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Sustainability and Resilience

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Sustainability and Resilience in the Italian Health System

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1. Introduction

The COVID-19 pandemic has undoubtedly been the most significant shock that the Italian National Health Service (NHS) has had to face since its establishment in 1978. Up to December 31 2020, more than 74,000 people had died, and more than 2 million people had been infected with the virus that causes COVID-19—SARS-COV-2. This pandemic has provided significant insight into the future sustainability and resilience of the Italian health system.

As part of the Partnership for Global Health Resilience and Sustainability (PHSSR), this report uses COVID-19 as a critical event to evaluate the sustainability and resilience of the health system in Italy according to five key domains:

- Governance
- Health System Financing
- Workforce
- Medicines and Technology
- Service Delivery

Findings: key themes for sustainability and resilience

The COVID-19 health emergency represents a rare opportunity to analyse key strengths and weakness of our healthcare systems. Although further detail will be provided in the following pages, Table 1 reports some key issues determined from our analysis.

Table 1: Summary of key findings

Domains	Key findings	
	Sustainability	Resilience
Governance	<ul style="list-style-type: none"> ▪ Regional devolution in healthcare has made regions accountable for healthcare, but central–regional relations are still unclear and often conflictual. This situation has made differences more profound region-to-region in terms of structure, processes and outcomes. 	<ul style="list-style-type: none"> ▪ The initial coordination by the central level has produced some protocols, guidelines, instructions and tools for regional healthcare systems in responding to the COVID-19 pandemic. Nevertheless, regions have attempted to use their full competencies on healthcare, producing different response models with varying outcomes.
	<ul style="list-style-type: none"> ▪ The centrality of hospitals in the healthcare delivery system is preventing the full integration of care among different levels (primary, secondary, tertiary). 	<ul style="list-style-type: none"> ▪ The initial response at the central and regional levels could have been faster and better coordinated if an up-to-date version of the pandemic plan was available (latest revision 2006)
Health system financing	<ul style="list-style-type: none"> ▪ The funding allocation mechanism does not consider social deprivation, education, employability or housing and family conditions. 	<ul style="list-style-type: none"> ▪ Since 2011, the NHS budget has grown less than the EU average, below inflation, and is not in line with growing healthcare needs. This

		discrepancy has led to excessive pressure on cost containment and resulted in a lack of adequate provision of hospital beds, staff and technologies.
	<ul style="list-style-type: none"> Scarce attention to value-based payments and, more generally, a system based on 'spending silos' (hospital, outpatient and pharmaceutical expenditure). 	<ul style="list-style-type: none"> Up to the end of 2020, €9.5 billion of additional funds have been devoted to the COVID-19 emergency. Some estimates suggest that the NHS has spent more than €12.5 billion to face this crisis.
Workforce	<ul style="list-style-type: none"> Chronic workforce shortages, particularly for regions under a financial recovery plan and lack of planning for a new healthcare workforce 	<ul style="list-style-type: none"> Significant resources dedicated to increased number of healthcare workers, which has limited the effects of years of high turnover and inadequate retention of staff.
	<ul style="list-style-type: none"> Scarce attention to task-shifting between professional groups and inconsistent collaboration between professionals. 	<ul style="list-style-type: none"> Long times to prepare calls to acquire personnel, not suitable for the management of a pandemic emergency. Worsening of the already heavy workload of healthcare workers (especially for some clinical specialties).
Medicines and Technologies	<ul style="list-style-type: none"> Low level of digitalisation: poor and fragmented diffusion of electronic health record - EHRs, scarce use of telemedicine (particularly before the pandemic), limited use of AI. 	<ul style="list-style-type: none"> During COVID-19, a strong dependence on other countries for the purchase of medical devices (masks, gloves, pulmonary ventilators). Low levels of stockpiles.
	<ul style="list-style-type: none"> Regional differences in timely access to innovative treatments, devices and telemedicine solutions. 	<ul style="list-style-type: none"> Participation in collective purchasing agreements in participation with other EU countries for COVID-19 vaccines.
Service delivery	<ul style="list-style-type: none"> Lack of continuity of care: despite some regional differences, there is an overall tendency for a hospital-centred approach. A lack of clear, homogeneous and effective approaches for primary care provision due to the still-unclear role of GPs. Scarce human resources for testing, tracing and other prophylactic measures 	<ul style="list-style-type: none"> The presence of good primary assistance has allowed some regions to avoid the saturation of hospitals, thanks to early patient care. Different maturity of primary care arrangements has produced significant outcome variations.
	<ul style="list-style-type: none"> Need for more well-timed and homogenous data on service delivery. In this sense, the lack of regional epidemiological observatories does not help in the provision of updated data 	<ul style="list-style-type: none"> The conversion of hospitals to COVID-19 hospitals led to the suspension of elective outpatient and surgical activities in several phases of the pandemic.

Background: the response to the COVID-19 Pandemic in Italy

In Italy, the epidemic has been experienced in two waves. The first exploded on February 21, 2020 with the identification of 'case 1' in Codogno, and was almost immediately contained with the increasingly restrictive measures that led the country to lock down between March 9 and May 3 2020. This wave predominantly involved the north of the country where the levels of incidence and prevalence were higher than in other parts. In contrast, during the second wave (October–December 2020), the incidence and prevalence, although on average more significant in the northern regions, rose throughout the country. At this juncture, the lack of restrictions on the movement of people soon made it impossible to track cases, leading to an explosion of infections up to the peak of new daily positives in November 2020. The Italian NHS reacted rapidly to the spread of COVID-19. In a few days, hospitals increased their number of ICU and non-ICU beds, and new personnel were hired. The regional system, albeit with some differences (discussed later), put in place different organisational solutions to handle increased hospitalisations.

Whereas in the first wave, regions reacted predominantly by increasing bed numbers, between the first and second waves, the health system utilised the resources available to strengthen the network of services. Another substantial challenge has been the care and management of patients who do not require hospitalisation, with the regions committed to finding adequate solutions, also on the basis of the pre-existing organisational model. Regarding diagnostics, in the first phase of the pandemic, the reduced availability of nasopharyngeal swabs led to significant regional variations in diagnostic and tracking capacity. The initial test centralisation strategy adopted by some regions was soon abandoned in light of more inclusive approaches adopted by other regions. Due to the large number of people affected by COVID-19 during the second wave, it was almost impossible to perform contact tracing.

The system has made a strong effort to counteract the pandemic, but this has had wider implications: the Italian NHS had to stop most elective care during the first phase of the emergency and, for some regions, in November and December 2020. However, there are positives to be drawn, for example the response to the crisis has given a strong impetus to the diffusion of telemedicine, particularly for cancer and chronic patients.

Cross-Cutting Themes

Alongside our analysis across the five key domains, we have also identified a number of cross-cutting themes. These are long-standing, interrelated and unresolved factors that have influenced the system's ability to respond to the pandemic:

- **Relationship between central government and regional/local government:** the pandemic has exacerbated tensions between central and regional/local governments. For some aspects of the response, regions have been slow to implement the organisational solutions made available at the central level. Regions have independently provided vital medical devices and have given different guidelines for swabbing methods. Even in aspects not directly related to health management, the lack of coordination has often led to regional variation with standards imposed at the central level. Ultimately, COVID-19 has worsened the existing regional differences in the organisation of healthcare services. Regions with efficient systems and well-organised territorial assistance were more ready to face the pandemic's challenges. Stronger and clearer mechanisms for cooperation should be a priority for future preparedness.
- **Regional differences:** COVID-19 has worsened the existing regional differences in the organisation and provision of healthcare service. These differences, which entail inequalities in terms of access and quality of care and life expectancy, have inevitably affected the management of health emergencies such as COVID-19, with those regions with efficient systems and well-organised

territorial assistance being more ready to face the pandemic's challenges. The modernisation of all regional health systems towards a model capable of facing the environmental complexity and challenges of modern medicine will be key to ensuring sustainability and resilience.

- **Hospital-centred system:** despite the already-mentioned regional variations, the pandemic has highlighted the need to invest in territorial assistance, which is often neglected. The absence of a primary care gatekeeping function and more generally of a 'filter' has caused a large number of patients, even with minor symptoms, to crowd the hospitals. Similarly, the lack of intermediate structures has slowed the discharge of frail and chronically ill patients, forcing regions to find quick-fix solutions. Continuity of care is essential for the future of our healthcare system, and will contribute to both its sustainability and resilience.
- **Workforce:** The NHS suffers from chronic workforce shortages across a wide range of professional groups (physicians, nurses, administrators and other healthcare professionals), which was intensified during the pandemic. The latter has undoubtedly intensified workforce attrition rates, and has emphasised the need to review personnel planning, particularly for primary care. The workforce is fundamental to continue to adequately respond to COVID-19 and is the base upon which to build the sustainability and resilience of the system.

Recommendations

The following pages contain various recommendations on potential action to put in place to ensure the sustainability and resilience of the system. The final aim is to protect the healthcare system against possible future shocks. The recommendations cannot be considered exhaustive, and further work and mechanisms to ensure that lessons are learnt from the pandemic are paramount.

Table 2: Recommendations across the five domains and case studies

Domain	Recommendations
Governance	<ul style="list-style-type: none"> ▪ <u>Recommendation 1A:</u> to improve the healthcare planning function to be based on timely, consistent and comprehensive data sets, at both national and regional levels, and to systematically measure the level of achievement of planning objectives. In this sense, the interconnectivity between databases should be improved in order to develop indicators to create incentives for the regions to reach specific and measurable healthcare goals. ▪ <u>Recommendation 1B:</u> to conduct a public and participatory review into Italy's response to the COVID-19 pandemic in order to strengthen the preparedness of the systems to health care crises. In addition, pandemic response plans should be regularly updated. ▪ <u>Recommendation 1C:</u> to work on the coordination mechanism between central healthcare bodies and regional/local levels providing new national organisational standards for primary care services and non-hospital care. The pandemic has highlighted a slow regional response to governmental guidance, and unclear rules between of engagement between institutional levels. ▪ <u>Recommendation 1D:</u> to accelerate the process of introducing new healthcare services within the core benefit package of services (so called LEA) to be covered by the National Health Fund ▪ <u>Recommendation 1E:</u> To reduce the administrative burden in order to increase the structural, organisational and operational flexibility of healthcare organisations with the aim of accelerating appropriate transformations.

	<ul style="list-style-type: none"> ▪ <u>Recommendation 1F</u>: to revise the role of general practitioners within a consistent primary care framework. ▪ <u>Recommendation 1G</u>: to increase the structural and organisational capacity to respond to the needs of controlling epidemics and pandemics.
Financing	<ul style="list-style-type: none"> ▪ <u>Recommendation 2A</u>: to enrich the inter-regional fund allocation formula to consider differences in terms of social deprivation, education, employability and house and family conditions that still exist among Italian regions. ▪ <u>Recommendations 2B</u>: to reduce out-of-pocket private expenditures and facilitate access to integrated funds via tax incentives. ▪ <u>Recommendation 2C</u>: to introduce value-based payment models. ▪ <u>Recommendation 2D</u>: To introduce measures to mitigate budgetary siloes, and develop a health expenditure forecast model.
Workforce	<ul style="list-style-type: none"> ▪ <u>Recommendation 3A</u>: to invest in healthcare workers, with adequate planning of the number of physicians, nurses and all other categories, enhancing the role of the Ministry of Health and of Regional Health Authorities. This recommendation includes a further increase in the number of contracts for resident physicians. ▪ <u>Recommendation 3B</u>: to simplify administrative procedures for the appointment of personnel during emergencies. ▪ <u>Recommendation 3C</u>: to care for the physical and mental well-being of health and social care staff, improving work conditions and reducing stress. ▪ <u>Recommendation 3D</u>: to continue the process of task-shifting between professional groups and foster team-based working models (see the case studies for more recommendations) ▪ <u>Recommendation 3E</u>: to develop a competence-based human resource management approach based on the definition of national standards for healthcare professionals, top and middle managers of healthcare organisation and regional health
Medicines and technology	<ul style="list-style-type: none"> ▪ <u>Recommendation 4A</u>: to promote the establishment of a National Agency for Health Technology Assessment or at least ensure a stronger coordination among existing key actors in HTA. To overcome existing differences in the pattern of the introduction of drugs, vaccines, medical devices and new medical-surgical procedures, as well as telemedicine and digital solutions, ensuring equitable access to technology in all regions promoting patients' and citizens' involvement in key phases of the process. ▪ <u>Recommendation 4B</u>: to promote centralised investments for developing a national telemedicine infrastructure and establish a nationally based reimbursement scheme for telemedicine. ▪ <u>Recommendation 4C</u>: to participate in collective purchasing agreements with other EU countries. ▪ <u>Recommendation 4D</u>: to establish a resilience-oriented procurement strategy, also by supporting the national production of critical devices.
Service delivery	<ul style="list-style-type: none"> ▪ <u>Recommendation 5A</u>: to continue to promote innovative solutions for the management of chronic conditions and the continuity of care (see case studies for further details). ▪ <u>Recommendation 5B</u>: to re-think the role of GPs and their systems, with the aim of their full integration in the healthcare system, also by providing specific role training.

- Recommendation 5C: to reinforce diagnostic services and elective surgery by increasing investment in technologies and personnel, also providing innovative organisational solutions (see case study)
- Recommendation 5D: to reinforce the structure and organisation of healthcare services dedicated to prevention and control of epidemics and pandemics

2. Domain 1: Health System Governance

2.1 Sustainability

2.1.1 Governance and strategic direction

The Italian NHS is a three-layer universal healthcare system, free at the point of care. The national layer sets the core benefit package of services (so-called LEA, Livelli essenziali di assistenza), to be guaranteed to all citizens in all regions, with priorities and the level of funding to be set by the national public budget for the NHS. The regional level is responsible for healthcare organisation and planning, whereas the local level, structured on a territorial basis involves a network of local health authorities (LHAs) and hospital trusts (public and accredited private), is responsible for providing health care services.

At the central level, the key actor in the governance of the NHS is the Ministry of Health (MoH). It is responsible for:

- promoting general priorities for the health care system;
- defining the core benefit package (LEA) of services that represent the constitutional right to healthcare of Italian citizens;
- promoting scientific research and managing relationships with other international and European Institutions and Agencies.
- defining the health planning guidelines at the national level in collaboration with regional health authorities;
- monitoring regional activities and the delivery of LEA, uniformly in all the regions.

The ministry's activities are mainly supported by those of five other entities:

- the National Institute of Health (ISS), which is the technical-scientific body of the Italian NHS;
- the Italian Medicines Agency (AIFA), which contributes to health throughout the pharmaceutical system by providing access to innovative medicines and orphan drugs for rare diseases, ensuring the economic balance of the system in compliance with expenditure ceilings, through safe and appropriate use of medicines, investments in research and development in the pharmaceutical sector and by strengthening relations with agencies of other countries and with the EMA;
- the Standing Conference State-Regions, which give binding opinions, conclude agreements and play a crucial role in defining the medical services guaranteed by the state (LEA) and the level of public financing for healthcare;
- the National Agency for Regional Healthcare Services (AGENAS), providing technical and operational support to regions and healthcare organisations with regard to organisational, economic, and efficacy of health interventions, as well as patients' centredness, quality and safety of care.
- The High-Level Health Council (Consiglio Superiore di Sanità), which is the scientific and technical advisory body of the Minister of Health. It expresses an opinion at the request of the Minister, in cases expressly required by law, and in any other case in which the MoH General Directorates request opinions for the adoption of regulatory or administrative measures.

2.1.2 Financial Model

The Budget Law annually determines the resources allocated to the NHS for assuring health services guaranteed by the state (LEA). The amount of funds is determined in allotments, which essentially defines the needs of each region and, consequently, determines the source and level of funding. Allotments are proposed by the MoH, approved by the Standing Conference of States and Regions and then implemented with a resolution by the inter-ministerial Committee for Economic Planning (CIPE). The above-mentioned resources come from:

- general taxation of the regions, particularly the regional tax on productive activities (IRAP) and an additional regional tax on personal income (IRPEF);
- revenue from NHS hospitals, coming from co-payments and revenue deriving from physicians' private practice;
- contributions of the special statute regions and the Autonomous Provinces of Trento and Bolzano;
- the state budget, which finances health needs not covered by other sources of financing, using incomes from VAT and excise duty.

Regions, in turn, assign funds to LHAs, which provide LEA services. Essentially, LHAs acquire hospitalisation services (from directly managed hospitals or from other autonomous public and private hospitals), outpatient services, general practitioners and long-term care. Regions can broaden, using their own funds, the coverage of medical services covered by the LEA.

2.1.3 Goal setting, priorities and accountability

MoH defines the priorities, objectives and healthcare services guaranteed by the state and the related allotment of resources. In turn, regions, through their institutional bodies (Regional Councils, Councillors for Health and Regional Agencies for Health), outline the regional health plan, regional allotment of funds and annually decide the program and objectives for LHAs. Each region has, adopted its own organisational model in order to meet healthcare goals. Moreover, the President of the Region directly appoints the executive management of LHAs and public hospitals. In terms of accountability, the health management of the regions is subject to verification by MoH, both in terms of economic and financial balances (repayment plans) and regarding compliance with the quality of services provided (LEA). Subsequently, General Directors of LHAs and public hospitals are assessed on the basis of their level of compliance with the objectives assigned and, in case of non-compliance, they can be fired.

2.1.4 Healthcare Planning at national and regional levels

Before the full implementation of the Constitutional Act which established the federal role of the Italian NHS (2001), the National Health Plan (NHP) was the institutional instrument for NHS planning, defining priorities and objectives and outlining evolution and the strategies implemented. The latter also established that the measurement of its results would be undertaken via a yearly Report on the Health Status of the Country, an official document of the Ministry that describes population health status, the use of resources and the quality of care. The most recently approved NHP was issued in 2006. This planning tool has been substituted by a governance model based on institutional collaboration between the government and regions, referred to as the 'State-Region Conference', which issues a three-year 'Pact for Health' that identifies priorities and shared actions and provides guidance for resource allocation.

At the national level, MoH is still issuing national plans for specific aspects of the health system, such as the National Plan for Chronicity (2017) and the National Plan for Vaccine Prevention (2017–2019). MoH monitors the application of national guidelines and LEA delivery by regions and the achievement of goals set through

the 'Pact for Health' using a grid of 88 indicators. At the regional level, the same regions prepare regional health plans with the aim of pursuing specific regional health policies.

2.1.5 Technical – Political interaction

In Italy, healthcare management is subjected to the spoils system: within seven months from the establishment of the government, the Minister of Health may remove from their offices the General Secretary at the MoH and the director of the controlled National Agencies (National Institute of Health - ISS, Italian Medicines Agency- AIFA, National Agency for Regional Healthcare Services - AGENAS). However, governance of the RHAs is politically autonomous.

At the regional level, the governance of the healthcare system is under the political responsibility of the Regional Governor and Regional Healthcare Ministry. The spoils system for the General Director of LHAs and public hospital trusts is subjected to an assessment of the clinical, social and financial goals achieved, considering management objectives set by the region. General Directors, in fact, can be formally removed only in the event of non-fulfilment of responsibilities or failure to achieve results and objectives assigned.

2.1.6 Citizen and patient involvement

Patients' and citizens' involvement in NHS decision-making processes is limited to only a few procedures.

At the moment, no formal involvement is foreseen for patients and citizen's advocacy organisations during the process of pricing and reimbursement for medicines by AIFA. Patients' organisations can participate in public consultations for specific concept and position papers issued by AIFA (see <https://www.aifa.gov.it/consultazioni-pubbliche>).

Citizen and patient associations, hospitals and companies can ask the MoH, using a specific procedure, to modify services included in LEAs or to include new services. Decisions on inclusion or modification of LEAs are made by a commission, composed of delegates of the MoH, the Ministry of Economy and Finance, ISS, AIFA, AGENAS and Standing State-Region Conferences. In fact, one of the delegates nominated by MoH is the secretary-general of the largest patient association—Cittadinanzattiva.

In addition, at the regional level, some regions have HTA commissions, which provide for participation in the HTA process for all those involved or affected, including delegates of patient associations. For example, in Lombardia, the regional commission for HTA comprises clinicians, general practitioners, hospital pharmacists, clinical engineers, nurses, rehabilitators, health economists, law experts and delegates of patient associations. In Emilia-Romagna, a representative nominated by the coordination of patients' associations is a member of the Regional Drug Formulary Commission.

2.1.7 Decision-making, transparency and accountability

Decisions made by AIFA on a particular medicine's authorisation and reimbursement are published in the Gazzetta Ufficiale, an open journal that is the official source of knowledge about public and private acts in Italy. Similarly, decisions of inclusion or modification of medical services guaranteed (LEA) are published in Gazzetta Ufficiale. Decisions made by the regional HTA commission are also generally available through executive decrees made accessible on the region's websites. Currently, full reports containing details of the assessment of the Scientific and Technical Commission (CTS) and Price and Reimbursement Committee are not publicly available. Instead, a short (2–3 page) report on the assessment of the declaration or denial of 'drug innovativeness' is made public on the basis of AIFA Decree n. 519/2017.

The Scientific and Technical Commission (CTS) and Price and Reimbursement Committee of AIFA are appointed by an MoH decree and are each made up of 10 members, nominated by MoH (3 members), the

Ministry of Economy and Finance (1 member) and Standing Conference State-Regions (4 members). For this reason, there is an underlying political mechanism: because they have been appointed by the government, these members must respond for their actions to the latter and should behave in line with the mission of the agencies.

Similarly, and as previously anticipated, some members of the LEA commission are also appointed by the government and the regions. Thus, their actions should reflect the decisions of the government.

2.2 Resilience

2.2.1 COVID-19 preparedness and response

In February 2006, Italy had approved a 'National Plan for a Flu Pandemic', however it was never subsequently updated. The plan, the main goal of which was to ensure preparedness, identified six different potential phases of a pandemic, basing on the level of risk. In addition, for each phase, the plan defined specific purposes, actions and responsibilities. Because this plan had not been recently revised, it was completely and rapidly redesigned by an expert task force established by Italian Civil Protection at the beginning of February 2020. Moreover, 16 out of the 21 regions had regional plans for a pandemic. However, even these plans had not been updated: their elaboration took place in the timeframe 2006–2009. This heterogeneity in regional preparedness resulted in different responses in terms of actions put in place to respond to the health crisis, and their timeliness.

Regarding epidemiological surveillance, The National Centre for Epidemiology and Health Promotion of the ISS is the major national institution responsible for this area. Epidemiological data are available on the EpiCentro website. EpiCentro aims to facilitate access to epidemiological data and share these data at the local level. EpiCentro provides information and data on infectious diseases and—particularly during the winter—on flu. Influenet surveillance is the national flu epidemiological and virological surveillance system. It is divided into epidemiological surveillance (which aims to determine the beginning, duration and intensity of the seasonal epidemic) and virological surveillance (which aims to monitor the circulation of the different types, as well as subtypes, of influenza viruses). Information is collected and disseminated in a weekly report. Moreover, coherent with its mission, EpiCentro provides data on COVID-19 in weekly reports with salient information, such as the mean age at death.

At a central level, the government boosted personnel and beds and delineated appropriate solutions to take care of COVID-19 patients. The first case not identified from a foreign country was discovered on February 21 2020. However, a scientific committee composed of experts and representatives of the Italian Minister of Health and other agencies was created on February 5 2020, more than 15 days before the first COVID-19 case. Between February 29 and March 1 2020, the Italian Ministry of Health ordered hospitals to boost by 50% the number of ICU beds, by 100% the number of infectious disease beds and, if necessary, to reduce other activities in order to make more beds available. At the time, Italy had only 1577 cases, of which 639 were in hospital and 140 in ICU. On April 30, the NHS could count on 8760 ICU beds, whereas at the beginning of the emergency, 5124 ICU beds were available: in two months, ICU beds were increased by more than 70%. Moreover, on March 9 2020, the government made available more funds for hiring new personnel and established special units (USCA), formed by physicians, with the aim of treating non-critical patients at home. On July 23, 589 of those special units were activated. Finally, despite some regional differences, the system rapidly increased the number of physicians: by November 18, 4,388 new units of physicians had been hired.

Despite these data, strong regional differences arose. Our research group found at least three different approaches undertaken by regions:

- *Hospital approach*, in which most patients were managed directly in hospitals, whereas less attention was devoted to organising territorial care.

- *Territorial care* approach, in which, in contrast, hospital care was reserved only for critical patients, whereas, thanks to the efficiency and capability of territorial assistance, a high proportion of cases were treated at home. Moreover, the regions implemented an active case research policy early on, largely aimed at testing groups at high risk.
- *Combined territorial/hospital approach*, in which the two previously discussed approaches were executed. In addition, these regions also organised an intermediate structure for COVID-19 patients in order to reduce the burden on hospitals.

The ability of the system to rapidly respond to the emergency can be attributed to a good level of coordination between healthcare sectors. General practitioners were generally the gatekeepers of the system and made decisions on appropriate settings for patients (hospital or home). For patients not requiring hospitalisation, home care (USCA) was activated. Moreover, for frail patients or for those who had tested positive but did not require hospitalisation, intermediate structures were arranged to reduce hospital burden. This system worked very well in some regions but not in others, resulting in substantial pressure on hospital services: during the first phase of the emergency, in Lombardia, the ratio between people in hospital vs those in home care was 1.14, whereas in Emilia Romagna, this ratio was 0.61.

Regarding coordination between levels (essentially the national level and regions), we found differences: some regions more rapidly adopted national guidelines and regulations, whereas others did not. For example, regarding the Reorganisation Plan, on May 19 2020, a decree required regions to establish a plan for the reorganisation of hospitals in order to be prepared for the second wave of the pandemic. Some regions took several days to prepare this plan, others more than two months.

During the crisis, protocols and guidelines were frequently updated. First protocols were elaborated upon and disseminated approximately one month before the first case. During the crisis, specific protocols and guidelines for managing patients affected by COVID-19, the use of diagnostic tests and personal safety protection devices and the management of frail patients or those at risk were developed. Most of the above-mentioned protocols and guidelines were outlined by MoH, and in particular from the Directorate for Health Protection. In addition, the National Institute of Health provided information on relevant issues, such as the use of PPE or the implementation of isolation and home health care. Finally, some regions developed additional guidelines on antigen tests and commercial activities, sports and recreational activities.

In terms of communication, during the first phase of the pandemic, a daily national press conference was organised with the aim of announcing the number of new cases, deaths, hospitalised and people in home isolation. Public information campaigns on television, radio and newspapers were carried out regarding prescribed behaviours, such as using masks or maintaining a safe distance. The Prime Minister spoke to the nation on several occasions, illustrating the measures implemented and the prescribed behaviours. The volume of public communications may have been excessive, particularly during the first phase, causing confusion among the public in some important areas (e.g. mask wearing).

2.2.2 Learning and adapting

To date, no technical or parliamentary commissions have been established to evaluate responses to the crisis. At a national level, the ISS provides weekly epidemiological information, whereas AGENAS publishes on a daily basis the rates of occupancy of ICU and non-ICU beds. Some independent research, including by our research group, was produced to evaluate responses to the pandemic. The health crisis has undoubtedly called into question years of cost containment policies, which, as discussed in the next paragraphs, have led to a reduction in personnel and resources (beds and available technologies) and scarce attention to territorial assistance. The first consequence was the need to increase the number of ICU beds from 0.12 to 0.14 per 1000 inhabitants. A further major lesson from the crisis was the need for updated pandemic plans. The MoH presented its new pandemic plan for 2021–2023 in the first days of January 2021.

2.2.3 Recommendations

Recommendation 1A: to improve the healthcare planning function to be based on timely, consistent and comprehensive data sets, at both national and regional levels, and to systematically measure the level of achievement of planning objectives. In this sense, the implementation of a system of indicators is required and should create incentives for the regions to reach specific and measurable healthcare goals.

Recommendation 1B: to conduct a public inquiry into Italy's response to the COVID-19 pandemic in order to strengthen the preparedness of the systems to health care crises. In addition, a frequent update of the pandemic plans should be performed.

Recommendation 1C: to work on the coordination mechanism between central healthcare bodies and regional/local levels. The pandemic has highlighted a slow regional response to governmental protocols.

Recommendation 1D: to accelerate the process of introducing new healthcare services within the core benefit package of services (so called LEA) to be covered by the National Health Fund

Recommendation 1E: To reduce the administrative burden in order to increase the structural, organisational and operational flexibility of healthcare organisations with the aim of accelerating appropriate transformations.

Recommendation 1F: to revise the role of general practitioners within a consistent primary care framework.

Recommendation 1G: to increase the structural and organisational capacity to respond to the needs of controlling epidemics and pandemics.

Recommendation 1E: to revise the role of general practitioners within a consistent primary care framework.

3. Domain 2: Health System Financing

3.1 Key macroeconomics indicators

The NHS, as previously discussed, is funded through national and regional taxes, complemented by co-payments for pharmaceuticals and outpatient care. In the last 10 years, healthcare expenditure in Italy has constantly decreased in relation to GDP, decreasing from 6.9% in 2009 to 6.5% in 2018. Simultaneously, we registered an increase in the population over 65 years: in 2009, 20.1% of the Italian population were aged over 65 years, whereas in 2018, this percentage had risen to 22.6. Over the years, moreover, there has been an increase in *out-of-pocket* expenditure. Finally, with respect to fund allocation, most resources were allocated for community healthcare, which saw a progressive increase over time, and hospital care, which registered a progressive reduction. A small percentage of available funds is for prevention.

Table 2: Key indicators 2009–2018

Indicators	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Health expenditure / GDP	6.9%	6.9%	6.7%	6.8%	6.8%	6.8%	6.7%	6.6%	6.6%	6.5%
Aged over 65 years out of total	20.1 %	20.2 %	20.3 %	20.8%	21.2%	21.4%	21.7%	22.0%	22.3%	22.6%
Public debt as a percentage of GDP	116.6	119.2	119.7	126.5	132.5	135.4	135.3	134.8	134.1	134.8
Italian social health insurance schemes (million euro)	n.a.	n.a.	n.a.	326	341	351	343	267	260	227
Italian voluntary health care payment schemes (million euro)	n.a.	n.a.	n.a.	2.909	2.852	2.937	3.076	3.367	3.705	3.929
Italian household out-of-pocket payment (million euro)	n.a.	n.a.	n.a.	31.509	31.456	32.529	34.405	34.510	35.875	36.044
Italian total health care expenditure (million euro)	n.a.	n.a.	n.a.	142.676	141.526	144.317	146.613	147.963	150.697	153.085

Out-of-pocket/total expenditure	n.a.	n.a.	n.a.	22.1%	22.2%	22.5%	23.5%	23.3%	23.8%	23.5%
Labour force participation rate	62.3	62.0	62.1	63.5	63.4	63.9	64.0	64.9	65.4	65.6
Prevention	4.2%	4.2%	4.2%	4.1%	4.2%	4.2%	4.2%	4.2%	4.4%	4.3%
Community healthcare	49.0 %	50.1 %	50.0 %	50.0%	51.1%	51.8%	52.3%	52.6%	52.4%	52.3%
Hospital/tertiary care	46.8 %	45.8 %	45.9 %	45.9%	44.7%	43.9%	43.5%	43.2%	43.2%	43.4%

3.2 Sufficiency, stability and flexibility

In the Italian NHS, with the reform of Title V of the Italian Constitution, health has become a matter of concurrent competence between the state and regions. The state determines the LEA, the level of financial resources and the performance monitoring system. Meanwhile, regions organise the regional health services. Since 2001, a system for monitoring the costs of these health services has been implemented. It is based on data from three sources: profit and loss statements (PLs), balance sheets (BSs) and costs of the assistance levels (LAs). These models are subject to continuous updating, the most recent of which was in 2019. The monitoring activity is also carried out through two technical committees, established in 2005: the committee for the verification of regional obligations, coordinated by the General Accounting of the State, and the LEA Committee, coordinated by the Ministry of Health. If the monitoring process shows a deficit, the suitability and adequacy of the coverage measures adopted by the region to fully cover regional health deficits are analysed in order to ensure compliance with the current legislation. In the case of persistent deficits, or deficits reaching a threshold of 5%, the region is subjected to a repayment plan requiring it to reduce expenditure to prescribed levels.

Specifically, the repayment plan is carried out with monitoring provided through a joint session between the two already-mentioned technical committees. In particular, they carry out, on the basis of the quarterly data of costs recorded with the PL model, financial projections up to the end of the year. Based on this analysis, if the coverage is not sufficient, they instigate the raising of some taxes (specifically, taxes on firms' earnings (IRAP) and individual earnings (IRPEF Regional Additional)) to the maximum levels allowed by the legislation. There is also a ban on non-mandatory expenses. The repayment plans are an integral part of the agreements, stipulated by MoH and the Ministry of Economy and Finance with the single regions involved, and they have a time horizon of three years. They represent restructuring programmes focussing on expenditure factors, such as:

1. bed numbers and the hospitalisation rate;
2. pharmaceutical consumption;
3. personnel expenses;
4. the number and value of services purchased by private structures as well as the related remuneration system;
5. expenses for the purchase of goods and services;
6. control of the appropriateness of doctors' prescriptions.

In addition to what has already been mentioned regarding the regional reimbursement plans, in 2016, a further measure was the introduction of the efficiency and requalification plans for hospitals (including teaching hospitals and Scientific Institutes for Research, Hospitalisation and Healthcare) that present a specific deficit or failure to comply with parameters relating to volumes, quality and outcomes of care. More specifically, the entities of the NHS are subject to a reorganisation if they have one or both of the following conditions: a) a deficit between costs and revenues (deriving from the remuneration of activities of the regional health service) equal to or greater than 7% of the same revenue or equal, in absolute value, to at least €7 million; b) failure to comply with the parameters relating to volumes, quality and outcomes of treatment. The procedural steps provided are:

1. The adoption of a decree by MoH, in consultation with the Minister of Economy and Finance, in agreement with the Standing Conference State-Regions, aimed at defining the methodology for assessing the deficit, the assistance areas and the reference parameters relating to volumes, quality and outcomes of care as well as the guidelines for the preparation of the related recovery plans;
2. The adoption of a further decree of MoH, to be issued in agreement with the Minister of Economy and Finance and after the agreement of the State-Regions Conference, for the redetermination of the

accounting schemes in order to give evidence and transparency of the costs and revenue before mentioned;

3. The identification by the regions, based on the methodology and defined parameters, of the bodies of their regional health service that fall into at least one of the two cases determining the obligation of a repayment plan, and institution—if not already present—a ‘centralised health management’ and registration in the budget of the same in order to guarantee the overall balance of the regional health service, of a quota of the regional health fund corresponding to the sum of any negative deviations referred to in the repayment plans;
4. The presentation to the region, by the entities identified, of a business recovery plan, which envisages the measures necessary for achieving economic, financial and equity balance and improving the offer of services;
5. The evaluation and approval of the plan by the region;
6. The quarterly verification, by the regions, of the implementation of the interventions envisaged in the company recovery plans and adoption of any corrective measures;
7. To make the measures envisaged by the recovery plans effective, general manager could be fired in case they do not employ the measures above described.

Seven Regions have been submitted for discipline regarding repayment plans (Abruzzo, Calabria, Campania, Lazio, Molise, Puglia and Sicilia), and two of them have been placed under temporary receivership (Calabria and Molise). Furthermore, during the last year, other regions have also been put under temporary receivership, including Lazio (2008–2020), Abruzzo (2008–2016) and Campania (2009–2020), whereas others have exited the repayment plan (e.g., Liguria and Sardinia in 2010 and Piemonte in 2017).

In short, the system has regulatory tools to control regional and provider economic performances.

However, the overall expenditure control system for healthcare is currently organised in ‘watertight compartments’ for hospital, pharmaceutical and territorial expenditure. This approach does not consider that potential investment in one compartment could offer benefits to another. Despite at the moment there being no predictive model for future healthcare expenditure, a pilot system has been prepared by MoH in collaboration with three Italian universities.

3.3 Coverage and fair financing

The capitation formula used to distribute funds for health among regions is based on historical expenditure for hospital care weighted by age and sex. Although it aims to ensure horizontal equity, it does not take into account different conditions in terms of social deprivation, education, employability and house and family conditions. As a result, there are variations in major indicators for health status between the north and south of the country. Moreover, disparities related to access to in-patient drugs, primarily oncology drugs and antivirals, exist. Even if AIFA approves drugs at the national level, the timeliness of availability of these drugs in regional drug formularies is rather variable.

The Italian NHS is a system of structures and services that aim to guarantee to all citizens, in conditions of equality, universal access to the provision of health services as the 32nd Article of the Constitution of the Italian Republic reports. Universality means extending health services to the entire population; in that view, health is not only an individual good but, above all, is a community resource. In practice, the NHS applies this principle through the promotion, maintenance and recovery of the physical and mental health of the entire population with a network of organisations throughout the country whose services are provided by local health authorities,

hospitals and private affiliated structures within the NHS. The system guarantees, in a uniform manner, the LEA to the population. Despite this, marked regional differences exist.

Equity, on the other hand, means that citizens can access NHS services without any distinction of individual, social and economic conditions. Citizens who do not belong to exempt categories are required to pay a ticket, which varies for each individual service provided for by the LEA. Finally, equity means that equal access must be guaranteed to all citizens in relation to health needs. This is the fundamental principle that aims to overcome the inequalities of access of citizens to health services.

3.4 Paying providers

The financing model for healthcare structures in Italy includes the presence of weighted capitation mechanisms and tariffs. The capitation fee (applied to local health authorities) aims to guarantee equity in access to health services, to respond equally to equal needs and to keep the dynamics of health expenditure under control. The remuneration of hospital services, based on tariffs (DRG) set by each region, pursues the aim of achieving increased operational efficiency and encouraging competition on the quality of the provision of hospital services. In particular, the allocation system involves the identification of three benchmark regions, selected on the basis of their efficiency and financial performance. On the basis of these regions, the standard cost for each macro level of assistance (collective, district and hospital) is determined as a weighted average per capita of the cost recorded by the reference regions, where 'weighted' means adjusted for the composition of the registry. The standard cost of the benchmark regions is applied to the weighted population of the individual regions to obtain the standard requirement, and the share to be allocated to the single region is given by the ratio between the region's requirements and the standard national requirements (i.e., the sum of the regional requirements). At a second level, the region assigns its local health units (ASL) a weighted capitation quota for hospitals based on the demographic, epidemiological characteristics and health needs of the population residing in the reference area, in compliance with the uniform levels of assistance provided for by the national health plan. At a third level, each local health unit finances hospital services (through the DRG tariff system) provided to its residents by different categories of accredited suppliers: a) hospitals with economic and financial responsibility managed directly by the LHU and b) external suppliers, in turn divided between i) hospitals with economic and financial responsibility belonging to other LHUs in the region, and ii) autonomous public hospitals and private hospitals located in and outside the region.

Ultimately, the level of financial resources allocated to each region depends on the age of the resident population compared to that of the other Italian regions. The standard costs, or the costs incurred by the benchmark regions, are used as a multiplication constant in both the numerator and denominator of the formula for determining the share to be allocated. As a result, there are significant differences between what the regions receive in terms of per capita funding. Furthermore, social deprivation, intended as a measure of disadvantage in terms of education, work, housing and family conditions, has never been included among the distribution criteria of the National Healthcare Fund, whereas the current scheme, introduced in 2011, only considers, for the determination of per capita expenditure, the registry composition of the population.

Currently, in Italy, there is no common method for analysing the existing approach and embracing value-based healthcare. A few single paths have been recently introduced that involve industry leaders, payers, providers and decision-makers to improve this strategy. The implementation of value-based healthcare represents a commitment that primarily implies a cultural change of all stakeholders, strong leadership and collaboration between the various professionals operating in healthcare, and importantly citizens. The major example of a value-based payment model is the application since 2005 of managed entry agreements (outcomes-based agreements for medicines) by AIFA. Among them, 'payment by results' is an approach that links the payment of new drugs with largely unknown benefit (mainly for oncology) to the achievement of specific outcomes agreed with the manufacturer in clinical practice.

Another weakness of the system can be seen in the absence of clear and widespread incentive mechanisms (economic or otherwise) related to increasing the quality of the provision of healthcare services or, in general,

to improving the performance of healthcare providers. However, there are performance incentives in place for directors, managers and other staff (both clinical and non-clinical). The amount and the award criteria are defined by various collective agreements but follow a common logic linked to performance, availability, shifts, overtime and productivity. These are intended to support the achievement of regional objectives determined on the basis of the state protocols specified in the National Health Plan. The region defines the annual and multi-year objectives, negotiating them with the individual provider's management. The management must designate these objectives to the managers of their unit, who in turn delegate the objectives to the employees assigned to the unit, who must contribute, according to the role and category of staff to which they belong, to the achievement of the same. There are, then, other specific cases of economic incentives in the form, for example, of bonuses intended to compensate for the participation of the professional in specific initiatives/activities; however, all of these examples are not linked to the results actually obtained or measured by specific indicators, as in the case of 'pay for performance' or 'pay for quality'.

3.5 Funds for the COVID-19 emergency

The government has allocated a total of €9.5 billion (<https://www.mef.gov.it/covid-19/Sanita-e-Protezione-Civile/>) to strengthen the hospital network to ensure the provision of personnel, tools and means for the health system, civil protection and law enforcement agencies to assist people affected by the disease and for the prevention, mitigation and containment of the epidemic¹. In particular:

- The National Emergency Fund was refinanced for a total of €3.73 billion.
- €1.4 billion for the reorganisation of hospitals, used for 3,500 new intensive care beds, the requalification of 4,225 new beds in the semi-intensive area, 300 intensive care beds in mobile facilities, as well as other upgrading and restructuring measures.
- €1.2 billion for the strengthening of community healthcare, aimed at improving the monitoring and early tracking of cases, assistance for patients in home isolation, increasing home therapeutic services and strengthening of district nursing services, with the introduction of family or community nurses, for the recruitment of up to 8 nurses for every 50,000 inhabitants, with contracts from May 15 to December 31 2020.
- Acquisition of new health personnel, especially physicians and nurses, for NHS and, to a lesser extent, for central institutions. The expenditure for scholarships for medical specialists increased by €105 million for 2020 and 2021 and by €109 million for each of the years 2022, 2023 and 2024.
- €500 million allocated for the use of additional services of medical personnel in order to promptly respond to requests of outpatient services, screening and hospitalisation not provided during the epidemiological emergency and to reduce waiting lists.

3.6 Recommendations

- Recommendation 2A: to enrich the inter-regional fund allocation formula to consider differences in terms of social deprivation, education, employability and house and family conditions that still exist among Italian regions.

¹ For more detailed information on fund for Covid – 19 please visit: <https://altems.unicatt.it/altems-ALTEMS%20Instant%20Report%202029esima%20edizione.pdf>

- Recommendations 2B: to reduce out-of-pocket payments and facilitate access to integrated funds via tax incentives.
- Recommendation 2C: to introduce value-based payment models.
- Recommendation 2D: to introduce measures to reduce budgetary silos and develop a health expenditure forecast model.

4. Domain 3: Workforce

4.1 Workforce numbers

The NHS suffers from a chronic shortage of healthcare employees. This shortage is has developed since the 2007 economic crisis and the imposition of national constraints on expenditure for health personnel, established by Law no. 296 of 2006 (Financial Law 2007), which reduced by 1.4% the 2004 level of personnel. Furthermore, this situation was exacerbated by measures to contain recruitment adopted in regions subjected to the above-mentioned repayment plan. In the context of constraints on expenditure, the level of permanent staff in the NHS in 2017 was lower than that of 2008 (i.e., approximately 42,800), with a continuous reduction starting from 2010 and a decrease of 6.2%. During the period 2013–2018 (latest data available), the ratio between healthcare employees for 1,000 inhabitants has remained stable (**Table 3**).

In contrast, the number of healthcare workers employed in long-term care (physicians, nurses, allied health professionals) slightly decreased during 2010–2016 (latest data available – **Table 4**). The same data show that growing long-term care needs have likely been met by turning to volunteers, whose numbers have grown.

Table 3: Healthcare employees for 1.000 inhabitants

	2013		2014		2015		2016		2017		2018	
	Healthcare employees	Healthcare employees for 1,000 inhabitants	Healthcare employees	Healthcare employees for 1,000 inhabitants	Healthcare employees	Healthcare employees for 1,000 inhabitants	Healthcare employees	Healthcare employees for 1,000 inhabitants	Healthcare employees	Healthcare employees for 1,000 inhabitants	Healthcare employees	Healthcare employees for 1,000 inhabitants
Total Medical Doctors	234,918	3.9	235,889	3.88	233,102	3.84	239,642	3.95	241,512	3.99	240,288	3.98
Nursing staff	306,044	5.08	320,705	5.28	330,602	5.44	337,515	5.57	351,008	5.8	346,949	5.74

Source: Italian national statistical institute - Istat

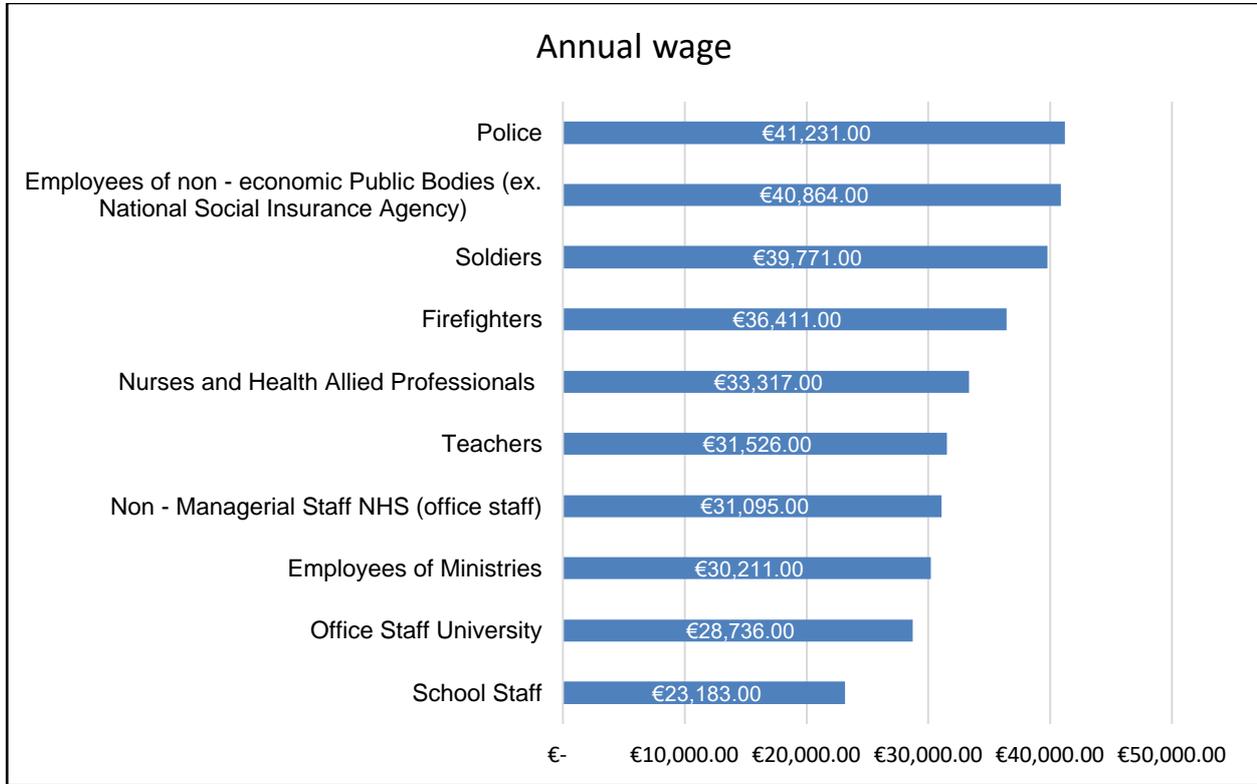
Table 4: Number of long-term care workers

2010		2011		2012		2013		2014		2015		2016	
employees	volunteers												
334,020	45,201	321,680	51,847	297,261	53,569	308,125	54,374	321,614	58,501	323,919	63,264	327,426	62,855

Source: Italian national statistical institute - Istat

Staff Salaries

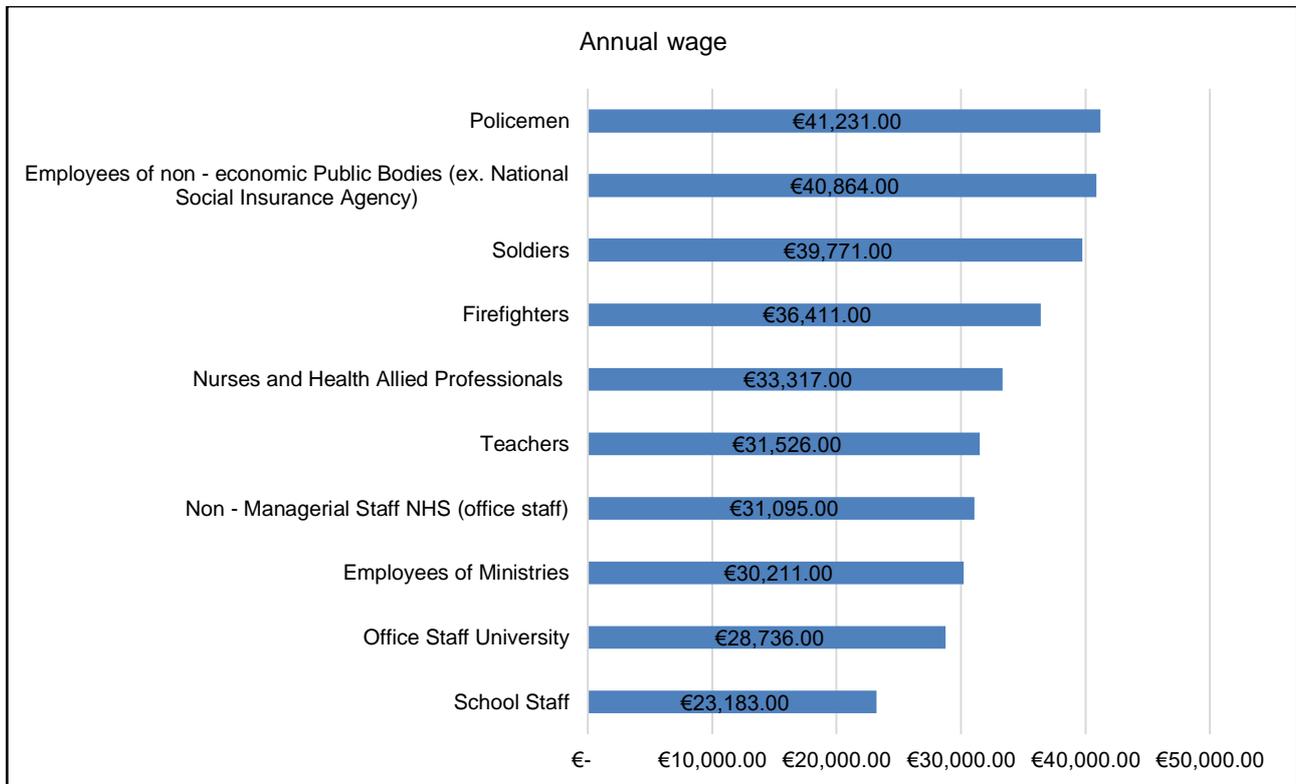
Figure 1: Comparison between salaries of public managers



Source: Italian Ministry of Finance, year 2018

The data show that the salaries of management roles in the health service are among the lowest among public managers (Figure 1): a healthcare manager earns much less than a peer who works in other public bodies. In 2018 gross wages per capita in the healthcare sector amounted to almost €83,000 a year for a physician, €73,000 for non-medical managers. At the same level, wages rise to €158,000 thousand in non-economic public bodies and to €137,000 for magistrates.

Figure 2: Comparison between salaries of public employees - non managerial roles



Source: Italian Ministry of Finance

The pay of non-managerial staff of the NHS (Figure 2) is in line with those of the Police Corps and the Armed Forces. Nurses and health allied professionals receive on average, more than teachers.

Workforce Vacancies

The Italian National Institute for Statistics (Istat) provides data about vacancies based on the competency profiles of the new employees required. Over the 7 years 2011–2019, 690.960 vacancies were estimated. The number of vacant positions has grown exponentially in recent years due to recruitment freezes and the growing attention to budget constraints. For most of these vacancies, considerable previous experience was required as well as the possession of a master’s degree in one-third of vacancies. The phenomenon of Italian doctors who move abroad is relevant: the data reveal that between 2008 and 2018, more than 11,000 doctors (approximately 10% of the total number) had moved abroad. However, Italy also benefits from foreign physicians: in 2017, the latest available estimates were that 18,000 doctors were from abroad, along with 37,000 nurses.

4.2 Workforce well-being

In Italy, there is no institutionalised system for monitoring staff well-being. Regarding absenteeism, the most recent survey was performed by FIASO (Italian Federation of Hospitals) in 2015. The research established that every year, the health workforce registers 30,000,000 days of illness, which cost approximately €3 billion.

The Italian Government provides data (Table 5) about the turnover compensation rate. When the rate is higher than 100, it indicates a hiring policy, whereas when it is lower than 100, it denotes a downsizing policy.

Table 5: Turnover Compensation Rate

Compensation Rate	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Average
TOTAL	97.2	96.8	81.9	78.2	68.9	85.6	80.5	76.3	97.2	97.7	103.6	87.6

Within Italian regions, this rate shows high variability. The rate of the Italian northern regions is higher than 100, whereas the rate in the Italian southern regions is around 50. The regions in the south are frequently subjected to financial recovery plans (so-called ‘Piano di Rientro’), representing a possible cause of the containment of new workforce hiring. When the compensation rate is lower than 100, in a long-term period, it can also be indicative of an ageing workforce.

A 2019 study conducted by FIASO affirms that in a sample of more than 3,222 health workers, of which 2,016 were senior (tenured) and 1,206 recently hired, 51% of tenured workers and 65% of young workers were convinced about the optimality of their working conditions. Besides this evidence, there is a fervent academic debate in which specific regional or organisational experience are described.

4.3 Sustainability of the healthcare workforce

The number of medical personnel in Italy is inadequate. The number of new hires does not compensate for those who retire. It has been highlighted several times that this is a structural problem, starting from the number of students admitted to university. Every year, the Italian Ministry of Universities and Research (MIUR) in agreement with the Conference of Regions and with the MoH establishes the number of new students admitted to medicine and surgery faculties. Only in recent years has the number of seats available for medical schools increased (Table 6).

Table 6: Numbers of students admitted to medicine and surgery faculties

Academic year	Number
2016–2017	9,224
2017–2018	9,100
2018–2019	9,779
2019–2020	11,568
2020–2021	13,072

Source: Italian Ministry of Universities and Research

Moreover, every year, an agreement between the Italian Ministry of Universities, the Italian Ministry of the Economy and the Italian Ministry of Health establishes the number of contracts for resident physicians. Additionally, regional financing can be provided to increase this number (Table 7).

Table 7: Contracts for residents’ physicians

Academic year	Total Number	Funded by Italian Government	Funded by Regions	Funded by other sources
2017–2018	6,934	6,200	640	94
2018–2019	8,776	8,000	612	164
2019–2020	14,455	13,400	888	167

Source: Italian Ministry of Universities and Research

Before COVID-19, the physicians' trade union Anaa-Assomed established that in 2025, the Italian NHS would lack 16,500 physicians. However, following the COVID-19 emergency, the situation has dramatically changed. The estimation in November 2020 by the Altems Instant Report Working Group evaluated that the potential need for healthcare workforce expressed by the Italian regions was around 4,788 staff as of November 2020.

A solution to the staff shortage could come from task shifting, around which there is a fervent debate. Nurses are ready to assume new responsibilities, whereas physicians have some doubts about that approach. Some institutional inputs on this topic: 'Patto della salute 2014-2016'; 'Piano Nazionale della Prevenzione 2014-2018'; DPCM 12/01/2017. Law 3/2018; CCNL (healthcare workers) 2016–2018, stress task shifting within multidisciplinary teams working on chronic condition treatments.

The pandemic has also suggested the relevance of managerial competencies of healthcare organisations' and system performance. Law Decree n. 502/1992 has introduced managerialism in the Italian healthcare system based on the principles of new public management. The intended goal was to promote a governing model for public healthcare organisations based on a clear division between technical, managerial and political roles in the healthcare system's governance. This evolution is still ongoing, and has seen the introduction of a National Register of Healthcare Managers (D.Lgs n. 171/2016). Clear and established criteria for training and the career paths to be followed by candidates are still required, and the average quality of acting general managers is still variable.

4.4 Workforce response to COVID-19

From a general perspective, to cope with the emergency, extraordinary procedures have been adopted for personnel recruitment to strengthen both territorial and hospital assistance. This approach has allowed the regions most affected by COVID-19 to hire more doctors and nurses, including in the military.

Moreover, some specific actions have been performed, in particular:

- 20,000 hires were made, and extraordinary measures were taken for the recruitment of health personnel, also in derogation from the legislation on public employment. In addition, the system also allowed for the use of temporary contracts for NHS personnel.
- Where it has not been possible to recruit new staff, has been given the opportunity to keep in service NHS personnel who have the requisites for retirement.
- 490 military medical and nursing personnel were hired.
- A call has been prepared for 3.000 physicians and 12.000 nurses dedicated to COVID- 19 vaccines.
- *Medical license*: a master's degree in medicine and surgery together with accomplishment of an internship period are sufficient to exercise the profession (no other examinations are required).
- *Academic qualification recognition of health professionals*: it is possible to temporarily practice as a medical professional by possessing qualifications obtained abroad. The regions and autonomous provinces can hire these professionals only until the end of the emergency, within the limits of the resources available.
- *General practitioners*: until December 31 2021, the medicine and surgery graduates in possession of their medical license and those enrolled in general medicine training can be hired as general practitioners.

- *Residents*: a higher level of expenditure has been authorised to increase their number.
- Conversion to permanent employment for *fixed-term employees*.

As affirmed previously, the estimated number of new healthcare workforce required after the COVID-19 emergency by the Italian regions is around 4,788 staff.

To understand the changes in terms of workload due to the COVID-19 emergency, we provide the example of anaesthesiologists and reanimators who, during the pandemic, were the most requested specialists. We built two indicators (Table 8), as follows. The first indicator, namely the ratio before Decree-Law 34, considers the number of 2,018 anaesthesiologists and resuscitators (latest available data) and the number of ICU beds. For the second indicator, to calculate the number of anaesthetists, the notices declared during the emergency and the ICU beds after the Decree-Law were considered and were found to be within the reorganisation plans of the hospital network of each region.

Table 8: Workload of anaesthetists and resuscitators

2019 anaesthetists and resuscitators	ICU beds pre DL 34/2020	Anaesthetists/ ICU beds pre DL 34/2020	Additional anaesthetists and resuscitators	2020 anaesthetists and resuscitators	ICU beds post DL 34/2020	anaesthetists /ICU beds post DL 34/2020
13134	5,124	2.53	572	13,706	8,400	1.63

Source: *Instant Report ALTEMS*

The indicators show that there was no balanced increase between intensive care beds and anaesthetists. There is a clear difference between the ratio pre- and post-Decree-Law 34/2020. At a national level in 2019, the rate was 2.53 (1.67). Ideally, considering the increase in ICU beds and anaesthetist medical staff, the ratio should be the same or higher. In spite of this, the number of anaesthetists per ICU beds during the emergency has decreased considerably, thus increasing anaesthetists' workload.

Several health authorities have already taken concrete steps to provide psychological support for healthcare workers. They are organising phone (or virtual) consultancies to support professionals (AUSL Romagna, Azienda Sanitaria di Trento, Azienda Ospedaliera Universitaria Pisana, ASLTO3, ASL di Viterbo, ASL Umbria 2). Others are promoting communication between healthcare workers and citizens over the Internet (AUSL Piacenza, ASL Bergamo and others).

Since the beginning of the COVID-19 pandemic, the Italian ISS (Istituto Superiore di Sanità) calculated that around 60,242 healthcare workers have contracted COVID-19 at work. They represent 5% of the total cases. The number of healthcare workers who have died from COVID-19 was around 134.

4.5 Recommendations

- **Recommendation 3A:** to invest in healthcare workers, with an adequate planning of the number of physicians, nurses and all other categories. This recommendation includes an increase in the number of contracts for residents' physicians.
- **Recommendation 3B:** to simplify administrative procedures for the appointment of personnel during emergencies.
- **Recommendation 3C:** to care for the physical and mental well-being of health and social care staff, improving work conditions and reducing stress.

- Recommendation 3D: to continue the process of task shifting between professional groups and foster team-based working models (see the case studies for more recommendations)
- Recommendation 3E: to develop a competence-based human resource management approach based on the definition of national standards for healthcare professionals, top and middle managers of healthcare organisation and regional health authorities.

5. Domain 4: Medicines and technology

5.1 Adoption of health technologies

In the Italian NHS, a unique model for regulation and health technology assessment is still lacking, and competencies are distributed among 4 different central bodies and 21 regions and differ depending on the kind of technology to be introduced (drugs, vaccines, medical devices, medical-surgical procedures).

Regarding drugs, AIFA is the national authority responsible for both drug regulation and reimbursement. In terms of the processes of assessment and adoption of new medicines, once authorised by EMA, Italy automatically accepts drug marketing authorisations by defining the supply regimen and initiating the pricing and reimbursement process.

If a manufacturer seeks reimbursement, the price for the product will be set through a negotiation between the manufacturer and the Pricing and Reimbursement Committee CPR ('Comitato Prezzi e Rimborso'). The drug is technically assessed by the Technical-Scientific Advisory Commission (CTS) on the basis of three major criteria: unmet need, clinical value and quality of evidence. Among the criteria used during the negotiations are: a) cost-effectiveness for pharmaceuticals where no effective therapy exists; b) Risk-benefit ratio compared to alternative pharmaceuticals for that indication; c) Therapy costs per day in comparison to products of the same efficacy; d) Evaluation of the economic impact on the NHS, F) Estimated market share of the new pharmaceutical and G) Prices and consumption data in European countries.

Regarding price setting, no formal cost-effectiveness/utility threshold is set. The budget impact of the introduction of the new drug is the most relevant evidence to be produced by a company to begin the negotiation within CPR. Hence, the recently issued Guidelines for Drug Negotiations (AIFA, 2021) have been criticised because they do not permit the clear application of a value-based pricing approach.

In general, no formal economic constraints have affected the accessibility of medicines in Italy. However, examples from the past have shown a lack of accessibility to authorised treatments in Italy due to restrictive prescription criteria and prices that are excessively expensive for patients (e.g., the hepatitis C medicine Sofosbuvir). In 2017, the Italian Minister of Health stated that generic drugs authorised for sale in other countries for personal use could be imported when no therapeutic alternative existed in Italy or when it was not accessible via parallel importing. Regional variations in the timing of new drugs available for patients are, however, still observed.

Regarding another key aspect of technology—disinvestment—no official program exists. Responsibility for revising the national drug formulary is held by AIFA. The latest revision was passed in 2005.

In general terms, AIFA's regulatory/pricing system is relatively inclined towards introducing new technologies. Examining cancer drugs, by searching the European Medicines Agency webpage (www.EMA.europa.eu) under the domain 'Medicines', 95 cancer drugs were identified that were approved in the period from January 1 2016 until November 13 2020 (drugs classified under L01 Antineoplastic agents in the Anatomical Therapeutic Chemical Classification System, ATC). In the same 5-year period, 84 of these cancer drugs were assessed and approved by AIFA and published in the Gazzetta Ufficiale, Italy's official journal (www.gazzettaufficiale.it). On the webpage of AIFA, it is possible to retrieve lists of all drugs approved for purchase in Italy. However, they do not list the year of approval, which makes it necessary to retrieve this information from the Gazzetta Ufficiale.

A study from 2017 showed that the timeline of authorisation and reimbursement for oncology drugs in Italy is roughly 248 days after authorisation from the EMA (SD 131; range 85–688). However, significant regional differences have been shown in both the timing and the number of drugs available for patients.

The assessment of orphan drugs is prioritised, and a 100-day limit is set.

AIFA is also promoting independent research on drugs. According to article 48 of Law 326/2003, all drug companies operating in Italy have to pay 5% of their promotional expenses to an independent research fund (Fondo AIFA 5%), of which half of the fund is devoted to providing access to medicines for rare diseases before market authorisation.

At the moment, the lack of an explicit model to involve patient and citizen associations during the assessment and appraisal process, as well as the lack of a clear role of economic evaluations to decide regarding pricing and reimbursement, suggest that a full HTA approach is still lacking in supporting the introduction of new drugs in the Italian NHS.

Regarding medical devices and medical equipment, the Department of Drugs and Medical Devices of the Italian Ministry of Health is responsible for the regulation. A National Program of HTA for Medical Devices was launched in collaboration with Italian regions in 2017 but is not still fully established. Currently, the path of introduction of new medical devices in the Italian market is following the EU regulation pathway; regarding pricing and reimbursement, any region is responsible for the assessment of pricing and reimbursement. AGENAS, since 2007, has promoted the coordination of an Italian network of HTA bodies active in some Italian regions (RIHTA, Regional Network for HTA). In the last 13 years, 45 full HTAs have been produced.

Finally, financial difficulties have affected the national investment in healthcare construction over the past decade, causing a decrease between 2008 to 2017 from €7.8 billion to less than €6 billion. However, recently in October 2020, Ministerial Decree 70 earmarked a foundation of €32 billion to modernise hospital infrastructure and technologies. In regard to the COVID-19 pandemic, a fund with a budget of €400 million has been established by the Ministry of Health for the purchase of COVID-19 vaccines and drugs for the treatment of patients with COVID-19.

With the COVID-19 outbreak, AIFA has immediately activated its Technical-Scientific Advisory Commission (CTS), which has designed a simplified procedure to promote regulation and supervise access to therapies potentially useful to counter the pandemic. In the period 11/03/2020–15/12/2020, 50 clinical studies were approved by the Agency, of which 34 were non-profit and 16 profit (68% vs 32%). At the same time, AIFA provided promptly updated information on drugs (11) used outside clinical trials, such as those marketed for other f, on the basis of often rather limited scientific evidence: low-molecular-weight heparins, azithromycin, darunavir/cobicistat, hydroxychloroquine, lopinavir/ritonavir. In addition, five compassionate use programs have also been authorised: remdesivir, ruxolitinib, canakinumab, solnatide and ribavirin for inhalation solutions.

5.2 Digital health

The adaptation of and accessibility to digital health services have significant regional variability in Italy, with northern regions generally being more digitally developed and integrated than the southern regions.

Although the 'National Guidelines on Telemedicine'² have been defined since 2014, the use of models and solutions in this area has, in recent years, been limited to specific projects and research activities, without becoming truly an integral part of the health system.

Generally speaking, two factors have been highlighted in relation to the digital divide in Italy: a lack of familiarity with information and communications technologies (ICT) and limited internet connection availability in given areas. The European Digital Economy and Society Index from 2020 shows that three out of ten people in Italy are not regular internet users, and more than half of the population still lack basic digital skills. Furthermore, it

² Available at: http://www.regioni.it/cms/file/Image/upload/2014/5_SR_20022014.pdf

is estimated that approximately 12% of the population does not have access to broadband or a fast internet connection due to a lack of adequate infrastructure. The Italian Government approved a Strategy for Ultra-Fast Broadband in 2015 to reduce the existing infrastructure and market gap, through the creation of more favourable conditions for the integrated development of fixed and mobile telecommunications infrastructure.

In April 2020, the 'Innova Italia' Call was launched by the Agency for Digital Italy (AgID) to pool technologies and innovation in the fight against COVID-19 virus and has resulted in gathering more than 2,000 digital initiatives. However, an integration of available innovative digital technologies and the diffusion of large-scale telemedicine solutions with data from the National Electronic Healthcare Records is being hindered due to the heterogeneity of available solutions, often unable to exchange common patients' data.

The Italian Ministry of Health specifies that telemedicine is not a separate medical speciality but, rather, a method for providing medical services through innovative technologies in situations where the patient and the healthcare professional are not in the same location. In fact, the use of ICT technologies can be reimbursed if: a) the service is already offered by the national or regional provider but will be provided by the use of ICT technology keeping the substantial content of the service unaltered; b) the service is already offered by the national or regional provider but with the use of ICT technologies will be performed in ways (particularly in relation to the place, time and duration) that can contribute to a relative improvement of the therapeutic content and strengthen the continuous monitoring.

To benefit from public reimbursement, an appropriate agreement must exist between the NHS and the ICT service provider but this has so far been relatively difficult because the reimbursement schemes and financing structures have not kept pace with changes in regulation and use of technologies. Italian regions carry out telemedicine services throughout the national territory in line with a Decree of the MoH no. 70 of April 2 2015. However, due to non-transparent and complex reimbursement models, the regions during 2020 jointly endorsed that telemedicine must become an LEA in order to be provided to all citizens, free of charge as a form of health care service that requires the same level of reporting and pricing as ambulatory visits.

Electronic Health Records (EHRs) are another pillar for digital health. According to the webpage of the Agency for Digital Italy (AgDI) (<https://www.fascicolosanitario.gov.it>), all 21 Italian regions have fully adopted or taken initiatives for the implementation of EHRs. The EHR is made, with the consent of the patient, by the regions and autonomous provinces for the purposes of prevention, diagnosis, treatment and rehabilitation. By law, a minimum dataset is required to encompass: a) Identifiable and administrative data of the patient; b) Medical reports; c) Emergency reports; d) Discharge letters; e) Patient summary; f) Pharmaceutical dossier; and g) Choice regarding the donation of organs and tissues. At present, however, there is regional variability in the mode of computerisation of the EHR and of the documents made available to the citizens. AgDI states that for the time being, 288,279,036 reports have been digitised and 28,206,659 healthcare records have been activated electronically. However, in seven regions, less than 2% of the records are electronically available.

The COVID-19 outbreak has created a significant boost for the implementation of telemedicine in Italy. On March 20 2020, the Head of the Department of National Civil Protection signed an executive order that introduced nation-wide electronic prescriptions, opening a Pandora's box. In less than 10 weeks, as reported by ALTEMS (altems.unicatt.it/COVID-19), more than 200 telemedicine solutions were promoted by regional authorities, LHAs, patient associations and industry. In response, the Conferenza Stato Regioni on December 17 2020 issued 'National Guidelines for Telemedicine-Based Healthcare Services'.³

³ Available at: <http://www.quotidianosanita.it/allegati/allegato2602365.pdf>

5.3 Research and development

According to Istat, total R&D expenditure in Italy was around 1.4% of GDP in 2018. The third largest sector for investment in R&D was pharmaceuticals, which accounted for 7% of total investments in Italy. R&D expenditure of the pharmaceutical industry was equal to 17% of the added value and the employees to 10% of the total employment: parameters for which the pharmaceutical industry is well above the national average (R&D expenditure/GDP 1.4%; R & D employees/total employees 1.1%).

5.4 Security of supply during COVID-19

The Italian healthcare system is highly regionalised, and the procurement of health supplies normally occur at a regional level. In the chain of medical needs during catastrophes, the Italian Civil Protection (ICP) assists when local organisations are unable to deal with the event with their own resources. On January 31 2020, the Council of Ministers declared a six-month state of emergency as a consequence of the health risks related to the Coronavirus outbreak. In this period, the Head of the Civil Protection Department was entrusted with the coordination of interventions necessary to deal with the emergency on the national territory.

During the first COVID-19 wave, valuable lessons emerged regarding insufficiencies in the supply chain. Italy was faced with an extremely urgent and overwhelming shortage of vital medical supplies such as masks, gloves, goggles and face-shields, as well as medical ventilators, testing kits and medicinal products. Early on, it was evident that local entities could not ensure continuity of supply, causing desperate needs, particularly for personal protective equipment. ICP assisted by sourcing overseas. However, insufficient expertise, unavailability and knowledge of global supply chains ultimately hindered them in securing everything that was needed. This issue resulted in parallel sourcing from hospital buyers, who contacted local established or new suppliers with varying results. Nonetheless, over time, the ICP managed to distribute 2,100,499,781 pieces of protection material related to the COVID-19 crisis, including 1,930,949,855 masks, 86,590,564 gloves and 4,167,804 visors until the time of writing this report (November 23 2020).

Italy has, together with 24 other EU member states, participated in a joint procurement of COVID-19 vaccines, masks of types 2 and 3, gloves, goggles, face-shields, surgical masks and overalls. Regarding the flu vaccination, the 20 regional authorities have so far ordered 17 million doses between them, accounting for almost 50% more than in 2019, in order to relieve flu-related stresses being placed upon hospitals due to the pandemic. However, because a suitable national flu vaccination plan was lacking, the regions were late in ordering the flu vaccinations in 2020, and it can, therefore, become a challenge to deliver the vaccines on time, particularly if all regions request the vaccine at the same time.

5.5 Recommendations

- Recommendation 4A: to promote the establishment of a National Agency for Health Technology Assessment to overcome existing differences in the pattern of the introduction of drugs, vaccines, medical devices and new medical-surgical procedures, as well as telemedicine and solutions, ensuring equitable access to technology in all regions promoting patients' and citizens' involvement in key phases of the process.
- Recommendation 4B: to develop a national telemedicine infrastructure and establish a nationally based reimbursement scheme for telemedicine.
- Recommendation 4C: to participate in collective purchasing agreements with other EU countries.
- Recommendation 4D: to establish a resilience-oriented procurement strategy, also by supporting the national production of critical devices.

6. Domain 5: Service delivery

6.1 Efficiency measures

Every year, the Italian Ministry of Health publishes a report on hospital activities, analysing the Hospital Discharge Form of all Healthcare Institutes, both public and private. The latest available data were published in 2019 and refer to the activities of 2018^{1,2}.

Despite this, in Italy, there is significant regional variability in healthcare planning, monitoring and evaluation that makes it difficult to provide comprehensive, complete and homogeneous national data. The regions and individual hospitals, in fact, have a high degree of autonomy that can lead to a lack of homogeneity of some indicators developed and analysed in terms of efficiency and appropriateness. Hence, the readmission rates in hospitals are not available at a national level (overall and for myocardial infarction), and only the readmission rates for schizophrenia (13.65%) are reported². Concerning myocardial infarction, the mortality at 30 days is the only available indicator (8.03%)³.

Considering the average length of stay in hospitals (acute-care activities under the ordinary regime) across the country, in 2018², a value of 7.0 days was recorded, slightly increased compared to the 2008⁴ value of 6.8 days (Table 9). It is important to underline the regional differences related to this indicator: Campania reported the lowest value (6.4 days), whereas Veneto showed the highest value (7.7 days).

Moreover, regarding acute myocardial infarction (AMI), the national average is equal to 7.6 days (110,310 hospitalisations). This value represents the average between cases with serious complications (average stay of 9 days), without major complications (5.5 days) and AMI with death of the patient (6 days). The average value of 7.6 days remains unchanged compared to 2008 (120,281 cases)⁴.

Table 9: Differences between 2008 and 2018 regarding average length of stay in hospital, average length of stay in hospital for AMI, 30-day mortality for AMI and readmission rate for schizophrenia

	2008	2018
Average length of stay in hospital	6.8 days	7.0 days
Average length of stay in hospital for AMI	7.6 days	7.6 days
30-day mortality for AMI	9.98%*	8.03%
Readmission rate for schizophrenia	13.08%	13.65%

AMI=acute myocardial infarction; *Last data available refer to 2012

6.2 Quality

Referring to standards related to the evaluation of clinical quality and patient safety, the Italian Ministry of Health in collaboration with AGENAS has established the Programma Nazionale Esiti – National Outcomes Programme (PNE)⁵. In particular, the PNE provides comparative assessments of effectiveness, equity, safety and appropriateness of care produced in hospital. The data for the PNE are processed on the basis of data from the hospital discharge forms of over 1,300 accredited public and private Italian hospitals. As is the case every year, in 2019, a set of 175 indicators (70 of outcome/process, 75 of volumes of activity and 30 of hospitalisation) was evaluated. These indicators represent evaluation tools to support clinical and organisational auditing programs aimed at improving effectiveness and equity in the NHS. The PNE, therefore, represents a fundamental tool that provides useful guidelines for developing corrective strategies if results are found in some regions that are not in line with national standards or international benchmarks. On the other hand, no economic incentives are provided at the national level if quality standards are met.

6.3 Role of primary care and coordination of care and new care models

Regarding the role of primary care, in Italy, every citizen has the right to care from a general practitioner (GP) free of charge. In Italy, the GP is not an employee of the NHS but a freelance contractor who has an agreement with the NHS. The contract provides for remuneration based on the services provided and the number of patients⁶. The general practitioner should be the patient's first contact point with the health system (diagnosis and treatment of acute diseases pertaining to general medicine, promotion of prevention through the recognition and elimination of risk factors, management and care of the chronic patient, first-level diagnostics for the treatment of complex chronic patients, pain therapy and palliative care, issuance of medical-legal certifications). In this context, the gatekeeper function of GPs is fundamental. In case of need for specialist care, patients should contact the GPs so that the service, once prescribed, is covered by the NHS.

Although in Italy the level of interprofessional collaboration and care coordination is insufficiently developed, there are some positive examples of integrated home care, assisted discharge and community hospitals in some regions (particularly Veneto and Emilia-Romagna). Moreover, recent reforms^{7,8} promote the refocusing of care from hospital to community care. An example of integrated care is the MoH IGEA project for the management of diabetes⁹.

6.4 Prevention and chronic diseases

In terms of chronic diseases, every year, approximately €67 billion are spent for the management of these diseases¹⁰, whereas only 4% of health expenditure is allocated to prevention¹¹. In Italy, roughly 41% of the population has at least one chronic disease, and half of them have multi-morbidities with important regional differences¹⁰.

In 2016, the Ministry of Health issued the National Plan of Chronicity (PNC)¹², which contains general guidelines for the management of chronic diseases and in-depth studies on diseases with specific characteristics and care needs. The proposed lines of action highlighted the expected results, through which to improve the management of chronicity in compliance with scientific evidence, the appropriateness of the performance and sharing of diagnostic therapeutic paths of care.

6.5 Services during COVID-19 emergency

Finally, the COVID-19 pandemic is having important effects on deferred diagnostic services, surgery and other interventions. In particular, since the beginning, this pandemic was associated with reduced access to inpatient (-48% for AMI) and outpatient services, with a lower volume of elective surgical procedures (in oncology, from 3.8 to 2.6 median number of procedures/week). For instance, 30.4% of oncology centres reported a contraction of their activities of 10–30%¹³. In this context, more than 1 million fewer screenings were performed between January and May 2020 due to the pandemic. Considering pregnancy and child health, an approximately 3-fold increase in stillbirths was reported¹⁴.

6.6 Recommendations

- Recommendation 5A: to continue to promote innovative solutions for the management of chronic conditions and the continuity of care (see the following case studies for further details).
- Recommendation 5B: to re-think the role of GPs and their systems, with the aim of a full integration in the healthcare system, also by providing specific role training.
- Recommendation 5C: to reinforce diagnostic services and elective surgery by increasing investment in technologies and personnel, also providing innovative organisational solutions (see case study)
- Recommendation 5D: to reinforce structure and organisation of healthcare services dedicated to prevention and control of epidemics and pandemics.

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7. Case Study 1 – Tumour boards: collaboration as a tool to promote better care and healthcare system sustainability

The development of a new model of coordination, regarding healthcare organisation and professionals, has been for years in the agenda of policymakers, managers and professionals aiming to improve the diagnosis, treatment and care of cancer patients. During recent years, even more attention has been placed on the development of new organisational models, such as for clinical cancer networks. Many studies highlight differences across the country in the adoption of new organisational models, but with ministerial decree 70/2015, oncological clinical networks have been formalised and spread among all the regions even if in different ways.

Clinical networks aim to ensure and develop a new organisational model based on correctly taking charge of the patient, through integrated structures, coordinated professionals and services with regard to different levels of assistance. This network is based on nodes and connections, defined a priori together with rules of functioning, systems of monitoring and requirements of quality and security of clinical pathways.

Within the oncological clinical networks, a specific clinical pathway (CPW) should be designed for each pathology. CPWs, also referred to as care paths or integrated pathways, are used to systematically plan a patient-focused care program.

The aim of the clinical pathways is to enhance the quality of care promoting patient safety and satisfaction, and optimising the use of resources (European Pathway Association). In Italy, the introduction of the CPWs has been associated with improved attention to quality of care as CPWs aimed to solve the conditions related to inequity of care and inappropriateness expenditure¹. Most studies reported a decreased length of stay and reduction in hospital costs and in in-hospital complications associated with the introduction of CPWs leading to an efficient use of resources and efficiency of care.

When discussing cancer care, it is known that the complexity of the path requires collaboration and cooperation among professionals with complementary skills and competencies, who work together to share the latest evidence, ensuring the best treatment through a personalised pathway. Advanced technologies and individualised treatment plans allow a regular interaction between professionals that becomes formalised through the institution of multidisciplinary teams.

Multidisciplinary meetings are a fundamental part of a complex care path through which professionals discuss a series of patients in order to achieve a definite staging and formulate a shared treatment plan. Consequently, they positively impact the healthcare system and its experience for patients and professionals, ensuring the best quality of care for patients and continuous learning and exchange of knowledge between these professionals.

In particular, when MTDs are focused on oncological patient care, they are termed ‘tumour boards’ and, over time, they evolved to acquire a more collaborative structure, including all aspects of cancer care such as rehabilitation, psychosocial needs and long-term care. More recently, with the use of advanced technologies, the possibility of a virtual team connecting people who are not all available in person has been introduced, particularly in that period where with the spreading of coronavirus, some activities have been stopped. Tumour boards have been demonstrated to have a positive impact on diagnosis, patient management and adherence to guidelines due to the fact that the discussion during meetings leads to modifications in both diagnostic paths and treatment plans to find the best alternatives for patients while simultaneously adhering to clinical guidelines².

7.1.1 Goal & relevant domains

Cancer care is an example of how combining available resources could lead to optimal results. To do that, there are some management assumptions:

- A multidisciplinary approach aimed to integrate different professionals in a team
- Accessibility of quality care to all patients that live in a specific country
- Equity in cancer care access to avoid any type of inequality
- Timeliness through the clinical pathway

Essential elements that are the basis for the constitution of this model are: high-level hospital services, professionals who are highly educated, clinical and organisational rules provided following an evidence-based approach, innovative technologies and easy access to clinical trials. From that perspective, an optimal model for cancer care is based on three main pillars: the implementation of a tumour board; the design of a clinical pathway and the use of a monitoring system.

Lung cancer is a major public health problem - one of the five most common cancers. With regard to this pathology, significant concerns have been raised about delays in the diagnosis and in relation to the high frequency of advanced disease at presentation. In addition, new treatment algorithms dependent on the histological and molecular profile of the tumour are emerging³. Lung cancer tumour boards bring together many health professionals, such as thoracic surgeons, medical and radiation oncologists, radiologists, pathologists and nurses. From a study conducted by Jackman and colleagues⁴, the implementation of a care pathway for patients affected by lung cancer was found to provide substantial savings after its implementation with an impact on survival rate.

7.1.2 The case

Fondazione Policlinico Agostino Gemelli IRCCS has 1,500 beds with 16 of them dedicated to thoracic surgery. It is a *comprehensive cancer centre* in Lazio and attracts patients from all regions coordinating all of the structures that provide cancer services, ensuring a continuity of care throughout the entire clinical pathway. The aim of this organisational model, identified within a document produced during the Standing Conference State-Regions on October 30 2014, is to offer better personalised care serving and assisting patients in all the stages of the disease. In fact, the hospital has implemented specific clinical pathways for each pathology following a multidisciplinary approach centred on the patient. The coordination among all professionals and activities allows them to ensure a global response through the use of *advanced technologies* in the diagnostic phase and in the therapeutic phase by also following the concept of humanisation of care. The use of technologies, such as *health meeting* software, provides an opportunity to make team decisions available to all professionals in real time at the end of the meeting. Furthermore, such software allows the sharing of clinical information among clinicians, together with information regarding the reservation of clinical examinations.

Within this new organisational model, clinical pathways have been developed, aiming to provide a multidisciplinary evaluation of the patient in different stages of care (diagnosis, treatment and follow-up). For lung cancer, this evaluation is addressed to 100% of patients that undergo a personalised pharmacological treatment.

The tumour board for lung cancer was implemented in 2018 and comprises a core team that includes:

- Thoracic surgeon
- Oncologist
- Pneumologist

- Radiologist
- Radiotherapist
- Nuclear doctor
- Pathologist

In addition, based on the characteristics and complexity of the patient, different professionals could be involved. The patient is typically presented by the oncologist, thoracic surgeon or radiotherapist, and meetings are scheduled weekly to discuss from four to six patients at a time.

Data from the monitoring system of the hospital show that starting from 2018, when tumour boards were implemented, the length of time between the surgical taking charge and to the beginning of the adjuvant therapy after the intervention began to decrease. In fact, the multidisciplinary evaluation by the tumour board preceded both decisions.

Comparing the first three trimesters of the last three years, there was a drastic reduction in the number of days required for a surgical intervention between 2018 and 2020 (Table 1). Furthermore, this reduction is associated with an improvement in the time taken for the oncologist taking charge after a surgical procedure for lung cancer, as shown in the table below (Table 2) This reduction of time for surgical intervention and for adjunct therapy positively impacts quality of care, patient satisfaction and in-hospital costs. Further investigations could also be related to a decrease in mortality rate.

Table 1: Length of time related to surgical procedure after first access at Policlinico Gemelli

Days required for surgical intervention					
Year	Average	N. patients	Std. deviation	Median	Range
2018	35,30	138	20,219	36,00	93
2019	37,29	147	23,784	36,00	98
2020	25,39	143	20,595	20,00	98
Total	32,67	428	22,202	30,00	98

Table 2: Waiting time for adjunct therapy for patients undergoing a surgical intervention

Year	Average	N. patients	Std. deviation	Median	Range
2018	53.57	46	31.488	48.50	117
2019	49.29	28	26.540	44.50	108
2020	50.71	45	28.111	47.00	111
Total	51.48	119	28.931	47.00	117

The tumour board has been developed to ensure the correct allocation of professionals given the appropriate provision of human and technological resources. The efficacy of the team is determined by a clear definition of the objectives of care shared among professionals, an optimal leadership and adequate modes of coordination together with advanced technologies, a patient-centred approach and the support coming from national and local authorities.

7.1.3 Final Recommendations

Today, new organisational models such as the tumour board have been implemented throughout the country, and further recommendations could be given because continuous improvements are necessary to promote a better quality of care.

Despite this success, tumour boards are recommended but not mandatory in Italy. Therefore, ensuring that tumour boards are similar to an LEA (essential level of assistance) could provide improved quality of care among the country, making it mandatory and defining the optimal conditions under which it should work.

Technological platforms could be implemented within the clinical network to ensure continuous evaluation of the tumour board and standardised ways of working. With regard to this development, the management of the Policlinico Gemelli hospital worked on an organisational structure that could enhance the coordination and communication with other hospitals and local structures in Lazio. In fact, with the use of 'health meeting', a piece of software that actually connects professionals within the Policlinico Gemelli and ensures access to patients' clinical histories at any time, it could be possible to discuss cases to provide continuity of care before and after access in the hospital, sharing all information with the professionals involved.

To enhance quality of care and the spreading of precision oncology, the implementation of a molecular tumour board and the use of next-generation sequencing could become a significant value-added factor in the provision of care. Indeed, the aim of these boards, which will be implemented in a few months at Policlinico Gemelli Hospital, is to identify and discuss all potential therapeutic strategies based on genetic analysis for patients who have not responded to gold-standard therapies.

In addition, to continuously monitor the impact of the choices made by the tumour board, with regard to the efficacy and adherence to clinical guidelines, it could be useful to monitor the activity through specific key performance indicators and periodically conduct actions of clinical and organisational auditing.

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8. Case Study 2 – Management of patients with multiple chronic conditions through community health centres: an organisational solution to ensure sustainability and resilience

8.1.1 Context

In Italy, as in most countries with advanced economies, there has been an inexorable increase in the prevalence of chronically ill patients. This phenomenon arises from the demographic trend of population ageing (37% of the population is over 55 years and 23% is over 65 years), correlated with increased survival (life expectancy at birth equal to 85.3 years for women and 81 years for men¹), the improvement of economic and social conditions and the rapid technological and scientific progress, particularly in the medical field. In Italy, approximately 40.7% (24.55 million) of the population is affected by one chronic disease⁴ at least, and those who suffer from multiple chronic conditions are increasing; in particular, 21% (12.67 million) of the national population is affected by two or more chronic conditions.

The transition from health care based on acute management to one based on chronicity has necessitated the development of different tools to respond, in an integrated and territorial way, to the needs of the population. The integration at a structural⁵ and/or functional⁶ level guarantees at the same time the multi-professionalism and multidisciplinary nature of care and the coordination of patients in the different hospital-territory care settings to ensure continuity of care.

In this perspective, the regions have defined health and social-health primary care interventions, which are different from each other but have three points in common: the redesign of the GP's role in the management of multidisciplinary and multi-professional teams; the coordination of health, social and health services and social assistance for the overall care of the patient; and the development of information and digital systems and telemedicine.

The main models of territorial assistance structure that have emerged are listed below.

In **Lombardy**, there are the territorial hospitals (Presidi Ospedalieri Territoriali - POT) and the territorial social health centres (Presidi socio-sanitari territoriali - PreSST)⁷

The first one comprises multi-service physical structures that provide medium- and low-intensity residential health and social health services for acute and chronic patients and outpatients and home care services. This structure offers residential health and social health services, including at least one of the following activities:

- hospitalisation for sub-acute patients;
- hospitalisation of intermediate-care patients;
- medium- and low-intensity hospitalisation;

⁴ The four main groups of noncommunicable chronic diseases (NCDs) with relative mortality estimates in Italy in 2017 are cardiovascular diseases (35%), tumours (29%), neurological disorders (14%), chronic respiratory diseases (5%) and diabetes (3%). *Global Burden of Disease Study 2017 – Institute for Health Metrics and Evaluation*

⁵ Focusing on the physical place of hospital-territory integration in which to provide health and social assistance.

⁶ Focusing on the processes of passage and connection of patients in the different hospital-territory care settings through the coordination of all professionals involved in the management of the case.

⁷ Regional Law of Lombardia n.23 August 11 2015

- community hospitalisations⁸.

The second one involves organisational methods that have the purpose of integrating health, social, health and social activities and services, contributing to taking charge of the person.

- They provide medium- and low-intensity outpatient and home health and social health services;
- They can activate intermediate, subacute, post-acute and rehabilitative hospitalisations, with low performance intensity ensuring continuity of care;
- They promote initiatives in health care, prevention and health education.

The social health plan of the **Veneto** 2012–2014⁹ identifies two specific types of structure of intermediate care: the community hospital (OdC) and the territorial rehabilitation unit (URT).

The community hospital is a short-term hospitalisation facility that performs an intermediate function between home and hospital settings. It is dedicated to the implementation of home care in a protected setting, to the consolidation and/or recovery of physical conditions in a non-hospital setting of patients from home, residential facilities, hospital wards or directly from the emergency room. Community hospitals have a limited number of beds (minimum 15) managed by nurses that guarantee 24-hour assistance. Medical assistance is ensured by general practitioners or paediatricians of free choice and by continuity care doctors; specialist advice is ensured as well. The target is those patients who require low-clinical-intensity health interventions potentially deliverable at home but requiring hospitalisation in these structures in the absence of home suitability.

The territorial rehabilitation unit is an intermediate setting characterised by a medium-term hospitalisation (approximately 60 days) that guarantees a rehabilitation path for patients with modifiable disabilities of various kinds who have passed the acute phase of the disease. 24-hour assistance is ensured by nurses and socio-health workers, as well as by adequate medical assistance.

In **Tuscany** and **Emilia-Romagna** regions, there are the community health centres (Case della Salute - CdS), born as experiments from Law n. 296/2006¹⁰, and that have been defined by the Decree of the Ministry of Health of July 10 2007 '*multipurpose structures capable of delivering all the social and health services in the same physical space, favouring, through the spatial contiguity of services and operators, the unity and integration of the essential levels of social and health services, which must represent the reference structure for the provision of all primary care*'.

The main features of this structure are:

- The presence of general practitioners and continuity of care doctors 7 days a week and 24 hours a day with strong integration with the outpatient specialist;
- The presence of health professions, particularly for rehabilitation and prevention;
- The presence of ambulance services for emergency assistance;

⁸ Short-term hospitalizations for patients who need continuous nursing care and/or low-intensity clinical health interventions that cannot be managed at home also due to the patient's life context

⁹ All B Regional Decree n. 15/DDL of July 26 2011 - Veneto

¹⁰ 'Finance Law of 2007' - Art. 1, paragraph 806, provides for the allocation of €10 million for the experimentation of community health centres.

- The presence of a nursing and outpatient clinic for small emergencies that do not require access to the emergency room;
- To provide a single-access desk for the integration between health and social assistance activities, as a tool for taking charge of the patient by defining/implementing the individual care path;
- The prevision, in contiguity with the single-access desk, of a single booking centre;
- To organise and manage integrated home care as a service for home hospitalisation and empowerment of the chronic patient and their family;
- To represent the place of participation of citizens and associations in the planning of services and in the evaluation of the results of health and perceived well-being;
- The use of telemedicine and teleconsultation in connection with the reference hospital.

8.1.2 Focus on Impact of Community Health Centres in Emilia Romagna

In Emilia Romagna, the process of building the community health centres began in 2010¹¹ (Decree n. 291/2010) and, to date, there are 120 structures in this region. A study by the Health and Social Agency of the Emilia Romagna analysed the impact of 88 operating community health centres in municipalities (non-provincial capitals) and of 16 structures in five capital cities in the period 2009–2019¹².

With regard to the 88 operating structures in the municipalities' non-provincial capitals, the results show:

- a reduction of 16.1% in access to the emergency room for white codes confirmed as non-urgent upon discharge, a percentage that increases to 25.7% when the general practitioner operates inside them;
- a 2.4% reduction in hospital admissions for ambulatory care sensitive conditions, such as diabetes, heart failure, chronic obstructive pulmonary disease, bacterial pneumonia; in this case, the presence of general practitioners in the CHCs produces a better effect (-4.5%);
- a 9.5% increase in home-care services, both nursing and medical.

In absolute terms, the community health centres have made it possible to prevent approximately 6,300 inappropriate accesses to the emergency room and 250 hospital admissions for ambulatory-care-sensitive conditions each year; at the same time, 3,000 more home-care services were provided. Analysing the impact of the 16 structures operating in the five capital cities¹³, results emerge relating to only one of the three indicators being analysed. In particular, the only reduction found refers to inappropriate access to the emergency room (-10.3%), whereas for the other two indicators, there are no significant changes. This difference between the impact of the CHCs in the municipalities' non-provincial capitals and in the provincial capitals is probably attributable both to the ease of access to hospitals in the city and to the presence of structures that arose before the establishment of the community health centres, and therefore, they already absorbed the demand for less complex services that are generally found in emergency rooms.

¹¹ With Regional Decree n. 2128/2016, the new guidelines on the CHCs have been approved which have identified the organisational and assistance tools to improve the integration of care and taking charge of patients.

¹² Valutazione di impatto delle Case della Salute su indicatori di cura 2009-2019 - Dossier 269-2020

¹³ Parma, Reggio Emilia, Bologna, Ferrara e Ravenna

Finally, with regard to the quality perceived by users, the 'CaSa Quality' survey on 22 CHCs highlights a high degree of satisfaction with the services received with an excellent reliability/trust rating (96.2%) and a high overall perceived quality (96%).

8.1.3 Conclusion

The survey about the impact of community health centres in Emilia Romagna shows how much the regional health system has been able to change its ways of assistance in order to adapt to the needs of a population that increasingly requires medicine of the territory centred on the complexity of the chronicity. Thanks to the work of multidisciplinary and multi-specialist teams, this regional model, similar to the other intermediate structures previously discussed, ensures coordination, continuity of care and social-assistance integration. The intermediate care settings, thanks to proximity and appropriateness, relieve hospital care from all of those inappropriate treatments generating a reduction in costs for the health service by making an increasingly sustainable system that has proven to be resilient.

The main futures developments are:

- the identification of 'a common strategic design intended to promote interventions based on a unitary approach, centred on the person and oriented to a better organisation of services'¹⁴;
- the change of the Italian health culture, which still considers, even if less than in the past, hospital care to be the fulcrum of the NHS.

¹⁴ *The National Chronicity Plan 2016*