# The role of Intermediate Entities in the governance of regional health systems: From the analysis of emerging structures to the case of Calabria

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Following the institutional and governance structure changes of the 1990s reforms, Italian regional health systems have undergone a re-centralization process which leads to the creation of Intermediate Entities located among the Region and health structures.
The study aims to provide an overview of the functions attributed to the Intermediate Entities, focusing on the Calabria Region, the last in the establishment.
The analysis of the functions performed provides the first observations about the points of convergence and divergence among the emerging institutional structures.
Regarding the Calabrian case, apart from the considerable advantages, the critical issues related to the establishment of the new Entity are not negligible, both relating to the internal regional order and to the future operational phase.

*Keywords*: governance, health systems, health groups, health structures, Intermediate Entities, Italy.

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## 1. Introduction

Since the 1980s, in European countries, reforms inspired by different approaches (known as New Public Management – NPM, and New Public Governance – NPG) have pushed towards the overcoming of traditional models of public administration, to make the public sector more efficient, effective, and accountable (Hood, 1991; Hood, 1995; Lapsley, 1999; Yamamoto, 2003; Simonet, 2011).
One of the practices commonly associated with these approaches was "decentralization" (Walliss, 1998; Manor, 1999; Baskaran, 2011; Smoke, 2015).
Decentralization can be defined as a process or reform comprising several public policies that transfer responsibility, resources, or authority from a

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higher to a lower level of government (Falleti, 2005; Alonso *et al.*, 2015). In decentralized public systems, i) authority is transferred from central to local levels; ii) central governments a) possess a smaller share of fiscal resources; b) allow to the local level more administrative autonomy and a higher responsibility for political functions (Schneider, 2003; Cavalieri and Ferrante, 2016).

Although the goal was to improve public-service quality, decentralization generated inequalities within countries and increased concerns regard potential failures in meeting national objectives, with subnational governments pursuing policies often inconsistent with national goals (Terlizzi, 2019).

In this context, starting from the early 2000s, the need to increase the overall governance capacity of public systems, by now perceived as not very controllable in a unitary logic, has emerged.

To achieve this aim, public systems have been invested by interventions associated with a recentralization process (Pollitt, 2007), such as the achievement of economies of scale, the standardization of public services, equity in using services by citizens, greater coordination of policies and programs at the national level, the search for greater accountability and efficiency of the public system (Del Vecchio and Romiti, 2017).

Health systems did not escape this decentralization and recentralization wave.

The trend towards decentralization of European health systems has been questioned since the early 2000s (Minas, 2010). The aging population, along with the continuous advancements in technology, has caused a surge in healthcare spending and the subsequent need to regulate public spending; in this sense, a greater role of the center can be considered a way to promote economic responsibility and improve the efficiency of the public health system (Saltman, 2008; Del Vecchio and Romiti, 2017).

In the search for better efficiency, the different European healthcare systems have resorted to common tools, such as concentration of purchases, reduction of administrative costs through economies of scale, restructuring – also through mergers – the hospital sector, reduction of fragmentation in financing, production and provision of services (Thomson *et al.*, 2015).

The dynamics described above, which have crossed the public systems of many countries, have also affected the Italian health system: although the reforms of the 1990s – known as "Aziendalizzazione" or healthcare corporatization – expressed a "decentralized" vision of the system, starting from the early 2000s, the decision-making space granted by the central authorities to the local ones, has shrunk. The inefficiency of some regional health service governance has required increased cooperation from higher up. Recovery Plans (RPs) – introduces in the mid-2000s for regions in imbalance – are an obvious example of intervention in the mechanisms and distribution of power between the central and regional levels, and between the region and healthcare structures (Ferrè *et al.*, 2012).

The severe decrease in autonomy – caused by the procedure in the regions that have tried it – denotes the revival of central authority, after the acknowledgement of the lack of suitable regional responsibility. In this framework, the same regions have amplified

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the constraints towards the healthcare structures, re-centralising responsibilities and decisions, up to intervening in areas of a strictly operational nature, previously under the full responsibility of the healthcare public structures (Mauro *et al.*, 2017) pressure towards regional centralization has led to the creation of "Intermediate Entities" which are entrusted with a significant role in the relationship between the Region and healthcare structures.

Interposing themselves between the Region and the healthcare structures, the Intermediate Entities have a role in guaranteeing the rationalization and efficiency of the healthcare services of the regional structures, through the efficient use of the resources assigned to them (Del Vecchio and Romiti, 2017; Bobini *et al.*, 2020; Gugiatti *et al.*, 2022). They exercise governance functions, or resource management and/or administrative process management.

This work is part of the theoretical framework of the institutional and governance transformations of the public health structures, with particular attention to the Italian regional health systems (Sistemi Sanitari Regionali – SSRs) and the more recent establishment of Intermediate Entities.

The Intermediate Entity takes the form of guarantor of a unitary and coordinated govern ance of the SSR, by centralizing and bringing back to itself planning, coordination, direction, and control competences of the healthcare structures.

Currently, there are about 20 Intermediate Entities in 9 Italian regions (Del Vecchio and Romiti, 2017; Gugiatti *et al.*, 2022) which performs different functions.

Following an institutional approach (Abimbola *et al.*, 2017), starting from a general overview of the institutional structures of the SSRs, the first aim of this study is to provide an overview of the roles and responsibilities of the Intermediate Entities in the SSRs.

The second aim is to provide evidence of the reasons and benefits arising from the establishment of an Intermediate Entity, as well as the emerging issues in the implementation phase of the activities.

This second purpose was achieved by examining the case of the Calabria region, the last region to establish an intermediate entity.

The paper is organized as follows: the following section provides background about the changes in healthcare systems' institutional and governance structures.; section 2 describes the method of the study; section 3 provides the main results and section 4 offers discussion and conclusions.

### 1.1. Background: Institutional and Governance structures changes in healthcare systems

The 1990s reform processes aimed at increasing efficiency and effectiveness, leading to significant changes in the governance and internal organization of European healthcare systems (Borgonovi, 2002; Neri, 2009).

Despite variations in choices among health systems, the reforms were focused transferring power and responsibilities from the central level (the Government) to the Intermediate level (i.e. the regions in Italy; the autonomous communities in Spain; the counties in Sweden) (Pollitt, 2007; Neri, 2009).

In response to these phenomena, many studies in the literature have

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been oriented towards defining and identifying the different governance structures of health systems.
For example, Brinkerhoff and Bossert (2008) described governance as "the set of rules that distribute roles and responsibilities among the actors of health systems and their interaction".
In Italian studies, governance is a multifaceted concept that includes i) the allocation of responsibilities and the degree of autonomy between the centre and the periphery (particularly the State and the Regions); ii) the methods and structures for exercising government functions at different levels; iii) the rules that regulate the functioning of structures (Del Vecchio, 2017; Bobini *et al.*, 2020).
According to Rhodes (1997), three different types of governance systems are commonly identified in the literature:

1) the hierarchical model, in which the central level (Regions) assumes the role of establishing strategic priorities and providing directives to the lower-level (health structures);
2) the market model, where the central level only sets operational regulations and mandatory restrictions for structures to follow and finally;
3) the network model in which coordination between central and peripheral levels has improved, leading to healthcare structures taking an active role in defining strategic choices.

The different archetypes are discussed in the literature on the basis of i) the nature of the decision-making relationships, distinguishing the top-down approach typical of hierarchical systems from the bottom-up one, generally present in network models or ii) on the mode of interaction between the actors of the system and the distribution of respective responsibilities (Morrell, 2006; Bobini *et al.*, 2020).
With regard to the determinants of the different types of relationships established between the different actors of the healthcare systems, the following are identified: i) "control" in which the center exercises its authority according to the top-down approach; "coordination" ii) in which the relationship between the center and the periphery involves the division of responsibilities rather than the "command and control" mode; iii) "collaboration" in which the center can exercise its authority in a limited way and the exercise of shared management of the system is necessary; iv) "communication" in which greater emphasis is placed on the informal exchange of information between healthcare organizations (Barbazza and Tello, 2014).
Regarding the state of diffusion of the different types of systems, the prevalence of hierarchical systems in the past has gradually given way to less centralized forms of government (Hill and Lynn, 2004; Bobini *et al.*, 2020).
The proliferation of network models has led to a shift from competition to collaboration, necessitating increased integration and coordination within the health system (Gugiatti *et al.*, 2022).
The Italian healthcare system is the best example for comprehending these institutional dynamics.
According to the reorganization decrees, each SSR appears to consist of a network of healthcare structures

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administered by a holding structure (Anessi Pessina e Cantù, 2003; Longo *et al.*, 2003; Cantarelli *et al.*, 2017).
The literature states there are two core components to the concept of health and public groups: i) legal autonomy and independence of the structures controlled by the holding; ii) the execution of the government's role by the holding (Longo *et al.*, 2003).
The economic subject has to act as a leader and coordinator to form a group, directing the structures within it. The controlled structure control has financial autonomy based on what is given to them by the holding (Longo *et al.*, 2003). Distinctions can be made, especially between:

1) holdings that have centralized the administrative and logistical activities and the strategic planning of healthcare operations of the structures under its control, mainly dedicated to clinical governance activities;
2) holdings that just have centralized strategic healthcare planning, leaving the managerial and clinical control functions to the controlled (Longo *et al.*, 2003).

The regional systems' coordinated division of work motivates the structures to specialize in certain disciplines (Longo *et al.*, 2003; Cantarelli *et al.*, 2017).
Considering the two essential objectives of the Italian National Health Systems (NHS): a) controlling costs and b) maximizing the value of health services, multiple interventions have been implemented at an organizational level and through the redistribution of roles (Cantarelli *et al.*, 2017):

1) a gradual transformation of regional council (i.e. "*Assessorato*") offices to various forms of operating holdings;
2) the establishment of regional agencies to support planning activities and the centralized administrative functions and,
3) the conversion of some of these regional agencies into structures.

To strengthen the centralization of some structure functions, new techno-structures were developed at the regional level (Fattore *et al.*, 2018).
The original concept was to develop an organization that would substitute for the councilorship (i.e. "*Assessorato*") and conduct regional health planning (Fattore *et al.*, 2018).
In essence, the "*Assessorato*" has been remodeled in terms of political direction and control functions, and it is structured as a holding structure where management functions are distinct from the main administrative ones (Fattore *et al.*, 2018).
Each Region, despite the individuality of their strategic choices, has strengthened its holding role within the regional public health group, directly or through the establishment of Intermediate Entity (Cantarelli *et al.*, 2017; Del Vecchio and Romiti, 2017; Furnari *et al.*, 2017; Fattore *et al.*, 2018); on the one hand centralizing the exercise of government functions and, on the other, strengthening the coordination of health structures (Cantarelli *et al.*, 2017; Del Vecchio, Romiti, 2017; Del Gesso, 2018).
The reorganization has created an environment where conflicts over roles and skills are frequent. Therefore, it appears, of extreme relevance, to understand the coordination sys-

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tems that link healthcare structures to the Holding and the responsibilities attributed to them (Bobini *et al.,* 2020).

## 2. Method

This study represents a case of academics-practitioners research collaboration (Amabile *et al.,* 2001); specifically, among the authors of the article and the Special Commissioner of the "Azienda Zero" of the Calabria Region.
The definition of the research objectives occurred through the delineation of the following research questions:
RQ1) What is the role of Intermediate Entities within the Italian healthcare system and what are the functions assigned to them?
RQ2) What are the reasons and benefits deriving from the establishment of the Intermediate Entity within the Calabrian *SSR*?
In order to analyze the roles and responsibilities of the "Intermediate Entities" in the *SSRs,* a desk research analysis was performed (Turoń and Kubik, 2021). Desk research analysis is a low-cost research method which comprises the analysis of data sources, including their compilation, mutual verification, and processing (Nooraini, 2013; Rahaman *et al.*, 2014).
We searched, analysed and re-elaborated information available online, extracted from government and institutional sources (such as regional laws, regional guidelines and Intermediate Entities' corporate acts).
5 phases characterize the development of this research method (Turoń and Kubik, 2021):

1) identifying the research topic;
2) identifying research sources;
3) collecting existing data;
4) combining and comparing data;
5) data analysis.

The second aim is to provide evidence of the reasons and benefits arising from the establishment of an Intermediate Entity, as well as the emerging issues in the implementation phase of the activities.
This second purpose was achieved by examining the case of the Calabria region, the last region to establish an Intermediate Entity.
To achieve this aim, a semi-structured interview with the Special Commissioner (i.e. "*Commissario Straordinario*") of "*Azienda Zero*" of the Calabria Region, who co-authored this paper, was conducted.
The semi-structured interview represents the most used data collection technique in qualitative research (Taylor, 2005; Kallio *et al.*, 2016): i) it is particularly versatile and flexible (Kallio *et al.*, 2016); ii) includes open-ended questions allowing for spontaneous and in-depth answers and greater empathy with the respondent (Smith, 2001; Ryan *et al.*, 2009; Baumbuch, 2010, Galletta, 2012); iii) unlike structured questionnaires, the reduced degree of rigidity of open questions allows to move more easily from one topic to another (Hardon *et al.*, 2004, Rubin and Rubin, 2005, Whiting, 2008; Polit and Beck, 2010) and iv) to leave space for participants' individual verbal expressions (Kallio *et al.*, 2016).
Although the semi-structured interview is perceived as an easy method of data collection (Wengraf, 2001), it is necessary for the researcher to follow different phases in the conducting interview (Bambusch, 2010). Following the framework of Rubin and Rubin

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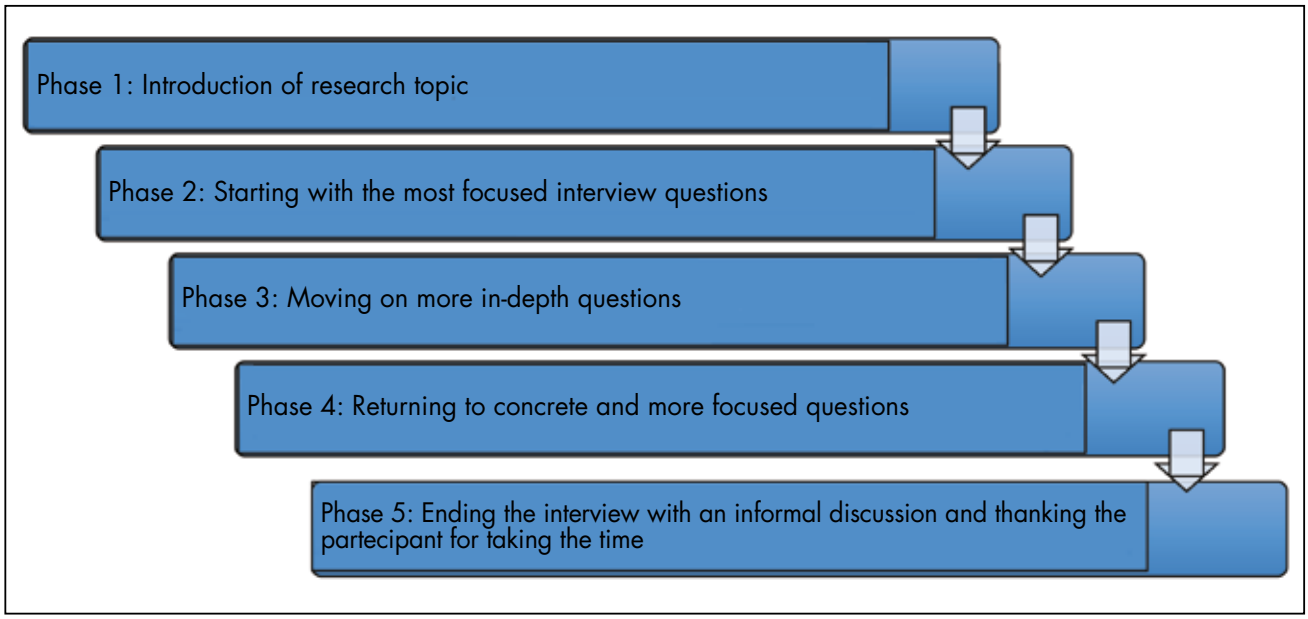


**Fig. 1**
Main relevant phases in conducting the semi-structured interview

*Source*: Authors' elaboration from Rubin and Rubin, 2005

(2005), the interview was conducted following the phases showed in Fig. 1. Conducted on 20 April 2023, the interview comprises 5 open questions, as shown in Tab. 1.

A face-to-face modality was selected in order to maximize understanding of the questions and responses,

given the direct dialogue with the interviewees (Durant and Carey, 2000).

The questions concern the following contents:

- reasons and potential benefits deriving from the establishment of the Intermediate Entity;
- role and functions attributed to the Intermediate Entity;
- main corporate Entities involving in Azienda Zero;
- organizational model, established by current legislation;
- emerging issues raised in the implementation phase of the activities.

The questions are specified in Tab. 1.

**Tab. 1** – Semi-structured interview track

| *Questions Track* |
|---|
| a) What are the main reasons behind the establishment of Azienda Zero within the Calabrian health system? |
| b) What is the role taken on by Azienda Zero in the new structure of the Calabrian health system? And what are the functions attributed to it? |
| c) What are the most essential corporate Entities within Azienda Zero? |
| d) Could you illustrate the organizational model chosen for the Azienda Zero as per the establishing laws? |
| e) In conclusion, what are the major criticalities for the subsequent implementation phase of the activity? |

*Source*: Authors elaboration

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## 3. Results

### 3.1. The role of Intermediate Entities in the SSRs

This section reports an overview of the changes occurred in the institutional structure of the SSRs following the establishment of an Intermediate Entity.

Starting from 2014, experimentation of the new governance models involves 9 Italian regions.

Tab. 2 shows the regions involved, the regional law by which the Intermediate Entity was established, and the major functions assigned to them.

The Tuscany region was the first to experiment with the new governance model. This region started creating a centralized system earlier than the others.

Tuscan healthcare is distributed on a wider scale ("Area Vasta") than healthcare in other regions, which is typically limited to the provincial level.

In particular, the Tuscan region identifies three "Area Vasta": Northwest, Central, and Southeast "Area Vasta".

In each "Area Vasta" several Local Health Authorities (Aziende Sanitarie Locali – ASLs) operate according to the areas' needs and at least one teaching hospital (Azienda Ospedaliera Universitaria – AOU), is always present to offer higher specialisation, and the skills to enhance the systems' quality (Persiani *et al.*, 2012).

The aim of the distribution is to unify the scheduling of healthcare services (and their delivery) and the coordina-

**Tab. 2** – Intermediate Entities

| Region | Intermediate Entity | Regional Law | Main category of function assigned |
|---|---|---|---|
| Tuscany | *ESTAR* | no. 26/2014 | Technical-specialist functions, administrative functions, support functions. |
| Lombardy | *ATS* | no. 23/2015 | Technical-specialist functions, administrative functions, government functions, monitoring and control functions. |
| Liguria | *A.Li.Sa.* | no. 17/2016 | Technical-specialist functions, administrative functions, accounting functions, monitoring and control functions, programming functions, coordination functions. |
| Veneto | *Azienda Zero* | no. 19/2016 | Technical-specialist functions, administrative functions, accounting functions, support functions, monitoring and control functions, coordination functions. |
| Friuli-Venezia Giulia | *ARCS* | no. 27/2018 | Technical-specialist functions, monitoring and control functions. |
| Sardinia | *ARES* | no. 24/2020 | Technical-specialist functions, administrative functions, accounting functions, support functions, monitoring and control functions. |
| Lazio | *Azienda Lazio.0* | no. 17/2021 | Technical-specialist functions, administrative functions, support functions, monitoring and control functions, coordination functions. |
| Piedmont | *Azienda Zero* | no. 26/2021 | Technical-specialist functions, support functions, monitoring and control functions, coordination functions. |

*Source*: Authors' elaboration

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tion of functions at a greater geographical level.
Until 2013, the three service units known as ESTAVs ("Area Vasta Technical Administrative Support Agencies" – "Enti per i servizi tecnico amministrativi di Area vasta") were responsible for administrative and support functions in each "Area Vasta". With the Regional Law no. 26 of 2014, the three ESTAVs were unified in a single entity, called ESTAR (Regional Entity for Technical-Administrative Support – Ente per i Servizi Tecnico-Amministrativi Regionali).
As its name implies, the new Tuscan regional health service entity has centralized all technical-specialist, administrative, and support functions into one.
Responsibilities, therefore, appear to be relevant in terms of: i) centralized purchasing management activities, operating as central purchasing entity, management of technological infrastructures and health technologies; ii) recruitment, selection and remuneration policies for healthcare system personnel.
In terms of the support functions, considering the particularity of the Tuscan territorial health context, ESTAR guarantees the programmatic and operational consistency of its activities with those of the other Entities in the "Area Vasta".
Lombardy revised the entire structure of their health system by setting up the difference between "Agenzie di Tutela della Salute" (ATS) and "Aziende Socio-Sanitarie Territoriali" (ASST), giving planning and commissioning functions to the former and characterizing the ASST and the "Istituti di Ricovero e Cura a Carattere Scientifico" (IRCSS) as suppliers of social and health services (Langella and Persiani, 2022).
As outlined by the regional law no. 23/2015, the governance model of the Lombard health system appears to be articulated on three levels (Bobini *et al.*, 2020; Gugiatti *et al.*, 2022): i) at the highest level are the organizational unit (UO) of the Presidency with the function of economic and financial planning, distribution of resources of the health system and support to the Management, the Department of Welfare, responsible for health planning and the various regional agencies characterizing the Lombard national health system which assume an increasingly important role in supporting planning activities; ii) at the Intermediate level are located the 8 ATS which implement the regional programming without the direct provision of hospital or territorial services; iii) at the lowest level, the public and accredited private providers, which assume an operational role in the provision of services, i.e. the 27 ASST, responsible for the provision of hospital and territorial services and the 4 IRCCS.
Regarding the Intermediate Entity, to the ATS are assigned, in particular, governance functions, including: i) the governance of taking charge of the person, managing all phases of the patients' health care pathway, with a view to appropriateness and continuity of care; ii) government of assistance in primary care; iii) governance of programs aimed at promoting preventive medicine. Added to these are monitoring and control functions on pharmaceutical expenditure and on the activity of other regional health structures (Fattore *et al.*, 2018).

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However, the exact attribution of functions to each of the three levels is not yet clear, and this turns out to be the most relevant criticality of the Lombard health system (Cantarelli *et al.*, 2017).

In Liguria, through the regional law no. 17/2016, many functions traditionally held by the "Assessorato" are attributed to the Ligurian health agency "A.Li.Sa." ("Agenzia Ligure Sanitaria"), which performs functions of health and social care planning, coordination, direction and governance of the others health structures and the related activities, including the management functions of technical-specialist activities, support to healthcare structures and other Entities (Cantarelli *et al.*, 2017).

With the regional law no. 19/2016, the Veneto regional health system undergoes two main interventions: i) the unification of the district healthcare units (Unità Locali Socio-Sanitarie – ULSSs) with a significant reduction from 21 to 9 and the establishment of "Azienda Zero" configured as a healthcare company receiving the Regional Health Fund (Fondo Sanitario Regionale – FSR) (art. 1), with the task of distributing all the resources received among the other structures and Entities of the SSR. However, it differs both from the other Regional health structures as its main function consists in the process of planning-allocation-transfer-accounting of the resources of the Regional Health Fund - and from other Regional Health Agencies as it centralizes all the activities previously carried out by the Region. In fact, it is not established as an instrumental entity of healthcare structures but, on the contrary, as a programmer of their functions.

Azenda Zero is also assigned centralized healthcare management functions (Gestione Sanitaria Accentrata – GSA[1]) in compliance with the relevant legislation (Legislative Decree no. 118/2011), becoming the entity responsible for the management of the administrative, accounting and consolidation system (Persiani and Bonin, 2018).

In fact, it is Azienda Zero that regulates the method of keeping the accounting records of the GSA and the subsequent drafting of the documents that make up the budget, the accounts of the regional budget.

Relevance assumes, among others, the activity of technical support to the Regional Council (i.e. "Giunta Regionale") in the definition and implementation of government objectives in health.

Since the enactment of the regional law no. 27/2018 with which Friuli-Venezia Giulia redefines the institutional and organizational structure of its health system, it is possible to distinguish three levels of government: i) the Region which ensures the implementation of the plans, programs and objectives defined by the political guidance bodies; ii) the Regional Health Coordination Agency ("Agenzia Regionale di Coordinamento per la Salute – ARCS") as an Intermediate Entity (replacing the previous entity for the "Ente per la Gestione Accentrata dei Servizi Condivisi – EGAS") which performs particularly tasks of a specialized technical nature, for the definition and implementation of the objectives of governance in health and social care matters and iii) the Central Manage-

[1] GSA is a dedicated reporting entity which covers the regional government's healthcare revenues and expenditures.

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ment which carries out guidance and supervisory functions on the ARCS (Del Vecchio and Romiti, 2017; Gugiatti *et al.*, 2022).
In 2020, the Autonomous Region of Sardinia (Regione Autonoma della Sardegna – RAS) proceeded with the organizational reorganization of its SSR: the regional law no. 24 sanctioned the spin-off of the ATS into 8 ASL and the establishment of the Regional Health Agency ("Agenzia Regionale della Salute – ARES"), as an Intermediate Entity that centralized the most significant technical – administrative and support functions for the provision of assistance services to other Entities.
More recently, Lazio and Piedmont established respectively the "Azienda Lazio.0" (regional law no. 17/2021) and the "Azienda Zero" (regional law no. 26/2021).
The Lazio Region, as part of its troubled economic-financial recovery process, being a commissioner and subject to a RP, did not intervene with significant changes to its central structure.
However, the Intermediate Entity is attributed, in particular: i) technical-specialist functions in terms of centralization of purchases and the system of payments to suppliers and management of Information and Communication Technology (ICT) and health technologies; ii) administrative functions relating to personnel selection, management and training procedures; iii) as well as various support, monitoring and control and coordination functions (Fattore *et al.*, 2018; Cinelli *et al.*, 2020).
Already previously, with regional law no.18/2007, Piedmont had experimented with forms of coordination among ASLs.
Without prejudice to the functions of direction and programming in the hands of the Region, according to the regional law no. 26/2021, the Piedmontese Azienda Zero is assigned many functions, including: i) management of the extra-hospital emergency-urgency, ii) coordination activities for innovation and research; territorial medicine; iii) coordination activities relating to European funding and projects; iv) technical support activities to the Giunta.

To compare the Intermediate Entities, Tab. 3 provides the complete list of functions assigned to each Intermediate Entity.
The specific functions have been classified by macro-category. In particular, the following are distinguished:

- technical-specialist functions;
- administrative functions;
- accounting functions;
- support functions;
- government functions;
- monitoring and control functions;
- programming functions;
- coordination functions.

The classification strictly refers to what is contained in the regional laws establishing the aforementioned Intermediate Entities and in the respective corporate documents.
As shown in the Tab. 3, it is possible to find numerous points of convergence or divergence with respect to the functions assigned to the Intermediate Entities taken into consideration.
In particular, it is evident that:

1) all the Intermediate Entities act as central procurement structure, except for the Lombard case in

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**Tab. 3** – List of functions assigned to the Intermediate Entities

| Assigned Functions | Intermediate Entity | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ESTAR – Tuscany | ATS – Lombardy | A.Li. Sa. – Liguria | AZIENDA ZERO – Veneto | ARCS Friuli-Venezia – Giulia | ARES – Sardinia | AZIENDA LAZIO.0 – Lazio | AZIENDA ZERO – Piedmont |
| **Technical specialist functions** | | | | | | | | |
| *Purchasing functions* | | | | | | | | |
| Central purchasing entity[1] | ■ | | ■ | ■ | ■ | ■ | ■ | ■ |
| Centralization of the supplier payment system | | ■ | | | | | ■ | |
| Warehouses and distribution logistics | ■ | | | ■ | ■ | ■ | ■ | ■ |
| *ICT management* | | | | | | | | |
| Information technology infrastructure management[2] | ■ | | | ■ | | ■ | ■ | ■ |
| *Health technology management* | | | | | | | | |
| Health technology management | ■ | | ■ | | ■ | | | |
| *Health Technology Assessment (HTA)* | | | | | | | | |
| Technical services for the evaluation of the HTA[3] | ■ | | | ■ | ■ | ■ | ■ | ■ |
| *Clinical risk management and quality measurement* | | | | | | | | |
| Clinical risk management and quality measurement | | | | | ■ | | | |
| Outcome measurement | | | | | ■ | | | |
| **Administrative functions** | | | | | | | | |
| *Personnel functions* | | | | | | | | |
| Personnel recruitment and selection procedures | ■ | | ■ | ■ | | ■ | ■ | |
| Processes for the payment of the economic fees of the personnel of the regional health service | ■ | | | | | ■ | | |
| Personnel Training | | | ■ | | | | | |
| Definition of experimentation policies of innovative organizational models for resource management | | | ■ | | | | | |
| Management of personnel attendance | | | | | | ■ | | |
| Continuing Medical Education (*Educazione Medica Continua ECM*) accreditation procedures | | | | ■ | | ■ | ■ | |
| *Litigious* | | | | | | | | |

[1] As a central procurement structure, the Intermediate Entity contributes to the definition of the purchasing strategies for goods and services needed by the health-care structures, with which it determines the related needs in close sharing and coherence with the regional indications oriented towards the appropriateness of use and to the economic-financial compatibility; organizes the annual planning of the contractual activity in order to rationalize purchases and optimize costs, through processes consistent with the type of good or service and guaranteeing regional levels of aggregation of needs

[2] The Intermediate Entity is competent and responsible for ICT management, according to a perspective of homogenization and development of the system within the *SSR*.

[3] Specifically, the Intermediate Entities guarantee participation in the regional evaluation processes for technological innovations.

(*to be continued*)

| Assigned Functions | Intermediate Entity | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ESTAR – Tuscany | ATS – Lombardy | A.Li. Sa. – Liguria | AZIENDA ZERO – Veneto | ARCS Friuli-Venezia – Giulia | ARES – Sardinia | AZIENDA LAZIO.0 – Lazio | AZIENDA ZERO – Piedmont |
| Management of labor and health litigious [4] | | | | ■ | | | ■ | |
| *Ticket* | | | | | | | | |
| To collect of ticket | | ■ | | | | | | |
| **Accounting functions** | | | | | | | | |
| Management of cash flows relating to the financing of regional health needs | | | ■ | | | | | |
| Keeping of accounting documents of *GSA* | | | | ■ | | | | |
| Drafting of the preventive and final balance of the GSA and of the related attachments | | | | ■ | | | | |
| Drafting of the preventive and final balance of the Regional Health Service and of the related attachments | | | ■ | | | | | |
| Accounting guidelines of healthcare structures and other Entities | | | | ■ | | ■ | | |
| **Support functions** | | | | | | | | |
| Guarantees the coherence of the planning of its activities with the planning of the healthcare structures and the Entities of the regional health service at the level of the *Area Vasta* (specifically Tuscany) | ■ | | | | | | | |
| Guarantees the territorial levels of intervention that are necessary for operational functionality, developing them according to principles of standardization and homogeneity | ■ | | | | | | | |
| Guarantees the development of organizational models aimed at identifying highly specialized structures | ■ | | | | | | | |
| Promotion of "*protocolli d'intesa*" with the National Anti-Corruption Authority (*Autorità Nazionale Anti-Corruzione – ANAC*) and with the National and Regional Spending Observatories | | | | | | | ■ | |
| Technical support to the "*Assessorato*" of Health in the definition of public contracts | | | | | | | | ■ |
| Support to the "*Giunta Regionale*" or to the *ad Acta Commissioner* for the implementation of the RP | | | | | | | | |
| Technical support to the "*Giunta*" | | | ■ | ■ | | | | ■ |
| *Management of healthcare structures' assets* | | | | | | | | |
| Management of the competition procedures for the maintenance, alienation, concession and lease of the healthcare structures' assets | ■ | | | | | | ■ | |
| *Clinical risk* | | | | | | | | |
| Technical support for management training and clinical risk | | | | ■ | | ■ | | |
| Technical support in the field of clinical risk | | | | | | | | ■ |

[4] The Intermediate Entities perform functions of support to the insurance model of the *SSR*, in particular for disputes and transactions.

(*to be continued*)



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| Assigned Functions | Intermediate Entity | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ESTAR – Tuscany | ATS – Lombardy | A.Li. Sa. – Liguria | AZIENDA ZERO – Veneto | ARCS Friuli-Venezia – Giulia | ARES – Sardinia | AZIENDA LAZIO.0 – Lazio | AZIENDA ZERO – Piedmont |
| **Government functions** | | | | | | | | |
| Negotiation and purchase of health and social care services from accredited structures, according to rates approved by the Region | | ■ | | | | | | |
| Governance of the process of taking care of the person in the entire network of health, social and health services, also through the multidimensional and personalized assessment of the need, and according to the principle of appropriateness and guarantee of continuity of care | | ■ | | | | | | |
| Primary care governance | | ■ | | | | | | |
| Governance and promotion of health education, prevention, assistance, treatment and rehabilitation programmes | | ■ | | | | | | |
| **Monitoring and control functions** | | | | | | | | |
| Management of emergency – urgency activity | | | | | | | | ■ |
| Implementation of regional guidelines and monitoring of pharmaceuticals, dietetics and prosthetics expenditure | | ■ | | | | | | ■ |
| Supervision and control of health, socio-medical and social structures and units | | ■ | ■ | | ■ | | | |
| Appropriateness checks | | | | | | ■ | ■ | |
| Monitoring and reporting aimed at allowing the identification of systems for reducing waiting list times | | | | | | | ■ | ■ |
| Management of information flows, auditing and internal control systems | | | ■ | ■ | | | | |
| **Programming functions** | | | | | | | | |
| Financial programming of regional healthcare in compliance with the constraints set by the "Giunta Regionale" | | | ■ | | | | | |
| Proposal of the objectives of the directors of the Health structures (AOU San Martino University and Institute national cancer research (specifically Liguria) | | | ■ | | | | | |
| Definition of the system of objectives and results of the Health structures and other Entities of the Regional Health Service, as well as the definition and monitoring of standard costs | | | ■ | | | | | |
| **Coordination functions** | | | | | | | | |
| Coordination of public relations offices in health and social care field | | | ■ | ■ | | | ■ | |
| Coordination in territorial medicine | | | | | | | | ■ |
| Coordination of activities related to European projects and funding in the health sector | | | | | | | | ■ |
| Coordination and development of the regional information system | | | | | | | ■ | |
| Regional coordination for innovation and research | | | | | | | | ■ |

*Source*: Authors' elaboration

which the centralization of purchases is entrusted to the Central Procurement Structure ("Agenzia Regionale Centralizzazione Acquisti – ARCA");
2) in general, all the Intermediate Entities perform the functions as classified, except for the Friulian ARCS which carries out activities falling within the specialist technical functions only and those of monitoring and control;
3) specific governance functions are attributable to the Lombardy ATS, while A.li.Sa., in Liguria, is purely entrusted with programming functions.

### 3.2. The case of "Azienda Zero" in the Calabria region

The second aim of this study is to provide evidence of the reasons and benefits arising from the establishment Intermediate Entity, as well as the emerging issues in the implementation phase of the activities. This second purpose was achieved by examining the case of the Calabria region, the last region to establish an Intermediate Entity.

The section presents an analysis of responses from a semistructured interview with the Special Commissioner of the Calabrian Azienda Zero.

*a) What are the main reasons behind the establishment of Azienda Zero within the Calabrian health system?*

Calabria included an Intermediate Entity in its institutional structure with the enactment of the regional law no. 32/2021. The article 1 (law no. 32/2021) provided for the establishment of "Azienda Zero" as the governance entitity of the Calabrian regional health service with "public legal personality and administrative, patrimonial, organisational, accounting, managerial and technical autonomy[2]".

As with the other regional governments, the reasons behind introducing the new model are based on organizational rationalization and economic savings, which would derive from the centralization of some functions. Last but not least, the need to strengthen the Regions ability to govern its own health care (Testi *et al.*, 2020). In essence, therefore, it was established in order to improve the integration of healthcare services, optimizing the levels of healthcare effectiveness, organizational efficiency and cost-effectiveness.

Already in the past, through the enactment of the regional law no. 9/2007, Calabria had reorganized the health supply by replacing the 11 existing ASLs with 5 Provincial Health Authorities (ASPs – Aziende Sanitarie Provinciali).

According to what is defined by the 2005 Finance Law, the regional law no. 11/2009 authorizes the Giunta Regionale to «define, propose, stipulate, implement, monitor and reformulate the Agreement with the Government for the recovery from the deficits of the health service», identifying the interventions necessary for pursuit economic-financial equilibrium in compliance with the Essential Levels of Assistance ("LEA").

Starting from 2009 the Calabria Region, proceeds with its RP to the new organizational model of assistance, identifying the major critical points on which to act in the insufficiency of local medicine, on the

[2] The regional law of 7 July 2022, n. 21 (Art. 1, paragraph 1, letter a), recognizes entrepreneurial autonomy for the Azienda Zero.

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demand side, and, in the excessive number of public and private structures, with very low hospitalization activities, on the supply side.
Therefore, in order to respond to the need to rapidly and significantly increase the level of response to the demand for health services, avoiding that the recovery of production brings the health system back into conditions of economic imbalance, it was decided to (i) remodel the governance structure of health policies and (ii) redistribute the functions of planning, governance, coordination and operational management among the various subjects at each level to increase the productivity of the health service (i) in the process definition and implementation phase decision-making (planning and governance) and (ii) in using of production factors (coordination and management).

*b) What is the role assumed by Azienda Zero in the new configuration of the Calabrian health system? And what are the functions attributed to it?*

In the new regional configuration, the Azienda Zero was conceived as an Intermediate subject between (i) the level of political government, Giunta Regionale or ad Acta Commissioner, of which it is an instrument both in the planning phase and in the coordination of government processes and (ii) that of the healthcare structures for which it carries out coordination functions in the processes of acquisition and use of production factors and in the regulation of supply channels (direct public and accredited private).
Azienda Zero is therefore filled with functions transferred from the upper level (regional administrative structures) in the context of planning and coordination of the health supply and from the lower level (health structures) in correspondence with the centralization of the functions related to the regulatory mechanisms supply (direct and accredited) and management of production factors, as showed in Fig. 2.
Furthemore, according to the regional law (art. 2), the objective will also be to centralize the administrative function in Azienda Zero, strengthening the entire process, to avoid the inefficiencies of healthcare structures.
In this regard, Azienda Zero i) will give accounting directives to the various healthcare structures and other Entities; ii) will prepare the consolidated financial statements of the sector; iii) will manage cash flows related to the region's healthcare needs; iv) will provide support to the Council and to the ad Acta Commissioner for the implementation of the RP.
Another significant responsibility will be to establish a central procurement that will invite proposals from healthcare structures in the region.

*c) What are the most important bodies within Azienda Zero?*

Azienda Zero carries out its functions under the coordination of the ad Acta Commissioner.
The ad Acta Commissioner, appointed for the implementation of the RP, annually i) determines the guidelines for the activity of Azienda Zero, ii) monitors their implementation and iii) carries out supervisory activities, while the healthcare structures that mainly perform functions of production and provision of healthcare services.

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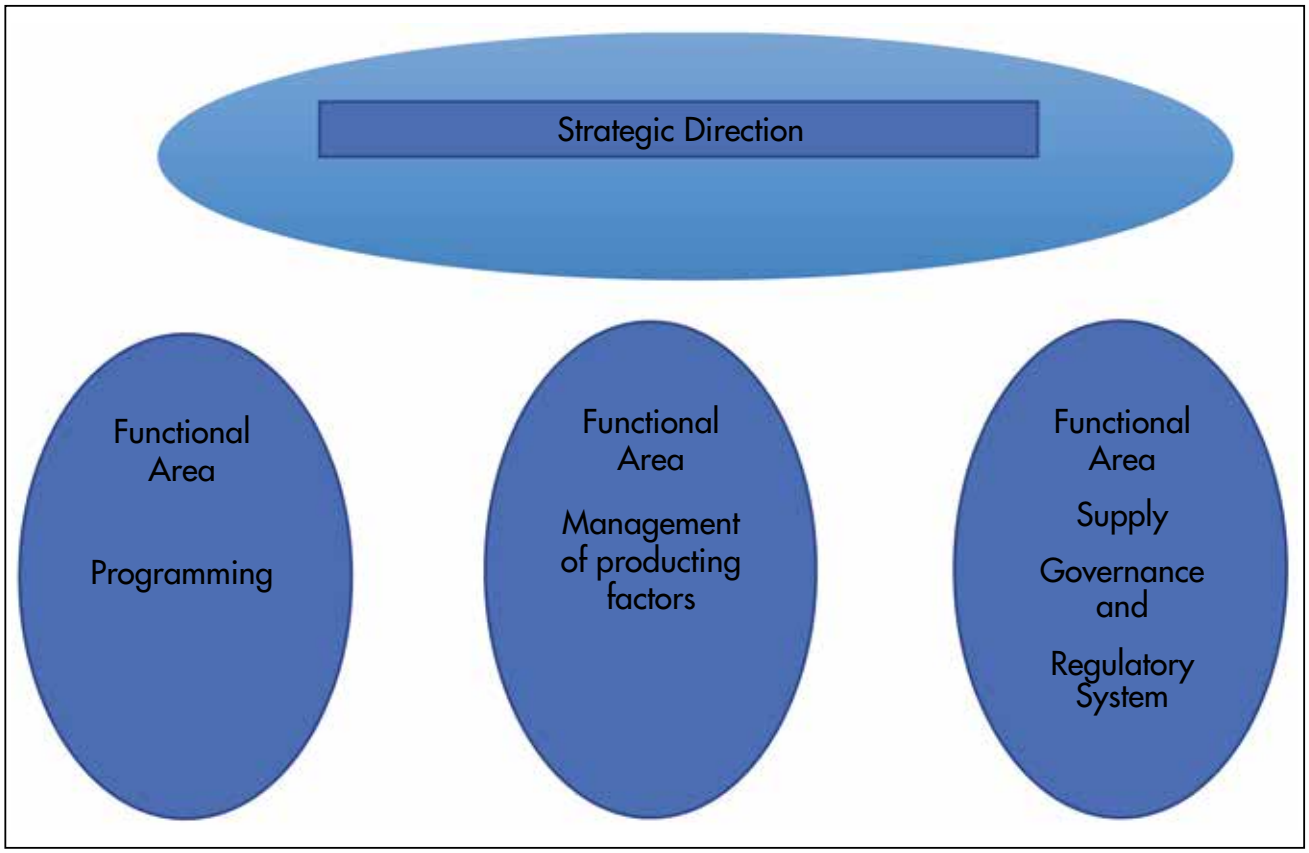


**Fig. 2**
The main functions assigned to Azienda Zero
*Source*: Authors' elaboration

In Azienda Zero there are three bodies (art. 4):

1) the General Manager ("Direttore Generale") (art.5) is the legal representative of the Azienda Zero. Furthermore: i) excrcises management and representation powers; ii) is responsible for the GSA and adopts budget documents; iii) adopts the acts of appointment of the Health Director ("Direttore Sanitario") and the Administrative Director ("Direttore Amministrativo"), the members of the Board of Statutory Auditors ("Collegio Sindacale") and the Independent Evaluation Entitity ("Organismo Indipendente di Valutazione"); appointment, suspension and revocation of the positions of the managers of the Azienda Zero structures; iv) draws up the annual report on the management performance ("Relazione sull'andamento della Gestione") of Azienda Zero;
2) the Board of Statutory Auditors ("Collegio Sindacale") (art.6) – which exercises the verification and control of the regular performance of the administrative and accounting activities, and
3) the Board of Management ("Collegio di Direzione") (art.7) – which assists and supports the General Management in the governance's function of the Azienda Zero.

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*d) Could you describe the organizational model chosen for the Azienda Zero following the institutive laws?*

The regulatory planning of the Azienda Zero required fourteen months of work and two regional legislative interventions, respectively in December 2021 with the institutive law no. 32 and in July 2022 with law no. 21 which completed the framework of functions and responsibilities, as well as two fine-tuning regulatory adjustments in March 2022.

In February 2023, the Corporate Act of Azienda Zero was launched which, following up on the inspiring model and implementing the regulatory framework created by the regional legislator, translated the system functions and objectives into organizational structures aimed at overseeing four areas of competence, three of which preordained to the Intermediate governance functions of the system (as shown in Fig. 3):

1) the area supporting the programming skills of the political level and of the ad Acta Commissioner (Research, Innovation and Programming Tools Department);
2) the area of supervision of the mechanisms for regulating the channels of direct supply (production and supply by the public) and indirect supply (accredited private) through the Department for the Governance of the Healthcare and Social Healthcare System;
3) the Production Factors Management Department is responsible for coordinating the processes and paths for the acquisition, management and use of production factors (human, financial and instrumental resources).

In the regulatory framework of Calabria, Azienda Zero also saw the attribution of the Regional Urgency Emergency system including the three levels of access and response represented by (i) Single Emergency Number 112, (ii) by the territorial emergency system 118 and emergency services and (iii) from the territorial emergency system 116-117.

The Corporate Act translated the legislative input at an organizational level into a specific and autonomous business unit structured as the Emergency Department and intended to house the structures and government figures of the emergency system (government, coordination and control operating centres) who have full operational control of the human and instrumental resources belonging to the ASLs.

Finally, The Staff Department is organized as a Functional Department.

Each Department is made up of operational structures that have similar or complementary functions and that work towards common objectives.

Apart from departmental divisions, the Corporate Act provides for a further subdivision into: i) Complex Structures (SC); ii) Simple structures within complex structures (SS) and iii) Simple departmental structures (SSD).

The Company defines the overall mapping and graduation of the personnel it needs. For managerial positions, each manager is guaranteed the assignment of a managerial role which can be: i) management or coordination of the Department; ii) management of Complex Structure; ii) management of Simple Structure also at departmental level; iii) professional, including highly specialised, consul-

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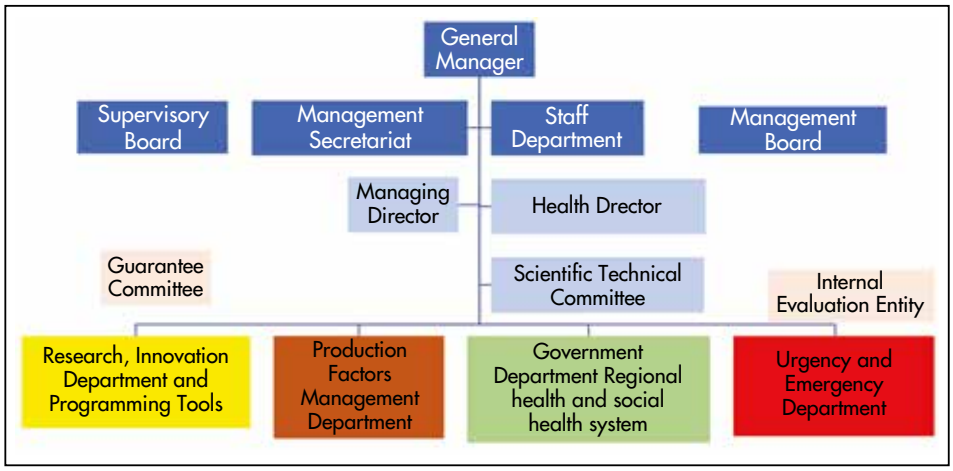


**Fig. 3**
The organizational model of Azienda Zero

*Source*: Authors' elaboration based on Corporate Act of Azienda Zero

tancy, study and research, inspection, verification and control activities.
Furthermore, Azienda Zero assigns the tasks attributable to the personnel of the sector: i) position; ii) organizational function and iii) professional function.

*e) In conclusion, what are the major criticalities for the subsequent implementation phase of the activity?*

The chosen model and the implementation path followed for Azienda Zero raise two questions for the subsequent phase of implementation of the activities.
Firstly, of an internal order to the regional legal system, is linked to the solution of the aspects of overlapping of competences that the transfer of functions to Azienda Zero can generate (i) with the administrative structures of the Region (Department Office) in relation to those coming from "high" (planning and coordination) as well as (ii) with the Health structures with regard to the potential compression of the areas of entrepreneurial autonomy which, in addition to being necessary for the optimal functioning of the system, are also governed by state legislation (Legislative Decree 502/1992).
Secondly, of a more general nature as it is necessarily to be shared with the Intermediate Entities that have adopted the holding model similar to that of Calabria, attributable to the typical issues of corporate governance that today see these holding Entities necessarily having to adopt the scheme envisaged by the laws national for the health authorities of the system.
In fact, due to their Intermediate location in the governance structures of policies and the number and characteristics of the functions assigned both from above and below, the fundamentally monocratic configuration typical of healthcare structures based on the figure of the Director General is (i) little or nothing representative of the general requests of the other levels of governance of the system (general political and operational management) and equally for the other stakeholders who revolve around the functions expression of the competences

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attributed to the Intermediate body-holding.
Therefore, both questions will necessarily have to be the subject of attention: at first, in the implementation phase, and secondly in the strategic analysis and system evaluation phase due to the systemic and long-term impact it will have on the disbursement capacity of the Italian healthcare system and its ability to respond over time to the principles that inspired it.

## 4. Discussion and Conclusions

This study was focused on the changes that occurred in the governance of healthcare systems, with specific reference to the Italian case, following the establishment of Intermediate Entities that populated the space between Region and healthcare structures within the public healthcare group.
The research objectives were aimed in a dual direction: 1. to present an overview of the Italian SSRs that have currently established Intermediate Entities and what functions are attributed to them and 2. to present a concrete regional case analyzing the establishment of the Azienda Zero in Calabria, the last region to introduce an Intermediate Entity within its healthcare system.
The mapping of the interventions establishing the Intermediate Entities in the various regions, as well as the analysis of the functions performed by them, provides initial observations about the distance among the emerging institutional structures: the Intermediate Entities often perform different functions and, despite some similarities, they do not it is still possible to arrive at a standard reference model. Despite this, the recent case of the Calabria region, seems to be inspired in many functions by the Intermediate Entities of other Italian regions: in particular, the Calabrian Azienda Zero is attributed government functions similar to the Lombardy experience, while with regard to the programming has many similarities with A.li.sa., in Liguria.
Various points of convergence are also found with the venetian Azienda Zero, regarding to the attributable technical-specialist, administrative and accounting functions.
As regards the second purpose of the study, that is to analyze the case of the Calabrian zero company, in terms of i) reasons behind the establishment of the new governance body and ii) benefits and critical issues deriving from the subsequent implementation phase, numerous points for reflection emerged during the interview administered to the Special Commissioner and from the analysis of the relevant legislation (law no. 32/2021).
First of all, as established in the art. 1 of the regional institutive law, the legislator recognizes the Calabrian zero company the entrepreneurial autonomy that it deserves in addition to the administrative, patrimonial, organisational, technical, management and accounting autonomy already recognized by Legislative Decree 502/92. This important element, however, is lacking in the regional laws establishing Azienda Zero in other regions (Veneto, Piedmont, Lazio, Liguria).
Secondly, the basic idea was to constitute a tool for connecting with healthcare structures, to which the administrative function could be centrally entrusted. Therefore, a tool for strengthening regional governance,

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especially in reference to the contribution that it could provide in terms of analysis of needs and support for planning as well as for determining the guidelines to be provided to the other Entities.
Indeed, Azienda Zero implements the principle of separation between the governance functions (planning, direction, commissioning, resource allocation and control), typical of the General Management, and the production functions (organization and management) entrusted to the structures.Regardless of the functions specifically attributed to the Calabrian Azienda Zero, it is possible to conclude that the creation of a body that takes charge of the government of the SSR can lead to various advantages:

a) eliminate any redundancy in the structures and in the supply services, calibrating the resources available to the system – e.g. number of beds by speciality, major technologies – compared to pre-established supply volumes at a regional level;
b) rationalization of some administrative functions or of some processes for the provision of health services – e.g. laboratory diagnostics, sterilizations – which could be centralized or assigned to a few subjects destined to serve specific areas;
c) promotion of the standardization of clinical-care pathways, guaranteeing equity and appropriateness of care.

Relevants issues emerge in the phase of implementation of the activities.
Some are of internal order to the regional legal system, and are linked to potential problems of overlapping of competences that transferring functions to Azienda Zero can generate (i) with the administrative structures of the Region (Department Office) in relation to those coming from "high" (planning and coordination) as well as (ii) with the Health structures regarding the potential compression of the areas of entrepreneurial autonomy which, besides being necessary for the optimal functioning of the system, are also governed by state legislation (Legislative Decree no. 502/1992).
Further problems can be traced back to the national schemes envisaged for Intermediate Entities. In matters of corporate governance, the Intermediate Entities are called to adopt the scheme envisaged by the national laws for the health authorities of the system.
However, the monocratic configuration typical of healthcare structures based on the figure of the Director General, is poorly suited to the functions and competences attributed to the Intermediate Entity – holding.
Although there are other studies in the literature that have a global vision of the role that Intermediate Entities assume within the regional health group (Cinelli *et al.*, 2017; Del Vecchio e Romiti, 2017, Gugiatti *et al.*, 2022), this is the first study to our knowledge which seeks to provide a detailed overview of the attributed functions with a specific focus on the Calabrian case.
However, our study is not without limitations. The main limitation is strictly connected to the methodology adopted. First of all, a mainly interpretative analysis was conducted due to the fact that, on the one hand, not all regions have reached the implementa-

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tion and operational stage of these Entities on the other, in the regions where the Intermediate Entities are operational, not it is possible to proceed with an evaluation of their effects, since, in fact, they have been operational for too short a time.

Secondly, various weaknesses can be associated with the collaboration between academics and practitioners: i) the fact of having involved individuals with specific roles and different research perspectives exposed the results to a wide margin of subjectivity; ii) divergences have been identified in the lines of research: in fact, while academics give priority to theoretical and methodological aspects, professionals prefer purely practical aspects;and iii) the feasibility of the study depended largely on the information made available by professionals.

Thirdly, the fact that the study focuses on a specific case (the "Azienda Zero" of the Calabria region) could compromise the generalizability of the results, preventing their applicability to other contexts.

This study is a first step towards the qualitative analysis of the institution of Intermediate Entities within the NHS with a specific focus on the Calabrian case, since the actual long-term operation is not yet evaluable.

Therefore, future research perspectives could be oriented towards a broader comparative analysis between the different Italian regions, identifying: i) the real impact that these Entities have produced on the provision of healthcare and on the overall effectiveness of the system also in terms of equity and access to healthcare; ii) the evolution of the various dynamics of healthcare governance through a more in-depth analysis of the perspectives of the various stakeholders; (iii) potential unintended consequences and the provision of recommendations aimed at refining existing models and designing more effective ones in regions where they have not yet been established.

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