

# 'Resilience and development of the National Healthcare System'

Case study of Italian ESF project under the study 'Progress Assessment of the ESF Support to Public Administration' (PAPA)



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### **PROJECT BACKGROUND**

RESILIENCE AND DEVELOPMENT OF THE NATIONAL HEALTHCARE SYSTEM	
Operational Programme	Operational Programme Governance and Institutional Capacity
Beneficiary organisation	Ministry of Health
Target groups	Regions and healthcare organisations / hospitals
Project duration	02/11/2016 – 30/04/2020
Budget	EUR 6,375,163.00 (ESF contribution)
Project manager (email address)	Andrea Urbani (pongovsalute@sanita.it)
Partners	Regions and autonomous provinces, National Institute of Health (ISS), Italian Medicines Agency (AIFA), National Institute of Social Security (INPS), National Institute for Insurance against Accidents at Work (INAIL), National Institute of Statistics (ISTAT)
Project/ organisation website	http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3966&area=i nvestimenti&menu=fondi http://ot11ot2.it/comitato-di-pilotaggio/catalogo-esperienze/resilienza-e-sviluppo-ssn

This case study was produced during the 'Progress Assessment of the ESF Support to Public Administration - PAPA' project that was contracted by DG Employment, Social Affairs and Inclusion of the European Commission. The purpose of this project was to present specific cases of ESF-funded public administration reform and capacity building initiatives, as well as to show the role of ESF financial support to public administration for accountability purposes. This report provides a story on the project 'Resilience and development of the National Healthcare System', which discusses its context and purpose; characteristics of the team implementing it; main challenges faced and difficulties encountered during implementation; key developments during the implementation process; results and impacts achieved; as well as lessons learned and the contribution of ESF.

# RESILIENCE AND DEVELOPMENT OF THE NATIONAL HEALTHCARE SYSTEM

## Introduction: context of the project

The Italian national healthcare system (NHS) was established in 1978 and is founded on the principles of universal coverage and social financing through the use of general taxation and non-discriminatory access to the health care services.

A major reform took place in 1992-1993, conferring autonomy to regions and healthcare organisations in order to foster efficiency and managerial innovation. The key principles of the reform were the responsibility of public healthcare organisations to balance the accounts, the consistency between uniform levels of health care and the clinical and epidemiological context of the different regions, and the link between volumes of care and available financial resources (law n. 502 of 30 December 1992, law n. 517 of 7 December 1993).

These reforms have produced mixed results. While interesting bottom-up innovations have appeared, especially in the north of Italy, the control of public expenditure and the growing north - south gap in terms of access and quality continues to raise concerns.

In 1999, the essential and uniform levels of assistance (LEAs) were introduced (Law n. 229 of 19 June 1999). These are minimum standards of provision (healthcare basket benefits) that have clinical appropriateness, and are correlated to the health needs of the population and compatible with the Maastricht criteria and other financial commitments. The LEAs are also the mechanism with which the Ministry of Health funds the regions and the health care providers. The funding mechanism is based on diagnostic-related tariffs that are the same all over the country.

### Three levels of LEA exist:

- Public health and collective prevention;
- Territorial assistance, i.e. health and social care proximity services; and
- Hospital assistance, including emergency care, ordinary care, day surgery and day hospital, long-term care, etc.

The 2000 Constitutional reform established the subsidiarity principle and reallocated institutional responsibilities, so that the State defines the amount of financial resources necessary to fund the LEAs, while any deficit is to be addressed by the regional fiscal system.

Managerial and decentralisation reforms have had negative effects on territorial inequalities, notwithstanding the universal access to medical care, and on public expenditure, which became more difficult to control.

In 2019, the current public healthcare expenditure was approximately EUR 118 billion, an increase of 2.3% compared to 2018<sup>1</sup>. Spending reviews carried out in 2014, 2016 and 2018 had addressed the NHS by introducing procurement aggregation procedures, efficiency plans and rewarding mechanisms.

<sup>&</sup>lt;sup>1</sup> Ministry of Economy and Finance, Economic and Finance document, 2019; Dossier of the Budget Service of the Parliament. Available at: http://www.quotidianosanita.it/allegati/allegato3027257.pdf.

In sum, the main challenges for the NHS include demographic ageing, the increase in health services demand, the difficulty of achieving a uniform delivery of LEAs all over the territory, the lack of integration between health and social services, promoting prevention and exploiting technological innovation.

What emerges from the reforms is a strong trade-off between equity and financial sustainability. Increasingly, the allocation of financial resources to the regions follows more their fiscal capacity rather than the population's needs<sup>2</sup>.

The project sought to intervene in this context by aiming to provide a different evidence base on which to take funding decisions which would safeguard both equity and financial sustainability. It is part of the European and national health policy and strategy that aims at introducing a structural change in the NHS, eliminating inefficient expenditure and reequilibrating health assistance to the citizens (see European Union position paper and Country recommendations issued in 2014)<sup>3</sup>. At the national level, the legislative framework for the project refers to the Health Pact 2014-2016 signed by the State and the regions in July 2014 and the government-regions agreement signed in 2015, which aims at identifying measures to improve the efficiency of the public healthcare expenditure.

The Ministry of Health is also carrying out another ESF project on Chronicity, which absorbs approximately 80% of the NHS' resources<sup>4</sup>. There are not relations between the two projects.

### Design and execution of the ESF-funded project

### Purpose of the ESF-supported project

The project aims at providing an expenditure planning mechanism that goes beyond historical expenditure levels (incremental approach) or basic indicators such as age and gender and is, instead, based on the use of big data to estimate future costs, demand features (social, epidemiological, etc.) and assistance volumes. It will allow the simulation of short, medium and longer-term effects of alternative economic manoeuvres and taking policy decisions on LEA and financial transfers to the regions that promote efficiency, effectiveness and equity. According to Nicola Ferrante, working at PWC, 'Such an objective of predicting mid-longer term scenarios of healthcare needs is very ambitious and this project is the first case among EU countries'.

Moreover, the project will contribute to moving public expenditure planning from a vertical logic – funding based on type of supply such as hospital, outpatient or pharmaceutical assistance – to a horizontal logic, based on pathologies. Therefore, it will be possible to have a complete vision of each pathology in terms of future demand volume, resources needed and related technological innovations and other influencing phenomena.

<sup>&</sup>lt;sup>2</sup> See: http://www.osservatoriosullasalute.it/wp-content/uploads/2018/02/Osservatorio-sulla-salute\_Ledisuguaglianze-di-salute\_15\_02\_2018.pdf

<sup>&</sup>lt;sup>3</sup> See: Country recommendations: https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:52014DC0413&from=EN; Partnering agreement: https://opencoesione.gov.it/media/uploads/documenti/adp/decision\_pa\_italia.pdf; and Position Paper: http://old2018.agenziacoesione.gov.it/opencms/export/sites/dps/it/news/2012/\_allegati/Position\_paper\_dei\_servizi\_d ella\_Commissione\_sulla\_programmazione\_dei\_Fondi\_del\_Quadro\_Strategico\_Comune\_xQSCx\_2014-2020\_ITA.pdf

<sup>&</sup>lt;sup>4</sup> Timeframe: 2017-2023. Budget EUR 21,154,946.00. See:

http://www.funzionepubblica.gov.it/sites/funzionepubblica.gov.it/files/documenti/Capacit%C3%A0%20amministrativa/progetti%20approvati/Cronicit%C3%A0xsito.pdf

More generally, the project aims at accompanying change and innovation at the NHS by monitoring the adequacy of the resource planning functions (people, services and resources) both by the State and the regions, in order to guaranty the equity and universality of the system, in a context of cutbacks and spending reviews. As Rita Romitelli, the project coordinator from the Ministry of Health describes it: 'the purpose is to improve the governance and self-governing mechanisms that determine the healthcare volume of services, which is differentiated among regions and should be adequate to the healthcare demand and the LEA, in turn determined by population age, birth rate, pharmacological innovations, etc.'

The project will contribute to develop two scenarios: a trending one that will predict how healthcare needs and expenditure will evolve over 20-30 years; and a planning one which will be based on the simulation of the effects of different preventing and innovative actions on healthcare needs and expenditure.

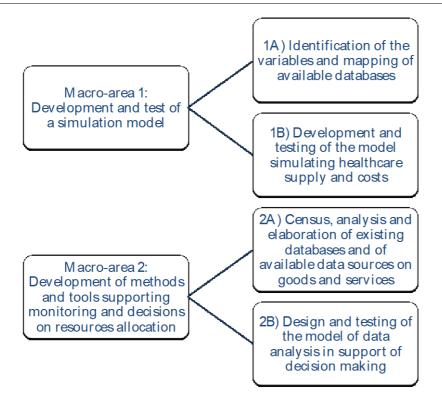
The project will result in methods allowing the analysis of effectiveness and operational efficiency levels of healthcare organisations, supporting them in identifying weaknesses in service delivery, also by benchmarking with other healthcare organisations operating at the regional and national territories. Such methods are being developed at the central level, in collaboration with the regions, and will be used in systematically planning and managing the healthcare expenditure. The expected benefits include better performances, thanks to the improvement of efficiency and the reduction of costs.

### Implementation of the ESF project: main developments

The project activities refer to two macro areas:

- 1) The development of a simulation model based on big data, which will include: a) the identification of social, economic, epidemiological, mortality, mobility and privation variables, among others; and b) the collection of data owned by the regions. In three regions Lombardy, Veneto and Emilia Romagna simulation models are already in use and these were considered in the project as well as their coordinators invited in the project working groups.
- 2) The development of an analysis model, which will include: a) the aggregation, elaboration and correction of the different data sources; b) policy decisions on LEA and resource transfers to regions; and c) the monitoring of healthcare services consumption.

Figure 1. Project main areas of activity



Source: developed by the case study author

The main actors of the project include different directorates of the Ministry of Health<sup>5</sup>, regions and autonomous provinces, the National Institute of Health (ISS), the Italian Medicines Agency (AIFA), the National Institute of Social Security (INPS), the National Institute for Insurance against Accidents at Work (INAIL), and the National Institute of Statistics (ISTAT). Moreover, the project implementation has been outsourced in August 2018 to RTI-Almaviva<sup>6</sup>, a consortium that has the task of collecting regional data. Finally, the National Agency for Inward Investment and Economic Development (Invitalia) will provide support during the stage of communicating results.

The key partners are the regions, first and foremost because some of them have already adopted similar simulation methodologies in planning their healthcare expenditure. They will, moreover, be actively involved in the development, test and experimentation of the national model. Healthcare organisations will also be involved in the development of the simulation and analysis methods, not only through their participation in working groups but also during specific events.

The project developed through the work of several working groups established in January 2019. These are composed of the ministerial different general directorates, representatives of the regions and the autonomous provinces, and of other institutions. Five working groups exist:

<sup>&</sup>lt;sup>5</sup> The general directorate on healthcare planning, the general directorate on the information system and health statistics, the general directorate for health devices.

<sup>&</sup>lt;sup>6</sup> Raggruppamento Temporaneo di Imprese Almaviva S.p.A. - Almawave s.r.I. - INDRA ITALIA S.p.A - PricewaterhouseCoopers Advisory S.p.A.

- 1) 'Core model' will develop a model of stratification of the population, classifying individuals based on the different consumption profiles and estimating the epidemiological, demographic and lifestyle dynamics in order to simulate the health needs of the population over a medium-long timeframe. This activity is almost concluded. It has proceeded through two laboratories that have closely interact with each other. The first comprises seven regions, some of which already use foresight models. The aim has been to identify the stratification model that will achieve the highest homogeneity levels among regions. The second laboratory has involved a panel of clinical experts that will validate the different pathologies to be included.
- 2) 'Economic-financial' will analyse the cost of the different diseases and assess the expected needs in terms of expenditure, regulations and organisational structures. This group will start its activities in October 2019.
- 3) 'Pathologies and innovation' will simulate the effects of planning decisions on pathologies and assess the impact of possible innovations (for example, in terms of drugs or technologies) and of other policy decisions. To identify the main innovations to be included in the simulations, two activities have been implemented: on the one hand, pharmaceutical companies have been invited to an audition; on the other hand, three universities have also been consulted on identifying key innovations in diabetes, cardiovascular and neurology fields.
- 4) 'Feeding the model and data analysis' is an operational group that will support the first three, developing the technological infrastructure and identifying the data necessary to feed the model.
- 5) 'Absorption of productive factors' will work in collaboration with the Ministry of Economy and Finance.

PricewaterhouseCoopers (PWC) has a coordinating role of the groups, in support to the Ministry of Health. As Nicola Ferrante explains: 'Although the project is characterized by a great complexity and a high number of subjects involved at different institutional levels, the latter have shown good levels of engagement and motivation and also display high expectations towards the project goals'.

In addition, 15 experts have been selected in 2019, while project coordination is entrusted to a control room composed of the different directors general of the Ministry of Health and including an Advisory Board with scientific and technical support functions. The Advisory Board comprises members of the control room, the head of the National Institute of Health (ISS), the director general of the Italian Medicines Agency (AIFA), two regional representatives (of Lombardia and Tuscany) and other external experts.

The project is not yet completed. Activities carried out since September 2018 and during the first part of 2019 were implemented according to the project's two main areas.

Regarding the first macro-area of the project – development and test of a simulation model – the first activities were carried out in 2018. These included preparatory actions, such as the identification of the main socio-economical and epidemiological variables, which can impact on

the state of health and can be used for predicting and defining the assistance needs of the population. In particular, for each of the model pillars (demography, epidemiology and lifestyles), the main variables of interest have been identified and the correlations between the variables and pathologies have been highlighted.

Moreover, the census of the existing national databases has been carried out, either owned by the Ministry of Health or by other administrations. The data sources have been classified according to their relevance and usefulness for each model area. Common characteristics have been underlined, as well as the specificities of each database.

Finally, a recognition and study activity of the main methods and instruments currently available at the Ministry of Health useful for analysing each pathology per assistance setting and per type of costs (personnel, technology, goods and services, etc.) was carried out. At the same time, a recognition and analysis of the main models used, at the national and international levels, for stratifying the population per pathology in the framework of governing healthcare demand.

During January-April 2019, in-depth research was carried out of data on the sustainability of the NHS, as influenced by the main demographic, technological, legislative and economic trends.

Additional research of national and international databases, both historical and predictive, was carried out in 2019. In particular, the following databases were identified: Programma 8mila Censius (ISTAT); Sorveglianza PASSI (Epicentro – an epidemiology portal edited by the ISS); SISTAN - Institute for Health Metrics and Evaluation; World Bank data and the European Health for All database (edited by the World Health Organisation).

A methodology was defined correlating the model variables through three different approaches according to the data features (projection of already available data, absence or inadequacy of existing data, presence of consistent historical series).

Another set of activities under the first macro-area includes the development and testing of the model simulating healthcare assistance and related costs. During 2018, it was planned to develop the model by constructing first the core model including basic modules representative of the main variables that influence the assistance needs and the expenditure levels. Satellite modules will be developed subsequently to assess the potential effect of planning decisions on different aspects of the NHS (health outcomes, organisational, costs, etc.). Each module will include sub-models aimed at disaggregating the estimates of overall trends per age, pathology, etc.

In particular, three basic modules have been defined:

- The demographic module will study the evolution of the population, identifying medium-long term projections, distinguishing per gender and age classes.
- The epidemiological module will study the distribution and the frequency of pathologies and health relevant events in the population, estimating medium and long term evolution.
- The lifestyle module will analyse its medium- and long-term effect on the population and its health conditions, distinguishing per gender and age classes.

Starting from the basic modules, the design of the expected outputs of the predictive model has been carried out, with the aim of allowing the simulation of short-medium-long term scenarios in support of strategic and operational planning.

At the same time, the development of the technological infrastructure has started, aimed at defining the data access and exchange modalities.

During 2018, the preparatory activities aimed at creating the working groups, and carried out by the control room, have required more time than was envisaged. During January-April 2019, the model development progressed on three pillars:

- Constructing a stratification model of the national population: an analysis of the models developed by some regions (Lombardia, Emilia Romagna, Puglia and the Autonomous Province of Bolzano) was carried out. A detailed analysis aimed at testing the new health informative system (NSIS) for the stratification was also performed, and the hosting infrastructure has been defined. A dialogue activity with the Italian Data Protection Authority (Garante per la protezione dei dati personali) has started in order to make sure that the integration of the different databases and data sources complies with the current regulation.
- Elaboration of a trend scenario: using a method for correlating the different variables of the model.
- Construction of a programmatic scenario.

This activity will be completed by the end of April 2020. Among the main obstacles encountered during this activity of model development was the need to include another area of population stratification. Such an area was not initially deemed necessary, as data of the National Plan on Chronicity was considered accessible. The sub-group working on this stratification, however, concluded its activities on 12 December 2018, without producing a useful result for the aims of the project. The solution has been merging the sub-group on stratification of the national chronicity plan inside the working group 1, dedicated to the construction of the core model.

Another obstacle has been the impossibility of making the different data flows of the new health information system (NSIS) inter-operable with the external data flows (this was, for example, the case for the data on mortality, income, exemption, etc.). The solution here has been to launch an institutional dialogue with the Italian Data Protection Authority (*Garante per la protezione dei dati personali*) and to make an in-depth analysis of compliance with the regulation on personal data protection. Overcoming this obstacle has required a modification of the current legislation on privacy, which did not include foresight among the motivations justifying the interoperability of public information systems. Such a revision is included among the articles of the last financial law.

Also, in this second macro-area of the project, the participation of the working group members has been fragmented and discontinuous, slowing down their progress.

Regarding the second macro-area of the project – development of methods and tools supporting monitoring and decisions on resources allocation – the census, analysis and elaboration of the existing databases and data sources were carried out during 2018. In 2019, the activity on the census of existing databases continued to support the procurement working groups. In

agreement with the Ministry of Economy and Finance, new meetings were scheduled and activities aimed at drafting the guidelines were carried out. The analysis of the bids has allowed identification of: i) the bargain form, the type of contract and, when possible, the announcement price for each product; ii) the variance of prices with those indicated by the National Anti-Corruption Authority (ANAC); iii) the common legal elements among different bids. It has also supported the compilation of some sections of the guidelines useful to the procurement working groups.

Regarding the consumption of resources, a method was designed to identify the reference prices for each product and to assess the efficiency gains in procurement processes for each region. Such an approach, able to estimate the economic savings, will be replicable for all the product categories, including the most complex ones.

The first application of the method has allowed: i) identification of the average price of health devices; ii) the conduct of benchmark analysis on regional unitary prices; iii) use of the unitary prices as a performance indicator of the procurement processes; and iv) estimates of savings. Moreover, an analysis of the ratio between prices and quantities was carried out with the aim of evaluating demand aggregation.

Difficulties in this area of the project included the fragmented participation of the experts and the existence of an internal variance of prices within the same category of devices. The first was addressed by enlarging the working groups membership with additional experts.

Regarding the activity of design and testing of the model of data analysis in support of decision making, which forms part of the second macro-area, preparatory activities during the first four months of the project included the activation of commodity<sup>7</sup>-related working groups gathering procurement centres (*soggetti aggregatori*). Available databases on these categories were mapped in order to estimate the potential savings. The data analysis enabled the consumption for each category of goods, limitations of the current official classification and price variations for each category of goods to be identified, while this latter variable allowed the potential savings to be estimated.

The results of the parallel analysis of the bids has supported the procurement working groups (soggetti aggregatori) in identifying ideal bid strategies, taking into account the type of goods and the current legislative framework (such as the public procurement code, legislative decree n. 50 of 2016). In particular, compliance with the procurement code does not allow for use of most of the results from the internal analysis and from the foreign models.

In 2019, the model has been fine-tuned, with particular attention to the constraints posed by the Prime Minister's Decree of 24 December 2015 identifying commodity categories. An analysis of the data for each category of product was carried out with the aim of identifying key managerial indicators. The evaluation of the validity of the indicators was based on a comparison between the estimated and the actual expenditure for each product category. This method was extended to other products, not part of the aforementioned decree, with the aim of identifying potential savings, benchmarking, improving the procurement processes, assessing trend and

<sup>&</sup>lt;sup>7</sup> Medication, needles, syringes, maintenance of electro-medical equipment.

planned scenarios, identifying performance indicators that will allow to integrate the model in order to estimate the costs of the services provided.

The main difficulties encountered in this area include the impossibility to directly correlate consumption of particular products to types of disease / pathology. This was addressed by creating the fifth working group on 'absorption of productive factors' to discuss a possible solution with experts. This activity will be concluded in April 2020.

Overall, the project encountered several difficulties. The main one was that the databases were mostly owned by the regions, rather than the Ministry of Health. Their access was subject to authorisation by the Italian Data Protection Authority (*Garante per la protezione dei dati personali*), to safeguard privacy. The different ownership posed also inter-operability issues. Both had consequences for the project implementation in terms of time and costs. Also awarding the contract to the private consortium produced some delay due to the administrative burden of the procedures.

The results achieved so far include the establishment of the control room and of the Advisory Board, as well as the award of the contract to the RTI-Almaviva consortium<sup>8</sup>.

Dissemination activities are planned with the aim of informing and involving all the key stakeholders (healthcare organisations, hospitals, central and regional public administrations, practitioners and health managers, but also citizens) on the project developments and results.

Finally, a supporting and coaching activity will be provided to other public administrations that intend to adopt similar methods.

### Conclusion

### Main results

The main expected impact of the project will greater efficiency and sustainability of the Italian National Health System. Benefits in terms of equity are also expected, making healthcare assistance independent from income and territorial location.

So far, the project has produced a national simulation and decision-making model of expenditure planning and allocation among the regions. This has been delayed by the privacy issues that hindered the interoperability of the different information systems. At the moment, the model is being implemented through the mapping of regional databases and their integration. The model will be able to simulate expenditure per each pathology and also enhance the integration between health and social / welfare services. This is an important shift towards evidence-based decision making.

Another relevant result so far has been, in the words of employee at PWC, 'achieving the full engagement of all interested parties such as regions, healthcare organizations, scientific societies and universities'.

<sup>&</sup>lt;sup>8</sup> See: http://www.ot11ot2.it/comitato-di-pilotaggio/catalogo-esperienze/resilienza-e-sviluppo-ssn

Also, the project has improved e-government, thanks to the simulation model and to the tools that support the expenditure efficiency gains. Finally, an improvement has occurred in digital planning competencies of all the members involved in the working groups.

### Lessons learned

The key lesson learned from the project is the need to establish effective inter-institutional collaborations at the outset of the project. Legal, technological and privacy issues – over which other institutional actors have authority – arose during the project implementation, producing delays. Having identified these earlier, and addressed them by engaging with competent institutions, would have helped project implementation to proceed more smoothly.

The network approach adopted during the project implementation has proved so far very effective in sharing information and competencies on a continuous basis and, most of all, in facilitating dialogue for reaching key decisions. Two important tools in achieving this were working groups gathering people from different regions and dedicated platforms for exchanging and sharing documents.

### Role of ESF support

The ESF support is recognised to have had an important role in presence of severe financial resource limitations. The interviewees were not able to identify other specificities to be ascribed to the ESF support, a part from a greater administrative burden during the project reporting activities.

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