



UNIVERSITÀ DEGLI STUDI DI PALERMO

Ph.D. Program in Model Based Public Planning, Policy Design and Management (Modelli per il miglioramento della performance nel settore pubblico)

Dipartimento di Scienze Politiche e delle Relazioni Internazionali (DEMS)

SSD: SECS-P/07

Tesi in cotutela con l'Università di Bergen

POLICY INNOVATION AND IMPLEMENTATION IN PUBLIC SECTOR: COMPLEXITIES, DYNAMICS AND UNCERTAINTIES

LA DOTTORESSA
PHD CANDIDATE

Olga Tolmachova

IL COORDINATORE
PHD COORDINATOR

Prof. Carmine Bianchi

IL TUTOR
THESIS SUPERVISOR
UNIVERSITA' DI PALERMO

Prof. Carmine Bianchi

IL TUTOR
THESIS SUPERVISOR
UNIVERSITA' DI BERGEN

Prof. Pål I. Davidsen

CICLO XXX
ANNO CONSEGUIMENTO TITOLO 2018

Scientific environment

This work has been done in cooperation with Fair Dynamics (<http://www.fairdynamics.com>), part of Engineering (<http://www.eng.it>).

Contents

Abstract.....	4
Chapter 1 – Introduction and Background.....	5
Introduction.....	5
Innovation	6
Impact Assessment.....	8
Need for dynamic perspective	12
Research questions.....	15
Methodology	16
Research outline.....	17
Chapter 2 – Problem (What?)	19
Increase in chronic health care expenditures	19
Chronic disease and healthcare costs in Europe and world	19
Chronic healthcare costs in Lombardy region	20
Chapter 3 – Hypothesis (Why?).....	23
Reasons for the increase of chronic patients.....	23
Aging population	23
Chapter 4 – Analysis (What happens if we do nothing?)	31
Lombardy Region projection for chronic health care costs	31
Triple Aim.....	33
Chapter 5 – Policy (How can we prevent this?)	39
CReG.....	39
CReG description.....	39
CReG results	45
PiCC.....	55
PiCC description	55
PiCC model and similar initiatives in the world.....	59
PiCC objectives.....	62
Impact Assessment of the PiCC program	63
Chapter 6 – Implementation.....	70
GPs cooperative model	70
Chapter 7 – Conclusions	80
References:.....	83
Appendix 1: List of figures	90
Appendix 2: List of tables.....	92

Abstract

This research is expected to contribute to the knowledge base on how an effective impact assessment and adoption of innovations in the public sector could be facilitated. The need for trans-disciplinary assessment of the long-term potential impacts of innovation-driven policies may well be met with system dynamics as part of the dynamic performance management approach by way of modelling based simulation and analysis. Moreover, such analysis may contribute to learning and the accumulation of a knowledge repository that enables strategy developers, policy designers and decision makers to arrive at unexpected (often called counterintuitive) conclusions prior to policy implementation. Such insights, consequently, improve the quality of such processes by providing transparency and effective communication across stakeholders. In this research, I will document how dynamic performance management approach, of which system dynamics is a part of, may facilitate model-based assessment of social innovation impact and its implementation processes in public sector domain. In particular, I will assess the implementation of chronicity management program in Lombardy Region, Italy, using a model that uncovers the dynamics of the policy and its consequences for different stakeholders in short-term and long-term timeframes.

Chapter 1 – Introduction and Background

Introduction

This research is intended to bring about new knowledge to facilitate an effective impact assessment and adoption of innovations in the public sector by way of system dynamics as part of dynamic performance management approach.

The current body of knowledge on the innovation and its adoption in the public sector lags behind in comparison to such knowledge in the private sector. Not all findings from the private sector are transferable to the public one. There are differences between the purpose of innovation as well as the domains of operation in the two sectors. In both sectors, there is a concern that the process of innovation and its implementation is not well understood and that the full impact potential of innovations is not being reached. In part, this is true because both the innovation and the implementation processes are complex and dynamic and are carried out in complex, dynamic domains. In this thesis, I will concentrate on theories, methods, techniques and tools that may shed light on the implementation and impact assessment of innovations in such public domains.

A large number of social innovation projects are currently in progress, and some have been completed, across EU. Health care sector is one of the areas where such innovations are taking place. Struggling to reconcile often conflicting goals, healthcare sectors of European countries strive to provide good quality of service for the current epidemiological situation at hand and within the tight budget constraints that current economic situations present. In particular, more and more innovative programs are introduced to battle the rising health care costs associated with chronic disease management. Therefore, in this work, one such program will be used as a case study to illustrate the insights that a dynamic performance management and system dynamics perspective may generate of relevance to the assessment of the longer-term impact of such projects and thus to the innovation and implementation processes themselves. Such a

perspective implies the employment of a model-based analysis of a) the relationship between the structural change that such innovations constitute, and b) the resulting dynamics characterizing the domain in which the innovation takes place.

Complex, dynamic, social domains are characterized by the fact that non-linear, feedback structures govern the dynamics exhibited. The result is, typically, that well-intended strategies, policies and decisions cause such systems to exhibit unexpected dynamics. The implication is that there is a need for effective impact assessment built into the innovation and implementation processes. It is my hypothesis that model-based simulations and analysis facilitate such assessments in complex, dynamic domains and, that when used throughout, produces a systems insight that would guide the social innovation process. The thesis will be designed to document whether so is the case.

Innovation

“The only way to thrive is to innovate. It's that simple.”

– *Alex Tabarrok (Canadian-American Economics) – 2009*

In the modern high-speed changing world, the pressure to innovate and change is ever growing. Organizations need to foster the development of better organizational processes and adopt best practices from others in order to be able to survive the competition and prosper. (Schumpeter J, 1942; Christensen, 1997; Baumol, 2002). However, the introduction of the new practices is not always smooth. Even though the literature examines the pitfalls and barriers on the path to successful adoption of innovations in the private sector (Becheikh et al., 2006; Rosenbuschet et al., 2011; Pfeffer & Sutton, 2013), the public sector literature on the matter is still sparse (Hartley, 2005).

Innovation in public and private sectors

Multiple definitions of the innovation could be derived from the literature, spread across the continuum from considering only radical breakthroughs to be worthy of the term, to more mild versions that indicate incremental changes. This research would be closer to the later ones, emphasizing the notion that innovation is not only a new, good idea, but it is that idea turned into practice (Altschuler & Zegans, 1997; Mulgan & Albury, 2003). As pointed out by Schumpeter, innovation belongs to both the business and the technology world. However, if it is only the technology that changes, it is merely an invention, only the moment the business picks it up, it becomes innovation (Schumpeter, 1934).

There are numerous examples of innovative activities and adoption of new technologies that have been undertaken by private and public organizations alike. The adoption of the Total Quality Control (TQC) systems in the private sector is a typical example. Many scholars have investigated the topic scientifically and have praised the multiple benefits TQC systems may bring to adopting organizations (Powell, 1995; Easton & Jarrell, 1998; Kumar et al., 2009). In the public sector, e-governance at large is a recent innovation that contributes to the improvement of organizational performance. (Marche & McNiven, 2003; Torres et al., 2006; Contini & Lanzara, 2008; Bianchi & Navarra, 2013).

Pitfalls in social innovation

Many organizations have experienced troubles in the adoption of new technologies, bearing losses rather than benefits from the innovations. Both private and public sectors alike have suffered from failed attempts at adopting new technologies. In some cases, the losses suffered during the implementation have caused full abortion of adoption of the good practice altogether, where all efforts have gone in vain. In others, the level of benefits achieved has been described as rather limited as opposed to the initial promise of the innovation. (Southon et al.,

1999; Wimmer & Traunmüller, 2002; Warren & Myungsin, 2007; Venugopal & Suryaprakasa Rao, 2011; Pfeffer & Sutton, 2013)

There has been intense research originating from failures of good practices adoption in various contexts (Goodman et al., 1979; Klein & Sorra, 1996; Pfeffer & Sutton, 2013), most of which is in the context of the private sector. Until recently, innovation research in the public sector was relying on the private sector insights. However, these insights could not be fully applicable to the public sector and do not account for its peculiarities (Hartley, 2005). In particular, there is a difference in the drivers of the innovation. While for the private sector innovation contributes towards the creation of competitive advantage, public sector innovates in order to increase the public value provided (Moore, 1995). Moreover, there is a difference in the domains of operation of the private and public sectors. The presence of a multitude of different actors involved in and affected by the innovation process presents the challenges for the social innovation (Contini & Lanzara, 2008), and they are often underestimated. In the case of the public sector, additional complications in social innovation result from the complex social context that the public sector constitutes (Hartley, 2005). To summarize, there is a lack of research devoted particularly to the public domain. Researchers agree that understanding of the process of innovation and its implementation is far from being complete and that the full impact potential of innovations is not being reached. The proper assessment of the innovation efforts (impact assessment) is a challenge on its own, and needs to be addressed to help decision makers to have clear objectives that are supposed to be achieved by the adoption innovation and structure the social innovation process accordingly.

Impact Assessment

Impact assessment (IA) could be defined as a process of systematic, evidence-based analysis of the likely economic, social, and environmental impacts of intervention by public authorities (European Commission, 2015). It is meant to be a part of policy (say, innovation) design

process that contributes to making the potential impacts of the discussed policy known to the public and the decision-makers. In doing so, the IA is not expected to substitute for the political judgement by presenting a definitive solution or final recommendation, but rather to explore the complex considerations that may result from the policy in question and inform the decision-makers about them.

Use of Impact Assessment in European Union

As such, the IA creates a knowledge repository on the outcome of potential policies (innovations) for decision makers and the public to develop effective strategies, design associated policies and make informed decisions. Impact assessment is also regarded as a communication tool, since the guidelines on Communication on general principles and minimum standards for consultation require consultations with involved stakeholders and interested parties that are expected to bring useful information for the analysis to the table by way of knowledge-based, sometime model-based, discussions on the topic (European Commission, 2002).

The increasing interest in impact assessment activities in European policy making can be traced back to the Lisbon Strategy of 2000 where the European Union set itself the goal of becoming the most competitive and dynamic knowledge-based economy in the world. The use of impact assessment tools and methods for policy planning has become widespread in OECD countries over the past years (Renda, 2006). This development is part of the European strategy for Better Regulation with the goal to reduce obsolete and “unnecessary” rules and instead increase the knowledge base for law making (OECD, 1997) and to enforce the principle of subsidiarity. In the Commission, the submission of policy proposals for impact assessment is generally considered the way to achieve a better knowledge base for new regulations. A sign of increased interest to lead the assessment procedures is the establishment of an Impact Assessment Board (IAB) in 2006. Although the policy assessments are becoming more frequent, the quality of the

assessments performed until 2006 had been severely questioned in a number of ways (EEAC, 2006; Lussis, 2004; Renda, 2006; Wilkinson et al., 2004) and seem to remain so thereafter.

Barriers and constrains of Impact Assessment

To perform a proper impact assessment takes at least two years, as several parts of the assessment process are time consuming – formulation, organization, communication and reporting. Moreover, there are well-grounded reasons for such long time – IA is far from an easy task. For once, it needs to analyse economic, social, and environmental impacts that are proven to be harder to represent as compared to the impacts on the physical environment (Lee, 2006). In part, this is true because economic, social, and environmental domains are complex and dynamic. The assessment would consult many disciplines to gain relevant data and would call for incorporation of different stakeholders' contributions. Moreover, the expected impact may manifest not in the short, but in the long time horizon, requesting for the tools that are able to assess the development of complex problem in complex and dynamic domains.

Comparative studies show that impact assessment work at the moment is primarily a phenomenon at the EU level although it is developing at a fast pace in several states such as UK, Netherlands and Denmark. The pattern of IA regulation on the national level is scattered. There is no apparent divide between West/East European or old/new member states as far as formal IA regulations and institutional capacity are concerned. Moreover, the quality of the Commissions assessments is regarded to be low, as expressed both internally and externally. Policy assessments appear under several different, partly overlapping, activities and concepts which make orientation in the field complicated. Regulatory Impact Assessment (RIA) covers a general structured framework of principles for how to investigate possible outcomes of one, or a range of policy options. General rules for ex-ante assessment of new legislation exist in many states, although the degree of cohesion, scope and depth of the activities vary greatly. A definition of a good RIA is one that considers a very wide range of impacts (Mandelkern,

2001). Special regulations about Sustainability Impact Assessment (SIA) are common in many countries. It is also common that RIA rules particularly specify sustainability principles for the assessments. The review of EEAC which has a main focus on sustainability aspects of the assessment work, points to the most significant problems: Socio-economic impacts of environmental policies are subject to more detailed scrutiny than the environmental effects and the framing is too restricted (EEAC, 2006). When the lead departments drive the assessments, the concerns of other sectors and alternative policy options are sometimes neglected. The isolationistic ways of working in the Directorate-Generals and even rivalry between them is often described as an obstacle for effective co-operation, resulting in sub optimal administration and policy making (Cini, 1996). There is a domination of numbers as ‘hard’ forms of analysis, such as financial cost-benefit analysis prevail over qualitative approaches. There is a sceptical attitude towards employing modelling tools among many practitioners. Among the arguments against modelling are that the processes are too complicated, not transparent enough and the belief that informed decision-making is better founded on expert judgment. The core of this question might concern a “cultural” difference between researchers’ and practitioners’ way of approaching a problem – especially practitioners in highly politicized administrations. Although a reluctant attitude towards modelling tools can be found in member states and in the EU administrations, the strong trends towards more knowledge-based regulation also evoke interest in such tools. Most administrations in Europe are at the moment taking, or are at least considering taking, measures to improve their regulatory practices in which IA plays a central role. This situation makes an introduction and application of dynamic perspective, in particular System Dynamics methodology, very timely and called for.

Need for dynamic perspective

New insights from exciting theories, System dynamics for IA

Effective problem solving implies that one does not “just” predict the future development of a system. One must identify the underlying causalities that will bring about that development and modify those causalities through effective policy design (innovation) and implementation with the intent to change course. In the “Impact Assessment Guidelines” of the Commission, it is claimed that “You need to establish the ‘drivers’ – or causes – behind the problem (how particular factors lead to the problem) and the ways in which these different drivers influence one another directly or indirectly” (European Commission, 2006, p.17). To that end, one needs a dynamic perspective and a fundamental understanding of the structure underlying the dynamics, i.e. a causal theory, of the structural origin of the development over time. Only based on such a structural understanding of the problem at hand (the unfavourable development), is it possible to identify new policies (structural modifications) designed to modify the dynamics and set it on a favourable course.

Even though scholars have developed theories explaining the low rates of successful innovation adoption and outlining important factors causing such findings, these lessons are not easily transferred to practice due to the complexity of the implementation process (Klein and Sorra 1996). There are challenges arising from our poor understanding of the complexity of structures underlying innovation and implementation processes. Such complexities include the development of resources over time and their influence on performance (Warren, 2005; Repenning, 2002; Bianchi & Navarra, 2013) as well as the interrelationship between variables that form non-linear feedback loops. As scholars have demonstrated, cognitive limitations prevent the proper assessment of the behaviour resulting from the interactions of feedback relationships in complex systems (Morecroft, 1983; Diehl & Sterman, 1995; Sterman, 2000; Sterman et al., 2007).

For instance, in the context of innovation, Repenning (2002) shows that system thinking and a dynamic perspective allow us to uncover counterintuitive insights that complement and enrich the understanding of the innovation process. His work also shows similarities in the theories describing the determinants of successful innovation implementation. *Figure 1* depicts the three feedback loops identified by Repenning (2002) in innovation theories:

- ❖ Reinforcement loop – stating that the effort allocated to the innovation implementation produces the results, which will in turn rise the commitment to innovation which will promote an increase in the effort allocated to the innovation (see R1 in *Figure 1*).
- ❖ Diffusion loop – as in the first loop, the effort allocated to the innovation implementation produces the results; the results will be noticed and linked to the effort that was input into the innovation, thus, rising the commitment to the innovation, which will prompt further allocation of resources towards the innovation (see R2 in *Figure 1*)
- ❖ Normative pressure loop – states that there is a certain managerial effort placed into maintaining manager’s commitment (set by manager’s goal for commitment). If the gap between the commitment to the innovation and the goal for commitment widens, the normative pressure for managers will increase, and if it narrows, the pressure will decrease (see B1 in *Figure 1*).

Through the use of the quantified version of the model described above, it has been possible to gain new and counterintuitive insights about how the system works, impossible to appreciate from studying the original theories. These insights are summarized by Repenning (2002) in three recommendations:

- Managers need to be prepared to maintain their commitment to the innovation long enough to achieve results and pass the threshold of motivation
- Managers need to focus their efforts on reaching the motivation threshold, and not on reaching early results

- Managers should be wary that early good results are not prerequisite to innovation adoption success

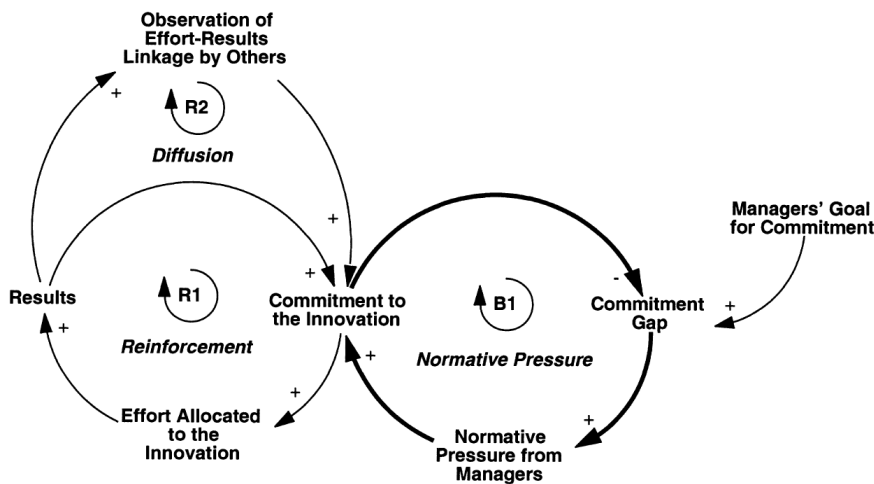


Figure 1: Positive loop of reinforcement R1 and of Diffusion R2, negative (balancing) loop of normative feedback B1, adopted from Repenning (2002)

Due to the need to consider complex problems that act in complex domains over long time horizons there is a call for methods that emphasis long term. This is clearly realized by the European Commission, stating that “We should make policy choices that ensure that our various objectives are mutually reinforcing. Actions that promote competitiveness, growth and jobs, as well as economic and social cohesion and a healthy environment reinforce each other. These are all essential components of the overarching objective of sustainable development, on which we must deliver.” (European Commission, 2006). System dynamics offer a way to accomplish such an assessment by way of modelling, simulation and analysis in complex domains. The transparent, graphical, interdisciplinary articulation of problems and policies facilitates knowledge transfer assisting institutionalization of impact assessment. Introduction of a tool that can ensure reasonably good and robust quantitative assessment quality (instead of currently applied less rigorous, qualitative methods or “common sense”) will greatly improve the present standard. Impact assessment is policy driven, it focuses on examining whether the impact of major policy proposals is sustainable and conform to the principles of

Better Regulation.” (EC 2002, p. 3). System Dynamics is a policy-oriented approach that can be applied to address comprehensive trade-offs in complex domains in a transparent manner emphasising simplicity as an end result.

A good example of application of system dynamics to policy assessment and design could be a Threshold 21 (T21) model. This system dynamics model has been developed by Millennium Institute that has applied the model for comprehensive development planning purposes in more than 20 developing and developed nations. T21 comprises component models of the economic, the social and the environmental sectors of such nations. It was highly regarded by the Head of the UNDP Capacity Development Group, Terrence Jones, in the 2005 report. Threshold 21 model was found to be appropriate due to its explicit analysis of the economic impact of social and environmental variables and vice versa.

With that in mind, this research aims to identify what insights dynamic perspective can bring to the innovation theories in public sector and how could simulation assist the policy makers in the impact assessment of innovation-driven policies.

Research questions

- What counterintuitive insights a dynamic perspective can bring to assessment of innovations into the public sector?
 - What pitfalls and opportunities could be uncovered by dynamic, feedback view
 - What key resources could be identified and build-up for the successful adoption of innovations in the public sector
- How the use of computer simulation can support the impact assessment of innovation in the public sector?

Methodology

This research uses a deductive approach to explore potential contributions of dynamic perspectives to social innovation in the public sector. Theories in the literature are used to understand, analyse, and explain empirical case study using system dynamics as part of the dynamic performance management analytical approach to address the social innovation with a dynamic perspective.

Dynamic performance management is combination of system dynamics and performance management (Bianchi, 2016) that focuses on the complex relationships driving performance outcome in the private and public sector. Dynamic performance management uses the strength of system dynamics to analyse the causes of behaviours over time to analyse why organization performance diminishes and to identify ways for improve it.

System dynamics is computer simulation modelling approach created by Jay Forrester (1961) to improve the performance of industrial systems. System dynamics is based on the assumption that the behaviour of complex systems can be understood by analysing the feedback loop relations between their variables (Richardson, 2011). Feedback relationships are circular causalities where cause influences consequence, but also the consequence influences the original cause (Senge, 1990).

Helpfulness of system dynamics is justified by its ability to deal with important characteristics particularly important for social innovation in public policy: their complexity and dynamics over the long time horizon, need to assist decision makers by knowledge building and communicate with stakeholder's, encouraging their involvement.

Social innovation and its impact assessment is complex because they have to account for many different variables (detail complexity) of many different types (social, economic, technical). Moreover, these variables are interrelated which each other in linear and non linear ways (dynamic complexity) (Senge, 1990). It is particularly the dynamic complexity that gives rise

to the other challenging characteristic, because initial assumptions change and evolve over time depending on how other variables have developed (Warren, 1999). Delays, spread across a system, make the root cause of a problem nearly inaccessible, and prevents one to identify the timing and dosage of effective interventions. It takes a structural (fundamental) understanding of such systems to effectively address associated problems.

Successful interventions in such systems are typically aimed at reinforcing the significance of favourable components and attenuating the significance of less favourable ones. System dynamics supports the analysis by: i) providing an analytical framework to represent, understand and explain the development of resources over time (Warren, 2005), and ii) explaining complex behaviours with computer simulations. System dynamics assumes that understanding of how resources have behaved over time fosters the explanation of system's performance history (Warren, 2005).

Moreover, analysis performed is supported by computer simulations that help policymakers to identify unexpected and counterintuitive behaviours that may occur during the social innovation, enriching the impact assessment. Experiments have shown that decision makers face troubles in understanding and predicting the behaviour resulted from the interactions of many feedback relationships in complex systems (Sterman, 2000; Sterman et al., 2007; Diehl & Sterman, 1995; Morecroft, 1983). For this reasons, systems dynamics literature has suggested that computer simulation models can enhance decision makers understanding of complex problems and improve the performance of their decisions.

Research outline

In this research, a PHAPI approach will be followed to structure the narrative of the work. The PHAPI stands for:

P – Problem – Chapter 2 of this thesis, where the problem that the case study is addressing is identified and explored

H – Hypothesis – Chapter 3 of this thesis, where a hypothesis is ventured of why the problem described before occurs

A – Analysis – Chapter 4 of this thesis, where analysis is presented, dealing with the projections of what would happen if we do nothing, if the problem describes is left to develop as it will and what situation is framing the problem

P – Policy – Chapter 5 of this thesis, where the solution is presented to the identified problem as well as how that solution intends to tackle the problem

I – Implementation – Chapter 6 of this thesis, where the way of delivering the policy, hence, its implementation is discussed

The work is concluded with the conclusions chapter, Chapter 7, where the research results are summarized and discussed.

Chapter 2 – Problem (What?)

Increase in chronic health care expenditures

Chronic disease and healthcare costs in Europe and world

Chronic diseases are the main cause of disability and mortality in the world, and represent a global health emergency due to the increase in frequency and complexity that has been occurring in recent years. Chronic diseases is a large group of diseases, including heart disease, stroke, cancer, diabetes, chronic respiratory diseases, etc., but also mental illness, musculoskeletal and gastrointestinal disorders, vision and hearing defects and genetic diseases. Chronic diseases may originate at a young age, but will take decades before they occur clinically. Given the long course, they require long-term care, but at the same time, they require different prevention methods. At the base of the most chronic diseases lie common and modifiable risk factors, such as unhealthy eating, tobacco consumption, alcohol abuse and lack of physical activity. These causes can generate so-called intermediate risk factors, namely hypertension, high blood sugar, excess cholesterol and obesity. Then there are risk factors that cannot be modified, such as age or genetic predisposition. Taken together, these risk factors are responsible for the majority of chronic disease deaths worldwide.

Chronic diseases, however, are also linked to implicit determinants, often defined as "causes of causes", a reflection of the main forces that drive social, economic and cultural changes: globalization, urbanization, progressive aging of the population , environmental policies and poverty.

Previously, chronic diseases were considered a problem of the rich population. Today we know that both poor and rich people are suffering from chronic conditions.

The economic implications of such diseases are serious. Chronic diseases severely reduce wages, savings, workforce and work productivity, as well as increasing early retirement, work turnover and disability.

The management of these diseases is increasingly affirming its importance in terms of economics and medical needs. The increase in prevalence of chronic diseases has made it difficult to maintain high quality standards of healthcare and the pursuit of the economic sustainability of healthcare services.

In fact, several studies show that as the number of chronic patients increases, the rate of adverse events also increases. For example, the rate of hospitalization for conditions that could be prevented with a good primary care service increases with the increase in prevalence of chronic diseases and the total costs of healthcare are rising greatly.

Health systems in most European countries are facing new challenges, due to the increase in chronic diseases, the aging of the population and the constraint to meet the budget allocated for the management of these diseases. Overtime, chronic diseases have become real public healthcare problems in the most developed countries, being among the main causes of mortality.

All these factors explain the reason why new models of management of chronic patients are continually studied with the dual purpose of improving the continuity of care for patients and guaranteeing greater economic sustainability.

Chronic healthcare costs in Lombardy region

The historical trend in healthcare spending shows a general trend of increase, which was only stopped in 2013, mainly due to the reduction in hospital admissions.

In Lombardy, 30% of the population (about 3.2 million people) is affected by one or more chronic diseases (including: Diabetes, Hypertension, Cardiovascular Malattie, COPD, etc.)

whose treatments account for more than 75% of health expenditure of the Region estimated at around 10 billion euros a year (Fait et al, 2016).

For chronic diseases, spending increased by 36% from 2005 to 2013. This increase being most relevant for patients with 2, 3, 4 or more co-morbidities respectively: + 22%, + 65%, + 143% (Figure 2) (Lombardy Region, 2015).

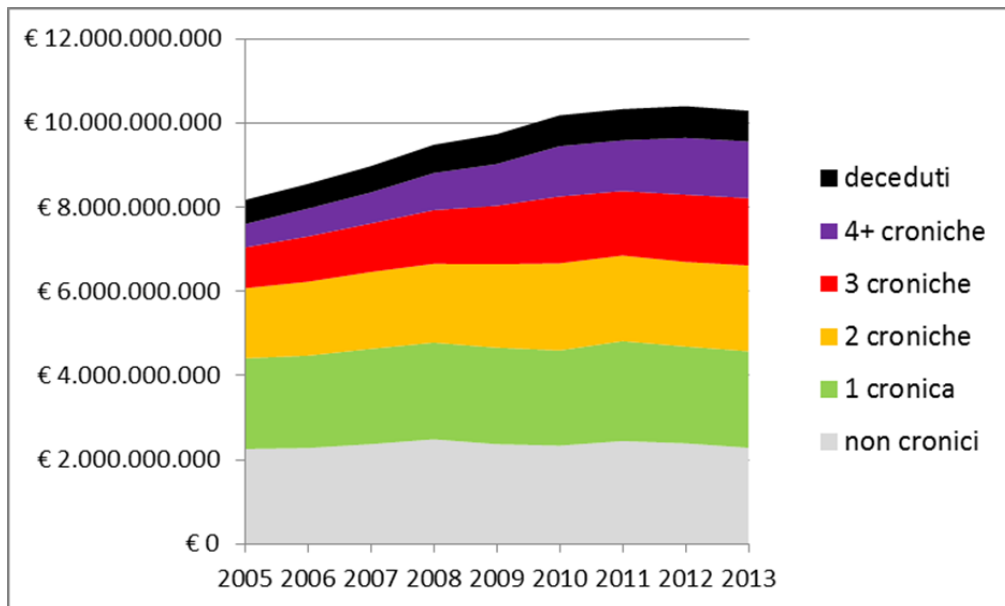


Figure 2: Historical total chronic healthcare costs 2005-2013 (pharmaceutical, outpatient and hospital) Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

It must be emphasized that the increase in health care costs is due to the increase in the number of chronic patients, especially the multiple-chronicity patients, given that the per capita health expenditure of chronic patients has decreased (Figure 3).

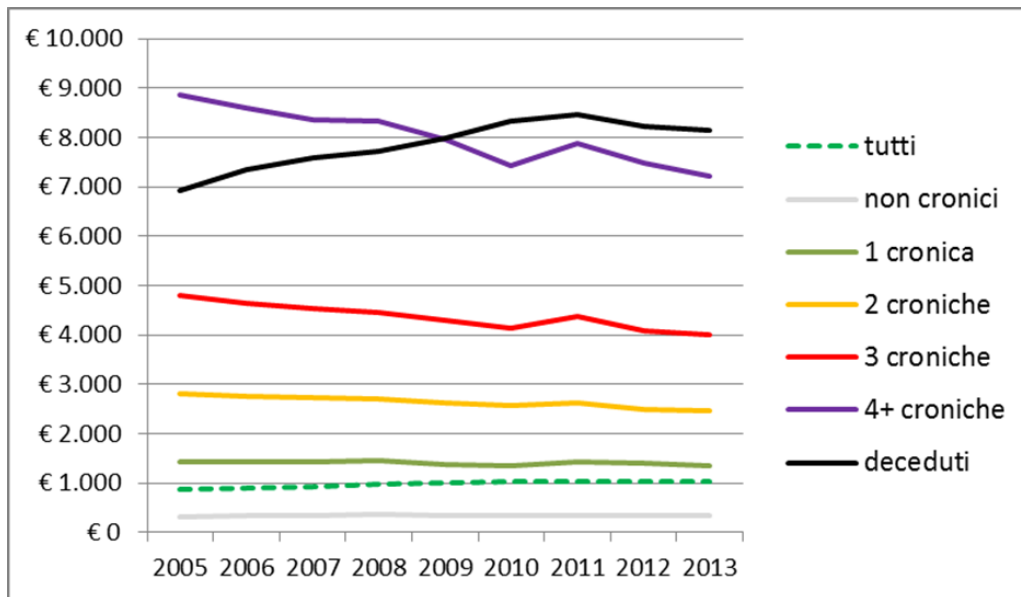


Figure 3: Historical chronic healthcare costs per capita 2005-2013 (pharmaceutical, outpatient and hospital). Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

Chapter 3 – Hypothesis (Why?)

Reasons for the increase of chronic patients

Aging population

The Lombardy Region, with about 10 million inhabitants, represents approximately one sixth of the Italian population. In Lombardy there are about 3.5 million chronically ill people, many of whom are over 65 year old; 75.6% of them suffer from one or more pathologies, while 48.7% are affected by two or more pathologies. The situation is even more serious if we consider those who are 74 or more years old, with 86.4% affected by one or more pathologies and 68.1% affected by two or more pathologies.

In Lombardy, people suffering from chronic diseases constitute about 30% of the population of the Region, a relatively small portion now, but destined to increase over the years. In this group of patients the number of people in conditions of socio-economic chronicity (non self-sufficient elderly people, people with disabilities, people suffering from substance dependency, etc.) is increasing, currently estimated at around 600.000 people. If we consider that chronic diseases in Lombardy account for more than 70% of global health expenditure, we can understand how the issue is crucial for the regional administration.

The ISTAT demographic data for the Lombardy Region (*Figure 4*) indicates an increase in the total population of the region in the last 10 years with a projection of further increase in the coming years and a progressive aging of the population.

The old age index (determined by the ratio between the number of people aged 65 and over and the number of subjects younger than 15 years.) of the Lombard population, which is currently around 140%, will exceed 200% in 2030.

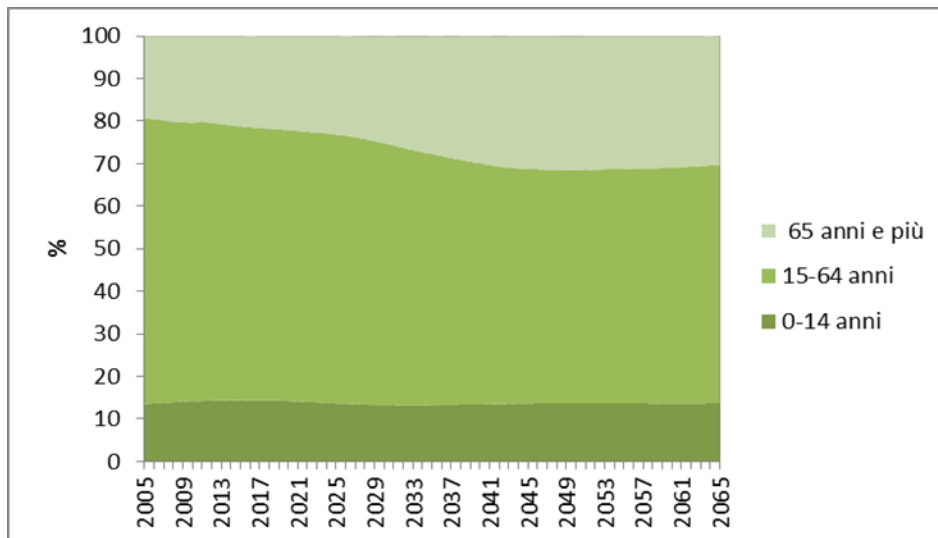


Figure 4: Demographic projections 2005-2065 of the Lombardy Region population Adopted from: ISTAT data processing, Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

This continuous aging of the population is one of the determinants of population conditions in terms of health.

In Europe the life expectancy at birth is growing by about three months a year. Based on 2014 data, average life expectancy is reaching 80.9 years, an increase of about 7 years compared to 1990. Among the 28 EU member countries, Spain, France and Italy are those which registered the highest values.

As can be seen in (Figure 5) significant differences still persist at the European level, although this gap has been considerably reduced in recent years. If the difference in life expectancy between the longest-living and shortest-living countries was about 16 years at the beginning of the 1990th, this distance has been reduced on average to 14 years between 2009 and 2010 and to 8.8 years in 2014.

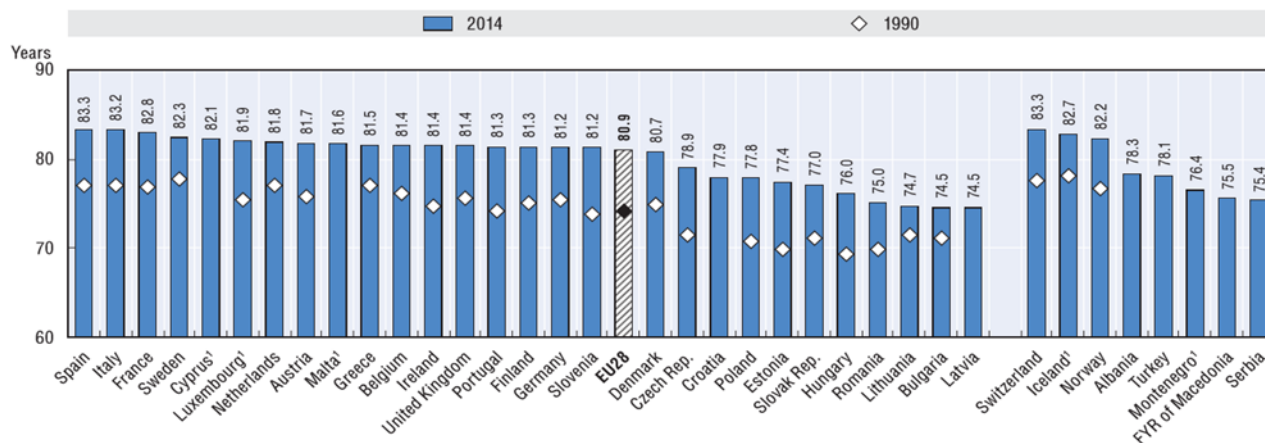


Figure 5: Life expectancy at birth, 2014 and 1990. Adopted from: European Commission (2016)

Another measure referred to for analysing the aging population trends is represented by the 65-year life expectancy. Also in this case since the beginning of the 2000s a general convergence among EU countries towards similar values was detected for this indicator. This indicator has gone from an average value of 15.7 years in 1993 to 18 years in 2011, and then risen to 20 years in 2014. This growth also seems to continue its trend, with Eurostat estimating an average increase of a further 4.7 and 4.5 years respectively for men and women from 2014 to 2060.

Other important indicator for assessing the health status of a population is mortality rates standardized by age. Spain, France and Italy are best in the list, with 848, 867 and 878 deaths per 100,000 inhabitants, while the worst is Denmark, with 1074 deaths. In this regard, the European Community has launched the Health 2020 program, which among its various objectives also includes the average annual reduction of at least 1.5% of the premature mortality rate associated with the four main non-communicable diseases (NCDs) (cardiovascular diseases, cancer, diabetes and chronic respiratory diseases).

The World Health Organization defines chronic diseases as "long-lasting and generally slow-moving diseases". Chronic diseases are responsible for the greatest number of deaths in the world and in Europe. In order to quantitatively express the impact of a disease on health, a

particular unit of measurement is used, developed by the WHO: the "disability-adjusted life year" (DALY). This indicator is used to quantify the impact on the population of premature death and disability by combining both of these conditions into a single indicator. The DALY indicator relies on the assumption that the most appropriate measure of the effects of chronic disease is the time for which a person is disabled by the disease or time lost due to premature death. DALY is equal to the sum of the years of life lost because of an early death and those experienced in illness rather than health. If, for example, DALY assumes a value equal to one, this equates to one year of life in good health conditions that was lost due to the illness.

Table 1 shows on the one hand the DALY indicator, and on the other, the total number of deaths caused by non-communicable diseases and their percentage in relation to the total in 2005, in Europe. (Singh, 2008)

In the same year, cardiovascular disease caused more than 5 million deaths, or 52% of the total, with a DALY value of 34.42 million.

Table 1: Spread of diseases and deaths from non-communicable diseases in Europe by cause (2005). Adopted from: Singh, 2008.

<i>Groups of causes</i>	<i>Disease burden</i>		<i>Deaths</i>	
	<i>DALYs (millions)</i>	<i>Proportion from all causes (%)</i>	<i>Number (millions)</i>	<i>Proportion from all causes (%)</i>
<i>Selected noncommunicable diseases</i>				
Cardiovascular diseases	34.42	23	5.07	52
Neuropsychiatric conditions	29.37	20	0.26	3
Cancer (malignant neoplasms)	17.03	11	1.86	19
Digestive diseases	7.12	5	0.39	4
Respiratory diseases	6.84	5	0.42	4
Sense organ diseases	6.34	4	0	0
Musculoskeletal diseases	5.75	4	0.03	0
Diabetes mellitus	2.32	2	0.15	2
Oral conditions	1.02	1	0	2
<i>All noncommunicable diseases</i>	<i>115.34</i>	<i>77</i>	<i>8.21</i>	<i>86</i>
<i>All causes</i>	<i>150.32</i>	<i>100</i>	<i>9.56</i>	<i>100</i>

Source: Adapted from Singh 2008.

In 2005, non-communicable diseases caused 86% of the 9.6 million deaths and the DALY of these diseases represented 77% of the overall DALY.

Overall, the main risk factors for chronic diseases are hypertension, tobacco consumption, high cholesterol, low consumption of fruit and vegetables, overweight and obesity, a sedentary lifestyle and alcohol abuse.

Table 2 shows the number of deaths and the DALY indicator attributable to the various risk factors. It is noted that, for example, hypertension caused 7.62 million deaths worldwide in 2001 (13.5% of total deaths).

Table 2: Diffusion of diseases and deaths attributable to common risk factors, in absolute values and in percentages with respect to the DALY / total deaths in the world. Adopted from: processing Lopez et al. 2006.

Chronic disease risk factors	Low- and middle-income		High-income		Worldwide	
	Deaths (millions)	DALYs (millions)	Deaths (millions)	DALYs (millions)	Deaths (millions)	DALYs (millions)
High blood pressure	6.22 (12.9%)	78.06 (5.6%)	1.39 (17.6%)	13.89 (9.3%)	7.62 (13.5%)	91.95 (6.0%)
Smoking	3.34 (6.9%)	54.02 (3.9%)	1.46 (18.5%)	18.90 (12.7%)	4.80 (8.5%)	72.92 (4.7%)
High cholesterol	3.04 (6.3%)	42.82 (3.1%)	0.84 (10.7%)	9.43 (6.3%)	3.88 (6.9%)	52.25 (3.4%)
Low fruit and vegetable intake	2.31 (4.8%)	32.84 (2.4%)	0.33 (4.2%)	3.98 (2.7%)	2.64 (4.7%)	36.82 (2.4%)
Overweight and obesity	1.75 (3.6%)	31.52 (2.3%)	0.61 (7.8%)	10.73 (7.2%)	2.36 (4.2%)	42.25 (2.8%)
Physical inactivity	1.56 (3.2%)	22.68 (1.6%)	0.38 (4.8%)	4.73 (3.2%)	1.94 (3.4%)	27.41 (1.8%)

Source: Adapted from Lopez et al. 2006.

Tobacco consumption remains the most significant cause of death in industrialized countries. In Europe, since the end of the 1970s, the number of smokers has decreased from 45% to 30%. However, in Eastern European countries, and particularly in the Baltic countries, smoking has continued to increase, particularly among young people and women.

Alcohol abuse causes chronic diseases such as addictions, vascular diseases (eg hypertension), cirrhosis and various cancers. Of the global DALY, 4.7% is caused by alcohol-related illnesses. The share of Eastern Europe is significantly high, 10.7%. (Jamison, 2006)

Overweight is defined by a body mass index (BMI or kg / m^3) of 25 or more. Persons with a value of 30 or more are classified as obese. According to this definition, at least a third of people living in Europe are considered overweight. The older age groups show a higher prevalence (up to 57% of men in Western Europe are between 70 and 79 years). However, an increasing number of European children are overweight: a study by the London Obesity Task Force has shown that 18% of children in Europe are overweight.

The contribution of chronic diseases to overall mortality varies between different European countries. However, with some diseases it is not known how much of this difference is due to the disease itself or how much is due to the different coding of the health workers in the various countries. (Pomerleau et al, 2008.)

Cerebrovascular diseases accounted for approximately 15% of all deaths (11% for men and 19% for women) and about 7% of total illnesses (6% and 8% respectively) in 2002 in Europe. However, the mortality attributed to this chronic condition varies between European countries. Mortality rates for diabetes also vary considerably. Age-standardized mortality rates in 2004 ranged from 4 per 100,000 in Ukraine, Belarus and Greece and 23 per 100,000 in Portugal, 31.8 per 100,000 in Israel and up to 68.6 per 100,000 in Armenia. However, it must be emphasized that these data can be underestimated since diabetes is not always reported as the underlying cause of death, particularly for older people.

Chronic obstructive pulmonary disease is also one of the major causes of premature death in Europe and, as for other diseases, its contribution to mortality differs between European countries. In 2004, this disease recorded values of 6.5 deaths and 91 DALY per 100,000 in Latvia, while in Kyrgyzstan recorded 96 deaths and 1,363 DALY per 100,000.

The prevalence of mental disorders is high in Europe. (Kessler et al, 2007.) Dementia among citizens aged 65 and over in 2000 was estimated at 6% in Eastern Europe and 8% in Western Europe (Wimo et al. 2003). More recent studies have estimated the prevalence of dementia among those aged 60 and over at 3.8% in Eastern Europe and 5.4% in Western Europe.

The WHO has estimated that one in five people develop depression in their lives and every year 33.4 million Europeans suffer from depression. In 2004, the age-adjusted DALY rate ranged from 620 to 1,340 DALY per 100,000. The lowest rates were in Spain, Greece and Portugal, with DALY rates of less than 700 per 100,000. The highest estimates were for Finland, Israel, Slovenia, Belgium and France, with rates above 1,200 DALY per 100,000. Suicide resulting from depression is the third most common cause of death among young people in Europe.

Future projections of mortality and disease spread show how chronic diseases will continue to be the major cause of mortality and disability in high-income countries. The share of DALY associated with chronic or non-communicable diseases in high-income countries is expected to grow from 86% in 2005 to 89% in 2030.

The forecasts for specific chronic conditions vary. For example, WHO predicted fewer deaths (-1%) and DALY (-17%) for cerebrovascular diseases for both sexes and for all age groups between 2008 and 2030.

Deaths directly attributable to diabetes are expected to grow from about 166,000 in 2009 to over 209,000 in 2030. The growth of type 2 diabetes is partly a result of the rising rate of obesity, especially among children.

The deaths in Europe from chronic obstructive pulmonary disease are expected to grow by about 20%, from 248,000 in 2008 to more than 300,000 in 2030. (Pomerlau et al, 2008.)

The condition that is expected to grow dramatically is dementia. In Europe, the number of those aged 60 and over suffering from dementia is estimated to grow from 7.7 million in 2001 to 10.8

million in 2020. Without effective prevention and treatment, this condition is expected to double up to 15.9 million in 2040. The increase varies between 31% and 51% in the different regions.

Chapter 4 – Analysis (What happens if we do nothing?)

Lombardy Region projection for chronic health care costs

In the next years, it is reasonable to expect a further increase in the number of people with chronic diseases, in particular the in patients with multiple chronic diseases, as is suggested from the projection of the Lombardy Region (*Figure 6*).

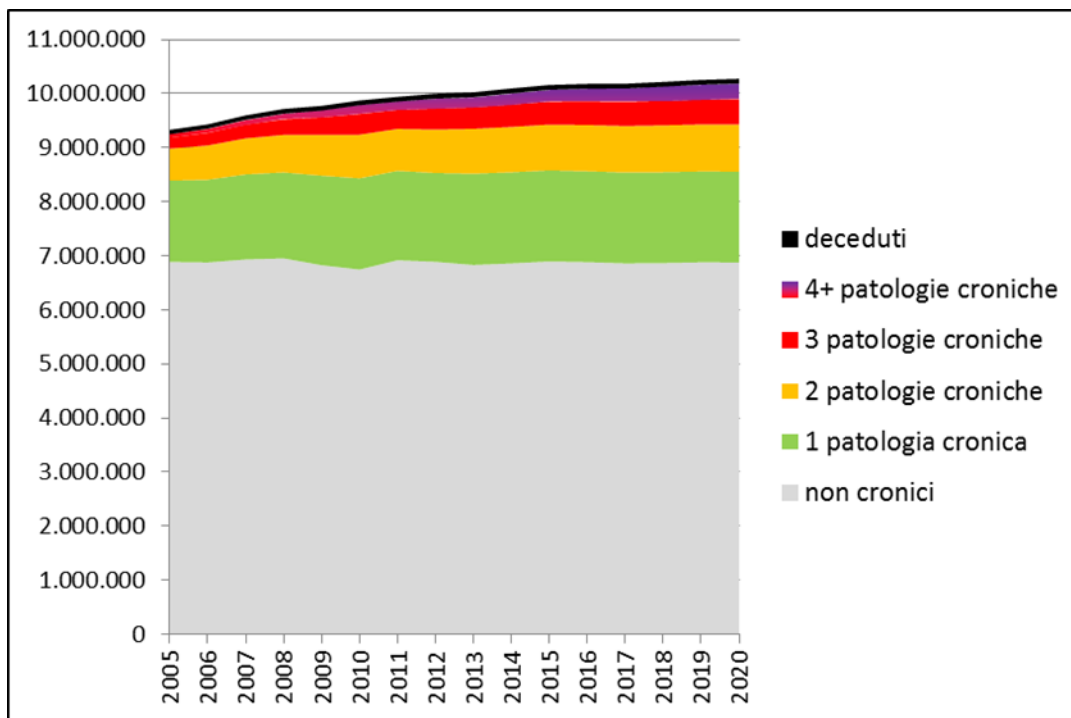


Figure 6: Historical series of frequencies of subjects with chronic diseases 2005-2013 and projection 2014-2020 (BDA data). Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

Although a simultaneous reduction in per-capita spending can be expected, it is likely that this will be reduced less rapidly than has been observed in recent years (*Figure 7*).

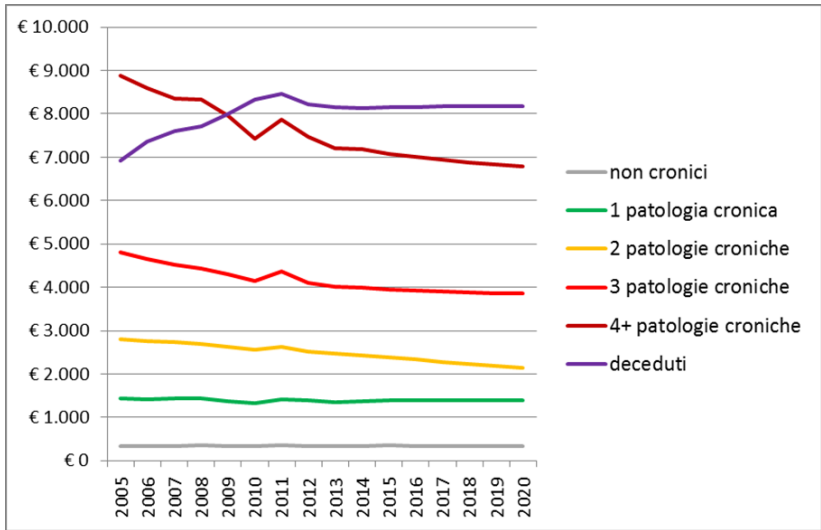


Figure 7: Historical chronic healthcare costs per capita 2005-2013 and forecast 2014-2020

Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

As a result, total spending is likely to increase over the next few years, mainly for the management of chronic pathological conditions, if no changes are done to the way the chronic disease care is managed.

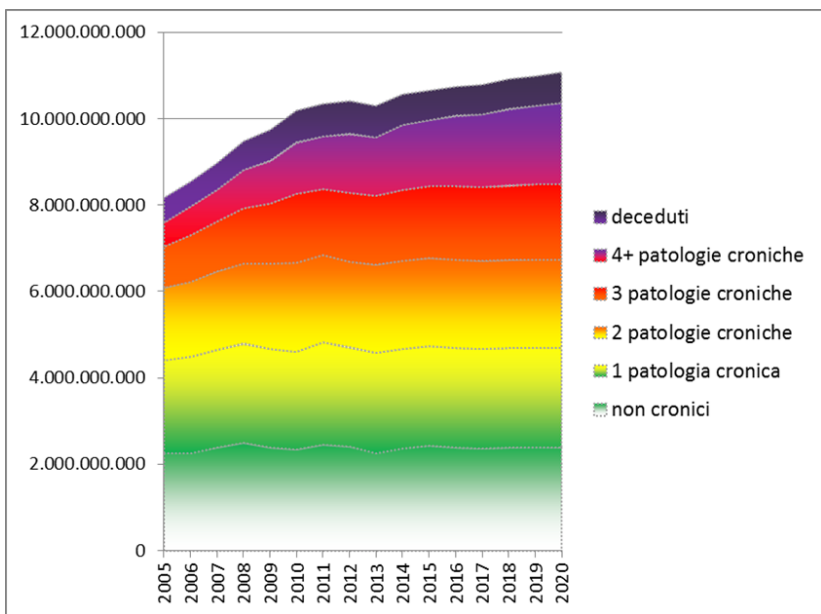


Figure 8: Historical total chronic healthcare costs 2005-2013 and forecast 2014-2020

Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.

Moreover, chronic diseases have economic repercussions in other sphere affecting not only health, but also social and financial wellbeing.

Increased chronicity can have a negative impact on the labour market. Some evidence indicates that the likelihood of employment decreases with chronic disease acquisition and the progression of the disease. That increases the likelihood of unemployment / absenteeism and the likelihood of retiring early from work.

A research published by Montanelli&Turrini in 2006 analysing the data of three Lombardy Region districts (Monza, Mantua, Val Trompia), highlighted how the costs for managing chronic diseases paid by households could amount to 32% - 51% of their total expenditure (Montanelli&Turrini, 2006). The same work also reported that the public funds that get spent in relation to chronic disease are representing a significant portion of the total spending of various supporting institutions. For example, INPS (civil disability pensions, accompanying allowance) spends 37% - 44% of total expenditure on chronic disease related payments, the Region (Health Fund, Social Security Fund) spends 6.5% - 23% of total effective expenditure, and local authorities 0.2% - 6.3%.

Triple Aim

The crisis of health systems and the need to implement the Triple Aim approach

Since the end of the 1980s, in an era marked by profound demographic changes (the aging process of the population, the presence of large migratory flows, the epidemiological transition in the prevalence of acute diseases and chronic diseases), the European health systems have been subject to successive waves of reforms. The attempt of these reforms is to reconcile often opposing needs. On the one hand, the containment of costs and the recovery of efficiency and, on the other hand, the improvement of the quality of services and, particularly, their reorganization to respond to the changing needs of the population. For instance, the reforms advocating for managerialization and administrative competition, the reforms for political and

administrative decentralization, as well as restrictive policies of supply and demand; all tried to reconcile cost with quality. These reforms have led to a widespread phenomenon of hybridization between the health systems of European countries.

In 2008 the effects of the economic and financial crisis and the related austerity policies, hit heavily the countries of Mediterranean Europe, including Italy. In these countries, it is possible to hypothesize that while processes continue progressing following the trends observed in the past two decades, the universalism of health system starts to be questioned. This rethought of the health systems is mainly due to the need for containing public spend. While constraints in the budgets have led to an extension of the use of managerial management tools in healthcare organizations, they have also pushed to adopt policies restrictive of the more incisive demand and supply that in the past. These new policies restrict supply to some extent that relevant sections of the population are cut off of accessing basic services, as was particularly evident in Greece. Similarly, the search for new sources of funding has promoted the return to forms of occupational protection, of an integrative or substitute type, as is happening, in very different ways, in Italy and in Spain.

Among the reformed areas most subject to revision there is decentralization, especially in some of the countries that have gone further in this area such as Italy and partly Spain or, in Northern Europe, Denmark and Norway. These policies focused on the decentralization of more or less extensive powers and responsibilities to lower-level government agencies were based on the belief that decentralized healthcare systems could ensure the achievement of greater efficiency, effectiveness and innovation. Decentralization was also assumed to result in a higher participation of citizens in the health production processes.

However, the need for pursuing common objective in terms of services provided, population health and cost containment is currently challenging the decentralization trend. In particular, the austerity policies linked to the economic crisis are pushing central governments not only to

regain more or less direct control of health spending, especially in the case of those subjects who have not proved themselves able to assure it autonomously as in the case of many Italian regions, but also to direct the use of scarce resources towards shared objectives throughout the national territory.

The economic crisis reduces the growth rates of the economies and increases unemployment, inflation and the number of bankruptcy cases. All this reduces the real income of households leading to a lower quantity and quality of food, a reduction in spending for health and the use of health facilities and a lower expenditure on education. Furthermore, the crisis has an impact on tax revenues, which is reduced, leading to a reduction in government spending on health and education. The final result in the field of health is given by a deterioration of living conditions. Mortality rates increase and life expectancy decreases.

Between 2007 and 2011, in Europe, the incidence of health spending on public spending, which reflects the propensity of a country to invest in health, has decreased somewhat everywhere. This is what emerges from the report "Economic crisis, health systems and health in Europe" published in 2015 by the European Observatory on Health Systems and Policies.

The report analyses the consequences of the economic and financial crisis in Europe since the end of 2007, comparing the repercussions on the health policies of 53 countries. In the 2007-2011 period, 44 of these countries recorded sharp decreases in the incidence of health spending on public spending. This happened, the report notes, mainly in those countries heavily hit by the crisis, with the exceptions of Norway, Denmark and Azerbaijan. Unexpectedly, however, the relationship has improved in countries in crisis such as Cyprus, Estonia, the Czech Republic and Italy.

Over the same period, public health spending per capita in many countries, including Italy, decreased, according to OECD data, at the end of 2012 lower than in 2009. The worst situation was recorded in Greece (-9,0%, the average annual variation of this indicator), Ireland (-3.7%)

and Portugal (-3.3%), countries for which the economic and financial crisis has required important interventions of international support, but also Luxembourg (-5.1%) and Croatia (-3.6%) were in low positions. In the period 2009-2012, the average of the 28 countries of the European Union was -0.6%, with Italy a little worse, -1.1%, in good company of Great Britain (-1, 3%) and Denmark (-1.2%). Also the share of public expenditure on total health expenditure declined between 2007 and 2012 in 24 of the 53 countries examined. In this case, the Italian figure is basically stable, from 78.3% in 2007 to 78% in 2012.

The impacts of the economic crisis in the health care systems call for new approaches that rely on an effective logic to implement better health care models. In response, the Institute for Healthcare Improvement (IHI) developed an approach called Triple Aim targeting at optimizing the performance of the health system by considering three key objectives:

- improving the patient care experience (including quality and satisfaction);
- improving patient health;
- reduction of the patient's per-capita cost.

To achieve this, the Triple Aim approach focuses on three areas: population health, experience of care, per capita cost (see *Figure 9*). These components are not independent of each other and changes in one of them will have an effect on the other two, sometimes negative and sometimes positive. For example, improvements in care can result in increased costs if these improvements are associated with new and more effective technologies or more expensive drugs. On the other hand, eliminating abuse or improper use of therapies and diagnostic tests can lead to both cost reduction and improved results. The situation is however made more complex by the fact that the effects of the actions are delayed over time. Good preventive care may take years to collect results in terms of costs or health of the population.

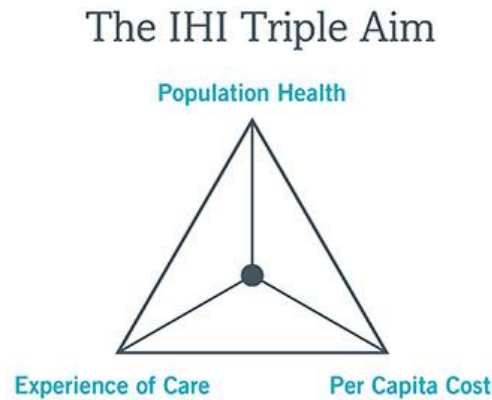


Figure 9: Triple Aim. Adopted from IHI

To date, no one in the majority of health care systems is responsible for all three dimensions of the Triple Aim. For the well-being of the communities and for the health of all patients, there is a need to address all three dimensions of the Triple Aim at the same time.

Obstacles for an effective improvement in the three dimensions are for example, the decisions on the amount of expenditure to be directed to healthcare or what kind of coverage to provide and to whom to provide it. Other relevant complications arise from shifting from a centralized supply to centralized demand, introduction of new technologies with limited impact on results, absent or limited foreign competition to spur domestic changes and a reduced appreciation of knowledge among doctors and organizations, leading them not to optimize the components of the system with which they are more familiar.

Several tools have been set up to try to measure and evaluate the experience of the population from the point of view of the three fundamental components. A complete set of metrics to be used could take into account methodologies that can keep track of the patient's outpatient experience, patient involvement and continuity, and preventive clinical practices.

Measuring per capita costs is still a big challenge; it requires capturing all relevant expenses, indexing them appropriately to the circumstances of the local market and being able to measure current costs in a healthcare system where they could hardly be detectable. The measures used to measure per-capita costs are essentially two:

- the total monthly costs per member of the population;
- the rate of use of hospitals and the emergency department.

Chapter 5 – Policy (How can we prevent this?)

CReG

CReG description

Chronic diseases are a growing problem for the regional health system and so, at the end of 2011, the Lombardy Region has introduced an innovative program called CReG (Chronic Related Groups) in five ASL. CReG was promoted with the aim of introduce continuity of care for chronic patients and reduce the costs of avoidable hospitalizations and disease symptoms worsening by providing an adequate treatment plan and disease management.

The Chronic Related Group (CReG) is a system of classification of the chronic pathology and related tariff enhancement, conceived and developed by the Lombardy Region, which represents the synthesis of the economic and professional resources necessary to remunerate an organic path of care, essential to ensure the basic needs of the citizen affected by chronic pathology. It is based on anticipated knowledge of the needs of the patient, their flexible management that is not restricted to a particular type of service or a specific provider (Lombardy Region, 2015.)

The CReG is therefore:

1. a system of classification of chronic diseases, in categories:

- clinically significant;
- homogeneous for absorption of health resources;
- which also take into account the multi-morbidity;

2. a method of flat-rate remuneration for the care of patients with chronic illnesses.

This program can be identified as an innovative way of taking care of chronic patients. It must guarantee the flow of care with all the extra-hospital services (follow-up, monitoring, therapeutic persistence, outpatient care, pharmaceutical prescription) necessary for a good

clinical management of chronic diseases. It is a new model of patient management that incorporates within it a real economic model for a five-year pilot model of chronic disease management at a primary level of care. The model is based on a concept that can be defined as "personalized medicine", characterized by the provision of a proactive treatment focused on the patient.

The chronic patient management model involves the identification of new operators called CReG providers who are responsible for managing the patient along his entire care path. This is a key aspect of the project: the manager is identified that ensures the continuity of the path and takes charge of patients, interacting with all the actors involved in the management of the disease. In the first phase of the initiative, the patient management bodies were essentially cooperatives of general practitioners, while from the second phase other organizations such as the territorial hospitals included.

The manager or CReG providers must guarantee:

- the definition of a PAI (Individual Assistance Plan) customized to each chronic patient and the patient's adherence to the PAI;
- a Service Centre available 24 hours a day and 365 days a year to facilitate and accompany the patient in the care path;
- telemedicine and tele-monitoring services;
- evaluation indicators;
- patient education;
- assessment of satisfaction of enrolled patients.

Many of these functions, such as the Service Centre or the tele-monitoring service, are actually provided externally to CReG manager, from the so-called technological partner.

CReG initiative was conceived to guide actors to focus on the long term, considering the whole life of the patient. For the payment of a fee, all services, outside the hospital, are required for

the correct clinical and organizational management of chronic diseases. The set of activities and services provided must be specific to each disease (or group of diseases) and targeted to ensure the basic steps of the various care pathways.

The CReG model is based on three pillars, three technological elements:

- Assisted Database (BDA), a technological infrastructure to identify and stratify chronic patients;
- PDTA (Diagnostic Therapeutic Assistance Path), or the standard guidelines to be respected to manage any disease or group of diseases;
- new remuneration system.

The three basic elements above represent the indispensable technological pillars on which new organizational platform was introduced. It allows to identify patients, identify managers and accredit them, assign resources and perform control of the performance of the program.

Assisted Database (BDA)

Correct identification of chronic patients is essential to implement the CReG program. As a solution to this problem, the first technological element listed above arises. BDA (Assisted Data Bank) implemented by the Lombardy Region starting from 2004 was used as the basis for classifying patients according to their characteristics and health needs. The BDA was experimentally established in 2002 at the ASL of Pavia, followed later by the ASL of Brescia, and assumed regional value from 2004 (Lombardy Region, 2015).

BDA is an organized collection of information regarding health and welfare activities provided to each individual citizen, enriched by the information contained in the registry of regional patients and in the archives. The data contained in BDA concerns outpatient activities, pharmaceutical consumption (territorial and so-called File F) and hospital admissions. Using algorithms oriented mainly to tracing chronicity (diabetes, tumours, cardiovascular diseases, respiratory diseases, etc.), which rework the data on consumption, each patient is classified

according to all the diseases for which treatments were received. This information is then processed through certain algorithms and is able to discern the chronic conditions that afflict the patient and their level of complexity. The algorithms are created for each single disease and work within the entire database providing a list of diseases for each citizen.

This methodology collects the relevant health information of a subject and identifies a series of health "profiles" based on the indicators presented above.

PDTA and guidelines

The second pillar is determined by the individual care plan that the general practitioner compiles for the patient. In this way, the general practitioner becomes a health manager of the patient. The PAI, that is the Individual Care Plan, is a summary document of the diagnosis and treatment program that allows the planning of interventions to be adapted to the individual context, based on specific health objectives. The PAI is defined starting from the standard guidelines suggested by the PDTA (Diagnostic-Therapeutic Assistance Paths). The diagnostic and therapeutic care pathways aim to identify the care needs of each chronicity. The procedures for the different types must be shared and standardized at the regional level in order to reduce the variability of the treatments. Chronic patients, individually considered, are widely different from one another and have differentiated levels of demand. However, the care approach defined by the PDTA is an important element of standardization.

In addition to providing a common standard of care, the PAI is an excellent tool for planning the management and monitoring of the path of the patients care, as well as useful tool for communication between all health care providers who are involved in taking care of the patient.

PAI an annual plan that plans all the health services that the patient must necessarily carry out to treat their condition, including visits to the general practitioner, specialist visits, examinations and monitoring. The plan is reviewed periodically and the patient has clear indications on how to monitor his or her chronicity. In order to create a PAI, the doctor in

charge adapts the standardized PDTA to the clinical peculiarities and the assistance needs for the individual patient.

The single PAI is the central tool through which the different professionals involved in the clinical management of the paths share the planning of the activities necessary for the care of the patient.

Service remuneration criterion

Finally, the last fundamental element in describing the structure of the CReG program is its innovative way of remuneration. CReG uses a tariff that represents a predictive "statistical summary" of the expected value of the treatment path of specific categories of chronic patients. The tariff is defined ex-ante on an expected statistical service to be provided but not yet disbursed. The tariffs for the different CReG classes are identified by referring directly to the real costs (pharmaceutical, F-file, outpatient specialist, etc.) that have been observed through BDA. For each of the CReG categories identified, the distribution curves for the costs are analysed and, after the exclusion of anomalous behaviour (outliers), the base rate for that category is estimated and any increase coefficient for additional diseases is added. The value obtained is the rate of the specific CReG class. The estimate of the tariff can be made in a concurrent manner, by evaluating the annual expenditure of subjects who in that year are classified as belonging to a specific CReG class, or in a forward-looking manner, evaluating the year's expenditure following the classification to incorporate the risk of evolution towards more complicated forms.

The CReG tariff describes the valorisation of the typical route, possibly broken down by type of expenditure (pharmaceutical, outpatient, hospital, etc.), of the chronic patient in general.

The remuneration method is one of the fundamental elements that characterize the provision of health system services. The CReG model introduces a "flat-rate" remuneration, assigning an

overall budget to the patient's manager for the patient's care path. In that way, it facilitates the integration between levels of service and makes the care manager responsible.

The "performance" remuneration system is therefore rejected, which is recognized as unsuitable for governing the treatment of the chronic patient, as it tends to segment the flow of services provided to the patient, which are fragmented among the various specialists.

The lump-sum remuneration method, therefore, responds to the patient's continuity of care needs and is consistent with the need for appropriateness of performance and planning of the expenditure required at the systemic level.

A predefined amount of resources (budget) is allocated to the manager subject to reimbursement of the entire treatment plan and not of the individual services. This is a virtual budget that corresponds to the sum of the CReG tariffs for each patient enrolled.

Applying this remuneration method overcomes the fragmentation of the service, provides continuity of care and empowers both the manager and the patient.

The remuneration that is recognized to the manager is made up of the differential value (delta) between the assigned virtual budget and the total costs that is of the health consumptions referring to the periods of actual taking charge.

Technological platform

All three technological pillars are combined in a final element of the CReG initiative: the technological platform. It is an organizational platform that aims to ensure continuity of care to patients by ensuring that the PDTA is followed. The platform must possess some organizational and functional features and must obtain specific accreditation attributes such as the usability by both technical and health personnel, an effective information system and performance measures for assessing the quality of the service offered. The technological platform is mainly used by three actors:

- the general practitioner is the main user; he can enrol new patients, enter relevant medical data, create PAI with the support from the platform and can review and modify existing care plans;
- the Service Centre is able to monitor the number of PAIs created and provide support for tele-monitoring activities;
- a case manager and an analyst who monitor the process and provide support to medical cooperatives in reporting the number of assisted patients to the region.

The strengths of the CReG project can be summarized as follows:

Table 3: The strengths of the CReG

QUALITY OF CARE	SUSTAINABILITY OF EXPENDITURE
<ul style="list-style-type: none"> • improves patient care • improves continuity of care • improves PDATA compliance • improves personalization of care 	<ul style="list-style-type: none"> • improves the forecast of spending scenarios • makes the managing organization responsible for the expenditure • reduces inappropriate and unnecessary procedures and optimizes consumption of health care services

CReG results

Initially, five ASLs were selected to test this new model as a pilot project and to assess whether it could be extended to the whole region based on the results obtained. The five participating ASLs were Bergamo, Como, Milan city, Milan Melegnano 2 and Lecco.

In the first application of CReG the identified pathologies were: chronic obstructive pulmonary disease (COPD), hypertension and ischemic heart disease, heart failure, type I and II diabetes, osteoporosis and neuromuscular disorders at higher levels of disability. After three years of the CReG program, the first results were drawn and their analysis are summarized in three categories:

1. Participation of general practitioners in the experimental program;
2. Participation of patients in the experimental program;

3. Impact of the experimental program on economic expenditure and health consumption.

The participation of general practitioners in the CReG program

Within this category of results, the number of general practitioners who have joined the initiative and their distribution within the participating cooperatives were analysed.

In addition, the profile of the doctors participating in the initiative were drawn, highlighting any differences between them and the doctors who did not choose to participate in the program.

The information collected regarding the general practitioners in or out of the CreG program included age, sex, total number of patients in their care and number of chronic patients in their care.

At the end of 2015, the 512 general practitioners participated in the CReG program. They belonged to 9 cooperatives spread around five ASLs involved in the project. *Table 4* details the ASL distribution and cooperatives to which the participating general practitioners belonged to.

Table 4: The CReG results at the end of 2015 – general practitioners distribution

ASL involved	GP Cooperatives involved	GP involved
ASL Milano Città	Coop Medici Milano Centro	72
	ATI Milano Città	31
ASL Como	Coop Como Medicare	36
	Coop Cosma 2000	32
	Coop MMG –CReG	21
	Coop Paxme Gestioni	12
ASL Bergamo	Coop Iniziativa Medica Lombarda	170
ASL Milano 2	Coop Iniziativa Medica Lombarda	39

	Coop CReG Servizi	25
ASL Lecco	Coop COSMA Lecco	74

Adopted from: Levato, 2016.

The profiles of general practitioners participating in CReG program as well as of those general practitioners who chose not to participate in CReG are summarized in the *Table 5*.

Table 5: The CReG results at the end of 2015 – GP profile in and out of CReG

Characteristics	GPs participating in CReG	GPs NOT participating in CReG
Number of GPs	512	2.194
% female	33,6%	35,8%
% under 40	2,0%	1,7%
% over 60	48,4%	45,0%
Average number of all patients in care	1.347	1.231
Average number of Chronic patients in care	375	338
Average number of Chronic patients enrolled in CReG	375	0

Adopted from: Longo et al. (2015)

The two groups of general practitioners, namely those who chose to participate in the program and those who chose not to, have both differences and similarities. The two groups seem to be similar in the number of female practitioners, as well as the age distribution of the GP.

The most interesting results, however, concern the average number of all patients in care and the average number of chronic patients in care. In fact, the doctors participating in the CReG care for an average of 1,347 patients each against the 1,231 patients of the non-CReG doctors (+ 9.4%) and more chronic patients (375 against 338, + 10.95%).

The general practitioners who choose to participate in CReG experience seem to have slightly more patients under their care as well as being more exposed to the target group of the program, the chronic patients.

Participation of patients in the CReG program

Here we try to trace the profile of the patients participating in the initiative, trying to investigate whether elderly, multi-pathological and complex diseases patients have been enrolled.

For each of the five ASLs enrolled in the CReG, the enrolment rate is analysed by the complexity of the patient's class. All chronic patients are divided into 4 respective classes according to the complexity of the diseases and comorbidities present. The classes are, going from the lightest forms of chronic diseases and least comorbidities to the highest, Low (Bassa), Medium-Low (Medio-bassa), Medium-High (Medio-alta) and High (Alta) are depicted on the *Figure 10* for all the 5 participating ASLs as well as the their collective data.

Tassi di arruolamento, per ASL e complessità della classe (2015)

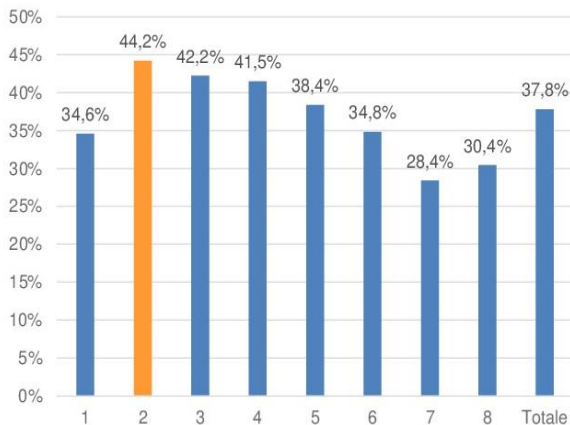


Figure 10: Patient participation rate – ASL and class complexity distribution (2015). Adopted from: Longo et al. (2015)

Examining the numbers presented, one could observe that in 2015 among all 5 participating ASLs the patient participation rate among all the levels of the chronicity was 38%. The highest levels of participation are recorded for medium-low complexity pathologies, which are

observed in each of the 5 participating ASLs. The highest participation rate is reported for Como, with Milano recording to have the lowest participation rate among all 5 participating ASLs.

Tasso di arruolamento per numero di patologie, 2015



Tasso di arruolamento per classe di età, 2015

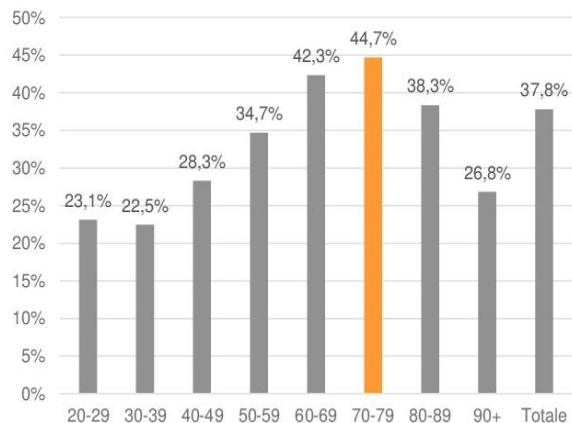


Figure 11: Patient participation rate – number of comorbidities and age distribution, 2015.

Adopted from: Longo et al. (2015)

The first graph of the *Figure 11* presents the participation of patients according to the number of comorbidities they suffer in 2015. The highest participation rate (44.2%) is registered for those patients who suffer from two comorbidities and the lowest (28.4%) is among the patients who suffer from seven comorbidities.

The second graph of the *Figure 11* depicts the participation rate distributed by age of patients. The age group that was using the services of CReG program the most were patients from 70 to 79 years of age, exhibiting 44.7% participation in their age group. While the lowest participation rate was among the age groups of under 40 years old.

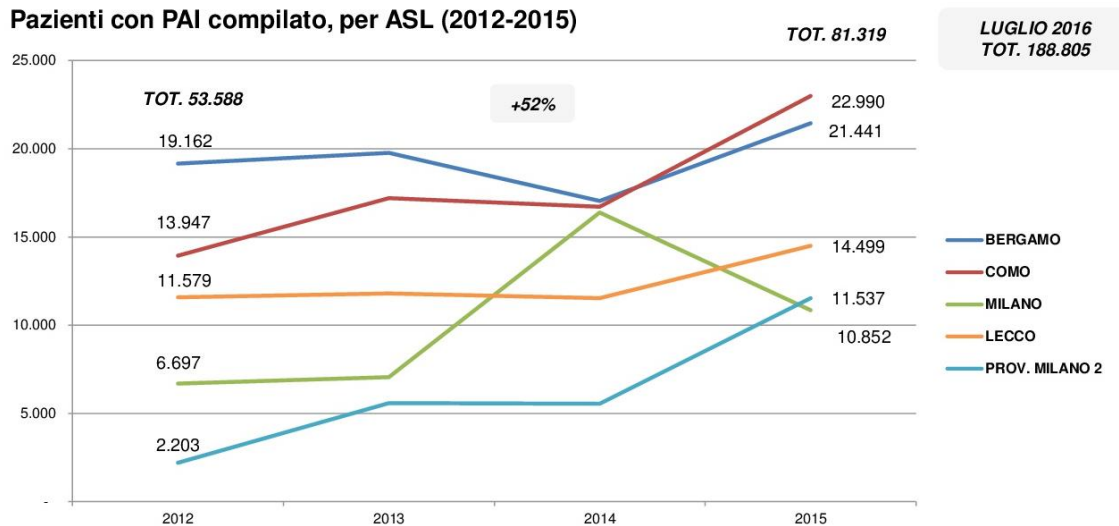


Figure 12: Patient participation rate – trend for ASL from 2012 to 2015. Adopted from: Longo et al. (2015)

Finally, the Figure 12 is illustrating the participation rate trend from 2012 to 2015.

Between the years 2012 and 2015 the participation rate increased by 51.75%. In fact, the number of participating patients increase from 53,588 patients in 2012 to 81,319 patients in 2015.

Impacts on health expenditure and consumption

Analysing the population, the CReG has produced a significant reduction in the number of hospital accesses and the risk of incurring emergency care. The magnitude of the effect increases when the analysis is restricted to the patients actually enrolled in the program.

When analysing the group of patients not participating in the program, although they are eligible, there are no significant differences in the risk of hospitalization or emergency admissions.

The program has produced positive results such as reduced access to the emergency room and hospitalization rate, increased adherence to treatment and clinical monitoring. Considering these improvements it could be concluded that actually the chronic patient is better taken care of and that this is a "proactive, personalized organizational modality, based on the adherence

between doctor and patient that favors the integration of the general practitioner and the specialist" (Giani, 2015).

From the preliminary data, in the period 2012-2013, among the patients managed in CReG, compared to other chronic patients, there is a reduction in access to the emergency room and the admission rate, while there is an increase in pharmacological and specialist services. These data demonstrate a better management of the chronic patient and, in terms of consumption, probably a recruitment of patients who previously did not adequately care for and perhaps a greater adherence to the treatment pathway. All these results translate into savings for the Region.

Let us analyse the component of healthcare consumption of chronic patients below. Consider the pharmaceutical consumption and consumption of hospital services.

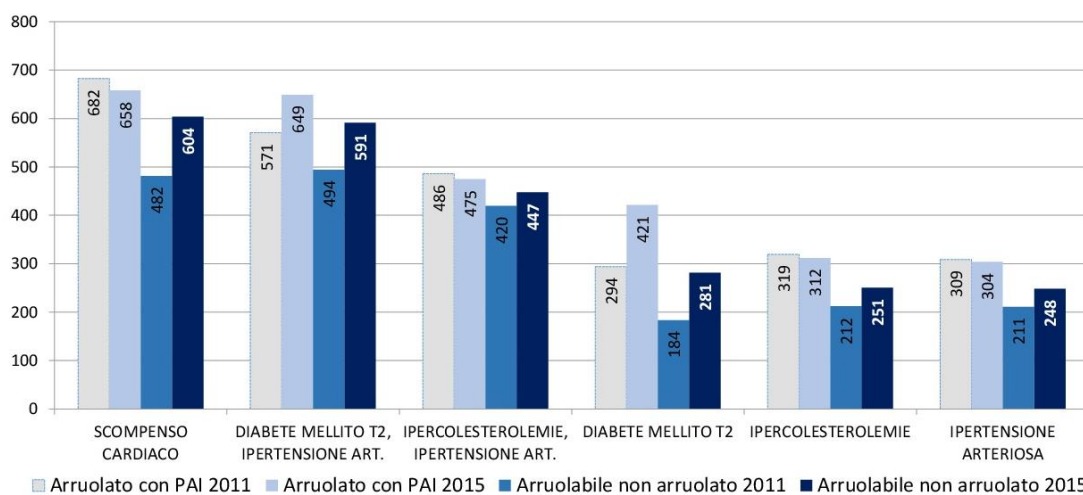


Figure 13: Impacts on health expenditure and consumption – pharmaceutical consumption costs per capita (2011; 2015). Adopted from: Longo et al. (2015)

Figure 13 compares pharmaceutical consumption per capita of patients participating (light colours on diagram) and patients not participating (dark blue colours on the diagram) in CReG. Number of both of those categories are shown for two years, 2011, the reference year when the CReG program has not yet taken effect, and 2015, the comparison year when CReG program

has been active for some years. With regard to patients participating in CReG, there is a significant increase in pharmaceutical consumption for patients with type 2 diabetes mellitus as well as for the patients with two comorbidities of type 2 diabetes mellitus and arterial hypertension. On the other hand, if we consider the patients not participating in CReG, there is an increase in pharmaceutical consumption from 2011 to 2015 in all diseases. When, on the other hand, the patient participating in CReG are compared with the patient not participating in CReG for the same year, it is evident that the pharmaceutical consumption is always higher for the first category of patients. It is also worth noting how this difference in pharmaceutical consumption between in and out of CReG patients has decreased for all the diseases from 2011 to 2015.

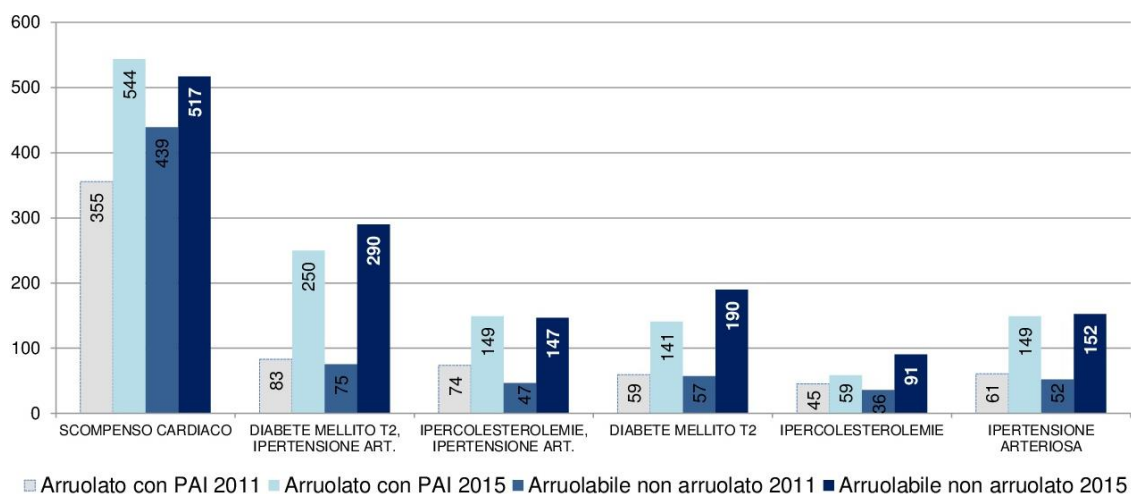


Figure 14: Impacts on health expenditure and consumption – comparison of hospitalization (due to disease complications) costs per capita (2011; 2015). Adopted from: Longo et al. (2015)

Figure 14 displays hospital consumption and, similarly to the previous figure, comparison is made between participating patients in CReG and not participating in the years 2011 and 2015. Hospitalization costs per capita increased significantly for patients participating in CReG from 2011 to 2015 for all diseases. But the same can be said about the not participating patients as

well. There is, therefore, a general increase in the hospitalization costs for all patients. When comparing the participating patients with non-participating patients, one can notice how in 2011 there was a substantial parity in hospitalization costs except for heart failure. In patients with heart failure, there was a discrepancy in favour of the non-participating patients who had higher hospitalisation costs. In 2015, the situation changes. Hospitalization costs of participating patients are lower for four out of six patients groups displayed.

In order to better understand the differences occurred over time, the variations are calculated, in absolute and percentage terms, for comparison between participating patients 2011 with 2015, non-participating patients 2011-2015, participating patients and non-participating patients 2011, and, finally, participating patients and non-participating patients 2015.

Table 6: The variations, in absolute terms, of the CReG and non-CReG costs (2011; 2015)

Cost of pharmaceutical consumption	CReG delta 2011-2015	Non CREG delta 2011-2015	CReG - nonCReG delta 2011	CReG - nonCReG delta 2015
Heart failure	-€ 24.00	€ 122.00	€ 200.00	€ 54.00
Diabetes and hypertension	€ 78.00	€ 97.00	€ 77.00	€ 58.00
Hypertension and hypercholesterolemia	-€ 11.00	€ 27.00	€ 66.00	€ 28.00
Diabetes	€ 127.00	€ 97.00	€ 110.00	€ 140.00
Hypercholesterolemia	-€ 7.00	€ 39.00	€ 107.00	€ 61.00
Hypertension	-€ 5.00	€ 37.00	€ 98.00	€ 56.00
Cost of hospitalization	CReG delta 2011-2015	non CREG delta 2011-2015	CReG - nonCReG delta 2011	CReG - nonCReG delta 2015
Heart failure	€ 199.00	€ 78.00	-€ 84.00	€ 37.00
Diabetes and hypertension	€ 167.00	€ 215.00	€ 8.00	-€ 40.00
Hypertension and hypercholesterolemia	€ 75.00	€ 100.00	€ 27.00	€ 2.00
Diabetes	€ 82.00	€ 133.00	€ 2.00	-€ 49.00
Hypercholesterolemia	€ 14.00	€ 55.00	€ 9.00	-€ 32.00
Hypertension	€ 88.00	€ 100.00	€ 9.00	-€ 3.00

Table 7: The variations, in percentage terms, of the CReG and non-CReG costs (2011; 2015)

Cost for consumption of drugs	CReG Delta 2011-2015	non CREG Delta 2011-2015	CReG - nonCReG Delta 2011	CReG - nonCReG Delta 2015
Heart failure	-4%	25%	41%	9%
Diabetes and hypertension	12%	20%	16%	10%
Hypertension and hypercholesterolemia	-2%	6%	16%	6%
Diabetes	30%	53%	60%	50%
Hypercholesterolemia	-2%	18%	50%	24%
Hypertension	-2%	18%	46%	23%
Cost for hospitalization due to adverse events	CReG Delta 2011-2015	non CREG Delta 2011-2015	CReG - nonCReG Delta 2011	CReG - nonCReG Delta 2015
Heart failure	36%	18%	-19%	7%
Diabetes and hypertension	67%	287%	11%	-14%
Hypertension and hypercholesterolemia	50%	213%	57%	1%
Diabetes	58%	233%	4%	-26%
Hypercholesterolemia	24%	153%	25%	-35%
Hypertension	59%	192%	17%	-2%

The pharmaceutical costs for patients participating in CReG decreased from 2011 to 2015 in many diseases, with the exception of diabetes and hypertension. It could be noted that both the CReG and non-CReG patients suffered increase in the pharmaceutical cost from 2011 to 2015. But overall, CReG participating patients incur higher pharmaceutical costs than non-CReG patients. For each disease, the delta between CReG and non-CReG patients has been reduced from 2011 to 2015.

Regarding the cost for hospitalization for adverse events, the situation is different. Indeed, if in 2011 CReG patients incurred a higher cost for almost all the diseases, in 2015 the picture is different; those patients who do not participate in CReG exhibit a higher hospitalization cost for most of the diseases considered.

It may be yet hard to make a definitive judgement regarding the results on pharmaceutical costs. However, there is a clear underpinning to say that the CReG program helped reduce the hospitalization costs for its participating patients in comparison to the non-CReG patients.

PiCC

PiCC description

After the trial of CReG, the regional government worked on introducing the governance model that improves the chronic patient management to the entire region. Learning on the experience of CReG, the new program PiCC (Taking Charge of Chronicity) was put forward. The description of the program and its underpinnings here is based on two resolutions passed by the Region: resolution no. 6164 of 30/01/2017 and resolution no. 6548 of 04/05/2017.

The program's innovative element concerns the legislator's desire to operate a paradigm shift, introducing a proactive system, oriented towards taking into account different groups of patients with their respective needs for care and assistance that aims to improve accessibility to services and ensure management of the entire care path of the patient.

Program introduces a new governance model that aims to ensure a real integration of the patient's path, overcoming the historical fragmentation of services. In this context, the care response should not focus solely on the disease, but should be planned according to the health demand, diversified by patient categories and customized according to individual needs and the family context.

The new management model of PiCC identifies new managing organizations to be responsible for the chronic patient's path, as well as new ways of remuneration.

The new patient management model confirms some principles already established in the regional reality. For example, the freedom of choice that the citizen enjoys in selecting the managing organization they wish to trust their care.

Demand stratification and patient classification

First, the patient classification model is changed from the one used in pilot program of CReG. The new patient identification approach is based on the patient's specific needs. In addition to the variables already considered in the CReG project (main chronicity and number of co-morbidities), other aspects were introduced for analysis, such as age, fragility index, economic and social condition.

Therefore, one of the changes introduced in the PiCC program is the different classification of the patients based on levels of complexity of the chronic condition. Patients are grouped into five levels according to the following criteria:

- the main disease;
- the presence of possible elements of social and health vulnerability;
- the level of complexity, which is defined on the basis of the number of co-morbidities or the presence of specific conditions of vulnerability.

The level of complexity, in particular, divides patients with the same disease into three levels of decreasing complexity in the following manner:

- first level: patients with high clinical fragility, with at least three co-morbidities in addition to the main chronicity (four or more diseases altogether), which is the highest clinical vulnerability linked to a situation of specific weakness;
- second level: patients with more chronic, poly-pathological diseases, who are afflicted by a main pathology and by one or two co-morbidities (two or three diseases altogether), or patients with fragile social and health conditions;
- third level: patients with chronicity in the initial phase who suffer only from the main chronicity.

The population is thus divided based on the aggregate information of the assisted database (BDA) based on the severity of the chronic conditions of patients.

The stratification of patients performed with the new criteria may therefore result in a change in the eligibility of patients to participate in the PiCC program as opposed to the pilot program of CReG.

Table 8: PiCC model classification of population

	Nm Patients / Users	Characteristics description	Needs description
Level 1	150,000	Clinical and / or functional fragility with prevalent hospital, residential and home care needs	Integration of hospital / domestic / rehabilitation / socio-health paths
Level 2	1,300,000	Multi-pathology chronicity with prevalent extra-hospital needs, high demand for integrated outpatient / frequent care and moderate social security fragility	Coordination and promotion of the therapy path (mainly pharmacological, psychological and educational support) and proactive follow-up management (more visits and exams per year)
Level 3	1,900,000	Chronicity in the initial phase, predominantly mono-pathology and social-health fragility in the initial phase, at the medium-low need of integrated outpatient and / or home-based care	Guarantee of outpatient / preferential outpatient pathways and control and promotion of therapeutic adherence
Level 4	3,000,000	'Non-chronic' population who uses services sporadically (first visits / rear outpatient needs)	Accessibility to all Outpatient Agendas available in the local are of habitation
Level 5	3,500,000	Population who does not use the services, but are still potential sporadic users	Only 'potential users', no current needs

Adopted from: Lombardy Region, 30/01/2017

Calculation of the tariff and remuneration of the managing organization

Another new feature brought by the PiCC model concerns the calculation of the tariff and the remuneration of the managing organization.

The Lombardy Region, with the resolution published on 4 May 2017, has brought significant changes regarding the financial component of the program and in particular, the composition

of the tariffs. The tariff paid to the managing organization to cover the costs of managing the care of the chronic patient was set at a fixed rate and a separate rate, not exceeding 10 €, was allocated for the general practitioner to remunerate efforts of creating the PAI.

In particular, the fixed rate varies according to the complexity levels of the chronic condition. Since the most serious cases require more care, a higher tariff is required for patients with higher complexity level.

Three different tariffs are then defined based on the level of complexity:

- € 45 for patients with more than three diseases (first level of complexity patients);
- € 40 for patients with two conditions (second level of complexity patients);
- € 35 for patients with one disease (third level of complexity patients).

These rates are paid to service providers and also include the €10 rate for PAI design and creation, dedicated for the general practitioner.

Summarizing, €10 are paid to general practitioners who creates the PAI of the patient while the fixed amount from which the €10 are subtracted, represents the remuneration for managing organization.

Table 9: Composition of the PiCC tariff

	Fixed rate for managing patient	Remuneration for the managing organization	Remuneration for GP for creation of the PAI
Level 1	45€	35€	10€
Level 2	40€	30€	10€
Level 3	35€	25€	10€

The process of managing the patients' pathway

First, the ATS receives the stratification of the assisted population in its territorial area from the Lombardy Region classification which assigns each subject to a level of complexity

according to their individual needs. For individuals who fall into one of the first three levels of complexity, the ATS selects the most suitable managing organization to handle their care.

The list of managing organizations is then sent by the ATS to the patient. Preserving the principle of freedom of choice, the patient is free to choose the managing organization from the provided list.

Second, before the patient is enrolled into the program, the managing organization selected by the patient carries out an assessment of his medical and care needs to ensure their ability to provide care for the respective patients' level of complexity. If the patient is assessed as "suitable", the managing organization proceeds to enrol the patient and they sign a contract of care, that begins the process of PAI. If the patient is assessed as "not suitable", the managing organization addresses the managing organization available.

Third, with the PAI created, the patient is now registered to be under the care of the Service Centre of the given managing organization. The Service Centre represents the proactive management element of the path, through clinical and administrative functions, and by monitoring the process and its outcomes they assist the patient.

Fourth, from the time of enrolment, all the information related to prescriptions and activities undergone by the patient are recorded. The remuneration for the activities performed by each managing organization will be carried out by the ATS.

PiCC model and similar initiatives in the world

The PiCC initiative is designed and developed with the "Triple Aim" logic in mind, in fact a correct implementation of the therapy allows to increase the quality of the treatment reducing the cost and improving the quality of life of the patients.

The aim of the PiCC initiative of the Lombardy Region is therefore to develop an integrated model of management of chronicity that sees the patient in the centre. Health care and social support operators coordinated by a managing organization based on an Integrated Assistance

Pathway (PAI) customized of the patient and his family based on the social and health needs follow the patient.

The PiCC initiative is in line with other similar initiatives that are taking place at the European level, such as:

- **Nordic model**, UK => Integrated Care Program, Waltham Forest, East London and City (WELC)
- **Continental model**, Germany => The Kinzigtal-way, The Netherlands => Blue Care
- **Mediterranean model**, Spain => Model for Patients with Complex Chronic Conditions (MAMCC)

These approaches, as well as the PiCC initiative of the Lombardy Region, are all moving in the same direction of a greater orientation both to the patient and to the integration of social and health assistance processes.

The main drivers (*Table 10*) of emerging models of chronicity care are:

- Organizational Innovation: introduction of Managing Organization for implementation of Integrated Assistance Pathway (PAI) of the chronic patient. Among these are the General Practitioners (GPs) who can become Managing Organization if they join into cooperatives. In addition to the GPs cooperatives, the Managing Organization may be all other public and private healthcare organizations (Hospitals, Health Centres, etc.).
- New professional figures: in order to qualify as the Managing Organization new professional figures such as Case Managers (CM) and Call Centre Operators (CCO) are required to support the PAI.
- Personalization of care pathways: the Managing Organization must be able to create and manage personalized and integrated care pathways (PAIs), designed to meet the needs of each patient's social and health needs.

- Development of a service network around the patient: the Managing Organization must take charge of the aggregation of the other social and health workers (such as: analysis laboratories, hospitals, welfare organizations, etc.) around each patient's PAI.
- Technological Innovation: use of innovative software for the management of the PAI and relations with CM, CCO, network of social and health operators and patients, including family and carers.
- Patient Empowerment: the PAI must empower patients and their family and carers to take control of the disease flow and stimulate active participation and adherence to the most appropriate therapies and lifestyles (not present in the PiCC initiative of the Lombardy Region).
- New incentive models for social and health workers: alignment of incentives, reimbursements and outcomes with a view of "triple aims" (not present in the PiCC initiative of the Lombardy Region).

Table 10: Drivers of emerging models of chronic care.

Driver	Regione Lombardia (PiCC)	Spagna (MAMAC)	Germania (Kinzigal-way)	Olanda (Blue Care)	UK (WELC Programme)
<u>Innovazione Organizzativa</u>	✓	✓	✓	✓	✓
<u>Nuove figure professionali</u>	✓	✓	✓	✗	✓
<u>Personalizzazione dei percorsi di cura</u>	✓	✓	✓	✓	✓
<u>Sviluppo di un network di servizi attorno al paziente</u>	✓	✓	✓	✓	✓
<u>Innovazione tecnologica</u>	✓	✓	✗	✗	✓
<u>Empowerment del paziente</u>	✗	✗	✓	✓	✓
<u>Nuovi modelli di incentivazione degli operatori socio-sanitari</u>	✗	✗	✓	✗	✓

PiCC objectives

The main objective of the PiCC model is to favour the transition from a model of chronic patient management oriented to the provision of clinical-care services to a model oriented to the individual needs of the patient able to guarantee a high level of personalization of the individual patient care pathways.

The objectives of the new model for chronic patient management are:

- development of a health and social care organization equipped to deal with the needs of the chronic patients and their families;
- reduction of the burden on the health care services dealing with chronicity;
- reduction of the burden of social services associated with the welfare needs that derive from the chronic diseases;
- introduction of new governance tools and models that address regional planning towards an integrated health care system;
- association of remuneration with the fulfilment of patient care pathways and not with a single benefit. A flat-rate remuneration is preferable to a performance-based remuneration, as was the case in CReG, because it is considered a better solution to ensure continuity of care.

The priorities that the PiCC model has are essentially four: continuity of care, personalization of the care path, coordination and management flexibility.

In order to achieve good results in these areas, the PiCC initiative utilizes a number of tools. It uses legislative instruments and economic resources made available by the Region, technological tools for the creation and control of PAI and the regional tariff plan for financing. Among the technological tools, Service Centre is one of the fundamental factors for a satisfactory implementation of the patients care pathways.

The PiCC involves a series of actors and shareholders, ranging from general practitioners, specialists and other health care workers, to technological providers and patients with their families. The main activities that are performed in the context of the project are clinical, such as taking care of the chronic patient, the creation and fulfilment of the PAI, and administrative, as the management of the service network.

The model is designed with the goal to pave the path to achieve short-term results, medium and long-term results. In the short-term, it aims to obtain positive results in terms of appropriateness of care, adherence to therapy and increased satisfaction of care. As medium-term results, it strives to have an increase in the patient's healthy life years and a more efficient reallocation of health resources. The impacts expected in the long-term are the reduction of the social cost of chronic patients and the reduction of the chronic health care expenditure.

Impact Assessment of the PiCC program

The PiCC program was conceived to battle the rising chronic health care expenditures that occurred due to the rise in the number of people ill with chronic diseases. Even though chronic diseases have multiple factors that contribute to their prevalence, people of older age are the primary group affected by the chronic diseases. With the aging of population, therefore, the number of patient ill with chronic diseases will continue increasing even if all the other conditions stay the same.

The *Figure 15* portrays the formation of the chronic health care costs. The total health care costs are dependent on the number of chronic patents are under care and per patient costs.

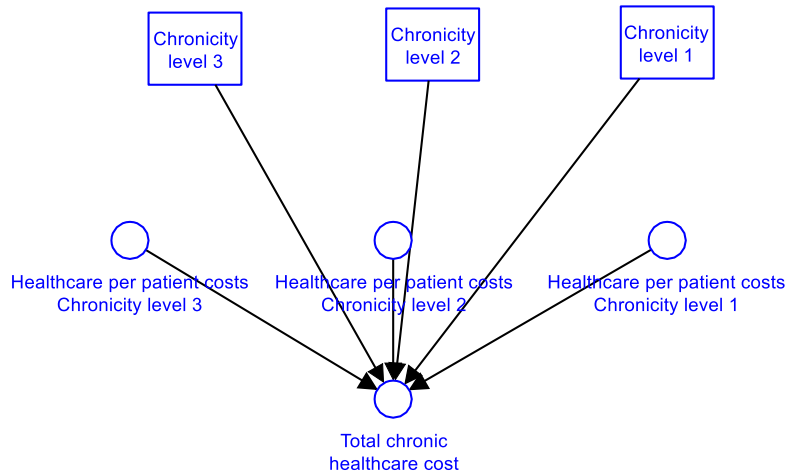


Figure 15: SFD – Chronic healthcare costs

Due to the nature of the chronic disease, it is considered that once a person is getting ill, there is no way to fully recover. Therefore, after the onset of the chronic disease, the patient can either stay in the initial level of chronic complicity (level 3), progress to more complicated condition (complexity level 2), migrate to/from the region or die (due to the chronic disease suffered or due to any other causes). *Figure 16* portrays the movement of chronic patients through the chronicity levels.

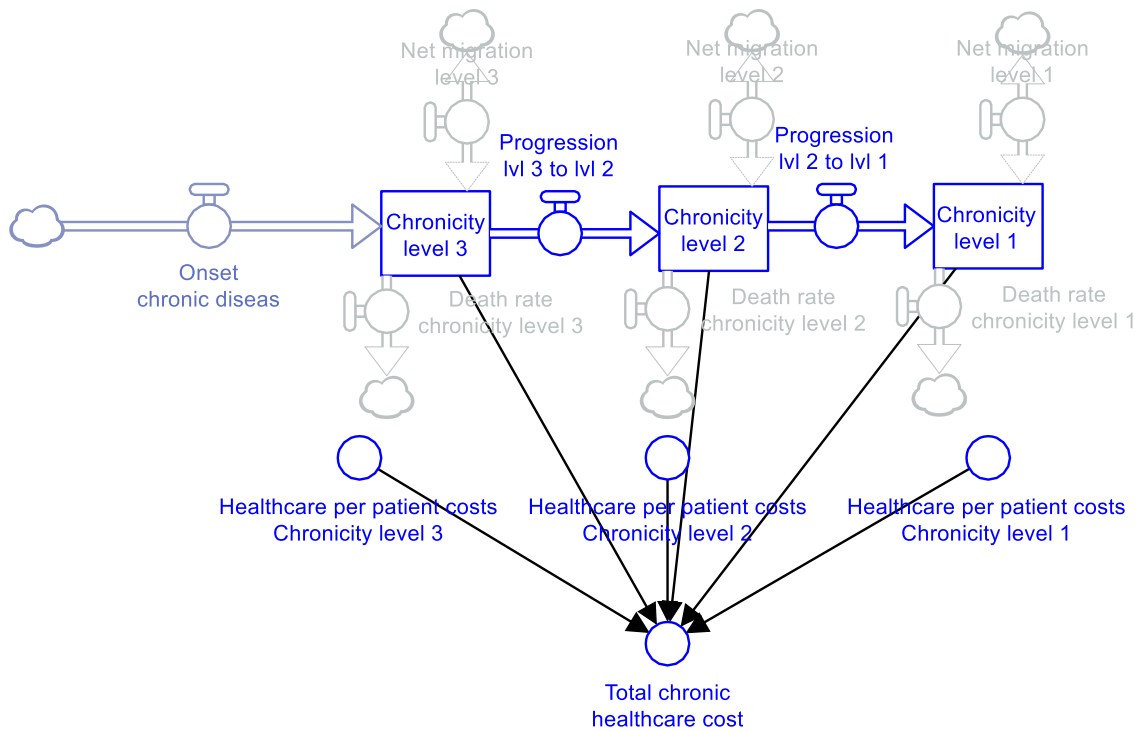


Figure 16: SFD – Chronic patient movement through the chronicity levels

An aging chain that consists of age groups represents the total population. People enter the system through Birth Rate flow, age overtime and progress to the next age group, migrate to/from the region or die through the respective death rate (due to chronic disease or die to any other reasons).

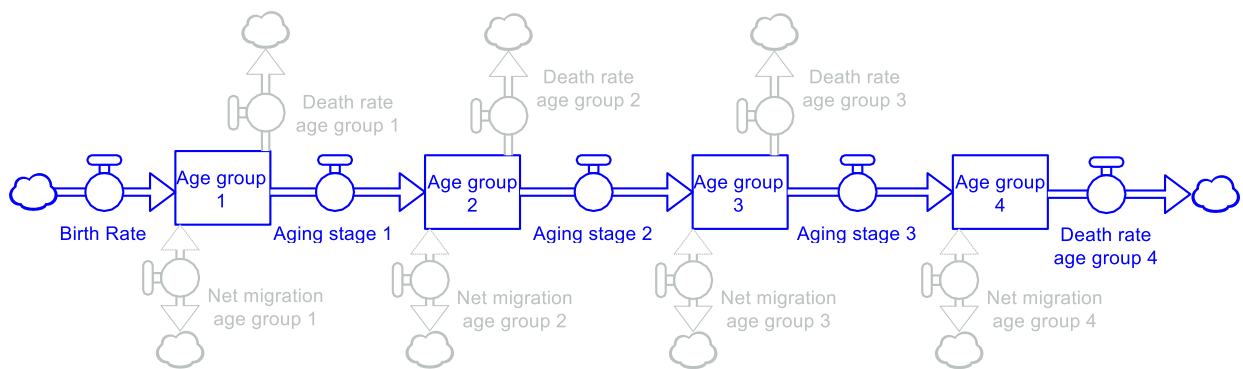


Figure 17: SFD – Aging chain of total population

People at any stage of their life can acquire a chronic disease, although people of older age have a higher rate of the chronic disease onset. Therefore, if there will be an increase in the amount of people in the older age groups (aging of the population), there will be an increase

in the onset on the chronicity and, thus, ceteris paribus, the increase in the number of chronic patients. *Figure 18* portrays the connection between the aging chain of population and the progression of population with chronic disease through chronicity complexity levels through the rate of onset of first chronic disease.

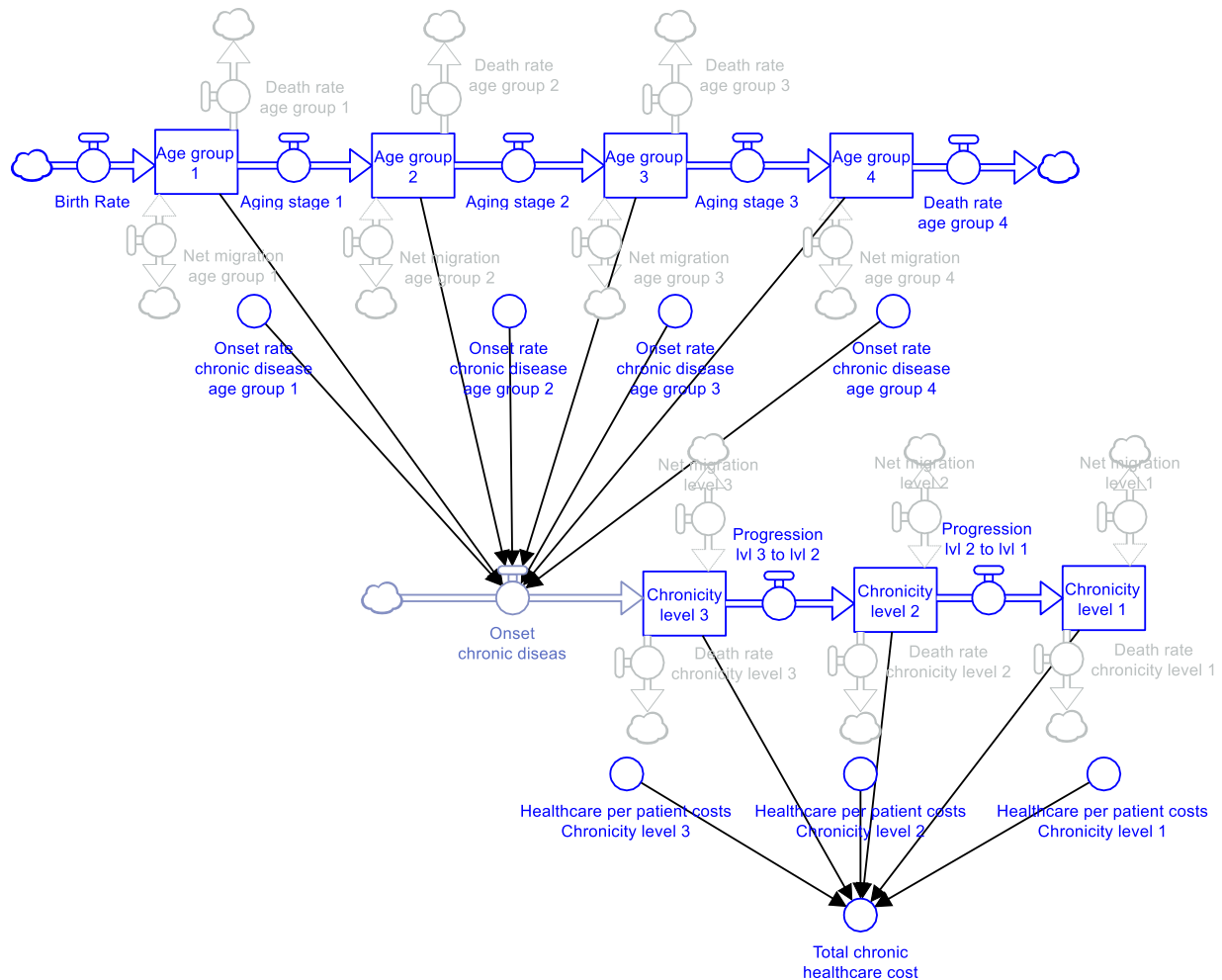


Figure 18: SFD – Aging chain of population, chronicity onset, progression and costs

PiCC program reorganizes the way the chronic patients are managed, with the triple aim goals in mind. Effectively, the objectives are to:

1. increase the quality of the treatment
2. reduce the cost
3. improving the quality of life of the patients.

Figure 19 illustrates how PiCC program influences the system described in the figures above. The cost reduction in the PiCC program is aimed to be achieved through better management of the care provided. By creation of PAI and adherence to it, patient is on a continues path of appropriate care and doesn't stray from it for unnecessary therapies.

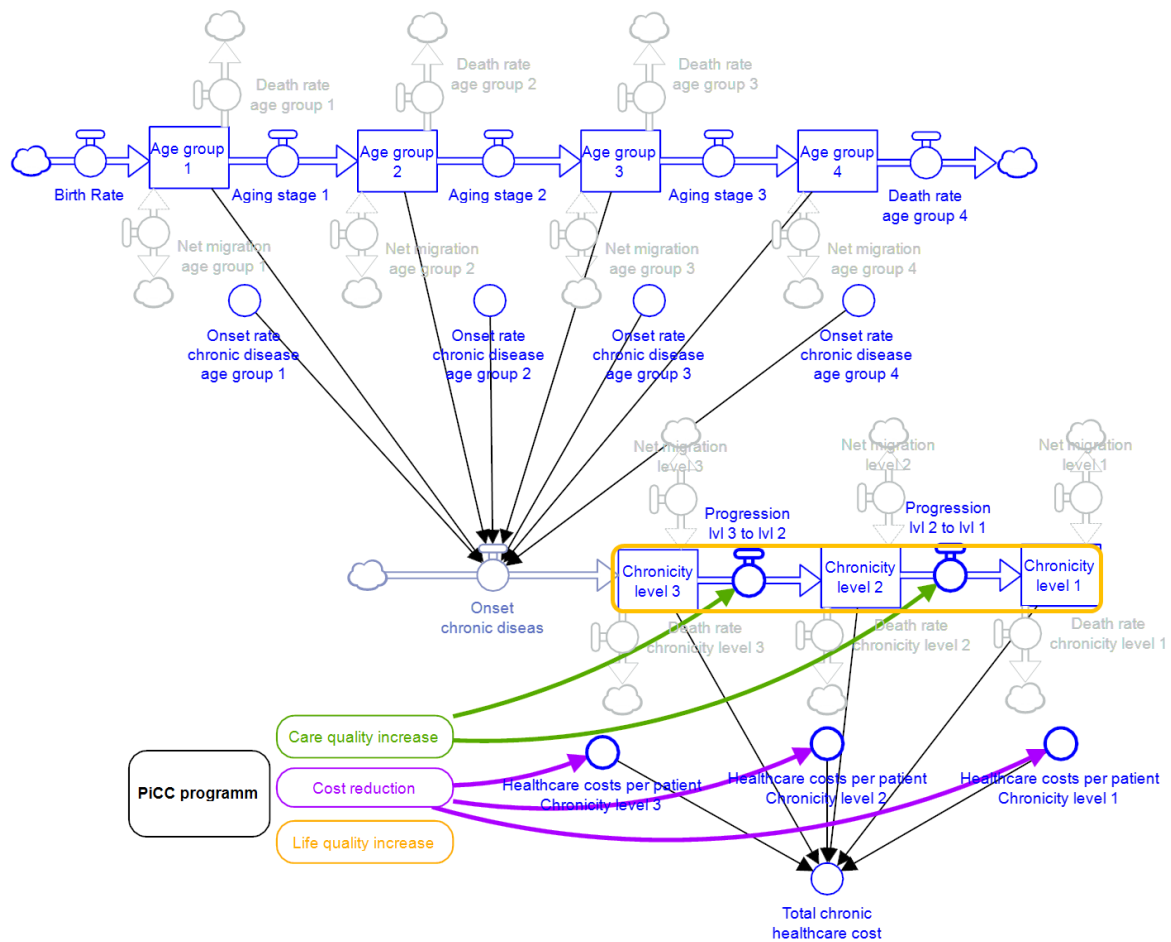


Figure 19: SFD – PiCC program triple aim influence

Increase in the quality of care/treatment is achieved through the PAI and patient level support that prompts adherence to the PAI. The result of this effort is twofold, patient is assigned appropriate treatment and patient is followed up to ensure adherence or proper execution by the patient of that treatment. Therefore, the treatment effectiveness is increased and, thus, the disease is well managed. When chronic disease is well managed, it means that the patient will

not progress to the next level of complexity as fast as he would have without a proper treatment. That means that the progression through levels of chronicity is slowed down by the program.

Finally, the increase in quality of life is achieved through good management of the patients chronic disease, thus, preventing the outbreak of symptoms and complications as well as keeping the patient at a lower level of the chronic complexity for longer. The lower complexity levels of chronicity, being represented by easier forms of chronic diseases and smaller amount of co-morbidities, are providing a better quality of life as opposed to the higher levels of chronicity.

With the successful implementation of the PiCC program assumed (implementation will be discussed in more detail in the next chapter), one may attempt to examine the consequences the program will hold.

Effective cost per patient reduction will decrease the total chronic healthcare costs. However, with the progression through levels of chronic of complexity being slowed down by the PiCC program there is an array of consequences that worth considering.

First, it reduces one of the outflows of the chronicity level stocks, thus, increasing the amount of patients in the stocks should the rest of the flows remain unchanged. Therefore, there will be more patients in the complexity level 3 and 2, since the slowdown in the progression flows will work to prevent patients moving through the chain on chronic complexity as active as they used to do.

Second, with the increased amount of patients staying in the complexity level 3 and 2, and thus not progressing so fast, the implications are that the mortality related to chronic diseases will decrease. That is due to the change of the proportional distribution of the chronic patients among the dedicated chronicity levels. With the PiCC program effective, there will be more

people in the lower complexity levels of chronicity, and since the death rate in those levels is lower than that of the higher complexity levels, the total amount of people dying due to chronic diseases will reduce.

Third, with the mortality rates attributed to the chronic disease decreased, the number of patients in the chronicity complexity levels chain will increase.

Therefore, since the total cost of chronic healthcare is dependant on the number of chronic patients as well as the per patient cost, the increase in the total number of chronic patients will prompt the increase in the total chronic costs.

Chapter 6 – Implementation

GPs cooperative model

In July 2017, 15 GP Cooperatives have applied as Managing Organizations for the PiCC initiative. These cooperatives each comprise of different number of GPs ranging between 50 and 700. The total number of GPs in participating cooperatives is 2,300 GPs (about 40%) among the total of 6,000 of all the GPs in Lombardy (*Figure 20*).

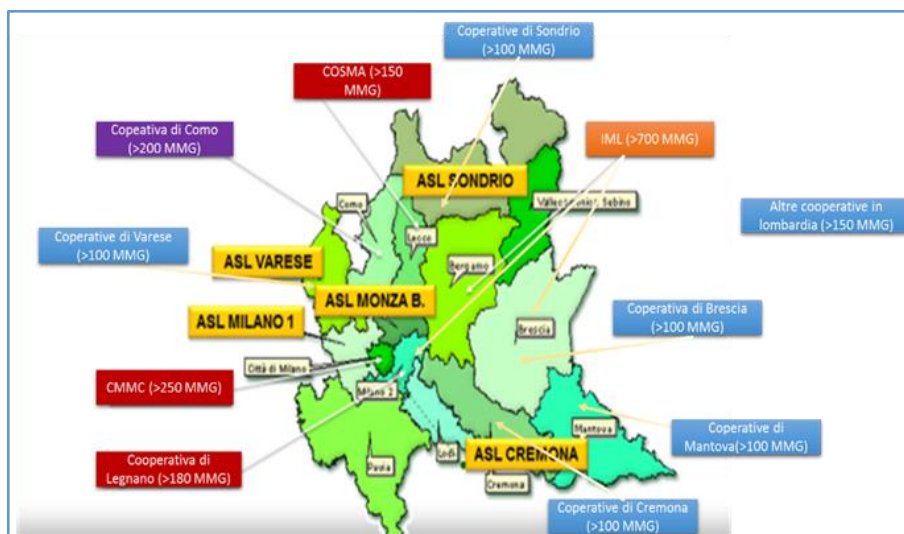


Figure 20: Distribution of PiCC participating GPs cooperatives

During the last three months of 2017, all the Managing Organizations accredited by the Lombardy Region must choose how to manage the Case Manager (CM) and Call Centre Operator (CCO) services as well as their Service Provider Network in order to start the PiCC activities for the 1 January 2018.

In order to assist the GP cooperatives in assessing their participation in the PiCC initiative, a dynamic model was created to represent the activities of the cooperatives within the PiCC program.

The three main elements that each participating Managing Organization has to provide for PiCC patients are:

- ❖ Case Manager (CM) – professional who will be overseeing the care of patients and liaison with other health care providers
- ❖ Call Centre Operators (CCO) – responsible for follow-up and monitoring of the adherence to the patients' PAI
- ❖ Software platform (SW) – program that allows for a unified point of data collection and management for enrolment, PAI creation, monitoring and performance reporting

To each Managing Organization, according to the enrolled patients, the Lombardy Region will recognize 10 € / patient / year for the design of the PAI (this amount must be recognized to the GPs that create the PAI) and an average rate of about 27.5 € / patient / year (averaged tariff with respect to the proportion of chronic complexity levels 1, 2 and 3) for managing of the PiCC program.

This means that a cooperative of 100 GPs that manages to enlist all the 44,000 chronic patients registered with them (100% enrolment rate), could have available about 1.2 million € / year to manage the service. In the hypothesis of 1 CM every 6,500 patients and 1 CCO for every 8,500 patients, the cooperative should use around 7 CM and 5 CCOs, in addition to paying for the use of the Software platform (SW) to manage the PAI, plus its own the operational costs.

Figure 21 shows the break-even point between the costs of taking charge and the rate provided by the Region (also known as the Break Even Point - BEP) manifests itself starting from GP Cooperatives of more than 30 doctors.

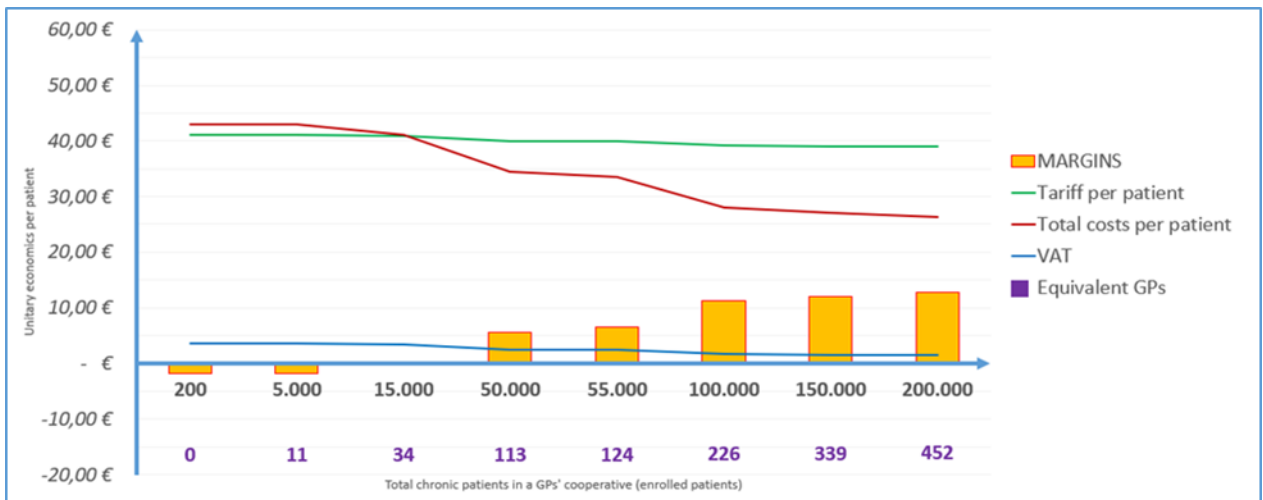


Figure 21: BEP analysis results in the case of 440 patients enrolled on average for GP (100% enrolment rate) and no abandonment of the initiative by patients in a year

However, the experience of the recently concluded CReG initiative suggests that patient enrolment rate, in some cases, could be no more than 50%. Moreover, a significant percentage of these patients of not less than 10% are subject to abandoning the initiative during the year.

In this hypothesis the BEP is reached if the number of GPs in Cooperative is more than 150 units (Figure 22).

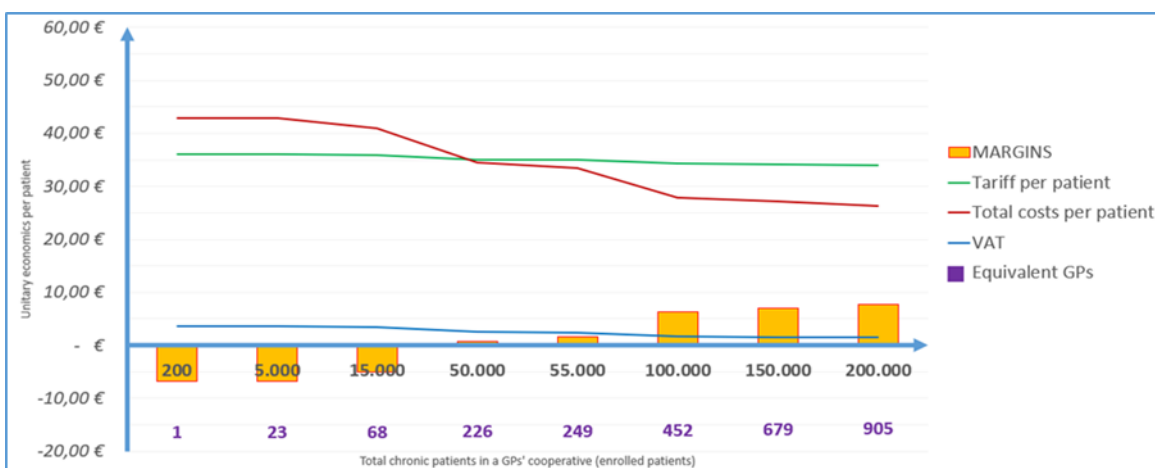


Figure 22: BEP analysis results in the case of 220 patients enrolled on average for GP (50% enrolment rate) and 10% abandonment of the initiative by patients in a year.

The verification of the sustainability of a cooperative of GPs is therefore a complex problem that must consider the systemic effect of various variables such as the effects of an increase in

the level of service of the CMs and CCOs on the adherence of patients to the PAI and their abandonment rate. It is also necessary to evaluate various alternative scenarios such as the price policies of technological suppliers as well as the costs necessary for the in-house or out management of CM and CCO services by cooperatives. In this way, it is possible to compare the "make or buy" choices of the GPs cooperatives.

Finally, the choices of each cooperative of how to set up their own service of care affect in turn the enrolment rate of GPs, the level of adherence to the PAI of patients and their rate of abandonment, which consequently impacts the cost of health service. The cumulative effect of the GPs Cooperatives actions could therefore translate into a reduction in overall health expenditure and an improvement in the quality of care for each individual patient adhering to the PAI. In this case, the problem becomes that of understanding if the savings generated by the initiative repay and the resources put in place by the Lombardy Region to reimburse the management activities of the management of the chronic patients by the Managing Organization are balanced.

The dynamic simulation model constructed, has allowed the GPs Cooperatives to understand the impacts of the various organizational choices in light of possible scenarios before the initiative is launched. *Figure 23* shows as an example the Input screen of the Dynamic Simulation Model.

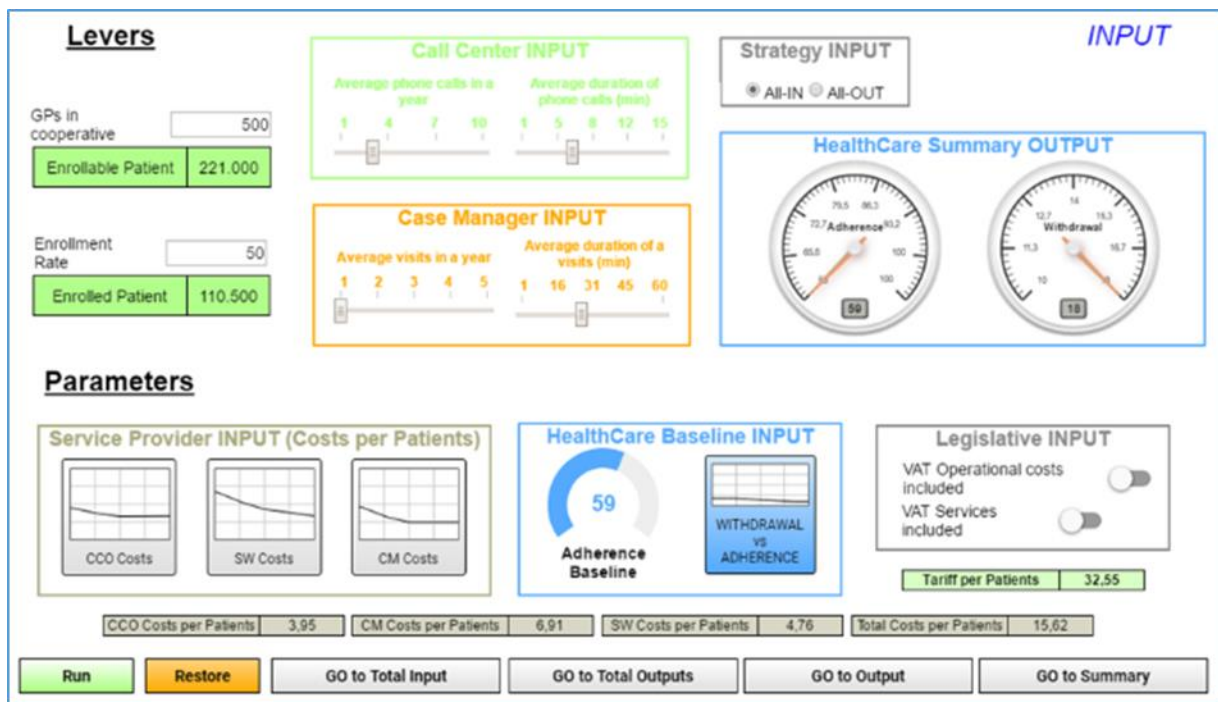


Figure 23: The PiCC sub-model elements of the MM Cooperatives.

Among the various hypotheses verified, thanks to the model, it was possible:

- ❖ to agree on better pricing policies with technological suppliers for the management of the PAI;
- ❖ to decide on buy vs make for the CM and CCO for GPs cooperative;
- ❖ to assess the consequences of scale economy, the relationship between the size of the GP cooperative and its possibilities in effective management of the chronic patients in a new way;
- ❖ to simulate the best level of service that guarantees a higher PAI adherence and a reduced abandonment rate;
- ❖ to verify the conditions of sustainability on a short-term horizon (2018-2020, period of duration of the regional initiative) and medium-long term (2018-2030); etc.

Figure 24 and Figure 25 show the aggregate results of the expected impact of the 15 GP Cooperatives accredited as Managing Organizations for the PiCC initiative.

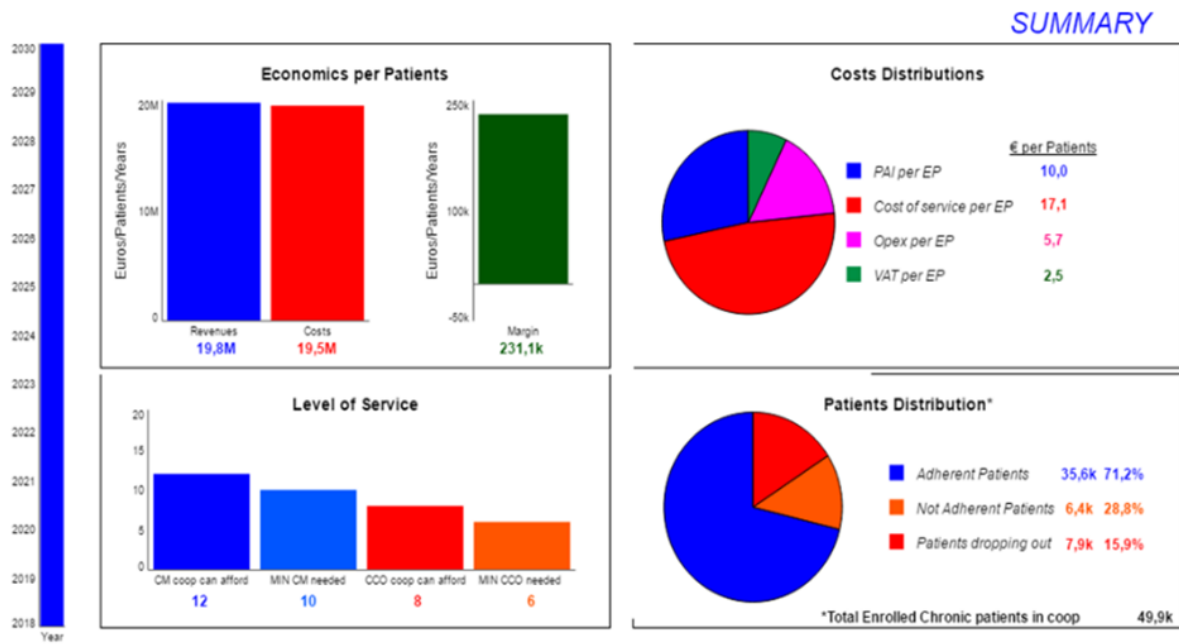


Figure 24: Level of expenditure for patients enrolled in PiCC and not enrolled

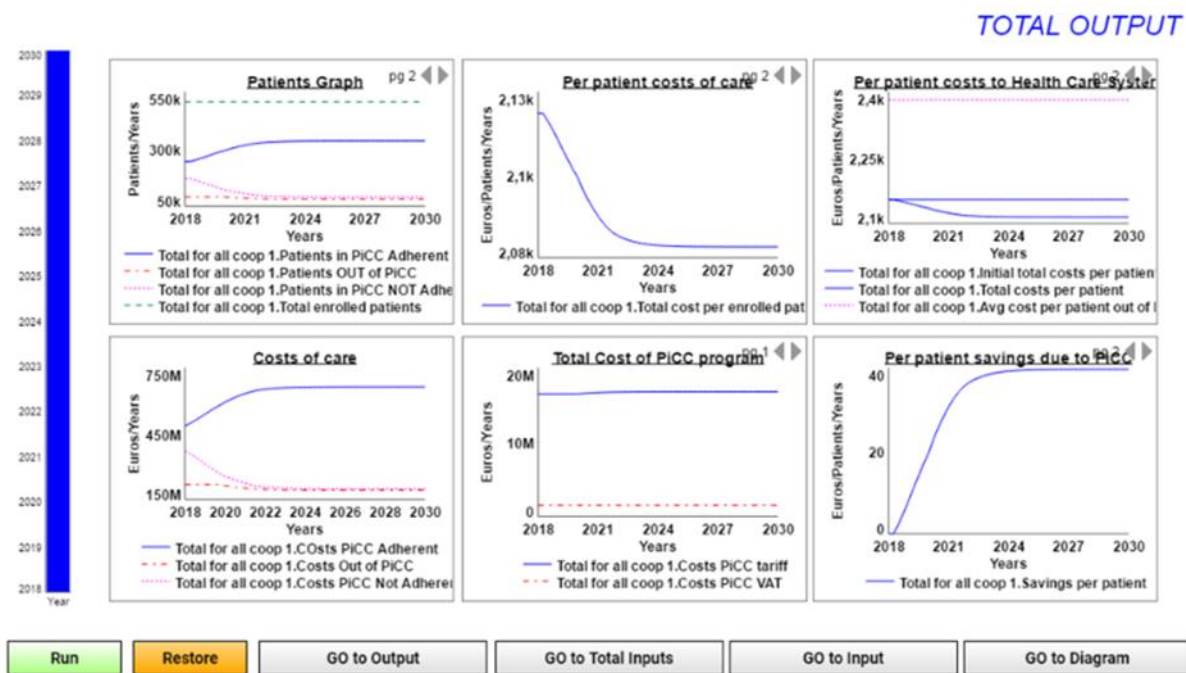


Figure 25: The PiCC outputs of GP Cooperatives

In order to identify the strategic resources and important end results of the implementation of the PiCC initiative within the case study of the GP cooperatives, a dynamic performance management approach has been used. Figure 26 portray the strategic resources, performance drivers and end results important to the work of GP cooperative within PiCC program.

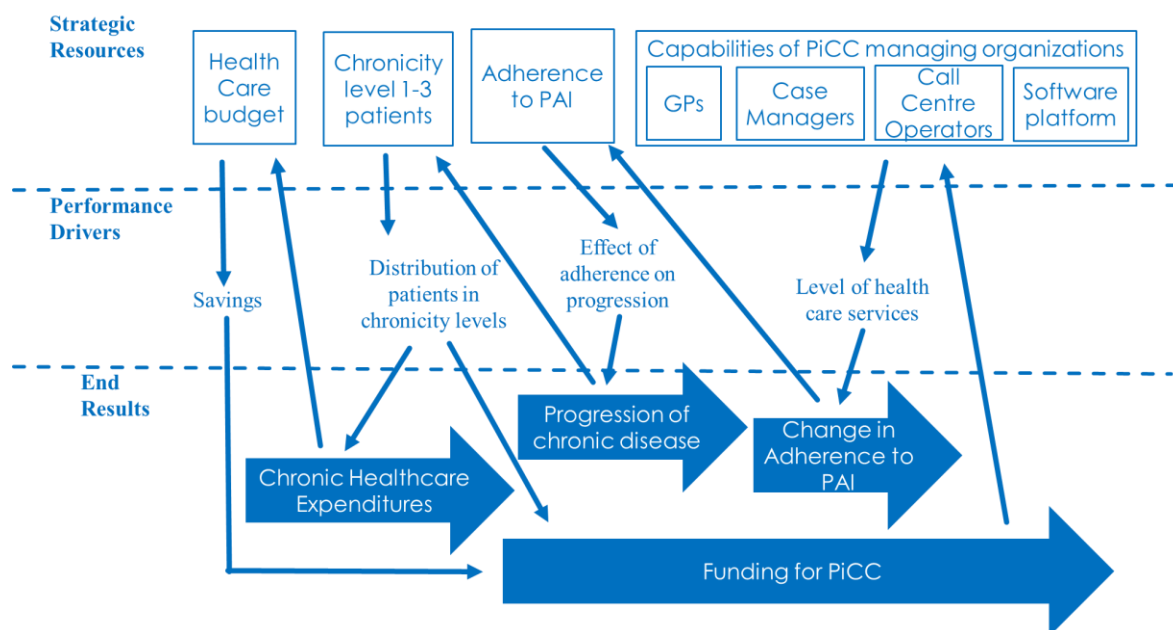


Figure 26: DMP approach model of strategic resources, performance drivers and end results of the work of the GP cooperative within a PiCC program

The capabilities of the GP cooperatives allow it to function and deliver on the new management system of chronic patients, instituted by the PiCC program. Among those important capabilities are the GP professionals, who are responsible for creating the PAI for each participating patient and make assessment throughout the care path. Software platform is the one capability that was identified by the GPs as such that is better to outsource to a technical provider, due to the high initial costs of creating one in house as well as the availability of the platforms on the market from third parties. Nevertheless, the software platform and its proper use within the GP cooperative is a part of the capabilities that allow delivery of the new pathways for the chronic patients, envisioned by PiCC program. Case manager and call centre operator are the two capabilities that were discussed among the GPs in regards of in-house or outside purchase. Regardless of the source, internal or external, these two capabilities are instrumental in support of the chronic patients in accordance with the PiCC program. All of the above mentioned capabilities are at work to increase the adherence of patients to PAI, through delivery of a good

level of services to the chronic patients. Adherence of patients to PAI is yet another important strategic resource. By following, or adhere, to PAI, patients are led by the best care path as identified by the PiCC program. This path provides efficient use of resources for each patient, thus reducing the costs, as well as the continuity of care that can improve the health and well-being of the patient. That, among others, translate into the change in progression of the patient through the levels of severity of the chronic disease. By following the PAI patients are expected to manage better their chronic disease and, thus, stay for longer at lower levels of illness severity, delaying their progression to more complicated levels of chronicity. With the increase in the severity level of chronic disease, the health care for each patient becomes more costly as well as the health and quality of life of the patient decreases. Therefore, it seems to be preferable for the patients to stay as long as possible in the lowest levels of chronicity, and slow down their progression to the next severity level. The number of the chronic patients who are in care of the GP cooperative represents a strategic resource of the organization because the remuneration received by the GP cooperatives is based on the amount of patients in their care. There is a different tariff paid to the cooperatives, based on the complexity level of the chronic disease of each patient. Therefore, distribution of the patients in the chronic levels does affect the funds received by the GP cooperatives. It also influences the expenditures of the Lombardy region on the health care of those patients. However, the relationship is reversed, the more severe is the complicity level of the chronic patient, the more funds the GP cooperative will receive from the government. But the patients with more severe chronic complicity levels cost more to care for the budget of the Lombardy region.

The funding GP cooperatives receive for the PiCC program are used to develop the crucial capabilities, discussed earlier, that enable the execution of the program. The chronic health care expenditures increase or decrease is influencing the budget available to the government for the care. With the decrease of the expenditures resulting from the implementation of the program,

savings may occur. It is hoped by the GP cooperatives that such savings may partially be reinvested into the program as an incentive mechanism for the managing organizations to work even better on the implementation of PiCC.

In order to capture the impacts of the implementation process on the overall policy impacts of PiCC program another dynamic performance model has been created. *Figure 27* shows the strategic resources, performance drivers and end results of PiCC program on the regional level.

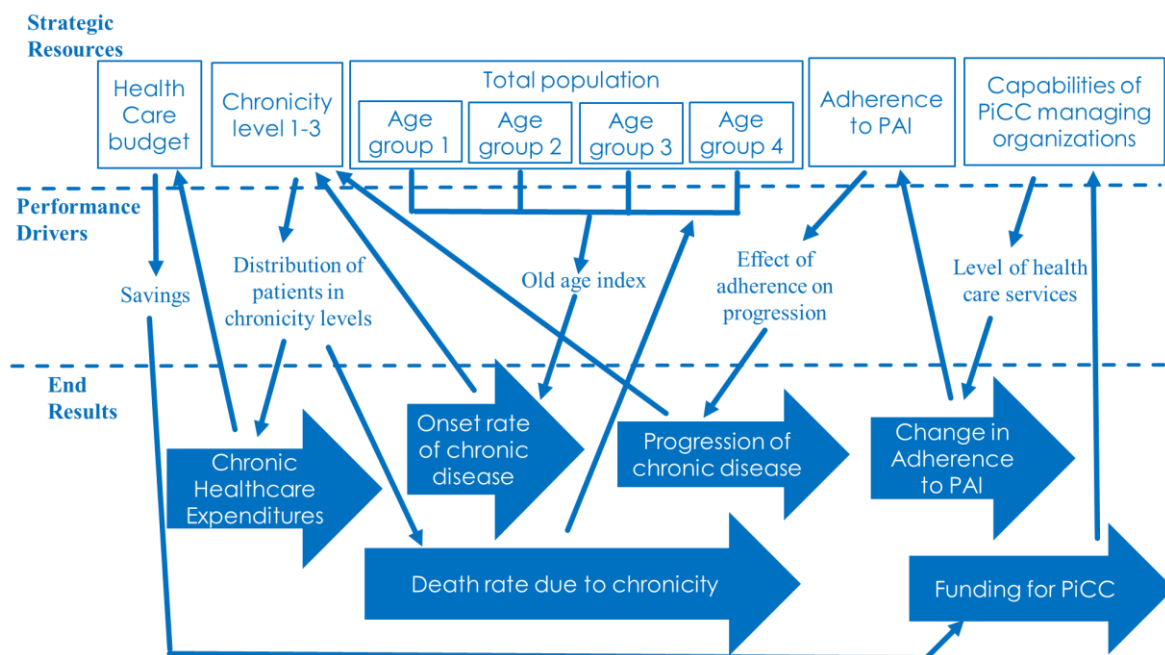


Figure 27: DMP approach model of strategic resources, performance drivers and end results of the work of the PiCC program in Lombardy region

Here we can see the reflection of the hypothesis as to what causes the increase of the health care expenditures. Total population is an important strategic resource of the region because its working population is the tax payer who enables the government to have funds for its programs. With the increase of the old age index, however, the population is aging and due to the increase of the people in the older age groups the onset of the chronic diseases increases. That result in the increase of the chronic patients in the health care system and thus the increase in the expenditures needed for the care of the patients.

With the PiCC program successfully implemented, it is expected that participating patients will be adhering to the PAI and therefore follow the cost efficient, continuous path of care that will improve their health. That improvement will slow down the progression of the chronic diseases, therefor keeping more people in the earlier levels of chronicity. And this change of the distribution of patient in chronicity levels is affecting death rates. Patients with more severe chronic illness level are more likely to die due to their illness. Therefore, when the distribution of patient places more patients into earlier stages of chronicity, it means that more people will be facing lower chances of death due to chronic illness, thus, reducing the death rate. With the reduction of the death rate of the senior layers of the total population, there will be more senior citizens in the population. Even though, the successful implementation of PiCC should reduce the health care expenditures, the better care provided by the program will result in better health condition of the patients and lower death rates. Lower death rates will increase the number of patients that are staying in the health care system and continue to require care, and thus, driving the expenditures upwards. It is important for the policymakers to have such implications of the policies in mind and plan for them accordingly. The knowledge may not change the current policies, but it may foster the new once that will ensure sustainability of the health care for the future.

Chapter 7 –_Conclusions

Innovation in public sector is an under researched subject, but a crucial one. More so is the process of innovation implementation that ensures success of innovation and achievement of the benefits it promises for the society. More often than not, innovations are implemented in a complex social and economic context, making assessment of impacts of the given innovation a complex and timely process. More research is needed that focusses on public sector peculiarities and conditions to enlarge the body of knowledge about innovation implementation, as well as effective and flexible tools are needed for the assessment of the innovation's impacts.

This thesis work contributed to furthering the knowledge of innovation implementation in public sector, its expected and unexpected benefits and consequences along with the implementation process challenges and decisions. Dynamic performance management with system dynamics modelling was used for assessment of an innovation in public health care, a case study of this research. Through these assessment methods, that are good for tackling complex, long-term problems, penetrating multiple levels of public sector and involving different actors, important considerations of innovation implementation were discussed and impacts on different actors identified.

The innovation taken as a study case was an undertaking of the Lombardy region of reorganization of the management of chronic patients in the health care system. The aim of the innovation was to tackle the increase of the health care expenditures of the region that are a result of the care for patients with chronic diseases.

In response to the increase of the health care expenditures related to chronic diseases, government has launched a trial innovation program CReG that was aiming at changing the way the chronic patients are processed through the health care system. This program was not covering the whole region and was voluntarily adopted by participating organizations. With

the knowledge of this trial experience, government then launched a regional wider program PiCC that will reorganize the way chronic patients are managed. This latest innovation became the case study for this work and was assessed through dynamic performance management and system dynamics model.

Based on the regional data of the costs structure, this study made the hypothesis that one of the reasons for the increase of costs could be attributed to the increase of chronic patients. The latest directly related to aging of population. To cope with the cost increase, the governmental response of PiCC program intended to manage each patient more efficiently, both in terms of costs and in terms of results achieved for the health and well-being of the patient. In fact, the program follows the triple aim approach, where its goals are threefold: a) to improve patients health, b) to improve the patients care experience, c) to reduce the costs of care. The impacts and implications of the program were further examined by looking closer at the implementation of the program, particularly, GP cooperatives, as one of the managing organizations of the program, were the basis for the case study of this research.

GP cooperatives, who were the primary participants for the trial program of CReG, had the most experience of new management of the chronic patients. Even though new GPs are joining the initiative in PiCC, the most numerous cooperatives have already been working on provision of the new care plan for chronic patients since CReG. During the modelling sessions with representatives of the GP cooperatives, the inner workings of the program have been discussed and the programme has been represented in a system dynamics model. Using dynamic performance management the strategic resources that enabled the delivery of the end results intended were identified, as well as the performance drivers that prompted the change. As part of the major strategic resources, capabilities of the GP cooperatives necessary for the delivery of the program were identified. The models constructed were used to facilitate discussion among stakeholders about the various routes the cooperatives could take in order to secure the

best quality of service for the best cost possible. In particular, the options of in-house development of the strategic capabilities vs the option to procure them from a service provider were analysed. In order to deliver the improvement in health care path for the chronic patients and secure better results for the health of the patients, the GP cooperatives need to maintain their work of the new management of chronic patients sustainable. The model was used to assess the financial sustainability of the GP cooperatives under different assumptions regarding the participation of the patients in the program, buy vs make scenarios of capabilities acquisition and variations in funding of the PiCC program by the Lombardy region.

In order to reflect on the program implementation and the influence of its success or failure on the health care system, dynamic performance management was used to assess the strategic considerations on the level of regional government. It was shown through the constructed model that the proposed PiCC initiative indeed works toward achievement of the triple aim goals. However, may encounter unexpected consequence in the long-term of the increase of the chronic patients. Such increase would represent a consequent rise in the health care expenditures that the policymakers need to note and anticipate in order to make future programs.

Further research is needed in order to establish implementation pathways and challenges of other participating managing organizations of the PiCC program to form a more detailed and holistic picture of the innovation implementation in the region. The research could be taken further, to study the impact of the health care costs increase on the national level and consider the consequences in more detail, as well as the possible innovations, current or planned that could help the government elevate the problem and bring about better service for the public.

References:

- Altshuler, A., & Zegans, M. (1997). Innovation and Public Management. *Innovation in American government: Challenges, opportunities, and dilemmas*, 68.
- Avery, A. J., Dex, G. M., Mulvaney, C., Serumaga, B., Spencer, R., Lester, H. E., & Campbell, S. M. (2011). Development of prescribing-safety indicators for GPs using the RAND Appropriateness Method. *Br J Gen Pract*, 61(589), e526-e536.
- Balanskat, A., Blamire, R., & Kefala, S. (2006). The ICT impact report. A review of studies of ICT impact on schools in Europe, 11.
- Baumol, W. J. (2002). Entrepreneurship, innovation and growth: The David-Goliath symbiosis. *The Journal of Entrepreneurial Finance*, 7(2), 1.
- Becheikh, N., Landry, R., & Amara, N. (2006). Lessons from innovation empirical studies in the manufacturing sector: A systematic review of the literature from 1993–2003. *Technovation*, 26(5), 644-664.
- Bertot, J. C., Jaeger, P. T., & Grimes, J. M. (2010). Using ICTs to create a culture of transparency: E-government and social media as openness and anti-corruption tools for societies. *Government information quarterly*, 27(3), 264-271.
- Berwick, D. M., Nolan, T. W., & Whittington, J. (2008). The triple aim: care, health, and cost. *Health affairs*, 27(3), 759-769.
- Bianchi, G., & Navarra, M. (2013). Enhancing Performance Management and Sustainable Development through e-government policies in Urban Areas A System Dynamics Approach. Paper presented at the 2013 ASPA Conference New Orleans, March 15 – 19, 2013

- Bocconi, S., Kampylis, P., & Punie, Y. (2013). Framing ICT-enabled Innovation for Learning: the case of one-to-one learning initiatives in Europe. *European Journal of Education*, 48(1), 113-130.
- Christensen, C. M. (1997). *The Innovator's Dilemma: The Revolutionary Book that Will Change the Way You Do Business* (Collins Business Essentials).
- Cini, M. (1996). *The European Commission – Leadership, organisation and Culture in the EU administration*. Manchester, University Press.
- Contini, F., & Lanzara, G. F. (2008). *ICT and innovation in the public sector: European studies in the making of e-government*. Palgrave Macmillan.
- Diehl, E. & Sterman, J. (1995) Effects of feedback complexity on dynamic decision making. *Organizational Behavior and Human Decision Processes* 62(2), 198-215.
- Easton, G. S., & Jarrell, S. L. (1998). The effects of Total Quality Management on corporate performance: An empirical investigation*. *The Journal of Business*, 71(2), 253-307.
- EEAC (2006). *Impact Assessment of European Commission Policies: Achievements and Prospects*. Statement of the EEAC (European Environment and Sustainable Development Advisory Councils) Working Group on Governance.
- European Commission (2002). *Communication on Impact Assessment*, COM 2002:276
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0276:FIN:EN:PDF>
- European Commission (2006). *Impact Assessment Guidelines*, SEC (2005) 791/3
http://ec.europa.eu/agriculture/sfs/documents/documents/sec2005-791_en.pdf
- European Commission (2015). *Guidelines on Impact Assessment*. http://ec.europa.eu/smart-regulation/guidelines/ug_chap3_en.htm
- European Commission (2016). *Health at a Glance: Europe 2016 State Of Health In The Eu Cycle*; OECD,.

- Fait, A., Agnello, M., Sciré, C., & Bergamaschi, W. (2016). The CreG (Chronic Related Group) model to prompt integrated chronic care management: the experience of Lombardy Region. *International Journal of Integrated Care*, 16(6).
- Forrester, J. W. (1961). *Industrial Dynamics*. Productivity Press: Cambridge.
- Giani F., (2015), "Il modello CReG funziona, parola di Regione Lombardia."
- Jamison T., Alleyne, G., Claeson, M., Evans, D. B., Jha, P., Mills, A., & Musgrove, P. (2006). *Disease control priorities in developing countries*.
- Goodman, P. S., Bazerman, M., & Conlon, E. (1979). *Institutionalization of Planned Organizational Change* (No. 1). CARNEGIE-MELLON UNIV PITTSBURGH PA GRADUATE SCHOOL OF INDUSTRIAL ADMINISTRATION.
- Hanlon, J. T., Weinberger, M., Landsman, P. B., Samsa, G. P., Lewis, I., Uttech, K., ... & Feussner, J. R. (1994). Appropriateness of medication prescribing in ambulatory elderly patients. *Journal of the American Geriatrics Society*, 42(12), 1241-1247.
- Hartley, J. (2005). Innovation in governance and public services: Past and present. *Public money and management*, 25(1), 27-34.
- Kardas, P., Lewek, P., & Matyjaszczyk, M. (2013). Determinants of patient adherence: a review of systematic reviews. *Frontiers in pharmacology*, 4.
- Kessler, R. C., Angermeyer, M., Anthony, J. C., De Graaf, R. O. N., Demyttenaere, K., Gasquet, I., ... & Kawakami, N. (2007). Lifetime prevalence and age-of-onset distributions of mental disorders in the World Health Organization's World Mental Health Survey Initiative. *World psychiatry*, 6(3), 168
- Klein, K. J., & Sorra, J. S. (1996). The challenge of innovation implementation. *Academy of management review*, 21(4), 1055-1080.

- Kumar, V., Choisine, F., de Grosbois, D., & Kumar, U. (2009). Impact of TQM on company's performance. *International journal of quality & reliability management*, 26(1), 23-37.
- Lee, N. (2006). Bridging the gap between theory and practice in integrated assessment. *Environmental Impact Assessment Review*, 26:1.
- Levato, G. (2016) "The CReG experimentation of the Lombardy Region"
- Lombardy Region (2015). "Indirizzi per la presa in carico della cronicità e della fragilità in Regione Lombardia, 2016-2018"
- Longo, F., Petracca, F. & Ricci, A., (2016), Analisi del modello CReG: da esperimento a elemento di sistema., Presentazione fatta durante il convegno "La Riforma Sanitaria Lombarda 1 anno dopo", Milano 21 Novembre 2016.
- Lopez, A. D., Mathers, C. D., Ezzati, M., Jamison, D. T., & Murray, C. J. (2006). Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. *The Lancet*, 367(9524), 1747-1757.
- Lussis, B. (2004). Extended Impact Assessment Review. Institut pour un Développement Durable. Working Paper, 9 Dec.
- Mandelkern Group (2001). Final Report http://ec.europa.eu/smart-regulation/better_regulation/documents/mandelkern_report.pdf
- Marche, S., & McNiven, J. D. (2003). E-government and e-governance: the future isn't what it used to be. *Canadian Journal of Administrative Sciences/Revue Canadienne des Sciences de l'Administration*, 20(1), 74-86.
- Montanelli R., Turrini A. (2006) *La governance locale nei servizi sociali*, EGEA Ed. Collana CERGAS, ISBN/EAN: 8823841380
- Moore, M. H. (1995). *Creating public value: Strategic management in government*. Harvard university press.

- Mulgan, G., & Albury, D. (2003). Innovation in the public sector. <http://www.sba.oakland.edu/>
- OECD (1997). Regulatory Impact Analysis: Best practice in OECD countries. Paris.
- Powell, T. C. (1995). Total quality management as competitive advantage: a review and empirical study. *Strategic management journal*, 16(1), 15-37.
- Pfeffer, J., & Sutton, R. I. (2013). The knowing-doing gap: How smart companies turn knowledge into action. Harvard Business Press.
- Pomerleau, J., Knai, C., & Nolte, E. (2008). The burden of chronic disease in Europe. Caring for people with chronic conditions. A health systems perspective, 15-42.
- Rahmandad, H. (2012). Impact of growth opportunities and competition on firm-level capability development trade-offs. *Organization science*, 23(1), 138-154.
- Renda, A. (2006). Impact Assessment in the EU – The state of the art and the art of the state. Brussels: Centre for European Policy Studies.
- Repenning, N. P. (2002). A simulation-based approach to understanding the dynamics of innovation implementation. *Organization Science*, 13(2), 109-127.
- Richardson, G. P. (1991). Feedback thought in the social science and systems theory. University of Pennsylvania Press, Philadelphia.
- Richardson, G. P. (2011). Reflections on the foundations of system dynamics. *System Dynamics Review*, 27(3), 219-243.
- Rosenbusch, N., Brinckmann, J., & Bausch, A. (2011). Is innovation always beneficial? A meta-analysis of the relationship between innovation and performance in SMEs. *Journal of business Venturing*, 26(4), 441-457.
- Sabaté, E. (Ed.). (2003). Adherence to long-term therapies: evidence for action. World Health Organization.

- Senge, P. (1990), *The Fifth Discipline: Mastering the Five Practices of the Learning Organization*, Doubleday, New York.
- Schumpeter, J. A. (1934). *The theory of economic development: An inquiry into profits, capital, credit, interest, and the business cycle* (Vol. 55). Transaction publishers.
- Schumpeter, J.A. (1942) *Capitalism, socialism and democracy*. Harper and Row, New York
- Southon, G., Sauer, C., & Dampney, K. (1999). Lessons from a failed information systems initiative: issues for complex organisations. *International journal of medical informatics*, 55(1), 33-46.
- Sterman J. D. (2000). *Business dynamics: System thinking and modelling in a complex world*. Boston: McGraw-Hill.
- Sterman, J. D., Henderson, R., Beinhocker, E. D., Newman, L. I. (2007). Getting Big Too Fast: Strategic Dynamics with Increasing Returns and Bounded Rationality. *Management Science*, 53(4), 683–696.
- Torres, L., Pina, V., & Acerete, B. (2006). E-Governance Developments in European Union Cities: Reshaping Government's Relationship with Citizens. *Governance*, 19(2), 277-302.
- Venugopal, C., & Suryaprakasa Rao, K. (2011). Learning from a failed ERP implementation: a case study research. *International Journal of Managing Projects in Business*, 4(4), 596-615.
- Warren, K. (1999). The Dynamics of Strategy. *System Dynamics Review*, 10(3), 1–16.
- Warren, K. (2005). Improving strategic management with the fundamental principles of system dynamics. *System Dynamics Review* (21) 4 329-350
- Warren, J., & Myungsin, C. (2007). Culture, organizational dynamics and workflow implementation: the case of a failed implementation. *Journal of Information Technology Case and Application Research*, 9(1), 20-37.

Warren, K. (2008). *Strategic Management Dynamics*. Chichester: John Wiley and Sons LT.

Wilkinson, D. et. al. (2004). Sustainable development in the European Commission's integrated impact assessment for 2003. IEEP.

Wimmer, M., & Traunmüller, R. (2002). Towards an integrated platform for online one-stop government. *ERCIM News, Special Theme: e-Government*, 48.

Wimo, A., Winblad, B., Aguero-Torres, H., & von Strauss, E. (2003). The magnitude of dementia occurrence in the world. *Alzheimer Disease & Associated Disorders*, 17(2), 63-67.

Appendix 1: List of figures

Figure 1: Positive loop of reinforcement R1 and of Diffusion R2, negative (balancing) loop of normative feedback B1, adopted from Repenning (2002).....	14
Figure 2: Historical total chronic healthcare costs 2005-2013 (pharmaceutical, outpatient and hospital) Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.	21
Figure 3: Historical chronic healthcare costs per capita 2005-2013 (pharmaceutical, outpatient and hospital). Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.	22
Figure 4: Demographic projections 2005-2065 of the Lombardy Region population Adopted from: ISTAT data processing, Resolution no. 4662 of 23/12/2015 of the Lombardy Region.	24
Figure 5: Life expectancy at birth, 2014 and 1990. Adopted from: European Commission (2016).....	25
Figure 6: Historical series of frequencies of subjects with chronic diseases 2005-2013 and projection 2014-2020 (BDA data). Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.	31
Figure 7: Historical chronic healthcare costs per capita 2005-2013 and forecast 2014-2020 Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.....	32
Figure 8: Historical total chronic healthcare costs 2005-2013 and forecast 2014-2020 Adopted from: Resolution no. 4662 of 23/12/2015 of the Lombardy Region.....	32
Figure 9: Triple Aim. Adopted from IHI.....	37
Figure 10: Patient participation rate – ASL and class complexity distribution (2015). Adopted from: Longo et al. (2015).....	48
Figure 11: Patient participation rate – number of comorbidities and age distribution, 2015. Adopted from: Longo et al. (2015).....	49

Figure 12: Patient participation rate – trend for ASL from 2012 to 2015. Adopted from: Longo et al. (2015).....	50
Figure 13: Impacts on health expenditure and consumption – pharmaceutical consumption costs per capita (2011; 2015). Adopted from: Longo et al. (2015).....	51
Figure 14: Impacts on health expenditure and consumption – comparison of hospitalization (due to disease complications) costs per capita (2011; 2015). Adopted from: Longo et al. (2015).....	52
Figure 15: SFD – Chronic healthcare costs	64
Figure 16: SFD – Chronic patient movement through the chronicity levels	65
Figure 17: SFD – Aging chain of total population	65
Figure 18: SFD – Aging chain of population, chronicity onset, progression and costs	66
Figure 19: SFD – PiCC program triple aim influence	67
Figure 20: Distribution of PiCC participating GPs cooperatives.....	70
Figure 21: BEP analysis results in the case of 440 patients enrolled on average for GP (100% enrolment rate) and no abandonment of the initiative by patients in a year	72
Figure 22: BEP analysis results in the case of 220 patients enrolled on average for GP (50% enrolment rate) and 10% abandonment of the initiative by patients in a year.....	72
Figure 23: The PiCC sub-model elements of the MM Cooperatives.....	74
Figure 24: Level of expenditure for patients enrolled in PiCC and not enrolled.....	75
Figure 25: The PiCC outputs of GP Cooperatives.....	75
Figure 26: DMP approach model of strategic resources, performance drivers and end results of the work of the GP cooperative within a PiCC program.....	76
Figure 27: DMP approach model of strategic resources, performance drivers and end results of the work of the PiCC program in Lombardy region.....	78

Appendix 2: List of tables

Table 1: Spread of diseases and deaths from non-communicable diseases in Europe by cause (2005). Adopted from: Singh, 2008.....	26
Table 2: Diffusion of diseases and deaths attributable to common risk factors, in absolute values and in percentages with respect to the DALY / total deaths in the world. Adopted from: processing Lopez et al. 2006.....	27
Table 3: The strengths of the CReG	45
Table 4: The CReG results at the end of 2015 – general practitioners distribution.....	46
Table 5: The CReG results at the end of 2015 – GP profile in and out of CReG.....	47
Table 6: The variations, in absolute terms, of the CReG and non-CReG costs (2011; 2015).	53
Table 7: The variations, in percentage terms, of the CReG and non-CReG costs (2011; 2015)	54
Table 8: PiCC model classification of population	57
Table 9: Composition of the PiCC tariff.....	58
Table 10: Drivers of emerging models of chronic care.	61