work. Moreover, in recent years, our country has set standards for certain specific sectors, including the control over risks of transmission of diseases from donor to host, facility certification procedures and the transparency of processes and results.
Significant developments have also been achieved in haematopoietic stem cells from bone marrow, peripheral blood, umbilical cord blood and tissue transplants.
Tissue donation and transplantation activities were very positive in 2010, consolidating Italy's position as a sector leader within Europe.
In 2010, important new measures were adopted in this sector: Legislative Decree 16/2010 assimilating European Directives 17 and 86 of 2006 that implement Directive 2004/23/EC concerning important technical prescriptions in the sector; the State-Regional Authority Agreement of 29 April 2010, on storage in foreign banks of umbilical cord blood for autologous use; and Ministerial Decree 116 of 16 April 2010 governing the transplantation of organs from live donors.
The organ donation and transplant activity data recorded this year must be considered as part of a broader scenario that makes it possible, for example, to connect the increase in life expectancy with that of the mean age of the donors and the increase in the patients on waiting lists.
The increase in the mean age of donors reported (which rose from 56.5 years in 2009 to 58.2 years in 2010) caused a moderate drop in the number of potential donors, i.e. subjects who underwent brain death verification, that in 2010 were 2,289 compared to 2,326 in 2009, equal to a 1 percentage point decrease. 1,095 donors were used in 2010 (compared to 1,167 in 2009), with an absolute drop of 6.2%, in which a considerable role was played by the age factor.
Last year there were 31.5% of objections to donation, compared to 30.4% in 2009, this trend is more or less stable and is in line with European standards. As far as haematopoietic stem cell (HSC) donation activities are concerned, in 2009 there were about 330,000 donors listed in the Italian Bone Marrow Donors Register (IBMDR), and the overall number of donors was 168.
Tissue donation and transplantation activities followed a positive trend in 2010, with about 11,750 donations (+11% compared to 2009) and 16,400 transplants (+6.4%), values that make Italy a sector leader.
The organ transplantation activity, after an initial significant increase, subsequently stabilised and, in 2008, the first signs of a drop appeared: in 2010 some 2,876 transplants were performed (1,512 kidney, 1,002 liver, 273 heart, 47 pancreas and 107 lung transplants) compared to 3,163 in 2009, with a percentage reduction of 9.1%.
This drop can be attributed above all to the trend concerning the age of donors and the reduction in the number of deaths of brain-dead patients (–8.7% in 2010 compared to 2009), especially in subjects under 40 and subjects with traumatic head injuries.
As far as the safety and quality of the procedures was concerned, Italy represents a reference point for the rest of Europe. The adoption of the Italian definition of donor risk levels in the European Council's quality and safety guide and the National Transplant Centre's participation in the drafting of the European Directive on transplant safety and quality (Directive 2010/53/EU) represent important results.
In 2010, Italian National Transplant Centre completed the framework of emergency programmes for the allocation of lifesaving organs, by approving the first national protocol for lung emergencies.
Once again in 2010, the national transplant program for difficult to transplant patients introduced specific electronic cross-matching for hyperimmunised patients, able to evaluate the immune and genetic characteristics of the donor and host. Three patients have already been transplanted under this new programme.
HSC transplants reached the 5,000-a-year threshold, of which approximately 15% are performed using non-family donors, thanks also to an increase in transplant centres and the expansion of clinical indications.
In 2010, 740 transplants were performed using HSC from non-familial donors (ap-

proximately 12% more than in 2009), of which 210 using HSC harvested from bone marrow blood, 414 from peripheral blood and 116 from umbilical cord blood. In addition, Italian Transplant Centres initiated 1,540 stem cells searches, which led during 2010 to transplants for almost 50% of patients for whom the search was activated. Over two thirds of transplants were performed using HSC from foreign donors.
For the continuing education of the various professional figures involved in the donation and transplant process, a national training plan was arranged, including approximately 20 courses. Pathways aimed at improving donor procurement and management processes have been promoted; for those working in the harvesting and transplanting surgery field, an international theoretical and practical course "The Donor Surgeon" has been available for three years and since 2009, a number of courses have been offered for handling experts and on HSC harvesting and banking methods.
As far as waiting lists are concerned, the data indicates a substantially stable position, confirmed by the mean duration of waiting times, which were substantially identical to those for the previous year. The migration of patients from the Regions of southern Italy towards the north still constitutes an important phenomenon.
Given the excellent results achieved, the transplant network must face new challenges concerning both organisational aspects and those that reflect national trends, in a similar way to the increase in the average age of donors.
The "structural" critical points of note concern: the shortage of nursing staff; the lack of incentives for those who deal with donation-related procedures and the difficulties facing hospital healthcare directorates in providing efficacious answers to the requests from the hospital departments involved in the donation process. The main objectives to be met are:

- the maintenance of the number of donations and transplants, one of the best in Europe;
- the on-going improvement in the quality of procedures using innovative techniques able to enlarge the pool of marginal donors;
- the reduction in the differences in donations between the North and South of the country;
- verification of the correct assimilation and application of guidelines, protocols and national programmes;
- the promotion of citizen information and awareness campaigns;
- the continuation of international cooperation activities between Italy, European countries and other nations around the Mediterranean.

In addition, in the light of the reduction in the number of transplants recorded this year, investigations will be conducted into the efficacy of combined strategies dedicated to severe organ shortages, to create a network of artificial organs, transplants and, in the future, the applications of stem cell research.

2.7. Transfusion services

The Italian transfusion system is an essential pivot for the operation of the National Health Service as a provider of services that support all areas of highly specialised, emergency and urgent medicine and surgery and one that plays a role in prevention to protect citizens' health. In this sense, the State-Regional Authority Agreement of 16 December 2010 defining the requisites for transfusion services and collection units and the template for the inspection visits to be performed by the Regional Authorities, represents an additional element of qualification of the whole transfusion system, guaranteeing the quality and safety of the blood, blood products and the medicinal products derived from plasma in Italy.
The third Annual programme of national self-sufficiency in blood and blood products was adopted in 2010, due partly to the implementation of SISTRA (Transfusion Services Information System) and coordination by the National Blood Centre (CNS).
As far as the banking of umbilical cord blood is concerned, a national network of banks storing umbilical blood for trans-

plant purposes coordinated by the CNS and CNT has been established and the requisites for cord blood banks belonging to the national network have been defined (State – Regional Authority Agreement of 29 October 2009).
The Decree of 18 November 2009 set forth provisions for the storage of umbilical cord blood stem cells for autologous and dedicated use.
Intense activities are still being conducted by the competent Organisms and Institutions for the continuation of work aimed at implementing the complex application procedure introduced by the law, particularly in connection with the production of blood products from national plasma and the regulation of the importation and exportation of blood and blood products.
The consolidated data published by the CNS show that in 2008, a total of 1,619,143 donors had given blood, making for a 3.2% increase on the previous year, albeit with significant variations between Regions, thereby confirming the growth trend observed over recent years. There was a 3% increase in the apheresis donors donating whole blood and a 2.5% rise in the donors donating through aphaeretic procedures alone.
On a national level, there has been a gradual increase in total donors, with a maximum of 41.5 donors per 1,000 inhabitants in Friuli Venezia Giulia and a minimum of 18.7 in Campania.
However, it should be pointed out that there are still certain Regions that are unable to guarantee the quantities required with their own blood collection and inter-regional agreements are therefore required so that those Regions that collect more blood than they need can compensate for Regions where there is a shortage. As a consequence, national self-sufficiency is critically guaranteed by scheduled inter-regional exchanges as well as occasional exchanges required to cover unexpected shortages. Three Italian Regions currently suffer from consistent shortages: Sardinia, Lazio and Sicily; however it is unlikely that Sardinia will ever be self-sufficient on account of the very high number of patients with congenital blood disorders (mainly thalassaemia) present in the region.
Overall, the Italian blood system has proven that it is able to steadily maintain its self-sufficiency in unstable blood components for transfusion purposes, albeit with critical shortages at times, particularly during the summer.
As regards the production of plasma to be forwarded for pharmaceutical processing and the self-sufficiency of blood products, it can be observed that Italian production (currently equal to 700,000 kg/year and on the constant rise) occupies second place in Europe after Germany, in absolute terms. In terms of production per 1,000, significant differences still exist between Regions, and the degree of self-sufficiency of blood products varies according to the type of medicinal product. As far as the two *driver* products are concerned, the levels of self-sufficiency were 45% for albumin and 70% for nonspecific immunoglobulins administered intravenously. However, as far as albumin is concerned, it must be noted that there is undoubtedly a large margin of inappropriate consumption, which is present primarily in central and southern regions.
In addition to overseeing the basic elements for regional and national self-sufficiency, the objectives of the national short- and medium- term blood system must also make it possible to overcome the North-South gap, handle critical situations connected with supply shortages during the summer season, guarantee the appropriate use of blood products and promote the quality and safety of the products and of the transfusion services provided, the work they do in connection with the collection and storage of haematopoietic stem cells, including cord blood banks, the loyalisation of donors and the gradual abolition of sporadic donations.

2.8. Caring for the elderly

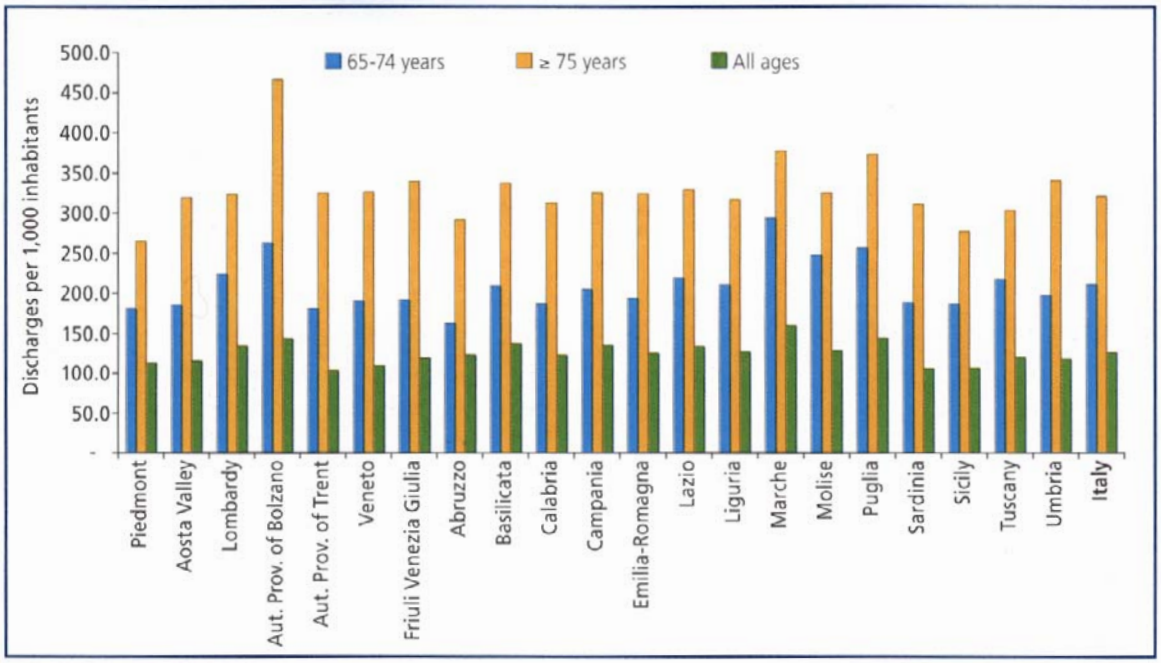
Increasingly favourable survival conditions have led to an increase over time of the number of people aged 65 or over, who now represent 20.2% of the Italian popula-

tion and are the main users of healthcare resources. This situation has led the Italian Health Service to carefully consider the need to rethink culturally and reconsider structurally its health procedures and the way they are provided, favouring the integration between prevention and treatment on the one hand and a response to social and health needs on the other, in the knowledge that in order to be efficacious, it requires adequate hospital-community continuity of treatment and a multidisciplinary approach as regards community care. The social and health system must provide adequate methods of intervention both for an elderly person living a "healthy" old age and in dealing with elderly subjects with morbidities, most of which are of a chronic-degenerative nature and in dealing with frail elderly people, in order to minimise the negative outcomes whilst optimising the function of his/her residual abilities. The organisation of care must envisage access to the system through Single Access Centres, places dedicated to receiving and decoding the initial request and to coordinating the provision of the services constituting the care plan.

In 2009, the data for ordinary hospital admissions for elderly subjects over 65 years of age underwent an absolute drop (3,190,247 compared to approximately 3,600,000 in 2006); however there was a simultaneous increase as a percentage of total admissions for the whole population, increasing from 40.4% in 2006 to the current value of 42.1%. Mean hospitalisation times, which were 7.8 and 9.1 days for the 65-74 and the 75+ classes, respectively, were lower than the previous data.

Integrated Home Support is one aspect of the network of services subject to gradual development, despite the persistence of regional differences. The percentage of subjects aged over 65 out of all patients receiving integrated home support is 91.7% in Liguria and 90.6% in Emilia-Romagna; whereas the lowest levels for the presence of the elderly out of total users of integrated home support was recorded in the Autonomous Provinces of Bolzano and Trent (57.4% and 55.4%, respectively). Equally significant differences can be observed across the country in the hours of service provided per case treated. The number of residential places available for patients who

Figure . Hospitalisation rates by age bracket (discharges per 1,000 inhabitants) [Year 2009].



Source: Ministry of Health – Healthcare Information System – Hospital Discharge Record.

cannot be looked after at home surveyed in 2009 by the Information System was 162,590. They are home to 237,000 people, for a total of more than 53 million days of care and a mean of 224.7 days per user. Both the number of places and the number of users is significant higher in the Regions of Northern Italy, with Lombardy in first place.

Regional Authorities are less conscientious in entering data on semi-residential activities, for which a great deal of data is missing. This seems to somehow indicate the need for improved community services, which could help reduce demands for more complex residential care.

In line with the points set forth above and the on-going debate in our country, the following programming indications are believed to be of priority importance:

- to favour the individual's active ageing to improve his/her state of health and prevent pathological conditions through the dissemination of behaviour that includes a healthy diet, suitable exercise and the elimination of the main risk factors for health (smoking and alcohol);
- to implement the diffusion of standard admission procedures and of single access centres within healthcare districts;
- to favour the knowledge and use of instruments such as multidimensional assessment, which are particularly well suited to a correct identification of the elderly person's needs;
- to implement the training for professionals in the prevention, care and management of the elderly person in all his/her clinical and care aspects, in order to guarantee continuity of care, particularly for frail elderly people;
- to strengthen and continue to develop both Integrated Home Support and care in residential and semi-residential facilities;
- to favour the exchange of knowledge between those subjects in charge of care and the world of scientific research, also as regards, in particular, the issue of multiple medications in elderly people and the frequent exclusion of elderly people with comorbidities from randomised clinical trials.

2.9. Management of frailness and non-self-sufficiency

Non-self-sufficient people are those who have suffered a permanent, total or partial loss of their physical, mental, sensory, cognitive and relational abilities and are consequently unable to perform the essential activities of daily living unaided. Frailness indicates an individual's greater vulnerability to stress. It restricts his/her ability to perform activities of daily living due to the presence of multiple comorbidities and a deterioration in health and the functional state, making him/her more prone to negative outcomes. More specifically, frailness affects elderly subjects with comorbidities and clinical instability, disability and risk of adverse events, with a high incidence of hospitalisation and/or death. The management of frail and/or non-self-sufficient subjects has taken on a priority role in the programming of health initiatives in recent years, precisely by virtue of the particular biological, psychological and social characteristics of these subjects.

In this sense, aspects of key importance are the multidimensional assessment and formulation of an individual treatment and care project intended to protect the person's dignity.

The integrated Individual Medical and Social Care Plan defines the aims and expected results in terms of the maintenance or improvement of the state of health of a non-self-sufficient person and identifies the level of complexity, duration of the programme and the medical and social services to be provided, as well as the practitioners who will follow the patient.

The social and medical care provided to frail and non-self-sufficient people contemplates the possibility of treatments to be administered at the person's home or in residential or semi-residential health facilities.

Home support, on the other hand, consists in an integrated set of medical, nursing and rehabilitation services, pharmaceutical as-

sistance and diagnostic investigations, performed at the person's home under the clinical responsibility of the GP, primary care paediatrician or the doctor in charge of pain therapy or palliative care, as applicable.

The document issued by the National Commission for the definition and updating of essential levels of care and entitled "New characterisation of home support in the community and of hospital procedures performed in the home" pin-pointed the characteristics of the different levels of home support, defining the intensity, complexity and duration of the support for each one.

Home support is complemented by social, medical, personal aid and protection assistance services governed by the Regional Authorities according to their own care models.

When it is not possible to perform the services at the patient's home, the NHS guarantees healthcare in residential and semi-residential facilities by offering, as clearly indicated in the document "Residential and Semiresidential Services" of the national commission for the definition and updating of the essential levels of care, services provided in nuclei of varying complexity and specialisation depending on the patient's individual medical and care needs.

Social and medical care, be it home-based or residential, depends on the Regional Authorities' ability to structure and guarantee the non-self-sufficient population a range of treatments that satisfy their care needs and it is an area assessed as part of the auditing performed on the essential levels of care by the competent institutional panels of experts.

Once the specific information flows for the monitoring of home support and assessment of residential and semi-residential services are fully implemented, they will provide detailed information on the quality of the assistance provided also on a local level and in some cases on the service provided.

Once again, the main aims in this sector are:

- to guarantee continuity of care to the frail or non-self-sufficient person during the hospital discharge process and subsequent management by community services;
- to favour the diffusion and use of multidimensional assessment tools;
- to favour the GP's involvement in the treatment process;
- to promote and improve the integrated home support service;
- to guarantee suitable care in residential and semi-residential facilities following discharge, and increase the availability of residential places where they are still inadequate and in line with the commitments undertaken for the pursuit of an economic balance;
- to implement the training of those working in the prevention, care and management of non-self-sufficient and frail person in all his/her clinical and care-related aspects;

As regards the implementation of the diffusion of standard management procedures and the Single Access Centres in community facilities, in 2007, the Ministry of Health/ CCM promoted and funded the "Identification and Implementation of a system for single access to the network of social and medical services for people with disabilities", in conjunction with Tuscany Regional Authority and Siena Local Health Authority, originating from the need to obtain a single point and procedure for the management of persons with disability. The objective is to achieve an organisational review that simplifies the investigation processes by connecting them with the assessments aimed at the construction of the patient management project and on the other hand to guarantee the person with disabilities a clear and well-defined model for the access to the welfare system, regardless of his/her age and the cause that generated the condition of disability, as well as a method for full participation in the evaluation and definition of the individual project. The solution proposed is the establishment of single access centres, conceived as an organisational method and set of standardised procedures for people with disabil-

ities aimed at providing unified access to medical, sociomedical and social services.

2.10. Protection of mental health

The protection of the population's mental health is one of a country's main objectives, at all levels of its institutional structure.

As far as the services supplied are concerned, in 2009 the number of hospital beds allocated for psychiatric disciplines was 6,380, lower than the number available in 2007 (when there were 6,780). The rate of total beds per 10,000 inhabitants over 18 years of age was 1,280, with significant differences between the various regions.

The number of Mental Health Departments coordinating the care network dropped from 214 in 2007 to 208, partly due to their incorporation into the local health authorities, whereas there has been a parallel consistent increase in Mental Health Centres in the community (from 708 to 1,387).

The SEME project, funded by the Ministry of Health and coordinated by the ISS aimed at detecting new cases of specific severe mental disorders, which has involved twenty-two mental health centres, guaranteeing the surveillance of 2,082,368 citizens and building a network that is still operative, registered, between March 2009 and December 2010, 407 new cases admitted: 168, equal to 41.2%, belonged to the psychotic disorders area (schizophrenia, schizophreniform disorder, schizoaffective disorder and delirious disorder), 120, or 29.5%, to the bipolar disorders area (bipolar disorder I and II), 80 cases, or 19.7%, has severe major depression and 39, equal to 9.6%, suffered from anorexia nervosa. It was discovered that despite the severity of their conditions, this was the first time that they had contacted the mental health centre, at a median interval of 4 years from the onset of the disorder.

The data relating to residential and semiresidential care shows a tendency towards an increase in the number of facilities compared to the 2007 survey: residential structures increased from 1,577 to 1,679 and semiresidential facilities from 755 to 763.

In 2009, the residential facilities for adults accommodated 30,375 people for a mean/user days of care 187.52, whereas the value for services provided on a semi-residential bases, relating to 32,030 people, was 67.01 days.

The staffing of the Departments of Mental Health underwent a reduction in 2009 for almost all professional figures, with the exception of doctors and social workers, the number of which rose slightly compared to the 2007 value identified using the Health Information System (SIS).

The indications for formulating better qualified and more efficacious intervention strategies included:

- accreditation and the assessment of service quality;
- promotion of the Mental Health Departments for the management of all mental disorders, in order to permit the continuity of care for severe patients and provide suitable support to their families,
- the validation, development and systematic diffusion of Mental Health Departments in evidence-based psychotherapy and rehabilitation programmes and their integration with the psychological and social treatment;
- the promotion of research activities and continuing education in EBM for operators and their integration with other professionals;
- the study and development of mental health promotion schemes in the school and in workplaces;
- the involvement of GPs, for the identification and early management of mental disorders;
- the completion of the mental health information system;
- the promotion of partnerships between the Psychiatric Diagnosis & Care Service and the other general hospital departments, to guarantee suitable counselling for mental health-related issues for patients hospitalised in these wards (for instance cancer, heart disease, dialysed and transplanted patients).

2.11. Drug addiction and alcohol abuse network

In 2009, there were 496 public drug addiction services out a total of 525 active facilities (94.5%). Data shows that 168,364 patients with substance abuse problems were managed. The most frequently used substance was heroine, with a treatment demand of 68.9%.

In relation to the total resident population, the public services treated 28 patients (50 males and 8 females) every 10,000 inhabitants. The male/female ratio of the patients managed by the Services was 6.2 and the dominant age range was that of over 39 years (34.0% of the total). The usership gradually "aged" over the years (mean age 33.8 years).

The substance for which treatment was most commonly requested was heroine (68.9% of patients), followed by cocaine (15.5%) and cannabinoids (9.3%).

As far as the type of treatments provided by the public services are concerned, 63.7% of patients participated in integrated pharmacological programmes and 36.3% had psychosocial and rehabilitation treatments.

The data for 2009 shows that the percentage of patients treated by the public drug addiction services who were HIV+, in relation to the total number tested (constituting less than 50% of new admissions), was 11.5%; 36.2% for hepatitis B and 58.5% for hepatitis C, all of which were lower than in previous years. In 2009, there were 484 deaths for acute intoxication (this figure does not take into account cases of overdose in which the judicial authorities were not involved and cases of drug-related death for causes other than overdose), which was lower than in previous years (653 in 2005) and had a male: female ratio of 9.7, with a mean age of 37 years. In most cases the cause of death was attributed to heroine. In 40% of cases the substance that caused death was not recorded.

Despite being representative of the services activities, the data recorded does not allow an exhaustive assessment of efficiency and efficacy in terms of the health results produced. In addition, there is no information on accredited private residential treatment facilities.

It would appear to be of priority importance to implement a greater sharing and coordination of the objectives between all the private and public central, regional and local institutions involved, on the basis of the National Plan of Action Against Drugs, in order to make drug policy more efficacious, taking into account territorial differences and autonomies. Specifically, it is necessary:

- to guarantee the multidisciplinary treatment services integrated with a rehabilitation programme that is firmly centred on social and occupational recovery;
- to implement evidence-based prevention initiatives, both those addressing the general population and those aimed at the more vulnerable target at behavioural risk of the juvenile population;
- to guarantee the provision of actions to prevent the diseases relating to the use of psychoactive substances in relation to treatment and rehabilitation services;
- to implement the cooperation and coordination between sociomedical services in order to guarantee all the services required for the global protection of health (psychiatric comorbidities, infectious diseases, etc.), in particular for prisoners;
- to implement testing for the main drug-related infectious diseases in public services (HIV, HBV, HCV, syphilis), subject to correct informed consent;
- to complete the implementation, in association with the Regional Authorities and with the coordination of the Department for Drug Policy, of the National Dependence Information System concerning patients being treated, to provide information on the treatment services and programmes generated by patients within dedicated facilities;
- to implement training and awareness programmes concerning new consumption trends, evidence-based programmes and the assessment of treatment outcomes.

Particular attention must be dedicated to drug addicted prisoners, by increasing

schemes in prisons and scheduling programmes for the prevention and reduction of drug-related risks (HIV, HBV, HCV infection and acute illnesses).
Specific skills must be developed in Emergency Admission Departments relating to the effects of psychotropic substances, ad hoc protocols must be drafted and comorbidity and differential diagnosis skills developed.
The adequate availability and accessibility of alcohol abuse services constitute some of the priority objectives for national planning. In 2008, there were 459 services or working groups for alcohol abuse, distributed across 19 regions, and some 66,548 alcoholic subjects were managed, more than in 2007.
In this network of services, in 2008, 3,886 resources were appointed to perform alcohol dependency-related activities, of whom 48.7% were social and health workers, 22.7% were doctors, 17.8% were psychologists and the remaining 10.8% were administrative or other staff.
Over time (between 1996 and 2008) there was an increase in the subjects treated with outpatient medical and pharmacological social rehabilitation and counselling treatments, whereas there was a significant reduction in that of the subjects in the self-mutual help groups (from 13.3% in 1999 to 7.8% in 2008) or referred for hospitalisation (from 10.3% in 1996 to 5.2% in 2008).
In accordance with the organisational and functional model adopted with the State-Regional Authority Agreement of 21 January 1999, about 86% of services performed reception, observation and diagnosis and defined and/or implemented treatment and rehabilitation programmes in 2008.
There appears to be fairly extensive, albeit decreasingly so, cooperation between alcohol abuse services and voluntary and private social organisations and associations, particularly with self-/mutual help groups, above all in the regions of northern and central Italy, where the inclusion in these groups is higher than the national average.
Given the series of new emerging problems, such as, in addition to fully-blown alcohol dependence, juvenile alcohol abuse, acute intoxications, binge drinking and hazardous lifestyles, the work of these services should have a more stable position in a broader context of intervention that involves other specialist service providers: hospitals, GPs, driving licence committees, social services and occupational medicine experts. The National Alcohol and Health Plan therefore envisages the construction of an accessible, efficacious and flexible treatment system, based on scientific evidence and the assessment of needs, with solutions for all the various phases, according to an integrated, multidisciplinary approach involving the various health and social actors involved and voluntary and self-/mutual help associations.

2.12. Palliative care and pain therapy

Palliative care is provided to all types of patient (including those in the paediatric age) suffering from chronic, degenerative diseases (cancer, genetic, neurological, heart diseases, etc.) with the aim of giving the patient a better quality of life, helping him/her to live his/her condition and the pain it causes in a dignified manner.
The epidemiological situation in Italy would appear to be very varied, as Istat data only concerns cancer patients and approximate estimates on patients suffering from other kinds of illness who might use palliative care. The data collected calls for an improvement of the palliative care network that allows the definition of programmes that are as customised as possible, particularly in the last months of the disease, in which there is a progressive loss of independence and the physical and mental symptoms become more acute, involving not only the patient, but also the family nucleus that faces this dramatic moment together. The need to improve the network is clear from the number of patients dying in hospital wards for acute patients with a primary or secondary cancer diagnosis, which continued to grow between 2004 and 2007 (55,934) and underwent a slight drop in 2008 (55,198). Approximately one

third of patients dying of cancer in Italy die in a hospital ward for acute patients, with an average hospital stay of about 12 days.
Ten years from the entry in force of Law 39/1999 converting Legislative Decree 450/1998 setting forth provisions for guaranteeing urgent action to implement the National Health Plan 1998-2000, which involved, amongst other things, a national programme of residential palliative care facilities, the results obtained cannot be described as satisfactory. Of the envisaged number of 201 residential facilities for terminal, primarily cancer, patients (hospices) with a total bed capacity of 2,232, only 117 are operative. In addition to these, which were funded using the state funds envisaged by Law 39/1999, we can add 46 hospices created using funds from different sources (regional, private, other). This result is disappointing, both because of the time that has elapsed, approximately 10 years from the time the law was passed, and the evidence of inequalities between regions, also as regards the use of the envisaged funds, with the majority of hospices being in the north of the country. Furthermore, the presence of hospices is not sufficient to guarantee an integrated system, which must include the establishment of a home palliative care service: the network, as defined in Law 38/2010, constituted "... by the set of health and care facilities and local hospitals, professional figures and the diagnostic and therapeutic initiatives available within the Regions and Autonomous Provinces, dedicated to providing palliative care...".
The palliative care context takes on a particular specificity for paediatric patients. The availability of paediatric palliative care services in the community would seem to be completely inadequate, if we consider that very few Regional Authorities have established paediatric palliative care networks and that there is only one hospice dedicated specifically to providing palliative care to minors, located in Veneto.
State-Regional Authority Agreements on this issue indicate the need to organise dedicated palliative care networks for paediatric patients, highlighting the specificity of this type of care and the ways in which it differs from palliative care for adult patients.
Law 38/2010 defines pain therapy as a set of diagnostic and therapeutic initiatives intended to control and suppress moderate to severe chronic pain. Our country has not yet acquired a full understanding of the "pain" issue, which is often handled in an unsatisfactory manner with negative repercussions on daily, occupational and relational activities, through a care and organisational network that is not always adequate and a more limited use of opioid analgesics for severe pain lower than in other European countries. Generally speaking, the "Ospedale senza dolore" [Pain-free hospitals] project launched in 2001 did not achieve the expected results and there is no information available on the number of Pain-free Hospital Committees established. Subsequently the Agreement of 28 October 2010 "Pain-free Hospitals and Communities" identified community care, with the involvement of GPs, as the focal point of this kind of service. In July 2011, the NHS Inquiry Parliamentary Commission chaired by Senator Ignazio Marino appointed the Carabinieri's NAS Division to verify the implementation status of Law no. 38 of 15 March 2010 in hospital facilities with at least 120 beds and the simultaneous presence of an oncology and a general surgery unit, thereby including some 244 facilities nationwide in the investigation. The inquiry was structured following various aspects concerning the presence of the Pain-free Hospital Committee, the presence of a Palliative Care and Pain Therapy Unit, a partnership with general practitioners, the consumption of opioids and indications of pain therapy on clinical records, all indications that are consistent with regulations on palliative care and pain therapy.
The results obtained show a non-homogeneous application across the country: Italy is substantially divided into three areas with percentages of adaptation that, whereas in the North they reach 91-93% in Regions like Veneto, Lombardy and Piedmont, they record very low values in the South, with percentages of 41% in Puglia.

The situation improves in the Centre of the country, with a mean of 75%, thereby indicating that Italy is a divided country and has a fragmentary healthcare network. More specifically, 23% of hospitals still do not have a pain-free hospital committee and project, thereby breaching a provision that is now over 10 years old (the State-Regional Authority Conference Agreement "Pain-free Hospitals" was issued in 2001). The geographical differences are even more evident when we analyse the data concerning the consumption of opioids for pain treatment. In the first half of 2011, 68% of the national value was consumed in Northern Italy, 26% in the Centre and just 6% in the South of the country.

Pain therapy would appear even more critical when it concerns paediatric patients. The lack of up-to-date epidemiological information on pain in children and the cultural, professional and organisational delays have had a negative influence on the state-of-the-art in paediatric pain therapy. To date only four paediatric hospitals in Italy have a pain treatment clinic. Paediatric pain therapy and palliative care for children is characterised by a specificity and complexity that require, as indicated in Law 38/2010, a single, dedicated and specialised network, coordinated by a regional reference centre able to attend to the needs of the patient and his/her family.

2.13. Vegetative state

In the last few decades, the number of patients with complex clinical conditions characterised by severe alterations in their consciousness and by a low responsiveness, including vegetative state and minimal consciousness due, for the most part, to severe acquired brain injuries, has significantly increased. Although it is not possible to consider these conditions totally irreversible, when a person reaches clinical stability and enters into a chronic stage, he/she is considered a patient with a "very severe" disability and therefore, similar to other individuals with very serious chronic illnesses, may be treated at home or, if this is not possible, may be transferred to facilities that can guarantee appropriate care. This transfer is considered a very delicate phase which requires a significant degree of health and social support to the patient and to the family, as the necessary routine healthcare must be guaranteed in order to prevent complications and to maintain the level of stability achieved, while ensuring easy access to healthcare facilities for acute conditions, if needed.

The healthcare and rehabilitation treatment of a vegetative and minimal consciousness condition represents therefore a very important health and social issue that strongly impacts society and families due to the high and growing incidence of the number of such cases as well as the increase in complex medical conditions which require a multi- and inter-disciplinary organisation capable of satisfying special healthcare needs. It is also necessary to have available dedicated facilities with strong rehabilitation resources that become involved from the beginning of the acute phase and provide information and psychological support to the family members, facilitating a therapeutic alliance with the healthcare team which can be highly valuable in terms of treatment.

In the last few years, the attention of institutions has been drawn quite often toward these types of patients through a series of initiatives including technical panels established for the purpose of drafting a document that would provide indications for a coherent sequence and integration of different interventions and types of healthcare settings based on the stages of the illness and on the medical condition of the patient, as well as on the family and environment situation. This commitment was reaffirmed through the issuing of Government and Regional Agreements, dated 25 March 2009 and 8 July 2010, which have identified, among the project guidelines for accessing the resources tied to priority objectives and national relevance, the "Promotion of healthcare organisational models for patients in chronic vegetative state and minimal consciousness", in compliance with which the Regions have launched specific projects aimed at enhancing the access to

Permanent Special Care Units (SUAP) by subjects in a vegetative or minimal consciousness state, and offering home care options, if possible.

An analysis was conducted by the Ministry of Health based on data collected from Hospital Discharge Records (SDOs) and referring to a three year period, from 2007 to 2009, regarding patients discharged with code 780.03 (ICD-9-CM), with any type of diagnosis corresponding to the "*Persistent vegetative state*" code. In these three years, 5,608 patients were discharged (including repeated hospitalisations) of which 1,811 in the year 2007, 1,950 in the year 2008 and 1,847 in the year 2009.

The total number of discharged patients during the three year period, without repeated hospitalisations, was 4,012. As regards the type of discharge, the "ordinary discharge from hospital to home" reached a national average of 34%. Only 1.4% of the discharged patients have used the Integrated Home Healthcare (ADI) which is not provided in eight regions. This is most likely due to the very specific type of healthcare that must be provided to the patient in a vegetative state who is cared for at home, due to the high complexity and diversity of interventions that are based on the progression of the medical condition, possible complications and the family and social environment. The age group most represented among these 4,012 patients, discharged during the three year period, from 2007 to 2009, is between 45 and 65 years of age (1,141) with a higher prevalence of males (730) to females (411).

From an analysis of the current situation and in line with the indications by the Italian National Healthcare Plan (PSN) of Essential levels of healthcare (LEAs) which help to determine the therapeutic paths to adopt, the necessity for national directives regarding the definition of treatment paths and the promotion of the development of regional healthcare networks targeting patients in a vegetative or minimal consciousness state, has emerged. To this end, two committees, working in partnership, have been established. The first has met with the associations of these patients' families and concluded its study with the publication of a "White Book on the vegetative and minimal consciousness condition - the point of view of the associations representing the families", which, *inter alia*, includes the good practices adopted within the national territory emphasising the issues and needs of family members. A Workgroup, at the national and regional level, was also established for the purpose of drafting an Agreement that would take into consideration the experience of the Regions, the current status of scientific knowledge based on the most recent medical literature and the overall evolution of healthcare and social policies in order to formulate the "Guidelines for the care of patients in a vegetative or minimal consciousness state".

2.14. Dental Healthcare

Currently, according to the provisions of the Presidential Decree of the Council of Ministers (DPCM) of 29 November 2001, public dental healthcare is provided only to some categories of individuals, i.e. those between the ages of 0-14 years and to individuals in health and/or socially vulnerable conditions. In addition, the National Healthcare System guarantees to the entire population the immediate treatment of analgetic-infectious emergencies; prosthesis rehabilitation is not provided.

In order to provide these healthcare services, many initiatives have been carried out lately entailing either a complete financial coverage provided by public bodies (Regions, Provinces and Municipalities) or a financial coverage funded partially or entirely by the citizen himself, according to a more specific definition of health and social vulnerability, based on criteria different from the usual "self-assessments" or exemptions.

3. The quality of the Italian National Healthcare System

3.1. Quality and clinical governance

Policies regarding quality are an integral part of the national healthcare programmes,

and the National Healthcare Plans (PSN) provide for the development of integrated activities toward the improvement of quality. Modernisation policies require a strategy toward quality that is shared by all the players and also require the design and testing of innovative clinical, organizational and management models aimed at ensuring effective responses to healthcare needs within the scope of clinical governance.
The objective is to steer the system so that the management of services goes hand in hand with the pursuit of quality, efficacy, safety and appropriateness of the services provided. Information and communication, supported by the proper information and computer systems, are fundamental strategies and are essential to the promotion of transparency and accountability based on measurement/assessment parameters.
The overall improvement of quality depends on the interaction of multiple system components, and the adoption of clinical governance practices requires the essential strengthening of the skills of the professionals whose training is indispensable to ensure that effective and safe treatment is provided.
The Ministry of Health, in partnership with the National Board of Physicians, Surgeons and Dentists (FNOMCeO) and the National Board of Nursing (IPASVI) has implemented the RCA Course, based on remote training (FAD), Continuing Education in Medicine (ECM) accredited, addressed to physicians and nurses. As at 10 June 2011, more than 40,000 healthcare operators had enrolled, with a ratio of 1:4 physicians to nurses. A remote training on safety and quality of treatment, addressed to pharmacists, was also offered with 16,000 pharmacists enrolling. The Ministry of Health has drafted a Clinical Audit Manual which provides a methodology regarding specific medical/healthcare issues and some aspects of the current practices, which are assessed in terms of structure, process or outcome. A set of rules for good practices applicable to the performance of an effective clinical audit has been defined and a training course has been developed for health operators, in remote (FAD) mode, in partnership with FNOMCeO and IPASVI.
As regards the implementation of clinical governance, the training must also be part of a coordinated system, must be centered on the patient, ensure consistency among clinical behaviours, organisational structures, areas of responsibilities, procedures, incentives, equipment and devices, processes and resources. The implementation of the National Program for Permanent Promotion of the Quality of the National Healthcare System (PROQUAL) is therefore a priority. The program seeks to support, in a systematic and continuous way, the quality of services provided in order to improve the general health of the population and the satisfaction of their needs, within the scope of safety, participation and shared responsibilities.

3.2. Patients safety

The monitoring of sentinel events (unexpected and severe occurrences involving death or serious injury to the patient) is an important requirement for public health and an indispensible tool for the prevention and promotion of healthcare safety. Since 2005, the Ministry has been monitoring and studying sentinel events. With a Ministerial Decree dated 11 December 2009, within the New Healthcare Information System (NSIS), the Information System for the Monitoring of Errors in Healthcare (SIMES), which reports to the National Body for the Monitoring of Sentinel Events (OsMES) at the General Directorate Office of Healthcare Programmes, has been established. The monitoring of sentinel events has the following objectives:

- Collecting information concerning the sentinel events occurring within the SSN;
- Analysing the factors that have contributed to and determined the occurrence of the events;
- Making recommendations to all the SSN facilities in order to minimize the risk of the occurrence of events;
- Ensuring that feedback is sent to the SSN facilities, to Regions and Provinces.

In November 2009, the Report on the mon-

itoring of sentinel events, with the results from 4 years of activities (September 2005 to August 2009) was published.
As regards the reporting of adverse events, the "Suicide or attempted suicide of hospitalised patients" has represented the most reported event (22.9%); the second category (17.1%) was represented by "non-classifiable events"; the event "Death or serious injury due to a fall of the patient" was the third category (9.9%), and the event "Death, coma or serious injury due to errors in pharmacological treatment" was 4.2% of the total. The "death" outcome was 54.8% of all reported cases. More than 40% of the events occurred in hospital rooms, whereas 25.7% occurred in the OR. Compared to the First Report, published in October 2007 and covering the period between September 2005 and February 2007, an increasing improvement in the methods applied to the analysis of the events was reported and in 40.5% of cases, a Plan of action was formulated in order to prevent the re-occurrences of those events; in the previous report, the number of these cases represented 20%.
As for the safety of pharmacological treatment, it was found that errors are frequently associated with "*Look-Alike/Sound-Alike*" (LASA) medicinal products, i.e. medicinal products that may be confused with others due to the similarity of their name design and/or spelling. A specific project, named "LASA medicinal products and patients safety" was developed and involved the compilation of a list of LASA medicinal products, which is now available on the Ministry of Health web site.
In compliance with the WHO program, "Safe Surgery Saves Lives", the Ministry has provided the translation and customisation of the WHO Guidelines and of the checklist for safety in the operating room. In particular, as regards the adoption of the Safety Manual and of the Safety Checklist by the facilities, it was found that 90% of the facilities that participated in the first survey have adopted these documents, the remaining 10% of the facilities that participated have not adopted the manual and do not use an OR Safety Checklist. It must be noted that the facilities where the Safety Manual and Checklist are adopted, have also set up the monitoring of their implementation, thus reaffirming their commitment to address these issues.
The Ministry has made available on its web site a dedicated section where the recommendations already formulated, or to be formulated in the future, can be accessed. These recommendations are based on issues emerged and experiences observed worldwide. Furthermore, in order to assess the implementation models of these recommendations within the facility, they will be the subject matter of a specific program commissioned by the Ministry to Agenas, in partnership with Regions and Provinces.
In Italy, the number of cases of infections associated with healthcare has been, for many years, in line with the trend reported in other European countries, with an average incidence between 4.5% and 7% of all hospitalisations (equal to 450,000/700,000 cases), with a 1% mortality versus 3.6% in Germany and 13% in Switzerland.
It has been scientifically demonstrated, for a long time, that 30% of the infections associated with healthcare is avoidable through the adoption of simple rules such as washing hands and washing the patient when care is provided. 70% of the infections are due to other factors such as the clinical conditions of the patient and the onset of bacteria resistant to commonly used antibiotics.
Since 2006, the Ministry of Health, in partnership with the National Centre for Disease Prevention and Control (CCM) has launched the project "National Project for Safe Treatments" under the name "National Prevention and Control of Infections associated with Healthcare" which, driven by the Emilia Romagna Region, has involved all the other Italian Regions. This project was completed in 2008.
This project coincided with the WHO campaign "Clean care is Safer Care" to which Italy has participated as a pilot site in the dissemination and implementation of the practice of hand washing in 14 Italian Re-

gions, in addition to the dissemination of information leaflets and brochures, preparation of training classes, planning and assessment of the impact of this campaign on the healthcare facilities involved.
The data collected showed that the health facilities, compared with data previously collected, have improved the monitoring and control activities on infections associated with healthcare, particularly in the Hospitals that have participated in the project, especially in Northern Italy. There are major differences among the Regions, which must be corrected, and the implementation of resources dedicated to personnel training and monitoring activities must be ensured.
The prevention and control of infections associated with healthcare represent one of the activities included in PROQUAL, a program that intends to promote, in a systematic and consistent manner, the quality of services provided.

3.3. Involvement of the stakeholders

The involvement of citizens and the participation of patients in the health and rehabilitation processes promote trust and compliance, increase their direct responsibilities in the efficacy of the services received and further the commitment of the facilities toward improvement. Within the scope of empowerment strategies, the Ministry has launched several initiatives, addressing facilities and organisations, seeking to encourage their involvement as the backbone of the healthcare system. The program "United for Safety" has led to the drafting and dissemination of nine Guides, the last 3 of which were completed between 2009 and 2010 aiming at clear and transparent communication on safety between operators and patients.
To establish a benchmark for all these initiatives, a Program titled "Developing appropriate tools to ensure the active involvement of patients and operators and all other subjects who interact with the SSN", was developed. The Program has carried out an assessment (INDACO – Enquiry on involvement) of the empowerment initiatives currently underway in our Country. The full results of the INDACO assessment can be accessed on the Ministry portal.
Within the scope of the program, a Guide for the operators was drafted so as to ensure the full involvement of the citizen/patient in all the phases of the medical-healthcare path and an international convention was held: "Humanising the services through the participation of patients" which was attended by representatives of the International Alliance of Patients Organizations (IAPO) and of the European Patients Forum (EUF).

3.4. Guidelines

Guidelines represent an important government medical tool aimed at improving the quality of healthcare and the appropriateness of the healthcare services provided by the Regions and Provinces.
National policies and strategies for the development of documents that help the healthcare operators in their healthcare decisions provide for consensus conferences in order to reach, through a formal process, an agreement among different professionals as regards particularly controversial and complex healthcare issues.
Within the national system for the monitoring and control of healthcare (SiVeAS), a programme has been developed aimed at improving the quality of healthcare through the drafting, circulation and implementation of Guidelines and recommendations regarding the appropriateness of clinical behaviours. This program was carried out through the National Guidelines System (SNLG) with the participation of government bodies, Regions and Provinces and scientific organisations.
For the purpose of the rational use of resources, it will be important to promote the drafting of new national Guidelines, with the support of government organisations such as Istituto Superiore della Sanità and AgeNaS.
The availability of Guidelines at an international level that are compliant with the criteria of a validated methodology also allows for their customisation according to the Italian context.

It is also important to develop programmes promoting a consistent application of the Guidelines by Regions and Provinces.
Finally, the promotion and diffusion of diagnostic-therapeutic paths, chosen in partnership with the Regions and Provinces, must also be achieved through training initiatives to be implemented within ECM regional programmes, in order to further the knowledge of professional personnel.

3.5. Accreditation and quality certification systems

Law 296/2006, article 1, paragraph 796 and s.m.i. has set forth the termination of the complex procedure for the Institutional Accreditation of Healthcare facilities, and stated that, starting on 1 January 2010, all healthcare facilities, in order to operate in the name and on the behalf of the SSN, must have met the quality requirements set forth in the so-called "institutional accreditation". The final deadline for its implementation was subsequently moved to 31 December 2010 for healthcare facilities.
An analysis conducted by AgeNaS has found that, as at 31 May 2010, private healthcare facilities fully accredited were 54.2% (7,161) of the total; those only partially accredited were 19.2% (2,536) and the remaining 26.7% (3,527) were placed in the category "Others" (comprising different cases not included in the mentioned categories).
The initial meaning of "accreditation", as a mostly administrative tool, is undergoing some changes with the adoption of measures that guarantee the quality of treatment, especially in terms of safety. The regulations concerning Accreditation must be reviewed also in consideration of the issues associated with the remuneration for the services provided.
The Ministry of Health has appointed a panel of experts entrusted with the review of the legislation on accreditation (TRAC) which must provide specific regulatory and technical-scientific guidelines that would guarantee the implementation of quality in the healthcare services provided by the accredited healthcare facilities, and that would also promote an integration among public and private facilities, giving more space for voluntary accreditation of excellence as a central element for national and therefore regional planning vehicles.

3.6. Pharmacovigilance

Pharmacovigilance is the process of a continuing monitoring of the safety of the medicinal products available on the market. The main objectives are the identification of any potential warning sign related to the use of medicinal products, the assessment and quantification of the risk of adverse reactions and finally, the adoption of measures for minimising such risk.
In 2009 and 2010, pharmacovigilance activities continued and were further developed also through the strengthening of the national pharmacovigilance network (with the involvement of the regional centres) and of its connection to Eudravigilance and to the WHO Uppsala International Drug Monitoring Centre.
The spontaneous reports of suspected adverse reactions to medicinal products have increased compared to previous years exceeding the historical maximum level reached so far (20,186 reported cases in 2010 compared with 9,741 in 2007).
In 2010, the national average exceeded the 300 reported cases per 1 million inhabitants, the gold standard set by WHO.
In 2009 and 2010, the active pharmacovigilance projects submitted by the Regions and/or Provinces were reviewed and monitored.
A particular effort was dedicated to the optimisation of information on the safety of medicinal products through the publication, on the AIFA site, of Important Information (NII) and through the email service for the exchange of information within the National Pharmacovigilance Network.

4. National Healthcare System (SNN) resources

4.1. Financial Resources

According to the first available data, the SSN expenditure in the fourth quarter of 2010 stood at 111.168 billion euro. The