in a context that is not just national, but also European or even worldwide.

3. Technological resources – Medical devices

3.1. Large equipment

Health equipment is a key element in the provision of LEA. There are currently various different systems for detecting data in any case traceable to certain types of equipment: the most consolidated and standard refers to the data of data collection models of managerial activities of the health structures (HSP14 and STS14); these record annual information on technical-biomedical equipment, according to type, present in the individual hospital and non-hospital structures, with specific reference to positron emission tomography (PET), integrated CT/PET systems, integrated CT/gamma camera systems, linear accelerators, systems for digital angiography and mammographies. For some large equipment (equipment in absolute value and indicator per 1,000,000 inhabitants), an increase was recorded in 2010-2012, in average national availability.

In order to ensure systematic, homogeneous data recording, assuring greater details than are already available, the Ministry of Health, in collaboration with the Autonomous Regions and Provinces, as part of the NHIS, has completed its "Feasibility study for the collection of information on health equipment used at healthcare structures". This has enabled the definition of essential elements in terms of: structuring into stages, equipment to be included in the recording, data sets to be recorded, structures to be involved, data interchange methods and data collection time. The document was supported by an experimental stage of recording, to which fourteen Regions adhered with 352 pieces of equipment (situation as at 14 February 2014).

Some of the most interesting aspects of innovation include the tumour adrotherapy device installed at the National Oncology Therapy Centre (CNAO) of Pavia, which has only recently become a resource of the NHS. The main accelerator of the CNAO is a synchrotone, a circular accelerator measuring approximately 25 metres in diameter. At the CNAO, which in December 2013 completed its clinical trial stage, approximately 180 patients have already been treated.

Keywords Accelerator, computerised tomography (CT), database, healthcare equipment, health technologies, medical devices, National Classification of Medical devices (CND), New Health Information System (NHIS), nuclear medicine, positron emission tomography (PET), radio diagnostics

3.2. Medical device sector governance

In recent years, the medical device sector in Italy has become a matter of great interest to the public institutions and the Ministry of Health and the drive of the legislator to investigate knowledge of supply and demand in Italy, has been very important indeed. The medical device market encompasses a multitude of products of which up until just a short while ago, the dimension was unknown; today, on the other hand, timely information is available on their number and specific technological characteristics. Moreover, a single instruments makes this wealth of information available to NHS structures, the Repertory of Medical Devices, where each device is also classified according to the structure defined by the CND. The classification enables the grouping of devices into homogeneous classes and therefore makes it easier to consult the range of data that, at end 2013, regarded more than 577,000 medical devices. In addition to knowledge of the supply gained through this Repertory, knowledge of the dimensions and structure of the market of medical devices acquired and used in the public health facilities of the NHS is also important. By collecting data on the "Information flow for the monitoring of consumption of medical devices acquired directly by the NHS" transmitted by the Regions to the Ministry of Health once a month, the various different levels of governance are provided with data on consumption and expenditure on medical devices with numerous possibilities of comparative analysis between the various territorial contexts. The data collected has also been disseminated to the public through the pub-

lication of the 2012 annual report and the subsequent First half 2013 Report, which, in addition to explaining the phenomenon, also provide an appendix detailing expenditure data collected for health and CND category structures, data which for 2013 came to more than three billion Euros.
Through the "Information flow for the monitoring of consumption of medical devices acquired directly by the NHS", data has also been collected on contracts relating to devices: for 2013, data was collected relating to more than 266,000 contracts.

Keywords Database, consumptions, medical devices, expenditure

3.3. Medical devices market surveillance

The Ministry of Health, the competent authority for medical devices, monitors the application of national legislation by implementing a constant programme of controls over the various components of the chain marketing medical devices. For lack of a preventive authorisation system by the public administration, this activity is a cornerstone of the CE marking system of medical devices. Surveillance takes effect in various control methods aimed at verifying the work of manufacturers, distributors, traders and importers, as a guarantee of public health and end users. In order to verify medical devices, the Ministry of Health can order inspections directly at the places of product production and/or storage, or may acquire all information necessary to the inspection and, where necessary, temporarily taking a sample of the device being inspected, to carry out examinations and tests.
Surveillance is launched following reports or controls carried out during routine audits (followed by inspections of manufacturers and economic operators, the medical device database, issue f "free sale certificates", management of CE marking certificates that have been withdrawn or suspended, checks on specific categories of products in order to examine knowledge of their characteristics and performance, etc.). Reports received from the territory are also essential (healthcare structures, air, maritime and border health offices of the Ministry, NAS, etc.), as well as constant communication with the other competent European authorities.
Further tools in support of market monitoring and surveillance include the registers of the systems, which have the twofold objective of assessing the performance of the device installed and promptly tracing the patient, if an adverse event should be reported.

Keywords CE mark, compliance, medical devices, monitoring, safety, surveillance

3.4. Inspections of economic operators of medical devices

Inspections of economic operator of medical devices aim to verify their work with a view to guaranteeing safe use of this type of products to protect the health of users.
As competent authority for the sector, the Ministry of Health is responsible for these controls, yet without replacing the Notified Bodies, which are responsible for issuing CE certifications for devices in the highest risk class.
During inspections, information is acquired, viewed, evaluated and/or documents acquired in relation to the work of the economic operator, but findings may also emerge that are duly reported by inspectors, in order to enable suitable corrective action to be taken by the operator being inspected.
To date, the Ministry has scheduled and carried out surveillance and monitoring inspections using specifically trained staff regularly updated in the specific sector.

3.5. Clinical investigations of medical devices

The development of biomedical technologies in recent decades and the consequent dissemination of a vast type of medical devices (arterial stents, defibrillators for implant, pacemakers, heart valves, joint prostheses, robotics, etc.), has given rise to a real revolution in the treatment of numerous disciplines, such as, for example, interventional cardiology, heart surgery, general surgery, orthopaedics, etc.
This development makes for the continued need for trials on humans to assess the performance and safety of medical devices. Italy sees a significant commitment by investigators, ethics committees and the competent

authority – the Ministry of Health – aimed at safeguarding the health of patients enrolled in the clinical investigations.
In Italy, the competent authority in matters of clinical trials involving medical devices is the Ministry of Health, which, in terms of protecting the health of patients recruited in clinical investigations, is responsible for evaluating those carried out using medical devices.
In 2010-2013, approximately 240 notifications were received of new clinical investigations, of which approximately 80% obtained a positive opinion for their conduct. In the remaining 20%, however, the evaluation was not successful.
Clinical investigations mainly take place in cardiology and heart and vascular surgery, neurology and neurosurgery, orthopaedics and surgery, and the majority (58%) are carried out with devices considered as "high" risk (e.g. pacemakers, heart valves, stents, etc.).
Investigations are promoted by Italian sponsors (manufacturers or institutions) for approximately 38%, by US sponsors for 36%, European sponsors for 16% and by manufacturers based elsewhere in the world (e.g. Israel and Japan) for the remaining 10%.
Most of the investigations carried out in Italy consist of international multicentre trials (i.e. they are carried out simultaneously in various countries of the European Community, United States, Canada etc. and other countries such as Japan and Israel).
Sponsors of clinical investigations are required to send the competent authorities of all countries in which investigations are underway, reports of any adverse events recorded.
In 2010-2013, in Italy and elsewhere in Europe, approximately 16,800 patients were recruited, with approximately 1,100 events relating to the device being studied and/or the related implant procedures.
These reports, together with those sent directly to the monitoring systems, enable monitoring of the safety levels of clinical trials and the development of suitable corrective action to ensure the safety of the subjects experimented and the reliability of device use.

Keywords Biotechnologies, clinical trials, medical devices

3.6. Medical device supervision

The monitoring of medical devices performed by the Ministry of Health prioritises the removal and prevention of risk situations to public health, seen on the territory following the use of medical devices, through national actions and joint action with Member States, organised with better defined, clear operating criteria, adopting more direct communication strategies with the territory, such as the making available of an on-line form on the website of this department, dedicated to the reporting of incidents by health operators involved.
In these latter years, in redefining priority interventions, the supervisors have finalised a new database referred to as "Dispovigilance", which, on equal footing with the European monitoring system "EUDAMED", aims to implement the continuous monitoring of the performance, security and safety of medical devices released to the market; it participates in monthly supervisory conference calls held between Member States, collaborating effectively, wherever necessary, with the NAS for protecting health and the technical body of the *Istituto superiore di sanità*.

Keywords Database, dispovigilance, EUDAMED, International Medical Device Regulators Forum (IMDRF), MEDDEV, Medical Device Expert Group (MDEG), medical devices, monitoring, National Competent Authority Report (NCAR), New Emergency Technologies (NET),

4. Ordinary and additional financial resources

4.1. Levels of NHS financing and measures for rationalising health expenditure

Italian Legislative Decree n. 502/1992, as amended by Italian Legislative Decree n. 299/1999 regulates the essential aspects of the relationship between the public subject and private suppliers of health services. Amongst other aspects, the annual contracts stipulated by each individual private supplier establish the maximum volumes of provisions the contracting party undertakes to assure and the estimated total price resulting from the application of the tariff values and remuneration according to

functions. With Ministerial Decree of 18 October 2012, the Ministry of Health adopted the new approximate reference tariffs.
Regional planning must consider budget restrictions and private structures – apart from the ceiling limit to expenditure assigned it – are in no way required to provide services.

Keywords Contracts, private suppliers, tariffs

4.2. Standard costs of LEA

Italian Legislative Decree n. 68/2011, as from 2013, established the introduction of standard health costs, to be implemented through the use of a set of indicators able to evaluate the levels of efficiency and suitability achieved in each Region, with reference to a set of supplies made within each of the three macro levels of healthcare assistance.
During the 2013 allocation, the cost values recorded in the three reference Regions were therefore applied to all Regions. The best practices are identified in the various regional contexts by means of a set of indicators defined by the Council of Ministers resolution of 11 November 2012.
The activity has already begun, aimed at revising and reclassifying the criteria pursuant to art. 27 of Italian Legislative Decree n. 68/2011, which is useful for identifying the Regions of reference in the years to come, according to the quality level of services dispensed, suitability and efficiency.

Keywords Best practices, indicators, Regions of reference ,standard costs

4.3. European structural funds: operating project for technical assistance for the Regions of the South

The Operating Project for Technical Assistance 2007-2013 – POAT Salute – of the Ministry of Health, developed as part of the European Community Cohesion Policy and co-financed with the European Structural Development Funds – ESDF – has now reached its conclusion. With this project, aimed at the four Regions of the Convergence Objective (Calabria, Campania, Apulia and Sicily), the Ministry of Health has sought to offer the Regions concrete support to strengthen their administrative and governance capacity for a targeted planning of services and resources, in harmony and coherence with the rationalisation of expenditure and reorganisation of services launched by the Realignment Plans and the national and European economic planning documents.
The project objectives have been identified through careful, accurate analysis of the needs of each individual Region, thereafter flanked operatively by local technical assistance entrusted to three external actuators with excellent competences and experience in strategic areas of intervention, such as:

- support with the identification of innovative organisational and managerial models to strengthen the healthcare and social-health assistance planning skills, including through operative support, to define, spread awareness of and use of tools by which to supplement the Health Impact Assessment (VIS) and the most widespread HTA methods;
- support with adhesion to international, European Community, national and regional cooperation and research projects;
- support with the development of innovation, computerisation in health and remote medicine projects.

The results achieved have satisfied the initial demands expressed by the Regions and achieved all project goals; in a great many cases, the standards required have been exceeded and some of the methodological documents prepared have already been effectively adopted by the Regions.

Keywords Convergence Objective, European structural funds, Health, POAT, Pon Gat, technical assistance

4.4. Public investments in health

The planning policy of public investments dedicated to the structural and technological assets of the NHS have closely followed the trend of the general reclassification policies of the healthcare offer, extending the objectives initially identified by the legislator, with Art. 20 of Italian Law n. 6/1998. Italian Law n. 67/1988 authorised a multi-year investment programme of 30,000 billion Italian lira, equivalent to 15,494 million Euros, struc-

tured into several stages. Resources have been increased up to a total of 24 billion Euros. The first stage of the programme came to an end in 1996 with the authorisation to spend the total amount of 4,855 million Euros. The second stage, which was started in 1998, aimed to implement a specific programme for the completion of structures that had been started and "make-safe" interventions for 1,291 million Euros. Resources totalling 15,286 million Euros have been allocated to programme agreements. As at 31 December 2013, a total of 68 Programme Agreements had been signed by the Ministry and Autonomous Regions and Provinces, for an amount of 10,206 million Euros. As at 31 December 2013, approximately 89.9% of the resources committed to Agreements signed was able to be tendered, and spending of approximately 9,171 million Euros was authorised. Nine Regions requested the financing of 100% of the resources subscribed, seven Regions more than 80% and five Regions requested financing of more than 50%. Another specific financing line, launched in 2012 and currently under development, is the programme pursuant to Art. 3-*ter* of Italian Decree-Law n. 211/2011, converted by Italian Law n. 9/2012 "Urgent interventions for fighting detention tension caused by the overcrowding of prisons". By inter-ministerial decree of 28 December 2012, resources were allocated to the Regions totalling € 173,807,991.00 for the development and re-conversion of non-hospital healthcare structures, in order to overcome legal psychiatric hospitals. In 2013, by specific Ministerial Decrees, the amounts necessary to fulfil the programme were assigned. The provisions pursuant to art. 2, paragraph 109 of Italian Law n. 191/2009 apply to the Autonomous Provinces of Trento and Bolzano.

Keywords Investments in health, overcoming OPG, Programme art. 20 Italian Law n. 67/1998, structural investments, technological investments

4.5. The certifiability of the NHS entities

Accounting standardisation is necessary in order to be able to guarantee the reliability and comparability of the budgets of the NHS entities. It must be flanked by the verification and potential re-definition of the procedures for the recording and auditing of accounting data. The matter of standardisation therefore comes into contact with that of certifiability, intended as the application of a regulation of the accounts and a system of administrative-accounting procedures enabling the entities, at all times, to be successfully audited and have their accounts audited.

Keywords Accounting standardisation, administrative-accounting procedures, certifiability

5. National Health Information System

5.1. New Heathcare Information System (NHIS)

The New Healthcare Information System (NHIS) is the instrument of reference for the measurement of quality, efficiency and appropriateness of the National Health Service (NHS), through the availability of information which, in its completeness, consistency and promptness, supports the Regions and the Ministry in exercising their roles for the purposes of NHS governance, monitoring the Essential Levels of Healthcare (ELH) and healthcare expenditure.

The development of the NHIS has led to the definition of information content and a common language in order to enable the interchange of data between regional information systems and the national level. Therefore, the information concerning the various fields of health has been identified and rules defined for the proper channelling of the information flows for the purpose of enabling a uniform reading of the data that constitutes the informational assets of the NHIS.

Currently, these project developments have led to the speedy provision of information, collected on an individual basis, that corresponds to a major part of the ELH that make up 85% of healthcare expenditure. The NHIS informational assets are a vital prerequisite for the creation of analytical tools that enable indicators to be drawn up in support of the analysis of the demand, in terms, for example, of appropriateness, healthcare mobility and waiting times, as well as carrying

out integrated, across-the-board analyses of the various ELH. The availability of the data concerning the entire national territory will enable comparative analyses to be completed between the various regional organisations and the respective comparisons to be made with the healthcare and financial-managerial performances within the sphere of the NHS. Moreover, it will enable the measurement of the improvement of the quality of healthcare delivered to the citizens and the efficiency with which the available resources are used.

Keywords Analysis of the demand, appropriateness, information content, data, information flows, indicators, reading the data, Essential Levels of Healthcare (ELH), New Healthcare Information System (NHIS), information assets, performance, healthcare expenditure

5.2. Healthcare on the web

During the two years 2012-2013, the Health Ministry has carried out actions to support the development and spread of healthcare on the web, at the national and community levels.

As regards the community level, in implementation of article 14 "Healthcare online" of the Directive 2011/24/EU concerning cross-border healthcare, the eHealth Network was established in January 2012. The purpose of this body is to develop and disseminate eHealth at the community level. Within the sphere of the eHealth Network, Italy is represented by the Director-General of the Directorate-General of the healthcare information and statistics system of the Health Ministry. In the two years 2012-2013, the Health Ministry also took an active part in the projects Cross-Border Patient Registers Initiative (PARENT) and the eHealth Governance Initiative (eHGI).

As regard the national level, the eHealth initiatives created by the Health Ministry in line with the programmatic strategies defined at the community level in collaboration with the regions are fundamental for the development of the national eHealth Information Strategy. In the dedicated paragraph, a brief update is given as regards the implementation status of the following initiatives: Systems of Single Appointment Centres (SAC), Systems of Digital Healthcare Folders (DHF), Digitisation of the clinical-healthcare documentation, Digital transmission of the sickness certificates, ePrescription, Network infrastructure for in-house freelance activity and Telemedicine. The Health Ministry considers it fundamental to continue along the path taken so far, aimed at creating uniform conditions across the national territory for the development of healthcare on the web, which is a strategic lever capable of triggering a process of change and enabling the bringing into being of models, processes and innovative healthcare pathways, necessarily more efficient, firmly focused on the citizens and personalised to their needs.

Keywords Cross-Border Patient Registers Initiative (PARENT), Digitisation of the clinical-healthcare documentation, Directive 2011/24/EU, eHealth Governance Initiative (eHGI), national eHealth Information Strategy, ePrescription, network infrastructure for in-house freelance activity, Systems of Single Appointment Centres (SBC), Systems of Digital Healthcare Folders (DHF), Digitisation of the clinical-healthcare documentation, Telemedicine, Digital transmission of the sickness certificates.

5.3. Food Safety and Veterinary Information Systems

The National Food Safety Veterinary Information System (SINVSA) is the information tool of reference through which the Ministry of Health collects health data from the entire length of the food production chain, useful to the governance of action aimed at protecting animal health and food safety. The SINVSA manages the data of zootechnical business, live animal transporters and means of transport, plants registered in accordance with Regulation (EC) n. 852/2004, animal feed manufacturers and operators in the animal feed industry. It has the zoonosis reporting systems and the programmes co-financed by the EU for the notification and management of centres of animal disease and management of official controls of the I&R system, animal welfare, the national control plans and prophylaxis in animal health. This system con-

tains a section dedicated to the management of controls performed in implementation of specific monitoring activities of environmental contaminants in animal-origin foods, a manual of veterinary medicines and the management system of animal trials.
Considering the flow of live animals and animal-origin products and in compliance with the rules of free intra-Community trade, in 1998, following Italian Legislative Decree n. 28/1993, Italy developed the national computer system SINTESI (Integrated System for Trade and Imports). The use of SINTESI-Trade, together with Italian Legislative Decree n. 27/1993, which established the Veterinary Offices for Compliance with European Union Obligations (UVAC), has laid the legal basis enabling Italy to have an effective system by which to monitor goods entering from abroad. Considering the effectiveness of the system shown in particular for the management of the traceability of goods in the health emergencies that have struck the EU in recent years (BSE, bird flu, dioxin, etc.), in 2013, it was re-engineered, with the following main advantages:

- adaptation of the model granting access to the system and simplification of the administrative requirements by companies towards UVAC offices and the ASL, in compliance with the provisions of the Digital Administration Code (Italian Legislative Decree n. 82/2005);
- guarantee of interoperability and applicative cooperation with other national and European Community systems (e.g. TRACES BDN, Customs systems, database of facilities recognised in accordance with Regulation 863/2004 and Regulation 1069/2009, national bovine database);
- improvement in the quality of data relating to structures (registered operators and reference structures) and their geolocation.

Keywords Animal health, food safety, information system, trade and imports

6. Registers of pathology and surveillance

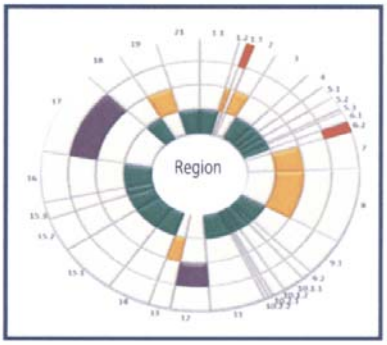
The NPP for 2010-2013 highlighted the fact that the choice and development of prevention actions must be based on suitable knowledge of the problems, the effectiveness of the solutions and suitability of the development processes. Surveillance is the main category of activities through which prevention constructs this knowledge focused on action, using both specific registers and surveillance systems and existing health and statistics information systems created for other purposes. The other main levels of healthcare have expressed similar needs for knowledge, particularly for the planning and monitoring of services and other activities envisaged in the LEA.
With the planning of the NCDC for 2011, one specific project has been envisaged for development, in order to "...prepare a memorandum of understanding on the registers and surveillance systems that is justified by relevance", also in view of the implementation of legislative provisions on registers and surveillance.
A great many systems of surveillance and registers operative in Italy are sources of information of great importance that have not yet been regulated in terms of the protection of confidentiality.
Only recently has the legislator established that their existence, justifications, subjects, responsibilities and forms should be made lawful through a specific decree and the related regulatory provisions thereafter, through Italian Decree-Law n. 179 of 18 October 2012; under art. 12 - paragraphs 10-14, this establishes that by Prime Minister's Cabinet Decree, on the proposal of the Ministry of Health, surveillance systems and registers of mortality, tumours and other pathologies, treatments consisting of transplants of cells and tissues and treatments based on medicinal products for advanced therapies or tissue engineering products and prosthesis implants, shall be set up.
This same legislation also establishes that at the proposal of the Ministry of Health, a regulation shall be adopted in which, in compliance with the provisions of the Personal Data Protection Code, the subjects are identified who may gain access to the mentioned registers and surveillance systems and the data of which they may become aware, as well as measures for the safe custody and security of data.

7. Monitoring, verification and suitability of LEAs

7.1. The system for evaluating the provision of levels of care in conditions of efficacy and suitability, the "LEA Grid"

With the State-Regions Understanding of 23 March 2005, the requirements were identified as applicable to Regions (with the exclusion of Valle d'Aosta, the Autonomous Province of Bolzano and Trento, Friuli Venezia Giulia and Sardinia, since 2010), in order to access the greater financing of resources allocated to the NHS. The Permanent Committee established to verify the provision of the LEA, instituted by Ministerial Decree of 21

Figure. LEA grid – set of indicators for monitoring the level of care.



Indicators:

1.1 Vaccination coverage in children at 24 months with basic cycle (3 doses (polio, diphtheria, hepatitis B, whooping cough, Haemophilus Influenza)
1.2 Vaccination coverage in children at 24 months with one dose of vaccine against measles, mumps, rubella (MMR).
1.3 Vaccination coverage for vaccination against influenza in the elderly (≥ 65 years)
2 Proportion of people who have had first level screening tests, in an organised programme, for: cervical, breast and colorectal cancer
3 Cost per capita of collective assistance in living or working environment
4 Percentage of local units checked against total to be checked
5.1 Percentage of herds checked for Bovin TB and prevalence trend
5.2 Percentage of herds checked for BRUCELLOSIS in sheep, goats, cattle and buffalo and, for Regions in which, in accordance with the Ministerial Regulation 14/11/2006, the times of rechecking and the reporting time of the laboratory results were respected in at least 80% of the cases and reduction of prevalence for all cases
5.3 Percentage of sheep and goat farms checked for sheep and goat registry (3%)
6.1 Percentage of samples analysed out of a total of the samples planned by the National Residue Plan
6.2 Percentage of sampling carried out from the total of those scheduled, in marketing and catering businesses, articles 5 and 6 of the Presidential Decree 14/07/95
7 Weighted total of the standardised specific rates for certain avoidable conditions/disease in ordinary hospitalisation: paediatric asthma, diabetes complications, heart failure, urinary tract infections, bacterial pneumonia in the elderly, COPD
8 Percentage of elderly people ≥ 65 years IHC
9.1 Number of equivalent places for care for the elderly ≥ 65 years in residential facilities per 1,000 elderly residents
9.2 Number of places for care for the elderly ≥ 65 years in residential facilities per 1,000 elderly residents
10.1.1 Number of equivalent residential places in facilities that deliver care to the disabled every 1,000 residents
10.1.2 Number of equivalent semi-residential places in facilities that deliver care to the disabled every 1,000 residents
10.2.1 Number of places in residential facilities that deliver care to the disabled every 1,000 residents
10.2.2 Number of places in semi-residential facilities that deliver care to the disabled every 1,000 residents
11 Active beds in hospices out of a total of deaths from tumours (per 100)
12 Percentage of annual consumption (expressed in DDD – Defined Dose per Day) of medicines belonging to the Home Healthcare Formulary
13 Number of specialist outpatient MRI services per 100 residents
14 Users taken care of by mental health centres per 100,000 inhabitants
15.1 Rate of standard hospitalisation (ordinary and day) by age per 1,000 residents
15.2 Day admission rate by diagnostic type per 1,000 residents
15.3 Rate of doctos accesses (standardised by age) per 1,000 residents
16 Percentage of regular admissions with surgical Diagnosis Related Groups (DRG) out of a total of regular admissions
17 Ratio between admissions attributed to DRG at high risk of inappropriateness (attachment B Health Pact 2010-2012) and regular admissions attributed to DRG not at risk of inappropriateness
18 Percentage of primary caesarean births
19 Percentage of Patients (aged 65 +) with main diagnosis of fracture of the neck of the femur operated on within two days on regular admission
21 Alarm-Target interval of ambulances

Source: Health Ministry. LEA Grid, LEA Committee – Year 2012.

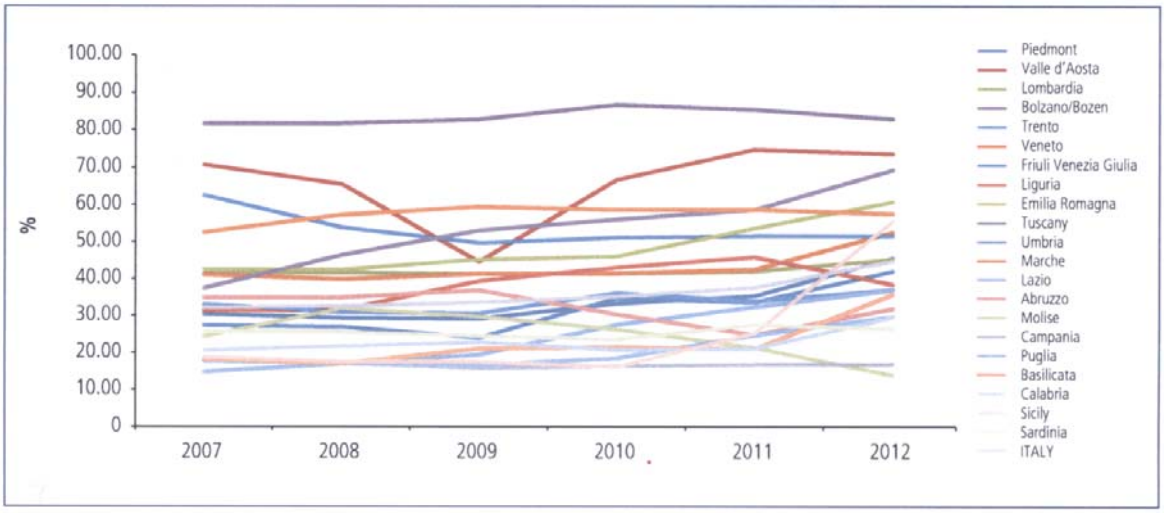
November 2005, is assigned the task of verifying regional compliance under the scope of the broader task of monitoring LEAs in conditions of efficacy and suitability.
For 2012, 38 compliances have been certified, of which some structured into several sections, making for a total of 48 evaluations; these cover the most important areas in terms of quality of supply of the LEA and the suitability and efficient use of the resources and information systems. The results of the audit have confirmed compliance for the Regions of Lombardy, Veneto, Liguria, Emilia Romagna, Tuscany, Marche, Umbria and Basilicata (although some Regions still have outstanding commitments to meet), whilst for the Regions on the Realignment Plan, although a progressive improvement has been seen to the reorganisation of the information system and treatment networks, a great many critical issues still remain.
Requirements include maintaining the supply of LEA, which is verified through the use of the "LEA Grid", a defined set of indicators divided up amongst care provided in life and at work, territorial care and hospital care. The LEA Grid is the main tool by which to monitor and verify the effective provision of services throughout national territory and replaces (in accordance with Art. 10, paragraph 2 of the Health Agreement 2010-2012), the system of guarantees for the monitoring of healthcare envisaged by Italian Legislative Decree n. 56/2000. The Grid method results in a score that enables the Regions to be classified as "compliant", "compliant with commitments" or "critical". For 2012, the central and northern Regions and Basilicata were found to be compliant; Sicily, Abruzzo, Molise, Apulia and Calabria were "compliant with commitments" and Campania was "critical".

Keywords Audit, committee, compliance, efficiency, evaluation, indicators, LEA Grid, Levels of care (LEA), monitoring, provision, rose, suitability

7.2. Hospital suitability indicators

With the reform of Title V of the Constitution in 2001, which introduced federalism into the organisation and management of health services, the Ministry of Health took on very much a guiding, monitoring and controlling role, aimed at guaranteeing the health of all citizens. The monitoring of the provision of LEA in conditions of efficiency and efficacy goes hand-in-hand with specific indicators aimed at promoting corrective action able to improve the performance of the regional health services.
"Suitability" is discussed in all national pro-

Figure. Percentage of fractures of the femur operated on within 2 days of admission – Acute admissions in regular admission (Years 2007-2012).



Source: Health Ministry. Hospital Discharge data bases – Year 2007-2012.

visions, agreements and understandings sanctioned in the State-Regions Conference. The 2010-2012 Health Agreement defines a set of indicators to be used to monitor the achievement of an appropriate delivery of services and health services, as confirmed in the 2014-2016 Agreement. The set of indicators, complete with reference parameters and benchmarks, enables national planning to promote all efficiency drives possible and evaluate the suitability of resources available with the provision of LEA and the regional planning to be applied directly to the health facilities in order to allocate the resources as efficiently as possible; this includes, for example, formulating objectives for general directors, rationally defining the threshold values within which to admit ordinary hospitalisations, establishing the tariffs to be applied to the provisions and defining the measures to be adopted for services beyond these thresholds.
The indicators used include the "percentage of hospitalisations with surgical DRG in ordinary regime out of the total ordinary hospitalisations" and the "percentage of patients (aged 65+) with main diagnosis of fracture of the femur, operated on within two days under ordinary regime". For the first, which measures the use of hospital structures for their primary function of hospital care for acute cases, in 2007-2012, we see a positive increase in values for all Regions apart from Liguria. For the second, which evaluates the capacity by the hospitals to manage their burden and response times for caring for patients with fractured femurs, we see a high level of regional variability, with 15 Regions showing a positive increase in 2012 as compared with 2011.

Keywords Control, guidelines, hospital care, indicators, monitoring, standard, suitability

7.3. Variability of the organisational suitability of care structures

The concept of "suitability" is essential to improve the quality of health services supplied and the correct use of the health system resources; the monitoring of the LEA evaluates both the organisational suitability in the choice of appropriate care settings in which to deliver the services and the clinical suitability, through a verification of the latter's effectiveness.
The analysis of the variability of the hospitalisation rates in the various ASL can allow for the identification of potential inappropriateness of the hospital care delivered. In the variability analysis, the event described as "hospitalisation for a given pathology" takes on a probability p, equal to the standardised national hospitalisation rate. If we use a binomial distribution to evaluate the probability of a given volume of hospitalisations with respect to the population resident in the territorial area considered, we can define a range of acceptability in the difference between the hospitalisation rate observed and that of reference p. This range varies in an inversely proportional manner to the population n of the territorial area considered.
Use of a dispersion graph, which, for each ASL, reports the resident population on the x axis and the rate of hospitalisation observed on the y axis, enables the effective viewing of variability, differences with respect to the reference value p and intervals of acceptability, forming a useful tool by which to monitor suitability and support health planning.
By way of example application, the chapter reports the graphs for 2009 and 2012 for the Clinical Aggregate of Codes (ACC) of procedure "0044 – Coronary artery bypass graft (CABG)" and for the ACC of procedure "0153 – Total and partial hip replacement".

Keywords Hospitalisation rate, inappropriateness, Levels of care (LEA), monitoring, suitability, variability

7.4. Monitoring of clinical trials

AIFA is the organisation in charge of monitoring all clinical trials conducted in Italy through a dedicated resource, the National Clinical Trial Database (OsSC), which also allows for information sharing among patients and healthcare operators.
The OsSC enables AIFA to collect and analyse data from all clinical data conducted nationwide. As at 31 December 2012, this large archive contained 8,835 clinical trials.
The percentage of Phase I and II studies conducted in Italy is confirmed in step with the

element of the past years in respect to the total research studies conducted in Italy, standing well over 40% of the total.
Similarly, Phase III studies confirm the trend started in 2005, i.e. remaining below 50% of the sample: in 2012, in fact, this portion accounted for 44.2% of the total.
The most researched therapeutic area is oncology (34.9% of the total), followed by cardiology/vascular disease (7.7%), blood and lymph system diseases (7.2%), neurology (6.0) and muscular-skeletal system diseases (4.6%).
The preliminary data for 2013 shows how all clinical trials and substantial amendments presented to the AIFA in its new role as competent authority respectively came in at 649 and 1,983, generally confirming the ratio previously seen between clinical trials and substantial amendments, of 1 to 3. 2013 basically saw a maintenance of the portion of clinical trials referred to as "early phase" I and II of approximately 46%, thereby showing that, despite the world crisis, Italian clinical research has remained competitive in the two years considered.

7.5. Monitoring of the use of medicinal products and pharmaceutical expenditure

In 2012, each Italian purchased an average of 30 packs of medicinal products through public and private pharmacies, for a total of more than 1.8 billion packs. Total (public and private) pharmaceutical expenditure came to 25.5 billion Euros, 76% of which was reimbursed by the NHS. On average, drug expenditure per Italian citizen was approximately 430 Euros. The total daily dose prescribed every 1,000 inhabitants in 2012 was 1,626.8. Total (public and private) territorial pharmaceutical expenditure has reduced on last year by –5.6% and came to 19,389 million Euros. The daily doses prescribed every 1,000 inhabitants by the NHS under the authorised care regime, were 985 (an increase of 2.3% on last year). Public territorial spending came to 11,823 million Euros and recorded a reduction of –8%.
During the first nine months of 2013, the Italians purchased a total of 1,398 million packs of medicinal products, for an average of approximately 23 packs per head.
In terms of consumption under the authorised care regime, 1,002.4 daily doses were prescribed every 1,000 inhabitants, showing growth (+1.8%) on last year. Total national pharmaceutical expenditure for the first nine months of 2013 came to 19.5 billion Euros, 74.7% of which was reimbursed by the NHS. During the same period, territorial pharmaceutical spending by the NHS came to 8,799 million Euros (148.1 Euros *per capita*), down –3.9% on the same period of last year. The expense for drugs used in the hospital came to 1.9 billion Euros, 68.1% of which consists of class H drugs, 16.7% class C drugs and the remaining 15.2% class A drugs.

Keywords Hospital pharmaceutical spending, pharmaceutical spending, territorial pharmaceutical spending

7.6. Realignment plans and formal and system monitoring

Italian Law n. 311/2004 gave rise to the operative programmes for the reorganisation, requalification or strengthening of the regional health service (hereinafter referred to as the "Realignment Plans"). The Realignment Plans identify the interventions necessary to pursue economic balance in compliance with the LEA. The first Agreements were signed in 2007. The Regions today involved in the Realignment Plan are: Lazio, Campania, Sicily, Abruzzo, Molise, Calabria, Apulia and Piedmont.
In 2013, the legislator enables Regions that had not achieved the structural objectives laid down by the Realignment Plans to proceed with the Operating Programmes.
For the three years 2013-2015, all Regions, assisted by the Ministry of Health, including through technical meetings, have presented the Operating Programmes.
With a view to limiting the costs of rationalising the care networks, the fallout on the implementation of the objectives of the Realignment Plan following Italian Decree-Law n. 95/2012, has been significant.
One important piece of news for 2012-2013 was the possibility of having an exception to the block of turnover introduced by Article 4-*bis* of Italian Decree-Law n. 158/2012. To

this end, the Ministry of Health has prepared a methodology by which to define the needs of staff in hospital structures, enabling the evaluation of the grounds of requests for an exception to be made to for the correct assignment of new staff. In 2014, only the Region of Campania correctly completed the procedure and with two inter-ministerial decrees, obtained authorisation to proceed with the hiring of 251 new members of staff.
Verification of the implementation of the Realignment Plan is carried out once a quarter and once a year, by the round table of compliances of the Ministry of the Economy and Finance and the Committee for verifying the provision of care in efficient, appropriate conditions of the Ministry of Health.
Regional spending and health planning provisions impacting the regional health service indicated in the Realignment Plan are sent to the Ministry of Health, which, together with the Ministry for the Economy, expresses an assessment in this regard. The Ministry of Health not only formally monitors the provisions established in order to achieve the objectives set by the Plans, but also verifies the substantial achievement of objectives in terms both of health and the reorganisation of the health services.
The monitoring of the Realignment Plans in 2007-2012 showed good achievement of economic objectives, except for a few exceptions, whilst the healthcare reorganisation processes were not quite as visible; these do, however, require longer time frames to highlight any significant structural changes.
The Ministry of Health regularly checks the state of provision of LEA in the Regions in the Realignment Plan to ensure that the standards of fairness, efficacy and suitability of the healthcare are assured, even when the economic purposes are pursued with cuts and limitations to linear resources.

Keywords Efficacy, fairness, Levels of care (LEA), Operating programmes for the reorganisation, operating programmes, personal need, Realignment Plans, reorganisation of healthcare, requalification or strengthening of the regional health service, suitability, turnover

8. Waiting times

The problem of waiting times for the delivery of healthcare services is common to countries with complex, universal systems of healthcare. Our country considers it a priority to reduce waiting times by promoting clinical and organisational appropriateness and interventions have been agreed between the Government, Regions and Autonomous Provinces, involving the accessibility of services and the speed of service delivery, in accordance with the guarantee of the use of classes of priority through an effective system of managing bookings (CUP).
The measures implemented over the years (Prime Ministerial Decree of 16 April 2002, the State-Regions Agreement of 11 July 2005, the National Plan to restrict waiting times 2006-2008 PNCTA) have rolled out the uniform management of the waiting lists across the entire national territory. Under the State-Regions Agreement of 28 October 2010, the National Plan of Governance of the Waiting Lists for the three years 2010-2012 was adopted and Regional Implementation Plans have been drawn up under that framework.
It has emerged from the verifications of Essential Levels of Healthcare that Regions and Autonomous Provinces have carried out the monitoring envisaged and diagnostic-therapeutic pathways (DTP) have been adopted in the oncological and cardiovascular fields. Some problems have emerged concerning the implementation of the aforementioned DTP, the management of the information flows and the prescriptive criteria, connected to the appropriateness and use of the classes of priority.
The scheduled actions underline the respect for the maximum waiting times for a list of diagnostic, therapeutic and rehabilitation services of specialist outpatient treatment and hospital treatment and the development of healthcare diagnostic-therapeutic pathways for the cardiovascular and oncological fields. The assessment and improvement of the appropriateness and prescriptive consistency are being promoted by identifying operational methods for the proper access to the services, and the monitoring of the waiting times is being reaffirmed both by *ex post* and *ex*

ante methods. Methods of the procurement of additional services are also being promoted, delivered through a freelance regime by the Agency, as are methods of communicating the waiting times to the citizens.

9. Institutional accreditation

Recent years have recorded a major drive towards the sharing of essential elements of the accreditation system, in order to guarantee fairness in the delivery of treatment nationwide and make it easier to recognise our model in supranational contexts, particularly during this historic period marked by major European challenges with respect to cross-border treatments (Directive 2011/24/EU). The drive towards convergence, together with the need to revise the reference legislation – highlighted in the latest Health Agreement – has enabled the launch of a close national and inter-regional examination, through a specific round table (TRAC); this has resulted in the preparation of the document entitled "Regulations for the revision of accreditation legislation". The Regulations, agreed upon in a permanent conference for relations between the State, Regions and Autonomous Provinces with the Understanding of 20 December 2012 (Rep. n. 259/CSR), have defined a common framework of reference for the accreditation of Italy's health structures, through the identification of 8 quality criteria, 28 requirements and 123 forms of evidence. The regional adjustment to comply with the contents of the regulation will require the definition of terms and conditions for adjustment and the identification of standardised criteria for the function of the "Certifying bodies".

Alongside the definition of shared, common criteria and requirements, the results are shown of the last monitoring, carried out in 2013 by AgeNaS, on the state of implementation of regional accreditation processes. The analysis has highlighted a substantial immobility of the authorisation and accreditation system of public structures, and a certain delay in the completion of definitive institutional accreditation of private social-health and health structures, as compared with the terms laid down by Italian Law n. 296/2006 as subsequently amended.

Keywords Accreditation, monitoring of accreditation state, requirements and accreditation criteria, technical rules for accreditation

10. Measuring the quality of the National Health Service

10.1. Portal of transparency in health services

The inter-regional project "Portal of transparency in health services" is an innovative initiative concerning communication and transparency to citizens in accessing health services; it was resolved on 24 January 2013 by the State-Regions Conference and is regulated by the Technical Coordination of the Health Commission of said Conference and financed (by CIPE resolution 2012), by the resources restricted for use for the achievement of the objectives of the NHP for 2011. The project will make use of the collaboration of the Ministry of Health, the Autonomous Provinces and Regions and AgeNaS, which will define and coordinate the development of the "operating programme".

The objective is to develop new forms of communication hinged on three specific areas of intervention: a) Portal of transparency in health services; b) National Results Programme (PNE); and c) Directive 2011/24/EU – Application of patients' rights in cross-border healthcare.

The development of the first area of intervention (the "Portal") will take place through the active involvement of institutions, organisations, professionals and citizens. Specific profiles are envisaged granting access to the Portal: consisting of the presentation of information specifically for the user, decision-maker and technician, with legible contents that can be improved by the direct contribution of the users.

The contents will be organised according to three major working pillars.

- First pillar: Health: health news; medical dictionary; vaccinations; screening; technological innovations, etc.
- Second pillar: Health Services
  1. The NHS: rights and principles sanctioned by the law, data on what the

NHS provides, how it is organised and how it invests its resources
2. Regional services database: presentation of the services supplied by the health and social-health structures operating on national territory
3. Evaluation of quality of service: indicators on how the services supplied guarantee health (accessibility, efficacy, safety, etc.), resources (efficiency), rights (humanisation, participation) and fairness

- Third pillar: The forum on health and services: space where users will interact with the system, asking questions and submitting feedback for the evaluation of the structures

Keywords Accessibility and usability of health and social-health services, institutional communication, empowerment of citizens, quality of services, transparency

10.2. National Results Programme (NRP)

The National Results Programme (NRP) is developing, within the SSN, the assessment of the outcomes of healthcare interventions as described in point 2 of the attachment to the resolution adopted by the Standing Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano n. 20 of 24 January 2013 and subsequently by article 12 paragraph 7 of the new Pact for health for the years 2014-2016 (Rep. n. 82/CSR of 10 July 2014) with the following objectives: observational assessments of the "theoretical" efficacy of healthcare interventions for which experimental assessments are not possible/available:

- assessments of new treatments/technologies for which experimental studies are not possible;
- observational assessments of the "operational" effectiveness of healthcare interventions for which experimental assessments of effectiveness are available;
- assessment of the difference between the efficacy of the treatments when estimated in experimental conditions compared to those observed in the "real world" of services, and the respective impact;
- comparative assessment between delivering subjects and/or between professionals with possible applications in terms of accreditation, remuneration, information of the citizens/users, with publication of the results of the outcome of all the facilities for "empowerment" of the citizens and their associations in the choice and assessment of the services;
- comparative assessment between population groups (for example, by socio-economic level, residence etc.), especially for assessment programmes and the promotion of fairness;
- identification of the factors of the healthcare processes that determine outcomes, for example, estimating what minimum levels of activity are associated with the best outcomes of the treatment and using the minimum levels as a criterion of accreditation;
- internal and external auditing.

The NRP assessments concern:

- the functions of production, assigning the patients/treatments to the treatment hospital or service, defined with specific criteria for each indicator;
- the functions of protection and commissioning, assigning the patients/treatment to the area of residence.

The 2014 version of NRP on 2013 data analysed 57 indicators of outcome/process, 49 levels of activity and 23 indicators of hospitalisation. In addition, there is a section dedicated to the audit instruments for the notification of critical or anomalous values and a section on interregional experimentations for the assessment of territorial healthcare and emergency. The NRP results can only be used in an appropriate way in contexts of critical assessment, especially within the sphere of integrated processes of assessment at the regional and local levels. The NRP measures are, therefore, assessment instruments in support of clinical and organisational auditing programmes aimed at the improvement of the efficacy and fairness of the SSN; NRP does not produce classifications, gradings, score cards, judgements.

Keywords Empowerment of the citizens, fairness, quality of the treatments, transparency, assessment of outcome

10.3. The National Guidelines System

In the last two decades, the Guidelines, intended to be instruments of rationalisation of clinical-organisational conduct, have acquired particular relevance with regard to the remarkable variability in the delivery of healthcare services and the spread of evidence-based medicine. In order to give a response to this need, the National Programme for Guidelines (NPG) was launched in 2006 with a portfolio that includes the preparation, disclosure, updating and implementation of Guidelines intended as a rational, ethical and efficient aid for decision-makers and users with regard to diagnostic and therapeutic pathways within the scope of the NHS.

In 2004, in the wake of the experience of the NPG, the National System for Guidelines (NSG) was established, by decree of the Health Ministry, which, in outlining its organisation, assigned tasks to the institutional bodies of the National Health Service. In carrying out the provisions of the decree, the ISS was assigned the role of coordinating the production of Guidelines in 2006, using methods that were in compliance with those used by the main international agencies concerned with appropriateness, such as NICE and SIGN, for example.

The objective is to promote processes of assessment of what is available in the scientific sphere in order to ensure treatment appropriate to the patients, guiding healthcare operators in their decisions and reducing the variability of clinical conduct.

The activities of the NSG are broken down into four principle areas: Guidelines production, Consensus Conference and Rapid Revision of Documents, Information, training on the Guidelines and Implementation of the Guidelines.

Implementation is the critical aspect and envisages collaboration between regional and local healthcare institutions, the verification of the impact and the monitoring of the variability in the application of the Guidelines, and assessing the causes. In order to favour implementation, the NSG has developed a platform, called GOAL, the tasks of which include the implementation of the Guidelines through the creation of healthcare projects at the local level, both clinical and organisational. This instrument also enables the recommendations contained in the various Guidelines to be shared, enabling, at the same time, the local organisations to be identified where these are not applied, and so that the reasons for the failure in application to be understood. Identification of the obstacles to local implementation will enable a consensus to be built up on the best way to overcome them.

10.4. Directive 2011/24/EU - Application of patients' rights in cross-border healthcare

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, has been transposed by Italian Legislative Decree n. 38 of 4 March 2014, which came into force on 5 April 2014. This legislation flanks the social security Regulations (EC) n 883/2004 and 987/2009, which already enable treatment to be received in another EU Member State, in the other countries of the European Economic Space and in Switzerland, extending the existing regulatory framework governing cross-border healthcare, consisting of the complex system of international mobility that charges the State with the protection of patients moving around and travelling for various reasons (tourism, study, work, etc.).

In actual fact, Italian Legislative Decree n. 38/2014 guarantees the right to access safe, high quality cross-border care, enabling the patient to be treated in another EU Member State through the choice of the public or private healthcare provider. Therefore, the scope of application of the Decree includes scheduled and unscheduled treatment as well as treatment provided by health professionals not accredited with the national health system. The Decree also acts as a supplementary regulation insofar as it eliminates the general need for preventive authorisation, apart from the cases envisaged under Art. 9, and recognises the complete right of any citizen to be able to request healthcare, apart from long-term healthcare, the assignment and access of organs for transplant and public vaccination programmes against contagious diseases.

In any case, as sanctioned by the Directive, Italian Legislative Decree n. 38/2014 also establishes that patients must not be deprived

of the most advantageous rights guaranteed by the above regulations if the conditions established therein are met.

The cross-border healthcare envisaged by the Decree is provided indirectly, i.e. through the patient paying costs in advance. Article 8 of the Legislative Decree establishes that costs incurred by an insured person in Italy making use of cross-border healthcare, may be reimbursed if and to the extent to which the provision made in another EU Member State falls under the scope of the LEA coinciding with current regional tariffs and without exceeding the effective cost of the healthcare received.

In addition to the above, one of the key objectives and points of the legislation in question is to strengthen the patient's right to be treated in structures he/she considers to be most appropriate for his/her clinical case, or which are closest to the place of residence of his/her nearest and dearest; it also applies where the person in question happens to be in a border Region and the nearest healthcare structure is effectively that of the neighbouring Member State.

In this regard, the aim set by Directive 2011/24/EU is to offer clear, transparent, intelligible information, accessible to all patients on their rights (high quality standards and safety, suitable monitoring, disabled access to hospitals, transparent bills and prices, clear vision of authorisation and the registration of providers and their insurance cover, procedures on claims and legal reports); this goal is pursued through the establishment, at the Ministry of Health, of the National Contact Point, in accordance with Art. 7 of Italian Legislative Decree n.. In actual fact, through this organisation, the patient can receive suitable information on all essential aspects of cross-border healthcare and, therefore, make an informed choice suited to their own clinical case.

Another innovative element introduced by the Directive and incorporated under art. 11 of Italian Legislative Decree n. 38/2014 is the encouragement of cooperation between Member States in order to achieve greater efficiency and transparency in the NHS and strengthen scientific and technological development.

Finally, a special mention must be made of the recognition of medical prescriptions issued in another Member State, which, with the aim of assuring continuity of care, is one of the most innovative aspects. It is a question of making available, both providers and users of the healthcare, specific instruments, including on-line tools, on the entire clinical path of the patient, in order that they can have advance knowledge of whether the treatment provided abroad and related medicinal products and devices can continue to be provided in the affiliated State.

10.5. Joint evaluation of quality

Under the scope of the Current Research Programmes financed by the Ministry of Health, AgeNaS has promoted and developed, in collaboration with the Agency for Civic Evaluation of Active Citizenship and with all the Autonomous Provinces and Regions, two research-action projects; these are aimed at defining a joint evaluation model of quality, in the firm belief that health systems must not only show good performance, promote transparency and report on results achieved, but that stakeholders must also be involved in the processes of evaluating policies and public services.

The research-action are focused on the construction of a model for evaluating and improving quality – classifiable under "Evaluation of the quality of services" in the Portal for the Transparency in Health Services. Through this, professionals and citizens can jointly report on the level of humanisation of the treatment structures.

According to a specific operative definition of the concept of humanisation, a reporting check-list has been prepared with the involvement of all stakeholders, representatives of the Regions and professionals of the structures, as well as citizens, through their representation associations.

A methodology has been finalised whereby citizens play an active part in managing the entire evaluation process. After having been trialled in 54 different hospitalisation structures, the methods and instruments are now used for a first investigation of the level of humanisation of hospitals and accredited private treatment centres; this involves more