



## WP5 – ProMIS

Short Technical Paper

mHealth Policies in Italy

mHealth Strategies, governance models and  
change management



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## 1. The Italian landscape of e-Health and m-Health

### Italian eHealth strategy implementation

Italy shows an articulated health care system aimed at ensuring citizens with Essential Levels of Care (LEA), in terms of quality and access to care. The roles and responsibilities between the State and the Regions have been modified by Constitutional Law 3/2001.

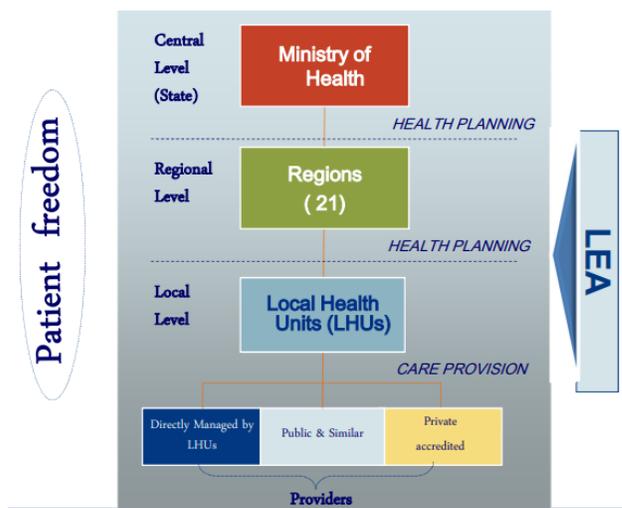


Figure 1. Overview of Italian health system.

#### *The Ministry of Health:*

- defines the fundamental health principles, and
- acts as point of liaison and guidance supporting NHS health policies

#### *The Regions:*

- are holders of the health policy, and
- are fully autonomous in organising and managing their regional system, but
- they must provide LEA as defined by the Ministry

In this background, the New National Healthcare Information System - NSIS is the common strategic framework. It facilitates the sharing of data at individual levels, providing tools and

methodologies to ensure quality, efficiency, appropriateness and costs monitoring.<sup>1</sup>

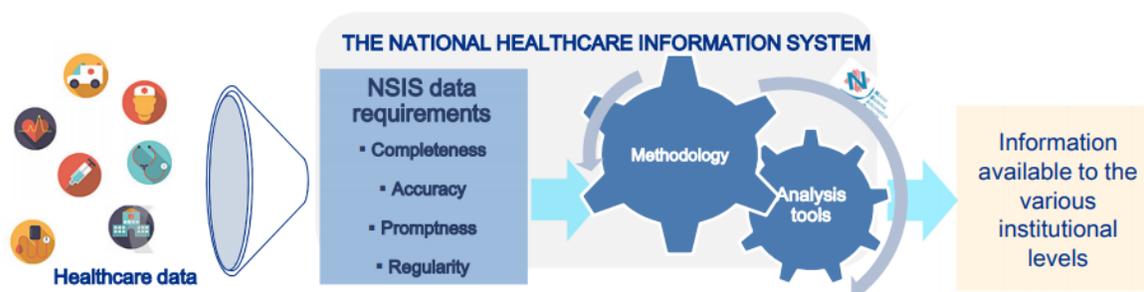


Figure 1. Overview of National Healthcare Information System

NSIS is the most important health database at national level to support national and regional health planning. The NSIS data management supports the Ministry of Health in the monitoring of Essential Levels of Care (LEA) and healthcare expenditure. NSIS allows to verify the appropriateness and quality of health services provided, and the efficiency in the use of human and financial resources. NSIS algorithms allow the evaluation of specific health phenomena, as well as quantitative analysis aimed at simulating the effects of policies including investments and financial contingency plan. The NSIS information system covers about 85% of costs of NHS, and includes health data flows dealing with managerial, organizational and economical dimensions.

<sup>1</sup> [http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=2978&area=sistemaInformativo&menu=presentazione](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=2978&area=sistemaInformativo&menu=presentazione)

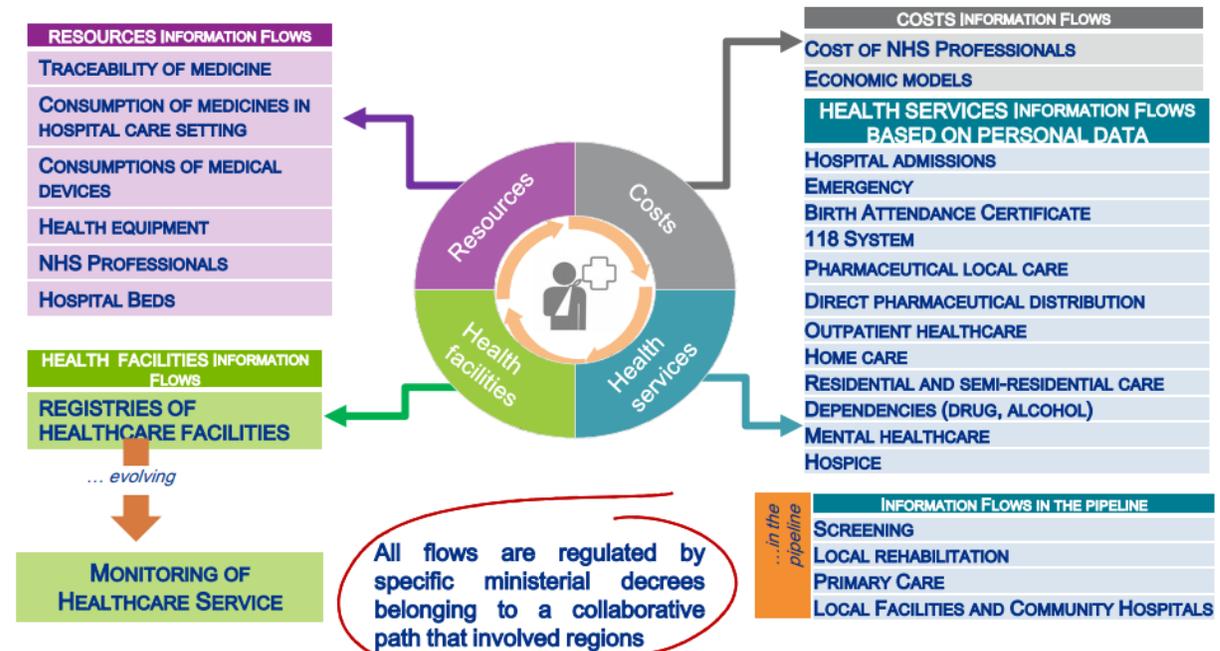
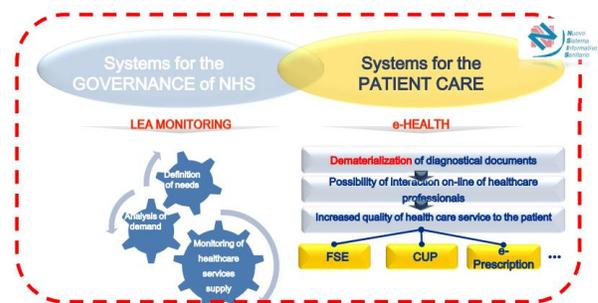


Figure 1. Overview of information flows

In the framework of NSIS the issue of e-health is becoming very important. In fact, speaking of information systems in health care means talking about two different worlds, although related, one more oriented to the GOVERNANCE of the NHS, the other to the PATIENT CARE.





The Italian Ministry of Health has identified e-health as one of the strategic goals to be reached, since 2008. Furthermore, e-health is one of the areas of the digital growth listed by the Italian Government in its document “Strategy for Digital Growth 2014 – 2020”.

Since 2008 the Ministry of Health has been implementing many different e-health initiatives nation-wide in collaboration with Regions. The e-health initiatives of the Italian Ministry of Health (MoH) concerned the improvement of administrative, managerial and organizational processes and the governance of the NHS, through the dematerialization of documents and the improvement of data flows from health organizations and facilities, to the regions and the MoH.



Figure 1. Overview of main e-health initiatives in Italy

The national e-health Strategic Plan, approved on July 7th, 2016, aims to achieve efficiency, transparency and sustainability of the NHS, through digital innovation in healthcare.



Figure 1. NSIS Steering Committee

The NSIS Steering Committee coordinates the implementation of the Strategic Plan for e-health, in order to ensure a shared set of interventions, focused on healthcare priorities already in place, and taking into account the national and European regulatory framework. In order to deploy the Strategic Plan, the NSIS Steering Committee adopted a Master Plan on the Italian e-health initiatives. This three-year plan includes a list of priorities, recommendations and pending issues on unmet health needs, regulatory and procurement aspects and public-private partnerships schemes. The main barrier to the implementation of healthcare services supported by ICT, is the lack of a reimbursement model for telemedicine to allow dynamic planning and cost allocation based on the evidence of the benefits for the system. The tariff definition for benefits in telemedicine is essential as well as ensuring appropriateness is pivotal to use telemedicine services not at discretion, as they are included in the standard care pathways (PDTA), adapted to the specific needs of the person (PAI). Hence the need for Italian NHS to establish a nomenclature of telemedicine services and define new PDTA (health and social) for the management of chronic disease in the territory when they are available as telemedicine services. Therefore the introduction of essential



levels of digital healthcare in the new LEA (Essential level of service), with reimbursement arrangements specific for telemedicine services is pivotal.

### **Focus on mHealth in Italy**

Digital Innovation into healthcare is recognized at international and national level as an essential element into healthcare systems in order to respond to new demographical, epidemiological and economic trends; these trends are negatively affecting traditional healthcare management model, Italian one included. In the last years, new regional governance models for ICT into healthcare system were born with the aim to rationalize and create homogeneity of services and processes into regional boundaries, promoting new innovative and technological solutions, including the use of mHealth devices. These solutions are not yet totally operational, or they are only partially realized, due to difficulties in the transformation of consolidated organizational systems as well as low digitally skilled health care professionals and patients.

In Italy, mHealth refers to the practice of medicine and public health supported by mobile devices such as mobile phones, tablets, personal digital assistants and the wireless infrastructure.

Within digital health, mHealth encompasses all applications of telecommunications and multimedia technologies for the delivery of healthcare and health information in the field of prevention.

At Italian regional health system levels, the most common digital health applications for mHealth include: Education and awareness; Diagnostic and treatment support; Disease and epidemic outbreak tracking; Healthcare supply chain management; Remote data collection; Remote monitoring; Healthcare worker telecommunication and training; Telehealth / telemedicine; Chronic disease management.

Numerous mHealth initiatives across Italian Regions have demonstrated the efficacy of using mobile devices to deliver such health solutions in a cost-effective manner:

1. Patients make and receive phone calls or text/voice messages related to health education, treatment adherence, contacting health workers or organizing transport to health services.
2. Healthcare workers are provided with needed resources to access the most up-to-date clinical guidelines, collaborate with colleagues, analyse data, receive diagnostic support, and interact with patients.
3. Medication adherence and chronic care management is supported—as evidenced by Smart Alert Systems that notify physicians via a cloud-based platform if a patient is not taking medications as prescribed, and requires intervention.
4. Access to quality care is optimized—helping to address the shortage of skilled healthcare workers, and lessening the burden on those trying to bridge the gap.

Presently, mHealth services are working as a means of entering patient data into national health information systems, and as remote information tools which provide information to the Italian government, healthcare clinics, home providers, and health workers. Moreover, it helps to identify the individual and community health needs from clinical domain with almost negligible importance on socio-cultural perspectives.

Due to the current COVID-19 pandemic situation, many trends have been strengthened in mHealth applications. In particular:

- Emergency response systems
- Home-based remote patient monitoring
- Human resources coordination, management, and supervision
- Mobile synchronous (voice) and asynchronous (SMS) diagnostic and decision support for remote clinicians
- Point-of-care clinician support which includes an evidence-based formulary, as well as database and decision support information

- Pharmaceutical supply chain integrity
- Patient safety systems
- Remote monitoring and clinical care
- Health extension services
- Health services monitoring and reporting
- Health-related mLearning for the general public
- Training and continuing professional development for healthcare workers
- Health promotion and community mobilization
- Support for chronic care management such as diabetes, asthma and cancer
- Peer-to-peer personal health management for telemedicine

### *mHealth and Covid-19 in Italy*

As above introduced, mHealth technology plays an important role in monitoring individuals who could be Covid-19 positive and are instructed to self-quarantine at home, as they experience mild symptoms. During their quarantine, some of these individuals experience an exacerbation of symptoms and require hospitalization. Based on the experiences of the Italian Regions, mHealth technology enables early detection of exacerbations and the deployment of clinical interventions before further complications arise.

When combined with diagnostic and immune status testing, mHealth technology is a valuable tool to help mitigate, if not prevent, the next surge of Covid-19 cases. Specifically, mHealth technology provides the means to estimate the probability of infection and prioritize diagnostic testing in individuals whose data suggests a moderate to high probability of infection. Three mHealth technologies suitable to achieve this goal emerged from regional technicians: 1) integrated regional systems, 2) wearable sensors, and 3) digital contact tracing technologies. Combining these technologies into an integrated, holistic mHealth solution would provide the opportunity to deploy an end-to-end solution incorporating tools for screening, risk profiling, achieving early detection, generating



referrals for testing, tracking infections, tracking isolation management/quarantine, assuring social distance compliance, proving remote care, and tracking recovery.

With the digital transformation of the healthcare system, mHealth technologies are expected to become better integrated in the clinical workflow. During the COVID-19 pandemic, this transformation of the healthcare system has been dramatically accelerated by new clinical demands including the need to assure continuity of clinical care services. This trend is likely to make us better prepared to address the challenges of future surges of COVID-19 cases and to minimize the effects of future pandemics on routine clinical service.

### **The assessment of health technologies in Italy**

In Italy, the National Agency for Regional Health Services (Agenas) has the strategic objective of giving support to Regions for the promotion of stable activities at regional and local level, for planning and evaluating the introduction and management of technological innovations (Health Technology Assessment - HTA) and for regional dissemination of the results of studies and assessments carried out at central level, encouraging actions and behaviours congruent with them.

A dedicated Steering Committee (SC) operates for identifying the evaluation priorities of national interest, in line with European guidelines, promoting and coordinating consistent and non-overlapping evaluation activities, validating methodological guidelines shared between all the actors and promoting the use and dissemination of assessments, verifying that virtuous behaviour in investment and divestment policies derives from them.

Recent internal documents from the SC report that several factors influence the integration, pervasiveness, and success of digital solutions. In resource-constrained environments, financing models widely affect the sustainability of these solutions. Indeed, in general, all the solutions require long-term financing needs, which are more relevant in the initial phases, and development and planning, and then slowly decrease over the long term. In contrast,

digital financing models generally follow a short-term approach without the need for a long-term commitment. Moreover, digital investments are often related only to the use or procurement of ICT and underestimate or ignore the cost and organizational efforts needed to manage the cultural and managerial changes resulting from the introduction of digital solutions. In several Italian Regions, the financial dynamics and models are described as barriers to digital solutions at various levels: a lack of resources for the introduction of digital health projects and nonrecurring expenditure for their continuation; excessively long processes for procurement and pre-financing procedures; and problems related to licensing and accreditation, reimbursement, and intellectual property right.

## 2. The 4 investigated policy areas

As already known, the Programma Mattone Internazionale Salute – ProMIS is a network that involves all Italian Regions, Ministry of Health and the National Health Agency with the aim of internationalizing Italian health systems. In the framework of the digital innovation of health system, 3 Regions (Tuscany, Campania, Piedmont) and the Autonomous Province of Trento contributed describing their own experiences in the following policy areas:

### 1. Health emergency

Source: Andrea Belardinelli, Head of digital health and innovation sector, Tuscany region

### 2. Innovation Management

Source: Maddalena Illario, Regional Council of Campania Region

### 3. Assessing the impact of innovations

Source: Valeria Romano, IRES - Piedmont Region,

### 4. Governance Model

Source: Diego Conforti, Autonomous Province of Trento

## 2.1 Health emergency

### Policy description

The Tuscany Region, with the aim of supporting health professionals of the hospital and local health units of the Region, as well as the Crisis Unit and the Regional Health Emergency Response Task Force, has decided to focus on technology and innovation and to develop its integrated information system. Indeed, it is evident that having sources of data and information that are complete, unambiguous and available among all the different actors participating in the emergency management process, is one of the key factors to better tackle the emergency itself. Starting from hospitals and their information systems, (including microbiology and virology laboratories), up to the territory, with its centralized information system for epidemiological investigations, ad-hoc integration components have been developed to communicate all the existing systems in real time (intercommunication and interoperability).

Real-time information is required to immediately implement the consequent actions. Therefore, facilitating communication among all systems through a regional platform has a dual purpose. These purposes are: allowing quick consultation of the results, directly within the ordering departments and; achieving a Rapid analysis of data through a centralized manner. Rapid analysis of data through a centralized manner allows the management of emergency in conjunction with the Crisis Unit and the regional Task Force through a secure, reliable and updated data. Additionally, the geo-referencing system used was able to easily represent information on the cartographic support in order to better organize interventions in the hospital network and home interventions of healthcare personnel.

### Policy options/Implementation options

The introduction of integrated information systems has introduced organisational and digital innovations and challenges. Challenges are being faced by hospitals, but more importantly by the territorial health organisations. All the territorial health organizations have special

continuity units for assistance, as required by law. These crews, made up of a doctor and a home nurse, are equipped with a single regional software (APP) in order to carry out and record home visits. Each patient is associated with a QR code and each provided service is registered by using a regional standardized catalogue. In real time, the regional dashboard reports some information regarding the patient such as the performance, the therapeutic indications and all the vital parameters detected during the examination. Therefore, it is fundamental that all the Regional Health System actors use the available information systems. In the short-medium term, there will be the opportunity to discuss needs for developing and customizing the applications, in compliance with information and management standards to be taken into account.

With regards to above, the Tuscany Region manages the regional "innovation governance". In order to guarantee sharing of information and data, and interoperability in real time, the Tuscany Region took the following actions:

- ✓ Made obligatory the use of tools that mostly already exist
- ✓ Created connections
- ✓ Centralized information collection
- ✓ Carried out networking activities among: hospitals, laboratories, prevention and public hygiene departments and territory (general practitioners, intermediate territorial structures, special continuity of care units but also prefects, mayors and police)

## Implications

The research and the development of a single integrated system at regional level, implemented particularly under the Covid-19 emergency, has to be envisioned as a crucial part of the so-called phase 2. However, it has also been seen as an essential part of the new approach regarding the organization and the handling process of the Regional Health System in the upcoming future.

The new approach is entirely data driven. This effectively governed approach allows rapid responses not only in the pandemic phase but in ordinary health services.

## Legal constraints leading to shaping up the policy

Management of the epidemiological emergency from Covid19 - Establishment of a technical coordination table for the functional link between the Health Task Force and the regional Coordination for maxi-emergencies.

## Examples of policy adoptions

[http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249808&nomeFile=Ordinanza\\_del\\_Presidente\\_n.34\\_del\\_14-04-2020](http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249808&nomeFile=Ordinanza_del_Presidente_n.34_del_14-04-2020)

[http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249809&nomeFile=Ordinanza\\_del\\_Presidente\\_n.34\\_del\\_14-04-2020-Allegato-A](http://www301.regione.toscana.it/bancadati/atti/Contenuto.xml?id=5249809&nomeFile=Ordinanza_del_Presidente_n.34_del_14-04-2020-Allegato-A)

## Analysis, gaps identification, trends

In addition to the loss of many human lives, health emergencies are also responsible for introducing new ways of providing services and of thinking about health services. In the emergency phase it is absolutely necessary to ensure the availability of qualified health care for chronic patients by resorting to alternative methods of delivery to the patient's presence in the clinic. In Tuscany, a single regional platform has been activated and it will have to be implemented in the near future, for the delivery of teleconsultation. However, it is necessary to create a single catalogue of outpatient services and to train staff about the way to deliver teleconsultation.



## Suggestions / recommendations

From our analysis, the following are the essential elements for activating a health emergency policy:

- ✓ Define the actors of the emergency management system which must also include the territory
- ✓ Act by ordinances that force all professionals connected to the system to use the digital tool (and strive for the inclusion of the "capable" citizen)
- ✓ Creation of micro-processes for the collection of gaps and the implementation of the tools (input from users)
- ✓ Centralization of information collection in real time with big data approach
- ✓ Data governance and monitoring, checking and decision-making of the interventions to be implemented
- ✓ Privacy guarantee
- ✓ Attention to the chronic patient who must be monitored / treated at home

## 2.2 Innovation Management

### Policy description

Health organisations are currently facing an extremely complex challenge characterised by increasing demand for services, rising costs and often insufficient funding. Healthcare models must be continuously adapted to improve in terms of organizational structures, human resources, processes, products, services and technologies, to meet this challenge while ensuring equity. It is therefore necessary that health systems increase their capacity to adopt and exploit innovations that can contribute to ensure quality and sustainability. Indeed, despite sometimes high cost, innovations, when effective, offer significant benefits to the system, hence the need to invest, although carefully assessing risk, cost benefit and

impact when evaluating the introduction of an innovation, to reduce the degree of uncertainty.

## Policy options / implementation options

Innovative technologies pose a serious governance problem, therefore any organization or health service provider should avoid introducing new and complex technologies without reliable evaluation, considering information useful to their use, expected benefit and impact. However, in order to be competitive, a service must be able to capture how research developments address specific needs, thus facilitating alignment with current practices at an early stage. Engaging users at the design stage usually facilitates the development of customized “products”. In Campania Region, innovation policies have been implemented by trying to create and maintain a balance between the identification of needs (by establishing a structured dialogue with the different local health authorities) and the real capacity to integrate and deploy innovations for the identified needs. For example, even the transfer of available innovative tools and good practices from other Italian regions has required an adaptation process: for example, in the case of RiskER algorithm, data retrieval from regional flows has been customized and validated, in order to ensure that risk stratification were reliable also in Campania context. The policies for the adoption of digital solutions have been embedded in Campania plan for the development of the regional health system, that has been also considering coherent organizational approaches (hiring of new human resources, training for health professionals) and allocation of economic resources (investment plan for health technology), for example within the framework of the Digital Agenda, and within the Prevention Plan (including the regional strategy for health promotion).

## Implications

When we talk about innovations, we do not only refer to technological innovations, but it is essential to talk about organisational innovations as well. Technological innovations usually involve reorganisation to allow a new model to be adopted. The implications of such

innovations are above all of an organisational nature since they modify the dynamics of collaboration and interaction between the various actors involved in the process, including citizens. This is why multidisciplinary education and training along the entire health and care value chain play a key role in the capacity building process for digital transformation. The training of human resources has been foreseen by the regional planning, in parallel with a health promotion strategy that includes health and digital literacy to empower citizens in taking an active role in their own health.

### Examples of policy adoptions

Campania Region approved the law n.2, February 12, 2018 on active ageing, that acknowledges the need to support active aging and enhancing the role of the elderly in the community through participation in social, economic and cultural life, to facilitate paths of autonomy and physical, mental, social well-being and to overcome all forms of categorization and welfare logic to mitigate the inconveniences and prevent discrimination based on age and ageism. The Law also identifies specific actions to undertake in terms of intergenerational activities, training of the workforce, maintenance of well-being, ensuring accessibility for older adults of tourism services and cultural activities, the setup of multifunctional social centers, providing meeting spaces and places, to prevent social isolation while incentivising the involvement of older adults in responsible and supportive active citizenship.

### Analysis, gaps identification, trends

Training the health and care stakeholders to multidisciplinary and multiorganization activities increases resilience, hence the need to overcome technological, cultural and technical gaps.

In emergencies management, as in the case of the Covid-19 pandemic, the approach to use and analyse the impacts of innovation cannot be reactive, it needs to be set up in advance to manage the response in an integrated way. Preparation requires the setup of a structured

connection between the services provided at hospital level with the community services, therefore the primary use of the technologies is to strengthen the hospital / territory integration.

Capacity building requires interventions at organizational level, but also for human resources since in the absence of adequate training and in a context where there is still a mainly "older" workforce, it's not possible to ensure a proper and timely use of technologies in a difficult or emergency circumstance. With the Covid-19 emergency, the need of a quick response has emerged, preventing, in fact, proper training of operators.

Another gap is the "digital divide". Throughout the national network, there is a technical problem of broadband coverage which is amplified, in particular, in inland, mountains and islands areas. Telemedicine would be an excellent tool for enhancing services in these areas, but it often happens that the signal strength is not adequate and / or sufficient.

In addition, the technological equipment made available to operators in regional health systems is often obsolete and inadequate. Even today, certain innovations are still considered as a "plus" provided to the doctor or administrative staff but not a real tool to be fully exploited. It is therefore necessary to review the roles and update the entire supply chain, engaging in training all those who contribute to the provision of services (from the general management, to the administrative management, and cascading to the districts and those who actually provide the service). The capacity building must include the whole supply chain, all the "pieces" (organization, administrative, economic, clinical, training, human resources) must be efficient and everyone must see the service in the same perspective. The amount of investment to be contemplated must be considerable and shared training moments cannot be omitted. This must be accompanied by investments in appropriate tools and technologies that also cover the field of occupational well-being.



## Enabling/Disabling factors

### Enabling elements:

- ✓ Strong political commitment that is effectively transferred/communicated and monitored along the management chain
- ✓ Shared vision
- ✓ Coherent investment plans
- ✓ 5G and fiber connections
- ✓ Updated, user-friendly technologies
- ✓ Interoperability
- ✓ Multistakeholders approach

### Disabling barriers

- ✓ Inconsistency of planning
- ✓ Inadequate training and education of workforce
- ✓ Lack of prioritization of citizens empowerment & literacy
- ✓ Weak communication strategy
- ✓ Obsolescence of technologies
- ✓ Inadequate evaluation approaches, procedures, planning and implementation

## Suggestions / recommendations

It would be necessary to map the processes for each Italian region and each area (macro, meso and micro). The mapping should cover national, regional and local processes. These, in order to be integrated with each other, need to be drawn based on data collected "on the field". A "serious" mapping requires analysis at all levels carried out by trained and qualified personnel. Such mapping would make it possible to reconnect the three national, regional and local levels in order to obtain an overview of their functioning and have a real efficiency boost. Technology makes service delivery better if it is embedded into organisational processes.

Finally, in order to identify individual needs - often conditioned by the local model - it is necessary to segment not only the settings but also the different age groups in order to be aware of their peculiarities. In this context, digital technologies are pivotal to personalise health interventions in a sustainable way.

## 2.3 Assessing the impact of innovations

### Policy description

In the Piedmont Region, Health Technology Assessment was regulated about 10 years ago through a rather embryonic model even if it took the Northern European and Canadian models as an example. Over time, since many training courses have been organized as well as working groups have been set up, a lot of dissemination has been made on Health Technology Assessment HTA, therefore both the Local Health Units and the Regional Health Authority have recognized the usefulness of HTA as a means of "reasoned" introduction of innovative healthcare technologies in the various healthcare facilities.

HTA provides evidence-based input to the policy-making processes concerning the use of technology in health services and thereby seeks to promote evidence informed policy-making.

In 2017 the HTA regional working group was structured more firmly through the establishment of a committee made up of expert managers of the Health Regional Authority, one representative of trusts and Care Units, the HTA Technical Team of IRES Piedmont (Economic and social research institute). In addition, Standard procedures recognized by the whole Region were also acquired to analyse the introduction of technological innovations.

## Policy options / implementation options

HTA's role is to create links between the policy and the research domains. It is an activity that can be understood only by analysing its context as this determines the best timing and the best possible way in which influence can be exerted on policy processes. At a project level – i.e. for a particular assessment – the link between HTA and policy-making is ensured when an HTA takes a specific policy question as a starting point. This is transformed into a number of HTA questions which can be answered through systematic reviews and analysis of research results. The answers and results are synthesized in an HTA report which is used as a basis for evidence informed decision-making within the policy process.

At the beginning, it was decided to carry out a very precise mapping to verify the presence of large / medium-sized technologies in healthcare and in hospital trusts/facilities in order to have knowledge of the regional "technology park". The IRES is therefore equipped with a database of biomedical technologies that collects not only the existing but also the new requests for the introduction or the replacement of technologies by Local Health Units. It is a kind of registration system through which hospitals and LHU in the Region can upload requests for new acquisitions or replacement of biomedical equipment. This system allows to keep track of the age of the technologies and to predict, together with the HTA Regional Committee, when it is time to replace technologies that have become obsolete.

## Legal constraints leading to shaping up the policy

National or European constraints don't lead to shape the policy on HTA adoption.

In Italy, some regions regulated the adoption of HTA through decree linked to the present regional government. A change of government could invalidate the decree.

## Examples of policy adoptions

Regional Decree 3/08/2017, n. 82-5513

[http://www.regione.piemonte.it/governo/bollettino/abbonati/2017/35/attach/dgr\\_05513\\_83\\_0\\_03082017.pdf](http://www.regione.piemonte.it/governo/bollettino/abbonati/2017/35/attach/dgr_05513_83_0_03082017.pdf)

## Implications

HTA's potential to serve as a mediation mechanism between the policy and policy research is dependent upon HTA producers having a thorough and detailed knowledge about policy-making and its conditions, and its users being aware (and having positive experiences) of the use of HTA. This need to share knowledge and experiences between producers and users sets the standard for future success in ensuring evidence informed policy-making. Therefore, the utilization of HTA in policy-making depends very much on mutual understanding, networking and responsiveness to user needs.

New networks of professionals have started working jointly together on different fronts, like on the front of sharing the introduction of new medical devices at a fairly early stage. The Regional HTA Committee try to programme the placement of high cost devices into *hub* trusts, based on the best evidence on effectiveness available, using needs' assessment allocation principles. In this regard, HTA should not be seen as a limiting factor for the entry of technological innovation into the health system, but instead, the aim is a weighted and reasoned introduction based on scientific evidence for understanding the appropriateness of a new health technology for the intended purpose of use in the local context, and allocation equity. All those involved are more aware of this process and as result, participate personally.

## Analysis, gaps identification, trends

Researchers and policy-makers comprise two very different communities with different values, ideologies, languages, backgrounds, institutional settings and reward systems etc. The general demand that output should be research relevant means that often it does not capture current policy problems on the political agenda. The increasing complexity of policy making and the involvement of a variety of actors/stakeholders leads to a broad view on the





policy context as well as multidisciplinary inputs to policy-making, acting as a facilitating factor for linking policy and research through HTA.

An obstacle encountered from the beginning is the incorrect interpretation of HTA which has not only occurred in the context of the Piedmont region, but also internationally, and which consists in seeing HTA as an inhibitor for the introduction of innovations in health systems and, also, a way to make spending cuts at the expense of innovation.

Through training courses, with the disclosure of the results of the data of the various reports carried out and shared with the various health trusts/organisations, it was possible to make the health professionals understand what the real intent of the HTA is and that is, to bring only the innovations for the system into the system, which are worth paying with taxpayers' money, based on cost effectiveness calculations and appropriateness in the regional territory.

In relation to the COVID-19 emergency situation, there was a derogation from HTA because the classic times of research in HTA are quite long and therefore it was not possible to go through a whole HTA analysis process.

Among other things, the technologies required in the first emergency phase of the pandemic were standard equipment specifically destined for intensive care units, and emergency rooms.

### Suggestions / recommendations

Since HTA is not part of a single discipline but belongs to multidisciplinary working groups and stakeholders, it is desirable working with multidisciplinary teams on the net and not through mono disciplinary ones. Working in a network with key stakeholders belonging to different sectors as well as with multidisciplinary teams is the winner strategy.

Within local health units, in elaborating priorities, the more the teams are multidisciplinary, the more they can work in an integrated and innovative way (organisational and technological) in order to address health systems practical needs as well as of patients.

## 2.4 Governance Model

### Policy description

The policy concerns the implementation of a quadruple helix approach where policymakers create the conditions for stakeholders to talk to each other and promote fair access to health services and improve the quality of care. The provincial law no. 16 of 2010 regarding “Health protection in the Autonomous Province of Trento” reserves a specific article (no. 24) to digital health which identifies it as a tool to face challenges related to demographic change and the consequent increase in the request for health care.

### Policy options / implementation options

In order to lead the development of digital health, the Autonomous Province of Trento (PAT) formally established with its own resolution no. 2412 of 2016 the competence centre of digital health TrentinoSalute4.0 (TS4.0) which involves PAT itself through the role of decision maker, and the provincial healthcare trust (APSS) as the provider of services and finally, the Bruno Kessler Foundation (FBK) as research institute. TS4.0 is also open to the participation of academia, citizens and industry.

### Legal constraints leading to shaping up the policy

The formal establishment of TS4.0 expresses the strong endorsement of policy makers in the promotion and implementation of digital health and lays the foundations of a sound collaboration among the public institutions (PAT and APSS) and the principal stakeholders involved in digital health. Furthermore, it provides a regulatory framework that clearly

defines the boundaries and roles of all those involved in the process of health promotion, prevention, taking charge, care, rehabilitation and assistance of citizens / patients through digital healthcare solutions.

## Implications

The establishment of TS4.0 allowed to pursue four main objectives:

- ✓ align the agendas of key stakeholders;
- ✓ cover the entire value chain in health services from research to innovation;
- ✓ accelerate the process from testing new technologies to implementing innovative health services;
- ✓ implement the 4-helix approach.

## Examples of policy adoptions

The main achievement pursued by the establishment of TS4.0 is the creation of TreC (from the Italian acronym “three C”, which means *Cartella Clinica del Cittadino*, i.e. Citizen Health Record). TreC ecosystem is a Personal Health Record that enables the citizens to access, supplement, manage and share their health and wellbeing information.

TreC offers to citizens the possibility to manage their own health information and facilitates the access to medical reports. Moreover, it also enables healthcare service to private and public providers to bring a plethora of quality health applications and services to the whole population.

The implementation of the TreC ecosystem provides a clear social benefit to the population in terms of healthcare services that can be deployed in a more efficient and opportune way, with personal health information duly tracked and timely available to all relevant stakeholders. The TreC ecosystem has become the main existing ICT asset in the Trentino

Province district and it has received several awards as a European best practice for EHRs and telecare initiatives.

TreC has been developed by following a Living Lab approach, informed by the direct involvement of citizens groups, clinical stakeholders and public-private entities for the implementation and validation of its innovative services. A unique characteristic is that it is an open platform designed to allow integration of third-parties applications through open APIs. This approach has been chosen to facilitate a paradigmatic change in the architecture of healthcare Information systems which was typically based on rather closed and monolithic architectures, in order to realize an ecosystem of innovative applications provided by both private and public parties. In this way, citizens can easily access to a high quality healthcare services and applications that are fully integrated with the public healthcare system (offered on B2B2C models instead of typically used B2C apps) whereas, a better partnership between citizens and healthcare providers is established in order to be able to support the development of innovative models of care and prevention.

### Analysis, gaps identification, trends

The main critical issues to be taken in consideration are:

- ✓ the interoperability of the public digital platform with medical devices developed by private companies, which has been overcome by the implementation of an open platform explicitly designed to allow integration of third-parties applications;
- ✓ the difficulty to perform procurement, which has been overcome by the acquisition of the development services of TreC through a national public contract (SGI Sanità - CONSIP);
- ✓ the resistance to the organizational change required to implement the new digital healthcare model, which can be overcome only with a strong endorsement of decision makers.

## Enabling/Disabling Factors

The main enabling factors are:

- ✓ Governance led by Public Authority.
- ✓ Convergence of the various public and private financing instruments in implementation of the programmatic and strategic lines defined at provincial level in the field of digital health.
- ✓ Availability of organizational models and technological infrastructures to ensure integration between all the subjects involved and also the exchange of data and information.

While the main disabling factors are:

- ✓ Resistance to the organizational change required to implement the new digital healthcare model.
- ✓ Interoperability and management of patients' data generated by private companies' devices.
- ✓ Complexity of the administrative procurement procedures and their implementation times.
- ✓ Difficulty of creating well-structured multi-disciplinary teams for the shared management of citizens / patients through digital healthcare solutions.

## Suggestions / recommendations

A key part of the success of TreC is the inclusive approach on healthcare management adopted since its conception. TreC enables citizen empowerment in managing their own health while supporting a coordinated approach by following a quadruple helix model that involves policymakers, healthcare professionals, research entities and the private actors for maximizing outreach. TreC services are designed and put into operation according to an innovative two steps approach. On one side, by integrating a consolidated and tested healthcare service in the platform, and on the other side, an upgraded, experimental version is used, in order to implement pilots of additional and more advanced services to ensure their

usefulness and usability check with all stakeholders, before their integration with the deployed TreC system.

As a result, very tailored, attentive and engaging interventions for health promotion are provided to users, enriching the amount and the quality of the available data in the citizens PHRs.

The strategic choice to implement a public digital health ecosystem allows us a strong ability to react and be flexible to develop specific solutions even in emergency situations such as Covid-19. In particular, in order to respond to the information and assistance needs of citizens / patients during the lockdown period, we have integrated into TreC the functions of remote home monitoring of Covid-19 patients and quarantined individuals and of remote medical examination.