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NEW TECHNOLOGIES AND NEW SERVICE MODELS IN THE ITALIAN DIGITAL HEALTH SECTOR

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Abstract

In Italy, the increase in life expectancy of the population is leading to the increase of chronic diseases and motor disabilities of the elderly, with negative consequences on the sustainability of the public health system (Brugiavini et al., 2010; Longo and Ricci, 2017). The Italian national health service has to be supported by additional actors (e.g. public health and social structures, the patient's family) who take care of sick people (Atella et al., 2017). Considering the high interactivity required in the relationship between these actors and hospitals, digital health technologies can represent a solution for creating a supply chain for taking care of the patient and fostering resource integration between actors involved in such supply chain. To provide a picture of the Italian digital health sector, this paper aims to investigate the fields of digital health in which Italian newcomers are investing. The research methodology involves a review of Italian SMEs, Start-ups and Spin-offs. The work highlights the promising developments of technology in response to the growing needs of patients and families, and provide an overview of Italian newcomers in the digital healthcare sector.

Keywords: *Digital Health, Digital Transformation, Life Expectancy, Chronic Care Model, Italian Digital Health Sector.*

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1. INTRODUCTION

Life expectancy, globally, has increased by over ten years in the last fifty years. According to Eurostat forecasts, the figure, concerning the EU, will increase in the coming decades (The World Bank Group, 2019; UN-Department of Economic and Social Affairs, 2019; Atella, et al., 2017). The bad news is that, if the statistics are struggling to disclose Lifespan optimistic, they cannot fail to notify the progressive decrease of the Healthspan.

Longevity is an achievement for humanity, but it involves a considerable expansion in the demand for health care, connected to the high incidence of chronic diseases in old age (Brugiavini et al., 2010). It is a wide range of diseases (including heart disease, stroke, cancer, diabetes, respiratory, neurological, neurodegenerative diseases, musculoskeletal and gastrointestinal disorders, vision and hearing defects and some genetic diseases - OMAR, 2020), for which the therapies have a purely ameliorative utility. The long course and persistent symptoms over time are elements that characterize chronic diseases. Also, the increase in demand for healthcare is borne by the National Health System (NHS). The Italian NHS boasts multiple strengths, from the low cost of performance to remarkable quality and outcome indicators that tend to be above the average of OECD countries. The main critical issues are related to the defining, which hit the sector in the aftermath of the economic crisis. Also, the Italian NHS shares, with most of the health systems of industrialized countries, the inadequacy of a response strategy to emerging care needs, with reference to the need to ensure adequate support for chronic patients. A country's health policies also depend on the demographic and socio-economic peculiarities of the populations to which they address, therefore, they must adapt to the evolution of these variables (Spandonaro et al., 2019).

In Italy, according to Istat data, we are witnessing an aging process of the population, due to the simultaneous reduction in births and mortality, in all regions, which do not correspond to an adequate response from the NHS. The pressure exerted on the primary care sector by the increase in chronic diseases has ignited an alarming light on the traditional approach to the health system (Mori, 2018). To this end, we believe that digital technologies have clear potential

Despite the undisputed potential of digital technologies applied to the healthcare sector and the birth of entrepreneurial realities inherent in the digital health sector, there does not seem to be any research in the literature to investigate the fields of activity in which newcomers in the eHealth sector are investing. In this regard, the objective of this work is to investigate the fields of eHealth activity towards which new entrepreneurs in the sector are pushing. Starting from this objective, we want to answer the following research question:

RQ. What are the fields of activity in which newcomers in the eHealth sector in Italy are investing?

2. THEORETICAL BACKGROUND

2.1. Towards the Healthcare Initiative: The Chronic Care Model

The circumstances described presently the forced choice of rethinking the health system. It is necessary to make a transition from traditional models towards new paradigms that elude the concept of “sick role” coined by Parsons (1951).

Today there is a tendency towards organizational approaches based on prevention, capable of supporting the patient. Organizational models are sought that can manage chronic diseases but at the same time capable of effectively addressing the onset of acute diseases.

In rethinking the structure of the healthcare system, it is migrating from the more traditional "waiting healthcare". In the latter, the citizen turns to the hospital, towards the "Healthcare initiative", where it is the NHS that reaches the citizen, guaranteeing the patient adequate and differentiated interventions about the level of risk and focusing on prevention and training (ARS-Toscana, 2020) (Regional Health Plan, 2008).

The Chronic Care Model (CCM) developed by Professor Wagner and his colleagues at the NcColl Institute for Healthcare Innovation, California, appears to be the most effective form of initiative healthcare and, therefore, the most coherent response to emerging care needs (Coleman, Austin, Brach, & Wagner, 2009)

The model focuses on the strengthening of six fundamental elements of the health system and their interconnectedness: community resources, health organizations, self-care support, team organization, decision support, and information systems. Healthcare organizations to respond to the health needs of chronic patients must be supported by community resources, i.e. voluntary groups, self-help groups, self-managed senior centers, and the like. The management of chronic diseases should be taken as a priority by health organizations to fuel innovations in care processes and the recognition of the quality of care. In chronic diseases, the patient lives with the disease for long periods, so it is right, from the point of view of the model, that he is an active protagonist of the care processes, learning to manage the disease itself. Self-care support indicates a set of activities aimed at helping patients and their families in acquiring competence and safety in managing the disease, equipping them with the necessary tools, and monitoring outcomes and problems. The adoption of the CCM implies a necessary rethinking of the organization of the care team. According to the logic of division of labor, doctors are

responsible for the assistance of acute patients and intervention in difficult and complex chronic cases; they also have the crucial task of training the team's staff. Non-medical staff will therefore be trained to support patient self-care and perform some specific functions including observation, control, and monitoring of patients. The adoption of clear and shared guidelines is essential to allow all team members to have well-defined standards based on which to provide adequate assistance. The adoption of computerized information systems is strategic, which support primary care teams in aligning with guidelines; provide feedback to physicians about their performance levels against chronic disease indicators and allow for the preparation of disease registers. The latter represent key points of the CCM and correspond to lists that group all patients affected by a specific chronic condition in the care of a primary care team. They are aimed at planning the specific care of each patient and managing "population-based" assistance (Maciocco, 2011).

Wagner's model pursues the aim of optimizing the use of existing resources and creating new ones, as well as encouraging a policy of interaction, based on a proactive approach, between healthcare personnel, patients, and caregivers of the latter (Coleman, Austin, Brach, & Wagner, 2009). The CCM aims to define non-generic acts of care, therefore aimed at the specific care needs of the individual. The Chronic Care Model imagines health services as a complex network system in which quality, safety, timeliness, efficiency, patient focus, and equity become the emblem of effectiveness. Continuity takes on particular importance in the model, specifically, the objective is to ensure continuity of information (informational continuity), relational continuity (relational continuity), and finally, organizational continuity (Taplin, et al., 2012).

The CCM weaves a network that complies with "management continuity" from the perspective of the "patient experience". In extreme synthesis, the model guarantees that the patient perceives the sensation of being "accompanied" by professionals in the network, avoiding the feelings of abandonment and loss.

In this context, IT systems, allowing the identification of individuals with specific risk factors or with certain pathologies, represent a precious ally for early primary and secondary[1] prevention interventions, in a perspective of "community-oriented primary care"[2].

The CCM accepted by the World Health Organization (WHO), has been adopted by numerous countries including the United Kingdom, Canada, Brazil, the Netherlands, and Germany, while in Italy, Tuscany was the first region to have integrated the model into its system. Regional Healthcare. Each of these countries has developed the Chronic Care Model in a way that is functional to its health system, which has led to interesting reinterpretations. However, the different interpretations of the model do not change its peculiar characteristic of combining the empowerment of the patient, obtained through the community approach, accessibility to care, information, proactivity, and self-care, to the needs of the whole community (Mori, 2018). The search for innovative care models dictated by the changing epidemiological needs, in conjunction with the relentless spread of eHealth, opens broad horizons for development.

The intersection between Healthcare and Digital is now a concrete reality with a high-resolution potential. Information and communication technologies (ICT) at the service of the health system are demonstrating an ability to fill gaps and inefficiencies in the health sector. The hope is that with ICT, the growing welfare needs can be effective accommodated, guaranteeing the dignity of each citizen and preserving their right to health (Article 32 of the Constitution).

2.2. Digital Health: New Digital Technologies to Support Healthcare

The digital health sector in recent years has been showing a continuous path of growth and development. Healthcare digitalization is driven by rapid advances in technology, the drive to provide ever more personalized health care (patient-centered), the demand for real-time access to information, and the massive increase in socio-health data (big data). The development of the Digital Health sector is also evidenced by the growth of this sector in the world health market (Global Market Insight, 2019; Varnai et al., 2018). The increase in the use

[1] Primary prevention includes a set of activities and actions that aim at the full physical, mental, and social well-being of the individual and the community. They aim to avoid the onset of morbid conditions, therefore they are aimed at healthy subjects. Secondary prevention, on the other hand, acts on subjects already affected by the disease, but at an early stage. The goal, in this case, is to make an immediate therapeutic intervention aimed at slowing down or interrupting the course of the disease (CNMR, 2014).

[2] Community Oriented Primary Care is the most evolved form of basic health care where primary care is integrated by a Public Health approach managed by the District and based on a systematic assessment of community needs, implementation of systematic interventions aimed at target groups of the population, monitoring the impact of these interventions to assess their usefulness for the needs of the population "(WHO - Regional Office for Europe, 2004).

of smartphones, tablets, and other mobile platforms, a rapid improvement of IT infrastructures, and government initiatives in favor of the use of digital technologies in the healthcare sector are contributing significantly to the growth of the digital health market at a global level (Gartner, 2016).

Digitization should not only mean technological development but a real cultural change that is revolutionizing both the internal organization of hospitals and the approach and expectation of patients towards the world of healthcare[3,4]. Healthcare digitalization, as reported by the Digital Innovation in Health Observatory of the Politecnico di Milano[5], is playing a fundamental role in the management of territorial networks (hospital-territory integration), thanks to the introduction of solutions for the management of prevention paths, for computerized treatment (Diagnostic Therapeutic Assistance Paths) of patients and the exchange of data and documents on patients (Patient Workflow Management and Patient Relationship Management).

This path will also be favored and accelerated by the evolution of the citizen. The latter, increasingly connected to the network, which is changing the degree of involvement of the same, concerning the treatment path and in the relationship with the doctor. We are witnessing a constant growth in the demand from citizens for online services, including access and consultation of clinical documents, communication, and consultation with general practitioners and specialists. Monitoring one's lifestyle (heart rate, sleep quality, daily steps, etc.) is increasingly relevant to citizens' needs, in line with greater attention to prevention. Citizens' approach is increasingly oriented towards sharing data relating to their lifestyle with the doctor, generating a mutual benefit for both citizens and doctors (Botti and Monda 2020).

In this scenario, new digital technologies are favoring the collection and processing of large amounts of data from health information systems, medical devices, patients/families, and external applications (internet of things, social platforms, telemedicine)[6]. Furthermore, they support the collaboration between the different actors of the socio-health network and the real-time visualization of the data and information collected. These technologies can provide valuable information for monitoring patients' health and quality of life and have the potential to revolutionize the ability to predict and prevent "harmful" changes in the course of

[3] Ministry of Health: Guidelines 2019: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2784_alnex.pdf
[4] European commission: Tools and methodologies to assess the efficiency of health care services in Europe (2019)
[5] https://www.osservatori.net/it_it/osservatori/innovazione-digitale-in-sanita
[6] EU Digital Single Market (2018). Transformation of Health and Care in the Digital Single Market. (https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_ehealth_infographic_en.pdf)

therapy/pathology, identify behavioral and physiological changes early in the patient, which can culminate in relapse or episodes of relapse (promptly reporting them to patients, caregivers, and service providers). Another aspect, not to be overlooked, is the possibility of acquiring data in a real context, with repercussions, in terms of efficacy and efficiency, on pharmacological therapies[7] [8].

According to a study conducted by McKinsey[9], at present, a patient, in most cases, enters the health system only when he is diagnosed with a disease. The treatment path is not optimized between the different nodes of a health network, it does not consider the patient's experience, any similarities, and/or potential risk classes. Doctors perform standard procedures for all patients with the same pathology ("one size fits all approach") and do not have much data available on the patient's history, personal characteristics, and behavioral factors, nor are they able to interact and communicate easily with the general practitioner and other network specialists. Patients, in turn, have poor access to clinical information, not always aware of the risk factors, and not particularly active and participating in their care path.

In this context, the application of Artificial Intelligence approaches will allow for better management, faster performance, and a higher level of accuracy[10]. The main advantage of AI is the ability to design digital health tools to assess potential risks of the evolution of certain pathologies, analyze the possible effects of therapeutic and/or pharmacological treatments on individual patients, integrate different sources, and correlate data. All this, thanks to the ability to acquire, store, and process large amounts of data and information on patients, medical devices, and information systems[11].

As reported by the 1st White Paper "Artificial Intelligence at the service of the citizen" published by the Agency for Digital Italy[12], these technologies can guarantee an improvement in the quality of life. The advantages are “greater accessibility to public services, favoring a reduction in their costs, with advantages in terms of reducing social spending, which can be reallocated. It will be possible to enhance many procedures with adequate automatisms, offering citizens the opportunity to interact in a more agile, effective, and personalized way.

[7] Ministry of Health: Pact for digital health https://www.camera.it/temiap/2016/09/29/OCD177-2387.pdf (2016)
[8] http://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=1300&area=Lea&menu=leaEssn
[9] Mckinsey Global Institute (2016). The Age Of Analytics: Competing In A Data-Driven World, December.
[10] EIT Health & McKinsey: Transforming healthcare with AI - The impact on the workforce and organizations (March 2020)
[11] Politecnico di Milano: Artificial Intelligence Observatory (2019/2020)
[12] Agency for Digital Italy (2018) https://libro-bianco-ia.readthedocs.io/it/latest/

We will all benefit from this, including the elderly, the disabled, and citizens belonging to disadvantaged categories.

The advanced levels of analytical computing capacity, according to Computational Intelligence paradigms (artificial neural networks, fuzzy systems, evolutionary processing techniques, intelligent agents, and so on), introduce an added value in terms of forecasts, real-time alerts, and automation of decisions, i.e. Predictive Analysis, Prescriptive Analysis, and Cognitive Analysis[13][14]. Predictive Analysis analyzes historical data to predict future events, Prescriptive Analysis integrates the results obtained from the predictive analysis with a series of recommendations and actions to solve/mitigate potential risks, Cognitive Analysis automates decisions, behaving in a similar to the human mind. These approaches will impact the development of digital applications for the diagnosis, treatment, and monitoring of the patient's health status, through measurements of biomedical parameters to be transmitted to the doctor, support for diagnosis, personalized management of care plans, logistical organization of the activities of health facilities.

The tools, based on these technologies, will support the doctor in "decision making", without however replacing the person himself, accompanying decisions in a more accurate and personalized way, and offering the possibility of dedicating oneself to value-added activities, such as [15][16]:

• Management of prevention, diagnosis, and treatment "personalized" on the real needs of the patient (active and aware), improving the "early" management and the clinical management of the diagnostic-therapeutic path between the different and fragmented nodes of a territorial network (reducing improper access, readmissions, hospitalizations, waste, ineffective treatments, etc.);

• Intelligent segmentation of patients, profiling specific risk classes and similarities, among those potentially subject to the development of certain conditions, so that they can be promptly directed to the best treatment and monitoring path, anticipating any complications.

• Real-time monitoring between specific biomarkers for the evaluation of clinical compliance with respect to standards of care (from biological, genetic, and other patient behavioral data), reducing errors (inadequate diagnoses, useless prescriptions, incorrect pharmacological dosages).

[13] Hindawi Publishing Corporation (2015): Review Article Big Data Analytics in Healthcare.
[14] Mckinsey Global Istitute (2016). The Age Of Analytics: Competing In A Data-Driven World, December
[15] Politecnico di Milano (2019). Digital Innovation Observatory in Healthcare.
[16] US Food & Drugs Administration (2017). Clinical and Patient Decision Support Software.

• Activation of alarms and personalized services, monitoring patients remotely, foreseeing early detection events, and proposing, in an intelligent way, activities, and services, based on the patient's behaviors and preferences, calibrated in the environmental context in which he lives daily.

The goal, as also emerged from the surveys conducted by the Observatory of Digital Innovation in Healthcare, is the need to make the collected data effectively useful, introduce tools that can analyze them, and above all make them easily accessible and viewable for doctors and health professionals.

2.3. The Obstacles to the Adoption of Digital Health Technologies

The level of use of Digital Health technologies is still limited, being in the early stages of introduction and dissemination on the market[17].

The main obstacle to the adoption of these technologies is the area of use. This is characterized by a complex multi-stakeholder environment, with a fragmented decision-making process, with different needs and requirements to be met, for different segments and classes of users, such as[1819]:

• The government and regulatory authorities, who approve and decide on the use of these solutions.

• The operators of health organizations, who must select the solution and purchase it.

• Doctors and health personnel, who evaluate and choose the solution.

• Patients, caregivers, and community associations, who influence and determine the success or otherwise of using these solutions.

• The technology providers and medical device vendors, who market and distribute the solution.

Another key aspect is, on the one hand, the rapid evolution of digital information technologies applied to the health domain, and on the other hand the reduced computerization/digitization of health information systems. Other obstacles concern:

[17] Deloitte (2019). Perspectives, potentials, impacts and models of Artificial Intelligence in the health sector.
[18] CONFERENCE "Artificial Intelligence and Chronic disease management" Artificial Intelligence in medicine: limits and obstacles (2018)
[19] https://www.philips.it/a-w/about/news/archive/standard/news/press/2019/20191107-future-health-index-2019.html

• Regulatory aspects, both in terms of compliance with the standards of interoperability of these technologies with other hospital health systems/solutions (eg. HL7)[20] and certifications to be met for placing and marketing on the market as a "medical device"[21];

• Data quality, in terms of security and privacy[22]. Digital solutions are based on data, often coming from databases created for other purposes and not for scientific research and care. This approach generates criticalities in terms of 1) guarantee of the data source: the administrative databases provide data collected for non-clinical purposes and the data in the electronic records are not always structured for adequate collection for scientific research and are sometimes not collected with completeness; 2) correct "representation" of an entire population and not of a subpopulation, such for example the subjects followed by a particular organization, in which, moreover, the collection of data may not be homogeneous in the various care centers; 3) quality of the algorithms; 4) validity and correct use of data: the input data, such as medical information, are not unique and precise and this affects the results produced. Digital Health technologies introduce problems for the respect of privacy in the sharing and transmission of patient data. Individuals live their lives freely on the assumption that some personal information is not known by those who are not authorized. The growing availability and exchange of health information supports advances in the individual care and public health, but also facilitates invasive marketing practices and discrimination outside the law.

• Ethical aspects[23], especially for solutions that use technologies based on artificial intelligence. Consider, for example, the risk: 1) coming from algorithms that could reflect the same human prejudices in decision-making choices. For example, an algorithm predicting a risk on a genetic basis can lead to errors if applied to populations in which there are no genetic studies; 2) to address solutions that satisfy administrative objectives but not the real quality of care, create decision support systems that favor the consumption of drugs or medical devices, without clinical users perceiving it; 3) to rely excessively on the answers suggested by technologies with the risk of going beyond the role of a support tool, guided by the universal principles of respect and benefit for the patient; 4) of data confidentiality: the use of data to build algorithms implies that no data can be omitted, under penalty of loss of validity. This problem has significant implications for the relationship of trust between doctor and patient.

[20] https://www.hl7.org/
[21] European Commission: guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices (2016)
[22] https://eur-lex.europa.eu/legal-content/IT/TXT/?uri=celex%3A32016R0679
[23] EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES Opinion on the ethical implications of new health technologies and citizen participation

2.4. Health Policies on Digital Health

In terms of digital health, national health policies are preparing guidelines to support new models of health services, based on continuity of care, care management, de-hospitalization, etc.[24] An example is the Pact[25] for Digital Health which constitutes the unitary and shared strategic plan for achieving the objectives of efficiency, transparency, and sustainability of the National Health Service, through the systematic use of digital innovation in healthcare.

The digital health initiatives that the ministry, in collaboration with the Regions, is conducting include the Electronic Health Record[26]; solutions and services for hospital-territory continuity of care (PDTAs); telehealth, teleconsultation, tele-reporting, tele diagnosis, telemonitoring, telerehabilitation, telemedicine[27]. The development of tools for disseminating information assets and enhancing public databases (according to Open Data approaches) is part of the technological innovation initiatives that are underway.

In particular, in the management of chronicity[28] and hospital-territory management (integrated clinical networks, such as stroke, oncology, cardiology, etc.), according to diagnostic-therapeutic protocols (PDTA)[29], digital health initiatives and solutions will find wide application to enhance and strengthen the current model, which shows a series of criticalities and weaknesses.

Finally, we mention the initiatives of EU and national legislation to introduce new procedures for the purchase of Digital health solutions by the Public Administration (PA), that is pre-commercial contracts and public procurement of innovative solutions[30].

3. METHODOLOGY

The research methodology for analyzing the role of new digital technologies in the evolution of the health system provided for a review of SMEs, startups, and Spin-offs belonging to the Italian context.

Starting from the analysis of the existing literature on new organizational models in healthcare, the research has emphasized the study of technologies currently used in healthcare, to highlight the functions they assume, the advantages they offer, and the resistance to adoption,

[24] Ministry of Health: Guidelines (2019) http://www.salute.gov.it/imgs/C_17_pubblicazioni_2784_alnex.pdf
[25] Ministry of Health: Pact for digital health (2016) https://www.camera.it/temiap/2016/09/29/OCD177-2387.pdf
[26] https://www.fascicolosanitario.gov.it/
[27] http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_alnex.pdf
[28] Ministry of Health: National Chronicity Plan http://www.salute.gov.it/imgs/C_17_pubblicazioni_2584_allegato.pdf (2016)
[29] http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=4893&area=demenze&menu=vuoto
[30] https://www.agid.gov.it/it/agenzia/appalti-innovativi

which often emerge. Subsequently, a review was conducted, aimed at developing a "snapshot" of the digital health sector in Italy, considering data relating to SMEs, start-ups, and spin-offs. The research, carried out in March 2020, provided for the data collection through two official portals: Business Register (http://startup.registroimprese.it/), which reports the official data of the Chamber of Commerce, and Knowledgeshare (https: / /www.knowledge-share.eu/about/), on which information is available relating to patents and technologies that represent the excellence of the scientific know-how of Italian universities and research centers. In particular, for SMEs and start-ups, the data were found from the Startup and innovative SMEs section of the Business Register portal, on which an advanced search was carried out, using two ateco codes (6201; 86) and seven keywords ("ServiziSanitari", "DigitalHealthcare", "sanitadigitale", "digitalhealth", "DigitalHealth", "ehealth", "eHealth"); while the data relating to the spin-offs were obtained from Knowledgeshare.

4. RESULTS

The results of the review of SMEs, startups, and Spin-offs in the eHealth field have made it possible to trace the characteristics of the digital health sector in Italy. In the Country, there are about three SMEs and twenty-one start-ups, whose business is linked to the production of software and devices for health care. Of these organizations, the three SMEs are all located in Lombardy, in the north of the country. On the other hand, the distribution of start-ups is more equitable: 48% of these are in the North, with the primacy of Lombardy; 33% in the Center and 19% in the South, between Campania and Abruzzo. Italy also boasts a widespread network of spin-offs operating in the biomedical sector. There are approximately 134 of which 75% in Northern Italy, with a prevalent concentration in Piedmont, Emilia-Romagna, and Lombardy; 31% in Central Italy, with a marked concentration in Tuscany; finally, only 13% of the spin-offs considered are based in the south of the country. The snapshot of the sector highlights mostly very small businesses with some employees, on average between two and ten and a capital that, only in a few cases, exceeds 50,000 euros. Many fields of activity converge in the digital health sector. Therefore, from the analysis of the data available on SMEs, start-ups, and spin-offs in the sector, it emerges that 16% of these organizations link their core business to the development of software and diagnostic support devices, to the interpretation of results. and decision making in the clinical field. 15% are involved in the implementation of platforms and devices for monitoring the patient's health status, which allows the detection of primary or relevant biometric parameters for specific pathologies (neoplasms, heart, respiratory, sleep disorders, etc.). A further 13% is dedicated to the implementation of solutions with an impact

on the strategic, organizational, and management areas of the Health System. In the area of telemedicine and the related design of software and apps for mobile devices, however, 11% of the organizations considered work. Finally, the remaining 45% is active in the field of the production of cutting-edge electro-medical equipment (11%); the implementation of innovative physiotherapy and rehabilitation techniques and systems (9%)[31]; R&D of new drugs, molecules, and biomaterials (9%); the development of wearable devices (8%) and finally the development of tools and devices to support surgery (8%). In Figure 1, the fields of activity of the eHealth sector.

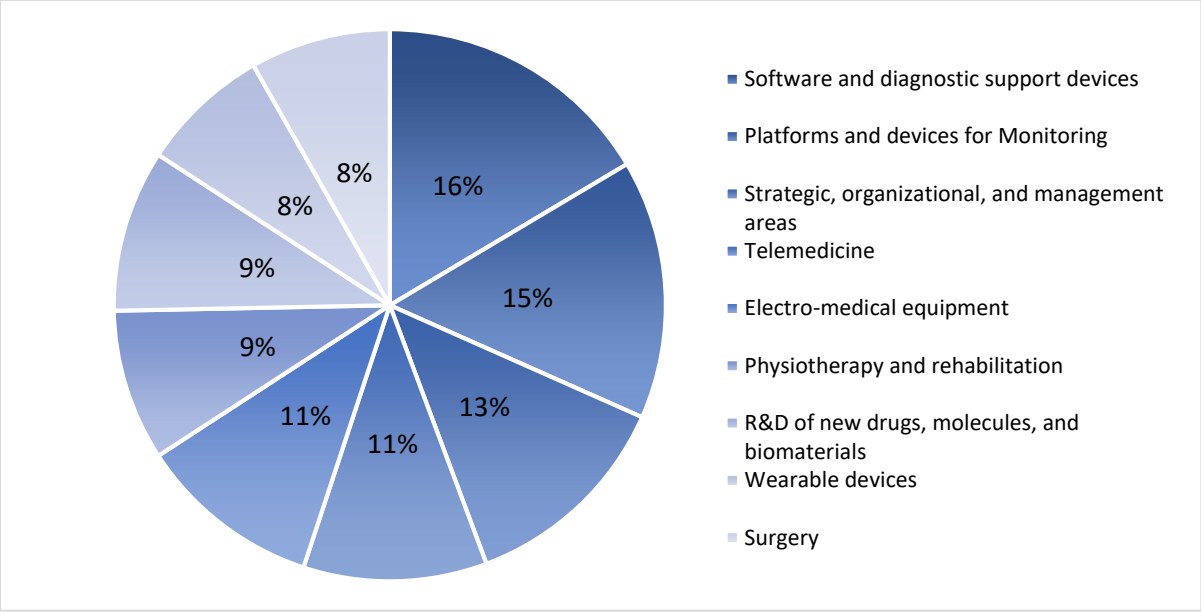

Figure. 1 - Fields of activity in the eHealth sector in Italy

Source: our processing of data from the Business Register and Knowledgeshare

5. CONCLUSIONS

The increase in the life expectancy of the population is linked to the increase in the incidence of chronic diseases and motor disabilities of the elderly (Brugiavini et al. 2010). This phenomenon has serious consequences for the sustainability of the public health system, due to the inadequacy or total absence of a strategy aimed at providing a valid response to emerging healthcare needs, with particular reference to the need to ensure adequate support for chronic patients.

[31] In this field the use of home automation and robotic applications is frequent, aimed at improving the quality of life of the disabled patient and/or patient involved in complex post-traumatic rehabilitation paths

Over the years, the NHS has been forced to increasingly resort to the support of many additional subjects, such as the patient's residential, semi-residential, socio-sanitary, social structures, and family of origin (Atella, et al. 2017). The presence of a real supply chain for taking care of patients suffering from chronic diseases poses a problem of integration between the different subjects, which can, in part, be solved by the advent of new digital technologies applied to the fields of health (digital health).

The transformation of new technologies on the health system is becoming increasingly concrete in recent decades. The healthcare system model towards which it is inclined is based on "connected care" paths that presuppose the idea of a "connected" healthcare ecosystem and governed by the principle of the centrality of the person (Farmaindustria, 2019). In this system, the technological devices act as the glue between the patient and health workers (specialist doctor, general practitioner, rehabilitation therapists, nurses, other health personnel, pharmacist, caregiver, researcher). Institutional web platforms, wearable devices, apps for monitoring and telemedicine constitute a single solid link, capable of enabling the empowerment, both of patients under treatment and of healthy people, towards health systems. Therefore, an unprecedented concept of "taking care" emerges, in which new technologies play a strategic role. They allow the implementation of a connected community through the implementation of innovative facilities, dictated by the need to focus on the patient with his specific needs.

From the epidemiological picture outlined in section 2.1, with particular reference to the aging of the population and the spread of chronic diseases, ambitious challenges emerge for health systems, related to the need to ensure monitoring and home care of patients suffering from chronic diseases and beyond.

In Italy, the entrepreneurial realities that deal with the production of software and devices for health care are still few. These are in most cases of spin-offs, concentrated in the northern part of the peninsula, and of start-ups equally distributed throughout the country. whose advancement of information systems allows the development of intelligent solutions for a double purpose: 1) the improvement of the management of diseases of chronic patients; 2) the improvement of the management of the strategic-organizational areas of the Health System.

To date, Italy includes mostly very small businesses in the sector, however, developed nations such as the United States, Germany, and Japan represent mature markets in the digital health sector, which bode well for rapid growth too. of the Italian market. Established health infrastructures and high adoption of medical apps among patients and doctors to improve

collaboration and monitor health are on the rise, allowing the growth of the digital health industry in developed countries.

The intersection of the different scenarios outlined therefore traces favorable prospects for the digital health market for which, by 2026, a 28.5% CAGR growth is estimated compared to 2019 (Global Market Insights, 2019). These data are certainly reassuring as, in addition to outlining progressively innovative future scenarios, they allow to prevent the collapse of the NHS thanks to the adoption of digital health solutions. Digitalization in the health sector, together with government initiatives to support the improvement of health infrastructures, lead to hopes for the growth of the digital health sector which would improve access to health care, affordability, quality, and safety of healthcare. sector itself.

References

ARS-Toscana. (2020), "Che cos'è la sanità d'iniziativa", tratto da *ARS Toscana*: *https://www.ars.toscana.it/aree-dintervento/problemi-di-salute/malattie-croniche/news/1578-che-cose-la-sanita-diniziativa.html*.

Atella V., Belotti F., Cincotti F., Fosti G., Furnari A., Kopinska, J., Lecci F., Longo F., Notarnicola E., Palma A. & Mortari A. (2017). *"La salute nel ciclo di vita della popolazione: come sta cambiando e come si può intervenire*", *I Quaderni della FondazioneFarmafactoring*, Fondazione Farmafactoring.

Botti, A. & Monda, A. (2020). 'Sustainable value co-creation and digital health: The case of Trentino eHealth ecosystem', *Sustainability*, 12(13), p. 5263.

Brugiavini A., Padula M. e Pasini G. (2010). "La domanda di Longterm Care" in Brugiavini A e T. Jappelli, *Verso un nuovo sistema di architettura sociale per la famiglia*, Il Mulino.

CNMR. (2014). "La prevenzione: definizioni", taken from *Centro Nazionale Malattie Rare*: http://old.iss.it/cnmr/index.php?lang=1&id=2473&tipo=77

Coleman K., Austin B., Brach C. & e Wagner, E. (2009). "Evidence On The Chronic Care Model In The New Millennium", *Health affairs (Project Hope), 28*: 75-85.

Farmaindustria. (2019). "2025. La salute che verrà".

Gartner (2016). Digital transformation and its impact on healthcare. https://www.gartner.com/en/industries/healthcare-providers-digital-transformation

GIMBE, (2019). "4° Rapporto GIMBE sulla sostenibilità del Servizio Sanitario", taken from *Fondazione GIMBE*: www.rapportogimbe.it.

Global Market Insights. (2019). "Digital Health Market Share Trends 2019-2025 Growth Forecast Report".

Mac A. (2019). "Epicura chiude un secondo round da un milione di euro", Il Sole 24 Ore.

Maciocco G. (2011). "Assistere le persone con condizioni croniche", tratto da *Salute Internazionale*: https://www.saluteinternazionale.info/2011/06/ assistere-le-persone-con-condizioni-croniche/.

Ministero della Salute. (2014). "TELEMEDICINA - Linee di indirizzo nazionali".

Mori D. (2018). "Chronic Care Model, il sistema salute va verso il paziente", taken from *Nurse24.it*: https://www.nurse24.it/specializzazioni/management- universita-area-forense/chronic-care-model-assistenza-cronicita.html.

OMAR. (2020). "Malattie croniche", tratto da *OMAR - Osservatorio Malattie Rare*: http://www.malattiecroniche.it/

Piano Sanitario Regionale. (2008). "Dalla medicina di attesa alla sanità di iniziativa" in *Bollettino Ufficiale della Regione Toscana, N. 25 - punto 4.3*.

Spandonaro F., d'Angela D. & e Polistena, B. (2019). "15° Rapporto Sanità - Il ritorno della Politica Nazionale in Sanità (?)", C.R.E.A. Sanità.

Startupbusiness.it. (2018). "Cos'è la scale-up e quali sono le sue caratteristiche", taken from *Startup Business*: https://www.startupbusiness.it/

Taplin S., Anhang Price R., Edwards H., Foster M., Breslau E., Chollette V., Prabhu Das I., Clauser S.B., Fennell M.L. & Zapka J. (2012). "Introduction: Understanding and influencing Multilevel Factors Across the Cancer Care Continuum", *Journal of National Cancer Institute. Monograph*, 2-10.

The World Bank Group. (2019). "Life expectancy at birth", taken from *The World*

Bank - Data: https://data.worldbank.org/indicator/SP.DYN.LE00.FE.IN

UN-Department of Economic and Social Affairs. (2019). "World Mortality 2019: Data Booklet", https://www.un.org/en/development/desa/population/publications/pdf/mortality/WMR2019/WorldMortality2019DataBooklet.pdf, United Nations.

Varnai et al., (2018). A study prepared for the AAL Programme (Active and Assisted Living) by Technopolis Group.

WHO - Regional office for Europe. (2004). "What are the advantages anddisadvantages of restructuring a health care system to be more focused on primary care services?", *Health Evidence Network*.