3.3. National health policy at EU level

During the 2012-2013 two-year period, Italy made a significant contribution to training initiatives on EU health-related law, particularly through constant and authoritative participation in political and technical talks dealing with health issues concerning various different sectors: general health policy strategies, cross-border threats to human health, antibiotic-resistance, organ donation and transplantation, smoking, clinical trials, medical devices and *in vitro* diagnostics, human medicines, European healthcare and National Health Service.

In addition to the sectors mentioned, Italy has also contributed to other technical areas in which the authorities have launched an evaluation process that is destined to be further developed in the years to come: childhood overweight and obesity, complex childhood disorders, including autism, hospital-acquired infections, mental health and wellness, vaccines and food labelling.

3.4. European-Mediterranean partnership projects

The 2012-2013 two-year period was a time of growth and maturation for the European-Mediterranean partnership projects.

Italy consolidated its role in the protection of health on an international level with its work to favour improvements in the health services and healthcare provided in the Mediterranean area, consistently with the goals set by the Union for the Mediterranean, through the management and, where necessary, the establishment of technical and scientific networks between participating centres and the National Health Services of the participating countries.

A number of public health projects were supported over the two-year period. The two projects in the oncology field (screening and early diagnosis, tumour registers) involved very close and constructive cooperation with the WHO, such as to allow the involvement of players from the various countries effectively involved in screening campaigns and in the implementation of Tumour Registers. Amongst the other projects it is appropriate to mention the transplant project, the "AMI Register" on acute myocardial infarction, the coeliac disease project, the "EpiSouth Plus" project, the respiratory insufficiency project and the project on female and paediatric health.

3.5. Bilateral health cooperation activities

In recent years, the Italian Ministry of Health has intensified its relations with other countries by stipulating and implementing bilateral health cooperation agreements. In the 2012-2013 two-year period, bilateral activities focussed on the geographical areas considered as priorities. The partnership with the People's Republic of China was further developed to compare the respective National Health Services and provide a model for the implementation of the Chinese health reform. In addition, two memoranda of intent were drafted (the first concerning controls on food products, pharmaceuticals, medical devices and cosmetics; the second concerning organ transplants).

A memorandum of intent was signed with the Russian Federation for cooperation in those sectors in which Italy holds a leadership position.

In the Mediterranean area, bilateral cooperation primarily concerned Malta, Tunisia and Libya and a forefront role was played by the regional authorities, in particular Lazio, Lombardy, Tuscany and Umbria.

The bilateral agreement with Tunisia was implemented with initiatives in the prevention, lifestyle promotion, female and paediatric health protection, haematology and environmental health fields.

A programme was launched with Libya to provide care for injured persons and AIDS/HIV-infected patients.

A memorandum of intent was drafted with Mexico for cooperation in the health technology and prevention sector.

The Ministry also participates in the EU-funded technical cooperation programme Eurosocial II.

A joint statement was signed with Liberia identifying three areas for cooperation: the improvement of health services, staff training and the prevention of HIV/AIDS infection.

Lastly, an important memorandum of intent was signed with the Republic of San Marino.

3.6. International food safety and veterinary activities

International food safety and veterinary activities are carried out, on the one hand, based on a partnership with international bodies and participation in work within the EU and, on the other hand, on the negotiation of health-related agreements with the authorities of non-EU countries to favour the exportation of animals and food products to international markets.

In order to protect the health of Italian consumers and the welfare of our livestock, in May 2013,the Ministry and the ten Experimental Animal Welfare Institutes signed a partnership agreement, with the OIE (*Office International des Epizooties*) aimed at reinforcing animal health monitoring activities and food safety programmes, particularly in the Mediterranean area.

As regards animal disease control, in 2012, the Global Steering Committee of the Global Frameworks for the Progressive Control of Transboundary Animal Diseases (GF-TADs), in which Italy participates as funder of the OIE's World Fund, adopted a five-year plan of action that involves, amongst other things, a significant boost to the previously mentioned campaign for the eradication of foot and mouth disease and the continuation of the fight against the small ruminant fever, rabies and Rift Valley fever. The Europe Region GF-TADs also adopted its five-year plan of action, concentrating, in particular, on the fight again African swine fever, which represents a significant concern for the EU, given the presence of the disease in Russia and the Caucasian area.

Thanks, once again, to its participation in the OIE's World Fund, Italy made an important contribution to the work of REMESA (*REseau MEditerranéen de Santé Animale*) by supporting the African Sub—regional Centre in Tunis, thereby protecting our southern borders from problems relating to the north coast of Africa and migration.

On a European level, it is important to highlight the role played by the European Food Safety Authority (EFSA) in the assessment of the risks relating to the safety of food, fodder and animal health and welfare. In the 2012-2013 period, the EFSA adopted more than 1,000 evaluations and opinions and, in order to compare and share the experiences of national experts and those of EFSA, the Ministry of Health organised various workshops in both Parma and Rome.

In the technical cooperation and negotiation of health certificates field, in the 2012-2013 period, the Department signed 2 new cooperation agreements in the veterinary sector (Lebanon and Mongolia) defined 65 new health certificates and amended/updated 37 existing health certificates, all of which were duly published on the Ministry's website.

Lastly, a definite increase in Italian exports was achieved thanks to the accomplishment of two important results: Italy was recognised by the OIE as a country with a "negligible risk" of bovine spongiform encephalopathy (BSE) and the United States acknowledged the macro region of northern Italy as being a swine vesicular disease-free area.

3.7. International pharmaceutical sector activities

The international work of *Agenzia Italiana del Farmaco* (Italian Medicines Agency, AIFA) aims to fortify Italy's role at the European and global level. European regulations on active substance control, pharmacovigilance, clinical trials and transparency concerning the reimbursement and price of medicinal products were discussed and approved. AIFA's cooperation with the European Medicines Agency (EMA) took the form of the implementation of shared activities in the pharmacovigilance, medicinal product innovation and scientific research for the treatment of rare diseases fields. AIFA made a special commitment to the EMA's scientific committees and scientific advices work group. The work groups dealing with Health Technology Assessment (HTA) and the active presence in the network of authorities competent in medicinal product pricing and reimbursement also deserve a mention. AIFA participates in the activities of the Council of Europe, performing evaluations on conformity with quality requirements and performing inspections all over the world on behalf of the European Directorate for the Quality of Medicines

and Healthcare (EDQM). The contribution from and the partnership with the European Centre for Disease Prevention and Control (ECDC), concerning counterfeit medicinal products are also worthy of note; in particular the contribution from the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI). As part of the European project Access to Medicines in Europe, AIFA coordinated the work on Managed Entry Agreements, as a leading country in the structuring of forms of conditional reimbursement for medicinal products, to guarantee healthcare service sustainability. AIFA's international activity involved the signing of bilateral agreements, inclusion in international coalitions, such as the International Coalition of Medicines Regulatory Authorities (ICMRA), its contribution to the WHO's international consensuses, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspections Co-Operation Scheme (PIC/s).

Keywords Active pharmacological ingredient, *Agenzia Italiana del Farmaco* (AIFA), clinical trials, European Centre for Disease Prevention and Control (ECDC), European directives, European Directorate for the Quality of Medicines & Healthcare (EDQM), European Medicines Agency (EMA), Health Technology Assessment (HTA), international activities, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Managed Entry Agreement, medicinal product innovation, medicinal product prices, pharmacovigilance, scientific advice, World Health Organisation (WHO)

3.8. International medical device activities

The medical devices sector in Europe is of key importance to healthcare, contributing to improving the level of health protection through the development of innovative solutions for diagnosis, prevention, treatment and rehabilitation.

The European regulatory framework in this sector is undergoing a profound overhaul: the competent authorities in conjunction with the European Commission are making every effort to implement legislation that aims specifically to improve patient safety and that, at the same time, creates a sustainable legislative framework that promotes medical device innovation.

The General Directorate for medical devices, pharmaceutical service and treatment safety is taking an active role in reviewing directives in cooperation with the Commission and other member states. The Regulations originate from the need to implement legislation to improve patient safety and, at the same time, to create a sustainable legislative framework that promotes medical device innovation. These actions can be summarised as follows:

- clear and simple rules, well-defined requirements and responsibilities and transparent decision-making processes;
- centralised databases and data available to the public concerning information on manufacturers/ authorised representatives, medical devices, clinical investigations, corrective field actions;
- use of modern computerised tools and Unique Device Identification (UDI), traceability and safety databases;
- information on the regulatory framework for medical devices and on other regulations/ laws that can have an impact on device manufacturers and on other players;
- product classification across various sectors (borderline with other products such as pharmaceuticals, cosmetics, foods, biocides, etc.).

The draft regulations are currently being discussed by the Council (Council Working Party) and the European Parliament.

Keywords *In vitro* medical and diagnostic devices, medical devices, regulations

The health of the population

1. Demographic structure, quality of life and mortality

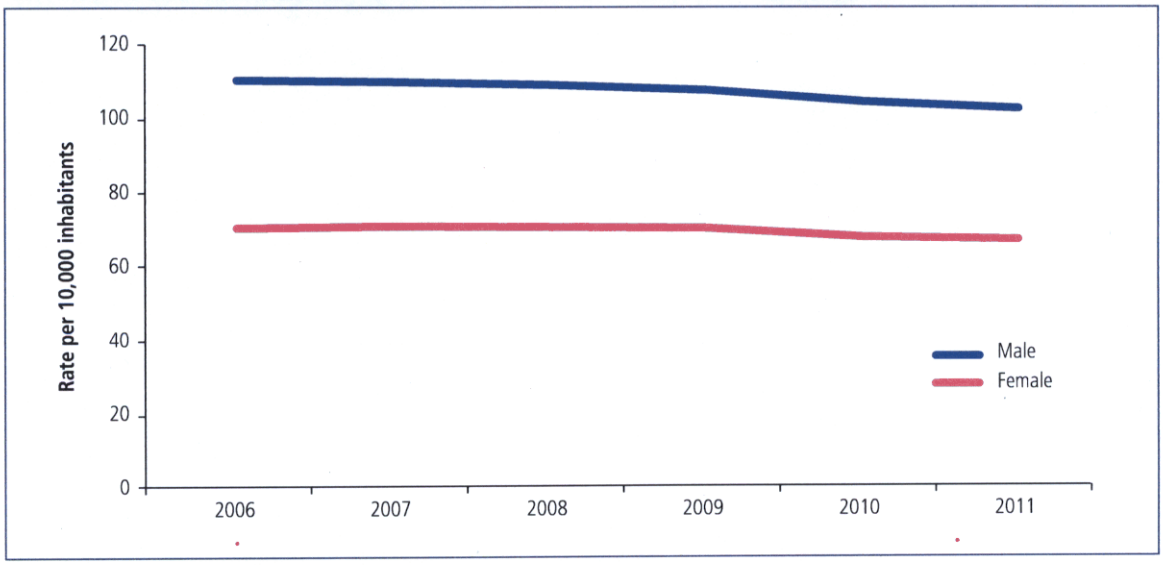
1.1. Structure and demographic dynamic

The 15th census of the population and homes was conducted on 9 October 2011 and shows a new legal population of 59 million, 433 thousand residents. Almost two years later, on 1 January 2014, the resident population is over 60 million (60,782,668 units). During 2013, the natural dynamic (difference between births and deaths) shows a negative balance of almost 86,000 units, as a result of 514 births against 600,000 deaths. The migratory balance is equal to almost 1 million 200 thousand units, thanks to the over 3 million new registrations and almost 2 million cancellations. There is a continuation in the ageing of the Italian population, which on 1 January 2013 had an ageing index of 151.4%. The over-65s now account for 21.2% of the population and youngsters up to 14 years of age for 14%, meaning that the active population, aged 15-64 years, is less than two thirds of the whole. On 1 January 2013, the foreign population resident in Italy amounted to almost four and a half million individuals, i.e. 7.4% of the total population, compared to 6.8% on 1 January 2012, with an increase of 335,000 units. Over the past decade, there has been a consistent increase in the presence of foreigners in Italy: on 1 January 2012, it was less than one and a half million people. Over about 10 years, foreign residents have increased by 3 million individuals, more than 200%. The foreign population belonging to the 18-64 years age group accounts for 74.9% of all foreign residents. The proportion of elderly subjects (over 65) is very low, with a percentage of less than 3%. The proportion of youngsters, on the other hand, is 22%.

1.2. General mortality and life expectancy

Since the start of the 1900s, significant progress has been made in Italy in improving the state of health and the most indicative consequences are undoubtedly the reduction in mortality levels and the gradual increase in life expectancy. In 2012, Italy had one of the highest life expectancies at birth (79.6 years for men, 84.4 years for women) in Europe, several

Figure. Standardised mortality rates (per 10,000 inhabitants) of the residents in Italy by gender (Years 2006-2011).



Standard population: Italian population at the 2001 census.
Source: Istat. Survey of deaths and causes of death– Year 2006-2011.

Table. Life expectancy at birth and at 65 years by Region of residence and gender (Year 2012)

Region	Life expectancy at birth a_0		Life expectancy at 65 years a_{65}	
	Male	Female	Male	Female
Piedmont	79.6	84.4	18.3	21.8
Valle d'Aosta	79.6	84.3	18.9	21.9
Lombardy	79.9	84.9	*18.4*	*22.1*
Liguria	79.4	84.4	*18.3*	*22.0*
Trentino Alto Adige/South Tyrol	80.7	85.5	19.2	22.7
Bolzano/Bozen	*80.6*	*85.0*	*19.2*	*22.3*
Trento	*80.8*	*85.9*	*19.3*	*23.1*
Veneto	80.1	85.1	18.6	22.3
Friuli Venezia Giulia	79.3	84.7	18.2	22.2
Emilia Romagna	80.2	84.9	18.7	22.2
Tuscany	80.1	84.8	18.7	22.0
Umbria	80.1	85.1	18.8	22.2
Marche	80.6	85.3	19.0	22.5
Lazio	79.1	83.8	18.2	21.4
Abruzzo	79.6	84.6	18.5	21.9
Molise	79.5	84.5	18.6	22.1
Campania	78.0	82.8	17.3	20.6
Puglia	80.0	84.5	18.6	21.8
Basilicata	79.9	84.3	18.7	21.7
Calabria	79.2	84.0	18.3	21.6
Sicily	78.8	83.2	17.8	20.7
Sardinia	79.1	84.8	18.4	22.2
Northwest	**79.8**	**84.7**	**18.3**	**22.0**
Northeast	**80.1**	**85.1**	**18.6**	**22.3**
Centre	**79.7**	**84.4**	**18.5**	**21.8**
South	**79.1**	**83.8**	**18.1**	**21.3**
Islands	**78.9**	**83.6**	**18.0**	**21.1**
Italy	*79.6*	*84.4*	*18.3*	*21.8*

Source: Istat.http.//demo.istat.it/ – Year 2012.

places above the European average. Since the second half of the 1990s, the gap between the two sexes has closed and, in the most recent year available, was less than 5 years.

A significant contribution to the increase in mean life expectancy can be attributed to the significant reduction in infant mortality. Death in fact occurs at an older age and the likelihood of death in the first year of life is increasingly slight. The infant mortality rate until 1910 was at levels that are now recorded in the world's poorest countries (approximately 150 deaths per 1,000 live births). Italy today has one of the lowest infant mortality rates: the rate in 2011 was 3.1 per 1,000 resident live births (1,691 deaths in the first year of life, compared to 546,585 live births).

In 2011, the total number of deaths amongst Italian residents had an absolute value of 590,612, with a crude rate of 10 deaths per 1,000 residents. Between 2006 and 2011, mortality, measured using standardised mortality rates, declined. For men, it dropped from 113.8 deaths per 10,000 inhabitants to 105.1 (–7.7%) and for women from 69.3 deaths per 10,000 inhabitants to 65.6

(–5.3%). The drop in Italy's mortality rate over the five-year period considered is the result of a drop that affected all Regions of the country. The difference in the extent of the reductions between different areas has increased the difference between mortality levels in the different Regions.

Keywords Average life, infantile mortality, life expectancy, life expectancy, mortality

1.3. The quality of survival and international comparisons

Europe continues to age: the population's average age is rising and there is an increase in the proportion of the population aged over 65 (from 17.1% in 2008 to 17.8% in 2012). One in five Italians is now over 65. Demographic scenarios suggest that the population will age further, with a consequent impact on health expenditure and economic and social policy. This impact will be less the more the increase in age is accompanied by an increase in the number of years lived in good health. In this study, it was decided to use life expectancy without limitations in the activities of daily living as an indicator of good health conditions, in that this measurement is available for all EU countries

Between 2008 and 2011 the increase in life expectancy in Europe (+1 year in men and +0.8 years in women) was greater than the increase in life expectancy without limitations in the activities of daily living (+0.6 years for men and unchanged for women). Italy undoubtedly occupies one of the most favourable positions, with one of the highest mean life expectancies in Europe. However, in 2011, the percentage of years lived without severe or moderate limitations in the activities of daily living is slightly lower than the mean European level (79.7% in men and 74.8% in women); in Italy, this percentage is 79.2% and 73.5% of life years, respectively.

Mean life expectancy over 65 years in Italy is one of the highest in Europe and in 2011 it reached 18.8 years in men and 22.6 years in women. Amongst men there was also an increase in mean life expectancy without limitations (from 7.6 to 8.1 years), whereas in women it remained largely unchanged (from 7 to 7.1 years). However, despite its high survival data, Italy seems to suffer a poorer quality of years lived, with values lower than the European average, similar to those of Cyprus (8 years) and Austria (8.3) for men and those of Slovenia (6.9 years) and Croatia (7.1 years) for women.

Keywords Life expectancy, restrictions in activities of daily living, survival

1.4. Health conditions: chronic illness and perceived health

Chronic diseases represent one of the biggest challenges for public health in all countries. Amongst the factors that determine these diseases, some are behavioural and can therefore be measured by the promotion of healthy lifestyles, others are genetic and others still pertain to socioeconomic and environmental aspects, which can also be removed through policies that are not purely health-related. At the same time, chronic diseases are responsible for many of the persistent inequalities in health, showing a significant socioeconomic gradient and considerable differences in gender in their diffusion; the impact that these conditions have on quality of life and perceived wellness on an individual level is also significant. According to the results of the last survey on the "Conditions of health and use of healthcare resources", conducted in 2013, 14.7% of the population stated that it had at least one severe chronic illness. This percentage is only increasing due to the effect of the population's ageing. Perceived health (one of the main indicators of subjective health that is recognised on an international level for its capacity to reflect conditions that are closely related to survival and the demand for healthcare resources), has not undergone significant changes over time. In 2013, the age-adjusted prevalence of those claiming to be ill or very ill remains stable at 7.3% in the population over 14 years of age and at 20.1% amongst the elderly; however, there has been an increase in the differences between genders, to the detriment of women, that were already considerable in 2005. Compared to the same year, there has been an improvement in physical health and a worsening in mental health. Persisting social and geo-

graphical inequalities penalise certain groups of the population, in particular the elderly in the south of the country.

Keywords Chronic illnesses, chronicity, perceived healthsocial inequalities

1.5. Causes of death

Mortality is a fundamental indicator for measuring the state of health of a population and mortality broken down by cause, in particular, makes it possible to describe the role of the various medical conditions. The indices presented were processed using official Istat mortality and population data. The most recent data available (that for 2011), classified using the ICD-10 system, was used. The following are presented: absolute number of deaths, crude and age-adjusted mortality rates, broken down by cause of death, analysed according to gender, age and Region of residence. Chronic degenerative diseases, associated with the known process of ageing of the Italian population continued to be the main causes of death: circulatory diseases and cancer combined have for a number of years now accounted for two thirds of deaths (68% in men and 66.4%% in women); however, whilst amongst men the weight of the two causes is equal (34% each), amongst women circulatory diseases exceed cancer by far (41% versus 25%). Respiratory diseases are the third cause, for both men and women (8% and 6%, respectively), followed for men by violent causes (5%) and by endocrine diseases for women (5%). The analysis according to Region of residence for large groups of causes shows significant differences; in terms of cancer deaths, the North of the country is in a critical situation: amongst men all the Regions with a mortality rate that is higher than the national mean are in the north (however Lazio, Campania and Sardinia are also present); for women, all the Regions with a situation that is less favourable than the national average are in the Nord (plus Lazio). Mortality for circulatory causes also has a clear geographical trend, with the south in a less favourable position, both for women and men; all the Regions with a mortality rate higher than the national average are in the south of the country (plus Lazio for both genders and Umbria for men alone). There is a critical situation in Campania, in terms of both general mortality and in many causes of death.

Keywords Cancer, circulatory diseases, mortality, territorial differences

1.6. The impact of disease

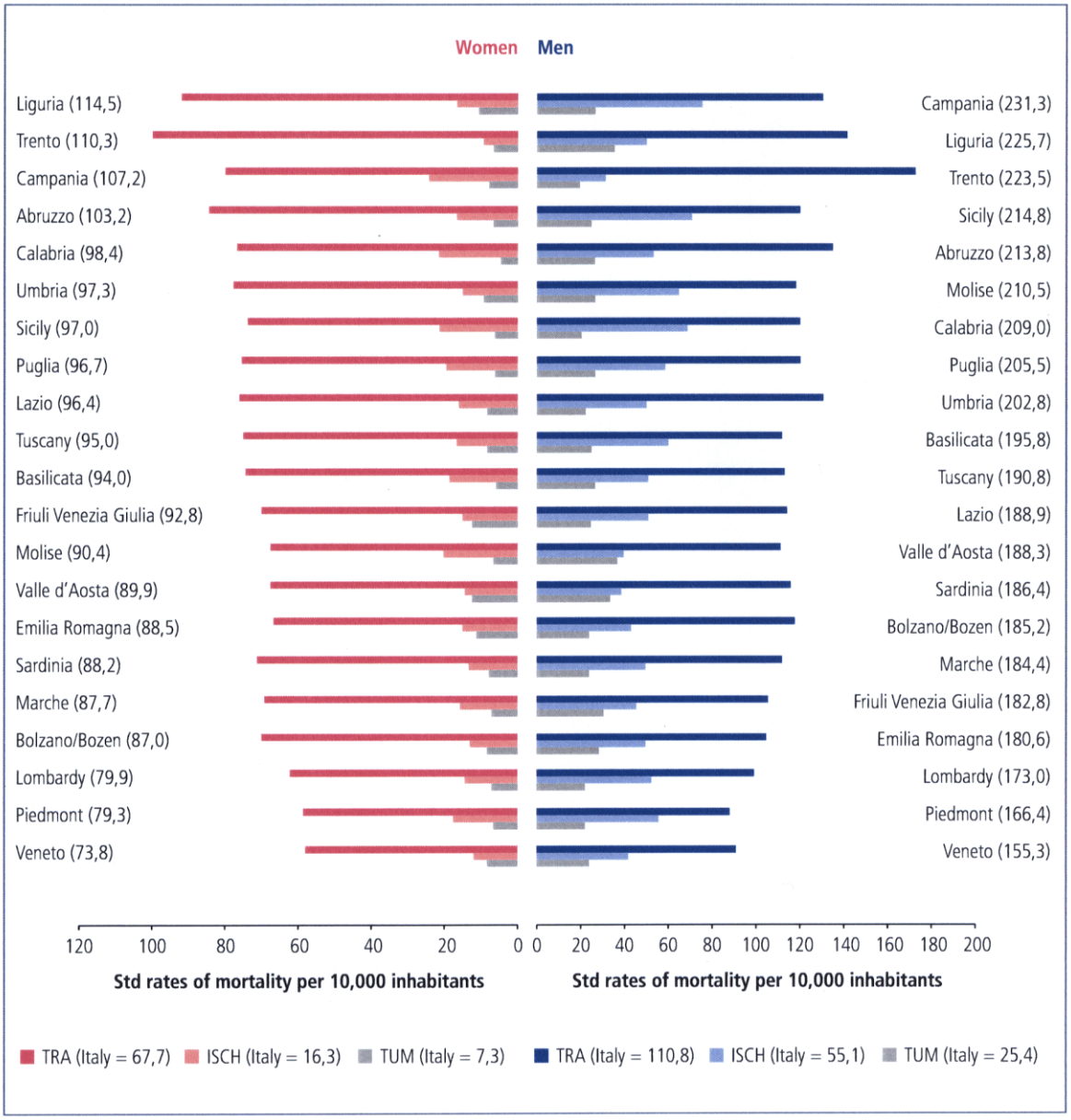
The data obtained from current information flows, such as mortality by cause and Hospital Discharge Register constitute important sources of complete, certified data that is made available at no "additional charge", for the monitoring of the impact of disease for public health and healthcare programming purposes.

By duly processing the data obtained from the aforesaid sources, two phenomena in particular are described in this chapter: avoidable death and the hospitalisation that could be averted with primary prevention initiatives to be implemented in the health service activities planning phase.

A cause of death is defined "avoidable" when interventions exist that are known to reduce the number of deaths that can be attributed to it, considering the 0-74 years age group. Avoidable death is split into three categories, according to the type of intervention able to prevent its causes: primary prevention, early diagnosis and treatment and hygiene and medical intervention. The first category includes those causes that could be effectively avoided or countered by adjusting lifestyles (such as diet, smoking and alcohol addiction), as well as by implementing effective prevention campaigns for violent deaths (e.g. those caused by road accidents). This category is of particular interest as it represents the largest portion of the avoidable death category (two thirds of the total for men and more than one third for women). The concept of causes that are "avoidable/preventable" using primary prevention interventions devised for mortality can, with certain precautions, be transferred to morbidity and, in the particular case of this publication, hospitalisations.

Even in the presence of a downward trend, once again in 2011 the deaths attributable to causes that could have been avoided with primary prevention interventions amount to just

Figure. Potentially preventable hospitalisation through primary prevention by Region of residence and gender (standardised rates per 10,000) [values of the total rate per 10,000] (Italy – Year 2011).



Source: Istat data processed by the Istituto superiore di sanità.

less than 50,000 and in the same year there were more than 750,000 hospitalisations for the same group of causes.
The chapter presents data on mortality and avoidable hospitalisations broken down according to gender and geographic distribution.

Keywords Avoidable death, avoidable hospitalisations, primary prevention

2. Diseases

2.1. Cardio- and cerebrovascular diseases

Cardio- and cerebrovascular diseases are some of the main causes of morbidity, disability and mortality.
An individual who survives an acute event becomes a chronic patient with significant repercussions on his/her quality of life and on economic and social costs; moreover, cardio-

and cerebrovascular illnesses are amongst the determinants of age-related disease.
The WHO's 2013-2020 Global Action Plan and the National Prevention Plan (NPP) include cardio- and cerebrovascular diseases amongst those to be monitored and included in prevention actions, in that they can to a large extent be prevented through the adoption of correct lifestyles.
In 2010, there were a total of 220,539 deaths caused by circulatory diseases; of these, 72,023 deaths were attributed to ischemic heart disease and 60,586 to cerebrovascular diseases. In humans, mortality due to ischemic heart disease begins to occur between 40 and 50 years of age before exponentially increasing with age; in women, from 60 years of age, rising rapidly after 70.
The weight of cardiovascular diseases on hospital admissions is on the rise. All the data available confirms that hospitalisations, invalidity and impairment increase with age.
The conditions most commonly at risk are arterial hypertension and hypercholesterolaemia.
Greater knowledge has made it possible to devise instruments for the global assessment of cardiovascular risk. Results confirm that the knowledge and support of healthcare professionals, combined with community prevention actions, can be useful for reducing and maintaining a favourable risk profile in the population. Prevention and the gradual increase in the percentage of the population at low risk represent the essential condition for defeating the cardio- and cerebrovascular disease epidemic.

2.2. Cancer

It is essential to know the territorial distribution and current trends of incidence, mortality and survival of cancer patients in order to establish healthcare programming aimed at improving cancer control.
Information on mortality is available from official Istat statistics. Data on incidence, survival and prevalence is provided by the Italian Cancer Register Association (AIRTUM), which record the details of all cancer patients living in a given area on the basis of medical or administrative sources. The AIRTUM database is used by the *Istituto superiore di sanità* [National Institute for Health] which, in association with other research centres, provides regional estimates for those types of cancer that have the greatest impact on the population.
The Ministry of Health and Regional authorities use the evidence available to guide their programme and to organise the healthcare system with a view to reducing the cancer risk, making management of the disease more efficacious, from the diagnostic to the follow-up phases and reducing geographical inequalities. Prevention planning includes both secondary and primary prevention interventions and within this context cancer screening programmes represent a fundamental pillar.
The most common type of cancer amongst men is prostate cancer, and the most common type amongst women is breast cancer; current trends indicate: a significant reduction in cancer of the stomach, lung cancer in men and cervical cancer in women; a constant increase in bowel cancer amongst males and in breast cancer amongst females; a stabilisation in the incidence of prostate cancer and of bowel cancer in women.
In 2011, cancer represented the first cause of death amongst men and the second amongst women (175,000 deaths); mortality dropped for all the most common types of tumour, except for lung cancer in women.
Survival five years from diagnosis for all types of cancer is 60% in women and 52% in men. Amongst the most common cancer sites, those with the best prognosis are prostate, breast and bowel cancer, whereas lung cancer has the worst prognosis.
In 2013, in Italy it is estimated that more than 660,000 women had been diagnosed with breast cancer at some time in their life time, that approximately 340,000 men had been diagnosed with prostate cancer and that more than 390,000 individuals had been diagnosed with bowel cancer.

2.3. Diabetes mellitus

Diabetes mellitus, together with its complications, represents a health issue of paramount importance. It is estimated that in

2013, in Italy, the prevalence of diabetes was 5.4%, equal to over 3 million individuals. Type 2 diabetes mellitus (T2DM) is often associated with a condition of socioeconomic disadvantage, with a higher prevalence amongst people with no academic qualifications and with economic difficulties. T2DM is also related to the presence of certain alterable risk factors, in particular overweight and a sedentary lifestyle. The organisational quality and efficiency of diabetes treatment are related to a better control of the disease. The fight against diabetes must, therefore, include both the promotion of correct lifestyles in the population and the prevention of chronic diseases in general, and the reorganisation of the healthcare aimed at preventing or delaying the onset of complications. Italy has therefore dealt with the issue of diabetes and of chronic diseases in general through: the drafting of the Diabetes Plan, which aims to harmonise regional measures and activities, by providing instructions for: the strengthening of prevention and healthcare; the development of the "*Guadagnare Salute*" (Better Health) programme, which promotes the adoption of healthy lifestyles by the population through the implementation of intersectorial dynamics with the participation of the various stakeholders; the implementation of the NPPs, which have involved regional projects and programmes to promote the adoption of multidisciplinary management programmes; the organisation of the IGEA project (Integration, Management and Assistance for Diabetes), aimed at coordinating and supporting the regional NPP projects for a multidisciplinary management of diabetes.

Keywords Diabetes, diabetes mellitus, Diabetes plan, "*Guadagnare Salute*", Healthcare, IGEA project, lifestyles, National Prevention Plan, risk factors

2.4. Chronic respiratory diseases

Chronic respiratory diseases are amongst the primary causes of morbidity, disability and early mortality and they have a high socioeconomic impact. Those of greatest interest in terms of public health are chronic obstructive pulmonary disease (COPD) and asthma. The 2006-2008 National Health Plan and the 2010-2012 NPP included chronic respiratory diseases amongst the priority areas of intervention.

In 2004, on an international level the Global Alliance against chronic Respiratory Diseases (GARD) was created; the Ministry of Health participated in this initiative and in 2009 it created GARD Italy (GARD-I).

The data available shows that over the past few decades there has been a general increase in respiratory symptoms/diseases in the Italian population. Asthma has reached a prevalence of 6-8% in samples of the general population and in young adults; 9-10% of children suffer from asthma. Epidemiological studies indicate that COPD is diagnosed in 10.4% of the population and airway obstruction has a prevalence that varies between 20% and 47%. Chronic respiratory diseases in the general adult population are a common condition that considerably worsens quality of life, in terms of the state of physical, mental and functional health.

The condition of individuals with chronic respiratory diseases is susceptible to great improvements for all the factors considered.

2.5. Rheumatic and osteoarticular conditions

Musculoskeletal diseases are a heterogeneous group of conditions that range from arthritis to osteoarthritis, osteoporosis, rheumatoid arthritis and neck pain. These are chronic invalidating diseases with important repercussions on the individual's social life. They share the pain symptoms in the joints and affect females to a greater extent than males, with a ratio almost three times that in men. Their prevalence, which is influenced by lifestyle, increases significantly with age. In Italy, it is estimated that over 10 million people suffer from these conditions, which resulted in national pharmaceutical spending, in 2012, of 1,315 million Euros. Joint replacement surgery is considered the best solution for end-stage osteoarthritis and rheumatoid arthritis. In 2012, more than 164,000 artificial joints (hip, knee and shoulder) were implanted.

In 2012, Italy occupied sixth place in Europe for the use of medication for musculoskeletal diseases. In women over-74 the prevalence of use reaches 50%; *per-capita* NHS expenditure increases with age and differs between the sexes, probably due to the greater use of bisphosphonates for the treatment of osteoporosis in women. New biologics could constitute a cost-effective alternative in the future.
Although musculoskeletal diseases are conditions that involve a considerable part of the population, there is no available data on their prevalence and burden on the NHS and social security system, above and beyond the multipurpose survey performed each year by Istat. The adoption of appropriate lifestyles, early diagnosis and swift, adequate treatment are still the most effective therapy for osteoarthritis, osteoporosis and fractures in patients over 65, with a consequent reduction in disability and improvement in prognosis and life expectancy.
Considering the high impact that musculoskeletal diseases have on both patient and NHS, the 2010-2012 NPP, which was extended to 2013, included amongst its lines of intervention.
In order to increase the number of Quality Adjusted Life Years (QALY) for patients suffering from musculoskeletal diseases, healthcare policies must aim to implement prevention and research programmes for the early identification of the disease, swift access to the most appropriate treatment and the acquisition of reliable reference data.

Keywords Biologics, implantable artificial joints, lifestyles, musculoskeletal, prevention, Regional care

2.6. Chronic kidney failure

Chronic kidney disease, defined as a "condition of impaired renal function persisting for more than 3 months", primarily affects the adult population. By measuring glomerular filtration volume (GFV), chronic kidney disease is classified into 5 stages, which end at stage five with the complete loss of kidney function (End-Stage Renal Disease, ESRD) and the need for renal replacement therapy: dialysis or transplantation. Approximately 8,000 patients/year start renal replacement therapy and just one sixth is able to have a kidney transplant. Chronic kidney disease is associated with an increase in the cardiovascular risk due to a high prevalence of traditional risk factors (old age, hypertension, diabetes, obesity and dyslipidaemia) and the presence of factors specific to kidney disease.
In Italy, the CARHES (Cardiovascular risk in Renal patients of the Italian Health Examination Survey) study, which was conducted on representative samples (4,077 individuals) of the general Italian population aged between 35 and 79 years, calculated a prevalence for chronic kidney disease of 8.1% in men and 7.8% in women, with slight differences between the various geographical macro areas. These percentages suggest that there are 2.5-3 million subjects with chronic kidney disease in Italy. Subjects with chronic kidney disease show a greater prevalence of hypertension, diabetes and obesity.
The prevention of progressive chronic kidney disease and therefore ESRD is identified by early diagnosis that can be implemented using simple and affordable tests: creatininaemia and/or the urine proteinuria test. It has been shown that early diagnosis and correct treatment, as well as therapeutic coaching can prevent and/or delay the progression of kidney disease towards ESRD. Early management of patients with chronic kidney disease is also particularly important as it slows down the progression of the disease, which reduces the number of renal replacement therapies and transplants required. From this point of view, a chronic kidney disease register is essential.
For the prevention of chronic renal disease, the Ministry of Health, together with the scientific societies, the National Transplant Centre, general practitioners and patient associations, established a working group that produced the "Guideline document for chronic kidney disease" that was approved by the State-Regions Conference at the session of 5 August 2014.

Keywords CARHES study, chronic kidney disease, creatininaemia, dialysis, proteinuria, transplantation

2.7. Diseases of the nervous system

A World Health Organisation (WHO) report has brought into sharp focus the fact that the global impact on health of neurological diseases has been underestimated for many years. A recent study conducted by the European College of Neuropsychopharmacology (ECNP) and by the European Brain Council (EBC) estimated that the global cost of diseases of the nervous system in Europe has increased by 107%. In recent years, various descriptive epidemiological studies have been published, conducted by various Italian organisations for certain neurological disease, such as amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and Parkinson's disease (PD). In particular, the incidence of ALS in the Friuli Region from 2001 to 2009 has been estimated at 2.38 cases for every 100,000 person years. The rate of MS in 2009 in the city of Campobasso was reported to be 91 cases per 100,000 inhabitants. Finally, for Parkinson's Disease, the prevalence on the Aeolian Islands in 2001 in subjects aged over 60 was estimated to be 442 cases per 100,000 inhabitants. All these epidemiological estimates conducted in Italy are in line with European statistics. After an overall assessment of the Italian situation, numerous criticalities in the implementation of clinical governance for neurological diseases can be identified, such as: 1) the limited use of healthcare information systems and current statistics that would enable the phenomenon of the main neurological diseases to be detected; 2) the lack of population registers for the main neurological diseases; 3) the difficulty in implementing processes of continuity in the treatments and territorial hospital integration; 4) the need for greater connectivity in order to improve the Italian performance in research, development and healthcare innovation in the field of neurological diseases; 5) the urgency of drawing up an overall system by the National System of Guidelines for the purpose of defining the priorities in the areas of greatest clinical and organisational uncertainty.

Keywords Dementia, Parkinson's disease, neurological diseases, amyotrophic lateral sclerosis

2.8. Dementia

According to recent estimates by the WHO and Alzheimer Disease International (ADI), worldwide there are approximately 35.6 million people suffering from dementia, with 7.7 million new cases each year and 1 new case of dementia diagnosed every 4 seconds. In Italy, approximately 1 million people suffer from dementia (7.23% of the population aged 65 years or over) and the number of carers is 3 million.

Demographic forecasts suggest that there will be an arithmetical increase in these numbers, as age is the main risk factor associated with dementia.

Recent studies estimate the overall cost of dementia in Europe (27 EU members plus Iceland, Norway and Switzerland) to have been 105 billion Euros in 2010, compared to an estimated 55 billion for 2004, i.e. a 91% increase, without including diagnostic and indirect costs. Estimated total expenditure in Italy in 2010 was approximately 9 billion Euros.

It therefore goes without say that a key role is played by prevention, as reported in many scientific papers, which identify seven changeable risk factors associated with the onset of Alzheimer's dementia such as diabetes, hypertension during adulthood, obesity during adulthood, smoking, depression, poor scholastic achievement and lack of exercise. It is estimated that about half of all cases of Alzheimer's dementia could be attributed to this set of factors. It has been calculated that by reducing each of these seven risk factors it could be possible to prevent between 1.1 and 3 million cases of Alzheimer's dementia.

Equally important is the promotion of a multidisciplinary care programme approach, with the organisation of a network linking the work of specialist centres dedicated to diagnosis and pharmacological and psychosocial treatment, with general practitioners' surgeries, sheltered housing facilities, integrated home care and nursing homes, in order to make the entire system both efficacious and effective.

These principles, which were echoed by the European Joint Action ALCOVE involving 30 partners from 19 different countries, in-

cluding Italy, form the basis for the National Dementia Plan, which is at an advanced stage of development and will be the subject matter of an Agreement at the Unified Conference, in order to adopt a common strategy for this sector.

Keywords Dementia prevention, integrated management, National Dementia Plan, service networks

2.9. Mental disorders

In May 2013, the WHO approved a global strategy aiming to promote mental wellness, prevent the highest-impact disorders, provide a network of treatment and rehabilitation services, promote human rights and reduce mortality, morbidity and impairment in individuals with mental disorders. In September 2013, a second strategy was approved – the European Mental Health Action Plan – which transforms the principles of the global strategy into operational guidance for the 53 countries of the WHO's Europe Region, highlighting in particular the role and importance of intersectorial and community work, quality of care, knowledge-sharing and a full involvement of patients in the choices concerning them.

Following the results of the work related to the European pact on mental health and wellness, in 2008 the European Commission launched its "Joint Action on mental health and well-being" for European cooperation in this sector. Italy has played an active part in all the initiatives mentioned and is currently involved in the European coordination of the Section of the Joint Action concerning "mental health amongst the young and school context".

In January 2013, an update to the Italian strategy for the sector was approved, with the National Action Plan on Mental Health (PANSM).

Future national, regional and local planning must promote: actions aimed at preventing mental illness and promoting well-being; the devising of programmes for the implementation and monitoring of PANSM and consequential operational documents, the strengthening of the epidemiological research, follow-up and monitoring of mental disorders; the involvement of the various stakeholders in the planning of programming lines for research and care; the fight against stigmatisation, empowerment and the promotion of the social inclusion of patients with mental disorders.

Keywords Depression, European Commission's Joint Action, PANSM (National Plan on Mental Health), social inclusion, WHO strategies for mental health

2.10. Rare diseases

Rare diseases, defined as those with a low prevalence (<5 cases per 10,000 inhabitants in Europe), have been a European public health priority and the matter dedicated special attention in Italy for many years now. Ministerial Decree 279/2001 established the National Network and National Rare Diseases Register (RNMR) within the ISS. For some years now, the ISS has been running the National Rare Disease Centre, which, in addition to organising the National Rare Diseases Register, rare disease hot line and website (www.iis.it/cnmr), develops and coordinates a number of research and public health projects on both national and international levels. Following Ministerial Decree 279/2001, the regional authorities identified the treatment and care facilities, information systems and regional rare diseases registers that contribute to the National Rare Diseases Register. On a national level, the Orphanet website provides information on are diseases and related services, orphan drugs and research projects. In the rare diseases sector, special attention is dedicated to rare forms of cancer and rare clotting disorders. The National Rare Cancer Network coordinated by *Fondazione IRCCS Istituto Nazionale dei Tumori* and an epidemiological monitoring system within the Italian Rita and the European RARECARE projects have been set up to deal with rare forms of cancer. For congenital clotting disorders, the Haemophilia Centres care network was established, in addition to the ISS Department of Haematology, Oncology and Molecular Medicine's National Congenital Clotting Disorder Register (RNCC), which

performs the epidemiological monitoring of these conditions.
By 30 June 2012, the RNMR contained 110,841 diagnosis sheets detailing 107,830 patients with a total of 485 rare diseases (some individual conditions, others groups of rare diseases) as described in Ministerial Decree 279/2001. The disease class most present is that of diseases of the nervous system and sense organs, which account for 26% of the total.
As far as rare forms of cancer are concerned, in 2008 it was estimated that 770,000 people in Italy had been diagnosed with a rare tumour during their lifetime, 22% of prevalent cases diagnosed with a tumour.
The RNCC's data on congenital clotting disorders estimate the prevalence of haemophilia A to be 5.9/ 100,000 inhabitants and that of haemophilia B to be 1.1/ 100,000 inhabitants.
To conclude, various initiatives are being conducted on rare diseases which, despite being individually very valid, would have a greater information potential if they were brought together to guarantee their interoperability.

Keywords Congenital clotting disorders, disease registers, epidemiological monitoring, rare cancer, rare diseases

2.11. Congenital malformations

Congenital malformations are a priority public health issue, as suggested by the prevalence data: cause of prenatal death and infant mortality and morbidity within the first year of life. The non-lethal forms frequently require medical, surgical and rehabilitation intervention and they are often associated with severe long-term clinical consequences that in turn cause severe impairment.
Data on congenital malformations is provided by a number of databases: i) the National Rare Disease Register (RNMR); ii) the flow of information provided by Birth Register (CeDAP); and iii) Congenital Malformations Registers (CMR).
For the 2007-2010 period, the National Rare Diseases Register contains 13,963 cases of rare congenital malformations in the general population, representing the fourth most reported class of rare disease included in the register.
In the CeDAP survey on the data for 2010, 5,789 babies were born with congenital malformations that were observed at birth or in the first 10 days of life.
During the 2008-2011 period, 6,494 (5,191 live births, 47 still births and 1,256 abortions) cases were recorded in the Congenital Malformation Registers consulted (Emilia Romagna and Tuscany) out of 290,891 births (still + live births) registered, for a total prevalence of 223.25/10,000 (i.e. 2.23% of births).
The analysis of the time trends for the 1998-2011 period shows a growing trend for chromosome-related congenital malformations (in particular Trisomy 21) and for certain structural congenital malformations such as gastroschisis and congenital adenoidal-cystic lung malformations. A decreasing trend has been observed for cardiovascular malformations and, in particular, for neural tube defects (NTD). Possible factors that can explain these downward trends are due to the application of primary prevention measures, such as the increase in the consumption of folic acid during the preconception period and better overall management of known risk factors for reproductive health, such as the clinical management of chronic and infectious maternal illnesses and the correction of unhealthy lifestyles (smoking, alcohol and diet).
The European guidelines for the primary prevention of congenital malformations were published recently. It is essential that these guidelines are incorporated into healthcare programming and planning (National Healthcare Plan and Regional Prevention Plans).

Keywords Abortion, adverse pregnancy outcomes, congenital abnormalities, congenital malformations, epidemiology, miscarriage, morbidity, neural tube defects, preconception health, registers, risk factors, still birth

2.12. Illnesses that can be prevented by vaccination

The National Plan for Prevention by Vaccination (NPPV) 2012-2014 contains the new "Calender of actively promoted vaccinations",

which provides the pro-active, free provision of mandatory and recommended vaccinations during childhood and subsequent boosters, anti-HVP vaccinations for girls during the twelfth year of life, the pneumococcal conjugate and meningococcal C vaccinations for newborns, the varicella vaccination for newborns in 8 Regions and, starting from 2015, throughout the country, and the influenza vaccine for the over sixty fives.
A coverage percentage of the target population has been established for each vaccination which, if reached and maintained over time, will display clear effects on the incidence of the target illnesses and, consequently, the efficacy of the intervention. The vaccination coverage percentages at 24 months of age are substantially stable, even if not yet satisfactory for the measles-mumps-rubella vaccination and, in twelve year olds, for the anti-HPV. The case of influenza is another matter, where the vaccination coverage percentage in the over sixty fives, although historically >75%, has dropped by 10 percentage points since the 2009-2010 season.

Keywords Vaccination coverage percentages, National Plan for Prevention by Vaccination, mandatory vaccinations, recommended vaccinations

2.13. HIV/ AIDS and sexually-transmitted diseases

HIV/AIDS. The National AIDS Commission (NAC), chaired by the Health Minister, which provides useful indications for scheduling health interventions in this field, has published National Guidelines for the diagnostic and clinical management of people with HIV. In line with the European and international indications, the work of the NAC has been concentrated on the issue of tracking the infection and on the policies on provision and the methods of executing HIV tests in Italy. Since the Commission intends to become a point of reference for the cases of HIV-positive people, particular attention has been paid to safeguarding civil rights, especially in the field of care, employment and confidentiality, and towards the most vulnerable groups. A scientific contribution has been made for the provision of the 2012-2013 information campaign on the prevention of infection by HIV and AIDS.
The National Register of AIDS, in operation since 1982, and the system of surveillance of new diagnoses of HIV infection, established in 2008, are key elements in order to direct national efforts in the control of the HIV epidemic in our country, giving guidance and directions for prevention programmes and the appropriate management of health and social services. Both systems are managed by the AIDS Operational Centre (AOC) of the *Istituto superiore di sanità* (National Institute for Health) that has the task of collecting, handling and analysing these data and to guarantee the prompt return of the information.

Sexually-Transmitted Infections. As regards the main sexually-transmitted diseases (SDTs), their prevention is currently one of the highest priority public health objectives. In Italy, the information available on the spread of STDs is provided by the Health Ministry and only concerns those diseases where notification is mandatory, that is, syphilis and gonorrhoea. In order to make up for the lack of information on the other STDs, which are not classified as mandatory notification, a sentinel surveillance system of STDs was launched in 1991 based on clinical centres. The system, currently in operation, is coordinated by the AOC. In order to improve awareness of the spread of STDs in our country and to respond to recent directives from international bodies on the issue of the surveillance and control of STDs, a sentinel surveillance system of STDs was launched in 2009 based on clinical microbiological laboratories.

2.14. Occupational illnesses

Despite the fact that, according to International Labour Organisation (ILO) data, occupational illnesses account for approximately 88% of all lethal employment—related events each year, their effects are often underestimated compared to occupational accidents, which only account for 12% work-related deaths each year.

In Italy, and in Europe in general, the incidence of occupational illnesses is grossly underestimated for a number of reasons, including multifactorial origins, the lengthy intervals between occupational exposure and the onset of the illness, etc., but also as a result of poor knowledge of and sensitivity to the issue by many doctors, despite the fact that they are under obligation to report any probable/possible occupational origin.
In order to tackle the phenomenon, the NPP envisages the development of information systems to improve the capacity to record, process and analyse information on professional illnesses.
The commitment to bring to light mis-recognised occupational illnesses has led, in recent years, to a constant increase in the number of reports made to INAIL (Italian Institute for Occupational Insurance), which has shown a reduction in the illnesses that were most common in the past, such as hearing loss, and the increase in "new" conditions, in particular osteoarticular and musculoskeletal conditions, which combined account for 56.1% of reports in 2012, followed for the same year by nervous conditions (12.1% of reports).
In terms of malignancies and, in particular, pleural and peritoneal cancer, the data obtained from the MALPROF project show that the subjects most affected are those over 65 years of age.
As far as the productive sectors are concerned, most occupational illness reports are concentrated in the industry and services sector.

Keywords Occupational cancer, occupational illness

2.15. Emerging or re-emerging infectious diseases

The emergence of infections like SARS, the influenza pandemic A/H1N1, the new Coronavirus (Mers-Cov), avian influenza from the A/H7N9 virus and re-emerging diseases like tuberculosis, HIV and arboviruses (Chikungunya, Dengue), have demonstrated how important epidemiological surveillance is for monitoring the phenomena and defining the best response at the national and international levels. Any infectious disease can become an emergency when it turns into an epidemic or when it is perceived by the population as dangerous and, depending on whether the microorganism is emerging or re-emerging, the possible causes and prevention measures to be implemented can vary.
Although the risk of the spread of the viruses A/H7N9, A/H5N1 and Mers-Cov in Italy is considered low, these diseases have demonstrated the necessity of reinforcing the capacity for monitoring and responding at the national and international levels. Moreover, with the coming into force in 2013 of the new Decision of the European Commission (n. 1082/2013/EU), Italy was called upon to develop a generic plan to prepare for a series of cross-border threats to health, both of biological origin (infectious diseases, resistance to antibiotics and nosocomial infections, biotoxins) and of chemical and environmental origin, or unknown menaces that could constitute a healthcare emergency of international proportions in the field of International Healthcare Regulation.

Keywords Emerging diseases, infectious diseases, re-emerging diseases

2.16. Eye diseases

The progress accomplished in the ophthalmology sector has led to a reduction in the number of subjects destined for blindness, but at the same time has increased the number of individuals with partial residual vision that is inadequate to maintain full autonomy.
In order to programme public health interventions, with a view toward protecting and promoting ophthalmological health, it is important to concentrate on the most common eye diseases. In the paediatric population, congenital eye defects represent more than 80% of the causes of blindness or loss of vision in children under 5 years of age and more than 60% up to the age of ten. As the Essential Levels of Healthcare do not include ophthalmological screening at birth, diagnosis is often late. The main eye conditions amongst the paediatric population are: congenital cataracts, congenital glaucoma, retinoblastoma, retinopathy in pre-term babies and amblyopia. In the adult population, on the other