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EDICIONES COMPLUTENSE

The Healthcare Model of the Lombardy Region (1995-2012): The Transformed System

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Abstract. The changes in health system models in Europe have become highly relevant in the last decades. The Welfare State had to confront its own transformation, adapting to the demands of the social and economic contexts. The model of the National Health Service of the Lombardy Region has undergone a transition and evolution that reflect a new approach to its health policy. The reform process is centred on the decentralisation of the production and provision of the healthcare goods and services. The introduction of market logic has favoured the outsourcing of the provision of these goods and services to the private sector, through the separation of the financing and the provision. The result is the creation of a new institutional scheme of the Lombard health system, which can be recognised by its own layout.
Keywords: New Public Management; Decentralisation; Lombardy Health System; Health system reforms; Public service's innovation.

El modelo sanitario de la Región Lombardía (1995-2012): El sistema transformado

Resumen. Las fluctuaciones y cambios que soportan los modelos de los sistemas sanitarios han alcanzado una gran relevancia en las últimas décadas. Debido al surgimiento de nuevos problemas, el Esta- do de Bienestar ha tenido que afrontar su propia transformación, adaptándose a las demandas proce- dentes del nuevo contexto social y económico. El modelo del Servicio Nacional de Salud de la Región de Lombardía experimenta una transición y evolución que muestran un nuevo enfoque de la política sanitaria. El proceso de reforma del sistema sanitario de Lombardía se ha centrado en la descentralización de la producción y la provisión de los bienes y servicios sanitarios. La introducción de lógicas de mercado ha favorecido la externalización de la provisión de estos bienes y servicios al sector privado , mediante la separación de la financiación y la provisión. El resultado es la creación de un nuevo esquema institucional del sistema sanitario lombardo, que puede ser reconocido por su propio diseño. **Palabras clave:** Nueva Gestión Pública; Descentralización; Sistema Sanitario de Lombardía; Reforma sanitaria; Innovación del servicio público.

Summary. 1. Introduction. 2. From model innovation to system transformation. 2.1. Subsidiarity. 2.2. New public management. 3. Evolution and regulatory framework of the Italian healthcare system.
3.1. The Italian healthcare system: The evolution of the healthcare model. 3.2. The main reforms: Decentralisation and regionalisation of the system. 4. The healthcare system in the Lombardy region. 4.1. regionalisation—Regional Law 31 of July 1997. 4.2. organisation of the Lombardy healthcare system.
4.2.1. Aziende Sanitarie Locali (Local Healthcare Authority—ASL). 4.2.2. Aziende Ospedaliere (Hospital companies-AO). 4.3. Territorial organisation of the healthcare system in the Lombardy region.
5. Conclusions. Bibliography.

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1. Introduction

The study of healthcare system models has become increasing relevant in the light of current facing healthcare policy challenges. The main causes confronting this public policy calls for a consideration of existing healthcare systems and their models, thus prompting a range of reform attempts focused on innovation in the design, management, and delivery of healthcare services, with the aim of responding to a pressing reality.

Healthcare systems in Europe and their models were conceived during the consolidation of the *Welfare State* (1960-1975), when the state assumed responsibility for the direct provision of goods and services. The shift in the economic cycle following the 1973 oil crisis interrupted the expansion of the Welfare State (Gallego, Gomá, and Subirats, 2003: 47), after which it became the subject of growing criticism from neoliberal and neoconservative sectors.

This situation led most European countries to undertake neoliberal reforms in the mid-1990s, marking a turning point in the nature and conception of the Welfare State[1]. These reforms demonstrated that the Welfare State is not limited to its Keynesian phase but rather faces continuous transformation in response to the demands of each historical and social context, while maintaining the commitment made to citizens at its inception (Mateos Buendía, 2015: 158). However, this transformation in health policy is currently linked to the emergence of additional collective challenges (Dente and Subirats, 2014: 44), particularly the rising costs of healthcare, driven both by innovation in new technologies and by the ageing of the population.

The case of the Lombardy Region, in the period between 1995 and 2012, seems to respond to this scenario with a new way of understanding and conceiving health policy and giving rise to a distinctive model in Italy. Although the causes influencing the change in model are like those that arose in other regional health systems, the reconsideration of the Lombardy system seems to stem from a specific way of understanding this public policy.

The following sections describe the specific process of change in the Lombardy Region's health policy. To this end, the conceptual framework within which the Lombardy health model developed will first be provided. This will be followed by an overview of the evolution and regulatory framework of the Italian healthcare system and finally a detailed description of the distinctive features of the Lombardy healthcare system.

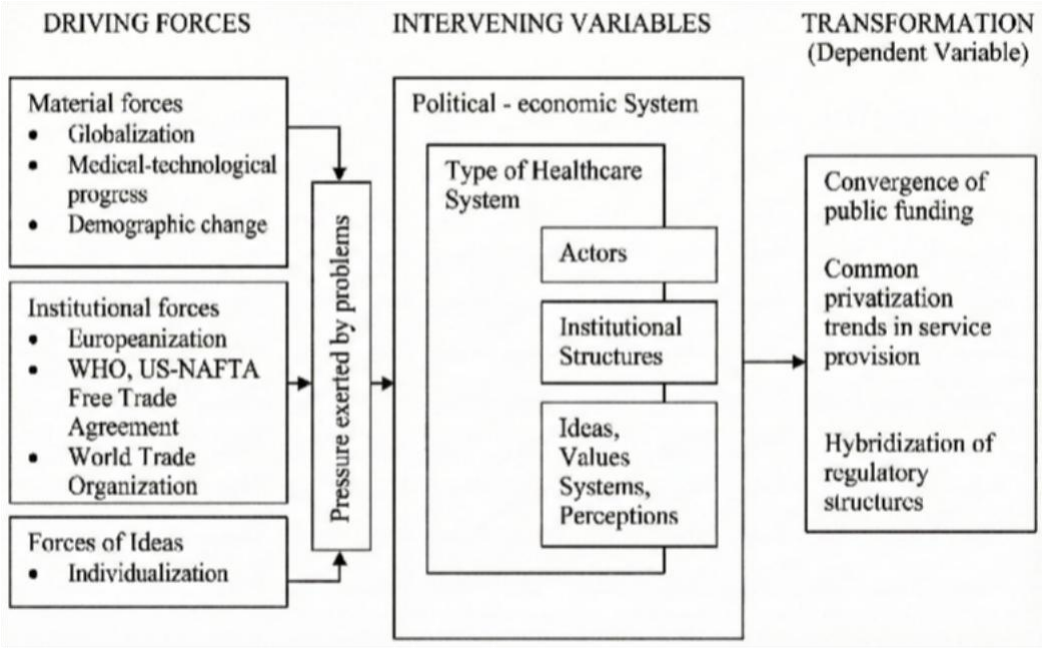
2. From model innovation to a transformed system

The description of the sections below shows how the healthcare system of the Lombardy Region has undergone a transformation, responding to, reshaping, and adjusting the governance of one of the system's main dimensions, namely service provision. To understand these changes experienced by the Lombardy healthcare system, it is essential to consider whether the reorganisation and management is due exclusively to the new emerging challenges mentioned above, or whether, on the contrary, the new healthcare system model has emerged as an innovation driven by other factors or actors.

[1] Readers should bear in mind that the Welfare State in Italy has undergone its own evolution due to several factors, such as delayed industrialization, the period of fascist rule, the influence of the Catholic Church, and the role of the family structure, specifically the role of women as the main source of welfare in Mediterranean societies (Ferrera, 1996:18). Therefore, although initially classified under Esping-Andersen's continental or Christian Democratic model, it has evolved into a mixed model where the State shares essential functions such as the production and provision of public services with other actors.

Schmid, Cacace, Gôtze, and Rothgang (2010: 460-463) reflect on the different results that healthcare systems present in terms of transformation, even when experiencing the same pressures. To this end, the authors propose a heuristic model designed to explain how healthcare systems transform in response to these driving forces.

Figure 1. Heuristic model of healthcare system transformation.



Source: (Schmid et al. 2010: 461).

The pressure exerted by driving forces act directly on the Welfare State, its political-economic system and, consequently, on the healthcare system. The transformation of the system may be in the hands of the actors that form part of institutional structures, but also the perceptions, values, or ideas that are present in the system of those same actors or other interest groups. Therefore, it would be appropriate to ask whether the cognitive resources - stemming from the system of values or ideas - are the primary factors influencing the mechanism of transformation and change.

Following this premise, it is essential to mention the principles on which the President of the Lombardy Region has based his governance model, which he himself described as "a way of creating a region that is increasingly becoming a system[2]."

The Lombardy model, shaped during the 17 years of governance by President Roberto Formigoni, despite operating under the same social and political context as the rest of Italy, is one of the few Italian regional models that has sought to grant organisational and decision-making autonomy to non-institutional actors, as well as to citizens themselves who, on their own initiative, wish to participate in the system.

2 "...the way of creating a region that is increasingly a system..." (Formigoni, 2012).

In this way, the essential function of the Lombardy Regional Government is not to adopt and perform the main functions of the system, but rather to enable society to operate as autonomous as possible, by involving it in healthcare policy and allowing it to carry out those tasks that it can perform independently through various forms of organisation (associations, NGOs, third sector, etc.) (Marotta, 2011: 22).

An analysis of the various policy documents produced by the Lombardy Region throughout the Formigoni administrations makes it possible to identify the principles and instruments that enabled the emergence of a new model and its transformation at the management level, which are discussed in the following sections.

2.1. Subsidiarity

President Roberto Formigoni's approach of creating a "system" as an institutional innovation has been guided by the principle of subsidiarity, which served as the driving force behind a new conception of the regional system's institutional role. In applying this principle, the Lombardy Region as an institution has allowed citizens and citizens groups responsibility and autonomy to respond, on their own initiative and competence, to the needs of society. To this end, according to Professor Vittadini, "it is essential to revive and sustain a strong alliance between the public sector, the private sector, and the non-profit private sector" [3](Marotta, 2011: 22).

The concept of subsidiarity promoted within the Lombard political system is identified in its theoretical formulation with the social doctrine of the Church. As conceived by the Catholic Church, this doctrine requires the State to fulfill a dual obligation: on the one hand, in a negative sense, it must refrain from intervening when individuals or lower- level associations can perform a certain function on their own; and on the other hand, in a positive sense, it must help and support initiatives...

Subsidiarity engages with individuals and social realities when necessary (Brugnoli and Vittadini, 2008: 23). Therefore, it is the government's responsibility to limit its actions and to help those in need, while recognising the freedom of citizens as a primary and constructive dimension in the social and institutional sphere.

In this way, for the politicians, intellectuals, experts, and other actors who influenced and inspired the creation of the Lombardy healthcare system, the principle subsidiarity has meant placing the human individual - endowed with complete freedom - at the center of social, economic, and political action, without censoring their personal desires, as these can ultimately contribute to the collective good (Brugnoli and Vittadini, 2008: 23).

Based on this principle, the Lombardy model has been built on three fundamental pillars, which will be explored in depth throughout this study. The first is freedom of choice for citizens. The second is the division of the functions of purchasing and providing healthcare services between the entity that manages the service and the entity that provides it. The third is the establishment of equal conditions for public bodies and accredited private structures, both of which are service providers with the same rights and obligations.

[3] This paragraph is based on the bibliography indicated, which in turn has reworked an interview with Professor Giorgio Vittadini, ideologist of the Lombardy welfare model under the governments of President Roberto Formigoni.

Without the application of this principle, the state - in this case the Lombardy Region - would assume direct control over healthcare provision. However, the inclusion of this principle into the healthcare model allows healthcare provision to be regulated by demand, reflecting the real needs of citizens. In this way, the principle of subsidiarity has shaped the way healthcare policy is made and understood in Lombardy and, consequently, has been central to the design and implementation of healthcare reform.

2.2 New Public Management

The second principle, which makes healthcare reform feasible under subsidiary criteria, stems from the influences of New Public Management[4]. During the Formigoni administration, the Lombardy Region used New Public Management instruments as a complement to the principle of subsidiarity, while maintaining a model strongly inspired by the Welfare State.

Although there is extensive literature on New Public Management, which proposes different approaches, it is not necessary to review the main authors here. The crucial point of our study is to understand the thinking of those intellectuals who influenced the evolution and reform of the model introducing the market logic to replace the political process, while relying on subsidiarity as a guiding principle.

The reforms carried out in Italy in the 1990s were marked by the promotion of a new culture of responsibility and management initiative in the healthcare sector, inspired by Margaret Thatcher's British government reform proposal[5]. This proposal advocated the introduction of an internal market between buyers and providers of services, aiming to simulate market conditions, and generate genuine competition between the public and private sectors (Maino, 2012: 212). The Lombardy Region adopted this idea and transformed its healthcare system, to allow for increased participation of the private sector in service provision.

New Public Management aims to promote a more dynamic system based on competitiveness, with the aim of improving the quality and efficiency of services provided to citizens. This approach entails a reduction in the role of the state in some of the functions assigned to it during the expansion and consolidation of the Welfare State, particularly in the management and provision of public services. A central instrument inspired by New Public Management is the introduction of quasi-markets, thus introducing a system in which the state finances services, but does not necessarily act as the provider of the public service. Instead, both public and private providers compete to attract users, receiving public resources in return (Brugnoli and Vittadini, 2008: 26).

[4] The conceptualization of New Public Management, forged by Christopher Hood in 1991, led to the emergence of a new paradigm which, in response to the problems experienced by public administration, proposed the introduction into the public sector of mechanisms and forms of action typical of private enterprise and the market as a solution to the deficiencies that the Welfare State had exhibited in the last decades of the 20th century (Hood, 1991: 3).

[5] Community *Care* Act of 1990: this focused on the service provision scheme, leaving aside the financing model on which the *Working for Patients* document was based. The *Community Care* Act introduced two major innovations: the internal market and *General Practitioner fundholding*.

The experience of quasi-markets in subsidiary governance promoted under the various administrations of President Formigoni has been fundamental as an innovative tool in health policy. In fact, from the theoretical paradigm to practice, it is possible to identify three essential tools introduced into Lombardy health policy (Brugnoli and Vittadini, 2008: 29) that show the connection between subsidiarity and New Public Management.

a) Pluralism of supply: To make this instrument effective, it was necessary to design a new system separating provider entities from programming entities, as well as separating provision from management (Brugnoli, 2008: 29).
b) Freedom of choice: to accommodate this principle, an accreditation system was put in place to allow private structures to become providers. In addition to the accreditation system, a quality assessment system was subsequently created for both public and private structures, allowing equal conditions for all providers in the system, both in terms of rights and obligations.
c) Fiscal subsidiarity: among the instruments that the Lombardy Region has made available to those groups of citizens targeted by these policies are bonds, vouchers[6], grants, and the implementation of a mechanism for tax deductions and allowances.

3. Evolution and regulatory framework of the Italian healthcare system

The Lombardy healthcare model and its crystallization into a system is contextualized in the setting where it originated, namely the Italian healthcare system. The table below provides a summary of the Italian national framework, highlighting the significant regulations and events in the evolution of the Italian healthcare system. The information presented, in addition to introducing the healthcare system in Italy, outlines the conditions in which the Lombardy healthcare system would later develop. The next two sections will briefly describe the evolution of the Italian healthcare system and analyses the reforms that transformed it into a regionalised healthcare system.

[6] *Vouchers* are a type of coupon that allows eligible citizens, according to criteria established by the Lombardy Region, to exchange them for a specific public service. An "eligible citizen" is defined as someone who meets a series of economic and social requirements to be a beneficiary of certain types of assistance.

Table 1. Significant regulations and events in the Italian healthcare system.

Significant regulations and events in the Italian healthcare system	
Year	**Event**
1948	**Approval of the Italian Constitution.**
1958	Establishment of the Ministry of Health.
1976-1979	Giulio Andreotti's government.
1978	**First healthcare reform. Establishment of *the Servizio Nazionale Sanitario* (National Health Service) through Law 833/78.** Evolution of the mutual insurance system (*Bismarckian*) to a National Health System (*NHS - Beveridge*).
1992-1993	Giulio Amato coalition government.
1992-1999	Period of political corruption scandals: *Mani pulite - Tangentopoli.*
1992	**Second healthcare reform (Legislative Decrees 502/1992 and 517/1993).** Start of the transfer of powers to the regions. Business organisation of the ASL - *Aziende Sanitarie Locali* and the AO - *Aziende Ospedaliere*. Introduction of internal markets.
1994	First National Health Plan. The first portfolio of services is established, guaranteeing compliance with the *Livelli Esenziali di Assitenza* (LEA).
1996-1998	Government of Romano Prodi (L'Ulivo).
1997	New steps toward federalism: Law 51/1997 delegates some key political powers to the regions. Law 446/1997 initiates the process of fiscal federalism.
1998	Second National Health Plan (1998-2000).
1998-1999	Political Coalition - Massimo D'Alema Government.
1999	**Third healthcare reform (Decree 229/1999).** Further development of decentralization; strengthening of cooperation and regulation to partially reorient the internal market; establishment of tools to define the set of basic services; regulation of the introduction of clinical guidelines for quality in healthcare.
2001-2005	Silvio Berlusconi Government.
2001	**Constitutional reform. The second part of the Italian Constitution (Title V) is amended**, granting more powers to the regions.
	Law 405/2001 introduces new regional government tools and increases responsibility for controlling healthcare spending.
2003	Third National Health Plan (2003-2005).
2005	Memorandum of understanding between the State and regional reforms on health care financing. Introduction of new mandatory financial rules.
2006	Fourth National Health Plan (2006-2008).
	2007 National Budget Law: introduces financial transfer (recovery) for regions with deficits.
2008-2011	Silvio Berlusconi government.
2009	Law 42/2009 establishes the framework for fiscal federalism. In the following years, a A series of decrees defines the distribution of local taxes to levels of government and the criteria for the equalization centre and the redistribution of funds.
2011-2013	Technical government of Mario Monti.
2012	Review of national budget expenditures, including cuts in health spending and reduction in hospital beds per capita.
	Decree 158 ('Balduzzi Law') modernizes the SSN at various levels: continuity of care; selection of general managers and primary care physicians based on merit; simplifications for access to homeopathy, innovations in pharmaceutical products, rationalisation of pharmaceutical spending and per capita spending.

Source: Adapted from based on Mateos Buendia (2015: 132-133).

3.1. The Italian healthcare system: the evolution of the healthcare model

The Italian Constitution, proclaimed in 1948, recognises in Article 32: "The Republic protects health as a fundamental right of the individual and as a collective interest." This statement transfers responsibility for health protection to public institutions and, of course, to the political authorities that govern them, based on a programmatic orientation.

However, it took more than a decade for the institutional and organisational framework of the Italian healthcare system to take shape. In the 1960s and 1970s, the political debate intensified over what the most appropriate healthcare model until the need for reform became evident. This fact, combined with the recognition of the regions as new institutional entities in 1970, created the necessary conditions for the approval of Law 833 of 1978 (Governo d'Italia, 1978).

Law 833 marked a significant shift in the Italian healthcare model[7]. Until that point, the system had been based on health insurance funds or mutual insurance companies, following the organisational system typical of the Social Security model[8] (*Bismarck* model). The law transitioned the system to a model based on a National Health Service[9] (*Beveridge* model), inspired by the English theoretical model (*National Health* System-NHS), while incorporating specific instruments established by Italian legislation (Crivellini and Galli, 2011: 397).

Law 833/78 introduced the principle of "universality," thereby replacing the mutual insurance system, which had generated so many inequalities among the population due to differences in coverage between the various mutual insurance companies (Brugnoli, 2008: 11). In terms of financing, a new system no longer required citizens to contribute on the basis of their health risk; instead, it was funded entirely through taxes (Ferré et al., 2014: 17).

The model promoted by Law 833/78 was characterised by the prevalent presence of the State at different institutional levels. The central level held key powers, such as legislating national laws and regulations, deciding on the financing of the system, and controlling healthcare activity. The regions, however, had a much smaller role, which would develop later. At the local level, a new legal entity emerged as a key part of the system: the Local Health Units (*Unità Sanitaria* Locale-USL). This new public body was responsible for providing services through its own facilities or through contracts with private providers (Ferré et al, 2014:17).

[7] In its report published in 1987, the organisation for Economic Cooperation and Development (OECD) identified three basic healthcare models that, until then, had been used by OECD countries: Social Security, National Health Service, and Private Insurance (OECD, 1987: 24).

[8] The Social Security model is also known as the *Bismarck* model, due to the creation of a Social Security system designed by Chancellor Otto von Bismarck to deal with illness and accidents at work in Germany in the late 19th century. This insurance consists of membership of a health insurance fund or mutual insurance company, financed by compulsory social contributions, with contributions shared between workers and companies.

[9] The National Health System model, or *Beveridge* model, originated in 1942 with the presentation of the "*Beveridge* Report," which aimed to redesign the British *Welfare State* system. The innovation of this report was to introduce the concept of public healthcare for all citizens, regardless of their purchasing power. This model is financed through taxes, and the state is responsible for providing services.

Therefore, from its approval, Law 833/78 allowed for the emergence of a potential mixed public-private system in functions traditionally assigned to the state, such as the provision and supply of health services. In fact, it should be noted that, although the reform of the Italian healthcare system was inspired by the *Beveridge* model of the National Health Service—which is based on a centralist and monopolistic approach—the *Servizio Sanitario Nazionale* (National Health Service) adopted a decentralized approach from the outset (Pelissero and Mingardi, 2010: 47), introducing joint responsibility for healthcare management by the regions and local authorities (Brugnoli, 2008: 11).

Although Local Health Units (USLs) were the cornerstone of the reform, jurisdictional conflicts soon emerged around them and between the different administrative levels, as the responsibilities and powers of each level were not clearly defined (Ferré et al., 2014:17). While the Regions were responsible for defining the functioning of the Local Health Units (USL), these units were administered by the municipal councils. As a result, the management of health services became excessively politicised. In addition to this structural contradiction, other challenges arose, such as increased health spending and persistent inequalities in the provision of services (Ferré et al., 2014: 17), which led to inevitable reforms.

3.2. The main reforms: decentralization and regionalisation of the system

In the 1990s, it became inevitable to implement new reforms that more precisely defined the roles and responsibilities of the different levels of government. Table 2 provides a schematic overview of the characteristics introduced by these reforms into national legislation. Legislative Decree 502/92 introduced the reform known as the "Lorenzo-Garavaglia Reform" (Brugnoli, 2008: 12), whose most important feature was the redefinition of Health Units.

Local Health Authorities (USL), transforming them into a new entity that facilitated the evolution of the system towards regionalisation and corporatisation of the health service. With this reform, the Local Health Units changed their name to *Aziende Sanitarie Locali* (Local Health Authority-ASL[10]), becoming the instrumental entity of the Region rather than the Municipalities, as had previously been the case (Cuocolo and Candido, 2013: 5). As its new name indicates, this entity adopted a business-orientated approach to management, introducing a separation between healthcare planning and delivery service. From that point onward, the Local Healthcare Authority (ASL) were run by several directors[11] , who were required to apply business and managerial criteria in their decision-making.

Similarly, public hospitals were reorganised as *Aziende Ospedaliere* (Hospital companies-AO[12]). A new public-private relationship was introduced at the national level, based on the principle of parity between all public and private providers. The latter gain access to the public system through an accreditation mechanism, thus allowing competition on equal terms. In addition, with the establishment of the Hospital companies- AO, a payment-per-service was also implemented, replacing the previous cost-based payment system.

[10] Instrumental body through which the regions in Italy produce, provide, and control all health services related to prevention, primary care, specialized and hospital care, as well as rehabilitation (Pelissero, 2009: 2).

[11] From this point on, Local Health Authorities will be headed by a Director General, who will be responsible for management, assuming, among other things, governance and control functions. He or she will be assisted by three other directors: the Administrative Director, the Health Director, and the Social Director.

[12] Hospital structure that provides both specialized care services and hospitalisation services for patients.

The transformation into companies and payment for services represent the two original innovations in the context of the reform of *Beveridge-type* healthcare systems (Pelissero and Mingardi, 2010: 56). This first reform represents the starting point of the entire process, thus completing the regionalisation of the management of the National Health Service[13].

Years later, Legislative Decree 229/99, also known as the "Bindi Reform," was approved (Brugnoli, 2008: 12), integrating and modifying the previous decree in an attempt to redirect the system towards a more centralised vision, reducing the elements of competitiveness introduced by the previous legislation (Pelissero and Mingardi, 2010: 57).

On the other hand, at the national level, it is also important to highlight the reform of Title V of the Italian Constitution, enacted through Constitutional Law No. 3 of October 18, 2001, as a legal element which granted the regions further autonomy in health matters. Folllowing the approval of this reform, the regions are no longer required to reach prior agreement with the central government on the fundamental principles guiding their legislation, instead, they exercise their own regulatory powers in healthcare matters while respecting the *Livelli Esenziali di Assistenza*[14] (Essential Levels of Assistance).

Essential Levels of Assistance (LEA), introduced by the so-called "Bindi Reform," function as centralising instruments designed to guarantee the rights of all citizens throughout the national territory (Mateos Buendía, 2015: 257-258).

Table 2. National Health Regulations

NATIONAL REGULATIONS	
Law of December 23, 1978, No. 833, on the National Health Service	Establishment of the National Health Service
Legislative Decrees 502/92 on the reorganisation of health regulations	regionalisation National Health Fund Transformation of public providers (ASL) into companies Transfer of management powers to the regional level Payment for services Accreditation: reorganisation of public service providers
Legislative Decree 229/99	Programming. Integrative funds Freedom of choice Accreditation and contracting of private providers Essential Levels of Assistance (LEA) New working relationship for physicians
Constitutional Law No. 3 of 2001, "Amendment to Title V of Part Two of the Constitution"	Exclusive legislative power for the regions in certain matters, including healthcare and organisation

Source: Mateos Buendía (2015: 258).

[13] Servizio Sanitario Nazionale (*SSN*) is the name given in Italy to the national health system.

[14] Essential Levels of Assistance are the set of benefits and services that the Italian National Health Service (SSN) must guarantee to all citizens free of charge or in co-participation with the citizens themselves.

4. The healthcare system in the Lombardy region

For years, the Lombardy regional Government was engaged in a significant dispute with the Ministry of Health, which even raised a question of unconstitutionality before the Constitutional Court. The dispute was ultimately resolved with the approval of the reform of Title V of the Italian Constitution in 2001 (Mateos Buendía, 2015: Appendix C: 8). This reform of Article 117 enabled the Lombardy Region to continue developing its process of change through Regional Law 31/97 and its subsequent amendments and additions, consolidating these provisions in the consolidated text of regional health legislation (Bullettino Ufficiale della Regione Lombardia [BURL], 2009), the fundamental basis of the Lombardy healthcare system.

Table 3. Chronology. Relevant Events and Health Legislation

TIMELINE. SIGNIFICANT EVENTS AND HEALTHCARE LEGISLATION				
Year	**ITALY**		**LOMBARDY REGION**	
	Government	**Event**	**Government**	**Fact**
1978	Coalition government (Giulio Andreotti– DC)	Creation of the National Health Service. Law No. 833 of December 23, 1978	Christian Democracy (Cesare Golfari)	
1992	Socialist Party (Giulio D'Amato)	**Legislative Decree 502/92** 'Lorenzo-Garvaglia Reform' Garvaglia'	Christian Democracy (G. Giovenzana)	
1995	Technical Government (Lamberto Dini)		Polo per le Libertà	**Roberto Formigoni[15]wins regional elections**
1997	Coalition government (Romano Prodi - L'Ulivo)		Casa della Libertà (Roberto Formigoni)	**Regional Law 31/97. Starting point for the Lombardy Healthcare System**
1999	Left-wing Democrats (Massimo D'Alema)	**Legislative Decree 229/99** Bindi Reform	House of Freedom (Roberto Formigoni)	

15 Roberto Formigoni was President of the Lombardy Region from 1995 to 2012.

2001	L'Ulivo (G. Amato)	**Constitutional Law 10 Nov 2001** 'Reform of Title V'	*Forza Italia* (Roberto Formigoni)	
2008	Forza Italia (Silvio Berlusconi)		Forza Italia (Roberto Formigoni)	**Regional Law 3/2008** Government of the network of the social and health care unit Healthcare
2009	Popolo della Libertà (Silvio Berlusconi)		Popolo della Libertà (Roberto Formigoni)	**Regional Law 33/2009.** Consolidated text of regional laws on health matters. Repeals Regional Law 31/97

Source: Mateos Buendía (2015: 259).

The detailed chronology presented in the table above shows that, since the approval of Law 33/78, numerous governments of different political orientations have succeeded one another at the national level[16]. In contrast, the Lombardy Region has been led by the same administration for nearly four consecutive terms[17]. This fact provides a unique opportunity to compare the evolution of the Lombardy Region's healthcare system and analyse the variables that really influence and shape the new institutional framework of the healthcare service.

4.1. Regionalisation—Regional Law 31 of July 11, 1997, "Regulations for the reorganisation of the regional health service and its integration with social services activities"

The reform process in the Lombardy Region has been developed through Regional Law 31/97 and its successive amendments and additions; it was finally consolidated in the single text of the laws on health with the approval of Regional Law 33/2009.

The Region's healthcare system embodies the basic principles of the National Health Service models: universality and solidarity. However, it is characterised by being based on a public-private system, in which private providers are allowed to operate, subject to centralised planning as a governance tool (Pelissero and Mingardi, 2010: 59).

Health policy was the most prominent public policy implemented by the Lombardy Region during the Formigoni administration. The objective was to establish a model based primarily on two pillars: freedom of choice for citizens and full parity of conditions for all actors participating in the system through the accreditation method (Istituto Regionale di Ricerca della Regione Lombardia [IRER], 2010: 104). Among these pillars, the key element around which the spirit of the Lombardy model is structured in the recognition of the patient's right to freedom of choice, enabling individuals to choose among different healthcare providers -public or private- without incurring any additional cost (Mateos Buendía, 2015: 261).

In order for this principle to be applied, the healthcare system had to separate the functions of purchasing and providing services. Procurement functions became the responsibility of Local Health Authorities (ASLs), while provision functions became the responsibility of Hospital Authorities (AOs), both of which were granted legal, economic, and financial autonomy, as established in Legislative Decree

No. 502 of 1992 (Formigoni, 2012: 4).

However, the Local Health Authority (ASL), as conceived in the Italian healthcare system, presents an inherent conflict, as it is the entity responsible both for producing and providing healthcare services, but also for controlling the quality of those services. In other words, the Local Health Authority (ASL) is the entity where the main functions are concentrated, thus favoring a rigid, centralised, and monopolistic (Pelissero and Mingardi, 2010: 58). To resolve this problem, the Lombardy Region has separated the functions assigned to Local Health Authorities (ASL), deciding that they should not provide any direct healthcare services. Therefore, Hospital companies-AO, whether public or private, are responsible for the provision of healthcare services, all of which subject to the same accreditation system controlled by the Region and the Local Health Authority-ASL of reference, as well as to a service control system operated through the Control-NOC operational centres[18] (BURL, 2007).

In this way, the Lombardy Region is able to guarantee real equality between public and private providers, thereby enabling citizens to exercise their right to choose (Pelissero and Mingardi, 2010: 60). In summary, Local Health Authorities (ASLs) retain the functions of planning, purchasing, and control, while no longer being responsible for direct provision of health services.At the same time, both public and private providers are required to comply with the same accreditation and control procedures (Mateos Buendía, 2015: 262).

Likewise, the Lombardy Region has designed a healthcare organisation interded to grant effective decision-making power to users of the system. To this end, it ensures that both public and accredited private hospital companies receive the same remuneration for the services provided through the Local Health Authority (ASL) of reference.For this purpose, the Lombardy Region adopted a single tariff system, based on the US DRG[19] (*Diagnosis Related Group*) model (Formigoni, 2012). This decision has allowed genuine competition among all providers, as accredited private structures have been required to offer the same services and functions as public hospitals (Pelissero and Mingardi, 2010: 61).

4.2. Organisation of the Lombardy healthcare system

4.2.1. Aziende Sanitarie Locali (Local Health Authorities - ASL)

As mentioned above, Local Health Authorities (ASL) were introduced into the Italian healthcare system through the approval of Legislative Decree 502/92, replacing Local Health Units (USL). This reform meant that, from that moment on, planning responsibilities were entrusted to the regional governments, while healthcare management became the responsibility of the Local Healthcare companies (ASL), which were required to operate according to business-oriented criteria (Brugnoli, 2008: 12).

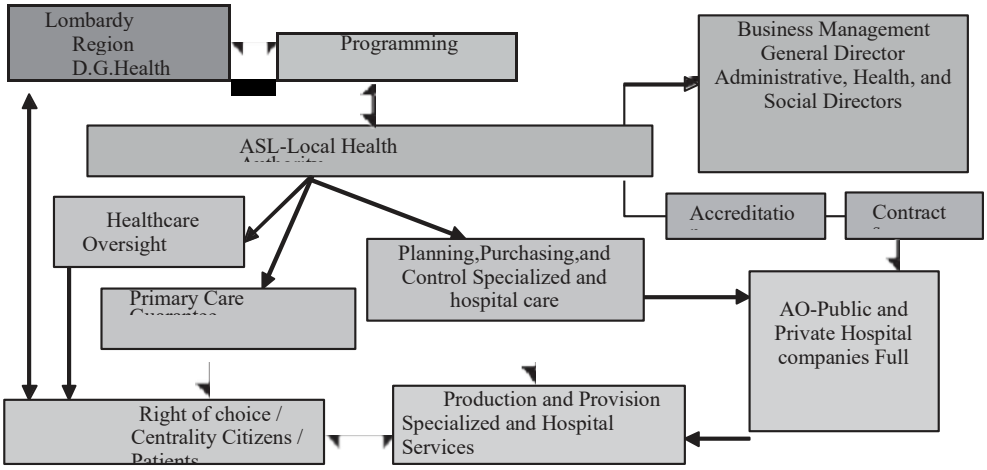
[16] The table above does not include all governments, but only those that have implemented regulations relevant to the present study.

[17] Regional mandates in Italy last for five years. President Roberto Formigoni was unable to complete his last term due to the crisis caused by the *Lega Nord* (Northern League), which forced him to resign after 17 years in power, specifically on October 26, 2012.

[18] System for monitoring and verifying consistency with the LEA (Essential Levels of Assistance) of the services provided by hospital companies (AO), both public and private.

[19] System that allows patients admitted to a hospital to be classified into homogeneous groups, with the aim of quantifying the resources used and remunerating each admission.

Figure 2. Functions, Competences, and Flows of Local Health Authorities (ASL).



Source: Mateos Buendía (2015: 265).

An analysis of how this reform was implemented in Lombardy shows that the Lombardy Local Health Authorities (ASL) are characterised by a clear separation of functions. They are responsible for public health, primary care, and PAC[20] functions related to specialised and hospital care (Pelissero and Mingardi, 2010: 60).

Through the PAC (Programming, Purchasing, and Control) functions, as established in Article 4.6 of Regional Law 33/09, the Lombardy Local Health Authorities (ASL) ensure that citizens are provided with the specialised care services - such as rehabilitation, diagnosis, laboratory services and hospitalisation - covered by the Essential Levels of Assistance (LEA) and defined in the National Health Plan and regional programming, through contracts or agreements with the various accredited structures.

The Local Health Authorities (ASL) in Lombardy constitute the main point of access for citizens to the entire healthcare network. In addition to monitoring and guaranteeing the quality of their hospital services, they are also responsible for public health and coordinating the network of family doctors and paediatricians in their territory, thereby ensuring primary care for the population. On certain occasions, the Local Health Authorities (ASL) in Lombardy may provide some healthcare services, but they can only be direct providers on a marginal and residual basis. In such cases, they may exceptionally deliver those services necessary to guarantee uniform levels of care when these have not been assigned to contracted professionals, public providers, or accredited private providers (Brugnoli, 2008: 13).

Finally, it should be noted that in the Lombardy model, Local Health Authorities (ASL) operate mainly through agreements with both public and private entities for the provision of all healthcare services in their territory, including primary care (IRER, 2010: 330).

20 PAC (*Programmazione, Acquisto e Controllo*—Planning, Procurement, and Control).

4.2.2. Aziende Ospedaliere (Hospital companies-AO)

Like the Local Health Authorities (ASL), the Hospital companies (AO) were established with the "De Lorenzo-Garavaglia" reform in Legislative Decree 502/1992 (Ministry of Health. Directorate-General for Health Planning, 1992). In line with the entrepreneurial spirit with which the reform was conceived, the transformation of the hospital entities underlying this reform, the decree promoted the transformation of the hospital entities of the previous system into Hospital companies-AO (Pelissero and Mingardi, 2010: 55-56). These, in coordination with the Local Health Authorities-ASL, are responsible for the production and provision of healthcare services in the areas of specialised medicine and hospital care.

In Lombardy, the relationship between Hospital companies (AO) and Local Health Authorities (ASL) has certain peculiarities that will be highlighted below and that make the Lombardy healthcare system different from those of other Italian regions.

Firstly, it is worth noting the establishment of a clear division of functions between the two instruments. Local Health Authorities (ASL), in addition to planning and procuring healthcare services provided by Hospital companies (AO) through contracts, have control over the production and provision functions of the latter (Pellisero and Mingardi, 2010: 60). Secondly, the Lombardy Region introduces full parity of conditions between public Hospital companies-AO and new private entities that are accredited through Local Health Authorities-ASL. In this way, each of the Hospital companies-AO, whether public or private, is required to compete and, therefore, to strive for efficiency (Formigoni, 2012: 5).

4.3. Territorial organisation of the Lombardy Region Health System

Italian regions were called upon to choose how to relate to the private sector by "institutionally" choosing not only the healthcare organisation model, but also the type of *governance*. As a result, Local Health Authorities (ASLs) have adopted different organisational models across Italy, giving rise to different types -integrated, separate, and mixed (Boni, 2007: 29) - which have led to different healthcare models. These differences are due to the increasing autonomy acquired by the regions, as a result of successive reforms that allowed the regions to choose different institutional and organisational models (Ferré et al., 2014: 2; Boni, 2007: 9).

As already mentioned, the 1992-93 healthcare reform (Italy, 1992, Legislative Decree 502/92 and Legislative Decree 517/93) transformed Local Health Units into companies "endowed with public legal personality and entrepreneurial autonomy" (Boni, 2007: 29). Most hospitals that met certain requirements were also granted the possibility of being recognised by the Local Health Authorities as independent from them, becoming Hospital companies-AO (Boni, 2007: 29), thus maintaining a new institutional relationship between both entities with negotiating power. This possibility of separation from the Local Health Authorities-ASL and their recognition by the latter of hospitals as a new entity in the system gave rise to three different models of Local Health Authorities-ASL and, therefore, three models of institutional organisation (Boni, 2007: 29-30). The first of these is the integrated ASL, characterised by the permanence of hospitals within the ASLs, which manage them directly.

Separate ASLs, which differ from the previous model because there is a complete separation between hospitals and the Local Health Authorities (ASLs) themselves, separating the production function of the Hospital Authority (AO) from the financing oversight function of the Local Health Authority (ASL). This separation establishes the necessary conditions for creating a system of competition between public hospitals and accredited private hospitals. Mixed ASLs, in contrast, are defined by the coexistence of the two previous models.

The territorial organisation of the healthcare system in Lombardy follows a separate institutional model, as the region decided to organise its healthcare system by separating entities and functions. This choice gives rise to the originality of its model, which is pioneering in Italy (Boni, 2007: 30). Therefore, the main feature of the Lombardy healthcare system responds to the need to separate the functions of production and provision from the functions of planning, purchasing, and control, promoting the complete separation between hospital companies (AO) and local healthcare authorities (ASL).

DLGS 517/92, in addition to transforming Local Health Units (USL) into Local Health Authorities (ASL), led to a reduction in their number, at least in Lombardy. As shown in the table below, the Lombardy healthcare system underwent an initial reduction, specifically from 84 USLs in 1992, before the reform, to 44 ASLs after it. This readjustment was not sufficient to meet the requirement to adapt the Local Health Authorities (ASL)[21] to the actual number of provinces in Lombardy. The approval of Regional Law 33/97, which established the Lombardy model, led to a further drastic reduction to the current 15 Local Health Authorities (ASL)[22].

Table 4: Evolution of Local Health Authorities (ASL) and Hospital Authorities (AO).

LOMBARDY REGION	**USL**	**ASL**			**ASL variation**	**Population per USL or ASL**	
	1992	1995	2000	2005	2000-2005	1992	2005
	84	44	15	15	0	108.436	616.453
LOMBARDY REGION	**USL**	**AO**			**Variation A0**	**Inhabitants per USL or ASL**	
	1992	1995	2000	2005	2000-2005	1992	2005
	84	16	27	29	2	108.436	616.453

Source: Mateos Buendía (2015: 268).

[21] The Lombardy Region is made up of 12 provinces: Bergamo, Brescia, Cremona, Como, Lecco, Lodi, Mantua, Milan, Monza, Pavia, Varese, and Sondrio.

[22] Although the Lombardy Region has 12 provinces, it was not possible to reduce the number of ASLs (Local Health Authorities) to this number for two reasons: population concentration, as in the case of Milan, which has three ASLs (ASL Milano, ASL Milano 1, and ASL Milano 2), and the territorial exception of the ASL of Valleca-monica- Sebino (mountainous area). D.L.G.S. 229/99 repealed the rule that provided for the establishment of ASLs coinciding with the provinces in order to safeguard this type of exception.

Conversely, the table above also shows that the number of Hospital-AO companies has increased. While there were 16 Hospital companies in 1995, their number s begun to increase from 2000 onwards, reaching the current total of 29. The interpretation of these data, i.e., the emergence of new Hospital-AO companies together with the choice to create separate Local Health Authorities-ASL, means that the institutional health model is characterised by its political orientation in favor of competition. This assertion is further supported by the opening of the hospital network to other public institutions such as the National Institutes of Scientific Research-IRCCS[23]and University Polyclinics and the entire accredited private network.

In conclusion, this section has demonstrated how the implementation of Regional Law 31/97 and its successive amendments have driven a transformation of the Lombardy healthcare system, establishing it as a mixed public-private model due to its separate structure and openness to multiple providers.

5. Conclusions

The brief description of the evolution of the Italian healthcare system has outlined how Italy transformed its model and, therefore, its healthcare system [24], abolishing the previous system of mutual aid societies and health insurance funds, establishing universal care linked to citizenship and residence status, regardless of the citizen's socio-health condition.

In the last decades of the last century, a general process of reform of the Welfare States began, in which the decentralisation of health systems took on significant importance, with dynamics aimed at the creation of internal markets and the outsourcing of services. In the Italian case, the healthcare reforms carried out by the Legislative Decrees mentioned in this study also led to a complete shift of healthcare powers to the regional level. Therefore, decentralisation in the present case study is close associated with two types of processes: increased involvement of the private sector and regional devolution of the responsibilities. This decentralisation process is also characterised by a certain form of privatisation; reflected in both in the system's shift towards market orientation and in its openness to collaboration with the private sector in healthcare.

In fact, the process of decentralising healthcare to the regions in Italy was accompanied by a process of corporatisation of the organisational model, transforming the political-administrative organisation (Local Health Unit-USL) into a technical-business organisation (Local Health Authority-ASL). This transformation is a crucial development in the system, as it represents both an evolution and a reconceptualisation of the healthcare model. As explained above, in the Local Health Units (USL), decision-making powers were vested in a management committee whose members had been appointed based on political criteria, while in Local Health Authorities (ASL), management powers are transferred to a non-political body, i.e., a management body, with a general manager responsible for its activities (Maino, 2012: 214).

[23] *IRCCS-Istituto di Ricovero e Cura a Carattere Scientifico***:** the National Institutes of Scientific Research were established by Legislative Decree 288/03. These are entities of high national importance, whose control and management are the responsibility of the state. They are hospitals of excellence, dedicated to biomedical research, focused on a specific area, but despite their national vocation, they are part of the health organisation and management of the regions, supporting the health activity of the Hospital companies-AO.

[24] As a result of the approval of Law 833/78, which established the *Servizio Nazionale Sanitario (National Health Service).*

As already explained, the regions in Italy had the possibility to determine their relationship with the private sector, choosing "institutionally" not only the model of health organisation, but also the type of "governance"[25] (Mateos Buendía, 2015: 175). The Lombardy Region opted to introduce market logic, redefining the distribution of responsibilities between the competent state authority and the market in one of the main functions of the healthcare system, namely the provision of services.

Therefore, the innovation promoted by the Lombardy model lies in the separation between funding entities and providers, thus choosing to establish a separate and open institutional model, unique in Italy at that time. This decision led to the emergence of competition between public and private structures on equal terms, which was also unique in Italy. The establishment of this institutional framework became functional due to the effective implementation of citizens' freedom of choice, a basic subsidiary principle of the Lombardy healthcare model.

Given the objectives set by the regional government, the innovation of the Lombardy healthcare system lies in strengthening the institutional capacity to support citizens not only at the point of access to healthcare services-guaranteeing healthcare and treatment as in other healthcare systems -but also by enabling them to take action at an earlier stage, providing a network where citizens can choose how and by whom they wish to be treated.

The introduction stated that the transformation of healthcare systems is linked to the emergence of new challenges affecting the Welfare State, including the demands of dealing with an ageing population and rising healthcare costs caused by innovation in new technologies. However, the evolution of model in the Lombardy Region seems to be driven not only by these challenges, but also by a novel conception of healthcare policy, resulting in an original model that introduces s a new vision for the organisation and delivery of healthcare.

[25] It should be remembered that Local Health Authorities (ASLs) adopt different organisational models across Italy, giving rise to different types of ASLs (integrated, separate, or mixed, and therefore to different models of healthcare organisation).

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