Italy's health care system and the crisis:
overview of policy actions and their implementation

O sistema de saúde italiano e a crise:
uma visão geral das políticas e sua implementação

Francesca Ferrè
Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, 56127 Pisa, Italy.

Guido Noto
Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, 56127 Pisa, Italy.

Federico Vola
Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, 56127 Pisa, Italy.

Abstract

Economic and fiscal crisis and political instability has put the Italian health system under strain during the 2010-2014 period that saw accelerated ongoing political changes. Government interventions in the Italian NHS have taken the form of either urgent decrees or measures in the annual state budget law rather than systematic reforms and have mostly consisted in caps on specific spending areas [1]. At the same time, higher co-payments for outpatient care and drugs have been introduced, adding to private spending on health. On the other hand, the 2015-2017 policy period provided more room for designing and developing long-term policy reform tackling macro-system aspects (appropriateness and quality of hospital care or national chronic care plan).

However, performance in terms of health protection and quality of care has showed large variation across regions, mainly (but not exclusively) between the northern and southern regions. The worsening economic conditions had a negative effect on access to health care services for the most vulnerable groups of the population and the short-term effect on health showed an increase in psychiatric disorders and quality of nutrition, posing major challenges in the long run.

The political challenge ahead is the reconfiguration of powers between the national and regional governments, where more wealthy regions are calling for greater (full) fiscal decentralization.

Key Words:
Italy, financial crisis, health care, policy actions.

Resumo

Em Itália, a crise económica e fiscal e a instabilidade política colocaram o sistema de saúde sob tensão durante o período de 2010-2014, durante o qual ocorreram diversas mudanças políticas. A intervenção governamental no sistema de nacional de saúde italiano assumiu a forma de decretos urgentes ou itens na lei do orçamento anual em vez de se terem realizado reformas sistemáticas e consistiu essencialmente em cortes em áreas específicas de despesas (recursos humanos, bens e serviços, medicamentos). Ao mesmo tempo, aumentaram as comparticipações dos doentes nos copagamentos das taxas moderadoras e medicamentos, aumentando a despesa privada com saúde. Por outro lado, o período político de 2015-2017 deixou mais espaço de manobra para o desenvolvimento de políticas reformistas de longo prazo, abordando aspetos do macrossistema (adequação e qualidade dos cuidados hospitalares e plano nacional contra a dor).

Contudo, o desempenho em termos da proteção da saúde e qualidade dos cuidados mostrou uma grande variabilidade regional, especialmente (mas não exclusivamente) entre as regiões do norte e sul. A degradação das condições económicas teve um efeito negativo no acesso aos serviços de saúde para os grupos mais vulneráveis da população e os efeitos a curto prazo na saúde mostram um aumento dos distúrbios psiquiátricos e na malnutrição, trazendo maiores desafios a longo prazo.

O desafio político futuro será a reconfiguração dos equilíbrios de poder entre o governo nacional e os regionais, pois as regiões mais ricas exigem maior (ou total) descentralização fiscal.

Palavras Chave:
Itália, crise financeira, cuidados de saúde, políticas de saúde.

DOI: https://doi.org/10.25761/anaisihmt.251

The Italian National Health System (INHS)

The INHS was established in 1978 by replacing a system based on multiple social health insurance funds and was modelled after the British NHS with provision of universal coverage largely free of charge at the point of service. It is mainly financed through general taxation (Beveridge model) and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care[1]. It is a comprehensive health care system, providing the full range of prevention, treatment and rehabilitation services. Since the early 1990s, legislative reforms have gradually transferred political, administrative, fiscal and financial responsibilities regarding the provision of health care from the national government to the twenty regions. The major 2001 Constitutional reform (Constitutional Law No. 3/2001), which redistributed legislative competences between the national government and regional governments – paving the way to the fiscal devolution (Law No. 42/2009) – framed a quasi-federal arrangement for the Italian state. Devolution was aimed at increasing regions' competencies and responsibilities over health care organization/planning and delivery.

The system is currently organized and governed at three levels: national, regional and local.

The central government has a stewardship role. The Ministry of Health and the Ministry of Economics and Finance – in agreement with the regions – determine the core health benefits to be uniformly granted across Italy ("Essential Levels of Care" - ELCs) and allocate to the regions the financial resources collected through general taxation. Since the early 2000s, the health care budget has been allocated to the regions based on capitation, partially adjusted by the age distribution of the population. The Italian Parliament defines the legal framework and other national agencies are in charge of contracting with key stakeholders[2]. The Ministry of Finance and the Ministry of Health may also intervene in the event of persistent financial deficit and take over regional health care management.

The regions oversee organizing and delivering primary, secondary and tertiary health care services, as well as preventive and health promotion services. They define their own regional health plans, coordinate the strategies of the regional Health Authorities, allocate the budget within their systems and monitor quality, appropriateness and efficiency of the services provided. Because of the devolution policy, Italian regional health systems differ from one another, in relation to the quality of care they provide, the level of health care expenditure and their financial performance.

At the local level, the Italian public health care system includes three main providers:

- *local health authorities* (geographically based organizations, which are responsible for delivering public health, community health services and primary care directly, and secondary and specialist care through directly managed facilities, or by commissioning services to public hospital institutions or private accredited providers):
- *public hospital institutions* (which often cooperate with Medical Schools and work as Teaching Hospitals);
- *private accredited providers*

In general, doctors and nurses employed by the INHS are salaried and have civil servant status. An exemption is represented by general practitioners and paediatricians, who are independent professionals, paid via a combination of capitation and fee-for-services for some interventions.

The Italian government's adjustment programme and the health care system

Coherently with its three layer-institutional architecture, Italy responded to the global economic crisis through: a) plans and other interventions devised by the central government; b) actions jointly taken by the national and regional levels of government; and c) initiatives autonomously endorsed by regions [1]. Starting from the economic, financial and fiscal crisis of 2008-2009, the central government has proposed cost-containment measures in different areas of health care expenditures. During the crisis up to 2016, the government adopted pro-cyclical approaches to the global crisis advocating reduced public spending and increased efficiency savings.

Indeed, numerous legislative initiatives addressing

1 - Public financing accounts for 74% of total health spending in Italy, while 26% is privately financed, through out-of-pocket (OOP) payments (23.6%) - especially for pharmaceuticals, outpatient care and dental services -, voluntary health insurance coverage and non-profit institutions serving households (2.4%) (2017 data - OECD Health Statistics; http://www.oecd.org/els/health-systems/health-data.htm).

2 -Such as the National Drug Agency (AIFA) with pharmaceutical industries and the National Agency for Collective Agreements (ARAN) with trade unions representatives.

spending review and cost-containment measures have been put forward (for example, Decree Law 98/2011; Decree Law 95/2012 and Stability Pact 2013) albeit no adjustment program was signed under the Troika. Different cutback management strategies were envisaged [2], from proportional cuts across the border (linear cuts) such as cut on volume/value of procurement contracts for good and services, to adoption of targeted cost-containment policies such as pharmaceuticals spending thresholds or reference pricing or measures seeking productivity and efficiency gains. In addition, policies targeting financial contributions to the health system were included (i.e., changes to publicly defined health budgets and changes in user fees) complemented with fiscal policy to earmark taxes for health[3] in situation of regional financial unbalance (see below).More recently, policies targeting benefits and quality of care were also promoted, such as changes to the range of publicly financed benefits available (redefinition of the benefits package),reduction of hospital sector overcapacity and standards of hospital care and chronic care model, among others.

Before presenting in detail the health policy responses to the crisis, it is important to mention that Italy implemented mechanisms to control public health-care expenditure already before the crisis broke out. Consequently, it is claimed that the main effects of the crisis on Italian health care policy accelerated ongoing policy changes rather than triggering the introduction of radically new ones [1].

After the devolution of power from national to regional level (Constitutional Law No.3 of 2001) public health-care expenditure was highly variable across the regions and generated over 38 billion Euros of cumulative deficit between 2001 and 2010 [3]. Therefore, the central government re-assumed an increasing steering role and oversight of regional financial performance and in 2006 introduced formal financial recovery plans (*Piani di Rientro*) after partial bail-out periods (2001-2005) to finance the past health deficits of regions.

Financial recovery plans were conceived as a debt-restructuring tool aimed at making regions accountable for their economic and financial deficit under the scrutiny of the Ministry of Health and the Ministry of Economics and Finance[4]. During the first recovery plan period (2006-2010) ten regions[5] negotiated and implemented deficit management measures using resources derived from: new regional prescription charges, savings on purchasing of goods and services, limiting the expenditures on health care providers, reclassifying drugs charged to the INHS, imposing mark-ups to the regional tax rates, and/or selling properties [3]. The overall effect of this was a decreased in the yearly level of overspending; In 2010, the total deficit of the public health care sector was 2.33 billion Euros, which is approximately one-third of the peak in 2004 [1].

During the crisis, recovery plans remained in place and from 2010 they became compulsory for all regions with a deficit higher or equal to 5% of the allocated funds. More recently, in 2016, hospital-level recovery plans were also mandated for either financial distress or standards of care below national targets (Law 208/2015).

Overall, the expenditure control measures implemented between 2006 and 2010 in deficit regions were extended well-after 2011 and were extended to all regions, especially through policies aimed at increasing the efficiency of public spending through improved accountability of the regions for the provision of essential services and respect for financial constraints [1].

EFFORTS TARGETING COST-CONTAINMENT AND MEASURE SEEKING EFFICIENCY GAINS

Cost-containment measures targeted mostly personnel and pharmaceutical costs and the purchase of goods and services.

Personnel costs

The expenditure reduction was achieved mainly by restricting medical doctors and other health care-professionals turnover, especially for the regions under a recovery plan, and by freezing salaries. In some Italian regions, incentives for early retirement were also introduced (from 2008 onwards). The same kind of measures were also applied to GPs.

Specifically, a threshold was introduced at national level in 2006 to limit expenditure on health-care

3 - Examples include additional mark-ups to the regional tax rates, such as the business tax (IRAP); surtax on the national personal income tax (IRPEF) and vehicle tax.

4 - Nevertheless, a full turnaround process was expected from financially distressed regions, including replacement of key members of top management positions, retrenchment or short-term actions to stabilize the regional performance and repositioning or long-term actions to re-establish strategic direction to successful performance [7].

5 - Abruzzo, Puglia, Calabria, Campania, Lazio, Liguria, Molise, Piemonte, Sardegna and Sicilia.

personnel. The expenditure threshold was fixed at the 2004 level reduced by 1.4%. As a result, the restrictions on workforce turnover caused a reduction of about 35,000 working units in five years (2010-2015) [4].

Pharmaceutical expenditure

As in other developed countries, drug expenditure levels were governed through reduction of expenses for non-innovative drugs (whose patents have progressively expired) and policies aimed at steering pharmaceutical governance at national and regional level, jointly leveraging appropriateness and efficiency. Regarding the regional level, policies have been differently devised and implemented across regions, but they generally entailed: strengthening the direct distribution of pharmaceutical products; centralizing the procurement process; and leveraging managerial tools (such as budgeting and pay for performance), in order to orient prescription towards off-patent and/or lower cost medicines.

At national level, three main tools have been envisaged to support appropriateness:

- *expenditure caps*: first set on indirectly distributed drugs (Decree Law 1st of October 2007, N.159, art.5, c. 2, letter d, and subsequent Law 222/2007) and later on directly distributed drugs. The National Drug Agency (AIFA) is in charge of monitoring potential deficits: in this case, pharmaceutical manufacturers are bound for paying back to the regions 50% of the amount that go over the set ceiling;
- *web-based "clinical registries"*: first introduced in 2007, they aim at granting prescription appropriateness and timely monitoring by supporting authorized prescribers along the prescription process;
- *managed entry agreements (MEAs)*: are conditional agreements AIFA signs with pharmaceutical manufacturers, in order to subordinate the payment of the drugs to their real-life efficacy (also known as performance-based risk sharing agreements).

Purchasing of goods and services

Cost containment was achieved through specific regulations at the national level[6] which called for the renegotiation of procurement contracts for goods and services (including contracts for hospital medicinal products, vaccines, blood products and medical equipment) in order to reduce the value of all active contracts by 5%. Only unit prices and/or purchase volumes were renegotiated, length of contract or other terms and conditions remained unchanged.

Moreover, central government placed increased attention on reducing expenditures on medical devices (MDs) and enhancing their monitoring through the introduction of national expenditure caps and payback mechanisms in case of expenditures that go over the set ceiling. In addition, the agreement reinforces the role and effort of the Ministry of Health (through the newly appointed HTA Steering Committee for MDs) to adopt new technologies following HTA approach.

To increase purchasing efficiency (or in search for savings), a structural policy reform was put forward which ask for the concentration of purchasing activities in regional or supra-regional entities. This resulted in the adoption of new organizational models using central purchasing agencies[7] at the regional level.

POLICIES TARGETING BENEFITS AND QUALITY OF CARE (PRODUCTIVITY)

The redefinition of the benefits package

The list of the publicly financed health benefits (ELCs) agreed in 2001 (DPCM 29th of November 2001)[8] details the services that had to be uniformly granted across Italy, ranging from prevention to primary and secondary care to rehabilitation. ELCs were slightly updated over the years but a major revision occurred in January 2017 (DPCM 12th January 2017)[9].

The revision extended the range of publicly funded services:

- the list of outpatient publicly-funded services was updated, including new technologies such as particle therapy and optical coherence tomography;
- the list of publicly-funded prosthetic and assistive equipment was updated;

6 - National regulation include the National Healthcare Plan (*Patto per la Salute 2014-2016*), the 2013 Stability Pact and Decree Law 95/2012.

7 - Voluntary and compulsory consortia to centralize technical and administrative activities between health providers (called *centrali d'acquisto*).

8 - http://www.salute.gov.it/imgs/C_17_normativa_1479_allegato.pdf

9 - http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=58669

- the list of chronic and rare diseases that are covered by the NHS was extended, by granting an increased range of services to people suffering from autism or endometriosis, for instance;
- new vaccines and neonatal screening were included among the publicly-financed services.

No significant delisting was performed. The revision was a negotiation that involved the main stakeholder of the INHS (the Ministry of Health, the regions, the scientific societies, some trade unions, some national health supporting agencies, such as the National Institute for Health and the National Agency for Regional Health Services), however, the lack of transparency in decision making process raised questions [5]. Also, there are concerns over the financial coverage for this extended benefits package. The 2016 Stability Law allocated 800 million Euros to the ELCs revision, however, regions suspect they may not fully cover their increased financial needs[10].

Productivity and quality standards for hospital care

Efforts oriented at re-designing the role of the hospital setting especially with reference to their relations with territory services occurred well before the crisis. Indeed, the demographic and epidemiological trends – e.g. ageing population, increased incidence of chronic diseases – have pressured the national government to reduce hospital overcapacity in favour of non-acute services. To reduce overcapacity, national Law 135/2012 have gradually required regions to reduce: (i) the number hospital beds (3.7 beds per 1000 population including 0.7 beds for long-term care); (ii) the hospital admissions (hospitalization rate lower than 160 over a thousand inhabitants) by increasing the use of appropriateness criteria to avoid unnecessary admissions; and (iii) the average length of stay. It is noteworthy that the regions with the highest debt (under recovery plan) were required to issue their implementation plans earlier than the other regions.
Also, policies towards increasing efficiency and effectiveness of care through increased appropriateness and quality of care have been introduced (Ministerial Decree N.70 of 2015). Indeed, the Decree reaffirmed the need of increasing hospital efficiency by acting on the beds occupancy rate and length of stay. The former was set at 90%, while average length of stay should be lower than 7 days for ordinary admissions. However, the overall aim of the Decree is to ensure that each regional health system guarantees the delivery of the ELC according to the principles of effectiveness, quality, safety, efficiency and patient centeredness. For selected clinical procedures (i.e., deliveries, oncological surgery, vascular surgery, femur fracture surgery, laparoscopic cholecystectomy) - for which there is evidence of an inverse relation between volumes and clinical outcomes (i.e., morality) - national quality standards have been applied at hospital level. For example, for breast cancer, the decree indicates a minimum number of 150 breast surgeries per year.

Effective primary care groups and chronic care plans

Following a common policy trend in primary care, the Italian NHS continued the attempts to reorganize the delivery of primary care, with the objective of moving from the traditional single GP practice to an integrated care model (e.g., GP group practices) that connects different health care services. Targeted policies have been adopted at national and regional level for more integration between hospital and primary assistance. Indeed, in 2012 the Decree Law N.158 reinforced the need that primary care should be reorganized into teams of professionals to provide 24-hour coverage and thus ensure continuity of care. On this development path, some regional health-care systems (Lombardy at the frontline) are developing integrated services for non-acute care involving GP groups as the principal agents to respond to post-acute and territorial chronic care needs.
As for chronic care, at central level, the Ministry of Health issued the National Plan for chronic care conditions in December 2016. The National Plan devised a process for tackling chronic care rooted in a population health management approach, introducing individualized and flexible health care program "*Piani di cura*" (Care Plans) modelled on clinical pathways for a selection of chronic conditions. Regions are redesigning the medical practice of chronic care with expected improvement in the quality of life of chronic patients through enhanced access to primary care, and long-term savings resulting from fewer hospital admissions, visits to hospital emergency departments and specialist

10 - http://www.sanita24.ilsole24ore.com/art/in-parlamento/2016-11-30/saitta-800-milioni-i-lea-buona-partenza-ma-potrebbero-non-bastare-184827.php?uuid=ADIeit4B

physician consultations. While some Regions, such as Lombardy, have already started radical reforms to address these requirements, others still have to take the first steps. The major challenge and possible obstacle for implementation is funding without any dedicated budget released by the Ministry of Health, regions are being asked to find the necessary resources from existing budgets through re-allocation of funds or efficiency gains. To oversee and monitor the operationalization of the Plan and its implementation at regional level the Ministry recently established a national commission.

MEASURE TARGETING FINANCIAL CONTRIBUTION

Higher co-payments (outpatient, emergency care and drugs)

Reduction in central funding was compensated primarily by higher co-payments and cost-saving measuresto reduce pharmaceutical expenditures. In late 2011 new more extensive co-payment system for outpatient/ ambulatory care, diagnostics and drugs was introduced by the regions adding to private spending on health. Specifically, beginning in October 2011, regions had to introduce a €10 co-payment for visits to public and private accredited specialists and a €25 charge for visits by patients aged 14 or older to hospital emergency departments that are deemed inappropriate. Exemptions defined by the Ministry of Health for low-income, disabled, aged and chronic patients remain in place; however, these co-payments were added to existing tariffs, placing a significant burden on patients. Notwithstanding the centralised nature of these interventions, the national government allowed regions to decide whether to apply these co-payments in full or to enact regional rules that allow for varying co-payments according to gross family income or service tariffs.

The performance of the health care system under the Italian government's adjustment programme

HEALTH STATUS RESULTS

Despite the crisis, a range of indicators shows that the health of the Italian population has improved over the last decades (Table 1). Average life expectancy at birth reached 81 years for men and 85.6 years for women in 2016, the second highest in Europe after Spain (OECD Health database) (compared with 78.1 years for men and 83.4 years for women for the OECD as a whole). However, intra-regional differences for both men and women life expectancy exists, reflecting the economic and social imbalance between the north and south of the country. For example, there is a gap of 1.1 years in life expectancy between the longest and shortest lived regions, for both genders)[11].

Life expectancy at 65 years is increasing at similar trend for both women and men, even though international statistics show a slight decline in the trend between 2014 and 2015 (Table 1).

Infant mortality in Italy is low and the decline has continued during the crisis, from 3.2 infant deaths every 1,000 live births in 2010 to 2.8 in 2016. Biological determinants and skilled assistance at delivery are particularly significant inexplaining the trend in neonatal mortality [6]. However, the sharp decline of the total fertility rate over the last 30 years is a matter of concern in Italy, as for other Western countries. From 1995, a reversal has been observed, partially due to the effect of immigration, and fertility rates have gradually increased until 2010 reaching 1.45 births per women (Table 1). From 2010 to 2016 fertility rate decreased again reaching just 1.35 births per woman, far below the replacement level of 2.1[12]. The population growth rate is, therefore, very low (-0.13% in 2017), one of the lowest in the European Union (EU), and immigration is the source of most of this growth[13] .Consequently, aging population is on the rise with higher incidence of chronic conditions.

As reported by Rechel et al. [7] and Karanikolos [8] the impact on population health of the financial and economic crisis may led to an increase in suicide and deaths related to alcohol use and also cause outbreaks of infectious disease especially among vulnerable groups. In Italy, suicide rates over the last 25 years have decreased from 7.6 every 100,000 in 1990 to 5.7 in 2015 ranking among the lowest in Europe; however, from 2010 to 2013 an average yearly increase of 0.5-percentage point was registered followed by a smooth decline the last two years.

11 - ISTAT 2017, http://dati.istat.it/Index.aspx?DataSetCode=DCIS_MORTALITA1

12 - The reasons behind this process are complex and could be explained by the delay in transition to adulthood and the difficulties experienced by Italian women in combining work and raising children (20).

13 - World Bank 2017, https://data.worldbank.org/indicator/SP.POP.GROW?locations=IT

Table 1 - Health status of the population (1990; 1995; 2000-2016)

	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Life expectancy, Female population at birth, Years	80,3	81,5	82,8	83,2	83,2	82,8	83,7	83,6	84,1	84,2	84,2	84,3	84,7	84,8	84,8	85,2	85,6	84,9	85,6
Life expectancy, Male population at birth, Years	73,8	75,0	76,9	77,2	77,4	77,3	78,0	78,1	78,6	78,8	78,9	79,1	79,5	79,7	79,8	80,3	80,7	80,3	81,0
Life expectancy, Total population at birth, Years	77,1	78,3	79,9	80,2	80,3	80,1	80,9	80,9	81,4	81,5	81,6	81,7	82,1	82,3	82,3	82,8	83,2	82,6	83,3
Life expectancy, Females at age 65, Years	18,9	19,9	20,7	21,0	20,9	20,4	21,3	21,1	21,6	21,7	21,7	21,8	22,1	22,2	22,1	22,6	22,8	22,2	22,9
Life expectancy, Males at age 65, Years	15,2	15,8	16,7	17,0	16,9	16,7	17,3	17,3	17,7	17,9	17,9	18,1	18,3	18,5	18,5	18,9	19,2	18,9	19,4
Infant mortality, Deaths per 1 000 live births	8,1	6,1	4,3	4,4	4,1	3,8	3,4	3,3	3,2	3,1	3,1	3,2	3,0	2,9	2,9	2,9	2,8	2,9	2,8
Fertility rate, total (births per woman)*	1,3	1,2	1,3	1,3	1,3	1,3	1,3	1,3	1,4	1,4	1,5	1,5	1,5	1,4	1,4	1,4	1,4	1,4	1,4
Suicide Deaths per 100 000 population (standardised rates)	7,6	7,7	6,7	6,5	6,5	6,4[b]	6,2	5,8	5,6	5,7	5,8	5,9	5,8	6,2	6,3	6,3	6,0	5,7	n.a.
Alcohol consumption, Liters per capita (age 15+)	11,0	9,6	9,8	9,7	9,3	9,3	9,0	7,4	7,3	7,2	6,8	6,4	7,0	7,0	7,5	7,4	7,6	7,1	7,1
Obese population, self-reported, % of total population	n.a	n.a	8,6	8,5	8,5	9	n.a	9,9	10,2	9,9	9,9	10,3	10,3	10	10,4	10,3	10,3	9,8	n.a.

Source: OECD Health Statistics 2018 - Frequently Request Data. June 2018.
* Source World Bank / b= Break

As a short-term effect of the crisis Italy registered an increase in prescribing of psychotropic drugs especially in those Italian regions most affected by the crisis [9], as well as a general increase in deaths from mental and behavioural disorders [10]. Among unhealthy practices, consumption of junk food and alcohol abuse increased during the 2010-2014 period. During the same period, self-reported obesity level reached highest peak in 2012 with about 10.3% of the population reporting BMI>30 kg/m2 (Table 1) with high level especially among men (11.3%) (OECD Health Database). Obesity trend in Italy are still below OECD average (16.5% in 2016) but posing major challenges as prevalence is increasing.

Over time, prevention policies have been successful in increasing coverage for the most important vaccinations. However, state retrenchment in Italy was found to be significantly associated with declining vaccination rates for Measles, Mumps, and Rubella (MMR) [11] despite the National Immunization Prevention Plan of 2012 that define the optimum vaccine coverage at 95% of the population. The recent introduction of mandatory vaccination for Italian children may help counteract this trend (Law 119/2017)[14].

IMPACT ON ACCESS TO CARE SERVICES

Fiscal pressure and cut to supply of services also affected equity and financial protection of citizens and had an effect on access to care services. Increased rate are registered in the incidence of individuals at risk of increasing of poverty (20.6% from 18.4% in 2009), in the share of those living in severely deprived families (12.1% from 7.3% in 2009), as well as that of the people living in low labour intensity families (12.8%, from 9.2% in 2009).Inequality, as measured by the Gini index, is stable at 0.33 from 2005 to 2009, however from 2009 to 2015 it increased to 0.35 indicating increased inequalities[15].

The worsening economic conditions of the population had an effect on access to health care services. Seven percent of the Italian population reported

14 - Under the new regime, all children under 16 years are required to have proof of vaccination against 10 common infectious diseases, including measles, prior to enrolment in public schools.

15 - https://data.worldbank.org/indicator/SI.POV.GINI

some unmet needs for medical careeither for financial reasons, geographical distance or waiting times. This is a higher proportion than the EU average (less than 4%) and has grown in recent years. The proportion of people in the lowest income group reporting some unmet needs for medical care is particularly high (over 15.0% in 2015), compared to less than 1.5% among people in the highest income group [12].

Statistics show that household expenditure for health care decreased significantly between 2008 and 2009 and remained stable until 2012 proportionally reflected the dynamics of income. Again, a sharp decrease was measured in 2013 after which a smooth increase followed till recent data (2016) even though household expenditure for health care have not yet reached the 2008 level [13].

IMPACT ON HEALTHCARE RESOURCES AND ACTIVITIES

Over the last eight years, the huge numbers of financial measures included in the National Economic and Financial Documents (DEF), the annual Stability Pact (budget and allocation rules), and the recurrent changes in contributions to public finances for the regions have had a significant impact on the resources allocated to the INHS. During 2010-2012 annual health care financing registered a modest growth (less than 1%), while negative growth of funding was recorded in 2012-2013 (from 107,961 million to 107,004 million of Euros) and in the period 2014-2015 (from 109,928 million to 109,715 million of Euros). In 2016, the overall INHS financing grew by 1.1% reaching 111,002 million Euros [14]. Overall, expenditure grew at a lower rate than the GDP growth (1.3 per cent on average in the 2013-2017 period) [15]. Currently, all regions are in substantial financial equilibrium once the regional tax revenues to cover health care expenditure have been accounted for; the accounts of the INHS seem to be under control again.

From 2011 to 2017, the percentage of governmental spending on total health-care expenditure decreased by almost 2% in favour of OOP spending. On average per-capita OOP expenditure remained stable in 2008-2010 periods (about US$ 640) probably reflecting reduced disposable income and, thus, privately paid for demand. Average OOP increased by US$ 63 in one year (from 2010 to 2011) and again another high-rise occurred from 2014 to 2017 (Table 2) partially because patients may have been forced to pay higher co-payments or to go fully private due to the cost-containment policies in the public sector. In this respect, it is interesting to note the emergence of low-cost initiatives in the private sector (e.g., for dental and eye care).

Another effect of rationing public sector expenditures and introducing or increasing user charges in outpatient care has been the reported increase in waiting times and the delayed provision of important medical care [5]. Indeed, if reducing public funding or freezing personnel and staff turnover is not compensated by efficiency gains, providers may reduce their supply of services or their quality, worsening health outcomes and again shifting care towards private services.

Looking at the different source of health care spending, personnel costs decreased until 2016 (the decline in nominal terms is 6% between 2010 and 2016), showing a slight recovery in the 2017 pending the renewal of public contracts [15]. Despite the measures aiming to reduce expenditure for personnel such as freeze on medical doctor turnover, international statistics show an increase in the ratio of practicing physicians, by 0.2 physicians per 1,000 population during 2009-2016 (Table 3). An increase was also registered in nurses' density even though Italy is far below the OECD average of 9 practicing nurses every 1,000 inhabitants (Table 3). A recent study of nursing workload documented that the nursing shortage together with a range of cost containment measures had negative consequences on increased workload and stress on nurses,mainly because of an increasing number of patients in hospital suffering from social problems [16].

Other expenditure items also showed decreasing trends. For example, drug expenditures (prescribed and over-the-counter medicines) are currently substantially stable (2015-2018) after significant reductions in the 2009-2013 period (Table 2). The same applies as well to services purchased from private accredited providers.

The only significant spending item still growing is related to purchasing of goods and services, which mainly reflects the growth of hospital pharmaceutical and medical devices expenditures [15].

The Italian INHS however, kept reducing or postponing infrastructure and technology investments. In 2010, a €1 billion cut to investments in recovery of hospital buildings and technological turnover was mandated by the central government [1]. The reduction is still on the

Table 2 - Health care expenditures (1990; 1995; 2000-2017)

	1990	1995[b]	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012[b]	2013	2014	2015	2016	2017*
Current expenditure on health, % GDP	7,0	6,9	7,6	7,8	7,9	7,9	8,2	8,4	8,5	8,2	8,6	9,0	9,0	8,8	9,0	9,0	9,0	9,0	8,9	8,9
Current expenditure on health, million US$ PPP (current prices, current PPPs)	n.a.	n.a.	84727	92338	96691	98627	106082	112869	123666	125642	138504	143341	145912	146844	147113	148181	149472	149142	154826	158863
Current expenditure on health, per capita, US$ PPP (current prices, current PPPs)	1302	1531	2048	2172	2261	2284	2412	2513	2736	2775	3031	3098	3138	3211	3245	3235	3250	3292	3429	3542
Government and compulsory health insurance schemes, % of current expenditure on health	81,3	71,3	72,6	74,6	75,0	75,3	76,2	77,5	77,8	77,5	77,7	78,3	78,5	77,0	76,1	76,1	75,6	74,6	74,5	74,0
Government and compulsory health insurance schemes, per capita expenditure, US$ PPP (current prices, current PPPs)	1058	1091	1488	1621	1695	1721	1839	1947	2127	2150	2354	2426	2462	2473	2471	2460	2459	2456	2554	2622
Out-of-pocket expenditure, % of current expenditure on health	18,0	27,7	26,5	24,5	24,1	23,7	22,8	21,6	21,3	21,5	21,3	20,7	20,5	22,0	21,7	21,8	22,1	23,1	23,1	23,6
Out-of-pocket expenditure, per capita, US$ PPP (current prices, current PPPs)	235	425	542	532	545	542	551	543	583	597	647	640	645	707	704	704	720	762	792	834
Current expenditure on pharmaceuticals (prescribed and over-the-counter) and other medical non-durables, % of current expenditure on health	21,4	19,5	21,2	21,9	21,9	21,4	21,0	20,4	20,1	20,0	19,2	19,0	18,8	18,5	16,6	17,0	16,9	17,8	17,7	17,7
Current expenditure on pharmaceuticals (prescribed and over-the-counter medicines) and other medical non-durables, per capita, US$ PPP (current prices, current PPPs)	279	299	433	476	494	488	506	512	550	555	582	587	588	595	538	549	551	585	607	628

b= Break / *= provisional value
Source: OECD Health Statistics 2018 - Frequently Request Data. June 2018.

Table 3 - Health care resources and activities (1990; 1995; 2000-2017)

	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017*
Physicians, Density per 1 000 population (head counts)[e]	n.a.	n.a.	3,4	3,5	3,6	3,6	3,7	3,7	3,7	3,8	3,8	3,8	3,8	3,9	3,9	3,9	3,9	3,8	4,0	4,0
Nurses, Density per 1 000 population (head counts)[e]	n.a.	n.a.	4,2	4,2	4,3	4,3	4,4	4,4	4,6	4,6	4,7	4,8	4,8	5,1	5,2	5,1	5,3	5,4	5,6	5,5
Medical graduates, Per 100 000 population	18,4	12,0	11,5	11,3	12,3	12,7	11,5	11,1	10,6	11,7	11,6	11,3	11,4	11,3	11,1	11,1	11,5	12,4	n.a.	n.a.
Total hospital beds, Per 1 000 population	7,2	6,3	4,7	4,6	4,4	4,2	4,0	4,0	4,0	3,9	3,8	3,7	3,6	3,5	3,4	3,3	3,2	3,2	n.a.	n.a.
Curative (acute) care beds, Per 1 000 population	7,0	6,1	4,2 [b]	4,1	3,9	3,7	3,5	3,5	3,4	3,3	3,2	3,1	3,0	2,9	2,8	2,8	2,7	2,6	n.a.	n.a.
Medical technology, Magnetic Resonance Imaging units, total, Per million population	n.a.	n.a.	7,8	9,1	10,9	11,9	14,1	15,0	17,0	18,8	20,1	21,6	22,5	24,2	24,6	25,2	26,2	28,2	n.a.	n.a.
Medical technology, Computed Tomography scanners, total, Per million population	n.a.	n.a.	21,1	23,0	24,1	23,9	26,2	27,8	29,3	30,6	31,0	31,9	32,2	32,6	33,3	33,1	32,9	33,3	n.a.	n.a.
Doctors consultations, Number per capita	n.a.	n.a.	6,1	n.a.	n.a.	n.a.	n.a.	6,1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	6,8	..	..	n.a.	n.a.
Diagnostic exams, Magnetic Resonance Imaging exams, Per 1 000 population	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	78	79,1	77,6	67,1	n.a.
Diagnostic exams, Computed Tomography exams, Per 1 000 population	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	115,3	115,7	122,7	127,2	126,6	139,1	141,3	140,6	131,3	136,3	n.a.
Inpatient care discharges (all hospitals), Per 100 000 population	15808	16780	17418	17274	16802	16007	15785	15488	15369	14862	14526	14238	13820	13238	12878	12377	12004	11856	11671	11555
Inpatient care average length of stay (all hospitals), Days	11,7	10,1	7,5	7,4	7,3	7,4	7,4	7,4	7,5	7,5	7,6	7,6	7,6	7,7	7,7	7,7	7,8	7,8	7,8	7,8
Data refer to practicing physicians. Practising physicians are defined as those providing care directly																				
Data refer to practicing nurses. Practising nurses are defined as those providing care directly to																				

*= provisional value
Source: OECD Health Statistics 2018 - Frequently Request Data. June 2018.

agenda and the average rate of obsolescence of the technologies (Computed Tomography Scan, Magnetic Resonance Imagingand mammography etc.) is increasing [17], with possible negative effects on the quality of diagnostic tests, negative effects in terms of risks for the patient and health workers, as well as being more expensive in terms of maintenance and costs management.

The supply of services has been affected by the different cost containment measures. The activity of the Italian INHS has contracted in all areas of assistance. Hospital admissions decreased, to 8.7 million in 2016, with a reduction of 16% in the period 2010-2016 as expected from the introduction of more stringent appropriateness criteria. Indeed, the declines affected above all hospitalizations of low complexity; however, this decrease does not seem to be supported by an adequate improvement of the outpatient care. The introduction of hospital standards of care (Law 135/2012) led also to a steep decrease in hospital beds in the 2010-2015 period. Total hospital beds declined from 3.6 to 3.2 per 1,000 inhabitants, this reduction was driven by a decrease in acute care beds from 3.0 to 2.6 per 1,000 inhabitants. Hospital average length of stay did not change significantly over time settling at 7.8 days in 2016.

Policy changes after the end of the acute crisis

The recent history of health care expenditure among European countries is marked by attempts to place stricter control over health spending for macroeconomic reasons and towards actions improving efficiency gains. However, the reforms which have achieved savings objectives have not always fitted well with the reforms that would be required to encourage performance improvement. Indeed, too often opportunistic measures to manage austerity and fiscal distress (e.g. linear cuts) are implemented in public health-care sector while efficiency gains requiring structural reform strategy are developed to a lesser extent [18][16]. In general, efficiency gains require deploying a consistent reform strategy, often including a mix of measures, such as setting priorities in services provision and user needs, using non-service approaches, building new relationships and creating alliances, exploiting technological innovation, and others. Another route to savings, perhaps more compatible with performance improvement is the adoption or increasing the use of block-budgeting and the application of strategic or targeted cuts. Here the central government sets policies and broad ceilings but, within that framework, delegates, responsibility for allocation to particular services, programmes, or projects to local politicians and/or managers. This approach somehow permits the local determination of priorities; in the quasi-federal INHS could allow regions to select actions following the different political options.

However, the Italian case showed centralization of decision making around the political elite and a top-down (planned) approach to regions following different cost-containment strategies. On the one hand, they strengthened control over total expenditure and made use of sanctions to ensure that regions did not overspend (introduction of Recovery Plans at regional and hospital level). On the other, they directly operated on the sources of regional spending (input costs) through measures on the payment of personnel, recruitment, standards for hospital care (e.g. minimum size of hospitals) and expenditure for goods and services [6]. To a certain extent, these policies have been effective as expenditure is now under strict control. But, due to the long period of cost cutbacks, there are signs that the economic crisis has worsened some health outcome indicators, maintained differences among regions in relation to the quality of care provided and increased demand for a variety of services (e.g., waiting times are on the rise and continuity of care and intermediate care for chronic diseases are still inappropriate). Thus, the current largest challenge facing the Italian health system is to achieve budgetary goals without reducing the provision of health services to patients and assure homogeneity of level and quality of service provision across health care providers. Specifically, a critical challenge for the Italian health care system includes ensuring equity across regions, where gaps in service provision and health system performance persist as well as ensuring the quality of professionals managing health care facilities, promoting group practice and other integrated care organizational models in primary care, and ensuring that the concentration of organizational control does not stifle innovation.

Over the last decade, the need for expenditure control strengthens the role of central government with reinte-

16 - In addition, contemporary behaviours are often constrained and structured by the aggregation of past actions and decisions even though past circumstances may no longer be relevant ("the power of past decision"). Thus, selection of cut back policies has multiple explanatory factors and the existing empirical studies point to mixed evidence [21], suggesting that decision-makers tend to cut those parts of the budget that are more controllable and where public opposition are minimized [22].

gration practices reaffirming the role of the state as the main facilitator of solutions. Even before the outbreak of the economic crisis, we assisted to the reconfiguration of powers between the national and regional governments with a greater role allocated to the central Economics and Finance Ministry, which directly monitored health care expenditure and had powers over regions(financial surveillance).

Moreover, it is interesting to note that between 2009 and 2014, under pressure from the international financial crisis and amid increasing political instability, government interventions in the INHS took the form of either urgent decrees or measures in the annual state budget law rather than systematic reforms and have mostly consisted of cuts to public expenditure. The policy period following the outbreak of the crisis provided on the other hand more room for designing and developing long-term national policy reform (e.g., the national chronic care plan, the hospital standard of care, or the implementation of clinical health records) tackling macro-system organizational aspects also with greater attention to European level strategies (e.g., Digital agenda for Europe). Over the crisis, the INHS showed resilience adapting and responding to the instability with reforms to improve health services and quality but with still strong differences in the implementation at regional level.

Protagonists of a progressive alternative

The health care sector was not particularly affected by the recent national election campaign (March 2018) that gave power, for the first time, to a new political coalition between the conservative and regionalist far-right Lega Nord (Northern League) party and the new anti-establishment (radical) Five Start Movement breaking decisively with the previous centrist policies. The policy program adopted by the coalition government identified as main priorities tougher laws on immigration, reform of pensions, a flat income tax and a universal basic income. As for health policies, the populist coalition buoyed the anti-vaccine movement supporting the idea to give to families the possibility to choose whether to vaccinate or not their children despite the mandatory vaccination decree established by the previous government to boost immunization coverage amid a surge in the number of measles cases in the country. Despite the recent national political situation, it is clear that the Italian health care system needs ambitious reforms in order to remain among the best health care systems worldwide. This is even more urgent at a time when government debt is on the rise, GDP growth is at a minimum, the tight fiscal parameters imposed by the EU are limiting government expenditure and an ageing population is putting strain on the resources. Over the last decade, there have been discussions about the role of public health care and the mix with private sector components, not only in the delivery of services but also in population coverage (i.e., financial protection). Over the last decade, we assisted to the rise of private expenditures (OOP) and services provided from business-like entities, with certainly forces that push towards a quick shift towards Integrated Health Funds (IHFs), providing complementary and supplementary voluntary health insurances. Although voluntary health insurances still account for a very small share of total health spending, it has recently attracted high interest in the media and policy discussions. In 2010, the government has called for further development of the IHFs as a strong second pillar of the health system to secure the financial sustainability of the INHS and to promote integration between health and social care – a position influenced by the financial and economic crisis [19]. At the same time, voluntary health insurances have been criticized on a number of grounds mainly because there are concerns about the possible gradual decrease in public investment in health, which may further affect access to care to patients without voluntary health insurances. But, more importantly voluntary health insurances can significantly increase income-related horizontal inequity in access to specialist services and could exacerbate the economic and social disparities between the North and the South of the country, especially since devolution of power and fiscal federalism is still on the government's agenda.

Indeed, fiscal federalism is the big political matter that fuels discussion among regions and national government. Some wealthy regions are demanding greater autonomy, beyond the regional political vision on health care (liberal vs. social) feeding into an ongoing discussion on constitutional reform calling for a more federalised country. The two wealthiest northern Regions (Veneto and Lombardia which are home to around a quarter of Italy's population and account for 30% of its economic output) voted through a referendum in favour of greater autonomy (October 2017) as another example of the powerful centrifugal forces reshaping European policies (e.g., Catalonia push for independence, and Britain's decision to leave the EU). The votes were not binding but they gave the right-wing leaders of the two regions a strong political mandate when they embark on negotiations with the

central government on the devolution of powers and tax revenues from central government, especially on the health care agenda, which account for more than 80% of regional expenses. Indeed, with lower unemployment and welfare costs than the Italian average, the two regions are large contributors to national government coffers. The two regions would like to roughly halve those contributions and ask for more say over infrastructure, the environment, education and health. The same path has been undertaken by Emilia Romagna region, whose regional council has begun direct negotiations with the central government. Many other regions (i.e., Toscana, Umbria, Marche, Abruzzo, Lazio, Piemonte, Liguria, Molise, Campania) are also examining similar solutions. As a consequence, a new regional paradigm oriented at re-defining the role of the regional administrative level may emerge in the next future, re-establishing autonomy and budgetary discretionof the regions in the healthcare sector.

References

1. De Belvis AG, Ferrè F, Specchia ML, Valerio L, Fattore G, Ricciardi W. The financial crisis in Italy: Implications for the healthcare sector. Health Policy (New York) [Internet]. 2012;106(1):10–6. Available from: http://dx.doi.org/10.1016/j.healthpol.2012.04.003

2. Ongaro E, Ferré F, Fattore G. The fiscal crisis in the health sector: Patterns of cutback management across Europe. Health Policy (New York) [Internet]. 2015;119(7):954–63. Available from: http://dx.doi.org/10.1016/j.healthpol.2015.04.008

3. Ferrè F, Cuccurullo C, Lega F. The challenge and the future of health care turnaround plans: Evidence from the Italian experience. Health Policy (New York) [Internet]. 2012;106(1):3–9. Available from: http://dx.doi.org/10.1016/j.healthpol.2012.03.007

4. Ministero dell'Economia e Finanza. Il monitoraggio della spesa sanitaria. Rapporto n.4. 2017.

5. GIMBE. 3° Rapporto sulla sostenibilità del Servizio Sanitario Nazionale. Roma; 2018.

6. Ferré F, de Belvis AG, Valerio L, Longhi S, Lazzari A, Fattore G, et al. Italy: Health system review. Health Syst Transit. 2014;16(4):1–166.

7. Rechel B, Suhrcke M, Tsolova S, Suk JE, Desai M, Mckee M, et al. Economic crisis and communicable disease control in Europe : A scoping study among national experts. Health Policy (New York) [Internet]. 2011;103(2–3):168–75. Available from: http://dx.doi.org/10.1016/j.healthpol.2011.06.013

8. Karanikolos M, Mladovsky P, Cylus J, Thomson S, Basu S, Stuckler D, et al. Financial crisis, austerity, and health in Europe. Lancet [Internet]. 2013;381(9874):1323–31. Available from: http://dx.doi.org/10.1016/S0140-6736(13)60102-6

9. Mattei G, Ferrari S, Pingani L, Rigatelli M. Short-term effects of the 2008 Great Recession on the health of the Italian population : an ecological study. 2014;851–8.

10. Vogli R De, Vieno A, Lenzi M. Mortality due to mental and behavioral disorders associated with the Great Recession (2008 – 10) in Italy : a time trend analysis. 2013;24(3):419–21.

11. Toffolutti V, McKee M, Melegaro A, Ricciardi W, Stuckler D. Austerity, measles and mandatory vaccination: cross-regional analysis of vaccination in Italy 2000–14. Eur J Public Health [Internet]. 2018;0(0):1–5. Available from: https://academic.oup.com/eurpub/advance-article/doi/10.1093/eurpub/cky178/5090999

12. OECD;, European Observatory on Health Systems and Policies. Italy Country Health Porfile 2017, State of Health in the EU. Brussels; 2017.

13. Del Vecchio M, Fenech L, Rappini V. I consumi privati in sanità. In: EGEA, editor. Rapporto OASI. Milano; 2017. p. 323–58.

14. Armeni, Patrizio; Bortolami, Arianna; Costa F. La spesa sanitaria: composizione ed evoluzione. In: EGEA, editor. Rapporto OASI. Milano; 2017. p. 207–55.

15. Corte dei Conti. Rapporto 2018 sul coordinamento della finanza pubblica [Internet]. Roma; 2018. Available from: http://www.corteconti.it/export/sites/portalecdc/_documenti/controllo/sezioni_riunite/sezioni_riunite_in_sede_di_controllo/2018/rapporto_coordinamento_fp_2018.pdf

16. Palese A, Vianello C, Cassone A, Polonia M, Bortoluzzi G. Financial austerity measures and their effects as perceived in daily practice by Italian nurses from 2010 to 2011: A longitudinal study. J Contemp nurse. 2014;48(2):168–80.

17. Porri E. Osservatorio parco installato: le apparecchiature di diagnostica per immagini in italia. 2017.

18. Ongaro E, Ferré F, Galli D, Longo F. Italy: set along a Neo-Weberian trajectory od administrative reform? Public Adm Reforms Eur. 2016;(2012):185–93.

19. Ferré F. Voluntary health insurance in Italy. In: Voluntary Health insurance in Europe Country experience [Internet]. 2016. p. 83–7. Available from: http://www.euro.who.int/__data/assets/pdf_file/0011/310799/Voluntary-health-insurance-Europe-country-experience.pdf

20. Rosina A, Caltabiano M. Where, in which way and to what extent can Italian fertility grow in the next 15 years? J Matern Neonatal Med. 2012;25(4):37–9.

21. Ringa R, Savi R, Randma-Liiv T. LITERATURE REVIEW ON CUTBACK MANAGEMENT [Internet]. 2013. Available from: http://www.cocops.eu/wp-content/uploads/2013/03/COCOPS_Deliverable_7_1.pdf

22. Bartle J. Coping with cutbacks: City response to aid cuts in New York State. State Local Gov Rev. 1996;1:38–48.