacy margin from 25.0% to 26.7% of drug prices, excluding VAT. At the time of writing, the rate, set in 1996 and still applied, is 26.7%. This rate does not consider special discounts that pharmacies might be able to negotiate with manufacturers. Conversely, ASLs are responsible for reimbursement.

In 1992, a fixed compulsory rebate on pharmacy margins was introduced for products covered by the SSN. The rebate was initially set as a fixed proportion of the price (2.5% of the price excluding VAT, 3% since 1995). However, since 1997[26] pharmacists have been obliged to apply a discount on products reimbursed by the SSN (Farmindustria, 2005). In particular, the SSN holds a so-called 'discount rate' based on a percentage of the overall price before VAT.

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[26] Law No. 662/1996.

Different discount rates apply to different price ranges so that the pharmacy's margin decreases with price. Table 6.12 shows discount rates levied in 2005. As already mentioned, discount rates are different with respect to pharmacy type (urban or rural) and its turnover.

Table 6.12 Discount rates for pharmacies, 2005

Drug classes by price (€)	Percentage urban pharmacies by turnover		Percentage rural pharmacies by turnover	
	€≥258 228.4	€<258 228.4	€≥387 342.6	€<387 342.6
0–25.82	3.75	1.50	3.75	Fixed rate 1.50%
25.83–51.65	6.00	2.40	6.00	
51.66–103.28	9.00	3.60	9.00	
103.29–154.94	12.50	5.00	12.50	
>154.94	19.00	7.60	19.00	

Source: Federfarma, 2005.

6.5 Rehabilitation/intermediate care

The patients' pathway for disabled people is rather complicated in Italy because it involves a complex set of different activities and health care interventions, which are carried out in a multidisciplinary setting. Rehabilitation care was first properly defined by the legislation that established the SSN.[27] The law also clearly stated that USLs (as the ASLs were then known) were responsible for delivering this type of care. However, it was only with Law No. 104/1992, 14 years later, that a precise health care programme was established and medical devices for rehabilitation were listed for reimbursement. Moreover, the law stated that where ASLs were not able to deliver this type of care, agreements with public or private hospitals had to be defined to guarantee service provision.

In 1994, the National Health Plan highlighted the importance of rehabilitation and the creation of a regional integrated network (including health and social services), as well as specific activities that had to be carried out at three different levels: (a) activities aimed to maintain patients' autonomy at the highest possible level, with the ideal setting being home care coordinated by a GP; (b) activities aimed at managing the disabling effects following trauma or disease, in cases of which intensive rehabilitation care could be delivered within specific settings, such as hospitals or ambulatory clinics; and (c) activities aimed at managing

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[27] Law No. 833/1978.

severe disabling effects following trauma or disease, in cases of which a specialized tertiary hospital would represent the best setting.

Guidelines for rehabilitation care issued by the Ministry of Health (Ministero della Salute 1998) defined the strategies that need to be adopted both in the delivery of care and the organizational levels at which care should be carried out. In particular, the guidelines established two different ways to deliver rehabilitation services.

- Intensive care – adopted in the post-acute phase of a disease when it is possible to positively influence the disablement. Usually, these interventions are carried out in AOs, and public or private hospitals.
- Extensive care (also called 'intermediate care'), which represents all the interventions that are not intensive. This kind of care is carried out in long term hospitals, outpatient settings, nursing homes and residential and semi-residential homes.

These guidelines still represent the main recommendations in this area by the Ministry of Health.

6.6 Long-term care

Long-term care usually requires a high level of coordination between health and social services (i.e. ASLs and municipalities). In fact, even though several laws[28] clearly state that this collaboration is necessary, efforts thus far have been insufficient to integrate health and social care. In particular, municipalities have traditionally been responsible for organizing the delivery of social care, and ASLs have managed health care services and social services relevant to health. The presence of different providers, however, has sometimes hampered unified social and health care services, and in response municipalities sometimes decide to delegate the delivery of social care to local health authorities. This choice often reveals a lack of coordination and partnership, and the level of integration between services is still at its early stages.

Usually, elderly and disabled people in Italy can be treated either in residential or semi-residential facilities (*residenze sanitarie assistenziali* (RSA)) and in community home care (*case protette*). RSAs are normally used for patients whose health status requires an intensive use of health care resources, while community home care is often utilized when patients do not have critical health conditions.

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[28] Decreto del Presidente del Consiglio dei Ministri of 29 November 2001, Law No. 328/2000 and National Health Plan 1998–2000.

Health care services provided in RSAs aim to guarantee, within a specific period of time, the regaining and maintenance of residual physical and mental abilities, as well as the possible prevention of functional damage due to complex pathologies that do not need hospital admissions. RSAs can be managed either by public or private hospitals and provide health care services in terms of physicians and nurses, rehabilitation care, drug therapies and aids for everyday life activities. Residential and semi-residential institutions have to comply with specific organizational standards set by the law, including having a physician or specialist (preferably a geriatric specialist) in charge of coordinating the RSA and who has to work for at least 4 hours a day; nurses and physicians available 24 hours a day; and other health personnel. In order to gain admission to a RSA, a patient first needs to make a request to the ASL, presenting a GP's prescription for the service; the GP then fills out the formal application and the RSA assessment unit evaluates whether or not the patient should be admitted. Costs are shared between the SSN and the patient, based on the latter's income. Patient co-payments vary dramatically from region to region.

Community home care is funded by the central government, and its main objective is to maintain patients' residual autonomy through primary care, rehabilitation care and delivery of drugs and medical devices. To access community home care, patients must make a request to their municipality, which carries out an assessment process.

In terms of future reforms and developments, it is worth highlighting that in Lombardy a Permanent Observatory on RSAs has been created to develop a specific database on all the RSAs operating in the region and to define and implement guidelines for an appropriate health care delivery system.

6.7 Services for informal carers

Informal care, defined as the provision of unpaid caregiving activities, is not an area of focus in terms of specific national policies. As a matter of fact, a large part of the population, mainly family members, provide informal health care without receiving any kind of subsidy from the government.

However, some regional health authorities (such as in the Autonomous Province of Trento) have carried out studies in order to assess the value of this kind of care. Moreover, the Italian association *Tribunale per i diritti del malato* (Tribunal for Patients Rights) has issued a report on home care in oncology, highlighting how home care still weighs on families. Unfortunately, this critical situation is far from being resolved, as only sporadic initiatives (at the regional level) have been implemented.

6.8 Palliative care

A national policy on palliative care has been in place since the end of the 1990s, which has focused attention on this kind of care and contributed to an increase throughout the country of palliative care services, such as hospices, day-care centres and palliative care units within hospitals. Although much still needs to be done to ensure the homogeneous diffusion of palliative care services, until 1999 availability was very small, and was concentrated mainly in northern Italy. Much was left to the efforts of voluntary organizations, which still play a crucial role in the delivery of these services.

The first important step was taken through the 1998–2000 National Health Plan. Highlighting the objectives in cancer policy, the National Health Plan underlined the importance of providing and disseminating guidelines for the care of terminally ill persons. The National Health Plan also stressed the importance of implementing rehabilitative programmes and palliative care, and improving health care for terminally ill patients by strengthening medical and nursing home care, palliative and analgesic therapy, psychosocial support to patients and their families, as well as promoting voluntary organizations and setting up new hospice structures. In subsequent years, home care for terminally ill patients was included in the LEAs (namely, in 2001), while the National Health Plan for 2003–2005 provided some guidelines and principles that regions are required to follow in delivering palliative care services, although they can freely choose their own organizational models. An important change is a widening in the scope of pathologies needing palliative care which, in the previous National Health Plan, were restricted to neoplastic pathologies. Instead, in the 2003–2005 National Health Plan, all patients suffering from any kind of progressive, incurable illness are considered to need palliative care. Secondly, the most recent National Health Plan has highlighted the importance of improving the health care network, implementing a quality assessment system, organizing communication campaigns to increase public awareness, and supporting voluntary organizations by integrating them into the palliative care services network.

To implement the 1998–2000 National Health Plan's objectives, Law No. 39/1999 was passed to provide regions with special funds for projects establishing hospice facilities. Additional funds were allocated by a Ministerial Decree on 5 September 2001. Many regions (although not all) made applications and the funds provided for the years 2000–2002 allowed the establishment of 19 hospices and/or palliative care units in Emilia-Romagna, Lazio, Lombardy, Liguria, Piedmont, Trentino-Alto Adige and Veneto. A National Programme for the creation of hospices was also provided by a Ministerial Decree of 28 September 1999. The National Programme provides that the establishment of new hospices should be implemented by converting underused existing public facilities. Moreover, some organizational principles for forthcoming palliative care services were set out: the assessment of palliative care quality through specific indicators; the organization of information and communication campaigns in the regions, and the definition of a palliative care network. The Programme strongly stressed the importance of organizing a network connecting the different levels of care (day hospital, home care, hospice and ambulatory care) and the voluntary associations, in order to guarantee continuity between residential care and home care. The programme also deals with the issue of health professionals' involvement in palliative care and the importance of training plans for palliative care providers.

With regard to the quality of palliative care, national legislation in 2000 defined the minimal structural, technological and organizational standards for hospices. Although related to the new facilities that regions could establish through the special funds provided by Law No. 39/1999, this legislation represents a national framework for homogeneity and minimal quality levels in palliative care.

A very detailed list of structural and technological standards is provided, while organizational standards are less detailed, although not less important. Some of the organizational quality standards outlined include, for instance, the integration of new hospices with the palliative care services network, and the presence within hospices of a multi-professional team made up of physicians, nurses, psychologists, social workers, technical operators and other professionals. Furthermore, assistance with respect to patients' religious needs must be assured and the involvement of voluntary organizations in the delivery of care must be promoted. National benchmarks related to outcome assessment were provided in March 2003, when an agreement was reached by the state and regions on a set of indicators for the assessment of palliative care quality and its outcome. The agreement provides that data collected by regions be sent to the Ministry of Health annually. The indicators are related to five different dimensions: accessibility, resources, activities, outcome and quality. Within this national policy framework, at a regional level, palliative care development and diffusion differs a great deal, reproducing the traditional gap between northern and southern regions.[29]

Usually, there are specialist palliative care units located within hospitals, and specialist palliative care services are also available at the community level, delivering home care when necessary. An important role is also played

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[29] Data on the distribution of palliative care centres and hospices, broken down by type and region, are available on the web site of the Italian Federation of Palliative Care (*Federazione Cure Palliative* (ONLUS)) (http://www.fedcp.org).

by voluntary associations, which, in many regions, have allowed terminally ill patients to benefit from palliative care, although the regional health service itself was not yet ready to deliver this kind of service. A patient needing palliative care would typically take the following steps. He/she would go to their GP to obtain a referral for integrated home care for terminally ill patients (*assistenza domiciliare integrata* (ADI)). GPs manage this service, in which nurses from the local districts and specialized physicians from hospitals are also involved. Alternatively, a patient can have free access to any public hospital where a palliative care and pain relief service are available. It is also possible for patients to approach a voluntary association delivering palliative care. These levels of care (specialist palliative care units within hospitals, hospices, day care centres and home care) are not available in all regions. Indeed, some regions have palliative care units within hospitals (so called *Unità Operative di Terapia del Dolore*), which provide pain relief therapies. Non-profit/voluntary associations play an important role in providing further services, such as psychological support, bereavement support to families, and so on. Regions differ also in the financing system for palliative care. In Lazio, for instance, a daily rate is given to providers as a reimbursement for both hospice and home care, while the cost of pharmaceuticals is not included since the ASL is supposed to provide the appropriate drugs. In contrast, in Lombardy, there are different rates for each level of care (hospital and hospice care), with the hospital palliative care rate being higher than that of hospice care.

In 2001 a national training course in palliative care was provided at the national level, but training is mostly organized by the regions, with differing results depending on each region's effort and involvement in palliative care services. A national study[30] stressed that training in palliative care is unevenly organized depending on the regional palliative care tradition (in Lombardy, for instance, 65 organizations provided courses from January 2001 to May 2003, while in other regions, such as Campania, the number of training organization was only 2). The same study stressed that courses are organized mostly by public organizations (ASLs or AOs) and voluntary organizations, and that they are dedicated to physicians and nurses. Only in a few cases are they open to psychologists and volunteers, and even more rarely to social assistants, spiritual assistants and physiotherapists. Therefore, much remains to be done to ensure homogeneous access and quality of training in palliative care throughout the country; spreading the culture of palliative care has just begun and there have

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[30] "Palliative care: training courses in Italian Regions" http://www.agenas.it/agenas_pdf/06_Formazione.pdf Document produced within the National Research project *Modalità organizzative delle strutture di assistenza palliativa e integrazione delle stesse nella rete dei servizi territoriali*, financed by the Ministry of Health and coordinated by ASSR (now AGENAS).

been strong improvements in many regions, which, until five or six years ago, did not deal with palliative care at all.

In 2001, legislation aimed at easing the use of analgesic and opiate pharmaceuticals in pain relief therapy changed the national policy for physical pain relief. The legislation revoked the penalties imposed by previous legislation, simplified opiate pharmaceuticals prescriptions for severe pain relief, providing dosages for a 30-day therapy (instead of the previous 10-day treatment). A new book of prescriptions for opiate pharmaceuticals delivered by the ASL allows physicians to lay in supplies. Health professionals working in public or accredited structures are authorized to administer therapeutic quantities of pharmaceuticals in patients' homes if they suffer from a neoplastic or degenerative disease. Nurses involved in home care and patients' family members, properly identified by a physician or a chemist, are also authorized to administer therapeutic quantities. A further Ministerial Decree, issued in April 2003, introduced some other simplifications in the prescription procedure for a list of 10 pharmaceuticals – namely, it removed the obligation for physicians to keep receipts for six months or to keep prescriptions of pharmaceuticals with buprenorphine in all its pharmaceutical forms.

6.9 Mental health care

Italy has experienced a significant change in its mental health sector, with a radical shift from old mental health institutions (before 1978) to new community-based psychiatric services. Moreover, due to the complexity and particularity of this field, economic considerations also have to be taken into account to manage its organization and objectives (Piccinelli, Politi and Barale, 2002).

The first comprehensive law on mental health in Italy dates back to 1904: admissions were compulsory and might last indefinitely and implied the loss of civil and political rights. Each province was responsible for the local provision and organization of mental health care and set up its own mental hospital, which was kept apart from the general health care system. Around 1960, the situation changed: several innovations were introduced, new services outside mental hospitals were created and long-term patients were discharged into the community. However, only in 1978 was there a proper change, as some political parties called for a referendum to close down mental hospitals all over the country. This reform measure was approved by the Italian parliament and later incorporated into a more comprehensive legislation that set up the SSN. The law dramatically modified the organization of mental health care, in particular:

- new admissions to existing mental hospitals were no longer allowed, no new mental hospitals or similar facilities were to be built and a gradual closure of existing mental hospitals was planned;
- prevention, care and rehabilitation in mental health were assigned to new functionally integrated community-based services; these services would deal with the full array of mental health needs of the community; and
- compulsory admissions to psychiatric wards were regarded as exceptional, had to be time-limited and were allowed only when outpatient interventions were ineffective or refused by patients themselves.

Unfortunately, the reform law set out some general principles and guidelines but did not provide any detailed standards for services and staff provision and did not allocate any specific budget for setting up the new services. In 1994, a national plan for mental health was launched, supporting the implementation of a comprehensive network of mental health services within each ASL, with specific emphasis on rehabilitation and crisis interventions, the creation of mental health departments, a greater attention to personnel training and the definitive dismantling of old mental hospitals. It is worth noting that the 1994–1998 national plan partially failed mainly because of a paucity of specific guidelines, insufficient monitoring of health interventions and the fact that hospital closure was not accompanied by proper plans to discharge patients and offer them social integration in the community.

Consequently, a second national plan for mental health was launched for the period 1998–2000 in order to provide a better definition of objectives and practical recommendations for health interventions. Standards were clearly set for residential facilities in the community to facilitate the discharge of patients still resident in mental hospitals and to prevent the new facilities from resembling the old-style mental hospitals. The new community-based services within the framework of the department of mental health had to deal with the full array of mental health needs of the population and operate as a real alternative to the old-style mental hospitals.

At present, even though routine collection of clinical and psychological data is poor at the national level (Ministero della Salute, 2001; de Girolamo et al., 2002; Picardi et al., 2006), departments of mental health, specific departments within ASLs, are expected to promote and coordinate mental health prevention, care and rehabilitation within defined catchment areas. The department is based on a multidisciplinary team, including psychiatrists, psychologists, nurses, social workers, educators, occupational therapists, personnel with specific training in psychosocial rehabilitation and secretarial staff. In particular, services operating in the department include:

- *The community mental health centre*. Generally in charge of planning and coordinating interventions across different facilities and settings; patients have direct access and no referral by a GP is required.
- *The general hospital inpatient ward*. This is located in hospitals that have an emergency department; they provide crisis interventions on a short-term basis and patients are then referred back to the community mental health centre for outpatient care or other types of intervention. Most admissions take place on a voluntary basis and only a minority are compulsory. Psychiatrists working in inpatient wards are usually involved in consultation programmes with medical and surgical wards located in general hospitals.
- *Semi-residential facilities (day hospital and day centre)*. Day hospitals allow complex diagnostic evaluation and health interventions in the short- and medium-term; they may be located within the general hospital, although separated from the inpatient ward, or outside the hospital, functionally integrated with the community mental health centre. The day centre implements programmes promoting self-care and the practical and interpersonal skills useful for everyday life activities.
- *Residential facilities*. Such services promote patients' psychosocial rehabilitation and integration and may offer different types of intervention in order to meet patients' needs. The law requires these facilities to have a specific number of beds and be placed in urban areas in order to avoid social isolation and to ensure intensity of care.

Despite common national guidelines, the establishment of new community-based services across Italy developed very slowly and was highly variable. Initially, greater efforts were devoted to the implementation of general hospital inpatient wards and outpatient clinics, but the increasing availability of outpatient services was not followed by a substantial reduction in hospital admissions and psychiatric beds. Table 6.13 summarizes the distribution of mental health services in Italy according to the most recent statistics.

So far, these services have operated independently, and contacts with the department of mental health have been sporadic, unplanned and not standardized. Better integration and closer collaboration between different services are now emerging as a leading principle in the mental health sector. 'Community Pacts for Mental Health' is a new strategy promoting the functional integration of health, social, economic and vocational resources (both public and private) available in a given catchment area. Within this framework, prevention and treatment interventions may be offered to individuals throughout their life by taking into account their specific and complex needs, their family and the local environment. Even though there are some available data at the regional level, it is worth noting that it is not possible to make a comparison among regions: high

Table 6.13 Distribution of mental health services in Italy, latest available data

Services	Number
Community mental health centres[a]	695
Outpatients facilities[a]	1 132
General hospital inpatients[b]	
No. wards	292
No. beds	3 647
Private psychiatric clinics[b]	
No. clinics	54
No. beds	4 862
University psychiatric departments[b]	
No. departments	23
No. beds	399
Day hospital[a]	
No. day hospitals	257
No. beds	942
Day centres[a]	481
Non-hospital residential facilities[b]	
No. facilities	1 377
No. beds	17 343
Mental health personnel (total)[a]	30 978
Psychiatrists	5 094
Psychologists	1 785
Nurses	15 482

Sources: [a]Ministero della Salute, 1998; [b]PROGRES Group (de Girolamo et al., 2002).

variability in services is mainly due to differences in regional health systems and their organization and financing.

With health and social expenditure being increasingly reduced, the community itself is expected to play a crucial role through vocational and self-help organizations. In 1997, 12 909 voluntary organizations operated in Italy's social sector, involving more than 360 000 participants (the PROGRES Group (de Girolamo et al., 2002)). About 75% of these organizations offered social support and health interventions, with mental disorders, learning disabilities and abnormal behaviours ranking high in their lists of priorities. Of the organizations in the mental health sector, 60% included relatives of individuals with mental disorders and about three-quarters retained close functional links with mental health services (de Girolamo et al., 2002). Most organizations were located in northern and central Italy, twice the number than in southern Italy. A positive correlation was found between the number of voluntary organizations in a given area and the socioeconomic level of the local population and availability of public interventions in favour of at-risk groups. This suggests that voluntary resources tended to gather in wealthy areas at the expense of those areas needing them most (de Girolamo et al., 2002).

6.10 Dental health care

At the national level, dental health care is included in the LEAs. In particular, dental care tariffs, which are centrally regulated, are paid by ASLs to contracted providers and these services are guaranteed by the government for specific populations such as children (0–16 years old), vulnerable people (disabled, people with HIV, people with rare diseases) and individuals who need dental health care in some urgency/emergency cases. Other members of the population purchase dental services out-of-pocket. Tariffs for dental services are centrally regulated by the national formulary, even though this dates back to 1980 and health authorities are planning to update it.

Apart from the benefits package that establishes nationally what is to be reimbursed and guaranteed, regions might also carry out their own initiatives autonomously. For example, the northeastern and central regions have already implemented some projects involving either the public or private sector to obtain a higher level of dental health care. In the Lazio region, dental care for the elderly has been successfully promoted and implemented.

It is worth noting, however, that there is no national institution in charge of monitoring the quality of dental health care; some regions, nevertheless, have implemented guidelines for assessing service quality in the public sector. In contrast, in the private sector, quality of care is evaluated by the National Dentists Association.

6.11 Complementary/alternative medicine

In the last few decades various treatments, remedies and spiritual/religious philosophies, often defined as unconventional, alternative, complementary and integrative, have been adopted in Italy as cures for several health problems (Raschetti and Mennini-Ippolito, 2005). Some years ago, physicians were very sceptical about complementary/alternative medicine (CAM), and saw it as a discipline that was not universally accepted and not evidence-based. In more recent years, however, doctors' and health personnel attitudes have changed a little due to increased requests from patients for these treatments. The idea is that it is important to maintain a rigorous evidence-based approach in treating patients but, at the same time, CAM should not be considered as an alternative to conventional medicine, but rather as a complementary discipline for which there is still not sufficient evidence (Raschetti and Mennini-Ippolito, 2005). In Italy, there is a lack of regulations regarding these kinds of treatments, and they are not included in the benefit package or reimbursed by the SSN. It is worth pointing out, however, that even though Legislative Decree No. 299/1999 clearly excluded CAM from the reimbursement process, at the same time the law cites CAM as a "potential" addition to health services due to its marked increase of utilization. As a matter of fact, in the last few years, some political parties have proposed many bills attempting to give CAM legal backing.

The ISTAT periodically conducts a multipurpose survey on health conditions and health services utilization (Indagine Multiscopo) on a sample of Italian families that is representative of the population. Almost 9 million people (15.6% of the total population) in the period 1997–1999 used CAM treatments, mainly homeopathy. Table 6.14 provides some data taken from this survey (ISTAT, 2001).

Other data from ISTAT highlight that mainly women use CAM (18.2% versus 12.9%) and the age group with the highest consumption is among 35–44 year olds. For children, the demand for such treatments is definitively lower throughout Italy, with homeopathy often being the most popular type of remedy (Mennini-Ippolito and Bologna, 2004).

Table 6.14 Distribution of individuals requiring complementary and alternative medicine at least once in the period 1997–1999, by types of treatment

			Usage (%)		
Therapy	**North-west**	**North-east**	**Centre**	**South**	**Italy**
Homeopathy	11.8	12.8	8.3	2.5	8.2
Manual treatments (therapeutic massages)	9.5	10.8	7.4	2.9	7.0
Herbal medicine	6.2	8.5	4.4	1.9	4.8
Acupuncture	3.8	4.0	2.9	1.5	2.9
Other	1.8	2.0	1.5	0.5	1.3
Total	20.7	24.1	16.3	6.5	15.6

Source: ISTAT, 2001.

To investigate this phenomenon further, a National Research Project on "Unconventional Therapies" has been funded by the Italian Ministry of Health and coordinated by the Italian Institute of Health in collaboration with ISTAT. The project, however, is still in its early stages (Mennini-Ippolito and Mozzanti, 2005).

6.12 Maternal and child health

In the past 40 years, many changes have occurred in the area of reproductive health: population ageing, a decrease in the birth rate and an increase in women's average age for pregnancy are some of the major determinants of these changes. The average number of children per woman in Italy is 1.2, one of the lowest in Europe. There also has been a gradual, but consistent, increase in the dissemination of knowledge regarding contraceptive methods, due mainly to the introduction of national legislation. It is worth pointing out, also, that one of the most recent laws (Law No. 40/2004) established principles and criteria with regard to assisted reproduction in order to address infertility problems, even though it is extremely limited compared with legislation in many other countries and is very controversial.

Changes have not occurred in the same way throughout Italy: as usual, marked differences exist between the north and the south, such as the higher recourse to Caesareans in the south, where there is also a higher mortality rate at birth. There are also differences in prevention and health care after birth. In some regions (Campania, Friuli-Venezia-Giulia, Lazio, Marche, Tuscany and Emilia-Romagna) several initiatives have been implemented to promote maternal and child health, such as a campaign to promote breastfeeding. Data from ISTAT highlight that, in order to guarantee a higher level of care, greater effort and investment should be made, mainly in southern regions, and that there should also be compulsory coordination of all regional projects and programmes at the national level.

Table 6.15 shows how child mortality has decreased in the period 1990–2001 (-46.3% at the national level) with a high variability among regions. Moreover, the rate is definitively higher in southern Italy and this trend is confirmed in both selected years.

Table 6.16 shows the perinatal mortality rate among Italian regions: in 2001, the mortality rate was equal to 3.3 per 1000 live births, ranging from a minimum of 1.6 (Trentino-Alto Adige and Veneto) to a maximum of 4.7 (Calabria). Trentino-Alto Adige, Veneto and Tuscany have mortality rates that are significantly lower than the national average. Comparing the rates in

Table 6.15 Child mortality rate by region, 1990 and 2001

Region	Child mortality rate per 1000 live births 1990	Child mortality rate per 1000 live births 2001	Decrease (%) 2001–1990
North			
Piedmont	6.4	3.6	43.8
Valle Aosta	6.1	3.6	41.0
Lombardy	6.9	3.9	43.5
Trentino-Alto Adige	6.4	2.3	64.1
Veneto	5.7	2.4	57.9
Friuli-Venezia-Giulia	3.9	3.7	5.1
Liguria	7.2	4.5	37.5
Emilia-Romagna	7.0	3.6	48.6
Centre			
Tuscany	6.2	3.3	46.8
Umbria	7.9	3.0	62.0
Marche	7.6	4.3	43.4
Lazio	7.1	4.4	38.0
South			
Abruzzo	8.4	5.0	40.5
Molise	7.9	5.8	26.6
Campania	10.2	5.4	47.1
Puglia	10.0	5.6	44.0
Basilicata	11.2	5.0	55.4
Calabria	8.9	5.9	33.7
Sicily	10.5	6.3	40.0
Sardinia	8.5	3.9	54.1
ITALY	8.2	4.4	46.3

Source: ISTAT (selected years from 1990 to 2001), *Annuario Statistico Italiano*.

the two years, at national level the reduction in mortality is equal to -58.7%. It is worth noting that these decreases were not more consistent in those regions presenting higher mortality rates than the national average.

The adolescent pregnancy rate (mothers aged less than 20 years old) shown in Table 6.17 highlights a reduction during the period 1990–1997, with rates ranging from 3.17 in 1991 to 1.69 per 1000 women in 1997; and this decrease could be due to the potential effectiveness of health promotion programmes.

Table 6.16 Perinatal mortality rate by region, 1990 and 2001

Region	Perinatal mortality rate per 1000 live births		Decrease (%) 2001–1990
	1990	2001	
North			
Piedmont	5.2	2.6	50.0
Valle Aosta	5.1	3.6	29.4
Lombardy	4.9	2.8	42.9
Trentino-Alto Adige	5.2	1.6	69.2
Veneto	4.1	1.6	61.0
Friuli-Venezia-Giulia	2.5	2.5	0.0
Liguria	5.2	3.8	26.9
Emilia-Romagna	5.4	2.7	50.0
Centre			
Tuscany	5.2	2.3	55.8
Umbria	6.8	2.1	69.1
Marche	6.1	3.1	49.2
Lazio	5.7	3.5	38.6
South			
Abruzzo	7.1	4.2	40.8
Molise	6.9	4.3	37.7
Campania	8.0	4.3	46.3
Puglia	7.9	4.2	46.8
Basilicata	8.5	4.0	52.9
Calabria	7.0	4.7	32.9
Sicily	8.3	4.6	44.6
Sardinia	6.3	2.6	58.7
ITALY	6.4	3.3	58.7

Source: ISTAT (selected years from 1990 to 2001), *Annuario Statistico Italiano*.

Moreover, maternal deaths have consistently decreased in the period 1990–2001 with a variation in the rate of -75%.

The enactment of the abortion law in 1978,[31] making the procedure legal within defined criteria, initially created a very high utilization rate for this intervention during the 1980s (see Table 6.18).

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[31] Law No. 194/1978.

Table 6.17 Adolescent pregnancy rate and maternal deaths, Italy (latest available years)

Year	Adolescent pregnancy rate (per 1 000 women)	Maternal deaths (per 100 000 live births)
1990	3.17	8.61
1991	3.07	4.85
1992	2.65	7.22
1993	2.73	4.34
1994	2.49	3.54
1995	2.28	3.23
1996	2.11	3.79
1997	1.69	4.37
1998	NA	3.38
1999	NA	2.67
2000	NA	2.97
2001	NA	2.07

Source: WHO Regional Office for Europe, 2005.
Note: NA: Not available.

Since then, a reduction in abortion rates has occurred all over Italy, ranging from 16.4 in 1981 to 9.3 per 1000 women in 2001. It is also interesting to look at the abortion rates by nationality. In fact, Italy's large-scale immigration in recent years could be the main explanation for the stabilization of the general incidence of abortion among Italian women (see Table 6.19). The number of abortions highlights large regional variations, due mainly to the fact that the immigration rate is greater in the north. The majority of foreign women requiring the intervention come mainly from eastern Europe. At the national level, finally, voluntary abortions by foreign women as a proportion of the total number of abortion is 22.4%. This high rate among foreign women should not be surprising considering that many foreign-born women often live in Italy in difficult conditions and are from countries where abortion is a commonly adopted practice.

Table 6.18 Number and relative standardized rates of voluntary abortions in women aged 15–49 years by region, 1981, 1991 and 2001

Region	1981		1991		2001	
	Number	Rate[a]	Number	Rate[a]	Number	Rate[a]
North						
Piedmont	21 890	21.6	10 571	12.0	11 031	10.7
Valle Aosta	547	25.1	387	12.8	279	10.4
Lombardy	35 351	17.0	24 579	10.4	21 865	9.7
Trentino-Alto Adige	2 013	10.3	1 670	7.3	1 629	6.2
Veneto	11 046	11.2	6 489	6.5	6 571	6.4
Friuli-Venezia-Giulia	5 030	16.7	3 067	9.7	2 139	7.8
Liguria	8 330	21.2	4 707	12.3	3 792	11.7
Emilia-Romagna	24 174	23.2	13 132	12.6	10 980	10.8
Centre						
Tuscany	16 883	20.3	11 041	12.4	8 174	9.6
Umbria	3 886	20.0	2 906	14.1	2 407	11.9
Marche	5 206	16.8	2 901	8.6	2 602	7.4
Lazio	20 368	16.5	17 737	13.0	15 173	11.0
South						
Abruzzo	4 466	17.0	3 319	11.9	2 633	8.8
Molise	1 031	14.7	1 254	14.8	719	8.5
Campania	12 020	10.0	13 722	9.6	12 552	8.5
Puglia	24 146	26.2	20 458	19.4	14 061	13.3
Basilicata	1 290	14.1	991	13.6	644	9.1
Calabria	2 104	10.2	3 991	8.4	3 365	7.0
Sicily	12 068	10.7	10 535	8.5	9 013	7.3
Sardinia	4 906	13.0	3 716	8.3	2 462	5.9
ITALY	216 755	16.4	157 173	11.0	132 073	9.3

Source: ISTAT (selected years from 1981 to 2001), *Annuario Statistico Italiano*.

Note: [a] Relative standardized rates per 1000 women, 15–49 years of age.

Table 6.19 Number of abortions by nationality and region, 2002

Region	Italian	East European	African	South American	Asian	Other nationality	Nationality not available	No. abortions in foreign women	Total
North									
Piedmont	7 897	1 885	834	519	131	60	2	3 429	11 326
Valle Aosta	246	14	10	3	1	4	1	32	278
Lombardy	14 471	2 384	1 556	2 402	986	164	83	7 492	21 963
Trentino-Alto Adige	1 559	160	68	39	27	4	0	298	1 857
Veneto	4 544	1 155	577	135	277	58	149	2 202	6 746
Friuli-Venezia-Giulia	1 721	216	142	45	32	13	7	448	2 169
Liguria	2 702	245	147	662	51	20	0	1 125	3 827
Emilia-Romagna	8 126	1 490	936	331	457	79	0	3 293	11 419
Centre									
Tuscany	6 100	1 101	293	249	294	111	14	2 048	8 148
Umbria	1 610	455	115	165	41	20	52	796	2 406
Marche	1 903	425	145	68	73	16	24	727	2 630
Lazio	11 096	2 808	390	786	445	100	0	4 529	15 625
South									
Abruzzo	2 483	307	57	33	34	12	13	443	2 926
Molise	623	13	5	3	2	0	1	23	646
Campania	8 845	832	93	43	63	37	3 000	1 068	9 913
Puglia	12 616	265	70	21	30	15	73	401	13 017
Basilicata	615	20	6	0	0	2	1	28	643
Calabria	3 120	219	16	7	15	8	40	265	3 385
Sicily	8 774	152	156	30	135	30	21	503	9 277
Sardinia	2 263	52	18	13	18	12	48	113	2 376
ITALY	101 314	14 198	5 634	5 554	3 112	765	3 529	29 263	130 577

Source: Ministero della Salute, 2002.

6.13 Health care for specific populations

Statistics on immigration in Italy have been available since 1970. During the earlier part of this period, immigration was not very consistent but during the last two decades it has become a phenomenon with strong expansion. In particular, in the period 1990–2000, immigrants in Italy accounted for more than one million people. In the past five years, data from the Ministry of the Interior have shown a dramatic increase and, at present, the number of immigrants has almost doubled (to 2 319 000). For several years, Italy did not have specific regulations related to health care for foreign people. In 1998, clear legislation for immigrants was enacted.[32] At the time of writing, regular immigrants are registered in the SSN in the same way as Italian citizens: they have access to primary care, ambulatory care, hospital care, rehabilitation and emergency care. If they are illegal (i.e. clandestine immigrants) they can have access to health care through the use of a specific form (*Stranieri temporaneamente presenti* (STP)), which guarantees their anonymity and allows them to obtain specific health care services. In these cases, people do not have access to primary care, but only to emergency care and specific elements of the benefits package, such as maternal and child health care, health care for people under 18 years of age, vaccinations and international preventive treatments, prophylactic services, diagnosis and care for infectious diseases, as well as ambulatory and hospital care.

Prisoners are considered to be the same as Italians and so are registered in the SSN with access to the whole benefit package of health care services (Legislative Decree No. 230/1999). If such prisoners are also immigrants they are registered in the SSN as long as they are in jail.

Military personnel have access to health care services even though they also can use military health care facilities such as military hospitals, which are financed by the Ministry of Defence.

Refugees can be categorized into two groups: those requiring asylum, in which case they are temporarily registered in the SSN; and those having refugees status, which gives them the same access rights as Italian citizens.

EU citizens are required to pay co-payments, where they exist, while delivery of health care services for non-EU citizens is regulated by bilateral treaties.

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[32] Legislative Decree No. 286/1998.

7 Principal health care reforms

7.1 Analysis of recent reforms

7.1.1 The first reform: the creation of the SSN in 1978

In 1978, Law No. 833/1978 launched a thorough reform of Italy's health care system and established a national health service. The change in health system structure involved three related objectives: universal, free access to all Italian citizens; tax-based financing; and expansion of public services. Given the marked north–south divide, not only in economic development but also in the distribution of public welfare resources, expanding the public health care sector was envisaged as a means of reducing the geographical imbalance in the distribution of services.

An additional, instrumental objective was to promote integration across levels and categories of care, to be achieved at the local level. This led to the creation of USLs modelled on the district health authorities in the United Kingdom in terms of their functions and reference populations. An important departure from the British model, however, was the fact that these local health units were to be governed by democratically elected institutions, the representatives of local councils, thus incorporating a feature typical of Scandinavian countries. Similarly, regional governments were given some responsibility in hospital planning and management and in securing a fair distribution of resources across local health units.

Despite this major reform, the dividing line between state and regional responsibilities remained blurred. In addition, since its inception in 1978, the SSN had been blamed for poor quality of care, excessive bureaucracy and insufficient accountability to the public, resulting in patient dissatisfaction.

Some of these criticisms resulted from the unintended negative effects of some reform measures, whereas others stemmed from incomplete implementation of the 1978 reform proposals, as discussed in the section on reform implementation (see below).

7.1.2 The second reform: introducing internal markets and regional devolution

The SSN's problems constituted the main driving forces behind the approval of the second health care reform in the early 1990s. Legislative Decrees Nos. 502/1992 and 517/1993 launched a 'reform of the reform', which introduced measures to establish an internal market similar to the British model that was operating at the time, and a process of devolving health care powers and financial accountability to regions.

The internal market reforms, as in the United Kingdom during the early 1990s, envisaged delegating significant managerial autonomy to major hospitals and local health organizations (transforming them into AOs and ASLs), introducing a partial split between purchasing and providing functions, and promoting competition.

In contrast to the United Kingdom, however, Italy's reforms:

- gave patients free choice over their preferred providers;
- restricted self-governing status to tertiary hospitals, while ASLs continued to directly provide most hospital care;
- did not identify contracts as the way to negotiate price, volume and cost;
- introduced a per-case payment system in the hospital sector;
- allowed citizens to opt out of the SSN by reducing their contributions to the public system and choose private insurance schemes instead (this option, included in Legislative Decree No. 502/1992, was later abolished by Legislative Decree No. 517/1993); and
- gave regions an even stronger role in the SSN, although the allocation of powers for health care between the state and the regions was not clear.

The general environment within which the market was expected to operate had two additional, marked differences compared with the United Kingdom. First, private providers under contract with the public system were already delivering many SSN services as a result of the (partly unfulfilled) 1978 plans to expand public health care services. Second, demand-side cost-containment policies ranked high on the political agenda during the 1980s and early 1990s, leading to high co-payments. During 1992–1993, these co-payments were again raised.

As in the United Kingdom, it was initially expected that market incentives would develop within the SSN, leading to increased responsiveness to patients' needs and demands, increased hospital productivity and progressive cost-containment. It was also perceived that smooth performance of the system required careful monitoring and regulation of the market to avoid episodes of market failure. Most of this task was left to regional governments following the process of regional devolution, which was launched simultaneously. A significant exception was the issue of quality, for which innovative central regulation was foreseen within the original reform proposals.

The main regional devolution measures were as follows. Regions were put in charge of regulating the internal market within their territory, monitoring the behaviour of ASLs and AOs and appointing their general managers. In addition, they retained responsibility for financing public health care from a weighted capitation budget received from the state.

However, regional governments' financial accountability to the centre was reinforced by the fact that the reform measures explicitly stated that they were responsible for their own deficits, which they should cover either by raising additional regional taxes or by increasing co-payments. However, regions were given little room to autonomously increase their resources, given the strong centralization of general and payroll taxes (which financed health care at the time) and the high level of co-payments.

7.1.3 The third reform: reinforcing the regulatory role of the new federal state

Not surprisingly, the 1992–1993 reforms did not fully achieve some of the expected results and created new, unforeseen problems (see the section on reform implementation, below). Therefore, measures were launched to address these perceived problems. First, within the context of a general transition towards a federal state, two packages of reforms aimed at establishing fiscal federalism were launched in 1997 and 2000. Second, to prevent each region from providing drastically different levels of health care, the National Health Plan for 1998–2000 set up basic guidelines and the first steps towards defining a core benefit package to be guaranteed by all regions. Third, through Delegating Law No. 419/1998, the parliament asked the central government to further regulate and rationalize the SSN by adopting a decree on its organization and functioning. The government completed this task in 1999 by passing Legislative Decree No. 229/1999, which launched the third SSN reform.

The reform measures adopted during 1997–2000 attempted to reinforce the role of the state in regulating the SSN while simultaneously reducing the state's role in directly governing the national health system in favour of the increasingly autonomous regions. The fiscal federalism reform aimed to clarify accountabilities by transferring to the regions full responsibility for providing a basic benefit package under a balanced budget. Nevertheless, the National Health Plan for

1998–2000 and the subsequent 1999 health system reform clearly established the leading role of the state in formulating the basic regulatory framework to which regions must adhere in exercising their new autonomy. This regulatory framework had four main goals: promoting strategic planning; regulating competition among public and private providers; assessing the quality of care; and promoting cooperation across levels of care and health care enterprises.

7.1.4 The road towards fiscal federalism

The process of regional devolution initiated in 1992–1993 was further regulated and refined in 1997 through two laws aimed at leading the transition towards a federal state: Law No. 59/1997 (the ‘Bassanini Law’), which regulated the transfer of powers to regions, and Legislative Decree No. 446/1997 (the ‘Visco Decree’), which introduced sources of autonomous financing for the regions as a first step towards fiscal federalism. These laws represented an important breakthrough towards regional financial autonomy and thus, towards genuine regional responsibility for ensuring the provision of a core package of health care services and benefits for the whole population.

7.1.5 Regulating the new SSN: the National Health Plan for 1998–2000 and the 1999 reforms

The reforms of the SSN regulatory framework launched during the late 1990s departed from the recognition that the internal market introduced during 1992–1993 required careful management and that this critical strategic task could not be left to the regions alone. The main issues of concern were the varying pace of implementation by each region, the perceived fragmentation in the operation of the internal market and the perverse incentives contained both in the new provider payment systems and in the co-payment schemes. In addition, the push towards federalism opened up the possibility of increasing interregional differences in the quantity and quality of health care services and therefore required reinforced mechanisms to guarantee equity of access and treatment across Italy. To this end, four sets of regulatory measures were launched to promote strategic planning, regulate competition, assess the quality of care and promote cooperation.

Promoting strategic planning

Strategic planning is now achieved by elaborating a National Health Plan every three years, which should define the basic benefit package guaranteed to every citizen and outline the main health targets to be pursued during the Plan’s time frame. Regions are responsible for formulating proposals for the National

Health Plan, taking into consideration local health needs and priorities (which should be assessed in cooperation with ASLs and AOs) and for implementing leading national objectives at the regional level. This task should materialize in the approval by regional parliaments of a regional health plan consistent with national guidelines and priorities but adapted to fit regional health needs. The link between regional and national policies is characterized by a mutual process in planning and approving the documents, with the Ministry of Health assessing the consistency between regional and national health plans and the regions putting forward proposals for the National Health Plan and expressing their opinions about the final version of this Plan. In this context, the National Health Plan for 1998–2000 laid out the main steps the central government should follow to define a basic benefit package.

In defining a core benefit package, the first step is to define the basic normative criteria to guide the selection of SSN services. The second step is to specify the broad categories of care to which access should be guaranteed, such as primary and community care, and hospital care. The third step involves specifying the broad health interventions that should be delivered within each broad category of care and the appropriateness criteria to be used in deciding among alternative treatments for the same condition and in prescribing specific interventions for specific categories of patients. The fourth step is to estimate the funds required to meet the specified list of services: this will form the basis for estimating the per-capita funding allocations for regions and the global public budget for health care. The fifth step is to design a monitoring system to evaluate the extent to which each region can guarantee the basic benefit package. Legislative Decree No. 56/2000 included special financial provisions on fiscal federalism to guarantee that all regions effectively establish adequate monitoring systems. In addition, the National Health Plan for 1998–2000 went on to define the first two steps of this ambitious planning process, leaving the other three steps for subsequent planning exercises. In particular, the normative principles that should guide decisions on the benefit package were defined as follows: human dignity; need; burden of disease and equity; and effectiveness, appropriateness and economic efficiency (see Chapter 2). The National Health Plan tended to concede more emphasis to need and effectiveness as the main selective criteria, giving efficiency a more limited role, restricted to deciding among alternative treatments for a similar condition.

With regard to the second step, the National Health Plan for 1998–2000 also defined the main categories of care to be provided by the SSN. In contrast with the National Health Plan for 1994–1996, it reduced the main areas of intervention from the previous six to three, a move that has been interpreted as an attempt to emphasize the need for further cooperation among health care providers and across levels of care, and the need to promote community care and public health at the expense of hospital care. The three main categories of care were defined as "public health services in working and living environments", "community health care" and "hospital health care".

Public health services in working and living environments mainly focus on preventing disease (vaccines and controlling infectious diseases), controlling environmental pollution (noise, water, human and industrial waste and beaches), occupational health, veterinary medicine (cattle disease eradication and vaccination) and food hygiene (laboratory tests on food and beverages and control over food-processing plants and over food stores). Community health care includes primary care (GP and paediatric visits and referrals for specialist ambulatory services, diagnostic procedures and hospital treatment), pharmaceuticals, home care (for elderly and disabled people), specialist care (specialist visits, diagnostic procedures and therapeutic treatments) and residential and semi-residential care (psychiatric care, rehabilitation, hydrothermal treatments, prostheses and drug addiction care). Hospital health care comprises acute patient care (emergency, ordinary and day-hospital care) and post-acute patient care (rehabilitation and long-term care). In addition to these measures, the National Health Plan for 1998–2000 also included significant steps towards promoting and assessing health care quality by establishing and regulating the National Programme on Health Care Quality and the National Programme on Clinical Guidelines, and towards improving health promotion programmes by setting and monitoring national health targets.

Regulating competition in the internal market

The 1999 health care reform introduced measures aimed at regulating the purchasing function, clarifying the boundaries between public and private services within the internal market and reducing the scope of private providers within the public system. Purchasing was first regulated by Legislative Decree No. 229/1999, which specifies that the comparative evaluation of quality and costs should be used in selecting the providers (public and private) allowed to provide services on behalf of and with funding from the SSN.

To promote fair competition between providers while simultaneously ensuring the quality of care, the 1999 reform established a four-step process for selecting providers to be applied to both inpatient and outpatient care, covering: (a) the authorization to establish new health care structures or to modify existing ones; (b) the authorization to deliver health care services; (c) the granting of institutional accreditation by regional authorities based on a wide-ranging quality assessment of the health care organization and their added value to the existing stock of facilities; and (d) negotiated contractual agreements between regional and local authorities, and providers, based on value-for-money (see Chapter 4 for a detailed account of the provider selection process).

Consistent with the federalization of Italy's health care system, the 1999 reform envisaged that regional governments would be responsible for establishing and managing the provider accreditation process, but implementation has been slower than expected for several reasons, ranging from delays by the central Ministry of Health in issuing the general guidelines for accreditation to specific regional problems (see Chapter 4).

Finally, various attempts were made during the period 2000–2001 to reduce demand-side cost-sharing, directed towards reducing the role of private sources of financing and the role of private, non-accredited providers within the health care system. The first proposal in this direction was an income-based co-payment system that was rejected by the parliament in 2000. According to this system, patients would be rated according to ability to pay as a family and not as individuals and then classified into three categories of income. Patients in the lowest income category would be completely exempted from co-payments on outpatient specialist services and pharmaceuticals; those in the second category would pay 70% of the total cost up to a maximum of €31; and those in the third category would pay 85% of the total cost up to €52. A more ambitious proposal was included within the Finance Law of 2001. In particular, starting in January 2002, the maximum amount to be paid by patients for outpatient care was reduced to €12, and co-payments for this category of care was abolished from 2003.

The Law also established that, starting in 2001, some procedures aimed at early diagnosis of cancer would be delivered free of charge:

- mammography every 2 years for women aged between 45 and 69 years;
- pap test every 3 years for women aged between 25 and 65 years; and
- colonoscopy every 5 years for people aged 45 years and older.

The Finance Law of 2001 also proposed significant changes to co-payments structures for pharmaceuticals, but these changes were subsequently modified and/or reversed.

Assessing the quality of health care

Both the National Health Plan for 1998–2000 and Legislative Decree No. 229/1999 laid down framework regulations to complement the previous quality assessment interventions launched by the 1992–1993 reforms. Taken together, the regulations passed during the 1990s covered the three main components of quality: input (quality of infrastructures and human resources); process (appropriateness and timeliness of interventions); and outcome (health status and patient satisfaction). In particular, the National Health Plan for 1998–2000 established a procedure for institutional accreditation of public and private providers, based on assessing the quality of their infrastructure and human resources. Moreover, the National Health Plan for 1998–2000 envisaged the development of a national programme on health care quality aimed at steering the SSN towards continuous and systematic improvement, assessment and monitoring of all dimensions of quality. Its main objectives were: to establish by legislation ways to make the promotion and assessment of quality compulsory both for private and public health care structures; to devise instruments to review and assess clinical and organizational practices within every service; to review the battery of quality indicators introduced by the 1992 reform (defined by two ministerial decrees approved in 1995 and 1996, respectively); to evaluate the impact of the changing financing systems on hospital and outpatient care; to promote the participation of health professionals and patients in evaluating ASLs and in promoting quality health care; and to allocate some of the research funds earmarked by the SSN to financing research and operational projects related to the programme. Not all the above-mentioned objectives have been implemented, this depending in part on regional capacity to find actual mechanisms to realize them and on central government delays (e.g. on issuing necessary guidelines for institutional accreditation so that this process may be used to make the promotion and assessment of quality compulsory) (see Chapter 4).

The set of quality-related measures included in the National Health Plan for 1998–2000 dealt with the effectiveness and appropriateness of health care interventions. In particular, the National Health Plan envisaged a National Programme on Clinical Guidelines (*Piano Nazionale Linee Guida* (PNLG)) and established the organizational levels to be involved in the process of designing and applying clinical guidelines: at the macro level (the central government, regions and ASLs), the meso level (health care centres) and the micro level (health professionals and clinical services). Ideally, these interventions should be targeted at steering the behaviour of health care professionals towards appropriate and effective provision of services. Legislative Decree No. 229/1999 actually established the National Programme for the Elaboration, Dissemination and Evaluation of Clinical Guidelines, which aims to design and disseminate guidelines on the treatment of the most relevant conditions, especially back pain, pregnancy, hypertension, cervical cancer, breast cancer and angina pectoris.

To better coordinate the organizational level involved in defining clinical guidelines, a Ministerial Decree in 2004 provided for the establishment of:

- a National Strategic Committee to promote clinical guidelines and communication, and to verify funding;
- an Organizational Committee for the PNLG at the ASSR to collect documents and coordinate the work of the national working groups involved in the elaboration of guidelines; and

- National Working Groups within the Ministry of Health, the ASSR and the ISS composed of experts from scientific societies who develop guidelines by also collecting stakeholders' points of view.

Since its establishment, the PNLG has produced 18 guidelines on different topics (from citizens' participation in health care services assessment to the management of influenza). A comprehensive list of all the guidelines and related documents are available on the national programme for clinical guidelines web site (http://www.pnlg.it).

The 1999 reform considered human resources to be a strategic factor in enhancing health care quality and patient satisfaction. Training allows health professionals to improve their skills and develop a new professional culture. Furthermore, the concept of continuing education in medicine (*educazione continua in medicina* (ECM)) was introduced for the first time: training is no longer seen as a preparatory activity to be undertaken solely before practising but involves participating in courses, meetings, seminars, study tours and research activities that can give professionals additional qualifications and improve their skills. Health professionals working in both the public and private sectors are expected to improve their knowledge and to keep up to date in order to be allowed to continue practising. Thus, according to the 1999 reform, private health care structures cannot be accredited if their private health care professionals have not earned the necessary training credits. The importance of managerial training courses as a tool for achieving the skills and knowledge required to manage a health care structure is also emphasized.

Indeed, all health professionals have to attend a managerial training course to access secondary or primary managerial positions within public sector health facilities. The third wave of reforms (in 1997 and 2000) asked for the establishment of a National Commission on Continuing Education in Medicine (NCCED), responsible for:

- establishing the criteria for public or private institutions to qualify as training agencies and to accredit them and the training and refresher activities they organize;
- determining training objectives of national interest;
- highlighting criteria for assessing and validating the training; and
- assessing the relevance and suitability of the regions' training activities (regions are required to submit a report).

The NCCED was established on 5 July 2000, together with the launch of the National Programme on Continuing Education in Medicine (NPCEM). The NCCED's membership is renewed every three years and members are chosen by the Ministry of Health (who leads the Commission), the Ministry of Universities and Scientific and Technological Research, the Department of

Public Administration, the Department of Equal Opportunity, the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces, and representatives from physicians' associations.

The NPCEM programme's first pilot stage started in January 2001 and gave the organization the chance to define the programme's general and specific training objectives, which were then approved by an agreement between the state and regions on 20 December 2001.

The second five-year stage started in January 2002 and was extended for a further six months in December 2006 (State, Regions and Autonomous Provinces Standing Conference Agreement No. 2709 of 14 December 2006), in order to allow a joint commission between the regions and the central government to produce a proposal for the future organization of the NPCEM on the basis of the 2001 training objectives (confirmed by two State, Regions and Autonomous Provinces Standing Conference Agreements: No. 1667 of 13 March 2003 and No. 2545 of 16 March 2004) and to decide on the number of credits that health professionals will have to earn in 2007. Currently, the activities of the NCCED has undergone some disruption due to the lack of agreement between the central government and the regions, which would like to have more influence on the future policy for continuing education in medicine.

Promoting cooperation across providers and levels of care

The National Health Plan for 1998–2000 described three different ways for improving the integration of health care and social care: institutional, managerial and professional integration. Municipalities and ASLs should agree to regulate and better integrate the provision of services by setting quality criteria and other guiding principles for providers. The district is the level at which managerial integration can be best realized, since ways for coordinating and organizing activities can be more easily found and guaranteed within this smaller unit. Professional integration is considered to be collaboration among all the different groups of professionals needed to provide care for non-autonomous people with multiple needs. Health and social care professionals should systematically collaborate within ad hoc professional groups aimed at identifying the specific needs of a particular patient and finding a suitable care path within a multidisciplinary context.

The emphasis on integration is also aimed at fostering the move from long-stay institutional care to care in the community. This is especially important for elderly and disabled people who may require help over long periods of time. In this respect, the National Health Plan for 1998–2000 envisaged an integrated home care scheme (called an ADI). This is based on the idea that health and social professionals (including GPs, nurses, specialized physicians and social workers) who work together, integrating their different skills and collaborating with a patient's family, can provide higher-quality assistance and, at times, avoid hospitalization. The ADI scheme aims to create a home care network to provide specialized and rehabilitation services, home nursing and housework for people who are appropriate candidates for this kind of care due to their health status.

The district is the organizational level responsible for coordinating the professional resources to carry out integrated home care, whereas regions only have to define the general conditions and methods of such care. The GP has a key role in delivering integrated home care in that he or she assesses the patient's condition and, if needed, requests the service. Once the request has been made, the GP, together with other physicians from the district (defined by catchment areas of 50 000 users), indicate which health and social care services are required. The GP is also in charge of liaising with the district director of social workers, as well as coordinating and supervising the activities of all of the health professionals involved in caring for the patient. Finally, in accordance with the 1998–2000 collective national agreement with GPs, these physicians are responsible for the outcome of integrated care given to patients.

Legislative Decree No. 299/1999 established the initial framework regulation required to promote cooperation among social and health care providers, which focused on defining the list of services to be supplied through such collaborative schemes. The Decree identified three types of service located at the interface between social and health care: health care services with social relevance (to be provided under the leadership of ASLs), social services with health relevance (led by municipalities) and a third group of services characterized by advanced integration of social and health care activities (to be provided jointly by municipalities and ASLs).

The Ministry of Health and the Ministry of Social Affairs further regulated this field by providing the criteria to define integrated care in a coordinating decree passed in 2001. According to this decree, health care services with social relevance are those services that, in close coordination with social interventions, aim to promote health by preventing, highlighting, removing and restraining degenerative or disabling outcomes of inherited and acquired pathologies, thereby contributing to individuals' capacity to participate in social life and to express themselves, given environmental factors. The SSN is mainly responsible for paying for these services, which are included in medium- to long-term personalized plans, and are provided within ambulatory care, home care, and within residential and semi-residential structures.

Social services with health relevance include all the activities of the social system that aim to support individuals with disabilities or to resolve problems arising from health conditions. Municipalities are responsible for providing these long-term activities, with citizens contributing to the expenses according to criteria set by each region. Services which fall under this category of advanced integration are related to areas such as maternal and child care, drug dependencies, HIV-related illnesses and care for the elderly. These services are paid for by the ASL.

To foster the integrated provision of social services with health relevance, in October 1999 a joint ministerial decree by the Ministry of Health and the Department of Social Affairs introduced two new professions in social and health care: massage therapy professionals and health and social care workers. Following respective vocational training courses, these workers' are responsible for helping mentally or chronically ill people, elderly people and other groups with special needs to enhance their quality of life and to provide them with extra support in their relationships with their families, ASLs, the SSN and health professionals.

In addition, the 1999 reform also laid out regulations to promote cooperation in public health services. Some of the schemes were directed towards promoting coordination of preventive activities among district health promotion divisions, GPs and paediatricians, and other institutions with overlapping tasks. In addition, it proposed agreements between ASLs, hospitals and the Regional Environment Agency (under the Ministry of Environment) to coordinate health policy and environmental policy with the ultimate goal of protecting the population from environmental hazards.

The social care sector has undergone parallel legislative reform, following 110 years of regulation based on the Crispi Law of 1890. In November 2000, after four years of work and discussions, the parliament succeeded in passing Law No. 328/2000 reforming Italy's social care system according to universal principles. The reform provides new benefits for people with difficulties (as defined by Art. 38 of Italy's Constitution), such as subsidizing the integrated home care system and the service sector (not-for-profit associations, private facilities, etc.), more financial help for low-income families, more opportunities for disabled people and the establishment of 'minimum income' and 'social services' charts. The charts are intended as a tool to safeguard citizens' rights concerning social services by, for instance, informing users on how to file complaints against social services providers if they do not respect their rights.

Municipalities, regions and the central government are the institutional actors responsible for implementing and furthering the integrated network of social services foreseen by the reform. Municipalities have managerial functions, and their role is central to the actual delivery of social services. Regions have planning and policy tasks: for example, based on the state's minimum requirements, they define criteria for accrediting, authorizing and supervising public and private social service providers and define the quality requirements for managing and providing services. The central government grants financial resources (through a National Social Fund) and defines the minimum levels of social care (a type of social benefit package) that every region has to guarantee. Every three years, the government, together with local governments, defines the National Social Plan, which sets the main objectives of social policy and the activities to be undertaken on behalf of non-self-sufficient elderly people, disabled people, children and their families, and immigrants, and implements measures against alcoholism and drug abuse. Since 2001, two national social plans have been approved, although actual implementation of what was envisaged in the reform of 2000 has not been homogeneous among regions, and much still needs to be done.

7.1.6 Health for All Policy

The main aims of the World Health Organization Health For All policy were systematically addressed for the first time within the National Health Plan for 1998–2000. In addition, the 1999 national health status report evaluated the progress made towards achieving each target. The National Health Plan for 1998–2000 identified five main objectives: promoting healthy behaviour and lifestyles; combating the principal diseases; enhancing the quality of the environment; improving the health of the worst-off people and reinforcing social protection; and promoting initiatives for SSN compliance with EU standards.

In promoting healthy behaviour and lifestyles, the following key aspects have been identified as the main areas for intervention: smoking cessation, good dietary habits, adequate exercise and moderate alcohol consumption. The main reasons for concern in this area are the increasing number of smokers among women, the growing prevalence of a fat-rich diet and the small number of people who exercise regularly.

The National Health Plan for 2003–2005 listed a number of health priority areas: tumours; palliative care; diabetes and rare, cerebral and cardiovascular diseases; metabolic diseases; AIDS and sexually transmitted diseases; rehabilitation; transplants; planning the SSN response to terrorist attacks; health of immigrants and the poor; health of the newborn, children and adolescents; drugs and toxic dependency; and health in the penitentiary system.

The main objectives of the latest National Health Plan (2006–2008) are: health of the newborn, children and adolescents; major pathologies (tumours, cardiovascular diseases, diabetes and respiratory diseases); health of the elderly and disabled people; mental health protection; drug, alcohol and smoke dependencies; family support; health interventions for immigrants and the poorer social classes; infectious diseases and syndromic surveillance (e.g. surveillance of symptoms in emergency units); food safety and nutrition; animal health; protection of workplace health and safety; and the environment and health. To reinforce initiatives in some of these areas, the Ministry of Health, together with the Standing Conference on Relations between the State, Regions and the Autonomous Provinces, recently passed the "National Plan on Health and Alcohol" for 2007–2009 (Ministero della Salute, 2007).

7.2 Reform implementation

7.2.1 The 1978 reform: the politics of democratic universalism

The 1978 reform envisaged an ambitious set of changes requiring a considerable increase in public financing of health care to make universal coverage, free access to the system and expanded public services effective. However, the profound economic crisis that started in the early 1970s was deeply felt by the late 1970s. Italy had persistent, sizeable public deficits, and the economy was highly dependent on external sources of energy and raw materials. In addition, the rather exceptional political context within which the first reform of Italy's health care system was passed contributed to further reduce implementation prospects from the start. In particular, the reform was approved by the National Solidarity government coalition, which, for the first time, included the support of the Communist Party, and which had a leading role in the process of formulating the reform.

By 1979, however, a new government coalition was formed that excluded the Communist Party and incorporated the Liberal Party, which opposed the core content of the 1978 reform and provided several Ministers for Health during the decade. Not surprisingly, by the early 1980s the government had already explicitly adhered to the alternative aims of cost-containment and rationalizing the welfare sector and announced the launch of a set of restrictive economic policies aimed at stabilizing inflation and reducing the public deficit. As a result of the initial expansionist goals of the 1978 reform, only universal coverage was implemented. Moreover, this was coupled with the introduction of co-payments for pharmaceuticals in 1979. The initially modest flat rates were replaced in the early 1980s by a proportional charge on OTC prices of 15%, which was also extended to specialist outpatient services. Co-payments were then raised several times during the 1980s, provoking strong popular opposition led by the trade unions. Nevertheless, by the end of the 1980s, co-payment rates were already 40% for pharmaceuticals and 30% for outpatient visits. Despite this, real pharmaceutical expenditure nearly doubled during the 1980s, while real public expenditure on health care increased by 22%. In comparative terms, real expenditure grew faster in Italy than in the OECD as a whole, both per capita and as a percentage of GDP. The government responded by launching some attempts to extend and enforce co-payments. First, in 1988, it extended co-payments to a set of pharmaceutical products that were previously exempted based on their high therapeutic value and to which consumption had been progressively reoriented during previous years. Second, it attempted to introduce co-payments on hospital stays, a measure fiercely opposed by the trade unions, which launched a general strike, forcing the government to abandon the idea. Third, in 1990, the government started to prosecute fraud on exemption cards where exempted users were buying an increasing share of prescriptions for non-exempted users. In fact, between 1988 and 1989, the share of prescriptions issued to exempted users had increased from 45% to 75%. Administrative and penal sanctions were introduced for users and physicians involved in these fraudulent practices.

An even more radical and controversial measure emerged during 1988–1989. Higher-income groups could opt out of SSN coverage and reduce their taxes and payroll contributions. In particular, the Christian Democrats proposed opting out for self-employed people; a year later, the Liberal Party devised a system similar to those in some European social health insurance countries, by which the upper socioeconomic groups were allowed to opt for private insurance, thereby reducing their public contribution rates by 60%. Other aims of the 1978 reform were either not implemented or rapidly reversed.

First, the aim of placing the management of local health organizations under democratic control led to the unintended consequences of excessive politicization of the system, inertia and inflexibility, low managerial performance and, in some cases, widespread fraud. Management positions were allotted to partisan cadres with little professional expertise and were divided across party lines (and, therefore, parties were often unable to reach a consensus on appointments), and managers were only weakly accountable. In 1986, the government took several steps to counteract these problems by rationalizing the management committees of USLs and reinforcing the auditing of their accounting practices. By 1989, plans to professionalize USLs' management were presented to parliament and later approved within the 1992–1993 package of reforms. Second, the shift towards a fully tax-based system was not implemented, partly because widespread tax fraud was acknowledged, especially among those on higher incomes. In addition, several measures were launched during the early 1990s to enforce tax obligations, especially for self-employed people. Finally, the 1978 reform had other unintended consequences on regional expenditure practices. The central government repeatedly attempted to contain costs during the 1980s by establishing strict aggregate budget ceilings, but the regions counteracted these by increasing their debt, which, in the absence of fiscal decentralization, the central government had to cover. This provided the regions with further incentives to overspend, leading to a vicious cycle of ever-increasing public deficits. In fact, this soon proved to be one of the most enduring problems of Italy's health care system and, accordingly, was the target of various reform packages passed during the 1990s.

7.2.2 The 1992–1993 'reform of the reform': towards conditional universalism and unmanaged competition?

Ferrera (1995) coined the term 'conditional universalism' to summarize a series of radical attempts made during 1992–1994 to modify the principle of universal public coverage and free access at the point of delivery introduced by the 1978 reform within a turbulent context characterized by a profound national political and financial crisis.

First, between 1993 and 1994, new measures were launched aimed at expanding the sources of public financing. Deductibles were established for higher-income groups in the form of annual charges of up to €52 for pharmaceuticals and specialist care and up to €44 for primary care services, and plans to introduce new co-payments on emergency hospital services were announced. Again, strong popular opposition prompted the government to abandon the planned measures. Second, co-payments on pharmaceuticals and specialist visits were successfully raised during the same period (from 40% to 50% for pharmaceuticals, subject to a ceiling of €52; and from 30% to 100% for specialist visits and diagnosis tests, also subject to a €52 ceiling). Third, the opting-out clause discussed during the late 1980s was effectively introduced within the 1992 reform legislation, involving partial opting out from the SSN with fiscal compensation. This was done under the crisis government formed in 1992 by non-partisan technical experts led by the former president of the Bank of Italy (Carlo Azeglio Ciampi). Fierce opposition by leftist parties forced the next government to reduce the scope of the 1993 reform legislation and to delay implementation until 1995. This led to a political storm, with the Democratic Party of the Left and Lega Nord starting to collect signatures to support the launch of popular referenda to repeal the 1992 and 1978 reforms, respectively. In January 1995, the Constitutional Court declared that submitting compulsory insurance to popular referendum was unconstitutional, and the opting-out clause was abandoned a few months later. However, during the late 1990s, new legislative measures in this direction were proposed by both rightist parties and *Confindustria*, the Confederation of Italian Employers.

7.2.3 The internal market reforms

Legislative Decree No. 502/1992, which launched the internal market reforms, allowed the regions to freely set up their own health care systems. In particular, since 1992 regions have been given the power to organize and manage health care services, allocate resources and regulate the number and dimensions of ASLs within the framework set by central legislation. Nevertheless, many detailed central provisions were issued during 1994–1995 aimed at guaranteeing uniform reform implementation across Italy. In particular, the national government prompted the regions:

- to reduce drastically the number of ASLs;
- to assign the status of public firms and considerable managerial autonomy to major tertiary hospitals and to ASLs, which should manage both ambulatory and hospital providers;
- to introduce a partial split between providing and purchasing functions; and
- to allocate resources to providers of specialized care according to the volume and type of services provided through uncapped fee-for-service financing to be applied to outpatient specialist services and to inpatient care (based on DRGs).

The 1992–1993 reform was rapidly implemented in most northern and central regions, as well as in some southern regions. Accordingly, the 659 ASLs were reduced to less than 200 in 2000 (and currently number 197), and 98 AOs were created during the same period. Considerable managerial and financial autonomy was transferred to them. Market competition was effectively promoted by introducing fee-for-service financing (based on DRGs) for inpatient hospital services and ambulatory care (outpatient departments and specialist physicians). The new financing scheme gave health care providers greater incentives to be efficient so that more patients could be treated. The delegation process was also sustained by radically changing organizational and management structures. Civil law replaced public law in regulating the basic organizational framework, leading to significant changes in the accounting system and labour relationships in ASLs and AOs. The 1999 reforms extended civil law to matters related to organizational design and strategic planning. In addition, public administration practices and bureaucratic provisions were replaced by managerial principles and tools typical of the private sector. More generally, implementation of the reform radically shifted the prevailing way regional health ministries politically control local purchasing agencies (ASLs) and autonomous providers from traditional *ex ante* administrative supervision to *ex post* monitoring based on financial and quality results.

Nevertheless, there were several deviations from this centrally devised internal market model. The smallest regions continued to have regional health ministries commission and monitor health care services. Several less-developed southern regions made almost no progress during the 1990s in implementing the internal market reforms, partly because managerial skills and support mechanisms were inadequate. In addition, when implemented, the internal market did not operate fully because of incomplete separation between purchasers and providers, as ASLs were responsible for providing health care through directly managed structures and for commissioning care to AOs and private contracted-out providers. In fact, the Italian Competition Authority established in June 1998 that the principle of competition was not being completely respected both because of the dual role of ASLs as providers and purchasers prescribed in the 1992 reform legislation and because of the absence of central regulation enforcing contractual agreements between purchasers and providers as well as clear and objective criteria according to which regions could select their preferred providers. This left room for discretionary choices, which caused inefficient resource allocation and infringed the principles of fair competition and consumer choice. More generally, many regions faced difficulties in guaranteeing adequate operation of the internal market since the necessary regulatory framework was only partly in place and they lacked the required political culture and managerial capabilities.

Moreover, the reform was perceived to create perverse incentives that fostered hospital activity and expenditure, fragmentation of the SSN into many separate units and poor collaboration among providers and between health care providers and purchasers. A further criticism was that the reform seemed to lack a clear strategy for improving clinical practice by ensuring that incentives to promote efficiency would not harm the quality of care. Other problems developed in implementation. In particular, private hospitals responded to the new competitive environment by expanding capacity and increasing technological endowment, whereas public hospitals were subject to strict policies to prevent excess capacity and were subject to persistent underfunding of capital investment. This was perceived to lead to an ever-increasing market share for private providers at the expense of public providers. In addition, fee-for-service financing led to increased levels of activity and expenditure within the hospital sector, which had accounted for an above-average share of health care expenditure before the reform compared with other EU countries. Finally, the devolution to the regions of accountability for expenditure was only partly credible, and the regional debt was therefore only reduced for a few years after the reform was passed, rebounding thereafter.

As discussed previously, the reforms the central government passed during 1997–2000 were aimed at solving some of these general problems. Prior to that, some regions launched innovative measures to implement the purchaser–provider split and to control hospital costs. In particular, in 1998

Lombardy gave AO status to all regional hospitals and further reduced by two thirds the number of ASLs, making them solely purchasing agents in an effort to increase their bargaining power over hospital providers. In addition, from the mid- to late-1990s, several regions introduced ceilings on fee-for-service financing, so that activity surpassing fixed volume limits would be reimbursed at a reduced rate.

7.3 Future developments

The National Health Plan for 2006–2008 (Ministero della Salute, 2006b), while confirming universality of health care and equity as basic principles of the Italian SSN, highlights some major objectives for its future development including:

- overcoming the large variability in the quality of health care among regions;
- providing a national policy for the governance of patient mobility;
- prevention of ill health and promotion of health;
- reorganization of primary health care;
- integration of health care networks (e.g. for emergency care, transfusions, transplants); and
- integration of the health and social care, and palliative care network.

The National Health Plan's main strategies for the achievement of these objectives are: the promotion of innovation, research and development (e.g. through implementation of health care service and biomedical research, and through HTA); citizen involvement in health care decision-making and health care assessment; training policies directed at personnel in the SSN; the improvement of clinical governance and waiting lists; managerialism, management experimentation, pharmaceutical policy and medical technologies.

In June 2006, the Minister of Health, Livia Turco, put forward her health policy programme during a speech to the Commission for Social Affairs ("A New Deal for Health") (Ministero della Salute, 2006c). According to the programme, the three major problems of the SSN that need to be tackled are: waiting lists, the low quality of health care in southern regions, and inequalities in the availability of oncology treatments. She summarized in nine key phrases the underpinning principles that should affect any future health care policy decisions: reliability, quality, humanization, a "united" health care system, responsibility, legality, assessing outcomes, alliance with all stakeholders, and with the "EU and world". A key issue she said would be addressed during her tenure is safety in four different fields: health care, work and domestic settings, the environment and food. Moreover, she listed ten health issues (some overlapping with the 2006–2008 National Health Plan's health objectives) that would receive attention, including: women's health, the protection of pregnant women, promoting natural delivery in childbirth, development of palliative care, enhancing health care quality in southern regions, new technologies and communication in health care.

The New Deal also proposes the piloting of a new mechanism to implement the principles of continuity, integration and multidisciplinarity in health and social care at the community level: *La Casa della Salute* (CdS). The CdS is an organizational model with a catchment area of 5000–10 000 users (compared to the district's catchment of 50 000–60 000 users) that is supposed to provide primary care services and guarantee continuity between hospital and prevention services. Health and social care operators should work together within the CdS, whose objectives are: integrated care, prevention and health education, self-care for chronically ill persons, and the active involvement of citizens. During the first national meeting held in March 2007 to discuss the project with stakeholders, some criticisms were raised over the probable overlap between the tasks to be undertaken by the CdS and those of the district, as well as doubts about the availability of financial resources for the additional health personnel required. Despite these criticisms, the project was also greeted positively as a means to better realize integration and continuity of care, which is still lacking in some regions.

Some of the major initiatives included in the National Health Plan, and mentioned in the "New Deal" speech have begun to be implemented through the launching of national programmes and the signing of agreements between the central government and the regions. The Ministry of Health and the Ministry of Economics signed (on 17 April 2007) an agreement to channel part of the money allocated by the EU (*"Quadro strategico nazionale 2007–2013"*, funded by the EU) to the development of eight southern regions' health care services (Abruzzo, Basilicata, Calabria, Campania, Molise, Puglia, Sardinia and Sicily), which constitutes the first step in reducing the variability in health care quality and provision between the north and south of Italy. With regard to waiting lists, an agreement to reduce them by applying the criteria of appropriateness, emergency status and transparency has been signed by the Ministry of Health and the regions. This is known as the "National plan to reduce waiting lists 2006–2008" (*Piano Nazionale per il contenimento dei tempi di attesa per il triennio 2006–2008*).

Moreover, in the last few years, a national strategy for patient safety has been outlined (see Chapter 2) and, in January 2007, the Ministry of Health signed a decree for the establishment of a National System for Patient Safety, which should also guarantee the creation of the first National Observatory on Patient Safety.

8 Assessment of the health system

8.1 The stated objectives of the health care system

Since the creation of the SSN in 1978, there have been three waves of reform (described in Chapter 7) introducing several innovations in order to increase the quality of care and to improve cost–effectiveness in delivering services, guaranteeing to all citizens a uniform level of assistance. Assessing the level of achievement of these goals is not easy, due to a lack of conclusive evidence in a sector of such complexity as health care. Here, we report some of the main evidence, discussed previously, that can help us to ascertain the extent to which the particular objectives have been reached.

8.1.1 To guarantee to all citizens a uniform level of assistance

In terms of *geographical equity*, data show a significant decrease in patient flows abroad in the 1990s (France, 1997), but, at the same time, there was a rise in interregional mobility, particularly from southern to central and northern regions, showing that the north–south divide is still present and that health inequality is still an issue in Italy (see Chapter 1).

In terms of vertical equity, data report significant inequality in health status in favour of higher income groups in Italy, although these differences are lower compared to other European countries (Van Doorslaer and Koolman, 2004).

There is also evidence that, in the period 2002–2004, there was a 'hard core' of groups experiencing social unfairness, consisting of 11% of poor families and 1.3% of those suffering impoverishment due to health care (ISTAT, 2006). These figures indicate that health costs caused an increase of about 10% in the number of poor people, with a strong concentration among the elderly (over 60%) and significant differences at regional level (Donia Sofio et al., 2006).

Access to health care is still limited by the presence of waiting lists, although several regions have introduced effective programmes for prioritizing the delivery of care on the basis of clinical appropriateness of the services prescribed and patient severity (France, Taroni and Donatini, 2005).

In terms of health care performance, data that are commonly used to make cross-country comparisons of the SSN show a positive trend and an improvement in the population's general health status (see Section 8.4).

With regard to perceived health, 59.6% of a sample of Italy's population self-assessed their health status as being good in 2002 (ISTAT, 2005b), although differences are evident across the north–south divide.

However, there is no clear evidence of a relationship between health system reforms and the improvement of health outcomes.

8.1.2 To increase quality and appropriateness of health interventions

Two main developments should be highlighted in terms of quality of health care and improvements in this area.

- Better designed and disseminated clinical guidelines have been implemented thanks to the PNLG. The programme involves institutions, organizations and professionals at different levels of the health care system and has produced several guidelines on different topics (see Section 7.1.5).
- A large investment in training and development, through the introduction of a programme of ECM, has contributed to improving health professionals' skills and to developing managerial capacities.

Nevertheless, in terms of patient satisfaction, the Eurobarometer survey in 2002 on public satisfaction with the health care system in 15 EU countries shows that Italy remained under the EU average, despite a slight increase after 1999 (OECD, 2006) and with significant differences across the north–south divide.

8.1.3 To improve cost–effectiveness in delivering health care services

According to the OECD Health Data, health expenditure in Italy in 2006 amounted to 9.0% of GDP, equal to the average of the other countries examined, and decreased to 8.7% in 2007. At the same time, as discussed in Chapter 3, the volume of public expenditure remains an important issue for the government. The prospective payment system in hospital care has certainly encouraged greater efficiency: a reduction in inpatient admissions and lengths of stay, a shift to day-hospital treatment and an improvement in the information technology system. However, in order to create better incentives for more virtuous behaviour by health organizations, it would be desirable for tariffs to be set for each individual type of organization, taking account of additional factors such as clinical case mix (Donia Sofio et al., 2006).

With this background in mind, there are still several challenges that the SSN will have to face in the near future. Among these, the most important are:

- meeting the needs of an ageing population
- managing chronic diseases
- improving risk management
- developing information systems
- reducing interregional differences in quantity and quality of care.

8.2 The distribution of the health system's costs and benefits across the population

The Italian health care system is required to guarantee the uniform provision of comprehensive care throughout the country. Nevertheless, responsibility for health care planning, organization and financing is shared between the central government and 19 regions and 2 autonomous provinces. The SSN's principles state that allocation of financial resources should be inspired by an equitable approach, so that every citizen should have equal opportunity of access to health care services. The health system's ability to pursue these objectives depends on both the funding and allocation systems used to distribute resources among the regions and, regarding the regions, by the allocation mechanisms used within each of them to allocate resources among ASLs and the populations they cover.

The main source of finance for the Italian SSN is a mix of taxes applied both at the regional and at the national level. As discussed in Chapter 3, the mix of taxes is as follows:

- *IRAP* is a regional corporation tax imposed on the value added produced by companies (corporations, partnerships and self-employed workers) at a rate of 4.25% and on the salaries paid to public-sector employees at a rate of 8.5%;[33] the tax is levied nationally but 90% of its revenue is allocated back to the regions in which it is levied.

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[33] Since 2005, regions have been allowed to increase these tax rates by 1% if they are faced with health care expenditure deficits.

- *Addizionale IRPEF* is a piggyback regional tax imposed on the IRPEF. It increased from 0.5% to 0.9%, with regions allowed to modify the total regional IRPEF rate from 0.9% to 1.4%. The IRPEF has a progressive structure with tax rates increasing with personal income.
- A set amount (€0.13 per litre) of the petrol excise tax; regions have the right to increase the petrol excise up to €0.026 per litre.

Because of the progressive structure of IRPEF, we can say that the taxation system provides the means for a reallocation of resources between income classes within the population.

The implementation of distributional justice within the SSN also depends on resource allocation criteria. The presence of fiscal federalism and the persistence of significant regional differences (in terms of GDP) produce potential inequalities in resource allocation for health care among the regions. In 2004, the regions' own-source tax revenues (IRAP and IRPEF) represented 41% of their total health care budget, but there is considerable interregional variation in the IRAP tax base. In fact, in 2002, the two richest regions, Trentino-Alto Adige and Lombardy, recorded, respectively, 130% and 128% of national GDP per capita (with Italy equal to 100), while the two poorest regions, Calabria and Campania, reported 63% and 65%. This translated into significant differences in own-source revenues per capita, with northern regions being significantly advantaged compared to southern regions. For this reason, IRAP does not seem able to introduce any distributional effect among citizens. Moreover, in the past, the imposition of IRAP resulted in the Italian government appearing before the European Court of Justice on the grounds that IRAP introduced a mechanism of 'double taxation' in so far as citizens already pay VAT on their consumption. However, IRAP was declared legitimate by the European Court of Justice on 3 October, 2006 (Case No. C-475/03).

To avoid inequalities among regions and to provide equal access to the LEAs to the whole population, regions receive a quota from an equalization fund (the National Solidarity Fund), which aims to reduce inequalities between the northern regions (which are traditionally the richest and therefore have greater own-source tax revenues to guarantee the core benefits package) and the southern regions. Aggregate funding for the regions is set by the Ministry of the Economy and Finance and the resource allocation mechanism for the pooled "National Health Fund"[34] for regional health care services is based on a capitation quota, which, from 2006 to 2008, was weighted by factors linked to

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[34] The National Health Fund should be phased out eventually and be replaced completely by the National Solidarity Fund when disputes over the latter's allocation formula are settled definitively. See Chapter 3 for further details.

Table 8.1 Structure of the weighted capitation formula, 2006–2008

Services delivered	Criteria for weighted capitation
Public health services (5%)	None
Hospital health care (45%)	Consumption by age and sex
Community care (50%)	
Primary health care	None
General practitioners	None
Pharmaceutical care	Financial budget defined on the basis of global needs
Outpatient clinics	Consumption by age and sex
Health care for the elderly (residential)	Capitation for population over 65

Source: Authors' calculations based on data from the Ministry of the Economy and the Interdepartmental Committee on Pharmaceuticals.

the demographic characteristics of each region's population, and the frequency of consumption of health care services by age and sex (Table 8.1).

The weighted capitation formula changes from year to year on the basis of annual negotiations among the regions. An adjustment for interregional patient flows is taken into account. This allocation mechanism has been used since 1997[35] with a view to establishing a pattern of distribution that is responsive objectively, equitably and efficiently to relative need. The aim of this resource allocation scheme is to guarantee equal opportunity of access to health care for people at equal risk. Therefore, the formula has been constructed in such a way as to not reflect past patterns of supply and demand for health services, but to respond to the relative needs of different regional populations for health care resources.

By statute, each region defines its own internal allocation formula using criteria that may reflect potential resource utilization by the different population groups within the various ASLs.[36] In fact, a complementary regulation[37] also states that ASLs are financed by regions on the basis of a weighted capitation formula, following criteria congruent with those in the primary legislation. Nevertheless, each region is free to set its own specific formula taking into consideration other criteria (Table 8.2).

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[35] In accordance with Law No. 662/1996.

[36] Also in accordance with Law No. 662/1996.

[37] Legislative Decree No. 229/1999 (Art. 2(d)).

Table 8.2 Criteria for weighting capitation rates adopted by the Italian regions, 2006

Regions	Capitation weighting	Resort to national criterion[a]	Capitation scheme	Weighting criteria				
				Demographic	**Geographical**	**Social deprivation**	**Supply characteristics**	**Health status indicators**
Valle d'Aosta	No	N/A	Unique	N/A	N/A	N/A	N/A	N/A
Piedmont	Yes	No	Weighted for levels and sublevels of care	Inhabitant population (prevention); age groups (primary care and hospital services)	Inhabitant population density	Yes (psychiatric assistance, drug addictions)	No	No
Liguria	Yes	No	Weighted for specific levels of care (pharmaceutical care)	50% inhabitant population, 50% consumption by age and sex groups	No	No	No	No
Lombardy	Yes	No	Weighted for levels and sublevels of care	Age groups; percentage inhabitants over 65 years	Inhabitant density; mountainous areas	No	Contracts between ASLs and providers for specialized care and hospital services	Mortality; percentage inhabitants with chronic diseases
Veneto	Yes	No	Weighted for levels and sublevels of care	Age groups; inhabitant number	Differentiated for mountains, islands, lagoon areas	No	Type and location of medical technologies	No

Friuli-Venezia-Giulia	No	N/A	Based on historical costs of ASLs	N/A	N/A	N/A	N/A	N/A
Autonomous Province of Trento	No	N/A	Based on costs of the local health services	N/A	N/A	N/A	N/A	N/A
Autonomous Province of Bolzano (2001)	Yes	No	Weighted for levels of care	Age groups	No	No	No	No
Emilia-Romagna	Yes	No	Weighted for levels and sublevels of care	Inhabitant population integrated with seasonal patient flows and students; age and sex groups with various modalities for each sublevel	No	Incidence of drug addictions	No	SMR
Tuscany	Yes	No	Weighted for levels and sublevels of care	Inhabitants divided by age groups (3% quota)	Inhabitant density; land characteristics	No	Quota weighting based on providers' efficiency and appropriateness	No
Marche	No	N/A	Based on costs of health care services delivered	N/A	N/A	N/A	N/A	N/A

Table 8.2 Criteria for weighting capitation rates adopted by the Italian regions, 2006 (cont.)

Regions	Capitation weighting	Resort to national criterion[a]	Capitation scheme	Weighting criteria				
				Demographic	**Geographical**	**Social deprivation**	**Supply characteristics**	**Health status indicators**
Umbria (2004)	Yes	Yes	Weighted for levels and sublevels of care plus specific quotas for attainment of specific regional health goals	Yes (national)	No	No	No	No
Lazio	Yes	Yes	Weighted for levels of care	Yes (national)	No	No	No	No
Abruzzo	Yes	No	Unique	Age groups	Size and mountainous areas	No	Hospital beds available, outcomes of external audits, presence of universities	No
Molise (2004)	Yes	No	Weighted for levels and sublevels of care	Inhabitants; consumption by age groups	Mountainous areas; inhabitant density	No	No	No
Campania	Yes	No	Weighted for levels and sublevels of care	Inhabitant number; age groups for primary and specialized care	Geomorphologic characteristics of the land; inhabitant density	Poverty index	Presence of universities	Square root of birth and child mortality rate

Puglia	Yes	Yes	Weighted for levels and sublevels of care	Inhabitant number; age groups	No	No	No	No
Basilicata	Yes	No	Weighted for levels and sublevels of care	Inhabitant number; consumption by age groups for primary and pharmaceutical care and for hospital services	Inhabitant density	No	Number of hospital structures; number of emergency points	No
Calabria (2004)	Yes	Yes	Weighted for levels and sublevels of care	Yes (national)	No	No	No	No
Sicily	Yes	No	Weighted for levels of care	Consumption by age and sex groups	Geographical characteristics; inhabitant population density	No	No	No
Sardinia	Yes	Yes	Weighted for levels of care	Inhabitant population; age groups	No	No	No	No
ITALY	Yes	N/A	Weighted for levels and sublevels of care	Inhabitant number; consumption by age and sex groups	No	No	No	No

Source: Adapted from Cicchetti and Ceccarelli, 2007.

Notes: ASL: Local health enterprise; N/A: Not available; SMR: Local health management organization; [a]In 2006, weights were based on inhabitant number and frequency of health care service consumption by age and sex.

Through the adoption of a regional weighting capitation scheme, each region can implement its own distributive justice model, which also takes into account territorial heterogeneity with respect to the resources needed to cover the diverse health care needs of the population. When carefully examined, the weighted capitation formula, as it has been applied in the Italian regions, has the tendency to allocate resources to address the health service requirements within subgroups of a catchment population rather than towards the potential overall improved outcome for the same catchment population (Cicchetti and Ceccarelli, 2007).

With regard to the distribution of the health system's costs and benefits across the Italian population, it is important to monitor how fiscal federalism and regional autonomy affect not only decisions by individual regions about the level of resources to be devoted to health care, but also the methodologies they adopt to allocate those resources. The situation, as it currently stands, is generating potential differences in distributive justice models across regions within the same country; and it is possible that what may emerge is no longer a single, national distributive justice model but, potentially, 21 different models.

8.3 Efficiency of resource allocation in health care

This section discusses the main characteristics of resource allocation within the Italian health care system. As described throughout this report, most health management powers regarding planning and financial allocation belong to the regions, while purchasing and delivery of services rests with the ASLs. In addition to tasks related to organization and regulation of the system, regional departments of health are in charge of resource allocation, tariff setting for hospital and outpatient care, and financing of specific types of health care for the population.

In the past, allocation of resources to ASLs was often the result of political negotiation, which also took into account historical spending. Currently, following national guidelines, most regions have chosen to transfer funds to the ASLs on the basis of a weighted capitation formula, with types of weight varying among regions. At the national level, the level of state funding allocated to each region is a result of a weighted capitation formula, although a good deal of political negotiation is also involved, with regional governors often spending several days negotiating the final allocation of resources.

The funds transferred from the central government to each region are earmarked for health care delivery, and regions are placed under a strong constraint not to overspend. However, overshooting of budgets has been a constant feature of the Italian health care system. Faced with systematic underfunding, regions have often resorted to this 'source of financing' in order to support health care delivery. Nevertheless, it must be pointed out that, in many cases, overspending also has been the result of inefficient and 'politics-driven' health policy-making at all levels of public administration.

The regionalization of the health care system, together with the wide interregional differences in socioeconomic indicators typical of Italy, seems to have produced a system that demonstrates strong imbalances among regions. Southern regions have a smaller bed stock, a greater presence of private facilities and a poorer endowment of advanced medical equipment. Partly for this reason, the south has had a history of heavy patient flows to central and northern regions and to other European countries.

Total doctor visits seem to be distributed according to need, but higher income groups consume more private specialist care than would be predicted. If regional differences in doctor availability are allowed for, the distribution of specialist visits appears less inequitable, while adjusting for private health insurance has only a marginal effect, possibly due to low rates of private insurance coverage and extensive use of out-of pocket payments. Greater use of private specialists by patients in southern regions may reflect the lower availability of public services and/or their perceived lower quality (France, Taroni and Donatini, 2005).

8.4 Technical efficiency in the production of health care

Technical efficiency in the production of health care can be considered both from the perspective of the system as a whole and from the perspective of users.

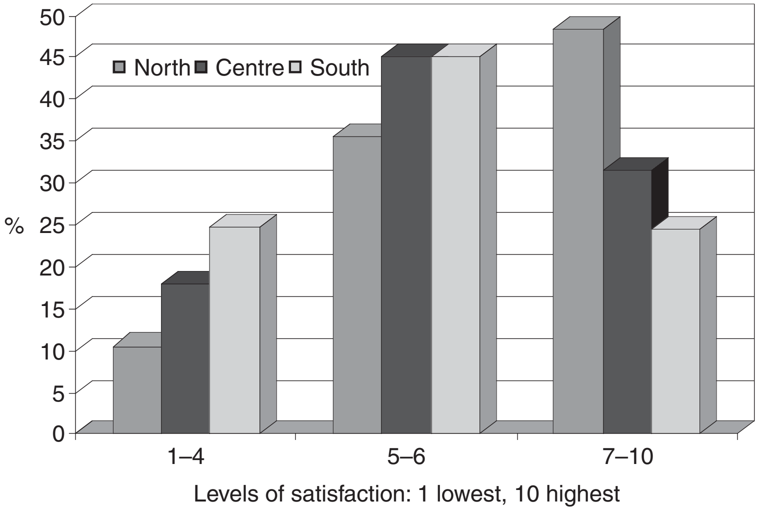
Although there are still several problems to be addressed by the Italian SSN, especially in terms of health care financing (see Chapter 3), on average, productivity within the system has generally improved. In the hospital sector, the introduction of a prospective payment system, combined with upper limits on the number of beds, has strongly encouraged an improvement in technical and allocative efficiency. As highlighted in Section 6.3.1, the reduction in the number of beds beginning in the 1990s has led both to a reduction in inpatient admissions and in length of stay, while the choice of day hospital as a form of hospital treatment is becoming increasingly frequent, also as a response to national and regional legislative provisions. In addition to technical efficiency, the DRG classification system and the prospective payment system have led to a strong improvement in information technology systems, with hospitals concentrating on developing the best discharge record management systems in order to better code each discharge and obtain the best tariff possible. Unfortunately, less is known about the impact of the prospective payment system on quality of care.

With regard to primary care, although GPs could, in principle, serve a gatekeeper function, their ability to negotiate with downstream providers is limited and they lack the incentives to manage the package of care their patients receive.

Users' satisfaction with the levels of service provision in each region reflects distinctive patterns: data from Section 2.5.1 and Fig. 8.1 clearly show the north–south divide that characterizes levels of satisfaction. Although in all cases percentages are below 50%, residents of northern regions tend to be much more satisfied with the level of care provided by their regional health care systems (nearly 50% of those interviewed gave a score greater than 7) than residents of central and, above all, southern regions, where only 25% indicated satisfaction with the system.

One of the current, most frequent and most deeply felt concerns of the population has to do with waiting times, especially for specialized outpatient care. Unlike in other OECD countries, attention has focused on waiting times for specialist consultations and diagnostic tests. National legislation has introduced strict requirements regarding timeliness of service; in addition, the Standing Conference on the State, Regions and Autonomous Provinces has reached an

Fig. 8.1 Levels of satisfaction by geographical area, 2005



Source: ISTAT, 2007b.

agreement that defines maximum waiting times for ambulatory care (60 days for 5 major diagnostic imaging procedures and 30 days for eye and cardiology visits) and for three elective hospital procedures (180 days for cataract surgery and hip replacement and 120 days for percutaneous transluminal coronary angioplasty). Generally, regions tend to perform worse for specialist visits, with only half of them able to meet the standard of at least 50% of patients being seen within 30 days. Regional programmes are being developed to prioritize delivery on the basis of the clinical appropriateness of services prescribed and patient need. France, Taroni and Donatini (2005) suggest that underfunding of the SSN and inefficient services are not the sole causes of long waiting times. Dual practice, for example, may have encouraged doctors to run long lists in their public practice to maintain demand for their private activity.

8.5 Accountability of payers and providers

Accountability has become a major issue in health care because it involves the procedures and processes by which one party justifies and takes responsibility for its activities. There are two prominent trends in health care today: first, increasing demands for accountability, and, second, increasing provision and quality of care through managed care organizations.

In the last few decades, Italy has made impressive efforts to improve its information technology and, consequently, health care service delivery, as well as to monitor the accountability of health professionals and institutions. As highlighted in Section 4.2.2, a new information system, NSIS, has been established by the Ministry of Health, making possible the creation of a huge database on all health care services. Moreover, in 2003, the Ministry of Health, in collaboration with the Ministry of Finance, initiated a project to introduce a citizens' electronic health card (e-card).[38] The e-card was disseminated across Italy, starting with distribution in some pilot regions, and gradually rolling out delivery to all citizens, who received their e-card with a letter explaining its main functions.[39] The e-card contains demographic information on individuals (fiscal code, date of birth and place of birth) and a magnetic code that will make it possible, in the future, to trace their entire patient pathway. Moreover, information on the e-card will be used to monitor pharmaceutical expenditure all over Italy; in some regions, this system has already been implemented, while in some others the quality of information is not very reliable. Since January 2008,

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[38] Pursuant to Law No. 326/2003.

[39] To deal with distribution problems, a call centre was set up to assist people who had not received their e-card.

the e-card has been used in pharmacies to validate out-of-pocket purchases of drugs for the purpose of tax deductibility.

In spite of these improvements, some problems still persist. Firstly, regulation and governance of third-party payers/service providers do not promote full accountability in final purchasing decisions, a problem that is also due to the fact that, in some cases, population health needs do not represent the main priority and health care delivery is often planned on the basis of political strategies and existing facilities and staffing. Secondly, while the devolution process has given greater autonomy to the regions, at the same time it has also created some problems regarding relationships and communication between the central and regional levels of government, creating concrete difficulties in the division of responsibilities, and often causing cost shifting and duplication of services.

Citizens' satisfaction with the health care system is an important consideration in the context of quality of care and accountability. Low levels of citizen satisfaction have been one of the most enduring problems of the Italian SSN. As outlined in Section 2.5.2, a European survey on patients' satisfaction levels with respect to the health care system (Eurobarometer 2003 in OECD, 2006) shows a slight improvement in the assessments scored by Italian citizens compared to previous surveys in 1996 and 1998. Despite this increase, Italy still ranked lower than the EU15 average in 2003 (OECD, 2006).

8.6 The contribution of the health system to health improvement

It is difficult to disentangle how much health policy decisions and public health interventions have contributed to the improvement of the population's general health status, given the number of different factors (cultural, economic, genetic, etc.) that compete in determining any health change. In general, over the last three decades the health status of Italians has been rising: life expectancy grew during the 1980s and 1990s, and infant mortality decreased during the 1990s (see Chapter 1). These improvements can be attributed to the health system, even if other factors surely had an impact. At the same time, a clear relationship between health policy reforms and health status improvements cannot easily be demonstrated. For such a link to be analysed, systematic and ad hoc evaluations would be needed, and these do not exist in the majority of health interventions.

With respect to public health measures, available data suggest their effectiveness in saving lives and improving health. Among these, the immunization campaigns of the last 30 years against, for example, pertussis, measles, tetanus and rubella for children under 24 months, are associated with a decrease of disease incidence that ranges from 54.3% to 93.9% (see Section 6.1 and Table 6.2). A report on Italy's health status (*Relazione sullo Stato Sanitario del Paese* (RSSP), 2003–2004) (Ministero della Salute, 2004) provides mortality and incidence rates data on various diseases (AIDS, cardiovascular diseases, cancer, etc.). With regard to breast and cervical cancer,[40] for which national preventive interventions have been implemented since 2001, data suggest that they have been effective. In fact, according to the RSSP report, the introduction in 1999 of cervical cancer screening in Italy is associated with a decrease in mortality rates (-70%). Nevertheless, the north–south divide is also reflected in this area: according to the Italian Group for the Screening of Cervical Cancer (*Gruppo Italiano Screening del Cervicocarcinoma*), the screening programmes in northern regions cover 63% of the female population, in central regions 82%, while in southern regions the percentage decreases to 29%. Differences are even higher with respect to breast cancer screening: 75% of the female population in northern and central regions and 10% in the south. With regard to HIV/AIDS, data highlights that the introduction of retroviral therapies for individuals with HIV has contributed to a reduction in AIDS mortality rates and to extending the length of life of HIV-positive patients (RSSP Report 2003–2005, Ministero della Salute, 2005c). The national Register of AIDS data show that the incidence of AIDS increased until 1995, but began to decrease in 1996 (11% less than in 1995) together with mortality rates (a fall of 9.3%) (RSSP Report 2003–2005, Ministero della Salute, 2005c).

Lastly, Italy is developing a new electronic information system (see Sections 4.2.2 and 5.1.2) and different projects are aimed at developing national clinical registers, which, once implemented, would provide reliable information upon which to base an assessment of health interventions' effectiveness. To date, it has not always been possible to rely on routinely collected information due to variations in data quality.

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[40] Cancer is the leading cause of death for people under 64 years of age.

9 Conclusions

Italy's national health care system, SSN, was instituted in 1978, based on the principles of universalism, comprehensiveness and solidarity, with the aims of guaranteeing uniform provision of comprehensive care throughout the country.

Substantial steps in improving public health, through preventive and therapeutic measures, have been taken in the last 30 years (1978–2008). Life expectancy has increased, while infant mortality has decreased during the 1990s. A decrease in the incidence of various diseases ranging from 54.3% to 93.9% has also been achieved as a consequence of immunization campaigns for children under 24 months (e.g. pertussis, measles, tetanus and rubella), and national preventive interventions for cervical cancer (1999) are associated with a reduction in mortality rates of 70%. The health status of Italy's populations as a whole has thus improved and is in line with that of other EU countries. However, notwithstanding these general improvements, disparities can be highlighted among regions.

A main and key feature of Italy's health care service is indeed a substantial regional variability in health care organization and provision. In the last 20 years, the degree of regional autonomy in health care matters has substantially increased, this process culminating in the 2001 constitutional reform. Responsibility for health care is now shared between the central government and 20 regions, which traditionally differ a great deal in terms of demography, culture, economic development and per capita income. Disparities can be found in almost any area of health care provision, in health policy-making, health care expenditure, quality of health care, public satisfaction, health care services organization and supply.

From a health policy point of view, regions vary in the application of national guidelines and have different health policy-making capacities. Since its inception, the SSN has been blamed for many problems: bureaucracy, insufficient accountability to the public and scattered quality of services. These criticisms were the main driving forces behind the first SSN reforms in the early 1990s, which introduced market-oriented principles (e.g. managerial autonomy to major hospitals and local health organizations, and a partial purchaser–provider split to promote competition), but did not fully achieve the expected results. The main issues of concern were the varying pace of implementation by each region and the perceived fragmentation in the operation of the internal market. The 1999 reform attempted to adjust the design of the early 1990s by establishing the leading role of the state in formulating the basic regulatory framework to which regions had to adhere in exercising their improved autonomy. Despite this, regions still continue to differ in a variety of ways in their enforcement of the major health care reforms and often end up implementing just one or a few elements of the national design (France, Taroni and Donatini, 2005).

With regard to health expenditure, in 2005 the country's health spending was slightly below the EU average, and regional data show differences in the total health expenditure and in the expenditure for primary care/community care, hospital care and public health interventions, particularly among northern and southern regions. The Italian population's satisfaction with the health care system remains under the EU average, but, again, satisfaction differs across the north–south divide, with the northern and central regions consistently obtaining above-average results, whereas all southern regions score under the average. Besides the specific characteristics of each single region, data almost always show a clear north–south divide in almost all health care sectors.

Under this framework, a major and critical challenge for the future of Italy's SSN will be to avoid a devolution process that enlarges differences among regions. New governance tools, such as the crucial new National Healthcare Information System, based on a common classification and coding language, will be fundamental to monitoring the LEAs, in order to promote an efficient exchange of information between the national and regional levels and to measure and compare quality, efficiency, and appropriateness of services.

Regions, for their part, will be asked to make fundamental decisions about the best instruments and strategies: exchanging views and experiences on the approaches taken to similar problems represents a great opportunity to learn from each other while respecting mutual autonomy. Indeed, notwithstanding all the above differences, Italy's regional health care services have to deal with some challenges that remain common to all of them, and to the Italian SSN as a whole: coordination between primary and secondary care, continuity of care for patients, reorganization of hospital networks, integration of health and social care services, and better implementation of managerial principles at the hospital and local health enterprise level.

Both regions and the central government will have to agree on the best methods needed to prevent disparities from becoming too marked, so that equal health care can be guaranteed to all citizens irrespective not only of their economic status and gender but also of their geographical provenance.

10 Appendices

10.1 References

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10.2 Principal legislation

2007

Delibera della Conferenza Unificata, 20 settembre 2007 [Deliberation of the Unified State and Regions Conference on the National Agency for Regional Health Services' new remit].

2006

Accordo Conferenza Stato Regioni del 14 dicembre 2006 [sulla formazione continua] [State and Regions Conference Agreement of 14 December 2006 on continuing education in medicine/ECM].

Accordo ponte Conferenza Stato Regioni del 16 marzo 2006 [sulla formazione continua] [State and Regions Conference Agreement of 16 March 2006 on continuing education in medicine/ECM].

Decreto Legislativo 163/2006 Codice dei contratti pubblici relativi a lavori, servizi e forniture in attuazione delle direttive 2004/17/CE e 2004/18/CE [Regulations for public contracts in relation to work, services and supplies implementing EC Directives EC/2004/17 and EC/2004/18]. *Gazzetta Ufficiale*, No.100, 2 May 2006 (Suppl. ord.).

Intesa in Conferenza Stato-Regioni 28/9/2006 "Patto nazionale per la salute" [State and Regions Agreement "National pact on Health" 28 September 2006].

2005

Deliberazione della Giunta Regionale del Veneto n. 954 del 18 marzo 2005, "Manuale del Sistema di Gestione per l'Umanizzazione" [Deliberation of the regional Council of the Veneto Region of 18 March 2005, "Handbook for the management of quality improvement from the patients' perspective"].

Intesa Conferenza Stato Regioni del 23 Marzo 2005 sulla formazione continua [State and Regions Agreement of 23 March 2005 on continuing education in medicine at national and regional level].

2004

Accordo Conferenza Stato Regioni del 20 Maggio 2004 Accordo tra il Ministro della Salute, le Regioni e le Province Autonome di Trento e di Bolzano sul programma di formazione continua per l'anno 2004 e sugli obiettivi formativi di interesse nazionale per il triennio 2003–2005, di cui ai commi 1 e 2 dell'articolo 16 ter del decreto legislativo 30 dicembre 1992, n. 502 e successive modificazioni [State and Regions Conference Agreement on the 2004 programmes and 2003–2005 objectives of the continuing education in medicine/ECM programme for the Autonomous Provinces of Trento and Bolzano].

Decreto del Ministero della Salute, 30 giugno 2004, "Costituzione del Sistema Nazionale Linee Guida" [Decree by the Minister of Health on the establishment of a national guidelines system, 30 June 2004].

Decreto Legislativo 156/2004, Interventi urgenti per il ripiano della spesa farmaceutica [Legislative Decree 156/2004 on urgent measures on public expenditure on pharmaceuticals]. *Gazzetta Ufficiale*, No. 186, 10 August 2004.

Deliberazione della Giunta Regionale del Veneto n. 2319 del 30 luglio 2004, "Progetto per la umanizzazione" [Deliberation of the Regional Council of the Veneto Region of 30 July 2004 "Project for the quality improvement of health services from the patients' perspective].

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2003

Accordo Conferenza Stato Regioni del 13 Marzo 2003 Accordo tra il Ministro della salute, le Regioni e le Province Autonome di Trento e Bolzano sugli obiettivi e sul programma di formazione continua per l'anno 2003, di cui ai commi 1 e 2 dell'articolo 16ter del decreto legislativo 30 dicembre 1992, n. 502 e successive modificazioni, proposti dalla Commissione nazionale per la formazione continua [State and Regions Conference Agreement on the 2003 Objectives and programmes of the continuing education in medicine/ ECM programme].

Deliberazione della Giunta Regionale Toscana n. 697 del 14 Luglio 2003, Impegni per la qualità del cittadino [Deliberation of the Regional Council of the Tuscany Region of 14 July 2003 on the "Regional commitment to healthcare quality"].

Legge 326/2003 del 24 novembre 2003, Conversione in legge, con modificazioni, del decreto-legge 269/2003, recante disposizioni urgenti per favorire lo sviluppo e per la correzione dell'andamento dei conti pubblici [Conversion into law, with modifications, of Legislative Decree 269/2003 introducing urgent arrangements to aid the development of and to correct the public accounts]. *Gazzetta Ufficiale*, No. 274, 25 November 2003 (Suppl. ord.).

2002

Deliberazione della Giunta Regionale Toscana, n. 808, 29 luglio 2002, Comitato Regionale Carta dei Servizi [Deliberation of the Regional Council of Tuscany Region of 29 July 2002 on the establishment of the Regional Committee for the Health Services Chart].

2001

Accordo Conferenza Stato Regioni del 20 dicembre 2001. Accordo tra il Ministro della Salute, le Regioni e le Province Autonome di Trento e Bolzano, sugli obiettivi di formazione continua di interesse nazionale di cui ai commi 1 e 2 dell'articolo 16/ter del decreto legislativo 30 dicembre 1992 n. 502 e successive modificazioni, proposti dalla Commissione nazionale per la formazione continua [State and Regions Conference Agreement on the objectives of the continuing education in medicine/ECM programme].

Decreto del Presidente del Consiglio dei Ministri, 14 febbraio 2001 "Atto di indirizzo e coordinamento in materia di prestazioni socio-sanitarie" [Prime Minister's Decree issuing the coordinating legislation on health and social services]. *Gazzetta Ufficiale*, No. 129, 6 June 2001.

Decreto del Presidente del Consiglio dei Ministri, 29 novembre 2001, Definizione livelli essenziali di assistenza sanitaria [Prime Minister's Decree on defining the basic package of health services to be guaranteed to all citizens]. *Gazzetta Ufficiale*, No. 338, February 2002 (Suppl. ord.).

Decreto del Presidente della Repubblica, 3 maggio 2001 Piano nazionale degli interventi e dei servizi sociali [National plan for social services].

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2000

Deliberazione della Giunta Regionale Emilia-Romagna, n. 678/2000 "Costituzione del comitato consultivo regionale per la qualità dal lato del cittadino" [Deliberation of the regional Council of Emilia-Romagna No. 678/2000 "Establishment of the regional committee for quality from the perspective of citizens"].

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1999

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1998

Decreto del Presidente della Repubblica 323/1998, Piano Sanitario Nazionale 1998-2000: un patto di solidarietà per la salute [National Health Plan 1998–2000: a solidarity pact for health]. *Gazzetta Ufficiale*, No. 288, 10 December 1998 (Suppl. ord.).

1997

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1995

Direttiva Presidente del Consiglio dei Ministri 19 maggio 1995 "Schema generale di riferimento della Carta dei servizi pubblici sanitari" [Prime Minister's Directive of 19 March 1995 on the Health Services Chart].

1994

Direttiva del Presidente del Consiglio dei Ministri 27 gennaio 1994, "Principi sull'erogazione dei servizi pubblici" [Prime Minister's Directive of 27 January 1994 on the principles for the provisions of public services].

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Decreto del Presidente della Repubblica 1 Marzo 1994, Approvazione del Piano Sanitario Nazionale per il triennio 1994-1996 [Presidential Decree of 1 March 1994, Approval of the National Health Plan 1994–1996]. *Gazzetta Ufficiale*, No. 171, 23 July 1994.

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Legge 335/1994 Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato [Arrangements for the national annual and multi-year budgets]. *Gazzetta Ufficiale*, No. 190, 16 August 1995 (Suppl ord.).

1993

Decreto Legislativo 517/1993, Modificazioni al decreto legislativo 30 dicembre 1992, n. 502, recante riordino della disciplina in materia sanitaria, a norma dell'art. 1 della legge 23 ottobre 1992, n. 421 [Modifications to the legislative decree 30 December 1992, No.502]. *Gazzetta Ufficiale*, No. 293, 15 December 1993 (Suppl. ord.).

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1992

Decreto Legislativo 502/1992 Riordino della disciplina in materia sanitaria, a norma dell'art. 1 della legge 23 ottobre 1992, n. 42 [Organization of health legislation]. *Gazzetta Ufficiale*, No. 305, 30 December 1992 (Suppl. ord.).

Legge 104/1992 Legge quadro per l'assistenza, l'integrazione sociale e i diritti delle persone handicappate [Law on establishing the framework for assistance, social integration and rights of people with disabilities].

Legge 210/1992 "Indennizzo a favore dei soggetti danneggiati da complicanze di tipo irreversibile, a causa di vaccinazioni obbligatorie, trasfusioni e somministrazioni di emoderivati" [National law on financial compensation for people who received permanent harm after a mandatory vaccination or transfusion].

1991

Decreto Legislativo 8 agosto 1991, n. 256 attuazione della direttiva n. 86/457/cee, relativa alla formazione specifica in medicina generale, a norma dell'art. 5 della legge 30 luglio 1990, n. 212 [Legislative decree of 8 August 1991 for the implementation of European Community Directive 86/457/EEC on general medical practice training]. *Gazzetta Ufficiale*, No. 191, 16 August 1991.

Legge 362/1991 Norme di riordino del settore farmaceutico [Law on the reorganization of the pharmaceutical sector]. *Gazzetta Ufficiale*, No. 269, 16 November 1991 (Suppl. ord.).

1986

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1979

Decreto del Presidente della Repubblica, 20 dicembre 1979, n. 761 (1), Stato giuridico del personale delle unità sanitarie locali [President of the Republic Decree of 20 December 1979 on the juridical status of health professionals and operators within local health units].

1978

Legge 833/1978 Istituzione del Servizio Sanitario Nazionale [Law on the establishment of the SSN]. *Gazzetta Ufficiale*, No. 360, 28 December 1978.

1968

Legge 475/1968 Norme concernenti il servizio farmaceutico [Law on the pharmaceutical sector]. *Gazzetta Ufficiale*, No. 107, 27 April 1968 (Suppl. ord.).

1904

Legge 36/1904 Disposizioni sui manicomi e sugli alienati. Custodia e cura degli alienati [Arrangements for mental asylums and inmates. Guardianship and treatment of inmates]. *Gazzetta Ufficiale*, No. 43, 22 February 1904.

10.3 Useful web sites

10.3.1 National level

Agency for Regional Health Care Services: http://www.assr.it
Federation for Palliative Care: www.fedcp.org
Italian Medicines Agency: www.agenziafarmaco.it
Ministry of Health: http://www.ministerosalute.it

National Association of Pharmaceutical Companies: www.farmindustria.it

National Association of Private Pharmacies: www.federfarma.it

National Institute of Health: http://www.iss.it

National Institute of Statistics: www.istat.it

National Plan for Clinical Guidelines: www.pnlg.it

10.3.2 Regional level

Abruzzo region: http://sanitab.regione.abruzzo.it/

Autonomous province of Bolzano: http://www.provinz.bz.it

Autonomous province of Trento: http://www.provincia.trento.it

Basilicata region: http://www.regione.basilicata.it

Calabria region: http://www.regione.calabria.it

Campania region: http://www.regione.campania.it

Emilia-Romagna region: http://www.saluter.it

Friuli-Venezia-Giulia region: http://www.sanita.fvg.it/ars/welcome.htm

Lazio region: http://www.regione.lazio.it

Liguria region: http://www.regione.liguria.it

Lombardy region: http://www.sanita.regione.lombardia.it

Marche region: http://www.regione.marche.it

Molise region: http://www.regione.molise.it

Piedmont region: http://www.regione.piemonte.it/sanita/index.htm

Puglia region: http://www.regione.puglia.it

Sardinia region: http://www.regione.sardegna.it

Sicily region: http://www.regione.sicilia.it

Tuscany region: http://www.salute.toscana.it

Umbria region: http://www.regione.umbria.it

Valle d'Aosta region: http://www.regione.vda.it

Veneto region: http://www.regione.veneto.it

Regional Observatory on Health Services Chart: http://www.salute.toscana.it/parliamodi/cartaservizi/osservatorio-regionale-servizi-sanitari.shtml

Regional Observatory on legal arguments in healthcare: http://www.salute.toscana.it/parliamodi/cartaservizi/osservatorio-regionale-permanente.shtml

10.3.3 Regional health agencies

Campania region: http://www.arsan.campania.it
Emilia-Romagna region: http://asr.regione.emilia-romagna.it/
Friuli-Venezia-Giulia region: http://www.sanita.fvg.it/ars/welcome.htm
Lazio region: http://www.asplazio.it/
Marche region: http://www.ars.marche.it
Piedmont region: http://www.aress.piemonte.it/index1.php
Puglia: http://www.arespuglia.it
Tuscany region: http://www.arsanita.toscana.it/

10.4 HiT methodology and production process

The HiT profiles are produced by country experts in collaboration with the Observatory's research directors and staff. The profiles are based on a template that, revised periodically, provides detailed guidelines and specific questions, definitions, suggestions for data sources and examples needed to compile HiTs. 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 most recent template is available online at: http://www.euro.who.int/observatory/Hits/20020525_1.

Authors draw on multiple data sources for the compilation of HiT profiles, ranging from national statistics, national and regional policy documents, and published literature. Furthermore, international data sources may be incorporated, such as those of the OECD and the World Bank. OECD Health Data contain over 1200 indicators for the 30 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 World Health Organization (WHO) Regional Office for Europe for the purpose of monitoring Health for 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. With its summer 2007 edition, the Health for All database started to take account of the enlarged European Union of 27 Member States.

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 profile consists of 10 chapters.

1. Introduction: outlines the broader context of the health system, including geography and sociodemography, economic and political context, and population health.
2. Organizational structure: provides an overview of how the health system in the country is organized and outlines the main actors and their decision-making powers; discusses the historical background for the system; and describes the level of patient empowerment in the areas of information, rights, choice, complaints procedures, safety and involvement.
3. Financing: provides information on the level of expenditure, who is covered, what benefits are covered, the sources of health care finance, how resources are pooled and allocated, the main areas of expenditure and how providers are paid.
4. Regulation and planning: addresses the process of policy development, establishing goals and priorities; deals with questions about relationships between institutional actors, with specific emphasis on their role in regulation and what aspects are subject to regulation; and describes the process of HTA and research and development.
5. Physical and human resources: deals with the planning and distribution of infrastructure and capital stock; the context in which IT systems operate; and human resource input into the health system, including information on registration, training, trends and career paths.
6. Provision of services: concentrates on patient flows, organization and delivery of services, addressing public health, primary and secondary health care, emergency and day care, rehabilitation, pharmaceutical care, long-term care, services for informal carers, palliative care, mental health care, dental care, complementary and alternative medicine, and health care for specific populations.
7. Principal health care reforms: reviews reforms, policies and organizational changes that have had a substantial impact on health care.

8 Assessment of the health system: provides an assessment based on the stated objectives of the health system, the distribution of costs and benefits across the population, efficiency of resource allocation, technical efficiency in health care production, quality of care, and the contribution of health care to health improvement.

9 Conclusions: highlights the lessons learned from health system changes; summarizes remaining challenges and future prospects.

10 Appendices: includes references, useful web sites and legislation.

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:

- A rigorous review process (see the following section).
- There are further efforts to ensure quality while the profile 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 European Observatory staff team, and they are responsible for supporting the other authors throughout the writing and production process. They consult closely to ensure that all stages of the process are as effective as possible and that the HiTs meet the series standard and can support both national decision-making and comparisons across countries.

10.5 The review process

This consists of three stages. Initially, the text of the HiT is checked, reviewed and approved by the research directors of the European Observatory. The HiT 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.

10.6 About the authors

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Kazakhstan (1999[g], 2007[g])
Kyrgyzstan (2000[g], 2005[g])
Latvia (2001, 2008)
Lithuania (2000)
Luxembourg (1999)
Malta (1999)
Mongolia (2007)
Netherlands (2004[g])
New Zealand (2001)
Norway (2000, 2006)
Poland (1999, 2005[k])
Portugal (1999, 2004, 2007)
Republic of Moldova (2002[g], 2008[g])
Romania (2000[f], 2008)
Russian Federation (2003[g])
Slovakia (2000, 2004)
Slovenia (2002, 2009)
Spain (2000[h])
Sweden (2001, 2005)
Switzerland (2000)
Tajikistan (2000)
The former Yugoslav Republic of Macedonia (2000)
Turkey (2002[g,i])
Turkmenistan (2000)
Ukraine (2004[g])
United Kingdom of Great Britain and Northern Ireland (1999[g])
Uzbekistan (2001[g], 2007[g])

Key

All HiTs are available in English. When noted, they are also available in other languages:

[a] Albanian
[b] Bulgarian
[c] French
[d] Georgian
[e] German
[f] Romanian
[g] Russian
[h] Spanish
[i] Turkish
[j] Estonian
[k] Polish

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HiTs are in-depth profiles of health systems and policies, produced using a standardized approach that allows comparison across countries. They provide facts, figures and analysis and highlight reform initiatives in progress.

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