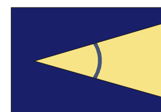
European Observatory on Health Care Systems



# Health Care Systems in Transition

## Italy

The European Observatory on Health Care Systems is a partnership between the World Health Organization Regional Office for Europe, the Government of Greece, the Government of Norway, the Government of Spain, the European Investment Bank, the Open Society Institute, the World Bank, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

# Health Care Systems in Transition

# Italy

**2001**

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RESEARCH AND KNOWLEDGE FOR HEALTH
By the year 2005, all Member States should have health research, information and communication systems that better support the acquisition, effective utilization, and dissemination of knowledge to support health for all.

Keywords

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# Foreword

The Health Care Systems in Transition (HiT) profiles are country-based reports that provide an analytical description of each health care system and of reform initiatives in progress or under development. The HiTs are a key element that underpins the work of the European Observatory on Health Care Systems.

The Observatory is a unique undertaking that brings together WHO Regional Office for Europe, the Governments of Greece, Norway and Spain, the European Investment Bank, the Open Society Institute, the World Bank, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine. This partnership supports and promotes evidence-based health policy-making through comprehensive and rigorous analysis of the dynamics of health care systems in Europe.

The aim of the HiT initiative is to provide relevant comparative information to support policy-makers and analysts in the development of health care systems and reforms in the countries of Europe and beyond. The HiT profiles are building blocks that can be used to:

- learn in detail about different approaches to the financing, organization and delivery of health care services;
- describe accurately the process and content of health care reform programmes and their implementation;
- highlight common challenges and areas that require more in-depth analysis;
- provide a tool for the dissemination of information on health systems and the exchange of experiences of reform strategies between policy-makers and analysts in the different countries of the European Region.

The HiT profiles are produced by country experts in collaboration with the research directors and staff of the European Observatory on Health Care Systems. In order to maximize comparability between countries, a standard template and questionnaire have been used. These provide detailed guidelines

and specific questions, definitions and examples to assist in the process of developing a HiT. Quantitative data on health services are based on a number of different sources in particular the WHO Regional Office for Europe health for all database, Organisation for Economic Co-operation and Development (OECD) Health Data and the World Bank.

Compiling the HiT profiles poses a number of methodological problems. In many countries, there is relatively little information available on the health care system and the impact of reforms. Most of the information in the HiTs is based on material submitted by individual experts in the respective countries, which is externally reviewed by experts in the field. Nonetheless, some statements and judgements may be coloured by personal interpretation. In addition, the absence of a single agreed terminology to cover the wide diversity of systems in the European Region means that variations in understanding and interpretation may occur. A set of common definitions has been developed in an attempt to overcome this, but some discrepancies may persist. These problems are inherent in any attempt to study health care systems on a comparative basis.

The HiT profiles provide a source of descriptive, up-to-date and comparative information on health care systems, which it is hoped will enable policy-makers to learn from key experiences relevant to their own national situation. They also constitute a comprehensive information source on which to base more in-depth comparative analysis of reforms. This series is an ongoing initiative. It is being extended to cover all the countries of Europe and material will be updated at regular intervals, allowing reforms to be monitored in the longer term. HiTs are also available on the Observatory's website at http://www.observatory.dk.

# Acknowledgements

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The current series of Health Care Systems in Transition profiles has been prepared by the research directors and staff of the European Observatory on Health Care Systems.

The European Observatory on Health Care Systems is a partnership between the WHO Regional Office for Europe, the Governments of Greece, Norway and Spain, the European Investment Bank, the Open Society Institute, 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, Head of the Secretariat and the research directors Martin McKee, Elias Mossialos and Richard Saltman. Technical coordination is by Suszy Lessof. The series editors are Reinhard Busse, Anna Dixon, Judith Healy, Laura MacLehose, Ana Rico, Sarah Thomson and Ellie Tragakes.

Administrative support, design and production of the HiTs has been undertaken by a team led by Myriam Andersen and comprising Anna Maresso, Caroline White, Wendy Wisbaum and Shirley and Johannes Frederiksen.

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# Introduction and historical background

## Introductory overview

Italy is a parliamentary republic with a population of 57.7 million in 2000. The territory covers 301 316 km$^2$, and the population density is 191 inhabitants per km$^2$. Italy is considerably smaller than France, Spain or Sweden and only slightly smaller than Finland, Norway or Poland. Italy is located in southern Europe and bordered by France, Switzerland, Austria and Slovenia. Enclaves within mainland Italy are the countries of San Marino and the Holy See, a papal state mostly enclosed by Rome, Italy's capital (Fig. 1).

In addition to the mainland, Italy includes the Mediterranean islands of Elba, Sardinia and Sicily and many smaller islands (Fig. 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 Italy, 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.

### Political background

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

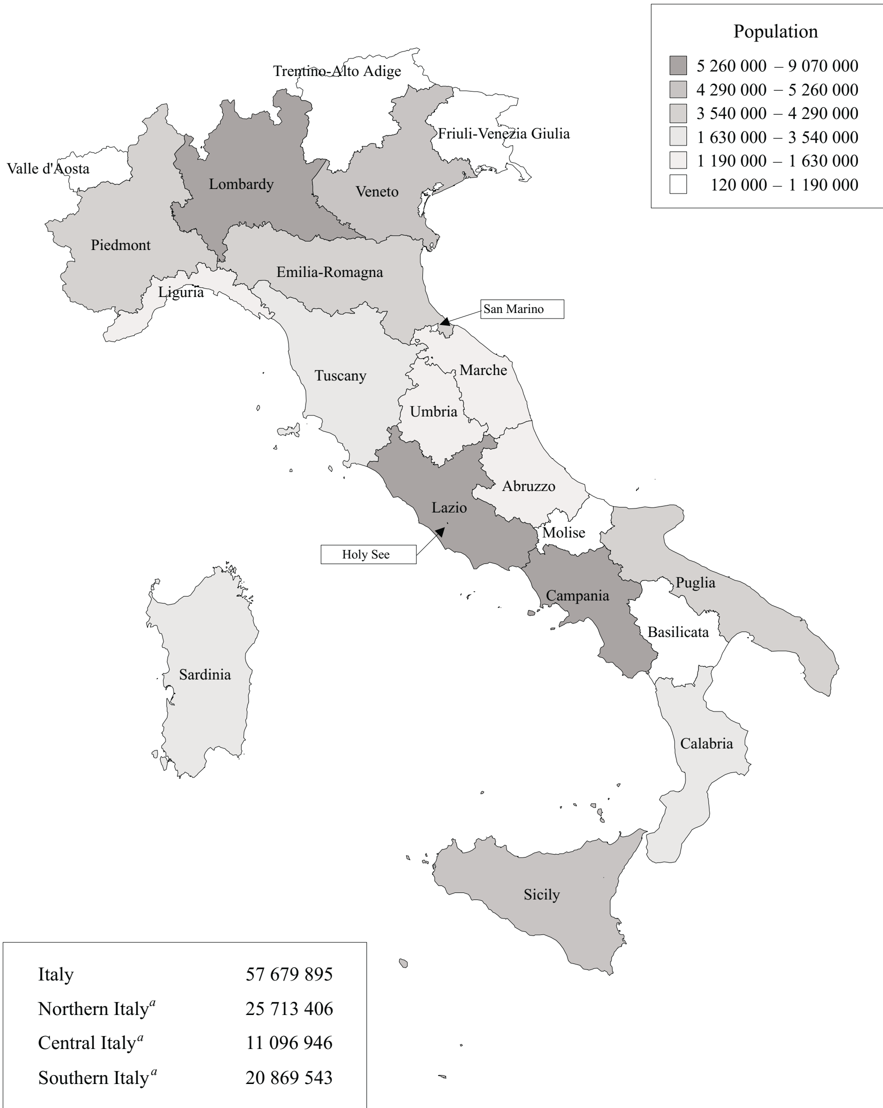
**Fig. 1. Map of Italy**[1]

*Source:* Central Intelligence Agency *(1).*

form the bicameral parliament. The members are directly elected for 5-year terms by universal suffrage. The President of the Republic is elected for 7 years by a joint session of the Chamber and Senate. The President usually has little to do with actually running the government. This is entrusted to the Prime Minister and the Cabinet of Ministers. The Prime Minister is chosen by the

[1] The maps presented in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the European Observatory on Health Care Systems or its partners concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitations of its frontiers or boundaries.

**Fig. 2. Italy's 20 regions and their population as of 1 January 2000**




*Source:* ISTAT *(2).*
[a] Northern Italy: Piedmont, Valle d'Aosta, Lombardy, Liguria, Trentino-Alto Adige, Veneto, Friuli-Venezia Giulia and Emilia-Romagna. Central Italy: Tuscany, Umbria, Marche and Lazio. Southern Italy: Abruzzo, Molise, Campania, Puglia, Basilicata, Calabria, Sicily and Sardinia.

President himself and must be endorsed by and have the confidence of the parliament, usually being 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 have been in power, consistent with an electoral system based on almost pure proportionality. During 1976–1979, the Communist Party entered the government coalition (which included the Christian Democratic Party, the Socialist Party, the Social Democratic Party and the Republican Party) for the first time, as it had been excluded during the previous decades. 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 left 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 prompted a profound political crisis that led to thorough reconstruction of democratic institutions. By September 1993, many political leaders were under criminal prosecution by the courts and the five-party government fell. A nonpartisan 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 was reformed, 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). From March 1994 until January 1995, the right-wing, conservative coalition held office at the national level. From then on, the centre-left alliance (which won the 1996 elections) occupied national government. Forza Italia, Lega Nord and Alleanza Nazionale formed a new government after elections in May 2001.

Italy's Constitution has administratively organized Italy's territory into 20 regions, which are extremely varied. They differ in size (Piedmont is 25 000 square $km^2$ and Valle d'Aosta is only 3000 $km^2$) and in population (Lombardy has 15% of the total population, whereas Molise has less than 1%) as well as levels of economic development. The regions also differ in age distribution. For example, 17% of Italy's population is aged 65 years or older; southern

Italy has fewer (15%) and central and northern Italy have more (19%). Each region is governed by an executive and a regional council, both democratically elected. The 20 regions are subdivided into 94 provinces. The provinces are led by a president and a council, both 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, which may range in size from a small village to a large city such as Naples. Italy has about 1000 municipalities, many of which are small villages with an ancient tradition of independent self-government. A council elected for a 4-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, one of which is further divided into two autonomous provinces, which also enjoy constitutionally based self-government rights. Their special status, based on specific statutes approved by constitutional laws, derives from the fact that they are border regions with a historically distinctive identity and specific language, 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 and forestry and transport), as defined by the Constitution and by their respective self-government statutes, approved by simple parliamentary laws.

All regions have some power to allocate freely the funding 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, culture and arts 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 revenue with state transfers sufficient to carry out their ordinary functions. Besides that, the regions own some health care centres (assigned by law) that are allowed to borrow to finance investment.

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. Starting in the mid-1990s, broader policy proposals to transform Italy into a federal state were debated and adopted.

In particular, a reform passed in 1997 known as 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 is now running parallel to the fiscal reform passed in 2000, which will grant regions significant autonomy over revenue in the regional budget and complete autonomy over the allocation of funds.

In January 2001, 8 of the 15 ordinary regions (Abruzzo, Calabria, Lazio, Liguria, Lombardy, Piedmont, Puglia and Veneto) were governed by centre-right parties, and centre-left parties held office in 7 (Basilicata, Campania, Emilia-Romagna, Marche, Molise, Tuscany and Umbria). Three special regions (Friuli-Venezia Giulia, Sardinia and Sicily) were governed by centre-right coalitions and one (Valle d'Aosta) by centre-left parties, and the two autonomous provinces of Trento and Bolzano by a coalition including both centre-left parties and small nationalist parties.

## Economic background

Italy has an open economy and is a member of major multilateral economic organizations such as the Group of Seven industrialized countries (G-7), the Organisation for Economic Co-operation and Development (OECD), the World Trade Organization and the International Monetary Fund. It is also a founding member of the European Union (EU).

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 on the Adriatic Sea. Most raw materials for industry and over 75% of the energy required have to be imported. The agricultural sector employs 5.9% of the workforce, although it accounts for only 3.2% of gross domestic product (GDP); industry employs 32.9% of the population and represents 29.2% of GDP; the service sector employs 61.2% of the population and comprises 67.6% of GDP. Tourism represents an important part of the economy, with 72.3 million visitors to tourist facilities in 1998. However, the seasonal nature of tourism and the large numbers of illegal

immigrants working in tourism make assessing its impact on employment difficult.

Since the Second World War ended, Italy's economic structure has completely changed from agriculturally based to industrially based, with about the same total and per capita output as France and the United Kingdom. The evolution of Italy's economy since then has placed the country in a position of international importance. According to the most recent OECD calculations, Italy's economy is the sixth largest among industrial powers. Its annual GDP accounts for 6.7% of the total GDP of the G-7 countries and 15.2% of the EU's total GDP. Per capita income, although 35.7% lower than in the United States, is at the average EU level.

Italy's economy has progressed in the last 5 decades because of a strong entrepreneurial orientation combined with liberal trade policies. In particular, the years from 1958 to 1963 are known as Italy's economic miracle. The growth in industrial output peaked at over 19% per year during that period, a rate surpassed only by Japan and the Federal Republic of Germany. Italy enjoyed full employment, and in 1963 the level of investment reached 27% of GDP.

The country did, however, suffer considerably from the two economic crises of the last quarter of the twentieth 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% (Table 1). The severe financial unrest forced monetary officials to withdraw the lira 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, state 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. At the same time, the private sector was increasingly emphasized as the primary engine of growth: to this end, a broad array of deregulation measures

**Table 1. Macroeconomic indicators, 1990–1999**

| | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| Annual growth rate in GDP (%)[a] | – | 1.4 | 0.8 | –0.9 | 2.2 | 2.9 | 1.1 | 1.8 | 1.5 | 1.4 |
| GDP per capita (thousands of US$ PPP)[b] | 16.3 | 17.2 | 18.1 | 17.9 | 18.9 | 20.2 | 20.8 | 21.3 | 21.3 | 21.8 |
| Percentage of total population employed[b] | 37.6 | 37.9 | 37.6 | 36.1 | 35.4 | 35.2 | 35.3 | 35.2 | 35.4 | 36.3[a] |
| Total unemployment (% of labour force[c] | 11.0 | 11.4 | 11.5 | 10.2 | 11.3 | 11.6 | 11.7 | 11.7 | 11.8 | 11.4 |
| Average annual rate of inflation (%)[d] | 6.5 | 6.3 | 5.3 | 4.6 | 4.1 | 5.2 | 4.0 | 2.0 | 1.9 | 1.2 |

*Sources:* [a]ISTAT *(3)*; [b]OECD *(4)*; [c]ISTAT *(2)*; [d]calculated by Bank of Italy staff using ISTAT *(3)*.
PPP: purchasing power parity.

were enacted. Since 1994, a massive programme for privatizing 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 economic policy 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. In 1999 the GDP increased by 1.4% over the previous year, lower than the average EU growth level of 2.3%. About 11.4% of the workforce was unemployed in 1999 versus the EU average of 9.2% (Table 1).

Some of the most remarkable, specific weaknesses of Italy's economy in the late 1990s were related to the labour market structure. In 1999, for instance, 32.7% of all unemployed people were younger than 25 years, one of the highest proportions in the EU. Women only accounted for 36% of the workforce, one of the lowest percentages among EU countries. In addition, temporary jobs play an increasing 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.

In general, welfare expenditure as a proportion of GDP was slightly lower than the EU average in 1999. Italy ranks first in expenditure for old-age pensions and survivorship annuities, has an intermediate-to-low position for health care expenditure and is markedly above average in the subsidies allocated to families with children, housing, unemployed people and socially disadvantaged people.

There have been recent promising developments, however, in the regulation of family allowances and income maintenance programmes.

The success of the corrective action undertaken during the 1990s has been highlighted by the participation of Italy in the new common European currency, the euro, since its introduction on 1 January 1999. Currently, Italy needs to address a fiscal reform, to revamp its communication system, to reduce pollution in major industrial centres and to adapt to the new competitive context derived from the ongoing process of economic integration and expansion of the EU.

## The north–south divide

One of the most enduring, critical 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), the situation was as follows. Certain northern and central regions (Piedmont, Lombardy and Tuscany) had reasonably well developed industrial enterprise commerce and agriculture, based on efficient modern structures and plentiful capital. In contrast, the central southern regions were characterized by generally backward agricultural systems, especially the *latifundia* (vast estates and few landowners), while industry, based on state enterprise, 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 widening the economic and social disparity between north and south.

The 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 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 the considerable economic development during the second half of the twentieth century, the income gap between north and south remains one of Italy's most difficult and enduring economic and social problems. At the start of the twenty-first 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: 22% for the south versus 7% for the centre and north in 1999. Another

important characteristic is the dual economy: 75% of the total GDP is produced in the centre and north (Lombardy accounts for 20% of GDP) and only 25% in the south (Table 2). Moreover, this proportion has remained almost the same over the last two decades.

**Table 2. Per capita GDP (in thousands of euros) and percentage of the national average in Italy's regions, 1996**

| Region | Per capita income (thousands of euros) | % of national average |
|---|---|---|
| Piedmont | 19.1 | 115.2 |
| Valle d'Aosta | 21.8 | 132.1 |
| Lombardy | 21.5 | 129.8 |
| Trentino-Alto Adige | 21.2 | 128.3 |
| Veneto | 20.3 | 122.8 |
| Friuli-Venezia Giulia | 20.6 | 124.1 |
| Liguria | 19.3 | 116.3 |
| Emilia-Romagna | 21.6 | 130.8 |
| Tuscany | 18.0 | 108.8 |
| Umbria | 15.8 | 95.4 |
| Marche | 17.5 | 105.7 |
| Lazio | 18.4 | 111.3 |
| Abruzzo | 14.5 | 87.5 |
| Molise | 12.4 | 75.4 |
| Campania | 10.4 | 62.7 |
| Puglia | 11.5 | 69.3 |
| Basilicata | 10.8 | 65.3 |
| Calabria | 9.3 | 56.6 |
| Sicily | 10.3 | 62.3 |
| Sardinia | 11.9 | 71.9 |
| Italy | 16.5 | 100.0 |
| Centre and north | 19.9 | 120.1 |
| South | 10.9 | 65.7 |

*Source:* adapted from International Monetary Fund *(5)*

## Health status

The structure of the population changed significantly between 1990 and 1999 because fertility rates declined and life expectancy increased. Italy has one of the lowest total fertility rates in the world: in 1998, it was 1.19, far below the replacement level (Table 3). The population growth rate is therefore very low, 1.8% annually (1997), one of the smallest in the EU, and immigration causes most of the growth.

The populations of all industrialized countries are aging. In 1999, Italy had 125 people aged 65 years or older for each 100 people 14 years or younger, the highest ratio in the EU (the EU average in 1997 was 91 people aged 65 years or

**Table 3. Health indicators, 1990–1999**

| Health indicator | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| Population (millions) | 56.7 | 56.8 | 56.9 | 56.4 | 56.5 | 56.6 | 56.7 | 56.9 | 57.0 | 57.0 |
| % of population 65 years or older[a] | 14.5 | 14.8 | 15.1 | 15.4 | 15.7 | 16.1 | 16.4 | 16.7 | 17.7[b] | 18.0[b] |
| Birth rate (per 1000 population)[b] | 10.0 | 9.9 | 10.0 | 9.6 | 9.4 | 9.1 | 9.2 | 9.2 | 9.0 | 9.1 |
| Death rate (per 1000 population)[b] | 9.6 | 9.8 | 9.6 | 9.7 | 9.7 | 9.5 | 9.7 | 9.6 | 9.9 | 9.8 |
| Female life expectancy at birth (years)[a] | 80.0 | 80.2 | 80.4 | 80.5 | 80.7 | 80.8 | 81.3 | 81.6 | 81.8[b] | 82.0[b] |
| Male life expectancy at birth (years)[a] | 73.5 | 73.6 | 73.8 | 74.1 | 74.3 | 74.6 | 75.0 | 75.3 | 75.6[b] | 75.8[b] |
| Infant mortality (per 1000 live births)[a] | 8.2 | 8.1 | 7.9 | 7.3 | 6.6 | 6.2 | 6.2 | – | – | – |
| Fertility rate[a] | 1.3 | 1.3 | 1.3 | 1.3 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | – |

*Sources:* [a]OECD *(4)*; [b]ISTAT *(2)*.

older for each 100 people 14 years or younger). This is a result of persistent low fertility and a corresponding decline in the proportion of the population 14 years or younger (14.4% in 1999). In contrast, the percentage of the population 65 years or older is increasing steadily: 18.0% of the population in 1999, with 22% aged 80 years or older (Table 3).

Life expectancy at birth rose substantially during the 1980s and continued to grow during the 1990s to just above the EU average in the late 1990s. The infant mortality rate has remained one of the highest in the EU, although it underwent the second largest decline during the 1990s (Table 3).

Cancer is the most frequent cause of death for people 64 years or younger, followed by cardiovascular diseases. However, when all ages are considered, cardiovascular diseases cause more deaths than does cancer. Age-specific mortality patterns show that up to 88% of all deaths in each age group have three main causes: accidental or other injuries (by far the main cause until age 35 years), cancer and cardiovascular diseases. Mortality from breast cancer is at the EU average and that 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 1999, the proportion of the population aged 65 years or older ranged from 15.3% (Sardinia) to 24.7% (Liguria). In addition, fertility rates ranged from the 0.94 of Emilia-Romagna to the 1.57 of Campania, while birth rates ranged from 6.6 per 1000 population (Liguria) to 11.9 per 1000 (Bolzano). The highest death rate is 13.9 per 1000 population in Liguria and the lowest 7.8 in Campania. Infant mortality, in turn,

ranged from 9.0 per 1000 live births in Sicily to 3.4 in Trento. In 1997, the highest and lowest regional life expectancy figures differed by 2.0 years, both for males (74.2 versus 76.2) and for females (80.6 versus 82.6).

Certain population groups often differ significantly, such as men and women, and overall measures do not detect these differences. For example, women's life expectancy at birth was 81.2 years in 1999, 5.4 years longer than that for men (75.8 years). The gender gap has widened slightly over the last decade. As for perceived health, 77% of a sample of Italy's population self-assessed their health status as being good in 1999. In particular, more men claim good health status than do women. Self-assessed health status decreases with age: only 29% of people aged 75 years or older stated that their health status was good.

The total number of smokers has declined in the last decade, and in particular, the proportion of the population that smokes has remained stable at about 25% during the last 5 years. However, 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 in Italy in recent years (8% of the population in 1999), in particular among children, has been related to increasing caloric intake resulting from changing dietary habits, including more snacks and reduced time for eating lunch. The Mediterranean diet, even if still the most prevalent, is losing ground to fast food. Only 19% of the population states that they regularly practice some kind of sport, but another 38% admits carrying out some physical activity during leisure time. During the 1980s and 1990s, beer consumption has been increasing in association with a reduction in wine drinkers. Beer is the preferred alcoholic drink of young people, whereas people older than 35 years mainly drink wine.

By the end of 1998, 1 250 000 foreigners were officially registered as residing in Italy; less than 1 million were non-EU citizens and the rest from the EU. Some 70% of the 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 sexual transmitted infections. Immigrants usually access the health care system through specific immigrant health offices created inside local health units and through some voluntary centres delivering health services for immigrants only.

## 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 twentieth 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 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 in 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 instituted, and tuberculosis insurance became compulsory. Some steps towards compulsory health care insurance for workers were also made. In 1925 the INADEL (Istituto Nazionale di Assistenza per i Dipendenti degli Enti Locali) was instituted as the national body for providing health care for the employees of local authorities. The regulatory framework of the trade union system issued during 1926–1928 included mandatory health care provisions for workers as a prerequisite for collective agreements to become effective. 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 (including health) insurance were created: the ENPAS (Ente Nazionale di Previdenza e Assistenza per i Dipendenti Statali), the national

body in charge of social insurance and health care for public employees, and the INAM (Istituto Nazionale Assicurazione Malattie), the national body for private 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*).

In 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 large deficits of the insurance funds led to a financial crisis, which prompted the government to intervene. In 1974 and 1975, Laws 386/1974 and 382/1975 transferred the responsibility for managing hospitals to the regions. Health insurance funds were abolished and the National Health Service (NHS) was established.

The 1978 reform (Law 833/1978), which created the NHS, introduced universal coverage to Italian citizens and established human dignity, health need and solidarity as the guiding principles of the NHS. The main objectives of the 1978 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 contributions. The main aim was to move progressively to a fully tax-based system.

The new health system was based on a decentralized organizational structure with national, regional and local administration. The central government was responsible for determining how many public resources to devote to health care and for planning – every 3 years and through the National Health Plan.

The central government would provide funding to the regions, and the criteria aimed at supplying regions with a level of financing adequate to provide health care and to progressively reduce regional imbalance. 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. Local health units were operational agencies responsible for providing services through their own facilities or through contracts with private providers. They were to be managed by management committees elected by assemblies of representatives from local governments.

The NHS created jurisdictional conflicts among the different levels of authority established by law since the 1970s. 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 reason for the constantly rising health care expenditure, which was not perceived to lead to a corresponding improvement in the quantity and quality of health care. 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 at increasing and extending co-payments from 1983. These were fiercely resisted by trade unions, leading to subsequent reversals in the announced policy changes.

Moreover, health care was markedly different in north and south, 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 local health units according to their electoral strength. In practice, the front-line administrators ended up being peripheral party cadres who lacked the relevant professional skills. 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 to launch a new reform of the health care system. Legislative Decrees 502/1992 and 517/1993 were the first steps of a progressive pro-competition reform that had the ultimate aim of retaining universal coverage while introducing a system of financing 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.

Dissatisfaction with the effects of the 1992–1993 reforms prompted the parliament to authorize, in 1998, the government to completely reorganize the NHS, 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 229/1999, which extended the regionalization process and strengthened the role of municipalities, making clearer the division of responsibilities among levels of government.

The regionalization completed by the 1999 reform began with Law 59/1997, which devolved new management powers to the regions, and with Legislative Decree 446/1997, which represented the first step towards fiscal federalism, as it provided some sources of autonomous financing to the regions. Regarding fiscal federalism, Legislative Decree 56/2000 prescribes the abolition of the National Health Fund to be replaced by various regional taxes. Regions unable to raise sufficient resources will receive additional funding from the National Solidarity Fund to be allocated annually based on criteria recommended by the government and the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces.

The 1999 reform also softens 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 elderly people, people with reduced autonomy and poor people.

The section on *Health care reforms* has further details on the reforms of the 1990s. Table 4 summarizes the main historical landmarks in the development of Italy's health care system.

**Table 4. Italy's health care system: historical background and recent reform trends**

| | |
|---|---|
| 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). |
| 1926 | Some centres for cancer diagnostic testing were created, following 1922 provisions. |
| 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 agreements. |
| 1942 | A national body was created to guarantee social insurance and health care for public employees (ENPAS). |
| 1943 | A national body for private 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 | The NHS was established by Law 833/1978. As a consequence, health insurance funds were abolished. |
| 1992–1993 | The government approved the first reform of the NHS (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. |
| 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 (third reform). It deepened the regional devolution process, envisaged reorienting 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. |

# Organizational structure and management

## Organizational structure of the health care system

Italy's health care system is a regionally based national health service that provides universal coverage free of charge at the point of service. The system is organized at 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 benefit package through a network of population-based health management organizations (local health units) and public and private accredited hospitals. Fig. 3 summarizes the main organizational actors, as well as the relationships among them.

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

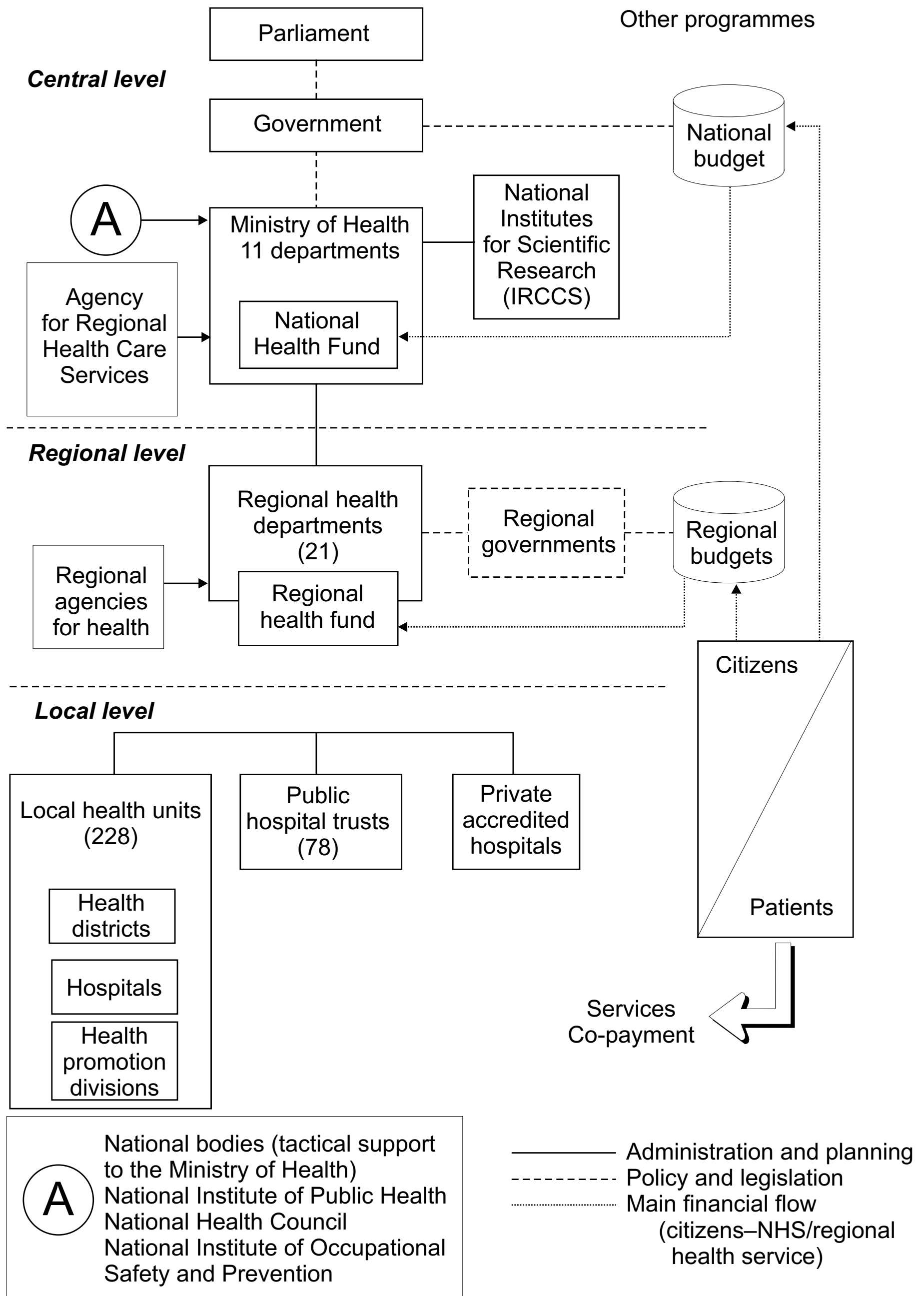
*Human dignity*. Every individual must be treated with equal dignity and have equal rights irrespective of her or his personal or social characteristics.

*Health need*. 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*. NHS 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 NHS should give highest priority to protecting and promoting citizens' health status.

**Fig. 3. Organization of Italy's health care system as of late 2000**



*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 organizations pursuing financial balance through efficient and effective behaviour.

## The central level

The main central institutions are the Ministry of Health, which manages the National Health Fund. Legislative Decree 56/2000 prescribes that the National Health Fund will eventually be abolished (see the section on *Health care financing and expenditure*).

Until 2001, the Ministry of Health, through its departments and services, ensured five different functions:

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

The first function has been managed by the Department of Health Care Planning of the Ministry of Health, responsible for defining the NHS health targets through the National Health Plan. The Ministry of Health, under its planning function, is responsible for proposing to the Treasury the level of public resources to be dedicated to health care. Through the national health planning process, the Ministry of 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 *(6,7)*.

The Ministry of Health also manages the National Health Fund and allocates resources to regions. Consistent with the emerging federal political system, its role in financing will be restricted to allocating the resources from the global national budget and targeted towards ensuring uniform availability of resources in the regions. The regions will finance the remaining health care expenditure from their own sources.

The Ministry of Health is also responsible for technically regulating health care activities in various areas: managing human resources at NHS institutions; optimizing the workforce in the NHS; maintaining disease prevention programmes with a nationwide focus; promoting nutritional health; and promoting veterinary health through the general regulation of a network of ten experimental zooprophylactic institutes. Italy is one of the few countries in which the national health service manages veterinary care.

The monitoring activity of the Ministry of Health includes authorization of drug use and research. Starting in 1992, following a series of corruption scandals, it stopped directly regulating prices and criteria for inclusion in the list of publicly financed drugs. Instead, it only established financial targets and the general framework for guiding the process. In 1994, an independent, non-partisan National Committee for Pharmaceuticals (CUF, Commissione Unica per il Farmaco) was established to decide on the specific brands that should be publicly funded and on the co-payment schemes that should apply to them. The members of the CUF come from the scientific community and are accountable to the Ministry of Health. In 1994, the Committee on Pharmaceuticals (CIP Farmaci), which was in charge of regulating drug prices, was abolished, and its functions were assumed by the Interdepartmental Committee on Economic Planning (Comitato Interministeriale per la Programmazione economica, CIPE).

In accordance with the decentralization process occurring in the NHS since 1992, the administrative control performed by the personnel of the Ministry of Health regarding the functioning, effectiveness and efficiency of public hospitals and local health units is becoming less relevant. These activities have increasingly been devolved to the regional health departments and to local health units.

The Ministry of Health, through a specific department, is also responsible for generally coordinating the activities of the National Institutes for Scientific Research (IRCCS), a network of 16 public and 16 private research hospitals. These hospitals use mainly public funding for basic and clinical work and research and for experimenting with new organizational solutions for hospitals and other health care settings.

The Ministry of Health draws on the input of a number of other ministries and institutions:

- the Ministry of Social Affairs, coordinating social services provided in the infrastructure owned by the NHS;
- the Ministry of the Treasury, a critical agent in the process of setting the health care budget and providing technical support and institutional control on financing health care services (with the prescribed merger of the Ministry

of Health with other ministries, the role of the Ministry of the Treasury in monitoring health expenditure is expected to grow);

- 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 consulting body for all the legislative activities with a regional dimension and can promote collaboration schemes across regions and the central government and propose its own acts;
- the National Health Council (CSS);
- the National Institute of Health (ISS);
- the National Institute of Occupational Safety and Prevention (ISPESL); and
- the Agency for Regional Health Care Services (ASSR).

The National Health Council provides important technical and consultative support to the NHS. The National Health Council is structured as a commission with a president and 50 members including scientists, physicians and other experts with nationwide expertise in health care. The National Institute of Health, National Institute of Occupational Safety and Prevention and Agency for Regional Health Care Services provide technical and scientific support to the Ministry of Health. The National Institute of Health 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 Health; since 1978, it has become the main technical and scientific body of the NHS. The National Institute of Occupational Safety and Prevention is a technical and scientific body of the NHS and is responsible for providing information and research on health promotion and healthy conditions in the workplace. Since 1995, the Agency for Regional Health Care Services has provided support to the NHS by promoting innovation in health care and through comparative analysis of the cost and efficiency of the services offered to the public. The Agency for Regional Health Care Services is accountable to the regions, which nominate its Chair, Management Board and Director, and to the Ministry of Health.

## The regional level

Regional governments, through their departments of health, are responsible for pursuing the leading national objectives posed by the National Health Plan at the regional level. Regional health departments are required to guarantee the benefit package to be delivered to the population through a network of population-based health care organizations (local health units) and public and

private accredited hospitals. They are responsible 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 and evaluation functions.

*Legislative functions*. The legislative functions at the regional level are shared between the regional council and the regional government. According to Legislative Decree 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 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 the departments of health, outline a 3-year regional health plan. Regional governments use this plan, based both on the National Health Plan indications and on the 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 local health units and public hospital trusts;
- 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 local health unit;
- appointing the general managers of local health units and public hospital trusts; and
- defining a regulatory framework for how the general directors of hospitals and local health units 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 local health units and to public and private hospitals. Other regions have formed a regional agency for health responsible for assessing the quality of the local health care and providing technical and scientific support to the regional health departments and to the local health units. 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 single providers in the region. The regions that have created a regional agency for health are: Emilia-Romagna (1994), Friuli-Venezia Giulia (1995), Campania (1996), Marche (1996), Piedmont (1998), Lazio (1999) and Tuscany (2000).

## The local level

The 1978 reform gave an important role to municipalities, which were in charge of governing the local health units. However, a series of reforms starting in the late 1980s progressively shifted municipal powers to the regional level. Starting in 1992, a network of public and private health care structures and providers was operating at the local level that can be divided into four different categories:

- local health units
- public hospital trusts
- National Institutes for Scientific Research
- private accredited providers.

*Local health units*. Local health units are geographically based organizations responsible for assessing needs and providing comprehensive care to a defined population. They were created in 1978 and numbered 659 before the 1992 reforms, which reduced the number of local health units, widened their population bases, increased their autonomy and profoundly reshaped their organizational structure and management system. Regions became responsible for determining the size and organization of local health units and monitoring their operation. As a result, the NHS had 228 local health units in 1995, with an average catchment population of 250 000 inhabitants. Between 1995 and 2000, the number of local health units remained constant in most regions, except for Lombardy, which radically reduced the number of local health units from 44 to 15.

Local health units provide care directly through facilities or through services rendered by public hospital trusts, research hospitals and accredited private providers (acute and long-term hospitals, diagnostic laboratories, nursing homes, outpatient specialists and general practitioners). A general manager appointed

by the regional health departments based on professional qualifications and technical skills manages each local health unit. General managers are appointed for 5 years, and their results are assessed every 18 months. The general manager is responsible for ensuring the sound financial performance of the organization 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 3-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. The services are structured under a typical divisional model. Each division has financial autonomy over and technical responsibility for 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 are salaried directly by the local health unit.
- 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 local health unit depends on its size and on other geographical and demographic characteristics. The district's physicians provide home care services and preventive services for drug addicts and people with terminal AIDS. Primary care physicians (47 157), paediatricians (5687) and other specialists (16 576) are requested to provide these services as independent contractors to the local health units.
- 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.

According to Legislative Decree 229/1999 and Law 662/1996, local health unit services are financed under a global budget with a weighted capitation mechanism. The global budget is also adjusted according to historical spending, and additional compensation is given for cross-boundary flows, which vary significantly region by region and inside each region. Hospital providers are paid fees for services based on diagnosis-related groups for inpatient activities through various mechanisms for outpatient and other specific health care services, such as intensive care, transplants and chronic patient management (see the section on *Financial resource allocation*).

*Public hospital trusts*. Public hospital trusts provide highly specialized tertiary hospital care (inpatient and outpatient). In 1995, Italy had 82 hospital trusts with the status of quasi-independent public agencies. By 2000, the number had risen to 98, mainly because the number of hospitals given trust status increased from 16 to 27 in Lombardy.

Public hospital trusts have a national or at least interregional catchment population and were given financial and technical autonomy starting in 1993. The conditions for obtaining trust status are: a divisional organizational structure; the existence of at least three clinical units considered by the law as "highly specialized"; a complete accident and emergency department with an intensive care unit; and a particularly complex case mix. The governing structure of hospital trusts mirrors that of local health units. Recent national legislation has provided general managers with more autonomy, which mainly materializes in the power to define their hospital's mission and objectives through a 3-year strategic plan, consistent with the recommendations of the regional health plan. Although prospective payment remains the main source of reimbursement, Legislative Decree 229/1999 states that providers are to be paid based on a global budget negotiated yearly by the regional health departments, local health units and trusts.

*National Institutes for Scientific Research*. The National Institutes for Scientific Research (IRCCS) are research-oriented hospitals operating at the local level. They are distributed all over Italy, and the Ministry of Health directly finances them and appoints the general managers. In addition to research funding, the Institutes receive a global budget that covers inpatient and outpatient care and specific health care services, such as intensive care and transplants (see the section on *Financial resource allocation*). In 2000, the overall organization of the Institutes was being revised and was to be approved soon by the parliament.

*Private accredited providers*. Private accredited providers provide ambulatory, hospital treatment and/or diagnosis services financed by the NHS. The regional health departments regulate this participation through the authorization and accreditation system. Authorization for construction and operation is required for:

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

Authorized organizations can receive public funding after having been accredited by the departments of health. Accreditation is conditional on several structural, organizational and technological prerequisites defined at the regional level. Other additional conditions set by regional health departments include:

- formal acceptance of the financing scheme;
- formal acceptance of the external system for auditing the quality of care;
- legitimacy and correctness of annual reimbursement claims;
- availability of quality peer-review programmes;
- participation by users in systematically reviewing the quality of the services provided;
- adoption of health service charts (see the section on *Health care reforms*); and
- acceptance of control based on clinical results.

### The role of insurance companies

The exact role of the private insurance sector in Italy is not well known. The estimates of the population covered in the mid-1990s vary between 10% *(8)* and 5% *(9)*. In 1999, however, an estimated 30% of the population was covered by private insurance (see the section on *Health care financing and expenditure*).

This additional coverage allows enrollees to obtain services through private providers who are not accredited by the NHS, which usually ensures easier, quicker access to the services and often more comfortable health care settings. Legislative Decree 229/1999 establishes regulatory guidelines for reorganizing complementary health care insurance. This provision defines the concept of a supplementary fund, which provides coverage for the services not included in the core benefit package of the NHS.

### The role of user groups

The role of user groups has grown in recent years. Various consumer associations are involved in monitoring the quality of care provided both by private and public providers. They do not, however, have any institutional role in health care planning and monitoring. Their role is to provide information to their members and to the general public on the quality of care provided in various settings. Some user groups are also very active in providing certain services to users such as training programmes for caregivers, social services and counselling (for example, the Italian Multiple Sclerosis Association).

## Planning, regulation and management

The 1978 reform established that the central and regional governments should be in charge of planning. However, no national health plan had been approved

before 1992, and only some regions had approved their 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 NHS away from a public integrated model towards a decentralized, market-oriented one. The main aim of the market-oriented model was to enhance efficiency, efficacy and the quality of health care services and of the whole NHS. The shift towards market solutions involved a parallel change in the way of conceiving the role of the state, which is in principle to be restricted to establishing and safeguarding the basic principles for health services and controlling global spending through appropriate framework legislation. In addition, the 1999 reform implied a departure from the market model, and a new, parallel 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 at fulfilling the main objectives of the NHS. The following paragraphs briefly describe what the tasks of the different actors should be – tasks that often go unmet.

## The central level

Depending on the resources available, set forth in the 3-year National Financial Plan, public funds are allocated annually to various welfare programmes through the annual national budget. Allocation of resources to health care is based on the National Financial Plan and the objectives defined in the National Health Plan. According to current legislation, objectives, targets and action in the National Health Plan should be defined taking into account the proposals elaborated each year by the regional health departments, based on the health status of the population and on supply. 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, with the help of quantitative indicators that must be met at the regional level. Each objective is linked to actions that represent an area of priority intervention to be included within regional and local plans.

The National Health Plan for 1998–2000, which was implemented by a Presidential Decree of 23 July 1998, pursues the following priorities:

- health promotion initiatives, including improving nutrition, reducing smoking and alcohol consumption and promoting physical exercise;

- disease prevention initiatives, including cerebrovascular and cardiovascular diseases, cancer, infectious diseases, injuries and occupational diseases;
- initiatives to improve the environment;
- projects to protect specific groups of people: low-income groups, migrant workers, drug addicts, children and elderly people; and
- initiatives to make the NHS conform to European Union standards.

Moreover, the National Health Plan for 1998–2000 defines the strategies for implementing change. In this context, it:

- envisages the definition of the basic benefit package and its funding;
- describes tools to assure the benefit package to citizens;
- promotes a national evaluation programme and a set of indicators to assess the quality of health care services delivered; and
- encourages continuing care for chronic and disabling illness and easier access to diagnostic and therapeutic services.

In order 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 Ministry of Health is responsible for supporting, monitoring and assessing implementation of the National Health Plan objectives, and an observatory established at the Health Planning Department of the Ministry of Health monitors the implementation of the National Health Plan and supervises health care providers.

The National Health Plan for 1998–2000 represents a new approach to planning that is still being implemented. For this reason, it is still difficult to assess whether most of the innovative measures introduced will improve how the NHS works.

## The regional level

The regional health departments 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 a standing conference for regional health and social care planning.

In addition, regions are accountable to the central government for fulfilling health care targets. Legislative Decree 229/1999 establishes that regions have

to develop an annual report on the state of implementation of the regional health plan. This report is aimed at monitoring and ensuring the accomplishment of the essential 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, already discussed in previous sections, consist of defining the boundaries of local health units and health districts, as well as the criteria for controlling the behaviour and performance of local health units.

### The local level

Local health units are responsible for delivering the benefit package by directly providing services or by funding hospital trusts 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. According to the 1999 reform (Article 3, Legislative Decree 229/1999), local health units have to guarantee equal access to services for all citizens, the efficacy of preventive, curative and rehabilitation interventions and efficiency in the production and distribution of services. They are responsible for maintaining the balance between the funding provided by regions and expenditure for services.

Local health units 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 structure 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 local health unit. The general manager of the health district has to be supported by a coordinating office to achieve these objectives. This office includes general practitioners, paediatricians and specialists to promote the integration of health care and social services, which is also accomplished by developing and disseminating general organizational guidelines.

## Decentralization of the health care system

The decentralization of the health care system has been a key issue in the development of the NHS 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. Following a process of informal expansion of regional power, Legislative Decree 502/1992 started an explicit, formal process of devolving political power and fiscal authority to regions. This process provided the regional health departments 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 NHS from the central to the regional level, thus strengthening the fiscal autonomy of the regional health departments.

In addition, the NHS underwent a process of delegation (*aziendalizzazione*) during the 1990s. All local health units as well as tertiary hospitals were transformed into autonomous bodies. Until 1992, the governance committee of local health units, according to Law 833/1978, was headed by a president elected by the members of the management committee of the local health unit, which represented political parties. Since 1992, the delegation process has been oriented towards providing management with autonomy from political influence. As a result, local health units and public hospital trusts started to be governed by a general manager chosen for technical reasons by the regional health care authorities. Under this new governance model, the local health units and the public hospital trusts 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 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 while simultaneously reinforcing the regulatory and monitoring roles of state authorities. The section on *Health care reforms* has more details on these reform packages.

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 underway. 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.

# Health care financing and expenditure

## Main system of financing and coverage

The 1978 reforms, which established Italy's NHS, envisaged universal coverage, a fully tax-based public health care system and an increasingly marginal role for private financing. Although the former aim was implemented rapidly, the latter two political aims were redefined during the 1980s and 1990s. As a result, the NHS is currently financed through a regional tax on productive activities (which replaced social health insurance contributions in 1997), general taxation collected centrally, various other regional taxes and users' co-payments. In addition, private sources of financing accounted for 33% of total health care expenditure in 1999. This has resulted from increased co-payments to the public system, growing utilization of private providers with direct out-of-pocket payments and increased numbers of people with private insurance.

During the late 1990s, the administrative and institutional settings of Italy started to become those of a federal state. The reforms that contributed to this transition including several packages that will modify the architecture of health care financing. The progressive move towards fiscal federalism started in 1997, and regional taxes finance most health care expenditure, with general taxation playing a complementary role. In fact, central funding is intended to be used primarily to redistribute resources to the regions with a narrower tax base, to ensure all residents adequate levels of care. Overall, regional funding targets are determined centrally according to a mix of weighted capitation and historical spending.

Following a series of measures passed in 2000, the move towards fiscal federalism will be completed in 2001 and accompanied by a shift in central

financing from general revenue to indirect taxes that the state will transfer to the regions (see the section on *Health care reforms*).

## Coverage of the population

Up to the late 1970s, 93% of the population was covered by public health insurance, although under markedly varying conditions. The 1978 reform 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 health care services, in particular treatments for infectious diseases and health care schemes for babies and pregnant women.

## Financing the NHS

Over the years, the financing of Italy’s health care system has undergone important changes. Although the stated aim of shifting to a tax-based system has not been achieved, the 1978 reforms increased the percentage of public expenditure financed by general taxation versus social health insurance contributions, which still represented more than 50% of total public financing throughout the 1990s. Out-of-pocket payments to the public system increased substantially during the 1980s and 1990s. In 1999, private health care spending represented about 33% of total health expenditure versus 20% in 1980.

As discussed in the section on *Historical background*, employers and employees were responsible for financing health care through health insurance funds until 1978. 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. The 1978 reform not only granted a homogeneous benefit package to all citizens but also rationalized the health insurance system by making contributions more uniform and pooling all resources into a single fund.

The 1978 reform created the National Health Fund, which was in charge of guaranteeing 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 local health units and hospitals and user co-payments.

These various sources of funding have gradually been both transformed and simplified. In 1997, before the latest fiscal reforms, the main sources were payroll taxes, co-payment income of local health units and contributions from regions governed by special statute.

*Payroll taxes*. Employees in the public and private sectors and self-employed people pay payroll taxes. The tax has a regressive structure, with rates starting at 10.6% and 6.6% for the first €20 660 of gross income for employees and self-employed people, respectively, and decreasing to 4.6% for both types for gross income between €20 660 and €77 480. The regions have received the revenue from the payroll tax since 1993.

*Co-payment income of local health units*. Local health units receive co-payments for pharmaceuticals, diagnostic procedures and specialist visits. Co-payments for pharmaceuticals simply reduce the expenditure incurred by local health units and do not represent an additional source of income as do co-payments for diagnostic procedures and specialist visits. Nevertheless, they are still included as revenue for local health units.

*Contributions from regions governed by special statute*. Since 1990, the five regions governed by special statute have contributed to financing their health care system by using part of their own budget, as they receive higher overall funding than average.

The system in place from 1978 clearly improved the previous situation in promoting heterogeneity in financing but, at the same time, was characterized by the following flaws.

- Important 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 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 €6000 million, 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 *(10)*.

## The architecture of fiscal federalism

Such issues were among the objectives of the 1992–1993 NHS reform (Legislative Decrees 502/1992 and 517/1993) and of the 1997 fiscal reform (Legislative Decree 446/1997). In particular, Legislative Decree 502/1992

addressed the problem of regional debts by stating that regions incurring budget deficits could not rely on general national taxation but had to raise the extra resources either through higher co-payments or higher regional taxes. The 1997 fiscal reform, in turn, aimed at eliminating disparity in the payroll tax rates, reducing negative incentives for employment and introducing elements of fiscal decentralization. Accordingly, a few local excise taxes and the payroll tax were replaced by two new types of new regional tax.

A regional tax was imposed on the value added of companies (corporations, partnerships and self-employed workers) and on the salaries paid to public-sector employees (IRAP – *imposta regionale sulle attività produttive*). The companies' value added is taxed at 4.25%, but the tax on public-sector salaries is 9.6% on the first €20 660 and 3.8% on the following €56 820. In both cases, the employer pays the tax. Starting in 2001, regions may raise the rate by up to 1 percentage point.

A piggy-back regional tax (the regional IRPEF) was imposed on the national income tax (IRPEF). Legislative Decree 446/97 set the rate, for the years 1998 and 1999, at 0.5%. The national income tax rates were accordingly reduced by 0.5% to accommodate the new tax. From 2000, each region can set the rate between 0.5% and 1.0%, with the national income tax rate decreasing accordingly to keep the total tax burden unchanged for the taxpayers.

The issue of fiscal decentralization, together with the enhancement of the responsibility of regional authorities in managing financial resources, was addressed by stating that the regions would receive all the revenue from these taxes, which would then be used as follows to fund the regional health system:

- all revenue from the regional IRPEF; and
- 90% of the IRAP revenue.

The central government was made responsible for filling the gap between the financial needs of each region and actual funding (the regional IRPEF + IRAP). Fig. 4 shows the direction and type of fiscal flows following the introduction of IRAP and the regional IRPEF.

Table 5 shows the sources of public health care financing. Until 1998, the relative shares of taxes and payroll contributions remained unchanged. In particular, financing from general taxation decreased from 41% in 1990 to 38% in 1998 and then, the following year, increased to 46%; while the contribution from payroll tax (which was replaced by the IRAP and the regional IRPEF in 1998) remained about constant at 53% and decreased to 44% in 1999. The somehow odd trends in the main two sources of funding in 1999 was reversed in 2000, when funding from IRAP and the regional IRPEF increased again to 53% and general taxation decreased to 38%:

| | | |
|---|---|---|
| Additional regional income tax + IRAP | €31 420 million | 53% |
| General fiscal revenue | €22 420 million | 38% |
| Local health unit revenue | €2 110 million | 4% |
| Contributions from regions governed by special statute | €3 250 million | 5% |

**Fig. 4. Fiscal flows in Italy's health care system until 2001**

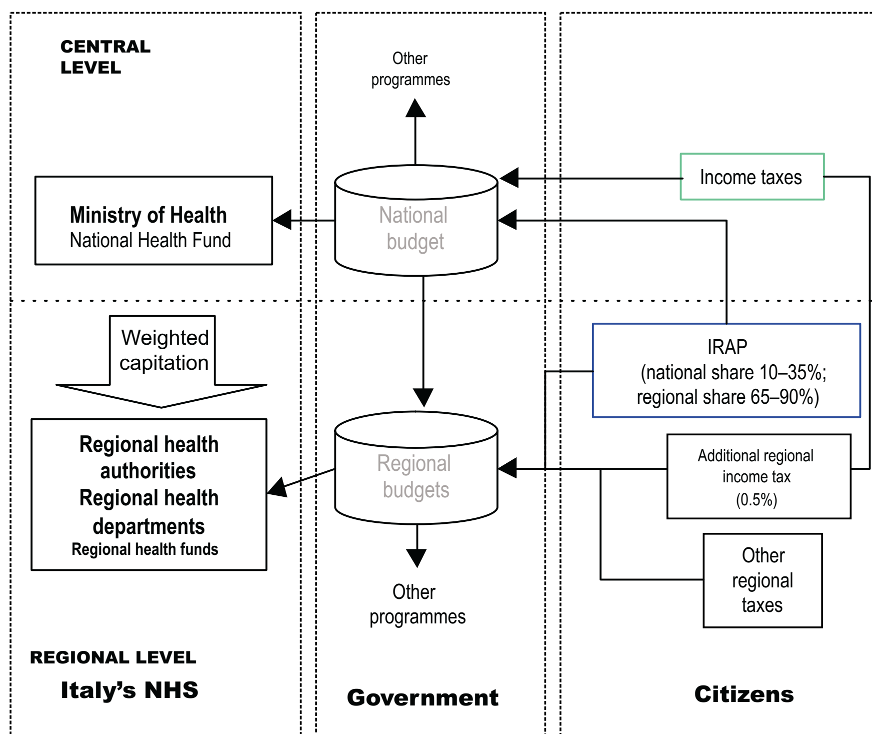



**Table 5. Sources of public health care financing, thousands of million euros, 1990–1999, selected years**

| Source of financing | 1990 Amount | % | 1995 Amount | % | 1997 Amount | % | 1998 Amount | % | 1999 Amount | % |
|---|---|---|---|---|---|---|---|---|---|---|
| General taxation | 17.1 | 41 | 20.1 | 42 | 19.9 | 39 | 20.0 | 37 | 24.9 | 46 |
| Payroll taxes[a] | 22.6 | 54 | 24.3 | 51 | 26.6 | 52 | 28.4 | 53 | 26.0 | 44 |
| Contributions from autonomous regions | 0.5 | 1 | 1.6 | 3 | 2.8 | 5 | 2.9 | 5 | 3.0 | 6 |
| Local health unit revenue | 1.2 | 3 | 1.9 | 4 | 2.2 | 4 | 2.5 | 5 | 2.2 | 4 |

*Source:* Ministry of Treasury and Budget *(11,12).*
[a] IRAP and the regional IRPEF from 1998.
The values in lire have been converted to euros at the current fixed exchange rate of Lit 1936 = €1.

The 1990 reforms of the financing system did not apparently solve the problem of generalized public debt. For instance, in 1998, health care expenditure was an estimated €58 560 million and the National Health Fund comprised only €54 000 million, producing a deficit of about €4560 million. Combined with the deficits from previous years (Table 6), the NHS has a total deficit of €14 210 million.

**Table 6. Cumulative deficits of Italy's NHS, millions of euros, 1994–1998**

| Years | Millions of euros |
|---|---|
| Up to 1994 | 1 750 |
| 1995 | 1 170 |
| 1996 | 2 070 |
| 1997 | 5 090 |
| 1998 (estimate) | 4 130 |
| Cumulative deficit | 14 210 |

*Source:* Corte dei Conti (Court of Auditors) *(10).*

In the past, regions managed to obtain extra funding from the state to cover excess spending, even though the additional funding was frequently made available long after it was needed. Despite the repeated contributions from the state (€3100 million for the years 1995 to 1997), the outstanding debt is about €11 110 million. Responsibility for covering the excess spending has been a source of major debate in Italy's health care arena. The regions claimed that the state should be fully responsible given that it determines the benefit package that each region must supply to its residents and accused central authorities of underfunding the NHS by providing far fewer resources than were actually needed. Nevertheless, in 1999 the state determined that the overall debt was overestimated by about €4650 million and that therefore only accepted about €5680 million as the actual deficit. However, the central government ended up accepting a higher burden than it was willing to accept initially, and paid €12 400 million to cover the deficit up to 1998 and also part of the excess spending for the year 1999.

A closer look at the data on regional expenditure (Table 7) shows a pattern characterized by a decrease in the size of the deficit in the years following the 1992 reform, with the annual overall deficit falling from €3670 million in 1993 to €1140 million in 1995, and then increasing steadily in the following years, to over €4900 million in 1997. Some regions had surpluses, as illustrated by the positive figures in Table 7. Most regions in the north and centre of the country tended to have higher debt burdens, especially regions governed by special statute.

**Table 7. Per capita health care deficits (minus sign) or surpluses in Italy according to region, euros, 1993–1997**

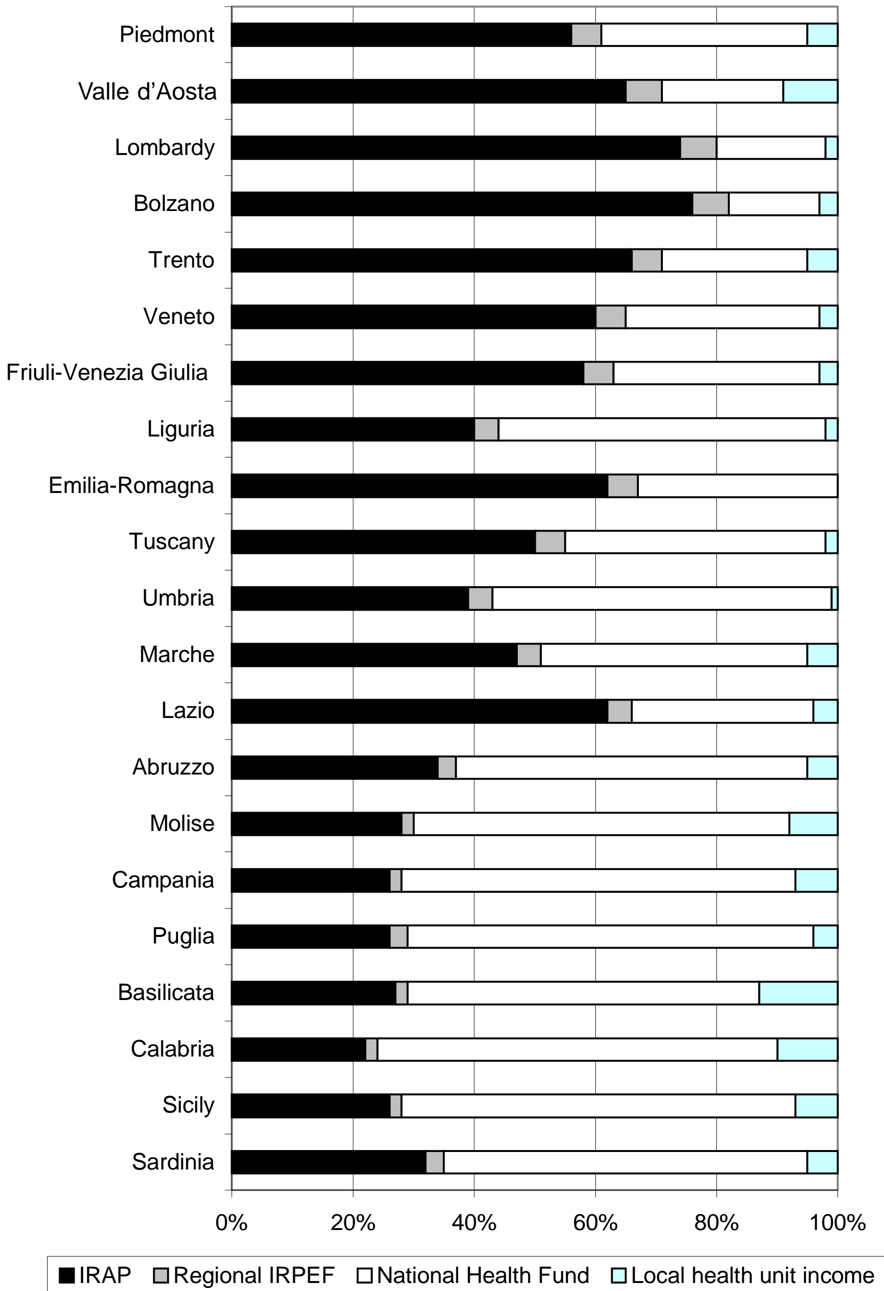
| Region | 1993 | 1994 | 1995 | 1996 | 1997 |
|---|---|---|---|---|---|
| Piedmont | –38.10 | –35.69 | 37.98 | 3.85 | –37.38 |
| Valle d'Aosta | –200.58 | –95.93 | –174.42 | –126.51 | –261.63 |
| Lombardy | –31.19 | –46.03 | –6.78 | –20.98 | –83.19 |
| Bolzano | –140.33 | –180.59 | –152.98 | –24.16 | –303.67 |
| Trento | –130.37 | –144.98 | –121.37 | –131.49 | –191.05 |
| Veneto | –51.16 | –59.69 | –26.63 | –55.01 | –111.66 |
| Friuli-Venezia Giulia | –76.31 | –92.79 | –17.78 | –21.68 | –115.77 |
| Liguria | –149.65 | –141.57 | –93.45 | –92.52 | –134.43 |
| Emilia-Romagna | –95.34 | –115.88 | –79.53 | –113.64 | –117.99 |
| Tuscany | –93.90 | –68.85 | –31.35 | –62.55 | –90.97 |
| Umbria | –69.71 | –70.34 | 30.14 | 1.88 | –94.20 |
| Marche | –91.76 | –92.84 | –5.74 | –54.12 | –78.14 |
| Lazio | –109.51 | –113.29 | –22.48 | –67.04 | –141.73 |
| Abruzzo | –31.37 | –17.52 | 24.45 | –34.23 | –81.49 |
| Molise | –29.55 | –57.54 | 51.32 | 10.89 | –66.87 |
| Campania | –69.94 | –37.85 | 44.95 | 11.87 | –112.55 |
| Puglia | –37.26 | –33.08 | 57.28 | 8.62 | –533.23 |
| Basilicata | –43.98 | 4.23 | 0.85 | –50.75 | –76.12 |
| Calabria | –82.60 | 3.73 | 37.07 | –20.15 | –96.78 |
| Sicily | –26.52 | –86.79 | 30.28 | 3.25 | 28.76 |
| Sardinia | –74.08 | –126.68 | –73.46 | –37.04 | –78.13 |

*Source:* Corte dei Conti (Court of Auditors) *(10).*
The values in lire have been converted to euros at the current fixed exchange rate of Lit 1936 = €1.

Given the significant steps taken towards fiscal federalism in the late 1990s, the fiscal capacity of regions is interesting. Fig. 5 shows the extent to which the regions had to rely on general taxation (the National Health Fund) for financing their health care systems in 2000. The resources available vary widely: autonomy from central funding is very high in some regions, such as in the northern regions of Lombardy and Bolzano (with, respectively, 81% and 82% of the financing coming from IRAP and the regional IRPEF), and low in other regions, such as the southern regions of Calabria and Campania (24% and 28% respectively).

These extreme differences in fiscal autonomy coexist with substantial geographical imbalance in per capita expenditure (see the section on *Health care expenditure*), which requires that fiscal devolution be complemented by substantial redistribution of funds through central transfers. To address this problem, a fiscal equalization mechanism (National Solidarity Fund) has been developed to transfer funds to the regions unable to raise sufficient resources. The Fund was authorized to spend €6560 million in 2001, or 10% of the overall

**Fig. 5. Sources of health care financing according to region, 2000**

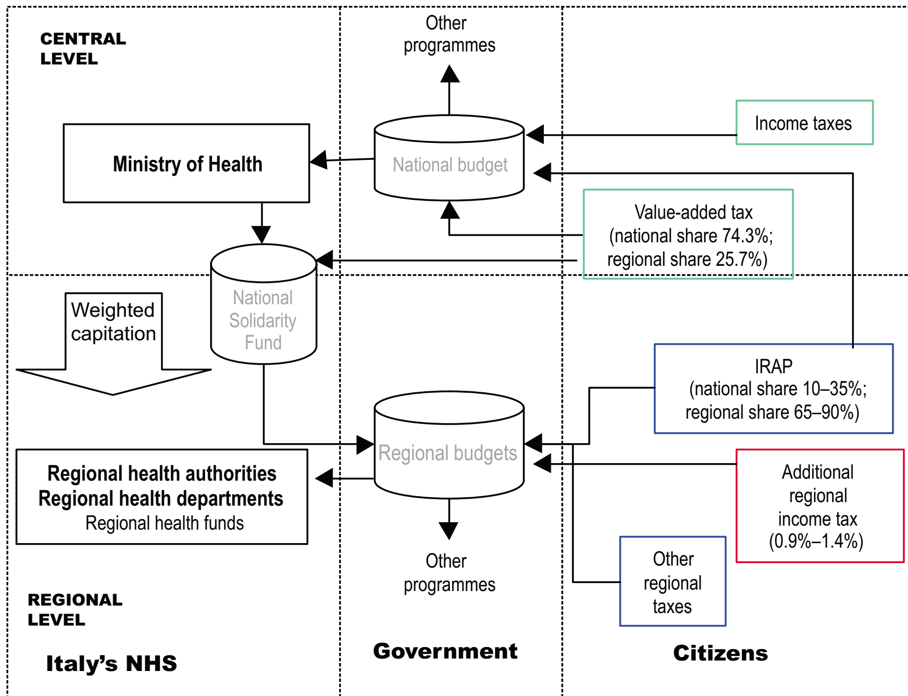



*Source:* Brenna & Veronesi *(13).*

regional funding. Following the reforms passed in February 2000, the Fund will be financed by indirect value-added taxes (VAT) and allocated to the regions initially based on historical expenditure and later according to weighted capitation targets aimed at guaranteeing interregional equity in access to public health care services. Given the considerably narrower tax bases of southern regions, the Fund will give the central government a substantial degree of control over the less well-off regions.

Fig. 6 shows the new flows of financing of the NHS from 2001 onwards, after the National Health Fund is abolished and the changes mentioned above are implemented (see the section on *Health care reforms*).

**Fig. 6. Fiscal flows in the health care system from 2001**




The fiscal federalism reforms undoubtedly represent progress in financing health care. They do have possible drawbacks, however.

The main negative features are as follows. As the tax base is unevenly distributed across the country, large equalization transfers will be needed, which might reduce the effective political autonomy of different regions unevenly. In

addition, poorer regions will have less room for manoeuvre to increase health care expenditure: in fact, recent International Monetary Fund *(5)* calculations estimated that high-income regions (Lombardy) can increase their revenue by up to 23.5% versus only 8% for low-income regions. An even more serious drawback is that, to obtain an equivalent cash increase, low-income regions will have to raise tax rates more than high-income regions, which will introduce negative incentives for business location and might therefore hinder economic development prospects in the more disadvantaged regions. Moreover, higher reliance on indirect taxes will make overall health financing more regressive.

On the positive side, IRAP is neutral with respect to factor mix and financing structure and therefore unbiased against employment. Further, the tax base, even if unevenly distributed across regions, has widened, as all businesses pay taxes, which were previously restricted to income earners.

The International Monetary Fund *(5)* report emphasizes that horizontal equalization efforts might be quite relevant in the regions in which the economy will not grow as rapidly as needed to raise enough resources, but it also highlights some of the most appealing features. In particular, the funds available for equalization are linked to the VAT, a rather elastic tax. Second, interregional inequality is limited through a very high solidarity coefficient (90%) set by the central government. Third, fiscal need and economies of scale in producing non-health care services are taken into account. Finally, fiscal effort is promoted at the regional level by taking into account potential rather than actual tax revenue. Hence, less-efficient regions will receive a VAT quota inferior to that they would have received had they put more effort into raising tax revenue.

## Financing capital investment

From 1980 to 1993, the Ministry of Health allocated a percentage of the National Health Fund for 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. From 1993, capital projects defined as being outside the National Health Fund have been subsidized by an investment programme approved by Law 67/1988 comprising about €15 500 million. By the mid-1990s, only some 10% of these funds had been spent. This indicates persistent underfunding of capital development. New legislation is pushing the investment programme to spend the available funds more quickly and equitably.

In the last few years, a few local health authorities and hospital trusts have developed some pilot experiences of a public-private mix in project financing. However, unclear legislation and uncertainty about the role that private firms

can play in managing public health care organizations is limiting the development of these experiences.

## Health care benefits and rationing

As in most industrialized countries, the definition of the benefit package has always been much debated within Italy's health care system. This has effectively meant that no explicit list of services has ever been published. Trying to establish what types of treatment the NHS should finance and the ones for which citizens should pay 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 local health units, it did not define the benefits to be included and excluded in detail, leaving such responsibility to the National Health Plan, a 3-year document that was intended to lay out the main guidelines for health care services in Italy and provide recommendations for achieving specific health targets.

Despite the efforts of successive governments, the first National Health Plan was approved in 1994, 16 years after the NHS was established. Once again, the National Health Plan did not specify the benefits to be provided by the local health units but simply defined six categories of intervention, ranging from hospital care to prevention and from specialist care to primary care.

A step forward was made with the approval of the second National Health Plan for 1998–2000. The Plan stressed the need for explicitly defining the content of a homogeneous benefit package that should be met by all regions and of the rationing mechanisms in play. In addition, it laid out the general guidelines as well as the initial steps required to define the benefit package. In the same vein, a clear commitment has been made to reduce waiting times, which were frequently used as an implicit rationing tool. The section on *Health*

*care reforms* provides more details on the content and implementation of the National Health Plan.

Despite these improvements, little progress has been made in developing a list of benefits to be provided by the NHS to all residents. So far, a positive list has only been developed in two areas:

- outpatient services, for which a list of the diagnostic procedures and specialist visits to be delivered by the NHS, together with the rates, was drawn up in 1996; and
- pharmaceuticals (see the section on *Health care delivery system*).

## Complementary sources of financing

### Out-of-pocket payments

Italy 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 for the purchase of private health care services and over-the-counter drugs. Mapelli *(14)* estimated that, in 1995, these two sources represented 27.2% of total health care expenditure and 91% of all private health care expenditure. The remaining 9% of private financing comprised mutual fund contributions and private insurance premiums. Co-payments to the public sector were estimated to be about 3% of total expenditure in the late 1990s.

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 (see the section on *Health care delivery system*).

Until 1993, users paid a proportion (from 15% in 1982 to 50% in 1991) of the total cost of each session of outpatient care provided up to a ceiling fixed by law. Since 1993, users have paid for the total cost but always up to a ceiling determined by law. The ceiling has been changed several times: rising from €21 in 1982 to €52 in 1993 and declining to the current €36. 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 general practitioner services, although restricted to higher-income groups; and in 1994 for hospital emergency services), but these had to be abandoned because of popular protest.

People with chronic or rare diseases, disabled people and pregnant women enjoy specific types of exemption. Other criteria for exemption, mainly based on income, were established in 1981 and have been modified several times since then. During 1993, a new legislative measure was in place for several months, which established a deductible of €52 for higher incomes, increased co-payments for the rest of the population and restricted the quantity of free drug prescriptions for elderly people. 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.

As an incentive to private-sector utilization, and to help families bear the burden of the co-payments, fiscal benefits to out-of-pocket payments were reformed in the early 1990s. Co-payments for pharmaceuticals and outpatient care provided by the NHS and direct payments for private health care receive tax benefits: this includes 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.

## Voluntary health insurance[2]

There are two types of demand for private health insurance: corporate, where companies cover their employees and sometimes also their families; and non-corporate, with individuals buying insurance for themselves or for their family. Both for-profit and not-for-profit organizations provide health insurance policies, either collective or individual.

In 1995, private expenditure represented 30% of total health care expenditure in Italy. Out-of-pocket expenditure represented 91% of the latter, while the remaining 9% came from premiums paid to private health insurance funds.

There are two types of demand for private health insurance: corporate, in which companies cover their employees and sometimes also their families; and non-corporate, with individuals buying insurance for themselves or for their family. Health insurance policies, either collective or individual, are supplied by both for-profit and not-for-profit organizations.

[2] This section was written by Margherita Giannoni-Mazzi.

Health insurance companies are 60% for-profit and 40% not-for-profit organizations. In 1999, almost 30% of families were covered by private health insurance: 16% by corporate insurance, 13% by non-corporate insurance and 1% by both. The demand for health insurance varies greatly geographically, with 32% of insured families living in the northeast and 31% living in large urban centres.

The private for-profit insurance market has grown rapidly since the early 1980s. The total premiums for health insurance as a proportion of those for the whole accident sector from Italian companies increased from 1.5% in 1982 to 4.5% in 1998. In 1998, the 125 for-profit insurance companies in Italy collected about €1140 million in premiums (Table 8). Because of the high ratio between reimbursements and collected premiums (79.1% in 1998), this sector has been in deficit since the early 1980s. The Italian Insurance Companies' Association (ANIA) estimated for 1998 a deficit of about €61 000 million.

**Table 8. Revenue of private for-profit health insurance companies in millions of euros, 1982–1998**

| Year | Premiums (millions of euros) | Annual increase (%) |
|---|---|---|
| 1982 | 71 | – |
| 1983 | 95 | 34.3 |
| 1984 | 123 | 29.3 |
| 1985 | 151 | 23.1 |
| 1986 | 187 | 23.5 |
| 1987 | 239 | 27.6 |
| 1988 | 301 | 26.2 |
| 1989 | 378 | 25.6 |
| 1990 | 468 | 23.9 |
| 1991 | 571 | 21.9 |
| 1992 | 624 | 9.3 |
| 1993 | 737 | 18.0 |
| 1994 | 829 | 12.4 |
| 1995 | 893 | 7.7 |
| 1996 | 952 | 6.7 |
| 1997 | 1 029 | 8.1 |
| 1998 | 1 137 | 10.5 |

*Source:* ANIA (Italian Insurance Companies' Association) annual reports.
The values in lire have been converted to euros at the current fixed exchange rate of Lit 1936 = €1.

No official statistics are available on the market for not-for-profit health insurance. Estimates range between 1.8 million and 2.5 million people insured by three types of organizations. The first are voluntary mutual insurance funds, which cover about 300 000 people. The rest are corporate and collective funds organized by employers or professional categories for their employees or members.

In contrast to other EU countries, such as Germany and the Netherlands, the private insurance sector is scarcely integrated with the public sector. As a consequence of this, private health insurance companies mainly provide services that substitute for rather than complement those supplied by the NHS.

Estimates from a 1999 national survey show that 60% of individual health insurance policies provided full coverage of expenditure; only 17% complemented the NHS services, and the rest were for special type of policies, such as long-term care.

The most requested private health services within the for-profit health insurance market in 1997 were diagnostic and outpatient visits. However, they only covered 8.5% of the total amount reimbursed by companies. Inpatient care with surgery represented 20.6% of total demand but accounted for 70% of total reimbursement. Inpatient care without surgery represented 11.1% of the total demand for services and 17.4% of total reimbursement. Day hospital services and interventions represented 6.5% of the total services and 3.9% of total reimbursement. Aesthetic surgery, mental health care, addiction disorders, alcoholism and AIDS are usually not covered.

In 1998, an estimated 60% of expenditure on health incurred by the not-for-profit health insurance organizations was for substitutive services, and the remaining can be considered complementary expenditure in the context of the 1999 NHS reform. The most important expenditure shares are represented by inpatient care (40%), diagnostics (15%), dental care (24%), outpatient consultations (14%), ophthalmic care (4%), drugs (0.88%), treatment of handicaps (0.13%) and aesthetic surgery (1.52%).

Private insurance is not directly tax deductible. From a fiscal viewpoint, however, the two main types of insurance differ.

- Individual health insurance is not tax deductible and does not qualify for a tax credit. Nevertheless, the cost of privately provided treatments generates a tax credit, even if this is reimbursed by insurance.
- Corporate health insurance premiums paid by the employers do not constitute part of the income of the employee; in contrast to individual health insurance, however, enrolled employees do not get a tax credit for the cost of treatment.

The need for controlling, at least in part, the growth of private health care expenditure shaped the 1999 reform of private health insurance funds. The reform aimed at expanding the market for supplementary health insurance funds, to cover co-payments and private payments for treatment provided by the NHS or by private providers under contract with the public system. In particular, the main objective is to promote the operation of private practice within public health facilities, thereby attracting private resources to the public sector. Fiscal benefits were established to promote the market for NHS supplementary funds.

This regulation has not been completed yet, since many regulatory aspects of the functioning of these new funds still need to be defined (see the section on *Health care reforms*).

## Health care expenditure

In Italy, as in most OECD countries, health care expenditure has steadily increased over time, therefore 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 has added importance to controlling health care expenditure.

In 1999, total health care expenditure (public and private) was about €85 000 million, with public expenditure of about €58 000 million (67% of the total) and private expenditure €27 000 million (33%). In 1960, health care expenditure was 82% public and 18% private. Expenditure as a proportion of GDP increased steadily until 1993: from 3.9% in 1960 to 6.6% in 1978 – when the NHS was established – to 8.1% in 1990, peaking in 1993 (8.6%), declining to 8.0% in 1995 and then stabilizing at 8.4% from 1997 to 1999 (Table 9).

A marked increase in pharmaceutical sales, the renewal of salary negotiations between physicians and the government, the shift in hospital financing to a diagnosis-related group system rewarding activity and citizens' free choice of health care provider have caused the increase in health care expenditure since 1995.

**Table 9. Trends in health care expenditure, 1980–1999, selected years**

| | 1980 | 1985 | 1990 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|
| Health care expenditure (thousand of millions of 1995 euros) | 43.7 | 48.4 | 67.3 | 72.9 | 74.6 | 79.9 | 84.0 | 85.5 |
| Health care expenditure as a % of GDP | 7.0 | 7.1 | 8.1 | 8.0 | 8.1 | 8.4 | 8.4 | 8.4 |
| Public expenditure as a % of total | 80.5 | 77.2 | 78.1 | 67.7 | 67.8 | 68.0 | 68.0 | 67.0 |

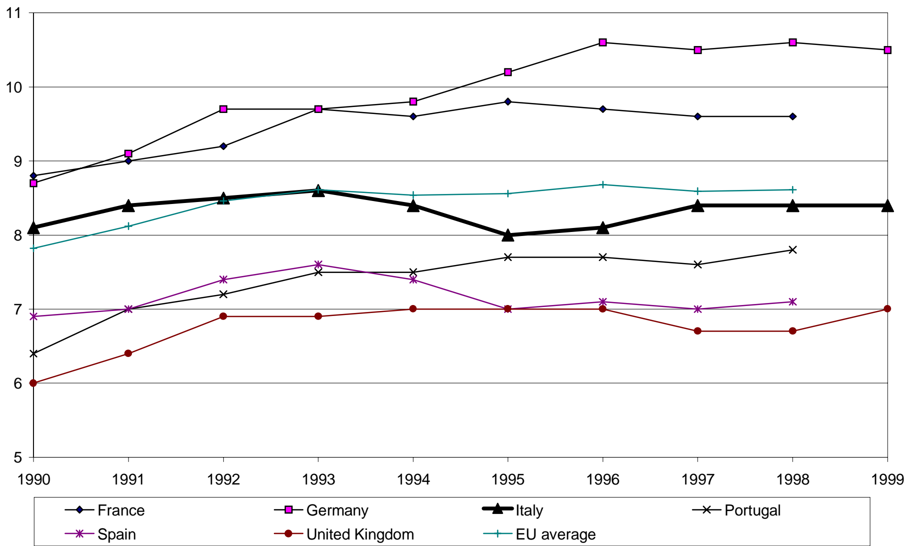
*Source:* OECD *(4).*
The values in lire have been converted to euros at the current fixed exchange rate of Lit 1936 = €1.

Among existing cost-control interventions, the reform of the pharmaceutical market has probably been the most effective, with expenditure on pharmaceuticals halved from 1992 to 1996. In addition, expenditure on staff increased relatively slowly during the early 1990s. The type of measures adopted were

temporary, however, which only delayed the problem. Indeed, wages have been controlled more or less successfully in other parts of the public sector, but similar attempts in health care have been unsuccessful. Expenditure for salaries and wages increased from 39% of overall health care expenditure in 1989 to 48% in 1998. Current non-labour expenditure (goods and services) and expenditure on private contracted-out hospitals have also increased since the mid-1980s.

Fig. 7 shows trends in health care expenditure as a percentage of GDP in selected western European countries during the 1990s. All the other countries increased or stabilized health care expenditure from 1990 to 1999. Italy increased slightly until 1993, declined to 8.0% in 1995 and stabilized at 8.4% from 1997 to 1999.

**Fig. 7. Health care expenditure as a percentage of GDP in Italy, selected western European countries and the EU, 1990–1999**




*Source:* WHO Regional Office for Europe health for all database.

Fig. 8 and Fig. 9 show Italy's position in health care expenditure within the WHO European Region. In purchasing power parity in US dollars, Italy was very close to the EU average. Italy was slightly below the EU average as a percentage of GDP in 1999.

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 to GDP from its 1960 level of 0.6% to 2.7% in 1997. Similarly, the private expenditure was 32% of total expenditure in 1999, one of the highest percentages in Europe.

Although Italy has one of the lowest public shares of total health care expenditure among the EU countries (Fig. 10), the volume of public health care expenditure remains an important issue for the government, both at the national and at the regional level, mainly because of the existence of a large public deficit.

## 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 10 shows the evolution of per capita regional health care expenditure since 1980.

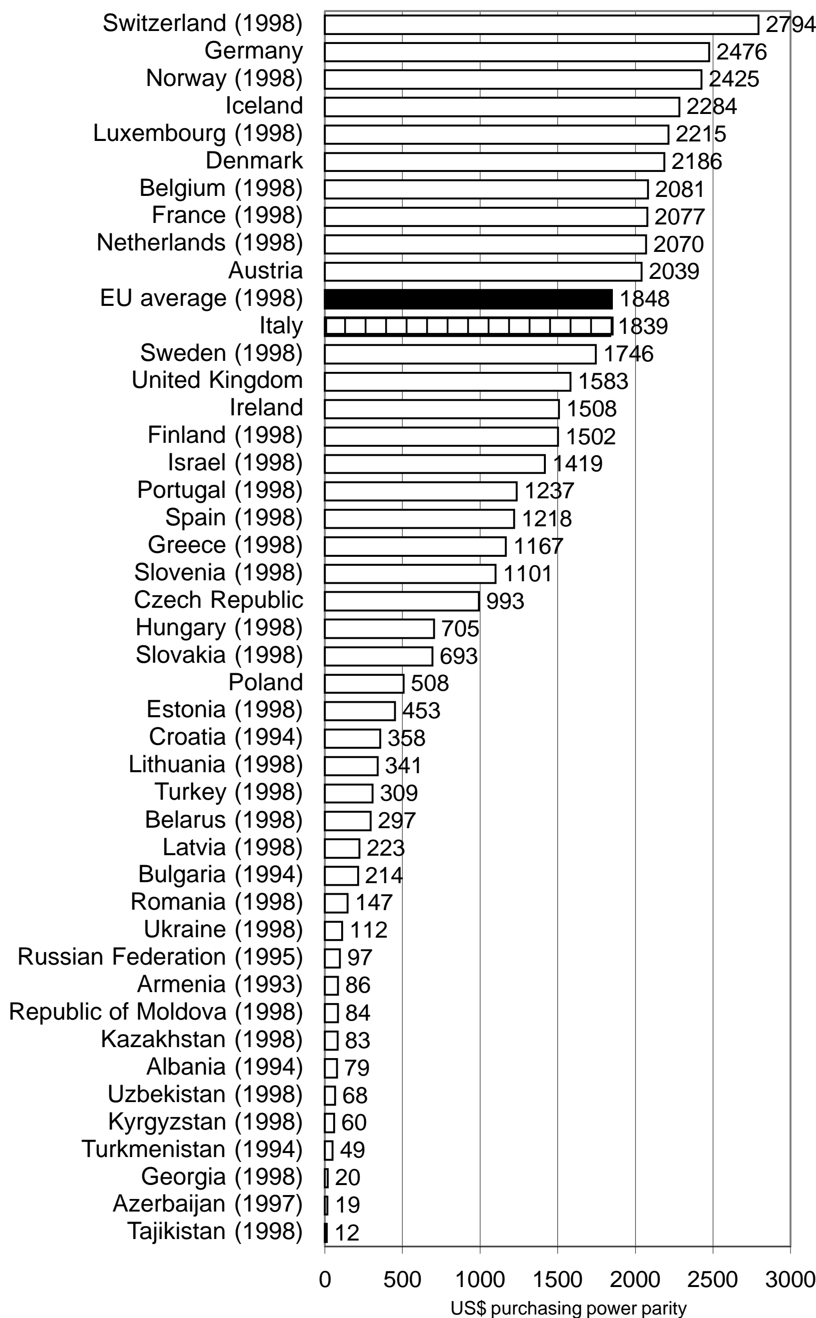
From 1981 to 1992, before the start of the second reform process, real per capita health care expenditure increased by 75%, but coverage was extended to an additional 7% of the population as a result of universalism. Regional growth varied substantially, ranging from 47% in Friuli-Venezia Giulia to 120% in Valle d'Aosta and Liguria.

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, recent econometric analyses on the effects of the 1992 reforms have shown that regional inequality persisted. Some regions successfully contained costs but not others.

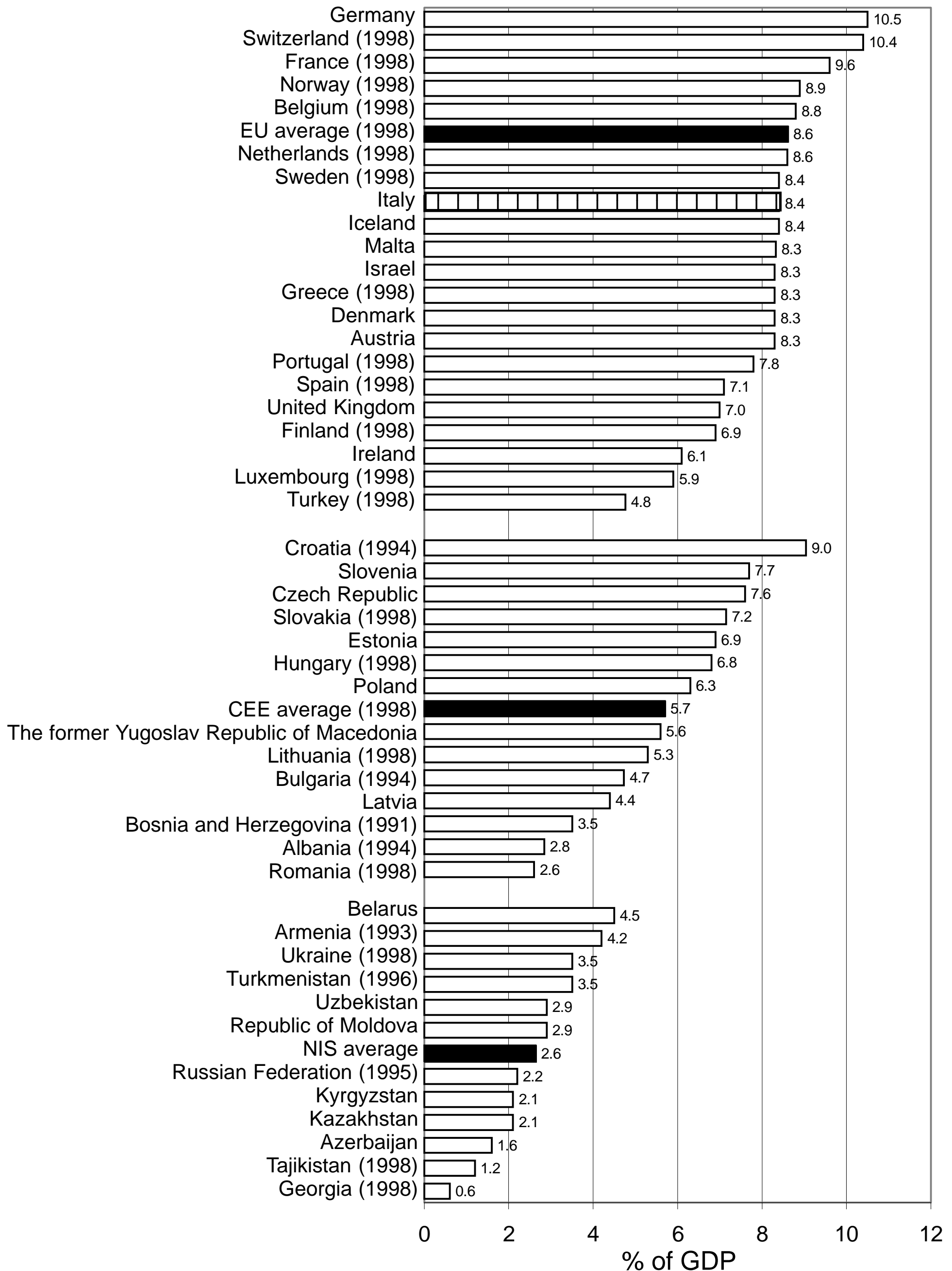
Fig. 11 shows the differences in regional per capita health care spending from the national capitation target in 1998. Against a national capitation rate of €1020, deviations in regional spending ranged from +35% for the Autonomous Province of Bolzano to –13% for the region of Campania. Available research 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.

**Fig. 8. Health care expenditure in US$ purchasing power parity per capita in the WHO European Region, 1999 or latest available year (in parentheses)**



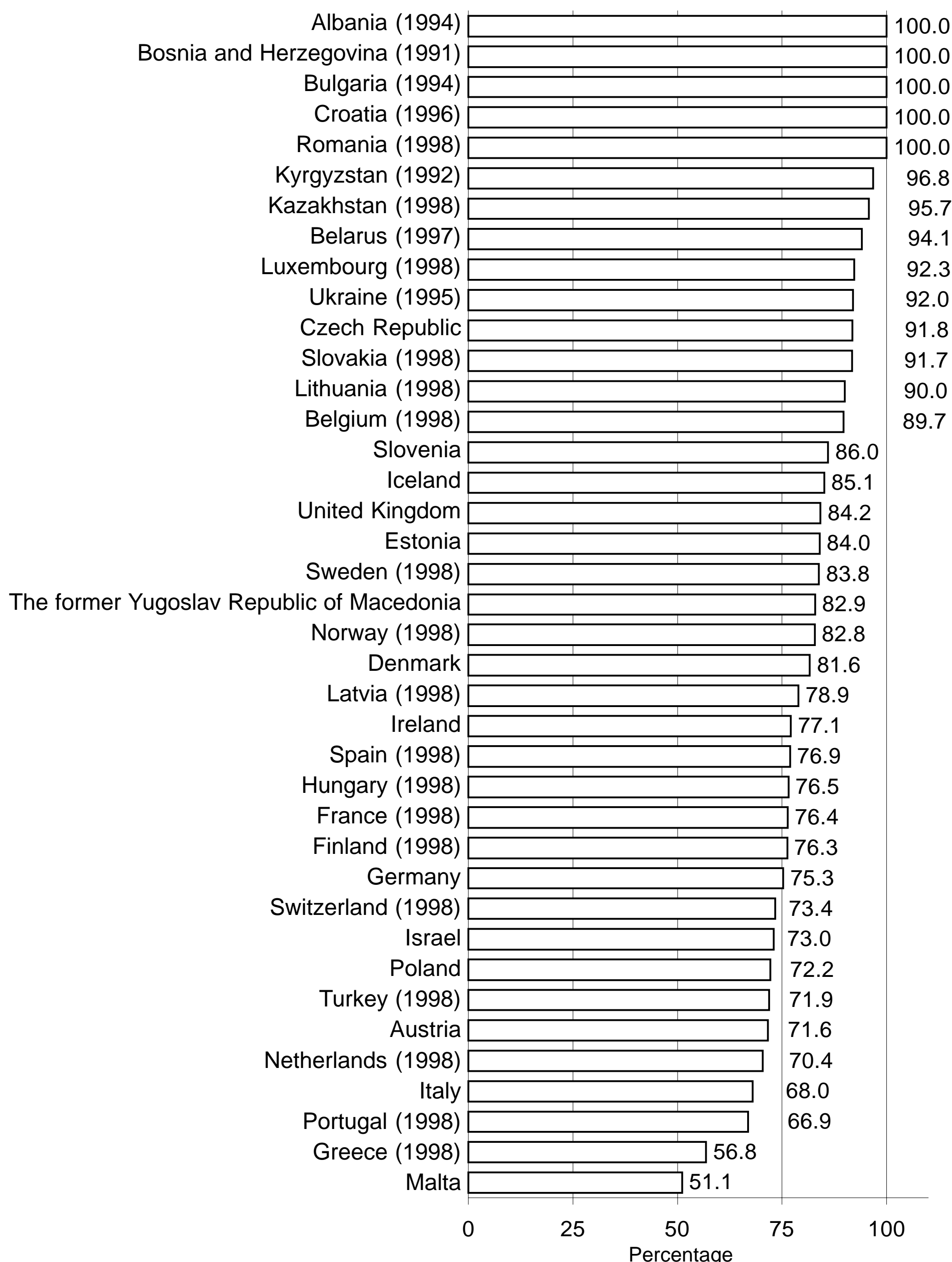

*Source:* WHO Regional Office for Europe health for all database.

**Fig. 9. Health care expenditure as a percentage of GDP in countries in the WHO European Region, 1999 or latest available year (in parentheses)**




*Source:* WHO Regional Office for Europe health for all database.
CEE: central and eastern Europe. NIS: newly independent states of the former USSR.

**Fig. 10. Health care expenditure from public sources as a percentage of total health care expenditure in countries in the WHO European Region, 1999 or latest available year (in parentheses)**




*Source:* WHO Regional Office for Europe health for all database.

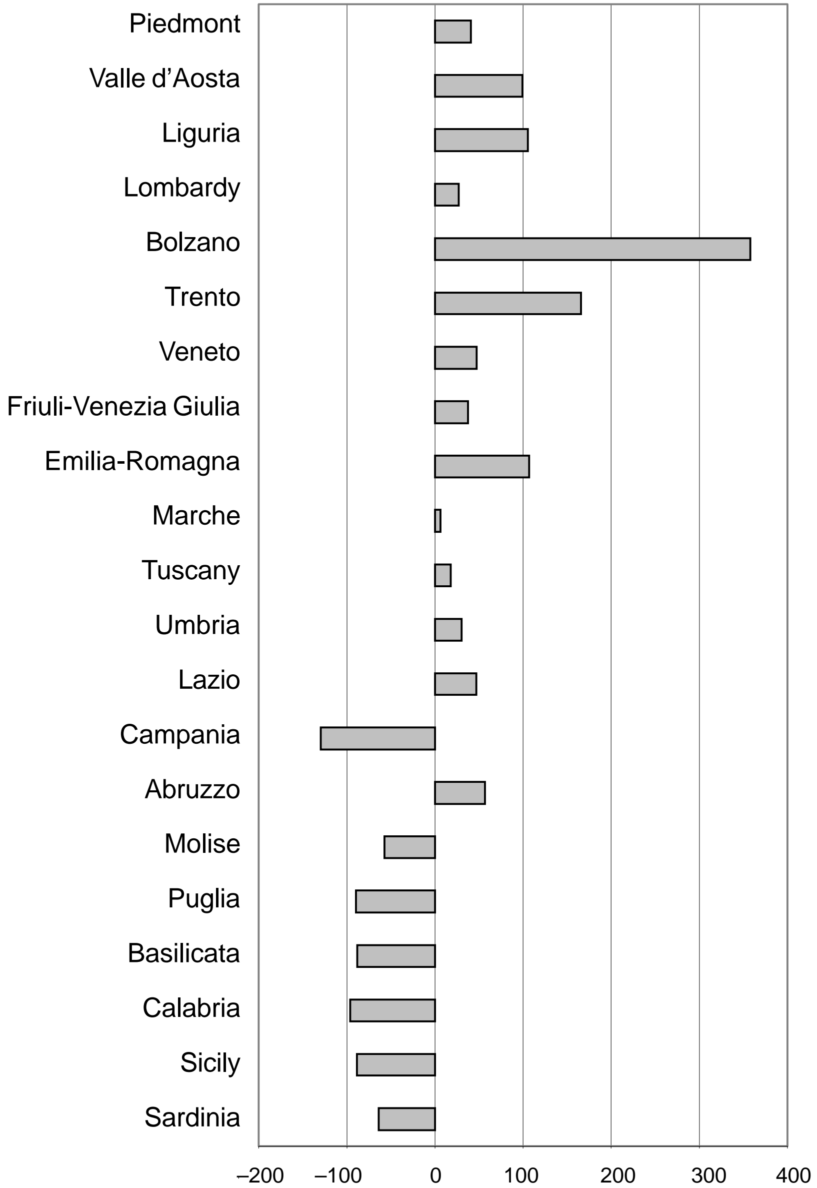
**Table 10. Per capita public health care expenditure in Italy's regions in constant 1998 euros**

| Region | 1981 | 1997 | Percentage change 1981–1992 | 1992–1997 |
|---|---|---|---|---|
| **North** | | | | |
| Valle d'Aosta | 511 | 1064 | 120.0% | –5.5% |
| Piedmont | 525 | 944 | 92.3% | –6.4% |
| Lombardy | 570 | 988 | 81.3% | –4.4% |
| Trento | 746 | 1109 | 51.8% | –2.1% |
| Bolzano | 590 | 1216 | 86.4% | 10.6% |
| Veneto | 658 | 1002 | 64.2% | –7.3% |
| Friuli-Venezia Giulia | 766 | 1022 | 47.5% | –9.6% |
| Liguria | 712 | 1104 | 72.1% | –9.9% |
| Emilia-Romagna | 672 | 1118 | 92.6% | –13.6% |
| **Centre** | | | | |
| Tuscany | 666 | 1051 | 70.5% | –7.4% |
| Umbria | 620 | 1034 | 81.6% | –8.2% |
| Marche | 653 | 1017 | 81.0% | –14.0% |
| Lazio | 711 | 1022 | 57.1% | –8.5% |
| Abruzzo | 608 | 948 | 63.7% | –4.7% |
| **South** | | | | |
| Molise | 472 | 933 | 109.7% | –5.8% |
| Campania | 575 | 866 | 72.9% | –12.9% |
| Puglia | 577 | 886 | 71.6% | –10.6% |
| Basilicata | 495 | 886 | 81.2% | –1.3% |
| Calabria | 540 | 877 | 65.0% | –1.6% |
| Sicily | 531 | 871 | 87.1% | –12.4% |
| Sardinia | 552 | 929 | 92.5% | –12.6% |
| **Italy** | 607 | 972 | 75.2% | –8.7% |

*Source:* adapted from Commissione Tecnica per la Spesa Pubblica *(15).*

The values in lire have been converted to euros at the current fixed exchange rate of Lit 1936 = €1.

**Fig. 11. Deviation of public per capita health care expenditure in Italy's regions from the capitation target, euros, 1998**




*Source:* Anessi & Cantù *(16).*

# Health care delivery system

## Primary health care and public health services

### Primary care facilities

Primary care is provided by general practitioners, 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) on their list. Although primary care physicians are given financial incentives to share clinic premises with their colleagues, they usually work in single practices.

Primary care physicians are authorized to work in the NHS after successfully completing a 2-year specialization course in general medicine and acquiring clinical experience as temporary staff in NHS facilities.

General practitioners 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 certifications and visit patients at home if necessary. People may choose any physician they prefer, provided that the physician's list has not reached the maximum number of patients allowed (1800 for general practitioners and 1000 for paediatricians).

In 1998, each general practitioner averaged 1030 patients. The regional range of averages ranged from 871 to 1756 and decreased from north to south. Each paediatrician averaged 721 children, ranging from 642 in Calabria to 807 in Campania. In some regions, children were mostly on general practitioner lists instead of paediatrician lists, partly because of insufficient paediatricians

and partly because of old habits. From 1996 to 1998, the number of children on paediatrician lists increased, especially in northern regions.

The 1999 reform introduced significant changes in primary health care services by reinforcing group practice, introducing economic incentives for general practitioners and promoting integration between primary care physicians and district services such as social care, home care, health education and environmental health (see the section on *Health care reforms*).

## Public health services

The local health unit is primarily concerned with protecting and promoting public health and is responsible for achieving the health objectives and targets established by national and regional planning.

Each local health unit 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; and
- veterinary medicine (surveillance of animal stock health, hygiene of food production and animal food safety and control).

Moreover, 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 flow was established from general practitioners through local health units to regional and national authorities to conduct epidemiological surveillance of communicable diseases. When the information flows were put into place, diseases were divided into five groups according to severity, epidemiological burden, treatment availability and relevance, with a faster path 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 reports that do not reflect the actual burden of disease in the population.

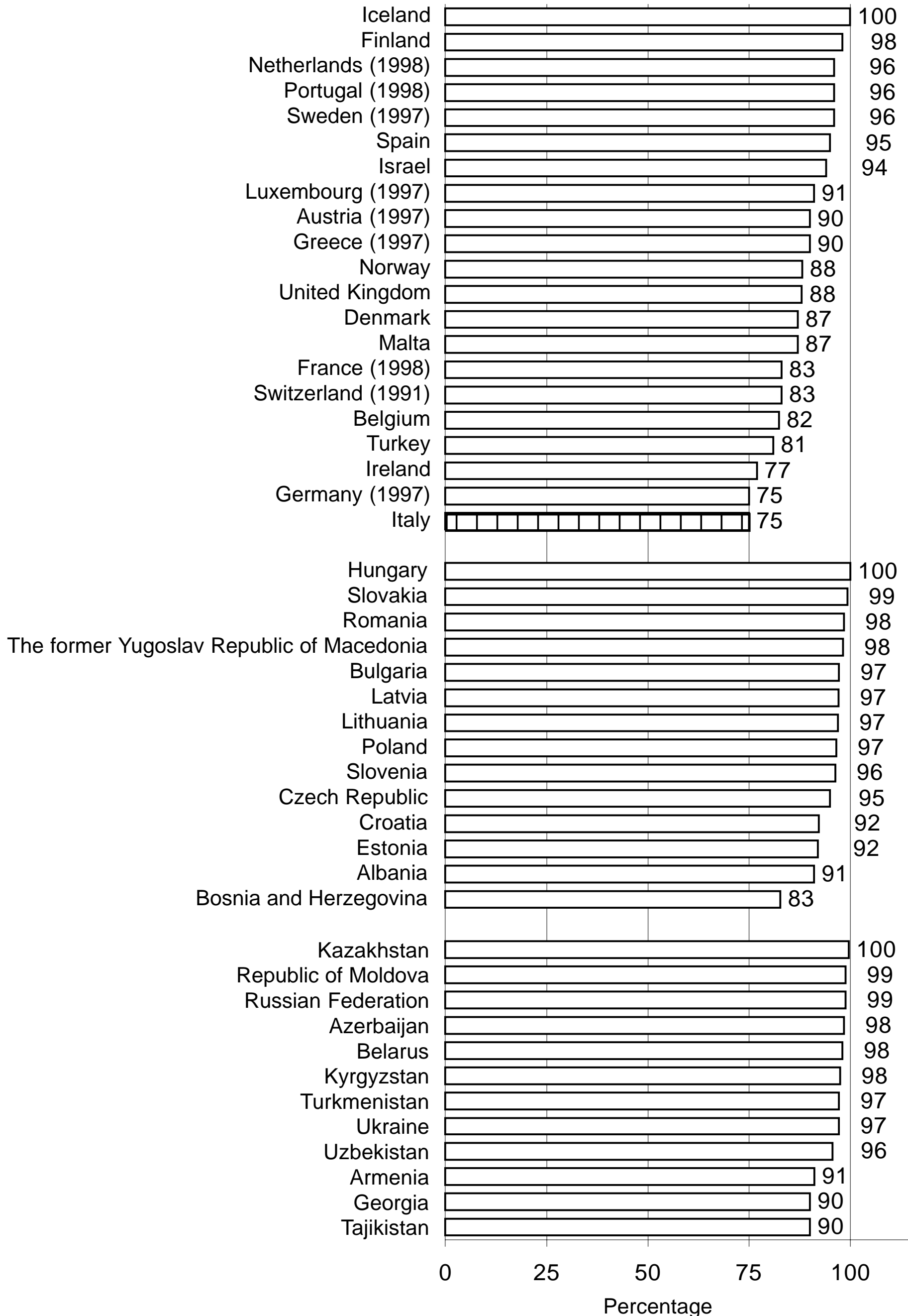
The compulsory vaccination programme includes all children under 24 months, protecting them against diphtheria, poliomyelitis, tetanus and hepatitis B. Other recommended childhood vaccinations are those aimed at protecting children from whooping cough, measles and rubella. The regional distribution of 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. Fig. 12 provides some comparative data on levels of immunization for measles in the WHO European Region. Italy's level (75%) is far below the average value of western European countries, indicating that the immunization coverage rate is still not in line with national requirements.

For several categories of the labour force, immunization against specific professional hazards is compulsory. 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).

No national screening programme exists, as regions are responsible for disease prevention activities. Differences in government performance and available resources across regions brought about considerable inequality in the access to preventive interventions during the 1990s, one cause of the considerable regional differentials in morbidity and mortality from preventable conditions. For instance, in the late 1980s, mortality rates differed four-fold for rheumatic cardiopathy, partly because people with rheumatic fever were managed poorly. Northern regions had rates of Pap testing twice those of southern regions. In the early 1990s, northern hospitals had twice as many mammography units as did southern hospitals, which resulted in sizeable interregional differences in the rate of women who had undergone mammography at least once. 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, and one prevention programme in Friuli-Venezia Giulia screens for cervical cancer among women.

In 1996, the National Commission on Oncology was established to elaborate 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 of enhancing evidence-based programme planning. The National Health Plan for 1998–2000 highlights the importance of prevention to achieve the expected targets in reducing mortality and refers to the work of the National Commission on Oncology as a landmark. Nevertheless, less than 10% of women are involved in cervical and breast screening programmes that follow the

**Fig. 12. Percentage of children immunized against measles in countries in the WHO European Region, 1999 or latest available year (in parentheses)**




*Source:* WHO Regional Office for Europe health for all database.

National Commission on Oncology guidelines. Nevertheless, about 3.5 to 4.0 million Pap tests are performed each year, meaning that one in four fertile women undergo such a diagnostic procedure each year, even if they are not included in a screening programme. Pap testing, mammography and colonoscopy was to be provided free of charge to people in selected age groups beginning in 2001 (see the section on *Health care reforms*).

Health promotion is principally carried out through disease prevention (especially immunization). Health education is pursued mainly through television campaigns and school education programmes managed jointly by teachers and health care professionals working for the local health units. No information is routinely collected about the dissemination and efficacy of these interventions.

## Secondary and tertiary care

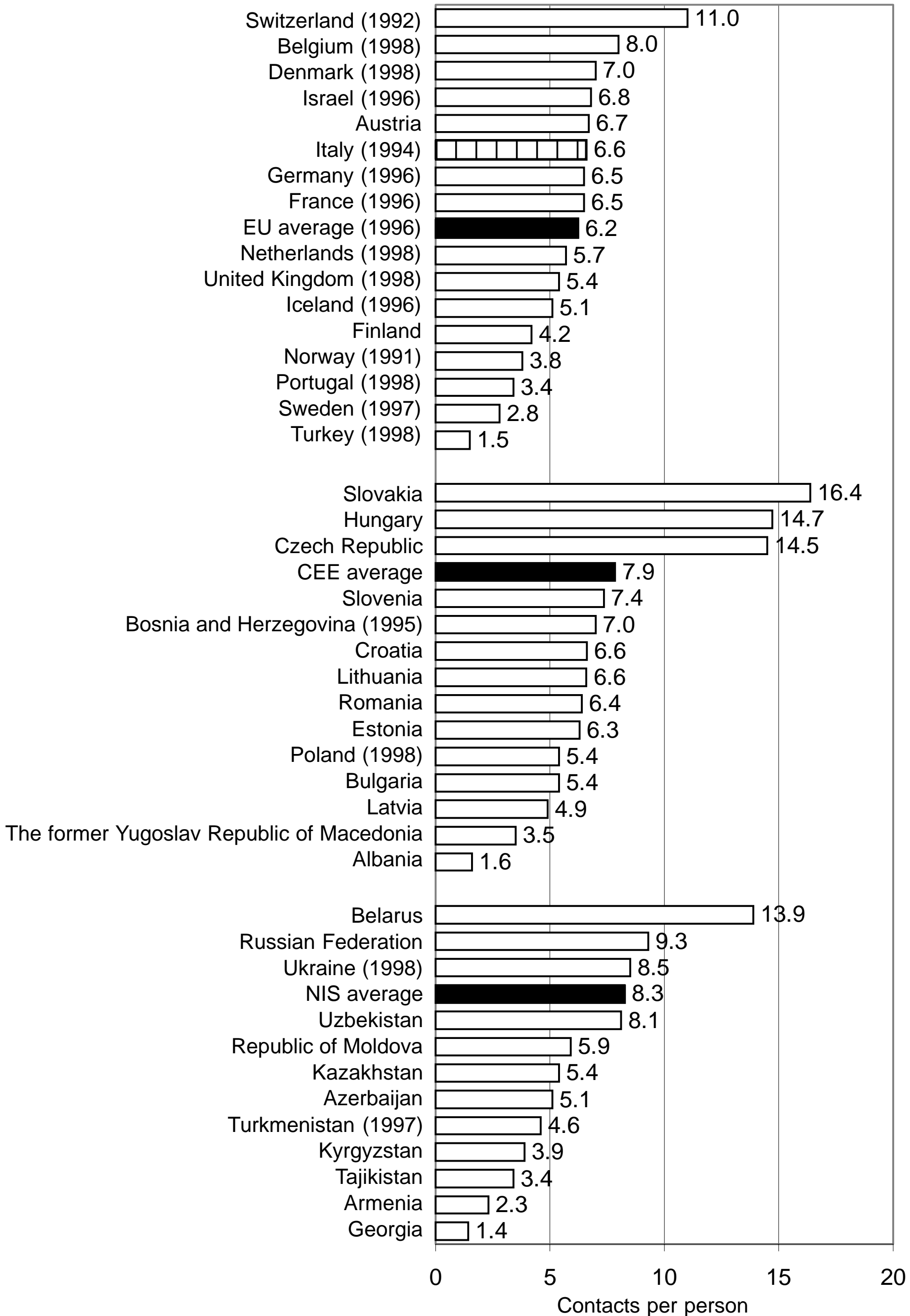
### Ambulatory care

Specialized ambulatory services, including visits and diagnostic and curative activities, are provided either by local health units or by accredited public and private facilities with which local health units have agreements and contracts. People are allowed to access specialist care only after approval by their general practitioner, who is responsible for the referral. Once the general practitioner has authorized the visit or the procedure, people are free to choose their provider among those accredited by the NHS. A 100% co-payment with a maximum of €52 is required as an additional source of financing and in an attempt to moderate the use of specialist ambulatory care (see the section on *Health care financing and expenditure*). Tests for monitoring chronic conditions and treatment requested by people with low income are provided free of charge.

Because waiting lists are long, co-payments high and the quality of services often unsatisfactory, especially in central and southern regions, many people seek care outside the NHS, especially if they have health insurance that covers the related costs. The utilization of private services differs greatly by region. In 1999, private providers performed 19.7% of the specialist diagnostic procedures: 23.9% in central regions versus 16.5% in northwestern Italy.

Fig. 13 provides comparative data on the number of outpatient contacts per person per year in the WHO European Region. Italy had 6.6 contacts per person in 1994, slightly higher than the EU average of 6.2.

**Fig. 13. Outpatient contacts per person in countries in the WHO European Region, 1999 or latest available year (in parentheses)**




*Source:* WHO Regional Office for Europe health for all database.
CEE: central and eastern Europe. NIS: newly independent states of the former USSR.

## Hospital care

The 1978 reform 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 reform (Legislative Decrees 502/1992 and 517/1993) aiming to promote efficiency by introducing a limited form of competition between hospital care providers. Accordingly, starting in 1994, local health units and to major hospitals (highly specialized hospitals with national relevance) were given financial and technical autonomy. The major hospitals were given the status of independent trusts. The rest of the public hospitals were kept under the direct management of local health units. In addition, patients were given the choice of opting for private, contracted-out hospitals required to be accredited by the government.

### Hospital and bed numbers

Currently, hospital care is delivered mainly by public structures (842 hospitals, corresponding to 61% of the total), which provide both outpatient and inpatient services. Nevertheless, local health units also contract out services to 539 private hospitals (39% of the total), especially not-for-profit institutions. In 1998, Italy had 276 000 beds: 91% were dedicated to ordinary admissions, 8% to day hospital activities and 1% to private health care. Of about 250 000 beds for ordinary admissions in 1998, 81.5% were public (versus 83% in 1993) and 18.5% were private but accredited by the NHS.

Table 11 shows the trends in hospital utilization for 1985–1997. In particular, the number of beds per 1000 population decreased slightly, from 7.2 in 1990 to 5.9 in 1997, which is still higher than the 5.5 value strongly recommended by the law in force (of these, 4.5 are acute beds and 1.0 are long-term and rehabilitation beds). The admission rate increased from 15.5 to 18.3 per 100 population from 1990 to 1997 and the average length of stay decreased by 3.6 days. The occupancy rate for acute care increased from 69.3% in 1990 to 72.5% in 1997. The changes in bed utilization are an expected result of the recent initiatives to control health expenditure, foster hospital efficiency and reduce waste. Moreover, the prospective payment system for hospital treatment introduced in 1995 and fully implemented since 1998 might have increased the volume of services delivered and reduced the average length of stay.

Despite improvement during the 1990s, Italy still had lower hospital productivity than most other western European countries in 1998 (Table 12). There is still therefore considerable room for improvement in this field.

**Table 11. Utilization and performance of inpatient services, 1985–1997, selected years**

| | 1985 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 |
|---|---|---|---|---|---|---|---|---|---|
| Hospital beds per 1000 population | 8.5 | 7.2 | 6.8 | 6.8 | 6.7 | 6.6 | 6.3 | 6.6 | 5.9 |
| Inpatient admissions per 100 population | 17.0 | 15.5 | 14.9 | 15.5 | 15.9 | 15.9 | 16.2 | 18.4 | 18.3 |
| Average length of stay in days | 12.2 | 11.7 | 11.6 | 11.2 | 11.1 | 10.8 | 10.1 | 9.4 | 8.1 |
| Occupancy rate for acute care (%) | 67.9 | 69.3 | 67.4 | 69.3 | 70.8 | 71.3 | 70.7 | 71.4 | 72.5 |

*Source:* OECD *(4).*

Fig. 14 shows the number of hospital beds in acute-care hospitals per 1000 population in countries in the WHO European Region, and Fig. 15 compares Italy's rate from 1990 to 1998 with those in selected western European countries. Both figures clearly show how Italy's rate is comparable to 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 similar trends from 1990 to 1996, with a generalized reduction in beds.

Patients' free choice includes either receiving treatment from the structures within their local health unit or choosing a provider in another local health unit (within the same region or in another region). Thus, local health units have to pay for the treatment provided to their residents by providers located in other regions or local health units (outward mobility) and, in turn, they receive payments for the health care provided to patients coming from other regions (inward mobility).

The principle of free choice has applied since the 1978 reform when 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 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 (outward mobility 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.

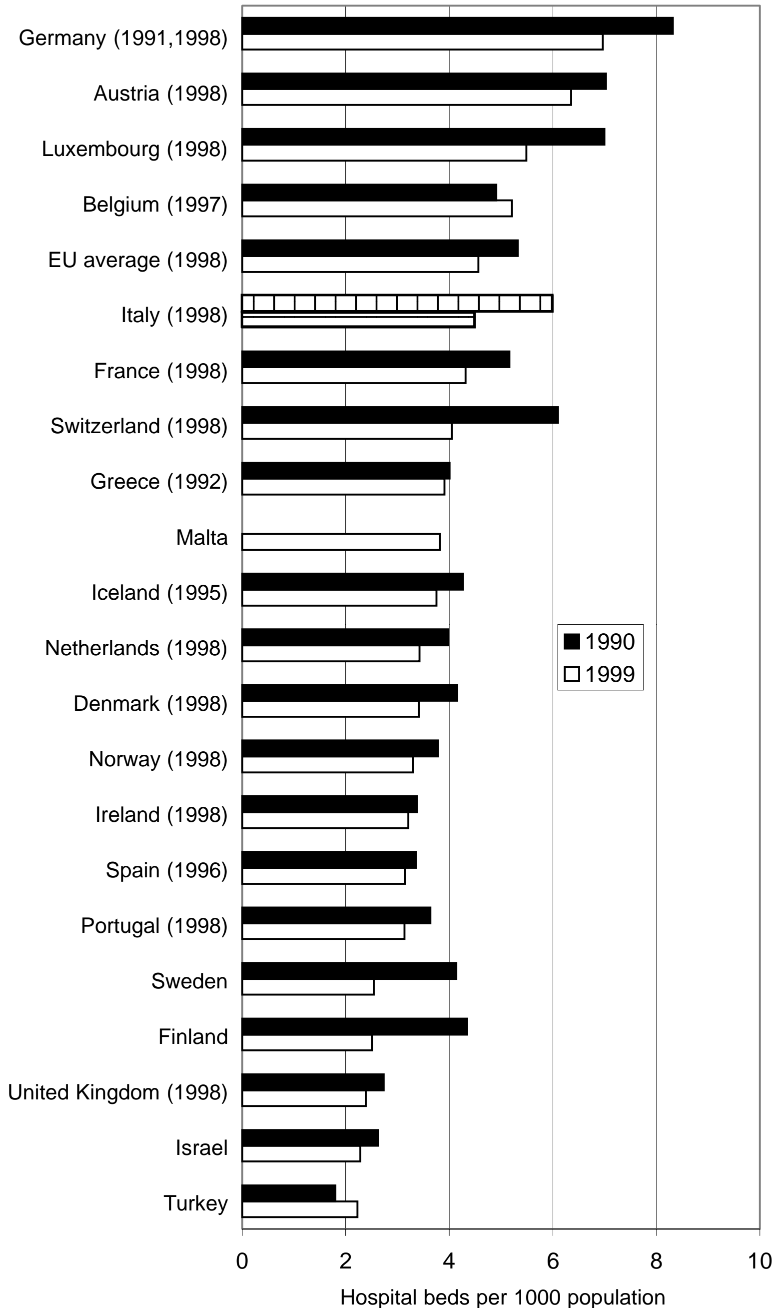
Fig. 16 reports the balance of inflow and outflow for inpatient stays for the year 1998. Northern regions attract more interregional patients than they lose

**Table 12. Inpatient utilization and performance of inpatient services in acute hospitals in countries in the WHO European Region, 1999 or latest available year**

| Country | Hospital beds per 1000 population | Admissions per 100 population | Average length of stay in days | Occupancy rate (%) |
|---|---|---|---|---|
| **Western Europe** | | | | |
| Austria | 6.4[a] | 25.8[a] | 6.8[a] | 75.4[a] |
| Belgium | 5.2[b] | 18.9[c] | 8.8[b] | 80.9[c] |
| Denmark | 3.4[a] | 18.7 | 5.7 | 78.3[a] |
| Finland | 2.5 | 19.7 | 4.5 | 74.0[d] |
| France | 4.3[a] | 20.3[d] | 5.6[a] | 75.7[a] |
| Germany | 7.0[a] | 19.6[b] | 11.0[a] | 76.6[b] |
| Greece | 3.9[g] | – | – | – |
| Iceland | 3.8[d] | 18.1[d] | 6.8[d] | – |
| Ireland | 3.2[a] | 14.6[a] | 6.8[a] | 84.3[a] |
| Israel | 2.3 | 17.9 | 4.3 | 94.0 |
| Italy | 4.5[a] | 17.2[a] | 7.1[a] | 74.1[a] |
| Luxembourg | 5.5[a] | 18.4[e] | 9.8[c] | 74.3[e] |
| Malta | 3.8 | – | 4.2 | 79.3 |
| Netherlands | 3.4[a] | 9.2[a] | 8.3[a] | 61.3[a] |
| Norway | 3.3[a] | 14.7[c] | 6.5[c] | 81.1[c] |
| Portugal | 3.1[a] | 11.9[a] | 7.3[a] | 75.5[a] |
| Spain | 3.2[c] | 11.2[c] | 8.0[c] | 77.3[c] |
| Sweden | 2.5 | 15.6[a] | 5.1[c] | 77.5[c] |
| Switzerland | 4.0[a] | 16.4[a] | 10.0[a] | 84.0[a] |
| Turkey | 2.2 | 7.3 | 5.4 | 57.8 |
| United Kingdom | 2.4[a] | 21.4[c] | 5.0[c] | 80.8[a] |
| **Central and eastern Europe** | | | | |
| Albania | 2.8[a] | – | – | – |
| Bosnia and Herzegovina | 3.3[a] | 7.2[a] | 9.8[a] | 62.8[d] |
| Bulgaria | 7.6[c] | 14.8[c] | 10.7[c] | 64.1[c] |
| Croatia | 3.9 | 13.2 | 9.4 | 87.2 |
| Czech Republic | 6.3 | 18.2 | 8.7 | 67.7 |
| Estonia | 5.6 | 18.4 | 8.0 | 69.3 |
| Hungary | 5.7 | 21.8 | 7.0 | 73.5 |
| Latvia | 6.3 | 20.0 | – | – |
| Lithuania | 6.4 | 20.6 | 9.1 | 78.8 |
| Slovakia | 7.0 | 18.4 | 9.6 | 69.8 |
| Slovenia | 4.6 | 16.0 | 7.6 | 73.2 |
| The former Yugoslav Republic of Macedonia | 3.4 | 8.8 | 8.8 | 63.0 |
| **Newly independent states** | | | | |
| Armenia | 5.5 | 5.6 | 10.4 | 29.8 |
| Azerbaijan | 7.5 | 4.7 | 14.9 | 30.0 |
| Belarus | – | – | – | 88.7[e] |
| Georgia | 4.6 | 4.7 | 8.3 | 83.0 |
| Kazakhstan | 5.8 | 14.0 | 12.3 | 92.6 |
| Kyrgyzstan | 6.1 | 15.5 | 12.8 | 92.1 |
| Republic of Moldova | 6.8 | 14.4 | 14.0 | 71.0 |
| Russian Federation | 9.0 | 20.0 | 13.7 | 84.1 |
| Tajikistan | 6.1 | 9.4 | 13.0 | 64.2 |
| Turkmenistan | 6.0[b] | 12.4[b] | 11.1[b] | 72.1[b] |
| Ukraine | 7.6[a] | 18.3[a] | 13.4[a] | 88.1[a] |

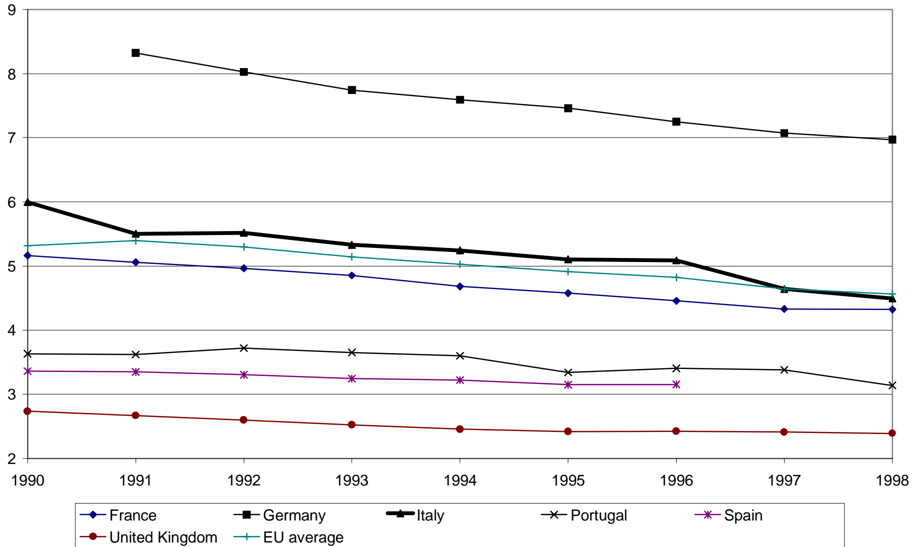
*Source:* WHO Regional Office for Europe health for all database.
Note: [a] 1998, [b] 1997, [c] 1996, [d] 1995, [e] 1994, [f] 1993, [g] 1992.

**Fig. 14. Hospital beds in acute-care hospitals per 1000 population in countries in western Europe, 1990 and 1999 or latest available year (in parentheses)**




*Source:* WHO Regional Office for Europe health for all database.

**Fig. 15. Hospital beds in acute-care hospitals per 1000 population in Italy and selected western European countries and the EU, 1990–1998**

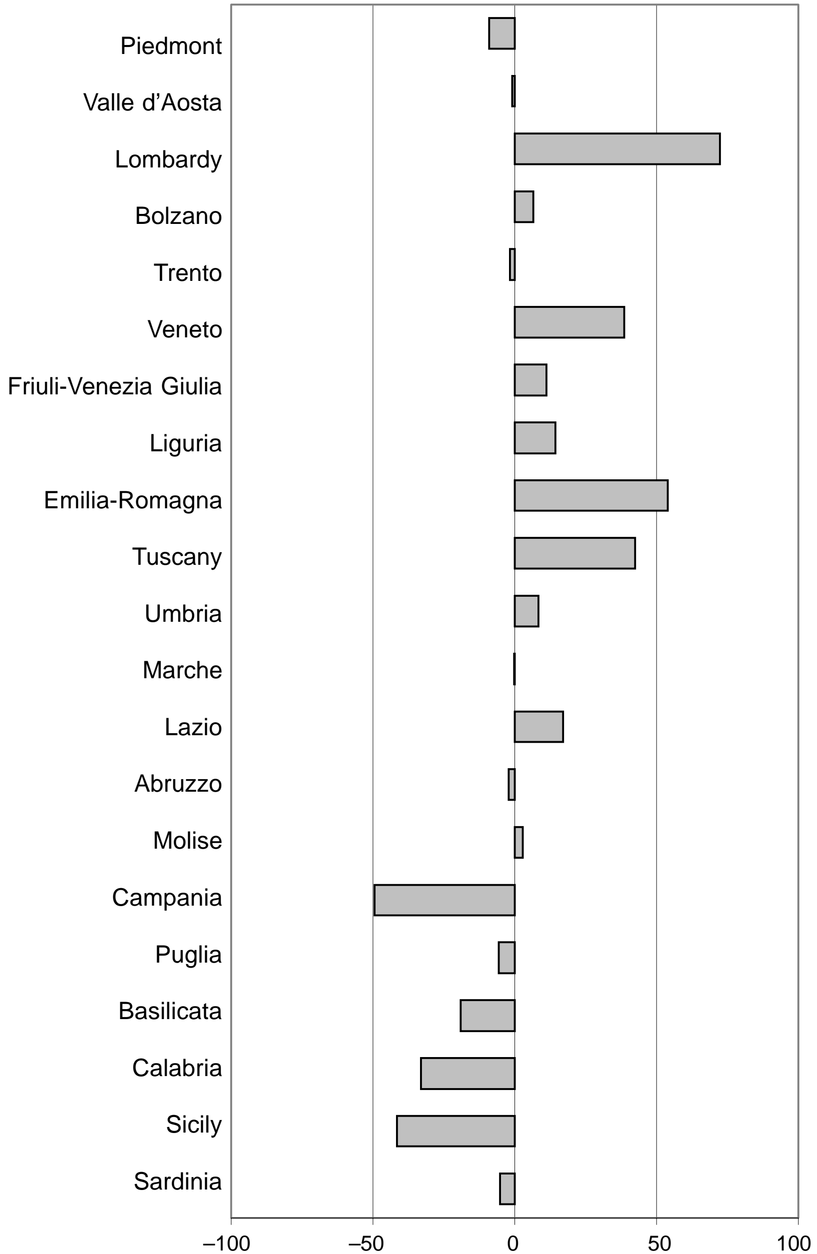



*Source:* WHO Regional Office for Europe health for all database.

to other regions, whereas the opposite is true for southern regions. In particular, Lombardy recorded a positive net inflow of 72 000 inpatient stays, whereas Campania and Sicily had the worst performance, with negative net outflow of, respectively, 49 400 and 41 500.

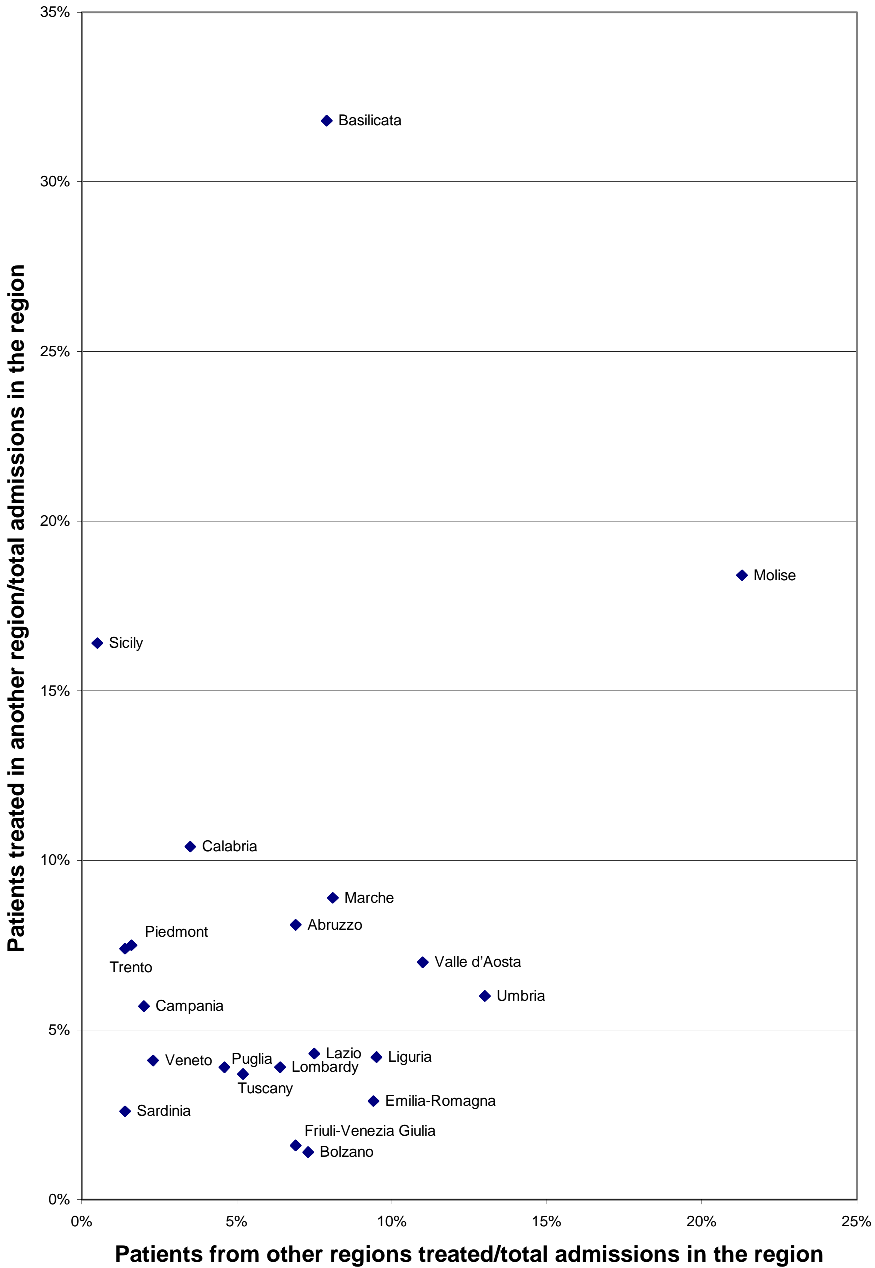
People living in northern Italy tend to obtain health care services in their own or nearby regions (Fig. 17). In contrast, most southern patients obtaining services outside their region go to northern regions, in which most tertiary hospitals are concentrated. This applies especially to Puglia, Sicily and Sardinia; in 1998, their residents chose northern or centre regions in 77%, 89% and 95% of the interregional cases, respectively. In contrast with Fig. 16, the data reported in Fig. 17, also from the Ministry of Health, exclude the admissions for which the origin of patients was registered as unknown. Several regions had very high percentages of patients of unknown origin: Sicily (35%), Veneto (29%), Marche (28%), Lombardy (24%) and Trento (9%). In the remaining regions, the percentage was below 5%.

**Fig. 16. Positive and negative interregional flow of inpatients according to region, thousands of inpatient stays, 1998**




*Source:* Ministry of Health (http://www.sanita.interbusiness.it/sdo/Software/datisdo.htm).

**Fig. 17. Interregional inpatient flow as a proportion of total admissions in Italy's regions, 1998**




*Source:* Anessi & Cantù *(16).*

## Social security and social care

Municipalities have traditionally been responsible for organizing the delivery of social care, and local health units 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. To solve this problem, municipalities have therefore often decided to delegate the delivery of social care to local health units. In many cases, this choice has revealed a lack of coordination and partnership between municipalities and local health units. Instead, coordination is supposed to play an important role in guaranteeing effective and appropriate care to the community. The National Health Plan for 1998–2000 and the 1999 health care reform provide guidelines aimed at improving the coordination and integration of health care and social care. In addition, the parliament adopted a major reform of the traditionally marginal, underfunded social care sector in 2000 (see the section on *Health care reforms*).

## Human resources and training

Training is one of the most relevant aspects of the recent reform of the health care system. In particular, both the National Health Plan for 1998–2000 and Legislative Decree 229/1999 have focused on this. The National Health Plan has provided a broad framework according to which the issue at stake has to be regulated, and Legislative Decree 229/1999 gives more precise instructions (see the section on *Health care reforms*).

### Physicians

Physicians have three different stages in higher education: university education, postgraduate education and continuing education.

Future physicians have to graduate from a medical faculty at a public or private university. The undergraduate programme lasts 6 years, during or after which students must work within a hospital ward for at least 6 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.

Future general practitioners and future hospital physicians have to follow two different career paths.

Physicians wishing to become a general practitioner 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 2-year general practitioner training course. Legislative Decree 256/1991, which implemented the EU directive on general practitioner training *(17)*, made participation in this 2-year course compulsory for practicing family medicine. Moreover, in accordance with Legislative Decrees 256/1991 and 368/1999, certificates issued by other EU Member States to practice as a general practitioner are equivalent to those issued in Italy and are therefore valid for practising in Italy.

The number of physicians increased in many European countries from 1981 to 1996. The number of health care professionals increased in Italy from 1970 to 1995 (Table 13). Specifically, the number of active physicians grew during the 1990s and so did the number of dentists. Italy has the most physicians per 1000 population in western Europe (Fig. 18 and Fig. 19).

The number of physicians and pharmacists per 1000 population entering the workforce in Italy was among the highest in western Europe. Alternatively, the numbers of new dentists and nurses were among the lowest of these countries (Table 14).

**Table 13. Number of health care personnel per 1000 population, 1985–1998, selected years**

| | 1985 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 |
|---|---|---|---|---|---|---|---|---|---|---|
| Active physicians[a] | 3.8 | 4.7 | 4.9 | 5.0 | 5.2 | 5.3 | 5.4 | 5.5 | 5.8 | 5.9 |
| Active dentists[a] | – | 0.2 | 0.3 | 0.4 | 0.4 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Certified nurses[a] | 4.2 | 4.7 | 4.7 | 4.1 | 4.4 | 4.3 | 5.4 | 5.4 | 5.3 | – |
| Active pharmacists[a] | 0.9 | – | 1.0 | 1.0 | – | – | – | – | – | – |
| Physicians graduating[b] | 0.2 | 0.2 | 0.2 | 0.2 | – | – | – | – | – | – |
| Nurses graduating[b] | 0.3 | 0.2 | 0.2 | 0.3 | 0.5 | 0.4 | 0.4 | 0.3 | – | – |

*Sources:* [a] WHO Regional Office for Europe health for all database; [b] OECD *(4)*.

## Nurses

Legislative Decree 502/1992 (Article 6, Section 3) and Ministerial Decree 739/1994 have introduced a major reform of the training system for nurses, which has led to the closing of the regional training schools for nurses. Previously, prospective nurses could enrol after just 2 years of high school and, upon completing the programme, were awarded a regional certificate by the Ministry of Health. According to the new legislation, those wishing to be registered as

qualified nurses are required to complete a 3-year university programme and 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. Further, Law 251/2000, passed on 19 July 2000, establishes the role of nurse management and establishes a degree in the nursing sciences for training managers and teachers in nursing.

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 auxiliary.

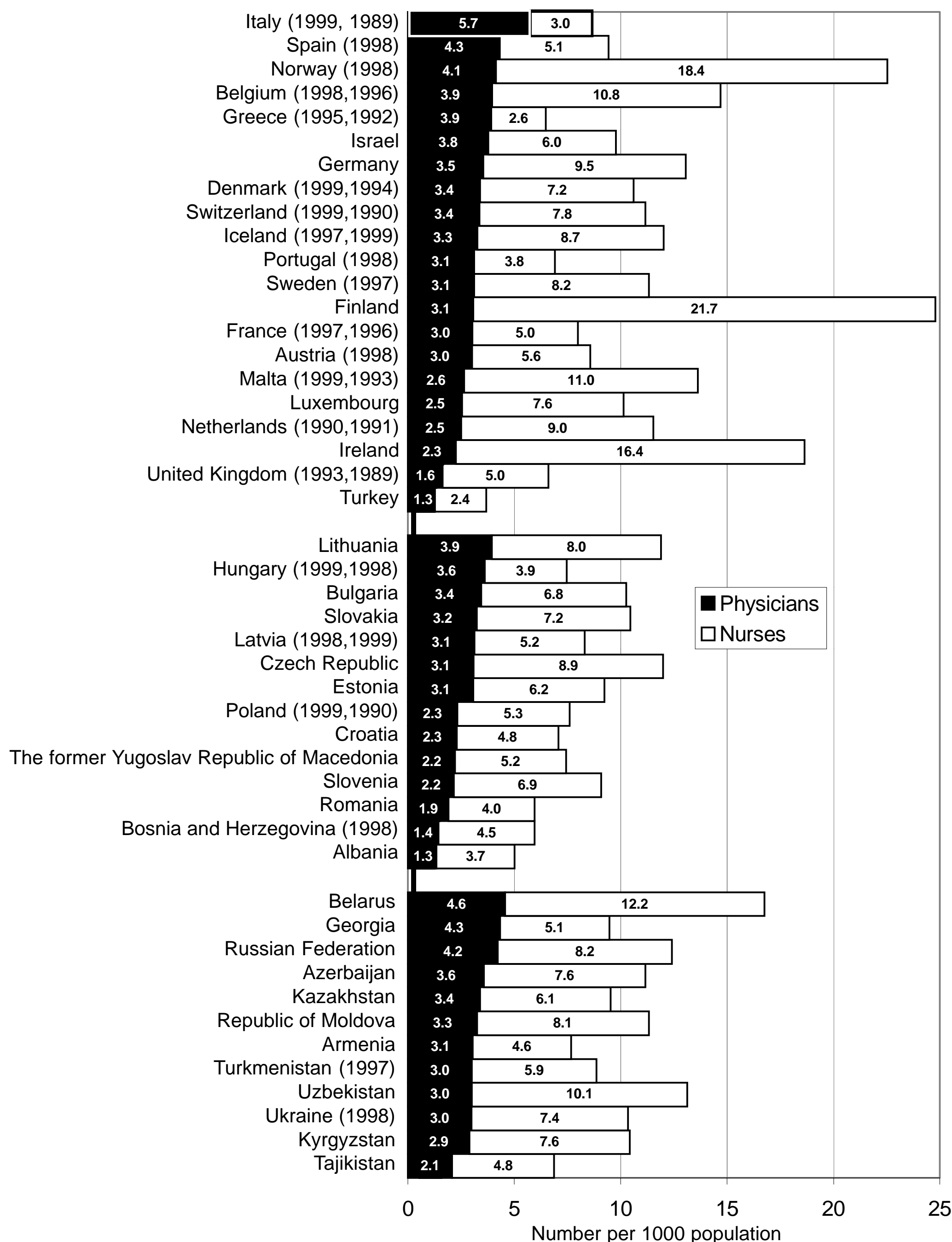
Italy ranked second lowest in the WHO European Region in active nurses per 1000 population the late 1990s (Fig. 18). This rate (3.0 nurses per 1000 population) has remained almost unchanged since the mid-1970s, although the number of certified nurses per 1000 population increased from 4.2 per 1000 in the mid-1980s to 5.3 per 1000 in the late 1990s (Table 14). Of the 47 countries listed in Fig. 18, only Greece and Italy have fewer nurses than physicians. Unemployment among nurses is high in Italy.

**Table 14. Number of health care personnel entering the workforce in selected western European countries per 100 000 population, 1996 or latest available year**

| | Physicians | Dentists | Pharmacists | Nurses | Midwives |
|---|---|---|---|---|---|
| Austria | 13.67 | 1.70[h] | 2.75 | 36.94[a] | – |
| Belgium | 10.13 | 0.61 | 1.72 | 55.33[d] | 2.28[d] |
| Denmark | 7.55 | 1.94 | 2.32 | 33.66 | 1.18 |
| Finland | 10.41[a] | 2.28[a] | 5.84[a] | 90.26[a] | 3.23[a] |
| France | 8.46[d] | 1.82[d] | 4.02[d] | 25.28[c] | 0.95[c] |
| Germany | 15.44[b] | 2.58[b] | 2.20[b] | 18.94[c] | 0.62[c] |
| Greece | 13.24[f] | 3.87[f] | 2.48[f] | 19.00[f] | 1.55[f] |
| Iceland | 12.35[b] | 2.99[b] | 2.62[b] | 25.44[b] | 0.00[b] |
| Italy | 15.33[e] | 1.16[e] | 3.84 | 31.22 | – |
| Luxembourg | – | 0.00[h] | – | 12.27 | 0.00 |
| Netherlands | 9.88 | 1.18 | 0.99 | 39.09[b] | 0.50 |
| Norway | 6.58[e] | 1.94[e] | 0.70[i] | 47.64[e] | – |

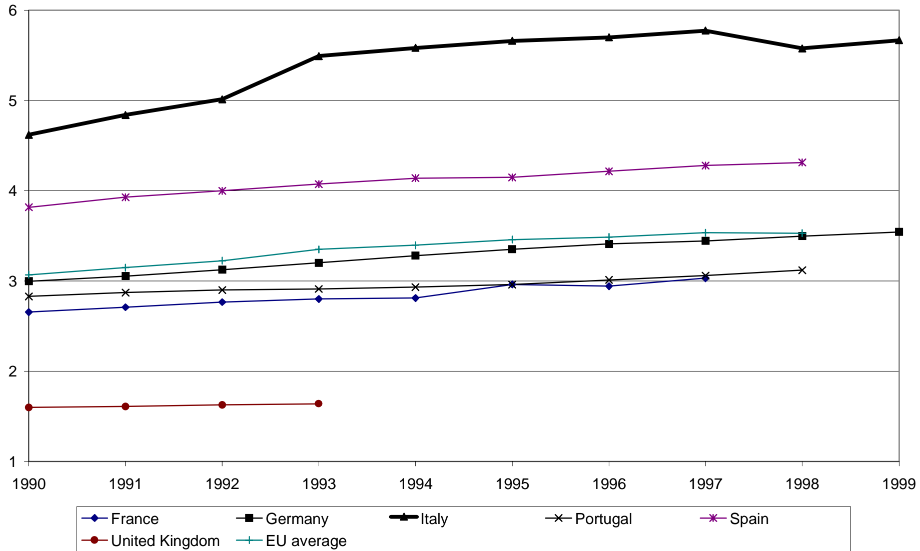
*Source:* WHO Regional Office for Europe health for all database.
[a]1997; [b]1995; [c]1994; [d]1993; [e]1992; [f]1991; [g]1989; [h]1987; [i]1986.

**Fig. 18. Number of physicians and nurses per 1000 population in countries in the WHO European Region, 1999 or latest available year (in parenthesis)**




*Source:* WHO Regional Office for Europe health for all database.

**Fig. 19. Number of physicians per 1000 population in Italy, selected western European countries and the EU, 1990–1999**




*Source:* WHO Regional Office for Europe health for all database.

# Pharmaceuticals and health care technology assessment

## Pharmacists

Italy's NHS allows both private and public pharmacies to coexist. Private pharmacies are owned by pharmacists who act as independent contractors under the NHS. Public ones, mainly municipal, are managed by pharmacists employed by the municipality in which the pharmacy is located. Despite this administrative division, both types of pharmacies are licensed to sell commercial products and, on behalf of the local health unit, pharmaceuticals. Commercial goods mainly include bandages, contraceptives, items for personal hygiene, baby products (such as diapers and infant formula) and cosmetics (some pharmacies also sell homeopathic products). Pharmaceuticals include drugs and dietary goods and can only be sold if a consumer has a prescription from a general practitioner.

All the revenue goes directly to the owner of the pharmacy: to the pharmacist if the pharmacy is private, and 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 Act) of the overall price before VAT: the most recent rate, set in 1996, is 26.7%. This rate does not take into account special discounts that pharmacies might be able to negotiate with manufacturers. Conversely, local health units are responsible for reimbursement.

## Pharmaceuticals

The turning-point for Italy's pharmaceutical sector was 1 January 1994, when Law 537/1993 came into force. The pressure to contain expenditure and an impressive series of scandals favoured the most radical change ever in Italy's pharmaceutical policy. Since 1994, regulatory policies have:

- redefined the positive list;
- implemented a nationwide drug expenditure budget;
- created new price-setting models;
- changed distribution margins;
- introduced generics; and
- attempted to influence the prescribing of general practitioners.

## A new positive list

In 1994, the National Committee for Pharmaceuticals was established. The 1978 positive list was abolished, and drugs were reclassified into four groups:

- group A: drugs for severe and chronic illness
- group B: drugs of therapeutic importance not included in group A
- group C: drugs not included in groups A and B
- group H: drugs provided only by hospitals.

Cost-sharing rules were also modified in 1994: for pharmaceuticals in group A, patients pay €1.55 if the prescription includes only one item or €3.10 for more than one item; and for pharmaceuticals in group B, patients pay only 50% of the price. Consumers pay the whole cost for pharmaceuticals in group C, which are not covered by the NHS.

The new list was established according to four criteria: 1) clinical efficacy, documented by evidence-based criteria; 2) the risk-benefit balance of the

therapy; 3) the acceptability of the therapy to patients; and 4) the cost of the therapy.

The National Committee for Pharmaceuticals also introduced caveats for some drugs; these can be considered guidelines for the use of pharmaceuticals.

## A nationwide drug expenditure budget

In 1994, 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 15).

The ceiling was €5165 million for 1994 and €7449 million for 2000. Since 1998, private companies, wholesalers and pharmacists have been made responsible for paying 60% of the deficit to control the growth of pharmaceutical expenditure.

**Table 15. Budgeted and actual public drug expenditure, millions of euros, 1998–2000**

| Year | Drug expenditure budget (A) | Actual expenditure (B) | Drug expenditure deficit (A – B) | % change in annual expenditure |
|---|---|---|---|---|
| 1998 | 6 302 | 6 802 | +500 | 8.7[b] |
| 1999 | 6 506 | 7 589 | +1 083 | 11.6 |
| 2000 | 7 449 | 8 844[a] | +1 395 | 16.5 |

*Source:* Agency for Regional Health Care Services, unpublished data.
[a] Forecast for the year 2000. [b] Actual expenditure for 1997: €6 255 million.

## New price-setting models

Pharmacists freely determine the prices of commercial goods; prices for each pharmaceutical product are fixed centrally through a negotiation process involving the National Committee for Pharmaceuticals and the representatives of the major pharmaceutical companies. In 1994, the price-setting system for drugs was modified. The Committee on Pharmaceuticals (CIP Farmaci), the body charged with regulating drug prices, was abolished, and a year later the Interdepartmental Committee on Economic Planning (CIPE) announced a new method for determining drug prices based on cost estimates derived mainly from information from private companies that effectively replaced the previous one. According to the new system, prices can be freely set without exceeding the average European price. The average European price was based on the five

most sold drugs, including generics. Only France, Germany, Spain and the United Kingdom were taken into consideration in deriving the average European price. Foreign prices were converted into Italian currency based on purchasing power parity (PPP), a price index used for international comparative studies.

The principle of similarity was adopted to identify the European equivalents of Italian products: the same active ingredient, the same route of administration, the same or therapeutically comparable pharmaceutical form and a similar dosage.

The pharmaceutical industry criticized the new model: in particular, restricting the comparison to only four countries, including generics in calculating the average European price and using PPP. As a result of the industry's dissatisfaction, the Interdepartmental Committee on Economic Planning (CIPE) introduced a sort of reference price in 1996, based on the principle of the same prices for the same drugs. The basic idea is that products in group A and group B that use the same active ingredient, have the same method of administration and have the same or a comparable pharmaceutical form should have the same prices per unit of compound. This pricing mechanism exists only for products in groups A and B, since the prices for Class C pharmaceuticals are freely established by the private sector.

Further, in 1997, the Interdepartmental Committee on Economic Planning defined a new price system for innovative drugs authorized by the European Agency for the Evaluation of Medicinal Products. Prices are set by negotiation between the National Committee for Pharmaceuticals and private companies, using the following criteria: a) cost–effectiveness; b) foreign prices; c) internal market forecasts; and d) investment by the company related to the introduction of the new drug.

Since July 1998, the average European price method (used for non-innovative drugs) has been modified to include all European countries and current exchange rates.

## Changes in distribution margins

Controlling public pharmaceutical expenditure required focusing on pharmacies also. Wholesale and pharmacy margins were traditionally set as a fixed markup on ex-factory prices and have not varied much during the last 15 years. From 1981 to 1997 the wholesale margin has changed from 8.0% to 6.65% and the pharmacy margin from 25.0% to 26.7% of drug prices excluding VAT.

In 1992, a fixed compulsory rebate on pharmacy margins was introduced for products covered by the NHS. The rebate was initially set as a fixed proportion of the price (2.5% of the price excluding VAT, 3% since 1995).

From 1997, pharmacists were forced to apply a discount to products covered by the NHS. Different discount rates apply to different price ranges to make the pharmacy's margin regressive (decreasing with the price). The discount was 3.75% for prices less than €25.8; 6% for those between €25.8 and €51.6; 9% for those between €51.6 and €103.3; and 12.5% for prices equal to or greater than €103.3.

## The introduction of generics

Despite all the interest in cost containment, Italy's authorities have not given generic drugs much attention. As a consequence, their use is very limited. The 1995 Finance Act introduced the term generic into legislation. The law provides pricing incentives to promote generics, stating that, if the product is marketed at a price at least 20% lower than the equivalent speciality, it is automatically listed in the same co-payment class. Other incentives come from the financial accountability of regions over health care and the consequent process of management improvement and cost containment in the local health authorities of the NHS *(18)*.

Because wholesale and pharmacy margins were traditionally set as fixed mark-ups, this has made the distribution of expensive drugs more profitable. Since 1997, the pharmacy margin on NHS-covered products became inversely related to the product's price. However, the regressive effect is still very slight and does not favour the use of generics. As a matter of fact, the generics market in Italy is still negligible. The latest data show that generics account for only 3% of all prescribed medicine units sold *(18)*.

However, recently passed regional acts (Tuscany being one of the most active regions) aim at promoting the prescription of generics by distributing lists of generics among general practitioners and encouraging them to prescribe generics. These reforms are nevertheless still in their early stages, and nationwide implementation is far from being achieved.

## Attempts to influence general practitioner prescribing

The prescriptions of general practitioners have never been strictly controlled. Only after the series of scandals affecting the whole pharmaceutical system did the 1992 reform of the NHS create greater incentives and opportunities for making general practitioners accountable for their prescribing activities, such as an expenditure budget for each general practitioner and incentives for general practitioners to achieve this target. The specific impact of each new regulatory measure is difficult to assess, even though the reclassification of drugs by the National Committee for Pharmaceuticals substantially affected NHS drug

expenditure. In particular, since 1993, the measures described above have had two main effects. First, they dramatically reduced NHS pharmaceutical expenditure from 1993 to 1995. The introduction of guidelines from the National Committee for Pharmaceuticals and the introduction of a nationwide drug expenditure budget largely achieved this aim (Fig. 20). Second, much of the reduction in NHS pharmaceutical expenditure resulted by 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 16).

Nevertheless, these cost-containment strategies were not long-run manoeuvres but just emergency measures to stop the never-ending increase in drug expenditure. This could explain why expenditure increased again rapidly from 1996 to 1999 (Fig. 20).

**Table 16. Expenditure on pharmaceuticals in millions of euros, 1992–1999**

| Year | Total | Public expenditure | Private expenditure | Public expenditure (%) | Private expenditure (%) |
|---|---|---|---|---|---|
| 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% |

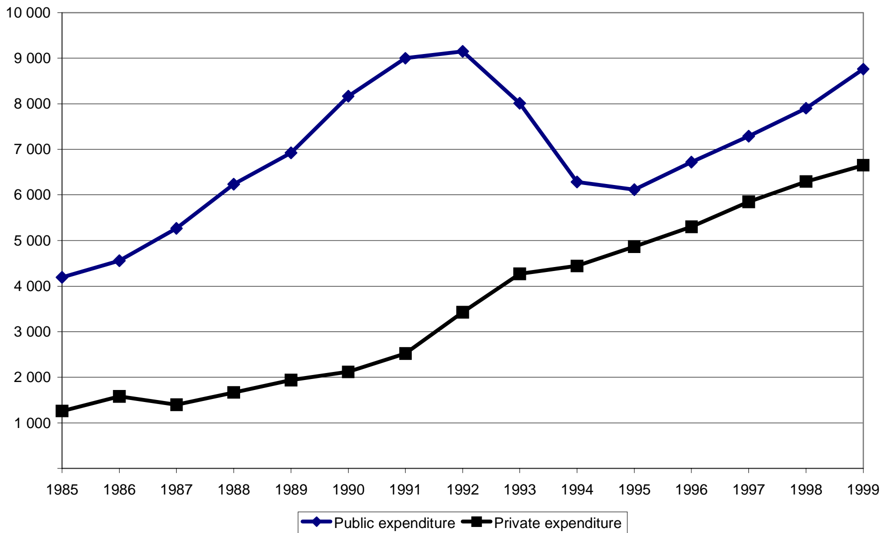
*Source:* Ministry of Health *(7).*

## Assessment of health care technology

Italy has no national agency responsible for promoting and financing health technology assessment activities. Quantifying with any precision the volume of health care technology assessment being carried out is therefore very difficult.

The creation of regional health agencies in regions such as Friuli-Venezia Giulia and Veneto appears to be a promising start. The regional health departments created these agencies so that skills and expertise would be available to provide technical support for the planning and evaluation process. The Centre for the Assessment of Biomedical Equipment, located in Trieste and established in 1989, can be considered Italy's first experience in health technology assessment. In 1997, the Ministry of Health funded this Centre to monitor the dissemination of major health technologies and to collect data on their technical characteristics and average purchase prices. From 1993, in

**Fig. 20. Public and private expenditure on pharmaceuticals in millions of euros, 1985–1999**




*Source:* Ministry of Health *(7).*
Drugs administered in NHS hospital settings are not included.

Veneto, a regional Centre for Technology Assessment and Quality Improvement in Health Care was created with the aim of carrying out integrated assessment of individual technologies (epidemiological, clinical and economic).

# Financial resource allocation

## Third-party budget setting and resource allocation

The guidelines the central government has used to allocate financing to the regions have been changed frequently over the past two decades, because they have not always been very clear. For example, although the 1978 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 at supplying regions with an adequate level of financing both for health care and for reducing interregional differences, but it failed to provide the means for doing this. The lack of clarity regarding the criteria meant that the formulas for allocating health care funds (Table 17) 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. The Ministry of Health is responsible for defining the capitation rate for health care services, which is expected to be published in the National Health Plan. The capitation rate should, theoretically, represent the resources needed to finance services included in the core benefit package. Accordingly, it should take into account the estimated need and utilization of health care services in the three categories introduced by the National Health Plan for 1998–2000 (community care, hospital care and public health services in working and living environments). Multiplying the rate by the total population should then equal the National Health Fund.

However, in reality, given the fact that the core benefit package has not yet been defined, the process is actually reversed. The central government

**Table 17. Formulas used (%) for allocating health care funds to Italy's regions during the years 1980–1997**

| Year | Historical spending | Population | Risk- and need-adjusted population | Health care utilization – adjusted population | Quota for specific projects | Other criteria | Development or equalization fund | General expenditure | Total |
|---|---|---|---|---|---|---|---|---|---|
| 1980 | 3.7 | 8.0 | 85.6 | – | 2.7 | – | – | – | 100.0 |
| 1981 | – | 25.4 | 71.7 | – | 2.0 | 0.9 | – | – | 100.0 |
| 1982 | 78.8 | 18.7 | – | – | 1.0 | 1.5 | – | – | 100.0 |
| 1983 | 68.5 | 26.8 | – | – | 2.2 | 2.5 | – | – | 100.0 |
| 1984 | 69.6 | 26.4 | – | – | 1.5 | 2.5 | – | – | 100.0 |
| 1985 | – | 5.3 | – | 85.0 | 1.4 | 2.1 | 0.4 | 5.8 | 100.0 |
| 1986 | – | 4.5 | – | 87.1 | 1.8 | 1.6 | 0.2 | 4.8 | 100.0 |
| 1987 | – | 3.4 | – | 86.8 | 1.1 | 3.0 | 0.4 | 5.3 | 100.0 |
| 1988 | – | 3.5 | – | 86.5 | 1.5 | 2.7 | 0.9 | 4.9 | 100.0 |
| 1989 | – | 3.6 | – | 85.8 | 1.7 | 3.3 | 0.8 | 4.8 | 100.0 |
| 1990 | – | 3.6 | – | 86.0 | 1.6 | 3.2 | 0.7 | 4.9 | 100.0 |
| 1991 | 0.4 | – | – | 97.0 | 1.5 | 0.7 | 0.4 | – | 100.0 |
| 1992 | – | 96.3 | – | – | 0.9 | 0.5 | 2.3 | – | 100.0 |
| 1993 | – | 97.8 | – | – | – | 0.6 | 1.6 | – | 100.0 |
| 1994 | – | 98.6 | – | – | – | 0.6 | 0.8 | – | 100.0 |
| 1995 | – | 98.7 | – | – | – | 0.6 | 0.7 | – | 100.0 |
| 1996 | – | 98.0 | 0.1 | 1.0 | – | 0.9 | – | – | 100.0 |
| 1997 | – | 48.2 | 17.4 | 33.1 | – | 1.3 | – | – | 100.0 |

*Source:* Mapelli *(14).*

determines the resources that should be devoted to health care and divides them by the total population to obtain the capitation rate. Multiplying the capitation rate by the regional population, weighted in terms of need and utilization indicators, determines how much each region should spend for health care.

The National Health Plan for 1998–2000 set the capitation rates as €927 for 1998, €955 for 1999 and €984 for 2000.

According to the specifications of the Ministry of Health, health care funding should be allocated to three different health care categories according to the following percentages:

- public health services in working and living environments (4%)
- community health care (47.5%)
- hospital health care (48.5%).

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

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

## Payment of hospitals

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 attempts 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 on a bed-day 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. The severe deficit mutual health funds faced during the early 1970s was therefore a predictable event to which the government responded in 1974 by shifting hospital management responsibility away from health funds and to regional authorities.

In order to reduce the number of beds and contain expenditure, public and teaching hospitals were no longer paid on a bed-day rate, which was maintained solely for private clinics and for religious hospitals, but instead 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 units: public hospitals were fully integrated into the administrative structure of local health units and were financed from the budget given to the local health units by the regional

authorities. The lack of a separate accounting system, however, made tracking expenditure and auditing very difficult: neither the costs nor the capital of hospitals could be properly evaluated or monitored. The reform also established that all hospitals independent from the local health unit but with public status (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, on the other hand, with which local health units could make agreements, were to be financed on a bed-day rate. However, the rate was not determined by the board of directors but was the result of a national contracting tender and was to be updated every 3 years.

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

Together with the distinction between the two types of hospitals, which aimed at introducing 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. From January 1995, hospitals and outpatient specialist providers were to be reimbursed for services rendered according to nationally predetermined rates. 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 diagnosis-related group scheme, whereas for outpatient care, diagnostic services and specialist treatments, reimbursement should be based on fees for services. The only two forms of treatment for which a bed-day rate should still apply 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.

The laws following the 1992 reform also specified that regions were allowed to set up specific financing schemes aimed at supporting the hospital activities that could be financed by the diagnosis-related group scheme. In particular,

these include: emergency wards; spinal cord units; burn units; organ transplant centres (transport, donor and receiver support and transplant activity co-ordination); AIDS centres; home-based care; training activities; and teaching and research activities, all of which receive additional funding from the regional government.

These rules have several exceptions. A special case is Lombardy, where all hospitals were given trust status starting in 1998. In this case, local health units 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 trusts). The prospective financing mechanism has not been implemented yet in some southern regions.

Finally, the 1999 reform strengthened the principle of a prospective payment system based on diagnosis-related group 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 diagnosis-related group; and
- payments based on the average production costs for: (a) care for emergencies and accidents and, more generally, care activities with high waiting costs; (b) prevention schemes; (c) social services; (d) transplant activities; and (e) management of chronic illnesses.

# Payment of health care professionals

## Physicians

The payment structure for physicians depends on the NHS sector in which they work. General practitioners and pediatricians 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, general practitioners and paediatricians were paid fees for services by the patient's mutual fund. Since the 1978 reform of the NHS, both general practitioners and paediatricians can choose to work full-time or part-time for the NHS, with local health units 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 list. Local health units can also pay additional allowances (agreed at the national level) for the delivery of planned care to specific patients, such as home care for chronically ill and handicapped people. Both types of physicians can also earn more by treating patients privately and charging fees, provided that the time general practitioners and paediatricians devote to private treatment does not interfere with the regular provision of primary care services.

The payment levels, duties and responsibilities of general practitioners are determined in a collective agreement every 3 years by consultation between the central government and the general practitioners' trade unions. The agreement also fixes the maximum number of patients each physician can have on his or her list. Full-time general practitioners and paediatricians can have up to 1500 and 800 patients, respectively, and the limits for part-time physicians are 500 and 400. When a general practitioner or paediatrician devotes more than 5 hours per week to private practice, the maximum number of 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 general practitioners and 1000 for paediatricians) as a result of previous laws and agreements can keep them.

The 1992 and 1999 reforms have tried to address some unresolved issues connected with general practitioner activities. First, to overcome the traditional division between general practitioners and emergency general practitioners (*guardia medica*) and thus guarantee medical assistance 24 hours a day, seven days a week, the reforms have envisaged incentives for general practitioners to set up medical associations or partnerships. These associations consist of teams that provide continuous care for ordinary activities. Second, as an incentive towards containing costs and reducing 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 latest collective agreement has fixed the per capita payment between €15.50 and €21.20 according to the number of years since the general practitioner received a degree. In addition, physicians who set up a joint medical practice get a 6% increase, with additional payments for protecting physicians against risks and for physicians working exclusively within the NHS. For example, the fixed compensation for a physician who received a degree 10 years previously working full time for the NHS and with 1500 patients can reach €42 400.

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: a proportion of the positive difference between expected and actual expenditure, including the cost of pharmaceuticals, laboratory tests and therapeutic treatments prescribed by the general practitioner. The fixed and variable parts are common to all general practitioners 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 for general practitioners because they have fewer patients. Payments vary between €35.10 and €49.10 depending on experience. Hence, the fixed compensation for a paediatrician working full time for the NHS and with 800 patients who received a degree 10 years previously is about €37 200.

**Hospital physicians**

The 1992 reform drastically changed the organization of hospital physicians by replacing several professional categories with first-level and second-level physicians.

All newly employed physicians start as first-level physicians (*dirigente medico di primo livello*). Physicians at this level have support and cooperation duties as defined by the medical officer in charge of the hospital unit.

Second-level physicians (*dirigente medico di secondo livello*) usually have duties connected with organizing and managing the hospital unit. Further, they help in choosing the most appropriate therapeutic, diagnostic and preventive treatments for patients.

Unlike general practitioners, hospital physicians are paid a salary by a hospital. Until 1992, hospitals had a multiple-layer hierarchical structure including such positions as chief medical officers (*primario*) and assistant medical officers (*aiuto primario*).

The payment structure follows the hierarchical structure based on two levels. First-level physicians earn about €41 300 per year, and second-level physicians receive about €62 000, including nights and weekends on call for both types.

Up to 1999, all physicians could earn additional income by treating patients privately on a fee-for-service basis. The 1999 reform has radically changed the organization and management of hospital physicians, provoking strong dissent. These are discussed within the section on *Health care reforms.*

## 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 non-medical NHS employees that includes technicians, clerks, caretakers and administrative staff. Similar to other public workers, their payment structure is therefore defined by a national collective agreement negotiated every 33 years by representatives of the trade unions and of the government.

The organizational structure of non-medical NHS workers has changed several times recently, 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, dietitians and technicians working in such areas as radiology, orthopaedics and ophthalmology, as well as higher-level administrative staff. Aside from specific professional duties, group D workers (such as ward sisters) also have decision-making responsibility and play a significant role in organizing the delivery of health care.

Aside from restructuring the professional hierarchy, the reforms have also reassessed the payment scheme to stimulate professional motivation by acknowledging and remunerating individual employees' skills. Hence, each non-medical employee in the NHS (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, where created, the nurses' officer evaluate workers' performance.

# Health care reforms

## Aims, objectives and content of reforms

### The first reform: the creation of the NHS in 1978

In 1978, Law 833/1978 launched a thorough reform of Italy's health care system aimed at instituting a national health service. This 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 local health units, modelled based 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 local health units were to be governed by democratically elected authorities, the representatives of the 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 was still blurred. In addition, since its inception in 1978, the NHS 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 unintended negative effects of some reform measures, whereas others stemmed from incomplete implementation of the 1978 reform proposals, as discussed within the section on *Reform implementation.*

## The second wave of reform: introducing internal markets and regional devolution

These problems constituted the main driving forces behind the approval of the second health care reform in the early 1990s. Legislative Decrees 502/1992 and 517/1993 launched a "reform of the reform" that instituted measures to establish an internal market similar to the British model and a process of devolving health care powers and financial accountability to regions.

The internal market reforms, as in the United Kingdom, envisaged delegating significant managerial autonomy to hospitals and local health units; introducing a partial split between purchasing and providing; 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 local health units kept on directly providing 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; and
- ultimately allowed citizens to opt out of the NHS by reducing their contributions to the public system and choose private insurance schemes instead (this option, included in Legislative Decree 502/1992, was abolished by Legislative Decree 517/1993).

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 NHS services, as a result of the unfulfilled 1978 plans of expanding 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, in addition, they were again raised.

As in the United Kingdom, it was initially expected that market incentives would develop within the NHS, 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 (see the section on *Reform implementation*).

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 local health units and hospital trusts 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, their financial accountability to the centre was reinforced by explicitly stating that regional governments were responsible for their own deficits, which they should cover either by raising additional regional taxes or by increasing co-payments. Regions were given little room to autonomously increase their resources, however, given the strong centralization of general and payroll taxes and the high level of co-payments.

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

Not unsurprisingly, the 1992–1993 reforms did not fully achieve some of the expected results and created new, unforeseen problems (see the section on *Reform implementation*). Measures were therefore 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 419/1998, the parliament asked the central government to further regulate and rationalize the NHS by adopting a decree on the organization and functioning of the NHS. The government completed its task in 1999 by passing Legislative Decree 229/1999, which launched the third NHS reform.

The reform measures launched during 1997–2000 attempted to reinforce the role of the state in regulating the NHS while simultaneously reducing the state role in directly governing the NHS in favour of the increasingly autonomous regions. The fiscal federalism reform aims at clarifying accountabilities by transferring to 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 NHS 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 co-operation across levels of care and health care authorities.

## 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 59/1997 (the Bassanini Law), which regulated the transfer of powers to regions, and Legislative Decree 446/1997 (the Visco Decree), which introduced sources of autonomous financing for the regions as a first step towards fiscal federalism. These represent an important breakthrough towards regional financial autonomy and thus, towards genuine regional responsibility for ensuring the population a core package of health care services and benefits. Before this reform, the state used general taxation revenue and compulsory health contributions to finance the National Health Fund, which was then redistributed among all regions. Starting in 1998, a portion of national income taxes (the IRPEF) was transferred to regions (the regional IRPEF), and health insurance contributions were replaced by regionally collected taxes (IRAP) on the value added by companies and on the salaries of public-sector employees (see the section on *Health care financing and expenditure*).

The latest fiscal reform affecting the financing of the NHS, Legislative Decree 56/2000, was approved in February 2000. Starting in 2001, regional financing will come from:

- the modified payroll contribution system, IRAP;
- the regional share of the IRPEF, which will be increased from 0.5% to 0.9%; regions will be allowed to modify the total regional IRPEF rate from 0.9% to 1.4% and will therefore have limited ability to increase their resources; and
- a set amount of the petrol excise tax per litre (€0.13); regions will have the right to increase the petrol excise by up to €0.026 per litre.

In addition, a fixed proportion (25.7%) of the national VAT revenue will be used to build a National Solidarity Fund, in charge of redistributing funds across regions. The funds transferred to or received from the National Solidarity Fund will be determined as the difference between two estimates of the VAT revenue quota. The first revenue quota estimates how much VAT revenue each region can theoretically raise and is based on the annual share of household final

consumption expenditure. The second aims at estimating the VAT quota needed for equalizing both regional fiscal capability and regional expenditure, based on weighted capitation targets calculated by the government. A positive (negative) difference between the first and second quota therefore means that the region has more (less) funds than actually needed and will therefore receive from the central government a VAT quota less than (more than) that determined solely based on the final consumption expenditure.

Redistribution is not left to the initiative of regional governments: in fact, as the state collects VAT revenue, all transfers will be from the central government to the regions. Regionally raised taxes (IRAP, IRPEF and petrol excise tax) will accrue to the regions that have raised them and will not be used for the National Solidarity Fund. In 2001, the first year of operation of the National Solidarity Fund, regions will receive a VAT quota based on historical spending to keep the regional financial situation unchanged. In the following 12 years, the quota of VAT allocated based on historical spending will be progressively reduced towards a quota based on the weighted capitation targets estimated to be required to provide a uniform benefit package across Italy. Starting in 2014, the VAT quota allocation will be based only on these targets. Current estimates predict that, initially, only seven regions (Lombardy, Emilia-Romagna, Veneto, Piedmont, Tuscany, Marche and Lazio) will be able to autonomously raise sufficient resources and hence contribute to the Fund, and the rest will have to rely on transfers from the Fund that will represent more than 40% of regional revenue in some cases.

An International Monetary Fund *(5)* report emphasizes that horizontal equalization efforts might be quite relevant in some regions if the economy does not grow as fast as needed to raise enough resources, but the report also highlights some of the most appealing features. In particular, the funds available for equalization are linked to the VAT, a rather elastic tax; interregional inequality is limited through a very high solidarity coefficient set by the central government; fiscal need and economies of scale in producing non-health care services are taken into account; and fiscal effort is promoted at the regional level by taking into account potential rather than actual tax revenue. Hence, less efficient regions will receive less VAT than they would have received if they had put more effort into raising tax revenue.

To prevent marked reduction in health care spending, Legislative Decree 56/2000 also stated that regions had limited autonomy in allocating funds among different regional functions. In particular, until 2003, they have to devote resources to health care at least equal to those provided by the previous national capitation rate. From 2004, the regions that establish appropriate output monitoring programmes will be free to determine, within the overall budget,

the resources for health care, which represented on average 73% of the total regional budget in 1997.

However, the timing of these provisions was modified in August 2000, when the regions and the central government agreed that regions would be free to allocate resources among programmes from January 2001 onwards, with the central government only suggesting the resources each region should devote to health care. Total autonomy in this respect remained conditional, however, on the implementation of the monitoring programmes foreseen in Legislative Decree 56/2000. Regions unable to meet the criteria will therefore have to devote resources to health care at least equal to those mandated by the Ministry of Health. According to the Legislative Decree, the Minister for Health and the Minister for Finance will jointly propose the monitoring system and will define:

- a series of indicators to measure the actual health services provided in each region and a set of supply parameters that should be respected;
- a set of rules for collecting, validating and analysing data; and
- the procedures for periodically publishing the indicators and for identifying the regions that do not respect the parameters.

The regions unable to establish the monitoring system will not only have less autonomy to decide on the resources to be dedicated to health care but will also see their global share of central funding progressively reduced by no more than 3% of the capitation rate. This will be replaced by fiscal transfers earmarked for establishing the monitoring system. This system was already foreseen within the National Health Plan for 1998–2000, as described previously.

## Regulating the new NHS: the National Health Plan for 1998–2000 and the 1999 reforms

The reforms of the NHS 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 to be achieved by elaborating a National Health Plan, which should define the basic benefit package guaranteed to every citizen and outline the main health targets to be pursued during the Plan's 3-year 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 local health units and hospital trusts) 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 the 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. The first step is to define the basic normative criteria to guide the selection of NHS services. The second step is specifying the broad categories of care to which access should be guaranteed, such as primary and community care and hospital care. The third step is 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 estimating the money 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 designing a monitoring system to evaluate the extent to which each region can guarantee the basic benefit package. Legislative Decree 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 the section on *Organizational structure and management*). As mentioned elsewhere, the National Health Plan tended to concede more emphasis to need and effectiveness as the main selective criteria, giving efficiency a more limited role, which should be restricted to deciding among alternative treatments for a similar condition.

As for the second step, the National Health Plan for 1998–2000 also defined the main categories of care to be provided by the NHS. 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 for promoting 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 (general practitioner and paediatric visits and referrals for specialist ambulatory services, diagnostic procedures and hospital treatment), pharmaceuticals, home care (for elderly and handicapped 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. These initiatives are described later.

**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. These are discussed in turn below.

Purchasing was first regulated by Legislative Decree 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 NHS. 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, as follows.

- 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.
- Authorization for delivering health care services is granted by the regional health departments once a minimum set of structural, technological and organizational requirements has been satisfied.
- 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, as explained 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 NHS.
- 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 local health units and the "preferred providers" chosen by the local health units 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 NHS. 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 federalization of Italy's health care system, regional governments will be establishing and managing the accreditation process. Nevertheless, all regions will have to respect the general criteria laid out by the Ministry of Health that will provide them with general guidelines and with the criteria to be used to select the providers. The criteria are being laid out to guarantee that all health care providers operate according to common quality criteria.

The 1999 reform also significantly changed the regulation of public hospital physicians in an attempt to clarify the boundaries between private and public practice and to suppress the perverse incentives associated with dual practice. The previous two-level hierarchical structure (the base level comprising physicians with only clinical responsibilities and the upper level with semi-permanent directive posts with clinical and managerial responsibility) has been replaced by just one level, with the salary structure dependent on the effective tasks and responsibilities performed. In addition, managerial, directive posts are reserved for physicians who choose to work exclusively for the public sector.

Similarly, the possibility for public hospital physicians to increase their salary by treating private patients has been abolished for all physicians employed after 1998. The physicians employed before 1998 were in two categories. Some had opted to work only part-time within the public sector, thus receiving lower public wages. According to the reform, they can continue doing so. Such a decision, however, hinders career progression and may prevent 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 may be 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 by the 1992–1993 reforms, was further regulated in the late 1990s by prescribing that public hospitals should reserve between 6% and 12% of their beds for private patients.

Two additional measures were launched in an attempt to redirect patients from the private sector to publicly financed providers. First, new types of insurance funds were introduced, and special fiscal benefits were established to promote them. In particular, the newly created funds reimburse user fees, services provided privately within public facilities and expenditure for services supplementary to the NHS core services: not included in the benefit package funded by the NHS and supplied only by the NHS itself or by accredited private contracted-out centres. A further incentive has been created for consumers to enroll by granting these new funds fiscal benefits higher than those granted to mutual funds. In contrast to the premiums paid by companies on behalf of their employees, which are not taxed as part of employees' income, the premiums for the new supplementary funds will be deductible from taxable income at an increasing rate: up to €1033 in 2002 and 2003 and up to €2066 from 2007.

Second, the 1999 reforms envisaged abolishing a controversial clause of the 1992–1993 reform allowing private providers not under contract with the public system to provide a few treatments and services indirectly (some types of dental care and ophthalmology and urgent specialist care), with the patient bearing the costs and then being reimbursed by the local health unit.

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-payment 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 Act for the year 2001. In particular, starting in January 2002, the maximum amount to be paid by patients for outpatient care would be reduced from the previous €36 to €12, and co-payments for this category of care would be abolished from 2003. The Act 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 2001 Finance Act proposes changing co-payments for pharmaceuticals, including:

- abolishing drug expenditure budgets;
- eliminating the previous group B drugs, subjected to both a flat rate for the prescription and a 50% co-payment on actual over-the-counter prices and shifting some drugs to group A (for which patients only paid a small flat rate) and some to group C (not eligible for public funding); and
- abolishing co-payments on pharmaceuticals belonging to class A.

### Assessing the quality of health care

Both the National Health Plan for 1998–2000 and Legislative Decree 229/1999 had laid down framework regulation to complement the previous quality assessment interventions launched by the 1992–1993 reforms (see the section

on *Reform implementation*). 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 NHS towards continuous and systematic improvement, assessment and monitoring of all dimensions of quality. The main objectives are:

- 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 local health units and in promoting quality health care; and
- to allocate some of the research funds earmarked by the NHS to financing research and operational projects related to the National Programme on Health Care Quality.

The last 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 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 local health authorities), the meso level (health care centres) and the micro level (health professionals and clinical services). Ideally, these interventions should be targeted at steering the behavior of health care professionals towards appropriate and effective provision of services.

In addition, Legislative Decree 229/1999 further regulated the quality issue by allocating responsibility across levels of government for the process of accreditation of health care providers, along the lines suggested by the National Health Plan for 1998–2000. In addition, it established the National Programme for the Elaboration, Dissemination and Evaluation of Clinical Guidelines, also

foreseen within the National Health Plan, which aims at designing and disseminating guidelines on the treatment of the most relevant conditions, especially back pain, pregnancy, hypertension, cervical cancer, breast cancer and angina pectoris. In addition, Legislative Decree 229/1999 instituted procedures for the reaccreditation of health care providers and professionals, as described later.

The latest health care reform considers human resources as 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. Further, the concept of continuing education is 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 further qualify professionals and improve their skills. Health professionals working in the public or the private sector are expected to improve their knowledge and keep up to date 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 the 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 in public health structures.

Legislative Decree 229/1999 provided for the establishment by ministerial decree of a National Commission on Continuing Education in Medicine. The Commission is supposed to be specifically responsible for establishing the criteria for public or private institutions to qualify as training agencies and for accrediting them and the training and refresher activities they organize. The Commission will also determine the training objectives of national interest (guidelines), determine the criteria for assessing and validating the training experiences of health personnel and assess the relevance and suitability of the regions' training activities, about which regions have to produce a report and submit it to the Commission. The members of the Commission are supposed to be renewed every 3 years and 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 National Commission on Continuing Education in Medicine was established on 5 July 2000 by a ministerial decree together with the initiation

of the national programme on continuing education in medicine. The programme's first stage is experimental and started on 1 January 2001: this stage is just aimed at testing the accreditation system for training activities worked out by the Commission. The second and final stage was supposed to start by 1 July 2001. All health professionals will be required to earn 150 continuing education training credits every 3 years to be accredited.

**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 local health units 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. Finally, professional integration is considered as collaboration among all the different types 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 envisages an integrated home care scheme. This is based on the idea that health and social professionals (including general practitioners, 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 integrated home care scheme aims at creating a home care network to assure specialized and rehabilitation services, home nursing and housework for people who are appropriate candidates for this kind of care because of health conditions. 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 integrated home care. The general practitioner has a key role in delivering integrated home care. The general practitioner assesses the patient's condition and, if needed, requests integrated home care. After this, together with the physicians from the district, the general practitioner indicates which health and social professional profiles are to be involved. He is also in charge of liaising with the district director of the social workers as well as coordinating

and supervising the activities of all of the health and social workers involved in caring for the patient. Finally, the general practitioner is responsible for the outcome of integrated home care according to the 1998–2000 collective national agreement with general practitioners.

Legislative Decree 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 provided through such collaboration schemes. The Legislative Decree identified three types of services located at the interface between social and health care: health care services with social relevance (to be provided under the leadership of local health units), 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 local health units). In a forthcoming decree, the Ministry of Health and the Department of Social Affairs intend to further regulate this field by providing an operative definition for these services and indicating the financial criteria to be adopted. Only a draft of the co-ordinating and directing decree is currently available. This still has to be examined by the National Health Council and the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces before being approved. According to this draft's operative definition, social services with health relevance include the financial facilities aimed at integrating disabled people (or people with drug-abuse problems) in the social and occupational networks. This means that, for example, municipalities are responsible for occupational and social rehabilitation, and the NHS pays for all therapeutic, rehabilitative and specialized services. Health care services with social relevance are defined as services that, in close coordination with social interventions, also influence environmental conditions, thereby contributing to allow the individual to participate in social life and express himself or herself. The services characterized by advanced integration of social and health care activities include the family planning advisory centres of local health units as well as the maternal and child services of hospitals and districts providing medical, social, psychological and rehabilitative activities. The NHS is mainly responsible for paying for these services.

To foster the integrated provision of social services with health relevance, the latest reform defines new professional profiles. The reform includes two kinds of profiles: one based on a 3-year university programme and the other on a vocational training course. In October 1999, a joint ministerial decree by the Ministry of Health and the Department of Social Affairs (referred to by Legislative Decree 229/1999) foresaw the introduction of two new professions in social and health care: massage therapy professionals and health and social care workers. After attending a vocational training course, these workers' new

responsibility is to help 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, local health units, the NHS and health professionals.

In addition, the 1999 reform also laid out regulation to promote cooperation in public health services. Some of the schemes were directed towards promoting coordination of preventive activities among the district health promotion divisions, general practitioners and pediatricians and other institutions with overlapping tasks. In addition, it foresaw agreements between local health units, hospitals and the Regional Environment Agency (subordinate to 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 had a parallel legislative reform, after being regulated for 110 years based on Crispi's Law of 1890. In November 2000, the parliament, after 4 years of work and discussions, succeeded in passing a general policy law (Law 382/2000) reforming Italy's social care system according to universal principles. The reform provides new benefits for people with difficulties (as defined by article 38 of Italy's Constitution), such as subsidizing the integrated home care system and the service sector (not-for-profit associations, private structures etc.), more financial help for low-income families, more opportunities for disabled people or the institutionalization of the minimum income and of social services charts. The charts are intended as a tool to safe-guard citizens' rights concerning social services. The charts, for instance, have to inform users how to file complaints against the people in charge of providing social services if these people do not respect their rights.

Municipalities, regions and the state 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 in the actual delivery of social services. Regions have planning and policy tasks: for example, they define, based on the state's minimum requirements, 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 (a National Social Fund) and defines the minimum levels of social care (a sort of social benefit package) that every region has to guarantee. Every 3 years, the government, together with local authorities, defines the National Social Plan (according to Law 328/2000, the first National Social Plan is to be issued in November 2001). The National Social Plan 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. The

National Social Plan also implements measures against alcoholism and drug abuse.

### Health for all policy

The main aims of the health for all policy were systematically addressed for the first time within the National Health Plan for 1998–2000. Based on the health for all targets and taking into consideration the previous annual national health status report *(6,7)*, the National Health Plan for 1998–2000 defined explicit targets for health policy. 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 to get the NHS to comply with EU standards.

In promoting healthy behaviour and lifestyles, key aspects have been identified as the main areas for intervention: nonsmoking, 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.

In Italy, as in many other countries, socioeconomic factors play an important role in determining health inequality as well as health-related behaviour. In addition, the existence of deep inequality in health status and in health care by geographical area is of concern, and accordingly, reducing inequality has been included among the main issues dealt with by national and regional planners.

## Reform implementation

### 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 being 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 reducing implementation prospects from the start. In particular, the reform was approved by the National Solidarity coalition, which for the first time included the Communists in central government, who had a leading role in the process of formulating the reform.

By 1979, however, a new government coalition was formed that excluded the Communists and incorporated the Liberals, 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 launching 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 to pharmaceuticals in 1979. The initially modest flat rates were replaced in the early 1980s by a proportional charge on over-the-counter 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.

Real pharmaceutical expenditure still 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 at extending and enforcing 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 the 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. Second, in 1990, the government started to prosecute fraud on exemption cards, by which 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 started to be discussed during 1988–1989. Higher-income groups could opt out from NHS 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 social health insurance countries, by which the upper classes 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 units under democratic control led to the unintended consequences of excessive politicization of the system, inertia and inflexibility, low managerial performance and widespread fraud. Management positions were allotted to partisan cadres with little professional expertise and were divided across party lines and therefore often unable to reach a consensus, and only weakly accountable. In 1986, the government took several steps to counteract these problems by rationalizing the management committees of local health units and reinforcing auditing of their accounting practices. By 1989, plans to professionalize local health unit management were presented in the 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 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 that, in the absence of fiscal decentralization, the central government had to pay. This provided the regions with further incentives to overspend, leading to a vicious circle 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.

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

### The road towards conditional universalism

Ferrera *(8)* 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 NHS with fiscal compensation. This was done under the crisis government formed in 1992 by nonpartisan technical experts led by the former president of the Bank of Italy. Fierce opposition by leftist parties forced the next government to reduce the scope of the clause within the 1993 reform legislation and to delay its 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 unconstitutional submitting compulsory insurance to popular referendum, 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.

### The internal market reforms

Legislative Decree 502/1992, which launched the internal market reforms, allowed the regions to freely set up their own health care system. In particular, since 1992 they have given the power to organize and manage health care services, allocate resources and regulate the number and dimensions of local health units 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 local health units;
- to assign the status of public firms and considerable managerial autonomy to major tertiary hospitals and to local health units, 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 diagnosis-related groups).

The 1992–1993 reform was rapidly implemented in most northern and central regions as well as in some southern ones. Accordingly, the 659 local health units prior to the reforms were reduced to less than 200 in 2000, and 98 hospital trusts 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 diagnosis-related group) 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 local health units and public hospital trusts. 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 departments politically control local purchasing agencies (local health units) 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 departments 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 local health units were responsible for providing health care through directly managed structures and for commissioning care to hospital trusts and private contracted-out providers. In fact, the Italian Competition Authority (AGCM) established in June 1998 that the principle of competition was not being completely respected both because of the dual role of local health units 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 difficulty 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 NHS 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 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, the 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 control hospital costs. In particular, in 1998 Lombardy gave trust status to all regional hospitals and further reduced by two thirds the number of local health units, making them solely purchasing agents 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.

### The quality of health care

In contrast with the lack of adequate central regulation to promote managed competition, the 1992–1993 reform package gave considerable attention to the quality of health care, and the central government implemented the correspond-

ing measures through several decrees issued during the mid- to late 1990s. They were mainly targeted at systematically measuring users' satisfaction as well as guaranteeing patients' rights and greater responsiveness to citizens' expectations. In addition, the 1999 reforms adopted further measures to assess and promote quality.

In 1995, a Legislative Decree launched by the prime minister's cabinet provided for health service charts to improve the relationship between users and health structures and to safeguard citizens' rights in public services. The chart should be established in all health care centres and should inform about the complaint system, quality indicators, waiting times and existing programmes to guarantee health care quality. In March 1998, 93.6% of centres had adopted the charts versus 61.5% in July 1996.

A Legislative Decree further implemented the 1992–1993 package of quality measures by identifying 79 satisfaction indicators to be developed throughout all levels of care in four related areas: personalizing and humanizing care, citizens' information rights, quality of hotel services and disease prevention policies. The indicators of personalized and humanized care include the ability to book appointments by telephone and the percentage of general practitioners who set up out-of-hours services. Citizens' information rights covers the existence of consumer relations offices, the dissemination of leaflets providing information on patients' rights to access inpatient care or the percentage of hospital wards that survey patients and relatives. Examples of indicators of the quality of hotel services are the ratio of toilets to patients and the percentage of rooms with no more than two beds. Finally, preventive policies are assessed through indicators measuring the coverage of screening programmes or the levels of avoidable morbidity and mortality.

## The way ahead: citizens' views on the evolving NHS

Low levels of citizen satisfaction have been one of the most enduring problems of the NHS. In fact, according to a survey financed by the European Commission in 1992, of the 12 EU countries at that time, Italy ranked second (after Greece) in public dissatisfaction with the quality and effectiveness of health care services, although expenditure was at the EU average. During 1992 and 1993, public satisfaction kept falling. Since then, however, satisfaction has increased at a higher than average rate, although partly because the starting level was low. The trends in public satisfaction with the NHS during the 1990s are shown in Fig. 21.

Despite significant progress, Italy was still markedly under the EU average in overall satisfaction with the health care system in the mid- to late 1990s. In

fact, the 1996 and 1998 Eurobarometers reported lower figures than those of the Ministry of Health. According to the Eurobarometer, Italy ranked lowest among the 15 EU countries in 1996, and only 20% of Italians surveyed were satisfied or fairly satisfied with the NHS in 1998. The 1998 figure placed Italy slightly above Portugal and Greece but still far below other national health service countries, such as Spain (40%), Sweden and the United Kingdom (50–55%) or Finland and Denmark (80–90%).

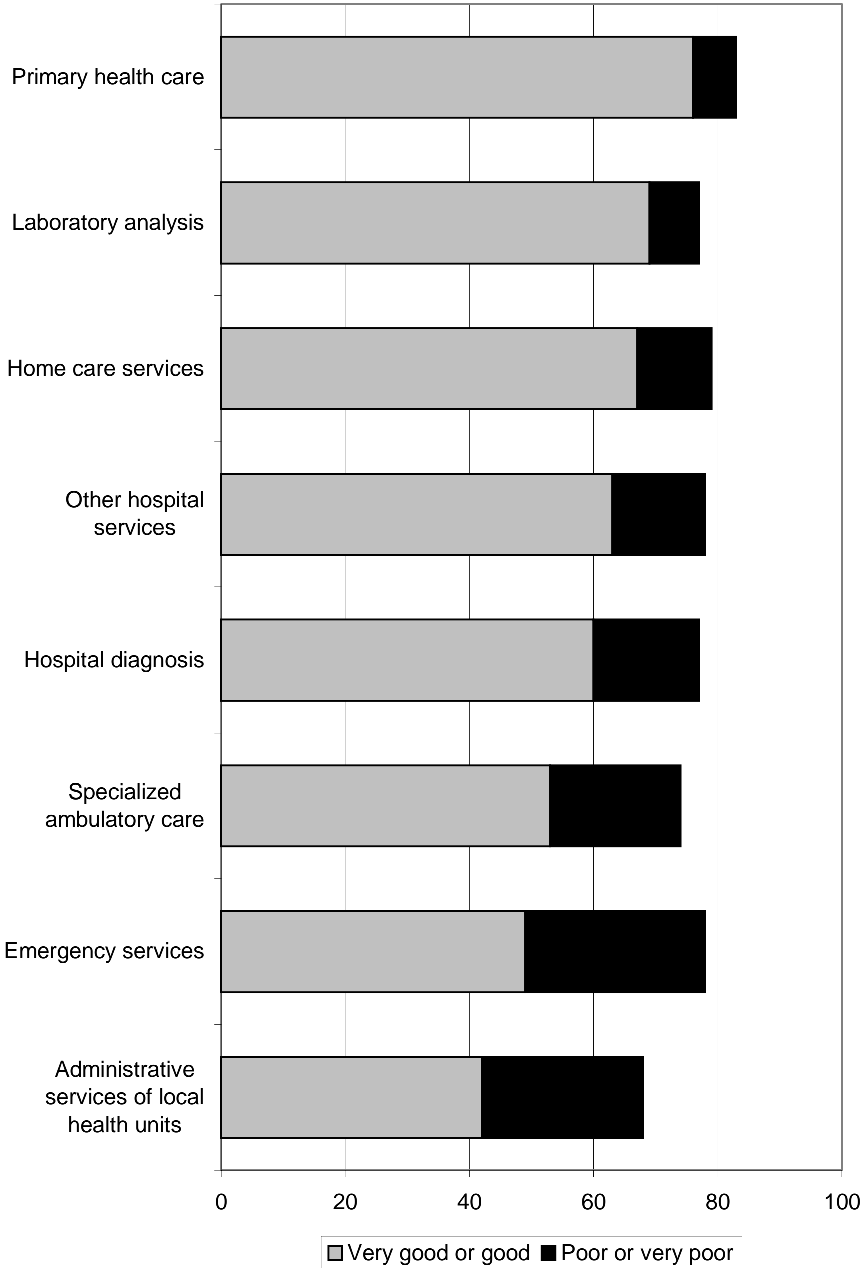
**Fig. 21. Percentage of people surveyed in Italy who said that they considered the NHS "good" or "very good", 1992–1997**

*Source:* Eurisko *(19).*

The picture of general citizen dissatisfaction improved slightly when the Ministry of Health polled the sub-sample of people who actually used various specific services in the past year (Fig. 22). Nevertheless, satisfaction for some critical services was still low. In particular, the main areas of patient concern in the late 1990s (receiving the fewest positive answers) were the administrative services of local health units, emergency services and specialist outpatient care. In addition, more detailed analyses (not shown) indicate problems of access (especially long waiting lists) and poor relationships with health and administrative personnel as the dimensions of service promoting higher dissatisfaction.

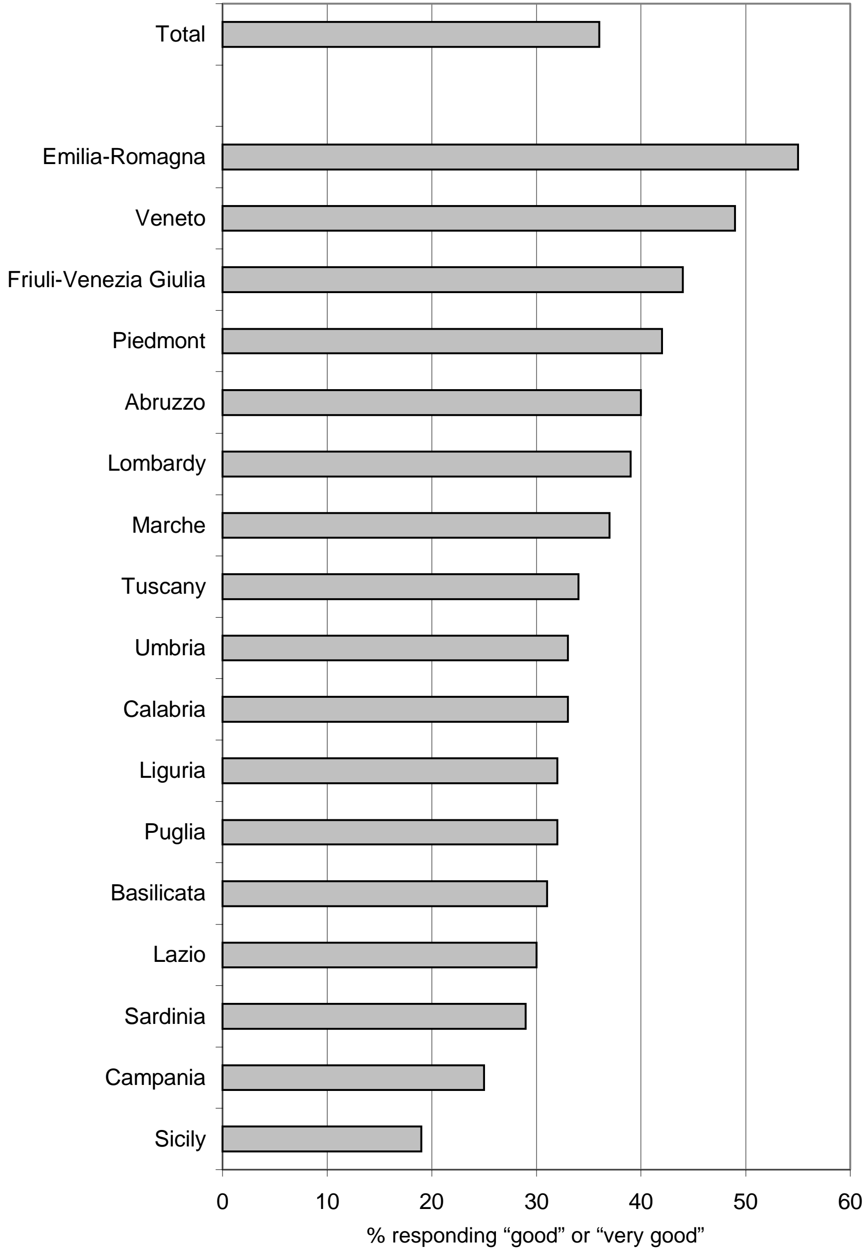
Moreover, satisfaction differs markedly across the north–south divide (Fig. 23). The northern and central regions consistently obtained above-average results, whereas all southern regions are under the average. Eurobarometer provides similar results. As reported by Fattore *(20)*, compared with the national average of 20%, the average percentage of citizens satisfied with the NHS ranged from 25% in the north to 14% in the south.

**Fig. 22. Satisfaction ("very good" or "good" versus "poor" or "very poor") of people surveyed in Italy who had used various NHS services in the past year (%), 1997**




*Source:* Eurisko *(19).*

**Fig. 23. Percentage of people surveyed in 17 regions of Italy who said that they were satisfied (“very good” or “good” versus “poor” or “very poor”) with the NHS according to region, 1997**




*Source:* Eurisko *(19).*

# Conclusions

Italy's health care system has experienced profound transformation during the 1980s and 1990s. The transition to the NHS model initiated in 1978 covered an additional 7% of the population, ultimately guaranteeing all Italian citizens access to a wide range of services, irrespective of their social and economic conditions. This signalled a strong commitment to equity, as a significant effort to increase public expenditure had to be made in a very unfavourable context characterized by considerable political turmoil and a severe economic downturn. In addition, according to available international research, in 1990 Italy compared well with other European countries in equity, ranking high in both the aggregate progressivity of health care financing and the equality of access and utilization levels across income groups.

Some of the critical aims of the 1978 reforms, however, had not been accomplished in the early 1990s. In particular, access was only free at the point of use for inpatient and primary health care, whereas specialist visits, diagnostic services and pharmaceuticals had relatively high co-payments. In addition, the envisaged shift to tax-based financing had only been achieved in part, with payroll taxes still financing about two thirds of total public expenditure for health care in the mid-1990s. A similar implementation gap applied to the expansion of public services, which constitutes a central pillar of the NHS model, as private providers serving both public and private patients received more than 40% of public health care funds in the early 1990s. Most seriously, deficits in public health care resources were still more prevalent in the less developed southern regions, thereby perpetuating a worrying pattern of geographical inequality.

Moreover, some of the most enduring problems of the NHS remained unsolved in the early 1990s *(21)*. In particular, the balance in macroeconomic

efficiency was mixed. Although aggregate expenditure was slightly under average, the results obtained in health status (as measured by perinatal mortality) were considerably under the average OECD levels. In addition, as reported by Ferrera *(8)*, citizen satisfaction was markedly under average in Italy in 1992, with more than two thirds of the population perceiving the quality of the health care system as being poor and 82% agreeing with the statement that "health services available to the average citizen are inefficient and patients are not treated as well as they should be". Similarly, research results obtained for the microeconomic efficiency of Italy's NHS indicate below-average productivity levels in the hospital sector and high pharmaceutical consumption.

Some of these persistent problems have been adequately addressed and significantly alleviated during the 1990s. The significant efforts at containing costs initiated during the 1980s and further developed during the early 1990s yielded positive results: the upward trend in expenditure was reversed, with total health care expenditure as a percentage of GDP actually dropping during the mid-1990s, pharmaceutical consumption declining by 15% and public deficit levels also decreasing rapidly. In addition, public satisfaction with the NHS more than doubled during the same period. Some of these good results can be safely attributed to the measures launched by the 1992–1993 reform, which initiated a deep process of political and financial devolution to the regions and aimed at introducing managed competition within the NHS. The reforms further promoted microeconomic efficiency by delegating considerable managerial autonomy to local health units and hospital trusts, changing resource allocation systems to motivate productivity and enforcing innovative monitoring systems aimed at improving the perceived quality of services and implementing patients' rights.

Similar to the 1978 reform, some of the changes introduced during the early 1990s either were not implemented or produced unintended negative side effects in some domains. First and foremost, the fact that in 1997 most of the complaints to Italy's health care ombudsman were related to perceived problems of access to health services and drugs (60% of them put forward by elderly patients) constituted the first worrying warning. In addition, strict cost-containment policies ended up promoting increased levels of dual coverage. In fact, the share of private expenditure at the end of the 1990s was more than 30% (one of the highest percentages in Europe), and private insurance coverage increased from 5–10% of the population in the early 1990s to about 30% in the late 1990s. The example of co-payments for specialist care, which were 100% subject to a ceiling of €52 from the mid-1990s, illustrates the incentives in place to opt either for direct payment for purely private care or for buying private insurance policies. As Ferrera *(8)* and Fattore *(20)* argued, other radical measures proposed during the period, such as deductibles for higher incomes

or the opting-out clause included within the 1992 reform legislation, touched the very heart of the NHS and provoked strong popular dissent. Finally, the fee-for-service system designed to promote competition among specialist providers and, ultimately, increase productivity, also generated an upward trend in hospital expenditure, which already consumed an above-average share of total public expenditure on health care compared with other EU countries.

Moreover, the purchaser–provider split envisaged within the 1992–1993 reform package was only partly guaranteed, as under the initial institutional design, most hospitals remained under the direct management of local health units, which were also in charge of purchasing. In addition, central regulation did not foresee contractual agreements between purchasers and providers and therefore did not issue the required guidelines to help regions choose their preferred providers. This raised complaints from the Italian Competition Authority, which in 1998 compelled the government to address these issues to guarantee true competition in health care. In addition, important interregional differences developed throughout the implementation of the internal market reforms, which advanced little in some of the southern regions mainly because of the lack of managerial skills and technical support to operate the innovative, private sector-like organizational structures and managerial systems prescribed by central legislation.

The period 1997–2000, in turn, witnessed a series of radical and innovative changes in state institutions and health care regulation. First, political devolution of health care powers to the regions was promoted, and the transition towards fiscal federalism started within the context of a profound transformation of Italy towards a federal state. The fiscal federalism reform undoubtedly represents a step forward in financing health care. The potential advantages and some possible drawbacks have been summarized as follows. On the positive side, the new regional taxes designed to replace payroll contributions are neutral with respect to factor mix and financing structure and therefore unbiased against employment. Further, the tax base is widened, as it is paid by all businesses, whereas it was previously restricted to income earners. On the negative side, as the tax base is unevenly distributed across Italy, substantial equalization transfers will be needed, which might reduce the effective political autonomy of different regions unevenly. In addition, poorer regions will have less room for manoeuvre to increase health care expenditure: in fact, recent International Monetary Fund *(5)* calculations estimated that high-income regions can increase revenue by up to 23.5%, whereas low-income regions can only increase them by 8%. An even more serious drawback is that, to obtain an equivalent cash increase, lower-income regions will have to raise tax rates more than higher-income regions, which will introduce negative incentives for business location and might, accordingly, hinder economic development prospects in the more

disadvantaged regions. Moreover, the higher reliance on indirect taxes envisaged in current legislation will make overall health care financing more regressive.

Second, in 1998 the parliament asked the central government to launch new reform legislation to accommodate the new federalist framework and further regulate the health care sector. As a result, the third reform of the NHS was approved in 1999, which represents one of the more ambitious attempts in Europe to produce a detailed regulatory framework that could guarantee adequate levels of health care quality, efficiency and equity without curtailing the political and managerial autonomy transferred to local actors.

Three components of the 1999 reform merit special mention: the first steps towards defining a core benefit package that all regions should guarantee as well as the system designed to monitor implementation at the regional level; the regulation of the steps to be followed by regions and local health units to guarantee institutional accreditation to their preferred public and private providers; and the exhaustive provisions aimed at promoting and monitoring the quality of care. Finally, the 1999 reform also envisaged eventually abolishing most co-payments from 2001 onwards and a set of parallel measures to guarantee fair competition between publicly funded providers and private ones.

Given how recent these reform measures are, however, there still is a great deal of uncertainty surrounding the actual likelihood and feasibility of the subsequent implementation process. So far, a positive list of benefits has only been detailed for outpatient specialist care and pharmaceuticals. In all other areas, and especially regarding hospital health care, diverging views still exist on how the list should be drawn up and whether this should be negative or positive. In this sense, current regulations only suggest a set of criteria: ineffective, inappropriate or inefficient procedures should be excluded as well as those that do not satisfy basic health care needs. Some uncertainty also exists on how detailed the list should be: broad guidelines within which physicians could choose the most appropriate treatment or a more detailed list of mandatory condition–treatment pairs. In addition, the monitoring system aimed at guaranteeing implementation of the benefit package and fulfilling quality standards at the local level still needs to be defined, a task that can prove difficult to achieve until the services to be included in the essential benefit package are clearly specified. In addition, it is still unclear which authority will be responsible for verifying the working of the monitoring system and the degree to which the set parameters have been respected.

The main perceived difficulties within institutional accreditation, selection and monitoring of providers are related to the potential interregional inequality that might develop. In this respect, existing evidence indicates that the organizational arrangements established by regions to control local health units

and providers, as well as the intensity and effectiveness of control mechanisms, vary considerably from region to region. This is in accordance with the more general, marked differences in government performance across regions found by previous research.

In sum, both the 1992–1993 and the 1999 reforms involved a profound process of decentralization of the NHS, both by devolving political and financial authority to the regions and by delegating considerable managerial autonomy to lower-level purchasing and providing organizations. This creates the need for a new regulatory framework that radically transforms the institutional rules of governance and simultaneously enables state authorities to adequately perform a new "hands-off" control role. The legislation adopted during the late 1990s addressed many of the crucial issues, such as guaranteeing political accountability over financial management, controlling pharmaceutical expenditure, training health personnel, and accrediting and regulating health care providers. However, some critical areas still have not yet been either addressed or fully regulated, such as reaccreditation of health care professionals, utilization review and clinical management. Most critically, it is still not clear to what extent the available institutional mechanisms will be able to guarantee the basic benefit package and a similar quality of health care across the regions.

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# Web resources

## National and regional institutions

Ministry of Health: http://www.sanita.it/sanita
National Institute of Health: http://www.iss.it/laboratori/index.htm
Agency for Regional Health Care Services: http://www.assr.it
Abruzzo region: http://www.regione.abruzzo.it/sanita/servizi.htm
Basilicata region: http://www.regione.basilicata.it/Regione_informa
Calabria region: http://www.regione.calabria.it/regione/regione1.html
Campania region: http://www.regione.campania.it
Emilia-Romagna region: http://www.regione.emilia-romagna.it
Friuli-Venezia Giulia region: http://www.regione.fvg.it
Lazio region: http://www.regione.lazio.it/internet/index.htm
Liguria region: http://www.regione.liguria.it/menu/0901_fr.htm
Lombardy region: http://www.sanita.regione.lombardia.it
Marche region: http://www.regione.marche.it/index.asp
Molise region: http://www.molisedati.it/homepage.htm
Piedmont region: http://www.regione.piemonte.it
Puglia region: http://www.regione.puglia.it
Sardinia region: http://www.regione.sardegna.it/ital/sanita/sanita.htm
Sicily region: http://www.regione.sicilia.it/sanita/index.htm
Tuscany region: http://www.rete.toscana.it/index.htm
Umbria region: http://www.regione.umbria.it/sanita
Valle d'Aosta region: http://www.aostavalley.com/REGIONE/index.html
Veneto region: http://www.regione.veneto.it/home/sanita.htm
Autonomous province of Bolzano:
http://www.provinz.bz.it/sanita_servizisociali.htm
Autonomous province of Trento: http://www.provincia.trento.it/menu.htm

## Regional health agencies

Campania region: http://www.arsan.campania.it
Emilia-Romagna region: http://www.regione.emilia-romagna.it
Friuli-Venezia Giulia region: http://www.sanita.fvg.it/present/pres.htm
Lazio region: http://www.regione.lazio.it/internet/index.htm
Marche region: http://www.ars.marche.it
Piedmont region: http://www.regione.piemonte.it
Tuscany region: http://www.rete.toscana.it/index.htm