

UNIVERSITA' DEGLI STUDI DI PAVIA Dipartimento di Scienze Economiche e Aziendali

UNIVERSITA' DEGLI STUDI DI BERGAMO Dipartimento di Ingegneria Gestionale, dell'Informazione e della Produzione

DOCTORAL RESEARCH IN ECONOMICS AND MANAGEMENT OF TECHNOLOGY (DREAMT)

Moving Knowledge into Action: Implementation Interventions for Health Technology Assessment Development

Supervisor: Professor Maria Chiara Demartini, University of Pavia

> Doctoral thesis of Valentina Beretta

XXXII Cycle

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Chapter 1: INTRODUCTION

ABSTRACT

The need to generate knowledge with practical implications is growing, especially in the healthcare field. Nevertheless, the gap between knowledge and action remains huge. In order to reduce this gap, different tools emerged. Among them, Health Technology Assessment (HTA) was introduced as a knowledge infrastructure tool, that allows the evaluation of the properties of health technologies, considering a variety of factors that can contribute in the final decision. Despite many advancements in the field have been done, there are uncovered research gaps that need further investigation. In particular, this study aims at analyzing the factors affecting the HTA development in decentralized countries, with a particular focus of the perceptions of healthcare professionals about local HTA.

Chapter 1: INTRODUCTION

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Chapter 1: INTRODUCTION

1.1 Brief Overview of the Thesis

Despite the growing interest in producing evidence with practical implications, especially in the context of healthcare, and the advancements made in the literature in this direction, the gap between knowledge and action remains huge. In particular, some research gaps are still unexploited in this area. First of all, further research is needed in order to analyze the factors that are affecting the Health Technology Assessment (HTA) development at different levels of analysis. In particular, HTA has been introduced as a support tool aimed at reviewing, assessing and summarizing the extant literature to regulate the introduction and the diffusion of healthcare technologies. Despite some studies recognized the relevance of both individual and organizational factors in affecting the involvement in knowledge production and translation, their relevance in the context of HTA is still underexplored. Second, research in decentralized countries need to be further analyzed in order to better understand how HTA could be successfully implemented in decentralized healthcare systems. Finally, despite perceptions of healthcare professionals are particularly relevant in HTA process, especially when it is conducted at local level, they are rarely captured, and they need further investigation. Therefore, this study is aimed at investigating factors that are affecting the development of HTA activities in decentralized countries with a specific focus of the analysis on perceptions of healthcare professionals related to the identification of possible HTA designs at local level.

1.2 Executive Summary

The remainder of this manuscript is organized as follows.

In Chapter 2 the literature review is discussed. It is widely accepted in the literature that researchers have to generate knowledge with practical implications (e.g. Lomas, 1997; Haines, Kuruvilla and Borchert, 2004; Holmes et al., 2017; Cheetham et al., 2018; Reed et al., 2018). For this reason, a growing field of studies analyze the factors affecting the process of KTE, demonstrating that the requirements for a successful KTE process change over time. The field has been shaped by the emergence of the Mode 2 Knowledge Production Theory, according to which knowledge needs to be generated by multidisciplinary teams that should consider context specificities for enhancing research findings uptake (Gibbons et al., 1994), and it is no more considered as a mere linear and researcherdriven activity (Gibbons et al., 1994; Etzkowitz and Leydesdorff, 2000; Nowotny, Scott and Gibbons, 2003; Graham et al., 2006; Wilson et al., 2010), but rather as a dynamic and iterative process characterized by complex interactions between users and producers of knowledge (Ward *et al.*, 2012). In this context, the implementation science emerged in order to face the difficulty of translating research results into the minds of users and the subsequent implementation, which can be facilitated by many strategies (Munn et al., 2018). Research uptake is particularly important in the context of healthcare. Indeed, the public demand for accountability has led to an environment in which the evidence-based decision making is expected (Jennings and Hall, 2012; Fox, 2015). For this reason, a growing number of scholars recognize the importance of health decision making processes being research-informed and grounded on scientific evidence (Hanney et al., 2003; Dobbins, DeCorby and Twiddy, 2004; Dobrow, Goel and Upshur, 2004; Hivon et al., 2005). However, current practices do not reflect research evidence to the extent that in theory they could (Kogan and Henkel, 1983; Frenk, 1992; Davis and Howden-Chapman, 1996; Sauerborn, Nitayarumphong and Gerhardus, 1999; Trostle, Bronfman and Langer, 1999; Gerhardus, Kielmann and Sanou, 2000; Lavis, Ross and Hurley, 2002). The lack of provision of timely and optimal use of research evidence can result in a reduction of the quality of care (Jernberg et al., 2011), in an inefficient use of resources (Davis et al., 2003; Madon et al., 2007), and in a reduction in the quality of health outcomes (Chalmers, 2005). Nevertheless, the gap between knowledge generation and utilization remains huge (Granados et al., 1997; Bero et al., 1998; Drummond and Weatherly, 2000; Lehoux et al., 2005) and the tools able to support the KTE process are just few (Rashiq et al., 2006). In particuarl, HTA emerged as a decisionmaking support tool aimed at reviewing, assessing and summarizing the extant literature, considering both the outcome and the quality of the evidence itself (Draborg et al., 2005; Rashiq et al., 2006).

The evaluation of health technologies can be conducted at three different levels: macro level HTA refers to both national and international institutions; meso level refers to regional and/or provincial health authorities; while micro level is represented by local institutions (Garrido *et al.*, 2008). While

macro level is the most widespread area of application, research is still needed at meso and micro levels (Catananti, Cicchetti and Marchetti, 2005). Despite many advancements have been done in the field, some research gaps still exist. In particular, the aim of this study is to investigate factors that can affect the HTA development in decentralized countries, with the consideration of the perceptions of healthcare professionals about the identification of possible HTA designs.

In Chapter 3 the methodological approach adopted in the study is presented. This study adopts a mixed methods approach (MMA), which, despite being subject to several debates (Howe, 1988; McEvoy and Richards, 2006; Biesta, 2010), it is currently considered as philosophically valid by several scholars (e.g. Greene, 2007; Howe, 1988; Johnson & Onwuegbuzie, 2004; McEvoy & Richards, 2006; Risjord, 2011; Teddlie & Tashakkori, 2010), since it allows a deeper understanding of the research problem and to improve the quality of the analysis (Wisdom *et al.*, 2012). In particular, the use of MMA has been notably advocated in implementation science (Proctor et al., 2009; Aarons, Hurlburt and Horwitz, 2011; Palinkas, Aarons, et al., 2011; Landsverk et al., 2012), since the quality related to the implementation of the evidence-based innovation can be enhanced (Palinkas et al., 2015) and it offers the possibility to have a deeper understanding of the complex research problem. Both quantitative and qualitative data are captured in order to answer the research questions: quantitative data are collected through a web-based survey, while qualitative data are gathered through semi-structured interviews. The analysis of quantitative and qualitative data is done following the triangulation protocol strategy depicted by O'Cathain et al., which previews an interpretation stage to integrate results and to get a broader image of the research problem (O'Cathain, Murphy and Nicholl, 2010). The theoretical framework that guides the analysis is the Ottawa Model of Research Use (OMRU), which allows the researcher to identify the barriers for the diffusion of the innovation, to design appropriate strategies to overcome the barriers, and to monitor the implementation intervention (Graham and Logan, 1998; Hogan and Logan, 2004; Logan and Graham, 2010).

In Chapter 4 quantitative results are discussed. The analysis is conducted in Lombardy Region, in Italy, where tailored implementation strategies, aimed at diffusing HTA culture at different levels of the healthcare system, have been developed. Quantitative data are gathered through a web-based survey delivered to healthcare professionals in the Lombardy Region during the period from

September to December 2017. In particular, the collection of quantitative data allows the identification of the profiles of potential adopters of HTA processes and the practice environment in which the HTA process is introduced. All the healthcare organizations of Lombardy Region have been included in the sample in order to represent the profiles of the whole population. The development of the web-based survey was guided by previous literature in the field (ISPOR Asia Consortium; Moharra et al., 2008; World Health Organization, 2015). The final survey was composed of 34 questions, related to four different areas of interest (demographic characteristics; knowledge; experience; attitudes, awareness and beliefs towards HTA), and it was written in Italian for facilitating its comprehension. Before starting the data analysis, the wave analysis was performed in order to test for nonresponse bias (Dillman, 2011). Results of the analysis showed that nonresponse bias was not a major concern in this study. Descriptive statistics are provided for the analyzed variables and the bivariate analysis performed to test differences among groups of respondents. A total of 41 healthcare organizations of the Lombardy Region took part at the survey, with the highest representation of the medical area. Results found that the majority of respondents is aware of the existence of the HTA processes, and some of them already participated at HTA activities. However, little knowledge of HTA networks and associations has been detected. The objective of HTA has been mainly found in providing support to planning and budgeting activities, with a widely recognized importance of evidence in informing the evaluation process. Barriers to HTA have been investigated, as well. While for the production of HTA, the lack of resources (especially qualified human resources), and knowledge of the methodologies to adopt may prevent the involvement of professionals in HTA activities, respondents declared that to foster the use of HTA reports it is necessary to increase the awareness of the importance of HTA.

In Chapter 5 qualitative results are discussed following the implementation outcomes analyzed. Despite the qualitative analysis has been usually criticized for lacking scientific rigor (e.g. Dickson-Swift, James, Kippen, & Liamputtong, 2007; Malterud, 2001; Mays & Pope, 1995), along with this study, drawing on previous research (Mays and Pope, 1995; Hoddinott and Pill, 1997; Seale and Silverman, 1997; Mauthner, Parry and Backett-Milburn, 1998; Popay, Rogers and Williams, 1998; Kitto, Chesters and Grbich, 2008; Mauthner and Doucet, 2009), quality of the analysis is measured by the rigor and the reflexivity of the study. The approach that has been adopted to investigate knowledge is a combination of deductive and inductive, through the use of a mixture of analytic induction and grounded theory (Corbin and Strauss, 1990; Strauss and Corbin, 1994, 1997; Charmaz and Belgrave, 2007; Charmaz, 2014; Glaser and Strauss, 2017). The analysis has started with the analytic induction, by considering the implementation outcomes planned by Proctor and colleagues

to analyze the intervention designed to promote the diffusion of HTA in Lombardy Region (Proctor et al., 2011), and the grounded theory approach was implemented so as to be open and reflective to new themes showing within the knowledge, by adding them into the initial framework provided by the analytical induction. Subsequently, an "open coding" approach was adopted in order to detect emerging themes associated with every outcome (Bohm, 2004; Moghaddam, 2006). The semistructured interviews were conducted in the period from April to May 2019 in 15 healthcare organizations in Lombardy Region. In terms of adoption of the innovation, at individual level, the majority of interviewees affirmed to have attended specific training courses on HTA, but only half of them are actively involved in HTA processes, while at organizational level, all the healthcare organizations have a commission that performs HTA activities, but not in all the cases this is already operating. The acceptability of the HTA process was analyzed. The interviewees recognized that having proper tools that can be adapted to the peculiarities of different contexts could increase the positive perception about the HTA processes among implementation stakeholders, which can also be enhanced thanks to the supportive role of the regional level. The appropriateness of the HTA process for supporting the evaluation of new health technologies has been widely recognized. Feasibility of HTA process in Lombardy Region could be enhanced by some features that characterize the activities, such as the mandate, the culture and competences, the resources, the networking activities, the obligation and monitoring, the process and the interactions among levels. Additionally, benefits, limits and future directions of the implementation process are discussed, such as the perceived impact of interviewees in terms of cost. The analysis of the penetration of the HTA process provide some insights related to the composition of the HTA commission across healthcare organizations. Finally, elements for ensuring sustainability of the process are discussed in terms of training, culture and awareness, resources, process, and tools.

In Chapter 6, a joint discussion of qualitative and quantitative portion of the results is provided. It is structured following the OMRU theoretical framework, that is employed in previous studies to provide guidance for the implementation intervention (e.g. Gifford et al., 2018; Giuliani et al., 2019; Luebbers, Dolansky, Vehovec, & Petty, 2017). First, in terms of Practice Environment, results support the importance of the interactions among different levels of analysis, the sharing of available knowledge, networking activities, leadership, engagement and learning in order to foster cultural flourishment at individual and/or organizational level. In addition, the gap between HTA process and the decision-making process, and the lack of resources have been recognized as limits in the HTA development. Second, concerning the profiles of Potential Adopters, results show that, while the HTA

reports, and some of the HTA features are recognized among the barriers that could prevent the diffusion of HTA, the building of a strong culture and competences, the mandate, the individual learning, the engagement and the availability of Champions/Opinion Leaders could help the involvement in HTA activities. Third, in terms of Innovation, the multidisciplinarity of the HTA process has been widely recognized as an important feature of the process. Additionally, clarity, simplicity, flexibility, transparency, HTA as a project, vocabulary, engagement, programming, and monitoring are recognized among the features of the HTA that could promote HTA development. Fourth, the Transfer Strategies adopted along with the intervention, are described adopting a fourstages process: the Pre-Conditions phase for the identification of information needed, the Pre-Implementation phase for the selection of strategies, and the preparation of the material, Implementation phase for initiating leadership and educating professionals, and, finally the Maintenance and Evolution phase to develop relationships and restructure strategies. Fifth, in terms of Adoption and Use, the intervention helped for the enhancement of the culture and awareness of HTA both at individual and organizational level. Finally, in terms of Outcome, a model for HTA development emerged. In particular, six elements are particularly relevant: identification of potential barriers, collection of healthcare professionals' perceptions, delineation of potential enablers, features and requirements of the HTA project, and, finally, interactions among different levels of analysis.

Finally, in Chapter 7 conclusions are discussed, contributions of this study presented, such as the implications that can be derived, and the limitations at which it is subject, that can open avenues for future research. Given the multidisciplinarity of the topic, this study provides contributions in different streams of literature. First, it contributes in advancing some knowledge in the HTA literature, by providing some insights related to the perceptions about the concept of HTA and its objectives, and by identifying the requirements of HTA design. In addition, further investigation of the factors fostering or hindering HTA development is provided. This study contributes also to the local HTA literature, since it provides an in-depth analysis of the relationships between different levels of analysis. In particular, it advances some knowledge related to the perceptions of healthcare professionals about HTA design at local level. This study contributes also to the stream of literature related to the Knowledge Management, by providing further insights on the understanding of KTE process in healthcare, and, more precisely, in the context of HTA. Finally, this study contributes to the implementation research literature, since it provides a practical application of implementation science in the field of HTA. Theoretical, policy and practical implications can be derived from this study. First, from a theoretical standpoint, this study contributes in advancing knowledge related to the design of HTA process. Second, policy implications are derived from the analysis of the relevance

of the relationships between different levels of analysis. Finally, concerning practical implications, by investigating the perceptions of the healthcare professionals, this study advances some knowledge related to the requirements of the HTA process. In common with applied research more generally, this study is not without limitations, which can open interesting avenues for future research. In particular, given the limitations identified in this study, future research could be conducted in the following areas: first, a comparison of different research areas (e.g. centralized vs decentralized countries) could be beneficial in order to identify dis(similarities) in terms of HTA requirements; differentiation between various typologies of healthcare organizations and the reasons that are driving them in HTA development could be further investigated; finally, further research could directly capture the regional perspective in assessing factors influencing HTA development.

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Chapter 2: LITERATURE REVIEW

ABSTRACT

Previous studies widely recognized the need to generate knowledge with practical implications. A growing interest in analyzing the process of generation, dissemination and use of new evidence has been detected. In particular, it is widely accepted in the literature that there is the necessity to adopt strategies aimed at increasing the uptake of research findings, since the percentage of current evidence that is translated into current practices is below the 20% and with an enormous delay of time. This is particularly true in the health field, where different tools for enhancing knowledge uptake emerged. Among them, health technology assessment was introduced as a knowledge infrastructure tool aimed at supporting evidence-based decision-making processes. Despite many advancements have been done in the literature in this context, there are still areas which need further investigation. First, while the literature related to the description of the barriers and enablers of health technology assessment (HTA) is growing, factors affecting the HTA development needs to be further investigated. More precisely, the perceptions of practitioners related to HTA development are rarely captured, even if they play a crucial role, especially when the analysis is conducted at local level. Second, previous studies identified a significant gap in the analysis of the establishment of evidence advisory systems at national or sub-national levels by comparing countries according to their system. More specifically, current literature lacks an in-depth analysis of how evidence analysis activities can be implemented in health-care systems characterized by decentralization. Therefore, this study is aimed at investigating factors that are affecting the development of HTA activities in decentralized countries with a specific focus of the analysis of perceptions of healthcare professionals related to the identification of possible HTA designs at local level.

Chapter 2: LITERATURE REVIEW

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Chapter 2: LITERATURE REVIEW

2.1 Introduction

It is widely accepted in the literature that researchers have to generate knowledge with practical implications (e.g. Lomas, 1997; Haines, Kuruvilla and Borchert, 2004; Holmes *et al.*, 2017; Cheetham *et al.*, 2018; Reed *et al.*, 2018). For this reason, a growing field of studies analyze the process of generation, dissemination and use of knowledge. In order to enhance the use of knowledge for changing current practices, a shift from linear to more dynamic models of knowledge transfer and exchange (KTE) process has occurred (Gibbons *et al.*, 2006). This has been supported by the emergence of the Mode 2 Knowledge Production Theory, according to which knowledge needs to be generated by multidisciplinary teams that should consider context specificities during KTE process for enhancing the uptake of research findings (Gibbons *et al.*, 1994).

Research uptake is particularly important in the context of healthcare. In fact, the public demand for accountability has led to an environment in which the evidence-based decision making is expected (Jennings and Hall, 2012; Fox, 2015). For this reason, a growing number of scholars recognize the importance of health decision making processes being research-informed and grounded on scientific evidence (Hanney et al., 2003; Dobbins, DeCorby and Twiddy, 2004; Dobrow, Goel and Upshur, 2004; Hivon et al., 2005). At this purpose, the evidence-based medicine (EBM) movement was developed after the middle of the 20th century (Daly, 2005) with the intention of integrating external clinical evidence with individual clinical expertise. In particular, it is considered as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett et al., 1996, p. 71). However, current practices do not reflect research evidence to the extent that in theory they could (Davis & Howden-Chapman, 1996; Frenk, 1992; Gerhardus, Kielmann, & Sanou, 2000; Kogan & Henkel, 1983; Lavis, Ross, & Hurley, 2002; Sauerborn, Nitayarumphong, & Gerhardus, 1999; Trostle, Bronfman, & Langer, 1999). The lack of provision of timely and optimal use of research evidence can result in a reduction of the quality of care (Jernberg et al., 2011), in an inefficient use of resources (Davis et al., 2003; Madon, Hofman, Kupfer, & Glass, 2007), and in a reduction in the quality of health outcomes (Chalmers, 2005).

Despite the disadvantages connected to the failure to translate research findings into practices, the gap between knowledge generation and utilization remains huge (Bero et al., 1998; Drummond & Weatherly, 2000; Granados et al., 1997; Lehoux, Denis, Tailliez, & Hivon, 2005).

Even though practitioners need to be informed about the new medical literature, the tools able to support the KTE process are just few (Rashiq *et al.*, 2006). Within the context of evidence-based medicine, the movement aimed at supporting the use of the best current available knowledge to take healthcare decisions (Sackett *et al.*, 1996), the Health Technology Assessment (HTA) emerged as a support tool aimed at reviewing, assessing and summarizing the extant literature, considering both the outcome and the quality of the evidence itself (Draborg *et al.*, 2005; Rashiq *et al.*, 2006). Despite the growing interest in HTA, and the advancements that have been made in the literature, further research is needed in order to have a better understanding of factors affecting HTA development.

The remaining of this Chapter is organized as follow: Section two presents the evolution of KTE literature; in Section three the functioning of decision-making process in health care is presented; Section four is dedicated to the analysis of the health technology assessment as a knowledge infrastructure aimed at supporting KTE process; in Section five literature gaps are presented and the research questions are stated; Section six is dedicated to the conclusions.

2.2 Knowledge Transfer and Exchange Literature

The benefits associated with the creation of new knowledge, like the improvement of health outcomes, and the optimization of scarce resources, are widely accepted in the literature (Cruz Rivera, Kyte, Aiyegbusi, Keeley, & Calvert, 2017; Graham et al., 2006; Grimshaw, Eccles, Lavis, Hill, & Squires, 2012; McLean, Graham, Tetroe, & Volmink, 2018). In particular, the interest in the field is growing fast, and this is justified by the emergence of international activities, like the launch of journals that are focused on research utilization, such as "Evidence & Policy" and "Implementation Science", and some international events, such as "Global Evidence Summit" (Parkhurst, Ettelt and Peters, 2018).

However, it is worth to notice that these benefits are rarely achieved by only the creation of new knowledge, but instead, its real potential of is in knowing how to use it (McLean *et al.*, 2018). In particular, after the stage related to the creation of knowledge, then the processes of synthesis, transfer and implementation can help in exploiting the majority of related benefits (Munn *et al.*, 2018), since only once knowledge results achieve their target stakeholders the cycle of knowledge creation and use can be completed. At this purpose, particular attention has been devoted during the years to the transfer strategies that can be adopted to vehiculate the information (Culyer, Jatulis, Cannistraci, & Brownell, 2018; Garforth et al., 2004; Gick & Holyoak, 1987; Graham et al., 2006). In particular, one of the major need of today remains the one of ensuring the communication of messages that are dynamic enough to reach different audiences in an effective manner (Munn *et al.*, 2018). Therefore, finding communication strategies that can effectively translate research results in a comprehensive way for different stakeholders is still a difficult task, and the KTE process is still considered messy and complex because of the need to have the possibility to easily translate knowledge for solving actual problems (Van Ruler, 2005; Graham *et al.*, 2006; Ward, House and Hamer, 2009; Hughes *et al.*, 2011; Bartunek and Rynes, 2014; Tucker and Lowe, 2014; Munn *et al.*, 2018).

Many scholars in this field of research started approaching the analysis of the KTE process and the strategies aimed at enhancing the communication and the uptake of research evidence. The presentation and the discussion on how the KTE process is conceptualized, the presentation of the strategies that can be adopted to translate knowledge into practice, the illustration of how the literature has evolved in this field, such as the identification of the factors affecting the process are provided in the following sub-sections.

2.2.1 Knowledge Transfer and Exchange Definition

Nowadays, literature related to the KTE is abundant. In particular, a variety of terms has been used to describe the process aimed at translating knowledge into action (Graham *et al.*, 2006; Davies, Nutley and Walter, 2008; Best and Holmes, 2010; McKibbon *et al.*, 2010; Oborn, Barrett and Racko, 2010; Greenhalgh and Wieringa, 2011; Rajic, Young and McEwen, 2013; Nilsen, 2015; Van Eerd, 2019).

KNOWLEDGE EXCHANGE			
"Process of generating, sharing, and/or using knowledge through various methods appropriate to the			
context, purpose, and participants involved" (Fazey et al., 2013, p. 20)			
KNOWLEDGE TRANSLATION			
"A dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound			
application of knowledge to improve the health of Canadians, provide more effective health services and			
products and strengthen the health care system" (CIHR - Canadian Institutes of Health Research)			
GENERATION	DIFFUSION	USE	
Knowledge Generation (e.g. Beal	Knowledge Transfer (e.g. Argote	Research Utilization (Weiss,	
and Dissanayake, 1986; Tsoukas,	and Ingram, 2000; Dixon, 2000;	1979; Morrow-Bradley and	
1993; Clarke, 1999; Soibelman and	Tsai, 2001; Broner <i>et al.</i> , 2001;	Elliott, 1986; Champion and	
Kim, 2002; Hahn et al., 2006; Wiek,	Jacobson, Butterill and Goering,	Leach, 1989; Funk <i>et al.</i> ,	
2007; Berkes, 2009; Kinsella and	2003; Kramer and Cole, 2003;	1991; Kajermo <i>et al.</i> , 1998;	
Whiteford, 2009)	Dobbins, DeCorby and Twiddy,	Estabrooks, 1999; Parahoo,	
	2004; Barwick <i>et al.</i> , 2005;	2000; Stetler, 2001;	
	Shamian and El-Jardali, 2007;	Estabrooks et al., 2003;	
	Mitton et al., 2007; Davies,	Hutchinson and Johnston,	
	Nutley and Walter, 2008; Rossiter	2004)	
	<i>et al.</i> , 2008)		
Coproduction of Knowledge	Knowledge Sharing (Gruber,	Research Uptake (Lomas,	
(Jasanoff, 2004; Kuusisto and	1995; Hendriks, 1999; Bock and	1997; Eccles et al., 2005;	
Viljamaa, 2004; Pohl <i>et al.</i> , 2010;	Kim, 2002; Bock <i>et al.</i> , 2005;	Damschroder et al., 2009;	
Armitage et al., 2011; Gillard et al.,	Chiu, Hsu and Wang, 2006)	Sumner <i>et al.</i> , 2011)	
2012; Meadow <i>et al.</i> , 2015; van der			
Molen <i>et al.</i> , 2015)			
Knowledge Creation (Nonaka, 1994;	Knowledge Mobilization (Bennet		
Nonaka and Takeuchi, 1995; Von	<i>et al.</i> , 2007; Dede, 2007;		
Krogh, Ichijo and Nonaka, 2000;	Kapczynski, 2007; Khan and		
Bathelt, Malmberg and Maskell,	VanWynsberghe, 2008; Walshe		
2004; Straus, Tetroe and Graham,	and Davies, 2013)		
2011)			
Knowledge Distillation (Baer, Allen	Knowledge Dissemination		
and Braun, 2000; Straus, Tetroe and	(Hutchinson and Huberman,		
Graham, 2011)	1994; Green and Johnson, 1996;		
	Enders, 2005; Green <i>et al.</i> , 2009;		
	Gagnon, 2011)		

Table 2.1 - Classification of terms used in the literature for describing the process of generation,diffusion and use of knowledge

Therefore, "each of the terms employed to describe the phenomenon that leads produced research results into practice is defined in many different ways throughout the scientific literature" (Siron, Dagenais and Ridde, 2015, p. 850). Despite the multitude of the definitions provided in the literature, their meanings can be grouped into few appropriate ones.

At this purpose, Table 2.1 summarize the most used terms for describing the process. As intelligible from that, the process can be split in to three different pillars: generation, diffusion and use of knowledge. Discussion of each element is provided below.

Knowledge Generation. The first element discussed refers to the generation of knowledge, intended as the production of new knowledge as output of a process (Fazey *et al.*, 2013). While knowledge creation and knowledge generation are used interchangeably, coproduction of knowledge refers to the process in which knowledge is produced though the interaction among different people, and knowledge distillation is used to refer to the creation of systematic reviews and/or guidelines (Straus, Tetroe and Graham, 2009; Fazey *et al.*, 2013).

Knowledge Diffusion. The second element refers to the knowledge sharing process. In this context, different terms are mainly used interchangeably. However, some studies used the terms knowledge transfer and knowledge diffusion to refer to the passive, untargeted and unplanned spread of research findings, and the term knowledge dissemination for a more active spread, based on planned strategies (Graham *et al.*, 2006; Nilsen, 2015). Discussion of the different strategies that can be adopted to disseminate research findings is provided in the following section.

Knowledge Use. Finally, the third element, that is the one considered more important and that represents the most difficult task to implement (Munn *et al.*, 2018), refers to the use of knowledge. The most used terms for this stage of the process are knowledge use and knowledge uptake, both used to indicate the extent to which knowledge is adopted to change practices and to change the minds of knowledge users (Munn *et al.*, 2018).

The entire process that combines the three elements described above is usually called in the literature as knowledge exchange and/or knowledge translation.

Many definitions have been provided in the literature for the process of knowledge translation. The National Center for Dissemination of Disability Research defined it as "The collaborative and systematic review, assessment, identification, aggregation and practical application of high-quality disability and rehabilitation research by key stakeholders (i.e., consumers, researchers, practitioners,

policy makers) for the purpose of improving the lives of individuals with disabilities" (National Center for Dissemination of Disability Research, 2005). According to Grimshaw and colleagues, knowledge translation is the process aimed at "ensuring that stakeholders are aware of and use research evidence to inform their health and healthcare decision- making" (Grimshaw *et al.*, 2012, p. 2). In particular, the definition provided by the Canadian Institutes of Health Research (CIHR) is among the mostly adopted in previous studies (e.g. Davis *et al.*, 2003; Graham *et al.*, 2006). In particular, it emphasizes the importance for knowledge to be turned into action and real practice, and, subsequently, underlining the necessity for research to achieve the minds of users, who can turn them in implementation (McLean *et al.*, 2018). Indeed, it states that it is "a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system" (Canadian Institute for Health Research).

This is consistent with the concept of knowledge exchange, introduced by Fazey and colleagues with reference to a multiple paths process (Fazey *et al.*, 2013). This implies that it can be conceived as a continuum exchange between researchers and target audiences (Kiefer *et al.*, 2005) in order to make relevant research findings available to all the stakeholders for translating them into policy-making practices (Van Eerd, 2019). This allows to give attention to multiple stakeholders across different healthcare practices, and to facilitate the transfer of research findings into practical changes (Lang, Wyer and Haynes, 2007). At this purpose, this is considered as a multidimensional, complex, dynamic and iterative social process that, even if it does not necessarily contribute to the change, it can increase the chance to adopt research findings in practice (Kiefer *et al.*, 2005; Ward, House and Hamer, 2009; Ward *et al.*, 2010; LaRocca *et al.*, 2012; Prihodova *et al.*, 2019).

In order to frame the research, it is important to explicitly state the definition of KTE that is adopted (Prihodova *et al.*, 2019). Along with this study, the conceptualization of KTE provided by Van Eerd, according to which KTE refers to the entire process of moving knowledge into action, by emphasizing its iterative and bi-directional nature is adopted (Van Eerd, 2019).

2.2.2 Knowledge Transfer and Exchange Strategies

Given the fragmentation of the KTE literature, it could be argued that it is a recent phenomenon. However, the history of the field is much older and one of earliest pioneers is Florence Nightingale in the 1800s, who underlined the importance of communicating knowledge in a format that can be understood by policy makers and other stakeholders in general (Mainz, 2004; Mackey and Bassendowski, 2017; Munn *et al.*, 2018). Despite the origins of the field go back to 1800s, Munn et

al. sustained that "presenting evidence in a formatted and comprehensible manner and providing education are still two key factors of evidence transfer today" (Munn *et al.*, 2018, p. 88). In order to ensure effective KTE, different strategies can be adopted (Van Eerd, 2019), and a variety of methods emerged in the literature along the years.

Since the interest in KTE increased, the requirements for a successful KTE process change over time. According to previous studies, it is no more enough to produce good scientific evidence to have it translated into practice (Banta, Behney and Willems, 1981; Institute of Medicine Committee for Evaluating Medical Technologies in Clinical Use, 1985; Feeny, Guyatt and Tugwell, 1986). Generally it is no more acceptable to consider KTE as a mere linear and researcher-driven activity (Wilson et al., 2010). On the contrary, the act of generating, sharing and using knowledge is mainly defined as a dynamic and iterative process characterized by complex interactions between users and producers of knowledge (Ward et al., 2012). In this context, research and practice gaps are considered as knowledge sharing and use problems, rather than knowledge generation problems (Van de Ven and Johnson, 2006). This concept has been highly debated and finally accepted in the literature (Ward et al., 2012). Nowadays, scholars agree that "one size does not fit all", meaning that, in order to enhance uptake of research findings, linear models of knowledge production, dissemination and use are no more sufficient, and at least the customization of the message for the different target audiences is needed (Mitton et al., 2007; Munn et al., 2018). Scholars suggest also that a change in the mindset of researchers is needed in order to ensure that evidence-based decision making would not only be the objective of research, but also part of KTE process (McLean et al., 2018).

Moreover, multiple strategies for KTE process are encouraged, better if sustained by a collaborative relationship (Pyra, 2003; Schipper *et al.*, 2015; Munn *et al.*, 2018), and the role of the context is incredibly important for enhancing the uptake of research findings (Kerner, 2006).

Despite the majority of the research is still university led (Raftery *et al.*, 2016), an increasing interest towards the need to engage in long term relationships and to encourage bilateral communication processes has been demonstrated (Oborn, Barrett and Racko, 2013; Raftery et al., 2016).

A description of the evolutionary path of KTE strategies is provided below.

2.2.2.1 Linear Models

KTE strategies have been traditionally represented by linear models (Weiss, 1979; Lavis *et al.*, 2003; Munn *et al.*, 2018), which tend to emphasize the causal connections between inputs, processes, outputs and outcomes (Raftery *et al.*, 2016). The first application of the concept occurred in the 1990s, when the term "knowledge transfer" has been introduced with reference to a linear, unidirectional
and passive process to vehicle research from its producers to its users, and vice versa (Weiss, 1979; Lavis *et al.*, 2003). The most used model in this regard is the "knowledge driven model", according to which the basic research would progress to practice and, eventually, lead to development stages (Weiss, 1979). This process has been conceived as a knowledge-driven and problem-solving model based on one-way interaction among researchers and decision-makers (Oborn, Barrett and Racko, 2013). At this regard, findings are published in journals, and presented at conferences, without ensuring that target audiences can have access to them (Munn *et al.*, 2018). The assumption upon which this simplistic approach is based is that research results are autonomously found by potential stakeholders (Munn *et al.*, 2018). The limitations of linear models have been indirectly addressed by previous studies, according to which evidence transfer needs three main components in order to be correctly executed:

- active dissemination of research findings, considered as the process through which they
 are publicized, presented, or communicated to target audiences. This is considered as a
 communicative function whose aim is to spread research findings across locations,
 settings and networks (McCormack *et al.*, 2013; Munn *et al.*, 2018);
- educational component remains essential in all evidence transfer strategies (Munn *et al.*, 2018). Independently from the delivery of the education (formal or informal), previous studies found that the more active is the learning, the more effective will be the educational program in achieving desired outputs (Vetter and Latimer, 2017);
- systems integration is the third element that is required in order to ensure that research findings are circulating broadly and consistently within the organization (Munn *et al.*, 2018). Contrarily, only ad hoc uptake of research can occur. In particular, previous studies from the knowledge management field defined systems integration as the process aimed at collecting and curating knowledge on one side, and connecting people on the other side (Sullivan *et al.*, 2015).

Given the limitations associated with passive dissemination of research results, these strategies are usually considered ineffective (Paterson-Brown, 1998). However, this is also the most commonly adopted strategy by researchers and healthcare organizations (Paterson-Brown, 1998).

Given the important role that linear models still plays (Munn *et al.*, 2018), previous studies suggest that they should be ideally used in combination with some of the active dissemination strategies that can influence current practices more successfully presented below (Paterson-Brown, 1998; Schipper *et al.*, 2015).

2.2.2.2 Dynamic Models

With the introduction of the EBM, there has been an increased awareness of the importance of incorporating research findings in the domain of health and medical practice in order to maximize efficiency (Sackett *et al.*, 1996; Lomas, 1997; Estabrooks, 1999; Gray, 2002; Oborn, Barrett and Racko, 2013). At this purpose, simple passive dissemination was not enough (Munn *et al.*, 2018), and the concept of a more dynamic process for KTE has been introduced in order to overcome the limitations of one-way communication, and to promote active dissemination characterized by interactions among researchers, decision makers and stakeholders (Caplan, 1979; Lomas, 2000; Lavis *et al.*, 2003; Graham *et al.*, 2006; Munn *et al.*, 2018).

For this reason, researchers are no more considered the sole producers of knowledge, but multiway interactions between researchers, policy makers and knowledge users are encouraged (Funtowicz *et al.*, 2000; Francis and Goodman, 2010; Fazey *et al.*, 2014). KTE moved from a linear process to a two ways flow which need active engagement to facilitate the knowledge utilization, by shifting the focus on interaction and collaboration (Oborn, Barrett and Racko, 2013). According to Wilson et al. dissemination is considered as "a planned process that involves consideration of target audiences and the settings in which research findings are to be received and, where appropriate, communicating and interacting with wider policy and health service audiences in ways that will facilitate research uptake in decision-making processes and practice" (Wilson, Petticrew, Calnan, *et al.*, 2010, p. 2). According to Wilson, therefore, dissemination needs more participation, the recognition of the context of application of knowledge and constant interaction between users and producers in order to be successful (Wilson et al., 2010).

However, it is important to bear in mind that, ideally, both passive and active dissemination strategies should be considered in order to enhance knowledge diffusion and uptake (Wilson et al., 2010; Schipper et al., 2015; Munn et al., 2018).

2.2.2.3 Implementation Science

An additional step forward with respect to the evolutionary path described above is represented by the concept of "implementation research", used to describe the increase of interactions among individuals involved in the KTE process (Oborn, Barrett and Racko, 2013). In particular, "the field of implementation science has gathered great momentum in the last few years" (Glasgow and Chambers, 2012, p. 48), with an evolution from the mere analysis of barriers and facilitators, to a

more complete approach that consider a cohort of investigations to improve adoption, implementation, and sustainability.

According to McLean et al., KTE activities can be classified in three major categories (McLean *et al.*, 2018):

- Push activities refers to all the activities that are aimed at pushing research knowledge into the hands of knowledge users (e.g. funding opportunities);
- Pull activities are aimed at facilitating the access to research findings for knowledge users (e.g. forum);
- Linkage and exchange activities refers to the establishment of a partnership between knowledge producers and users in the different stages of research.

The last category is the one that gets closer to the concept of implementation research. In particular, activities falling in this category are those encouraging the participation at the process of both researchers and non-researchers (e.g. managers, patients, etc.) (McLean et al., 2018). Its emergence is justified by the difficulty of translating research results into the minds of users and the subsequent implementation, which can be facilitated by many strategies (Munn et al., 2018). Among them, in the first years of 2000, the implementation science emerged as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services" (Eccles and Mittman, 2006, p.1) to face the complexity of clinical and organizational practices. Implementation science is considered as the response to the need of achieving more evidence-based practice (Nilsen, 2015). Under the term "implementation science" scholars usually indicate "the use of theories, models and frameworks to gain insights into the mechanisms by which implementation is more likely to succeed" (Nilsen, 2015, p. 1). With this term, scholars refer to the whole process aimed at integrating new practices within a specific context (Nilsen, 2015). Its use is mainly aimed at describing the KTE process, or at understanding the factors affecting the implementation outcomes, or at evaluating implementation (Nilsen, 2015).

Despite the growing interest in this field has been testified by the increasing number of publications, a lot of researchers are still adopting traditional models, also because of the lack of alternative frameworks (Glasgow and Chambers, 2012). Previous studies identified four different elements that should be considered when designing implementation interventions:

- Adopting a system perspective is essential to detect systems characteristics;
- The achievement of robust, practical goals refers to the possibility to define specific questions and to use them to answer to stakeholders' needs;

- Different research methods can be implemented to enhance relevance to identify the most suitable strategies;
- Flexibility is needed in order to encourage the inclusion of different perspectives.

In particular, Glasgow and Chambers affirmed that in order to better integrate research into practice there should be a shift in the scientific perspective, in the direction of contextual and systems perspectives, in the research goals, with more focus on the pragmatic approaches, and robustness across conditions, in the research methods, that should be more rapid, adaptive, and convergent, and, finally, towards a flexibility of research (Glasgow and Chambers, 2012).

Within the field of implementation science, many frameworks for the proper translation of knowledge into practice have been applied (Nilsen, 2015; Fisher, Shortell and Savitz, 2016). According to recent studies, there is a wider recognition of implementation science as a way to establish the theoretical bases for strategies to facilitate implementation (Nilsen, 2015). The main goal of implementation research is to reduce the factors that are limiting the access or increasing the difficulty of translating evidence into practice (Granados *et al.*, 1997).

The aim of implementation science is threefold (Nilsen, 2015):

- Describe and/or guide the process of knowledge translation into practice;
- Understand the factors that influence implementation outcomes;
- Evaluate implementation.

Different implementation strategies can be adopted in order to reduce the gap between knowledge and practice. Among them, tailored implementation strategies are intended to meet specific needs with reference to a specific context (Baker et al., 2010), and they are expected to be "most helpful if these effectively address the most important determinants of practice for improvement in the targeted setting" (Wensing et al., 2011, p. 2). They are based on the idea that changes in practices and/or health professionals behaviors are limited by different barriers, and, therefore, changes will be more effective if implementation strategies are selected to address the identified barriers (Baker et al., 2015). More specifically, tailored implementation interventions are designed to promote changes in clinical practices that are based on the assessment of their determinants (Baker et al., 2015). Three key steps characterized their implementation (Wensing et al., 2011): first, determinants, intended as barriers and enablers, are identified; second, implementation interventions are designed according to the determinants identified; and third, the interventions are applied and assessed. In particular, factors that can be used to target intervention are related to different areas. For this reason, different strategies to perform the above-mentioned tailored implementation interventions can be adopted according to the specificities of their context. First of all, "healthcare professionals are heterogeneous in relation to their definition of quality; their perception of the need for quality improvement; their attitudes to

quality improvement initiatives; their attitudes to clinical guidelines and evidence-based practice" (Eccles *et al.*, 2009, p. 2), and, therefore, different strategies can be more or less effective in achieving different categories of healthcare professionals. Second, previous studies found that a single set of measures shared among different patients does not exist (Eccles *et al.*, 2009), and, therefere, appropriate measures should be selected according to the different categories of patients. Finally, the arrangement of healthcare system, and the organization of healthcare should be considered when designing intervention, since centralized and decentralized healthcare systems face different challenges (Frumence *et al.*, 2013).

2.2.3 Theoretical development

The shift from linear to more dynamic models for KTE has been sustained by an evolving trend of the theory upon which the process is based (Figure 2.1).



Figure 2.1 - Synthetized map of evolution of KTE from Mode 1 to Mode 2 Knowledge Production Theory

Consistently with the change in the field of the KTE literature, the production of knowledge has lived at the end of the 1990s a shift in theory upon which it is based, moving from Mode 1 to Mode 2 Knowledge Production Theory (Gibbons *et al.*, 1994; Ferlie and Wood, 2003; Nowotny, Scott and Gibbons, 2003; Van Aken, 2005).

In Mode 1, the knowledge is produced in a disciplinary and cognitive context (Gibbons *et al.*, 1994). According to this paradigm, there is an hegemony of theoretical or experimental science; disciplines are internally-driven; and there is autonomy between scientists and their institutions (Nowotny, Scott and Gibbons, 2003). The knowledge production process in Mode 1 is purely academic and mono disciplinary (Ferlie and Wood, 2003; Van Aken, 2005).

However, at the end of the 1990s, the need to reinvent the language of research, in order to be able to capture all its priorities and uses, was increasing, and two main trends have justified the shift from Mode 1 to Mode 2 (Nowotny, Scott and Gibbons, 2003): first, the increase in the number of students asked for a balance between the democratization of education and the distribution of knowledge

production; second, since scientific knowledge became more and more socially distributed, a tool for managing knowledge as a key resources for the society was needed. Given the social needs expressed before, the Mode 2 paradigm was introduced with reference to a broader, transdisciplinary social and economic context for knowledge production and application (Gibbons *et al.*, 1994; Nowotny, Scott and Gibbons, 2003; Hessels and Van Lente, 2008; Carayannis and Campbell, 2010; Jahn, Bergmann and Keil, 2012).

In particular, differently from the previous paradigm, according to the Mode 2 Knowledge production theory, the knowledge is produced in the context of application, since it is the result of a broad range of considerations, in which the interests of various stakeholders are included (Gibbons et al., 1994; Gibbons, 2000; Tranfield, Denyer and Smart, 2003; Carrier and Nordmann, 2010). Second, transdisciplinary, intended as the integration of different skills in a framework of action, which goes beyond any single contributing discipline (Hessels and Van Lente, 2008), is encouraged. Third, heterogeneity and organizational diversity are embraced in order to include differences in skills and experinces that people can bring, and in the sites of knowledge production (Gibbons et al., 1994; Godin, 1998; Rip, Jacob and Hellstrom, 2000; Rip, 2002; Hessels and Van Lente, 2008).

MODE 1	MODE 2
Problems set and solved in a context governed	Carried out in a context of application
by the largely academic interests of a specific	
community	
Disciplinary	Transdisciplinary
Homogeneity	Heterogeneity
Hierarchical and tends to preserve its form	Heterarchical and transient
Different types of quality control	Socially accountable and reflexive

Table 2.2 - Differences between Mode 1 and Mode 2 Knowledge Production TheoriesSource - Adapted from (Gibbons et al., 1994)

Fourth, the ability to influence to outcome of research process has gained importance in a context in which public interest can be urged in different ways (Gibbons et al., 1994). Therefore, social accountability and reflexivity underline the importance of the interpretation and diffusion of results, but also the definition of the problem and the setting of research priorities considering the possible research outcomes (Godin, 1998; Hessels and Van Lente, 2008). Finally, to assess the quality of the knowledge produced, a wide range of criteria, which consider intellectual, social, economic and/or

political interests are considered (Gibbons et al., 1994; Weingart, 1997; Godin, 1998; Hemlin and Rasmussen, 2006; De Wit, Dankbaar and Vissers, 2007; Hessels and Van Lente, 2008).

Table 2.2 shows the main differences between the two theories.

According to Raftery and colleagues, all the phases that are composing the knowledge production process – i.e. planning, execution, dissemination and implementation of research – are interwoven and characterized by a joint participation of different stakeholders (Raftery *et al.*, 2016). It is intended as a dialogic process represented by a conversation between multiple actors of the process (Raftery *et al.*, 2016).

Despite the advancements made in this research area, the gap between knowledge and practice remains huge (Kogan and Henkel, 1983; Frenk, 1992; Davis and Howden-Chapman, 1996; Sauerborn, Nitayarumphong and Gerhardus, 1999; Trostle, Bronfman and Langer, 1999; Gerhardus, Kielmann and Sanou, 2000; Lavis, Ross and Hurley, 2002). Discussion about the decision-making process in healthcare is provided in the following section.

2.3 Decision-Making process in Healthcare

For many years the medical practice was mainly based on previous experience of clinicians (Clancy and Cronin, 2005). However, ideally, research evidence should be incorporated in taking management decisions, developing policies, and in implementing programs (Brownson *et al.*, 1999; Clancy and Cronin, 2005). This is the reason why the evidence-based medicine (EBM) emerged for the integration of the optimal care based on the current best evidence (Brownson *et al.*, 1999).

In particular, the ability to link decisions to evidence has been increased by a variety of reasons (Clancy and Cronin, 2005). First, an explosive growth has been registered in medical studies (National Institutes of Health). Second, this explosive growth is connected with the increased need of tools that can be used to analyze and synthetize knowledge. This allows the emergence of transparent tools that grant the consideration of the quality of evidence used. Finally, also the emergence of information technologies helped in the achievement of the double objective of reducing costs, while improving quality.

In recent studies much attention has been dedicated to the possibility to improve strategies for the consideration of research evidence, in combination with specific local needs (Clancy and Cronin, 2005). Recent trends demonstrated a shift in the nomenclature used in the field. Indeed, while previous studies used the term "evidence-based" to refer to decisions that are grounded on evidence, more recent studies recognized in the term "evidence-informed" the need to include, as a basis for decision, additional elements with respect to research evidence, since evidence is conceived as "one influence on policy amongst many" (Parkhurst, Ettelt and Peters, 2018, p. 222). As stated by Battista, "making informed choices is unavoidable" (Battista, 1992). Indeed, as supported by previous studies, research evidence is only one source of evidence among different sources of knowledge (Gabbay and Le May, 2004; Morton and Seditas, 2018), which should be often animated through discussion (Morton and Seditas, 2018). In particular, the evidence-informed decision making refers to the possibility of incorporating research evidence in decision making processes in health (Dobbins *et al.*, 2009). The main reason of this movement is rooted on the ability to achieve improved health outcomes when choosing the current practice with reference to the available knowledge (Lavis *et al.*, 2003).

Additionally, in order to better understand how the research evidence can support the decisionmaking process, it is important to first understand the meaning of research for policy makers (Parkhurst, Ettelt and Peters, 2018). Since the evidence that is used in decision making processes "is not entirely compatible with notions of instrumental rationality" (Parkhurst, Ettelt and Peters, 2018, p. 5), Carol Weiss presented the different meanings of research utilization (Weiss, 1979). In particular, different variants of research utilization have been proposed: "knowledge driven" models occurs when new social problems emerged from basic research; in the "political" model research is used in a strategic way in order to achieve pre-defined goals; and the "enlightenment" model refers to the situation in which research is used to influence "broader thinking more generally" (Parkhurst, Ettelt and Peters, 2018, p. 5). However, as advocated by more recent studies (e.g. Parkhurst, Ettelt and Peters, 2018), the current domain in health sector is more appropriately described by the "problem solving" model, according to which a specific decision is informed by the direct application of research findings. However, independently from the model adopted, previous studies agreed on the need to contextualize both the problems that the research has to address, and the solutions proposed. In addition to Weiss, Nutley and colleagues proposed in 2007 an expanded version of the map proposed by Weiss, in which they proposed the research use as an instrumental or strategic process. First, an instrumental use is adopted when most instrumental meanings are assigned to research utilization, such as "knowledge-driven" or "problem-solving" (Weiss, 1979; Parkhurst, Ettelt and Peters, 2018). In particular, this approach "refers to cases where knowledge is directly used for decision making and problem solving" (Landry *et al.*, 2001).

Second, strategic use of research occurs when evidence is used to achieve pre-defined goals (Parkhurst, Ettelt and Peters, 2018). Examples of this type of use of research findings are represented by the influence exerted in UK by the government and by the tobacco industry to present arguments in favour and/or against the policy on tobacco control (Lee *et al.*, 2004; Bero, 2005; Ulucanlar *et al.*, 2014; Parkhurst, Ettelt and Peters, 2018).

2.3.1 Knowledge to Action Gap

Given the rise of evidence-based decision making, the need for accountability of public decisions is more and more stringent (Jennings and Hall, 2012; Fox, 2015), but health policies at different levels of healthcare systems do not reflect research evidence to the extent that in theory they could (Kogan and Henkel, 1983; Frenk, 1992; Davis and Howden-Chapman, 1996; Sauerborn, Nitayarumphong and Gerhardus, 1999; Trostle, Bronfman and Langer, 1999; Gerhardus, Kielmann and Sanou, 2000; Lavis, Ross and Hurley, 2002). Despite the various initiatives that have been undertaken (e.g. introduction of the role of knowledge brokers; increased involvement of decision-makers in the different stages of research production; increased accountability of researchers; training opportunities for managers) in order to reduce the knowledge-to-action gap (KTA), the extent to which research is used in order to take decisions remains low (Graham & Dickinson, 2003). Despite the interest in translating knowledge into action date back to the 1960s, and the evolution of the theory from Mode 1 to Mode 2 was aimed at fostering and facilitating KTE process, the extent to which research findings are provided in a timely fashion and are implemented in current practice in order to provide evidence-based, cost-effective and accountable healthcare is still limited (Graham et al., 2006). However, this necessity has stimulated interest in the KTA gap, which refers to the use of knowledge findings in current practice (Haines, Kuruvilla and Borchert, 2004; Dopson and Fitzgerald, 2005; Graham et al., 2006). The identification between the evidence produced and the clinical practice represents one of the first steps in knowledge translation (Graham et al., 2006). In particular, many models have been developed in order to overcome the barriers of knowledge translation from research to practice (Oborn, Barrett and Racko, 2013). However, current evidence demonstrates that the conversion of knowledge into practice still occurs slowly and inconsistently (McLean et al., 2018). According to previous studies, 85% of the research is wasted (Chalmers and Glasziou, 2009), and the time estimated for the translation of only the 14% of research findings into practice is of 17 years (Lenfant, 2003; Morris, Wooding and Grant, 2011; Munn et al., 2018). This translation chasm is consider unacceptable from different stakeholders in healthcare (Balas and Boren, 2000; McGlynn et al., 2003; Clancy and Cronin, 2005), since it represents the "gap between the promise of evidence-based health care and its current level of adoption" (Clancy and Cronin,

2005, p. 155).

However, the importance of having a proper access to knowledge has been recognized by many scholars. In particular, according to Pang and colleagues, one of the world challenges is to ensure an adequate access to clean and clear knowledge and to ensure that the appropriate information and knowledge goes in the hands of those who can formulate improvements (Pang, Gray and Evans, 2006).

In order to favor the production of practice-relevant research, some mechanisms that are focused on more directed research programs have been adopted (Phillipson *et al.*, 2012). This is in line with previous studies, according to which the main strategy to reduce the KTA gap is the one of providing solutions that can ensure that the research produced is relevant, valid, and practical (Connick and Innes, 2003; Raymond *et al.*, 2010).

Many studies in the literature recognize the need for bridging disconnections between research and practice. However, given the evolution of the field in the last years, something in the way research is conducted and facilitated is changing (e.g. Funtowicz *et al.*, 2000; Nowotny *et al.*, 2001; Planet Under Pressure, 2012). In particular, there is much more awareness of the importance of studying the research process and many fields of research (implementation science, knowledge translation, etc.) have seen a peak in the last years (Fazey *et al.*, 2014).

Among the advancements that have been done, previous studies identified the following points:

- More emphasis has been put on the need to have an explicit research process, such as on the participatory aspects that allows researchers to be inspired by stakeholders in their research creation (La Peyre, Reams and Mendelssohn, 2001; LWEC, 2012; Fazey *et al.*, 2013, 2014; Mauser *et al.*, 2013);
- There is a strong recognition of the need to design KTE process in order to favor and enhance participation and engagement (LWEC, 2012; Fazey *et al.*, 2014).

These advancements are not immediately translated into changes in practice. In fact, the working environment of academia is still primarily based on the more simplistic model represented by the linear production and dissemination of research findings (Davies and Powell, 2012). However, since the debate and the discourse about how to conduct research and how to disseminate results is ongoing, this can leave some spaces open for the adoption of more innovative mechanisms for knowledge production and translation (Fazey *et al.*, 2014).

In addition to knowing that the gap exists, previous studies identified the necessity to understand the reason why this exists (Kitson and Straus, 2013). In particular, this usually represents issues in the whole systems, not only in the providers (Kitson, 2009; May *et al.*, 2009). Battista recognized in 1992 that the discrepancy between science and policy making could be motivated by their two underlying paradigms (Battista, 1992). Indeed, while the science is based on the positivist paradigm, according to which there is some "truth", policy making is considered an interpretative process which considers multiple stakeholders and interactions among them, and, therefore, the "truth" is the result of these complex interactions (Battista, 1992). Lack of understanding between these two worlds could cause delays in the translation of the research results (Battista and Hodge, 1995).



Figure 2.2 – Distance between knowledge production and utilization Source - Adapted from (Battista et al., 1999)

As shown in Figure 2.2, since, as previously stated, science and policy making are based on different paradigms, they should be considered as two connected but separate processes, and the main difficulty of researchers and policy makers is to find the right distance between the production and the utilization process in order to ensure that the political environment is not included in the evaluation process (Battista *et al.*, 1999; Battista, 2006)

In addition, previous studies identified the reasons of this gap in the following elements (Clancy and Cronin, 2005). First, the field is not advancing as rapidly as it could in developing new models and methods for favoring the reduction of KTA gap because of the limited resources. Second, the availability of relevant and timely information is undermined by the publication processes that characterize the academic arena. This represents the knowledge chasm in the field. Third, the need of adopting a systems approach has been widely advocated in previous studies (Donaldson, Corrigan and Kohn, 2000; Clancy and Cronin, 2005). Finally, the poor accessibility to available knowledge remains among the important barriers that prevent to use of research findings in current practice.

2.3.2 Health Technology Assessment for bridging the Gap

Health researchers have a strong need to generate knowledge with an impact on healthcare systems, where, given the limited availability of resources, this allows the maximization of research benefits and the minimization of research waste (Cruz Rivera *et al.*, 2017). In particular, translating research-based knowledge into healthcare policy has been considered of a great interest over the last two decades (Nutley, Walter and Davies, 2007). Scholars agree on the benefits that new knowledge can generate on health outcomes, but they also support the idea that the mere creation of new knowledge is not enough to meaningfully impact people's lives (McLean *et al.*, 2018). In fact, as supported by Scott, healthcare professionals and researchers are good at creating new knowledge, but they can be even better by considering strategies that can encourage dissemination and use of research findings (Scott *et al.*, 2016).

Having a proper KTE process would allow researchers and practitioners to face the various advancements that have been made in medical science and medical technology in recent years. This allows the emergence of various opportunities for the improvement of quality and efficiency of care. As a result, many innovative health technologies have been introduced in healthcare systems. Innovation in the medical field is conceived as a series of improvement steps that are able to change procedures, improve practice, and modify existing know-how (Consoli *et al.*, 2015). Under the concept of "medical innovation ecologies"¹, the medical innovation recognizes that problems have to be solved by many actors in different organizations. At this aim, the set of individuals that are creating new knowledge and the components that ensure the flow of information are crucial in managing medical technologies (Consoli *et al.*, 2015). In fact, the introduction of a new technology implies

¹ The term "medical innovation ecologies" refers to the interactive and continuously evolving context that characterize the medical technologies after their market authorization (Consoli *et al.*, 2015).

many efforts (its acquisition, use, dissemination, and routinization of clinical practice, while ensuring its access from patients) and these efforts implies many human relationships. These dynamics of innovation have been studied by many scholars, who all agree on the crucial role they play in innovation systems (Gelijns and Rosenberg, 1994; Etzkowitz and Leydesdorff, 2000; Rye and Kimberly, 2007; Webster and Wyatt, 2007; Faulkner, 2008; Van Est and Brom, 2012; Consoli *et al.*, 2015).

Medical innovations also refer to societal issues, which arise from the complexity of healthcare systems, from increasingly informed patients, rising medical needs, and the constant request of accountable public decisions (Gagnon *et al.*, 2014; Sampietro-Colom and Martin, 2017). In order to face these complexities, there has been a shift from traditional linear models, to more interactive and non-linear models for managing medical innovation, in which the overlay of social interactions, interdependencies and networks among different stakeholders play a fundamental role.

In particular, a growing interest in the use of evidence in decision-making processes has been detected in recent years (Parkhurst, Ettelt and Peters, 2018). For this reason, "a proliferation of formal structures, bodies, processes and mechanisms [...] designed to facilitate the use of evidence in decision making" (Parkhurst, Ettelt and Peters, 2018, p. 221) emerged.

Among them, Health Technology Assessment (HTA) emerged as a knowledge infrastructure that can be adopted to let different ideas converge, and as a method aimed at systematically evaluate the properties, effects and impacts of health technologies in the KTE process, in order to support decision makers in making decisions (Goodman, 2014; Martelli *et al.*, 2016).

After its first introduction, in the 70s, as knowledge-based tool aimed at regulating the introduction and the diffusion of healthcare technologies with a particular interest in societal perspectives (Banta, 2001; Lehoux *et al.*, 2005; Lucivero, 2015), many institutions are now involved in HTA processes.

The aim of HTA is to build a bridge between the two worlds previously described: science and policy making (Battista, 1992). However, given the different paradigms upon which they are based, difficulties in performing the assessment could be encountered (Battista, 1992; Battista and Hodge, 1995). Indeed, given that HTA was born by the need to organize knowledge in a way that could facilitate its involvement in decision-making processes, it is considered as an integrating process across disciplines, rather than a one (Battista and Hodge, 1995).

A discussion of HTA literature, such as the advancements made in this field, is provided in the following section.

2.4 Health Technology Assessment Literature

The HTA emerged as a knowledge infrastructure tool to support decision making process (Van Kammen *et al.*, 2006). The interest in technology in the medical field date back to the 1990s, and, from that period, many evolutions of the area occurred. In this section, the evolutionary path of the field, the theoretical background, the different contexts in which the analysis can be performed and the factors affecting the HTA development are discussed.

2.4.1 Technology and Health Technology Definition

After the 1990s, there has been an increasing interest in technology in the medical field. Despite many definitions of the term "technology" have been provided in the literature, one of the most commonly agreed is that of Banta, who defined technology as the use and the knowledge of tools able to control and adapt to the social and physical environment, as well as the awareness of their consequences (Banta and Jonsson, 2009). In particular, when contextualized to the medical field, the term "health technology" can be defined in a more narrow or quite broad way (Garrido et al., 2010). From the narrowest perspective, drugs, devices and procedures that are aimed at delivering health services constitute health technologies across healthcare systems² (Garrido et al., 2010). On the contrary, from a broader perspective, health technologies include also interventions aimed at promoting healthcare, outside the healthcare systems (Garrido et al., 2010). Despite there is not consensus in defining the boundaries of healthcare systems, as, subsequently, of health technologies, for the purpose of HTA, health technologies are usually considered as any "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives" (World Health Organization), or "An intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery" (HTA Glossary). They refer to the possibility to use the terms "health technology" with reference to any instrument that is used for the delivery of healthcare and any organization that can provide healthcare services (Office of Technology Assessment, 1978; Fineberg and Hiatt, 1979; Banta, Behney and Willems, 1981).

Goodman introduced, in 2014, a more detailed classification of health technologies, classifying them according to the level of analysis considered (Table 2.3).

 $^{^{2}}$ Health systems are considered the arrangement, the individuals and the institutions that allow health service to be provided, organized and controlled (Garrido *et al.*, 2010).

MATERIAL NATURE	PURPOSE OF	STAGE OF DIFFUSION
	APPLICATION	
Drugs	Prevention	Future
Biologics	Screening	Experimental
Devices, equipment and supplies	Diagnosis	Investigational
Medical and surgical procedures	Treatment	Established
Support systems	Rehabilitation	Obsolete/outmoded/abandoned
Organizational and managerial		
systems		

Table 2.3 - Levels of analysis of health technologySource - Adapted from (Goodman, 2014, pp. 13–15)

Despite this classification helps the identification of a broad range of health technologies, some of the categories identified are not mutually exclusive (Goodman, 2014). In fact, while the material nature of health technologies is clearly defined in the stage of its development, when it comes to the purpose of application, some overlapping categorizations can occur. In fact, many "combined" technologies include characteristics of drugs, devices or other categories of technology (Goodman, 1993, 2014; Lauritsen and Nguyen, 2009). In addition, the stages of diffusion do not follow a linear path, and, therefore, a single technology can result in different categories according to the different indications it has been developed to. Therefore, in HTA, the term health technology is used to consider all the methods that are used by health professionals "to promote health, prevent and treat disease, and improve rehabilitation and long- term care" (Gagnon, Sánchez and Pons, 2006, p. 2).

2.4.2 Health Technology Assessment: Definition and Historical Development

HTA has been promoted as a method that aims at systematically evaluate the properties, effects and impacts of health technologies, in order to support policy makers in taking decisions (Goodman, 2014). Over the years, many definitions of HTA have been provided in the literature, underlying different aspects of the topic. Table 2.4 summarizes some of them.

"Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making." (World Health Organization)

"Health technology assessment ... is a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision" (US Congress, Hous of Representatives, 1967)

"Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value." (EUnetHTA)

"The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies." (HTA Glossary)

Table 2.4 - Definitions of HTA

An important aspect, that is barely captured by the definitions of HTA, is that HTA is representative of the healthcare system of the country, since it reflects its history, culture, and many values and preferences (Banta, 2003). For this reason, the mere consolidation of many standardized items does not always fit the necessities of the population of a specific country.

Starting from 1960s the importance of technology assessment (TA) started raising because of the relevant role played by the technology in the society (Goodman, 2014). Two important events occurred in that period:

- In 1965 the congressman Emilio Daddario identified in the ability to support policy making in taking decisions with the social, economic, and legal implications the main purpose of TA;
- Subsequently, in 1969, the TA was recognized as a support tool for the Congress which allowed the consideration of both private and public interests to maximize the society's welfare (National Academy of Engineering, 1969).

Some years later, technology was defined by Galbrait as "the systematic application of scientific or other organised knowledge to practical tasks" (Galbraith, 1977), and Brooks and Bowers affirmed that both intended effects of technologies and the unintended social, economic and environmental effects can be exploited through TA (Brooks and Bowers, 1970).

Also, formal organizations emerged: first, the Office of Technology Assessment was authorized in 1967, founded in 1973, operationalized in 1974 and adopted in the health programs in 1975, and, second, in 1976, the first Office of Technology Assessment (OTA) Health Program report was issued (Goodman, 2014).

Only in the 1980s the concept of HTA crossed the American borders, with the establishment of the Swedish Council on Technology Assessment in Health Care (SBU), which represents an important step towards the diffusion of HTA in Europe (Banta and Jonsson, 2009), where it lived a rapid dissemination (Sorenson and Chalkidou, 2012).

The following years were characterized by a rapid diffusion of the awareness of the real effectiveness of health technologies, combined with a sharp increase in health expenditures in Europe, which allowed to reinforce HTA culture (Oliver, Mossialos and Robinson, 2004; Banta and Jonsson, 2009). In 1992, the Cochrane Collaboration has been established. This is as a worldwide network of centers and people that are aimed at critically reviewing the healthcare interventions' literature in order to provide a database in which extensive and accurate information are provided to support decision-making processes (Bero and Rennie, 1995). This is one of the first collaborations that are now in place for the harmonization of HTA activities among different countries. However, additional improvements are required in order to enhance the transferability of HTA reports outside national borders and to promote contextualization of research findings.

2.4.3 Theoretical Background

From a theoretical point of view, HTA has been approached by different fields of study (e.g. welfare economics, decision theory, etc.) (e.g. Censor, 1977; Mongin, 1997; Drummond and McGuire, 2001; Eckermann and Willan, 2007; Opris and Ionescu, 2016).

Among them, studies related to the KTE started approaching the field of HTA in order to analyze the factors affecting the process of producing knowledge in HTA (the production of HTA reports), the process of knowledge diffusion (dissemination of HTA reports) and the determinants of knowledge utilization (HTA reports uptake) (e.g. Tjørnhøj-Thomsen and Hansen, 2011; Ciani *et al.*, 2015; Mohtasham *et al.*, 2016; Gough and Boaz, 2017; Liu *et al.*, 2018).

This area of study deals with a multitude of theories.

Table 2.5 summarize the most recurrent ones.

HTA studies in KTE field	
MODE 2 KNOWLEDGE PRODUCTION THEORY	It refers to the changes in the epistemological, institutional, and normative settings of scientific knowledge production and application (Graham and Dickinson, 2003).
TRIPLE HELIX THEORY	It is mainly focused on changes on the application of scientific knowledge (Graham and Dickinson, 2003). In particular, it emphasizes the relationship between science, industry, and government. Three different patterns have been exploited: first, the state mandates relationships between industry and academia; second, the three institutions are separated and they have strong borders and limited interactions; third, the three bodies are characterized by institutional integration and the normative convergence (Etzkowitz and Leydesdorff, 1999, 2000; Graham and Dickinson, 2003).
POST-NORMAL SCIENCE (PNS) THEORY	It refers to the democratization of the science and politics when complex and contradictory environmental policy problems arise (Graham and Dickinson, 2003). This theory is mainly aimed at understanding the role of science in policy process. In particular, it argues that in situations of low clarity, an extended decision making and responsibility could be the solution (Graham, 2008).

Table 2.5 - KTE theories used in HTA studies

As intelligible from Figure 2.3, there is a highly piecemeal theoretical background of HTA. Among the different areas of interest, the one of knowledge production and exchange is needing particular interest. In fact, the number of publications related to the knowledge-system models increased significantly from late 90s to early 2000s (Graham and Dickinson, 2003). Although many times the theories have been used jointly, among them, the Mode 2 is the most studied and applied one (e.g. Wouters, 1997; Gibbons, 2000; Meyer, 2002; Nowotny, Scott and Gibbons, 2003; Thelwall *et al.*, 2003; Thelwall, Harries and Wilkinson, 2003; Van Aken, 2005).

In particular, the Mode 2 theory has been applied in order to understand the flows of knowledge among different professionals and in different health-knowledge systems (Graham and Dickinson, 2003). Among them, the context of evidence-based health care has been investigated (Hanney *et al.*, 2003). At this regard, the Mode 2 helps in the reconceptualization of the development and implementation of health policy, since it aims at increasing the research utilization by reorganizing the knowledge production towards potential users' interests (Graham and Dickinson, 2003; Hanney *et al.*, 2003).

2.4.3.1 Mode 2 Knowledge Production Theory in Health Technology Assessment

As previously described, Mode 2 Knowledge Production theory helps in identifying how to properly create, distribute, and apply knowledge in complex societies (Graham and Dickinson, 2003). Given the difficulties associated with this activity, tools supporting the KTE process are necessary. At this purpose, the HTA has emerged as a mechanism aimed at using research evidence in supporting healthcare decisions (Hanney, Gonzalez-Block and Kogan, 2002).

Although the main commissioning model in HTA remains the Mode 1, the literature on Mode 2 is increasingly relevant in healthcare (Raftery *et al.*, 2016). In particular, the term "multi-stakeholder health services research collaborations" emerged in order to define the structure of the contemporary research, characterized by complexity, multidisciplinary, and networking (Hinchcliff, Greenfield and Braithwaite, 2014; Raftery *et al.*, 2016). It refers to the organized networks of researchers, knowledge intermediaries, policy makers, and all the stakeholders who are involved in the process of research uptake and application, recognized with the term "health research systems" (Hanney, Gonzalez-Block and Kogan, 2002; Hanney *et al.*, 2003; Raftery *et al.*, 2016).

The Mode 2 theory is considered relevant in the HTA context since, according to Kincheloe, it is considered as a process of considering different and competing (academic and practical) perspective for solving problems (Kincheloe, 2001). In fact, when multiple perspectives are considered, the different aspects of the reality can be detected and distinguished from those that can be representative of only a particular view of the problem (Kincheloe, 2001).

Despite the majority of the health research is still related to university-based activities, something is changing (Raftery *et al.*, 2016). In particular, the introduction of the Mode 2 calls for a joint consideration of multiple stakeholders in knowledge production, such as for non-linear dynamics for the production, the dissemination, and the uptake of knowledge (Raftery *et al.*, 2016), moving from the "knowledge translation" concept to the joint "knowledge production". Within this field of study, an important stream of the literature analyzes the reasons of the KTA gap, considering the barriers and facilitators of HTA translation and exchange.

2.4.4 Levels of Analysis

The process of translation of research into decision making has been captured in the conceptual framework proposed by Battista and Jacob in 1994 (Battista and Jacob, 1994; Battista *et al.*, 1999). As advocated by the framework in Figure 2.4, the starting point for the knowledge translation is its production. Subsequently, the synthetization of the research findings occurs in a variety of methods (e.g. meta-analysis or systematic reviews). Results of this synthesis can be combined with primary data in order to perform the HTA process, which can be complemented by social and ethical factors affecting the evaluation. The regulation of the use of a health technology can vary according to the different levels of the healthcare system.





It is for that reason that the evaluation can be performed at micro, meso or macro level. Subsequently, different activities aimed at evaluating the quality of the assessment can be implemented. This allows the creation of databases that can additionally inform the technology assessment. Additionally, according to the authors, all the activities along the journey should be customized according to the content, process and administration in which the evaluation is conducted. Therefore, the link between

all these activities is of particular importance in defining the success of the itinerary.

Literature on HTA grew significantly once it has been recognized worldwide as a tool for supporting decision-making processes through the use of research evidence. One of the main concerns of policy makers, however, remains the fact that decisions related to the choice of which assessment conduct – e.g. diseases areas, population and intervention of analysis - are not always made in a transparent or rational way (Ham, 1997; Robinson, 1999), especially when considering local level decision making processes. In particular, the consideration of "the specific characteristics, the functioning, and (most importantly) the regulating mechanisms of the health care system" (Jacob and Battista, 1993, pp. 564–565) in which the assessment is conducted is of particular relevance. Indeed, as emerged from the framework above, the context in which the analysis is conducted at three different levels: macro level HTA refers to both national and international institutions; meso level refers to regional and/or provincial health authorities; while micro level is represented by local institutions (Garrido *et al.*, 2008).

When taken together, macro and meso level constitute the policy level (Garrido *et al.*, 2008). In particular, macro level is the most widespread area of application, while meso and micro levels still need further investigation (Catananti, Cicchetti and Marchetti, 2005).

Despite the different levels at which they are conducted, the National/Regional and Local HTA are characterized by some similarities. First, the type of technologies assessed is the same between different levels: Drugs, Capital equipment, Medical devices, Diagnostic tests, Organizational technologies (Sampietro-Colom *et al.*, 2015; Sampietro-Colom and Martin, 2016). Second, also the information requirements are similar. Indeed, only minor differences in terms of areas of analysis between different levels have been underlined in previous studies (Sampietro-Colom *et al.*, 2015; Sampietro-Colom and Martin, 2016). In particular, except for the technical description of the health technology³, which is required only at National/Regional level, information about Health problem and current use of the health technology, Safety, Effectiveness, Ethical, organizational, legal and social aspects, Economic evaluation are required at both levels (Sampietro-Colom *et al.*, 2015; Sampietro-Colom and Martin, 2016). Third, also the background knowledge that is required when conducting National/Regional or local level HTA is the same, but the tools, the data required, the timing frame and the criteria used for the assessment may vary across settings (Sampietro-Colom *et al.*, 2012).

³ The Description and technical characteristics of the technology has been defined in the literature as the "Features of the technology, investments and tools required to use the technology, training and information needed for utilising the technology" (Sampietro Colom *et al.*, 2015, p. 66). In particular, the guidelines for the drafting of the Alert HTA requires that the first section of the report is dedicated to the description of the health problem and related procedures and health technologies available, considering the also their authorizations and regulatory status (Regione Lombardia, 2019).

While some similarities exist, Table 2.6 shows the main differences among the various levels.

When HTA is conducted at policy level, its main objective is to support decision makers in designing effective and efficient policies for the fair allocation of scarce resources (Sampietro-Colom and Martin, 2016). In this context, it is important that the characteristics of the country and of the healthcare system are considered when evaluating the reimbursement and the coverage of a new health technology (Sampietro-Colom and Martin, 2016). On the contrary, when considering the introduction of a new health technology at the hospital level, the safety, effectiveness, efficiency and sustainability are fundamental criteria that have to be judged (Sampietro-Colom and Martin, 2016). Given the different finalities between national, regional and local level, local HTA is still required in order to ensure that the local and specificities are considered when taking decision (Kerner, 2006; Sampietro-Colom and Martin, 2016). In addition, according to previous studies, since many decisions related to health technologies are taken in the hospitals, there is the need to have an HTA process performed at local level (Cicchetti *et al.*, 2008).

Feature	National/Regional HTA	Local HTA
Comparator	HT most used in the	HT used in the hospital
	country	
Primary target	Policy makers	Hospital and clinical managers
audience		
Type of decision	Payment, coverage,	(Dis)Investment, strategic alliances,
	reimbursement, regulation	collaborative public- private research
Time for the	12-24 months (full HTA	1-6 months (mini HTA ⁴ or rapid reviews)
assessment	report)	
Performance of	Scientists at	Scientists at HB-HTA unit
the assessment	national/regional agency,	Clinicians trained in HTA assisted by HB-HTA
	University scientists	unit or university Scientists from
	(commissioned)	national/regional HTA agency working for
		hospital
Initiators	Policy makers, healthcare	Clinicians
	payers	
Adaptation to	Limited	Frequently total
local needs		

 Table 2.6 - Differences between National/Regional and Local HTA

 Source - Adapted from (Sampietro-Colom & Martin, 2016; Sampietro-Colom et al., 2015)

⁴ Mini-HTA is a management and decision tool, first introduced by the Danish Centre for Health Technology Assessment (DACEHTA) in 2005 as a list of questions covering the aspects related to technology, patients, organization and economy which can be easily adapted to local objectives, decision criteria and time schedules (Ehlers *et al.*, 2006).

Local HTA is most commonly known as hospital-based HTA (HB-HTA), and it is aimed at supporting managerial uptake or disinvestment decisions (Sampietro-Colom and Martin, 2016). This can be considered as a strategy adopted to improve practices (Granados *et al.*, 1997) by providing context-relevant scientific evidence (Gagnon, Sánchez and Pons, 2006). Indeed, even if HTA is usually done at national or regional level, "many local health services and hospitals consider that it makes sense to move the assessment closer to the point of care, where the costs, impacts, and benefits of technologies can be directly assessed" (Gagnon *et al.*, 2014, p. 2).

According to previous studies, the political analysis is strongly influenced by institutions (Lowndes and Roberts, 2013; Parkhurst, Ettelt and Peters, 2018). Therefore, the analysis of the organizations in relation to the evidence use is of particular interest. At this purpose, the first definition of HB-HTA has been provided by Uphoff and colleagues in 1998, who presented the local HTA as a model for supporting the decision-making process to manage resources in the hospital context (Uphoff and Krane, 1998). The main difference with the classical HTA process conducted at regional and/or national level is represented by the heavy relevance of local economic, organizational, and ethical elements (Johnson *et al.*, 2009). In particular, since previous studies recognized in the objective of the local HTA the ability to improve local efficiency, and to integrate and adapt decisions to the local requirements (Cicchetti *et al.*, 2008; Balduini *et al.*, 2010), the HTA activity does not have to remain confidential, but it has to be widespread to the different levels of the organization (Lettieri, Masella and Nocco, 2008; Gagnon, 2012).

The main goal of HB-HTA, however, goes beyond the production of context-specific reports, but refers also to the ability to organize HTA activities with a multidisciplinary and evidence-based approach (Sampietro-Colom and Martin, 2016). HTA in hospitals has the necessity to be tailored to the context specificities of the hospital and has to be integrated in the managerial decision making processes (Sampietro-Colom *et al.*, 2015; Sampietro-Colom and Martin, 2016).

The main reason why HB-HTA is needed is that hospital often perceive national/regional HTA reports as loosely connected to their needs and practices (McGregor, 2006), since there are different prioritization, informational requirements and response-time needs (Kidholm *et al.*, 2009, 2015; Sampietro-Colom *et al.*, 2012).

The acknowledged relevance of HTA worldwide can be also testified by the growing trend of HB-HTA, that represents the growing need for healthcare organizations to justify their decisions (Battista and Hodge, 2009).

HB-HTA could be relevant for a number of reasons. Among them, the need for an evaluation culture that foster clinical practices and management decisions to be based on scientific evidence is of particular interest (Umscheid, Williams and Brennan, 2010; Gagnon, 2014). In addition, the

systematic involvement of healthcare practitioners in conducting HTA would increase the acceptance of the results of HTA processes (Sampietro-Colom *et al.*, 2015).

While National HTA is the most widespread concept of HTA, local HTA is gaining awareness as a way to complement National one. At this purpose, recent studies suggest that the complement of the two levels HTA improve the decision making process and the stakeholders' involvement (Martin *et al.*, 2016).

However, even if many HTA agencies exist, HTA decisions at local level are mainly based on current standards, customs and past experience (Johnstone and Lacey, 2002; Mitton and Donaldson, 2002; Eddama and Coast, 2009) and, therefore, the number of healthcare practices based on current evidence is really small (Smith, 1991). Instead of using research evidence, decision-makers choices are often based on the knowledge and experience of professionals operating in the healthcare system, patients' characteristics, financial incentives, costs' awareness and fear of malpractice litigation (Sood, Sood and Ghosh, 2007).

Despite the interest on HB-HTA is growing, such as the number of hospitals performing HTA (Martelli *et al.*, 2013), and it is more and more considered as an appropriate way to improve the allocation of scarce resources in healthcare organizations, by contextualizing HTA results at the local level (Gagnon, 2014; Menon, 2015), many challenges are still faced by local HTA producers (Martin *et al.*, 2016), who need a better understanding of the factors that can foster or limit KTE of HTA reports (e.g. training, support, etc.), and of the strategies for HTA activities integration within healthcare organizations (Gagnon, Sánchez and Pons, 2006). In addition, there is not only a single model for conducting HTA at local level (Cicchetti *et al.*, 2008; Balduini *et al.*, 2010). At this purpose, between 2007 and 2008, the working group of the Health Technology Assessment International Association (HTAi) distributed a survey in order to have a better understanding of how HTA is organized at local level (Cicchetti *et al.*, 2008). From this survey, four different models that can be adopted to perform HTA emerged (Gagnon *et al.*, 2014): the HTA Unit, the ambassador model, the internal committee, and the mini-HTA (Table 2.7).

		Focus of actions	
		Clinical practice	Managerial decision making
Organizational complexity	High (team, group, unit)	Internal Committee	HTA Unit
	Low (individual	"Ambassador" model	Mini HTA

Table 2.7 – Different HB-HTA modelsSource – Adapted from (Cicchetti et al., 2008)

First, the HTA Unit, is the structure that is entirely and exclusively dedicated to the evaluation of new health technologies, with dedicated professionals (Cicchetti *et al.*, 2008). Different organizational models of HB-HTA units are presented in the literature, according to their level of integration, formalization, and specialization (Sampietro Colom *et al.*, 2015). Following "a sort of organizational life-cycle for HB-HTA units" (Sampietro Colom *et al.*, 2015, p. 62), new HB-HTA units are generally more informal and with less connection with the external environment (Independent Groups).

When the units are of small size, with potential involvement of external actors in their activities, they take the form of Integrated-essential HB-HTA Units. More mature HB-HTA Units are usually more formalized with specialized procedures (Stand-alone HB-HTA Units). Finally, Integrated-specialized HB-HTA Units represent the most formal and specialized organizational model of local HTA units. Second, the ambassador model is based on the support of intermediaries called ambassadors to disseminate the recommendations produced at national and/or regional level (Cicchetti *et al.*, 2008). In particular, in this model, changes in practice are promoted through a specific HTA dissemination approach according to which the key opinion leaders are recognized as ambassadors of the message both within their healthcare organization and between different levels of analysis (Gagnon *et al.*, 2014).

Third, the internal committee is composed of a multidisciplinary group that is responsible to make recommendations in the settings of the hospital (Cicchetti *et al.*, 2008). Altough this models allows the reduction of operating costs, since components of these committees are already employed in a healthcare organization, some studies underlined the possibility that they may not have the expertise to properly analyze scientific evidence (Weingart, 1995; Cram, Groves and Foster, 1997).

Finally, the mini-HTA is a decision support tool that can be used in to take decisions at local level, given its simplicity and usability (Cicchetti *et al.*, 2008). In particular, "mini-HTA facilitated implementation of recommendations because key stakeholders' participation in the assessment favored a higher degree of ownership and willingness to implement the new technologies" (Gagnon *et al.*, 2014, p. 11). However, insufficient quality of evidence evalutation and/or excessive emphasis on financial factors have been identified in the literature among the main drawbacks associated with this organizational model for HB-HTA (Ehlers *et al.*, 2006).

From the literature review performed by Gagnon and colleagues in 2014 emerged that the majority of the publications related to HB-HTA adopted an internal committee, often adapted to the local needs (Gagnon *et al.*, 2014).

Despite the literature in the field is still limited, both positive and negative impacts of the different models of HB-HTA has been reported for supporting (dis)investment decisions in hospitals, while positive perceptions are detected from both managers and clinicians (Gagnon *et al.*, 2014). In

particular, the legitimacy and the transparency of the decision-making process can be enhanced by adopting one of the models previously described (Bodeau-Livinec *et al.*, 2006; Ehlers *et al.*, 2006; Robinson, 2008; Saaid *et al.*, 2011; Sampietro-Colom *et al.*, 2012; Nunes *et al.*, 2013). On the contrary, the delay of the information and the lack of synchrony between request, evaluation, and decision have been recognized among the drawbacks of the above-mentioned models (Féry-Lemonnier, 2002; Bard *et al.*, 2006; Bodeau-Livinec *et al.*, 2006; Gallego, van Gool and Kelleher, 2009; Umscheid, Williams and Brennan, 2010).

2.4.5 Factors affecting Health Technology Assessment development

Given the need for accountability of public decisions (Jennings and Hall, 2012; Fox, 2015), many scholars started to analyze the factors that were affecting the KTE process. In particular, in order to contribute to the analysis of the strategies that can be adopted in order to translate knowledge into practice, starting from the 1990s, many studies analyze the facilitators and impediments to the KTE process (Sackett *et al.*, 1996; Lomas, 1997; Estabrooks, 1999; Gray, 2002).

In particular, Battista and Hodge identified six different areas that can contribute in explaining the HTA development across jurisdictions (Battista and Hodge, 1995):

- First, *healthcare costs* can justify the emergence of the HTA activities in different settings.
 Indeed, when healthcare expenditures rise, the concern about the optimization of scarce resources is given more attention.
- Second, the identification of *information needs and policy making* is important to increase the impact of health research on policy making.
- Third, the higher is the level of *expertise in evaluative sciences*, the easier is the developmental phase of HTA across jurisdictions.
- Fourth, *management culture* plays a pivotal role in increasing the attention on the topic.
- Fifth, *physicians* are considered as a central part to both the healthcare system and the technology assessment process.
- Finally, the *public* can be both directly (through the role played by healthcare consumers), and indirectly (through the members of healthcare organizations) involved in the process.

From the areas presented above emerged that individual and organizational perspectives are equally necessary in the analysis of HTA development.

INDIVIDUAL	RESULTS OF PREVIOUS STUDIES
DETERMINANTS	
Beliefs and	Within the category, the most studied item is represented by the attitude
attitudes	towards research, for which results confirmed its statistically significant and
	moderate power towards KTE (Champion and Leach, 1989; Lacey, 1994;
	Wells and Baggs, 1994; Varcoe and Hilton, 1995; Hatcher and Tranmer,
	1997; Prin and Mills, 1997; Estabrooks, 1999; Estabrooks, Wallin and
	Milner, 2003)
Involvement in	This area has been investigated by many scholars, who associated with this
research activities	category, a variety of items. However, given the dissimilarities in the results,
	conclusions on the relationship between individual characteristics and
	involvement in research activities cannot be drawn (Squires et al., 2011a).
Information	Information seeking characteristics have been measured in terms of the
seeking	impact of attendance to conferences on KTE process (Covle and Sokop.
	1990: Butler, 1995: Michel and Sneed, 1995: Rutledge <i>et al.</i> , 1996:
	Estabrooks, 1999). Most of these studies found a positive statistically
	significant association between them (Squires et al., 2011a).
Education	This is the first most commonly studied category among the individual
	determinants (Squires et al., 2011a). Within this category, the increasing
	levels of education and type of degree are the two statistically significant
	determinants in the majority of the studies (e.g. Butler, 1995; Rutledge et
	al., 1996). Even if also the completion of research classes is expected to
	have an impact on KTE, it has been found not significant in many studies
	(e.g. Coyle and Sokop, 1990).
Professional	This is the second most commonly studied category among the individual
characteristics	determinants (Squires et al., 2011a). Experience, current role, clinical
	specialty and job satisfaction are expected to have a positive association
	with individual determinants. While results of the last three items
	demonstrated the positive statistically significance, the experience does not
	influence KTE process (Squires et al., 2011a).
Socio-demographic	While many studies expected a positive impact of socio demographic and
and socio-economic	economic factors on KTE, no studies found this significant association
factors	(Squires et al., 2011a).
Kinds of research	More recent literature is also analyzing the different kinds of research
utilization	implemented in KTE process. In particular, the individual characteristic
	mostly studied in this area is the critical thinking, considered as the personal
	attitudes towards personal, professional and civic affairs (Facione, Facione
	and Sanchez, 1994), and which has been found to have a positive
	statistically significant influence on KTE (Squires et al., 2011a).

Table 2.8 - Individual determinants of knowledge production and exchange from previousstudies

The individual perspective has been extensively studied by many scholars (e.g. Estabrooks *et al.*, 2003; Squires *et al.*, 2011). Previous studies show results distributed in seven different categories (Table 2.8).

Despite the interest in understanding the individual determinants of KTE is growing, the number of studies focusing the attention on the role played by individual determinants in HTA are just few (e.g. Chaudoir, Dugan and Barr, 2013; Gagnon, 2014; Liu, Shi, Raymond W. Pong, *et al.*, 2014; Wooding *et al.*, 2014; Rajan, Gutierrez-Ibarluzea and Moharra, 2011). However, if there is the need to continuously focus on this area of determinants, it is important that further research is conducted in order to ensure that scholars agree on an inclusion list of variables and common approaches to measure them (Estabrooks *et al.*, 2003). In addition, at individual level, there is the need to understand which are the most resilient barriers for knowledge flows (Oborn, Barrett and Racko, 2013).

The organizational perspective, instead, is represented by the idea that organizational structures are important elements in understanding the knowledge production and exchange process (Belkhodja *et al.*, 2007). In particular, decision making processes are influenced by the following contextual variables (Belkhodja *et al.*, 2007): organizational interests, differences between researchers and users' interests and interactions among them. The first category of KTE determinants suggests that the extent to which research is implemented in decision making processes increases when researchers conduct studies guided by users' specific needs (Frenk, 1992; Orlandi, 1996; Chelimsky and Shadish, 1997; Silversides, 1997; Landry, Lamari and Amara, 2003). On the contrary, when there are controversies between knowledge researchers and users' needs, the utilization of results decreases (Caplan, 1979; Rich, 1979; Webber, 1987; Frenk, 1992; Oh and Rich, 1996; Landry, Lamari and Amara, 2003). Last, given the nonlinear conceptualization of research production (Gibbons *et al.*, 1994), interactions between knowledge producers and users are important elements in determining research utilization (Dunn, 1980; Yin and Moore, 1988; Huberman and Thurler, 1991; Nyden and Wiewel, 1992; Oh and Rich, 1996; Landry, Lamari, 2003).

According to Belkhodja et al., the organizational perspective of research utilization can be rapresented by the dimensions reported in Table 2.9 (Belkhodja et al., 2007). It shows that many organizational aspects are expected to be correlated to KTE. In particular, a positive association between learning variables, linkage mechanisms, organizational culture, variables related to organizational absorptive capacity and KTE has been found (Belkhodja et al., 2007). However, as for individual determinants, also for organizational determinants a comprehensive and agreed list of explanatory variables is needed and further empirical research would help the identification of the factors that best explain research utilization (Belkhodja *et al.*, 2007).

ORGANIZATIONAL	RESULTS OF PREVIOUS STUDIES
DETERMINANTS	
DETERMINANTS Learning variables	Time allocated to and experience in research are essential elements for capturing learning variables. In order to enhance the influence of HTA on decision making processes, many tailored interventions have been implemented. In fact, according to previous studies, training is among the most efficient enablers of HTA development, and, consistently, the lack of trained human resources represent one of the major barriers (Rajan, Gutierrez-Ibarluzea and Moharra, 2011). In order to perform successful HTA programs, appropriated training strategies have to be implemented in order to fulfill expressed needs (Rajan, Gutierrez-Ibarluzea and Moharra, 2011). In particular, many tailored implementation strategies aimed at involving practitioners in HTA processes have been intended to meet specific needs this context (Rashiq <i>et al.</i> , 2006). This aspect will be discussed in the following section. In addition, improved organizational learning routines, known also as "double loop" learning (the ability to know how to learn), allow learning to persist over time and to obtain performance advantages (Argyris and
	Schön, 1978; Oborn, Barrett and Racko, 2013).
Organizational absorptive Capacity	The size of the organization and the number of people within the organization payed for doing research affect the absorptive capacity of
	organization.
Organizational Culture Variables	The intensity with which research sources are consulted represents the
Culture Variables	organizational culture towards KTE.
Adaptation Efforts	associated with higher utilization of knowledge produced.
Facilitation Mechanisms	Collaboration between HTA doers and users is essential. In particular, collaboration in healthcare has gained awareness in recent years, since it can enhance the production and the use of research evidence in taking decisions (Kothari et al., 2005; Hofmeyer, Scott and Lagendyk, 2012). HTA users and doers have been jointly considered and encouraged to collaborate in many studies (e.g. Martin et al., 2016). Collaboration between HTA users and doers can be beneficial, such as the creation of long-lasting relationships between HTA researchers and users (Lomas <i>et al.</i> , 2003; Pivik, Rode and Ward, 2004). However, collaboration between them is a poorly documented field in the area of HTA, and, therefore, further research is needed in order to better understand the benefits gained from the collaboration (Tantchou Dipankui, 2016).

Table 2.9 - Organizational determinants of KTE from previous studiesSource - Adapted from (Belkhodja et al., 2007)

In particular, a more in-depth evaluation of how organizational routines may enable organizational learning, and, in turn, move the focus away from individual decision makers is needed (Oborn, Barrett and Racko, 2013). At organizational level, in addition, further research is needed to explain differences in KTE across health organizations (Belkhodja *et al.*, 2007), such as a better

understanding of how routines might facilitate organizational learning (Oborn, Barrett and Racko, 2013).

Differently from previous studies, according to which timely information and the use of non-technical language were essential elements for improving KTE process (Entwistle *et al.*, 1998; Greer *et al.*, 2002), more recent studies affirmed that features of research products affect KTE less than individual and organizational determinants (Landry, Amara and Lamari, 2001).

It is widely accepted in the literature that the factors that are influencing KTE are represented by the researchers' behavior, the context in which users are operating and the receptive capacity (Landry, Amara and Lamari, 2001). While individual determinants are crucial in understanding the actors' involvement, organizational features play an important role in predicting research utilization (Chagnon *et al.*, 2010).

2.5 Purpose of this study

While many advancements in the fields have been done during the years, the challenges that HTA has to face are still various.

In particular, Battista, in 2006, identified a research agenda for future HTA studies (Battista, 2006), by identifying three major areas of interests:

- 1. *Adapting HTA*: there is the necessity to expand the breadth of the evaluated technologies, but, bearing in mind that the political environment should not be incorporated into the HTA context. In fact, in order to avoid that HTA and political environment come closer, further research is needed in order to set the boundaries between the different contexts;
- 2. Translating HTA: one of the main objectives of HTA is to support decision making processes, regardless their nature (policy, management or practice decisions). In order to do so, the most commonly widespread thought is that once the results of a study are published, they can be used. However, many limits of this approach have been identified in previous studies (Gibbons et al., 1994; Lavis et al., 2003; Champagne and Lemieux-Charles, 2004). For this reason and given that the translation of evidence in decision is considered a social process (Champagne and Lemieux-Charles, 2004), new approaches have to be proposed. In addition, when speaking about decision making, three different levels can be considered: macro (policy makers), meso (institutions), and micro (practitioners and patients). At the macro level, future development should consider the creation of policy forums to set priorities, make the assessment and translate them into policy decisions. At the meso level, a huge gap between the assessments produced at national level and their incorporation in decision making process at institutional level can be observed. Further investigation at this level is needed in order to better understand the training and the linkages needed to increase the HTA uptake. At the micro level, practitioners' behavior is usually influenced by a passive diffusion model. However, further investigation of the mechanisms needed to engage practitioners and increase the incorporation of evidence and HTA results is needed.
- 3. *Evaluating HTA*: the area needing investigation in this field refers to the role played by the organizational approach in influencing the technology diffusion. Despite this is an area of great interest, little attention has been given to it in previous studies.

While some advancements have been done in the very last years in the adaptation and evaluation of HTA, its translation at different levels is still a very fragmented field of research and many studied

testified that further investigation is needed (e.g. Grieve and Briggs, 2015; Cheung *et al.*, 2017; Jepson *et al.*, 2017; Sihvo, Ikonen and Mäkelä, 2017). Indeed, as suggested by Trammer and colleagues, poor research transfer is among the most important barrier to evidence-based healthcare (Trammer *et al.*, 1998). So far, the gap between the evidence recommended and used has been justified by the lack of researchers trained to produce it and the lack of dialogue between HTA producers and users (Yuba, Novaes and de Soárez, 2018).

As advocated in previous studies, passive dissemination strategies are not sufficient in influencing clinical practice (Grol and Grimshaw, 2003) and that the majority of evidence is disseminated through ineffective routes (Grol and Grimshaw, 2003; Scott et al., 2007). Indeed, even if the simple diffusion model is the most adopted one, the limits that are associated with that, and described in previous literature (Gibbons et al., 1994; Lavis et al., 2003; Denis, Lehoux and Champagne, 2004), are discouraging the use of research findings also in field of HTA (Battista, 2006). However, nowadays "the challenge of implementing more effective alternatives remains unfinished work for HTA organizations and their partners" (Battista, 2006, p. 277). In particular, further research is needed in order to better define and analyze the strategies and the training programs that could increase research findings use (Battista, 2006; Hurst and Mickan, 2017). Indeed, there is still a strong need to invest in research, in training qualified researchers and decision makers, and to promote communication among the parties (Yuba, Novaes and de Soárez, 2018). Further investigation of these aspects is needed in order to have a better understanding of the whole picture, and, in particular, future challenges will be related to the intensification of implementation efforts (Battista and Hodge, 1995). According to previous studies, the research related to the methods for getting evidence into policy has only limited analyzed the description of how research and decision-making processes can interact (Parkhurst, Ettelt and Peters, 2018). Therefore, there is a call for more research related to the description of the tools and methods that can be adopted to bridge the connection between research and policy. The extent to which different factors works to shape research utilization in different context should be analyzed more in-depth (Parkhurst, Ettelt and Peters, 2018). In particular, more research is needed in order to design an HTA process that could be attractive for a variety of stakeholders at different levels of analysis (Battista and Hodge, 2009).

The understanding of the mechanisms of KTE could also be of particular relevance in order to identify needs of different stakeholders, and to design appropriate strategies for the dissemination of the results (Battista and Hodge, 2009). In particular, the next phase of HTA is represented by the possibility to shift from simple linear dissemination strategies, to more complex interactive communication strategies which adopts a view to assist stakeholders in making choices (Battista and Hodge, 1999). Indeed, despite during the years many studies have been conducted to analyze the

factors affecting of knowledge transfer, further research is needed to analyze the gap between HTA researchers and decision makers (Wei *et al.*, 2017). Translating HTA is considered an attempt to ensure that decision making processes can be supported by the best available research evidence (Landry, Lamari and Amara, 2003). However, in order to enhance the role of evidence, a better understanding of factors affecting HTA development is needed (Wei *et al.*, 2017). Previous studies analyzed independently the role played by individual and/or organizational determinants on research utilization (Estabrooks *et al.*, 2003; Belkhodja *et al.*, 2007; Squires *et al.*, 2011). However, further research analyzing linkages between organizational and individual perspective of knowledge would clarify the mechanisms that are linking different factors affecting KTE process (Belkhodja *et al.*, 2007).

Despite some advancements have been done in the literature, and the field of KTE in healthcare is constantly evolving, there is an urge need to foster the translation of HTA into decisions at the different levels of healthcare systems (Battista, 2006; Gagnon, Sánchez and Pons, 2006; Martin *et al.*, 2016). Despite various studies adopted an institutional perspective to analyze the use of evidence in supporting decision-making processes, there is still a limited engagement of the role of institutions in explaining the use of research evidence in health-related literature (Liverani, Hawkins and Parkhurst, 2013; Parkhurst, Ettelt and Peters, 2018). In particular, according to Nutley and colleagues, insufficient attention has been given to the possible arrangements of organizations to facilitate research use (Nutley, Davies and Walter, 2002; Parkhurst, Ettelt and Peters, 2018). This is also testified by the study of Parkhurst and colleagues, who affirmed that there is a lack of exploration of functioning of evidence use below the national levels (Parkhurst, Ettelt and Peters, 2018). Consistently, according to previous studies, there has been an increasing attention to the need to analyze the impact of decisions on healthcare organizations (Banta *et al.*, 1995; Coons, 1996), which still remain a critical challenge for the future (Battista, 2006).

In addition, the impact of technology assessment appeared to be more easily identifiable at macro level of analysis. However, understanding the local conditions to act consequently remains unquestionably important (Battista and Hodge, 1995). However, very little is known about the KTE process in the context of HB-HTA (Liu *et al.*, 2018). In particular, "continued attention to local conditions is an integral part of the technology assessment process" (Battista and Hodge, 1995, p. 298) which requires particular attention in the research arena in order to sustain the effective role of HTA activities in supporting decision-making processes. At this purpose, since many decisions related to health technologies are done at local level, identify the factors that can foster or hinder HTA diffusion at this level is essential for the effective dissemination (Battista and Hodge, 1995).

While the literature related to the description of the barriers and enablers of HTA is growing (e.g. Ehlers and Jensen, 2012; Oliver *et al.*, 2014; Merlo *et al.*, 2015), the perceptions of practitioners related to HTA processes are rarely captured. Indeed, as advocated by previous studies, decision-making at micro level has been proven to be more difficult to implement, since practitioners tend to be more resistant to technology assessment activities (Battista and Hodge, 1995). However, at the same time, the relevance of their perceptions is higher in solving local level issues and it has been proved to be particularly relevant since according HTA is considered a process of considering different and competing perspectives when solving complex problems in a collaborative, multidisciplinary and dynamic context (Gibbons *et al.*, 1994; Van de Ven and Johnson, 2006). Further research is needed in order to have a better understanding of how healthcare professionals can learn and develop their knowledge-in-practice (Hurst and Mickan, 2017).

Additionally, previous studies identified a significant gap in the analysis of the establishment of evidence advisory systems at national or sub-national levels by comparing countries according to their system (Parkhurst, Ettelt and Peters, 2018). More specifically, current literature lacks of an indepth analysis of how evidence analysis activities can be implemented in health-care systems characterized by decentralization (Ciani, Tarricone and Torbica, 2012). More specifically, at European level, only few studies analyzed the role played by HTA in decentralized countries, in which an increasing autonomy is assigned to lower levels of analysis (regional and/or local) (France, 2000; Andradas *et al.*, 2008; Cappellaro, Fattore and Torbica, 2009; de Solà-Morales and Granados, 2009; Favaretti *et al.*, 2009; Sampietro-Colom *et al.*, 2009). Given this gap, the investigation of the adoption, the diffusion, and the role of HTA in this context is relevant both for the scientific community and for policy makers (Ciani, Tarricone and Torbica, 2012). In addition, the impact of technology assessment in decentralized countries is less identifiable with respect to centralized healthcare systems (Battista and Hodge, 1995).

The research gaps discussed above allow to identify the research question(s) that this study is aimed at answering, such as its objectives. In particular, this study is aimed at investigating factors that are affecting the development of HTA activities in decentralized countries. More specifically, perceptions of healthcare professionals are captured to identify possible HTA designs at local level. For the reasons aforementioned, the aim of this study is to address the following Research Questions (RQ):

RQ1: Which factors affect the HTA development?

RQ2: How local HTA can be successfully designed?

2.6 Conclusions

This Chapter presents a literature review in the area of knowledge translation and exchange in healthcare. In this field of studies, there is a growing interest in analyzing the process of generation, dissemination and use of knowledge in order to have a better understanding of the factors that are encouraging knowledge uptake. In fact, previous studies underlined the necessity to adopt strategies aimed at increasing the uptake of research findings, since the percentage of current evidence that is translated into current practices is below the 20% and with an enormous delay of time. At this purpose, the Mode 2 Knowledge Production Theory, introduced by Gibbons in 1994, suggests that evidence is more likely to be understood and used if it is produced in its context of application by multidisciplinary teams.

In particular, within the context of healthcare, the movement of evidence-based medicine was established to foster the adoption of research findings in health practices. Among the tools aimed at supporting this movement, the Health Technology Assessment, intended as a KTE process, emerged as the process through which existing available knowledge is revised and synthetized in order to produce safety and efficacy assessments of health technologies. Additionally, after the diffusion of Mode 2 Knowledge Production Theory, HB-HTA emerged as a way to customize the assessment to local needs and to actively involve healthcare professionals in different hospitals in the KTE process. Despite these advancements, there is still a strong need to have a deeper understanding of the factors that are facilitating or limiting knowledge generation, dissemination, and use in the context of HB-HTA. The aim of this study is to contribute in generating some knowledge in this field of study.

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Chapter 3: METHODOLOGY

ABSTRACT

Along with this study, a mixed methods design is adopted, in which both quantitative and qualitative data are captured in order to answer the research questions. The possibility to have a deeper understanding of the complex research problem is conceived as justification for the use of a mixed methods approach. Quantitative data are collected through a web-based survey, while qualitative data are gathered through semi-structured interviews. The analysis of quantitative and qualitative data is done following the triangulation protocol strategy, according to which, after a separate analysis of data coming from both approaches, an interpretation stage is followed to integrate results and to obtain a broader picture of the research problem.

The analysis is conducted in Lombardy Region, in Italy, where a tailored implementation intervention, aimed at diffusing HTA culture at different levels of the healthcare system, was developed.

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Chapter 3: METHODOLOGY

3.1 Introduction

Along with this study, a mixed methods design is adopted. This implies that both quantitative and qualitative data are captured in order to answer the research questions identified in the Chapter 2 related to the literature review. Despite it has been subject to many debates (Howe, 1988; McEvoy and Richards, 2006; Biesta, 2010), the mixed methods research is now considered philosophically acceptable by many scholars (Howe, 1988; Johnson and Onwuegbuzie, 2004; McEvoy and Richards, 2006; Greene, 2007; Teddlie and Tashakkori, 2010; Risjord, 2011). In fact, the use of a mixed methods approach (MMA) enables a deeper understanding of the research problem, for which the use of quantitative and qualitative data can answer to two slightly different research questions that can complement each others to have a bigger picture of the researched phenomenon. The use of MMA is also legitimized by the complexity of the research, for which one single method would be insufficient (Wisdom et al., 2012). In particular, the use of mixed methods designs has been particularly advocate in implementation science (Proctor et al., 2009; Aarons, Hurlburt and Horwitz, 2011; Palinkas, Aarons, et al., 2011; Landsverk et al., 2012), since the complexity associated with the implementation of an evidence-based practice could be hardly faced by a single methodological approach (Palinkas et al., 2015). In addition, mixed methods research is particularly preferable in systems in which the relationships are both vertical and horizontal (e.g. between organizations and the regional/national level and between different organizations) (Palinkas et al., 2011; Palinkas, Aarons, et al., 2011; Palinkas, Ell, et al., 2011).

The analysis of quantitative and qualitative data is done following the triangulation protocol strategy delineated by O'Cathain et al., according to which, after a separate analysis of data coming from both approaches, an interpretation stage is followed to integrate results and to obtain a broader picture of the research problem (O'Cathain, Murphy and Nicholl, 2010). According to previous scholars, in fact, the exploration of any corroborating or contrasting result can lead to a better understanding of the research questions (Fielding and Fielding, 1986; Farmer *et al.*, 2006; Moffatt *et al.*, 2006; O'Cathain, Murphy and Nicholl, 2010). The Ottawa Model of Research Use (OMRU) has been

adopted as theoretical framework for guiding the discussion of the results (Graham and Logan, 1998; Hogan and Logan, 2004; Logan and Graham, 2010).

The remainder of this Chapter is organized as follow: in the first Section the mixed method as a research design is first described from a theoretical point of view, and then contextualized to healthcare and to this study; Section two presents the data collection methods, differentiating between quantitative and qualitative data collection; in Section three data analysis methods are presented, such as the integration of the quantitative and qualitative results; finally, conclusions are presented in Section four.

3.2 Mixed Methods Design

3.2.1 Mixed Methods Research: An Introduction

The mixed methods research, defined as "the class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study" (Johnson & Onwuegbuzie, 2004, p. 17), has gained popularity because it is considered as a step forward with respect to the utilization of a single research method (Creswell, 2007). The main advantage that is associated with the adoption of a MMA is that the combination of quantitative and qualitative methods allows for a more complete analysis of the research problem (Greene, Caracelli and Graham, 1989; Tashakkori and Teddlie, 1998).

When considering quantitative research, isolated variables are causally related to themselves in order to determine the magnitude and the frequency of the relationships with a postpositivist claim (Charles, 1998). On the contrary, when considering qualitative research, a broader picture of the study is developed and a constructivist or advocacy/participatory claim is approached (Guba and Lincoln, 1982; Creswell, 1998; Mertens, 2003). Taking both types of research into consideration, a mixed methods approach assumes that what is working is the truth (Howe, 1988) and the variables chosen for the analysis are those that can best answer to the research question(s) (Tashakkori and Teddlie, 1998).

Additionally, several benefits can be associated with the implementation of mixed methods research. Besides the incorporation of the strengths of both qualitative and quantitative research, it can answer a greater range of research questions since it is considered as an attempt to legitimate the use of different methodologies, instead of restricting or constraining researchers' choices (Johnson and Onwuegbuzie, 2004).

Research projects can adopt quantitative or qualitative approaches according to the different research questions they are aimed at answering. Many differences between quantitative and qualitative approaches occur, especially in terms of ontological and epistemological perspectives, and data collection (McEvoy and Richards, 2006). Usually, a positivist paradigm is associated with quantitative approaches, whose aim is to find generalizable laws (Schrag, 1992; Tobin and Begley, 2004; McEvoy and Richards, 2006; Tuli, 2010; Aliyu *et al.*, 2014). On the contrary, an interpretivist paradigm is associated with qualitative approaches, whose aim is to have a better understanding of a specific situation (McEvoy and Richards, 2006; Walsh and Downe, 2006; Tuli, 2010; Arghode, 2012; Thanh and Thanh, 2015). The mixed methods research design, instead, is associated with the critical realism paradigm (McEvoy and Richards, 2006; Modell, 2009; Zachariadis, Scott and Barrett, 2013),

firstly introduced by the philosopher Roy Bhaskar, and subsequently emerged as a way for incorporating strengths and weaknesses of relativism, idealism and positivism (Clark, Lissel and Davis, 2008). According to this philosophical paradigm, the world is not seen as an unknowable chaos, but, instead, the importance and the influence of humans are exalted (Clark, Lissel and Davis, 2008). Considering the critical realism as part of post-positive paradigm (Lincoln, Lynham and Guba, 2011), the main objective of the research is to find the causes of a specific phenomenon that is included in a social structure that is constantly changing and to obtain a deeper comprehension and explanation (Wainwright, 1997; Appleton and King, 2002; McEvoy and Richards, 2006).

At this purpose, the consultation of multiple data sources is encouraged by the need to consider multiple perspectives (Clark, Lissel and Davis, 2008). In particular, the view of critical realism encourage the consideration of both quantitative and qualitative research methods (Maxwell and Mittapalli, 2010). In this context, quantitative data can advance some knowledge of possible causal mechanisms, providing descriptions of dependencies among variables, their patterns and associations, while qualitative data help the recognition of new themes that do not emerge from quantitative analysis, but that can be used in order to complement quantitative results (McEvoy and Richards, 2006).

In addition, in a critical realist approach, the process of retroduction is usually implemented (Sayer, 2000; Bhaskar, 2013). Differently from deduction or induction, this approach allows the researcher to extend her/his knowledge beyond the empirically observable reality, by considering the internal relations between phenomena (Ekstrom and Danermark, 2002). For this reason, the results of this approach are considered tendencies, which can be influenced by the interactions among structures, which, in a critical realism approach, do not operate in a close system, but, instead, in open systems where interactions help explain differences across people and places (Cruickshank, 2012; Bhaskar, 2013). Along with this study, the approach of retroduction is adopted, because of the complex nature of healthcare organizations in order to have a better understanding of the reality by considering internal relations between phenomena (Ekstrom and Danermark, 2002).

3.2.2 Mixed Methods in Health Sciences

In healthcare, the adoption of the MMA is growing (e.g. Collins, Onwuegbuzie and Jiao, 2007; Andrew and Halcomb, 2009; Coyle *et al.*, 2018; Hudon *et al.*, 2018; Rider *et al.*, 2018). While 2001 is considered the year in which proliferation of MMA in healthcare occurred (Collins,

Onwuegbuzie and Jiao, 2006), between 2003 and 2007 only 2.8% of studies in the top health services research journals adopted it (Wisdom *et al.*, 2012), and Doyle and colleagues recognized the MMA

as the emerging dominant paradigm in healthcare research only in 2009 (Doyle, Brady and Byrne, 2009).

In particular, MMA has been introduced with the purpose of conducting health services research, intended as the study of the impact of many factors (social, financial, organizational, procedural and personal) on the access to healthcare, its cost and quality, and, subsequently, to the health and wellbeing (Lohr and Steinwachs, 2002), to fully understand health services phenomena (Wisdom *et al.*, 2012).

According to previous studies, different situations can justify the appropriate use of MMA (Brannen, 1992; Creswell *et al.*, 2011): insufficiency of a single data source to understand the topic, need for additional explanation, generalization of exploratory findings, or complexity of research objectives. Studies conducting a mixed methods research in healthcare are mainly focused on the analysis of organizational and individual decision making processes, outcomes or effects of policies or

initiatives, experiences and perceptions, and on the creation of measurement tools (Wisdom *et al.*, 2012).

There are various levels at which mixing can occur (Biesta, 2010), and different typologies of mixing qualitative and quantitative data (Sandelowski, 2014). According to Creswell and colleagues, many reasons can guide the adoption of mixed methods research in healthcare (Creswell *et al.*, 2011): to view problems from multiple perspectives, to contextualize information (considering both the macro picture of the system – hospital – and the micro picture – individuals), to develop complementary views of the problem, or to compare, validate or triangulate results related to a single view.

Previous studies in healthcare use a combination of different methods to obtain (Greene, Caracelli and Graham, 1989; O'Cathain, Murphy and Nicholl, 2007b):

- Complementarity of approaches different methods are used to address different aspects of the same research question;
- Expansion of results different methods are used to answer to different research questions;
- Development of research question one method is used to inform the development of the other method.

However, the main justification for its adoption in health sciences' studies remains to advance some knowledge on the understanding of complex phenomena related to the evidence-based care (Creswell *et al.*, 2011; Parlour and McCormack, 2012; Schiller, 2016; Fletcher, 2017; Pilgrim, 2017). In particular, it allows the consideration of both quantitative and qualitative data sources that reflect the complexities of healthcare.

3.2.3 Contextualization of Mixed Methods Research to this Study

The aims of this study are to analyze the factors that are influencing the HTA development across decentralized jurisdictions. Hence, along with this study, both quantitative and qualitative data are adopted in order to have a broader picture of the research problem, using them differently in order to answer to two slightly different research questions.

As advocated by previous studies, MMA is particularly encouraged in this field in order to gain further insights (Wei *et al.*, 2017). By adopting an MMA, completeness of the phenomenon of factors affecting HTA development can be achieved by integrating different data. While qualitative data would allow the researcher to achieve an in-depth understanding of the research problem, and quantitative data to achieve breadth of understanding (Patton, 2002; Palinkas *et al.*, 2015), the use of the MMA is justified by the need in implementation research "to develop a science base for understanding and overcoming barriers to implementation" (Palinkas, Aarons, *et al.*, 2011, p. 44). This would allow the researcher to have a better understanding of the research problem, rather than the use of a single approach (Robins *et al.*, 2008; Palinkas, Aarons, *et al.*, 2011).

At this purpose, both quantitative and qualitative data are gathered and used to have a deeper understanding of the factors that are affecting the development of HTA activities, and the perceptions of healthcare professionals about HTA designs.

From a theoretical point of view, the issues that should be considered in the design of a mixed methods study are the following (Creswell, 2007):

- The priority of the methods (quantitative or qualitative) should be assessed in order to define at which one more emphasis is given along with the study;
- The implementation of the methods has to be assessed in order to define the sequence of the data collection;
- The connection of the results has to be clarified.

At this purpose, Creswell proposed different strategies that can be adopted in order to perform mixed methods studies (Creswell, 2007), which differ according to the timing of data collection and/or analysis, and to the primary method implemented.

In this study, the concurrent embedded strategy will be adopted in order to balance the weaknesses of each method with the strength of the other (Creswell, 2007). In particular, Figure 3.1 represents the links between the two methods. The qualitative method is embedded within the predominant method, represented by the quantitative one, since it addresses a slightly different question.



Analysis of Findings

Figure 3.1 - Concurrent Embedded Design Source - Adapted from (Creswell et al., 2003)

Following a side-by-side integration of the resulting discussion, this strategy allows the identification of an overall composite assessment of the problem (Creswell, 2007). Additionally, a multilevel design is followed (Tashakkori and Teddlie, 1998), since the different methods are implemented to investigate the problem at different levels: the quantitative analysis investigates the factors that are affecting the development of HTA activities, while the qualitative method is implemented to capture healthcare professionals' perceptions about HTA designs.

This strategy allows the identification of the general picture of the research problem through the quantitative data. Subsequently, statistical results will be more deeply explored and explained by qualitative data. Strategies for ensuring reliability and validity in the quantitative and in the qualitative portions of this study are presented in the dedicated sections in this Chapter.

3.3 Context of analysis

The study is conducted in Lombardy Region, in Italy.

In this context, the Lombardy Region prepared to the introduction of a tailored implementation intervention to diffuse at regional and local level of analysis the HTA process for the evaluation of medical devices. In order to analyze how the different healthcare organizations in Lombardy Region act to implement the change, different periods have been monitored.

First, in 2017 and 2018 the "Key Evidence Leaders" (KEL) project has been launched with the aim of training and educating professionals on the basic principles of HTA. The design of this project followed the classical stages of a tailored implementation intervention (Wensing *et al.*, 2011), in which the analysis of the determinants of HTA development guided the design of the intervention. In particular, based on the results emerged from the web-based survey and presented below, the implementation strategy has been designed by offering many opportunities for training, as suggested by Dobbins and colleagues (Dobbins, DeCorby and Twiddy, 2004):

- A virtual learning platform has been designed for introducing users to HTA;
- Frontal and practical classes for training users in selecting the available sources of evidence and managing them through a software;
- On site practical training.

Therefore, while the initial phase of the KEL project was at Regional Level, a systematic involvement of healthcare organizations at local level was expected in the second phase.

Subsequently, after the defrosting period, a deliberation was issued at the end of 2018, with the indications for 2019. This deliberation was issued with the intention of promoting the systematic knowledge of professionals of the purchase proposals in the Lombardy Region and their direct involvement in the assessment in the HTA processes (Regione Lombardia, 2018).

3.3.1 Italy

Lombardy is one of the Region in the North of Italy. Italy is among the European countries with the highest life expectancy, with an average of 82.7 years, despite regional and socioeconomic groups' differences (European Commission, 2017). In order to overcome the disparities between different groups, a redesign of the allocation of resources among different regions is expected. The health spending in Italy is around 2,502 euro per capita, which includes a set of essential services for free. In addition to that, out-of-pocket spending occurs especially for pharmaceuticals and dental care.

Evolution of the Italian NHS and the development of HTA in Italy are described in the following subsections.

3.3.1.1 Italian National Health Service

The Italian NHS is founded on three fundamental principles (Mapelli, 2012): universality, equality and equity. Different steps characterized the introduction of the NHS in Italy (Ascoli and Pavolini, 2012; Mapelli, 2012). First of all, in 1861, at the occurrence of the unification of Italy, the situation of the health status of Italian citizens was dramatic. Only in 1888, with the law Pagliani - Crispi the healthcare started to be approached as public health, and, subsequently, in 1907, the consolidated text of healthcare laws was introduced. In 1948, the health became a fundamental right, since it is represented in the Article 32 of the Italian Constitution. Since Italy was the first European Country in which this right is recognized in the constitution, this has a double value: it is an individual absolute and inviolable right, and it represents an asset of collective importance. Ten years later, in 1958, with the law 296 of 13 March, the Ministry of Health has been constituted (Ascoli and Pavolini, 2012; Mapelli, 2012).

Subsequently, with the Law 883 of 23 December 1978, the Italian NHS was introduced as a set of functions, structures, services, and activities that are aimed at promoting, maintaining, and recovering the physical and mental health of the whole population.

After the reform that promoted the introduction of the NHS, a gradual increase of the regional responsibilities occurred (Amigoni *et al.*, 2005). More specifically, during the 1990s, the need for a constantly increasing demand of financial resources required changes in the actual NHS. At this purpose, the power of the Regions was strengthened and the concept of privatization of a state-owned company introduced in order to guarantee to all the citizens uniform essential levels of assistance. In particular, with the reform of 1999, which promoted "cooperation among healthcare providers and partnerships with local authorities for health promotion and community care" (Favaretti *et al.*, 2009, p. 127), and that allowed the regions to have substantial legislative, administrative, and regulatory powers (Artoni and Saraceno, 1997; Reviglio, 2000; Giannoni and Hitiris, 2002; Anessi Pessina *et al.*, 2012), the decentralized power of the regions was strengthened. Following the reforms of that year, the Italian NHS is now strongly regionalized (Favaretti *et al.*, 2009).

3.3.1.2 Health Technology Assessment in Italy

In this context, the concept of HTA started to be widespread in Italy in the 1980s at the National Institute of Health (France, 2000). Subsequently, some HB-HTA experiences started in some university hospitals across Italy (Favaretti *et al.*, 2009).

The increasing relevance of the topic is justified by the occurrence, in 1993, of the conference of the International Society of Technology in Health Care (ISTAHC), which was held in Sorrento (Favaretti *et al.*, 2009). However, it is only in 2006 that there was the first institutional acknowledge of the HTA, when it was mentioned in the National Healthcare Plan (Ministero della Salute, 2006).

Despite the rapid evolution of the HTA in the last years, which testifies that it is recognized as an important tool for supporting decision making processes (Favaretti *et al.*, 2009), the lack of resources has not enabled the homogeneous diffusion of HTA in the whole territory. Indeed, the changes that have been introduced in the devolution reform of 2001 produced disparities among different Italian regions (Osservatorio Nazionale per la Salute nelle Regioni Italiane, 2008; Favaretti *et al.*, 2009). In particular, HTA can be conducted at three different levels characterize the healthcare system (Favaretti *et al.*, 2009): while the general objectives and the fundamental principles that should be guaranteed by the healthcare system are provided by the national level, the delivery of the services is ensured by the regional level, through the local level (Local Health and Social Authorities, and public and private hospitals) (Taroni, 1999; Donatini *et al.*, 2001). Despite these advancements, HTA processes in Italy are mainly conducted at National/Regional level, and just few studies focus on HB-HTA (Catananti, Cicchetti and Marchetti, 2005; Favaretti *et al.*, 2009).

At support of the different levels of analysis, many HTA agencies and organizations emerged.

First of all, in 2007, the National Agency for Regional Health Services (AGENAS) was appointed by the conference between the State and the Regions, with the role of assessing, adopting, and managing technology (Conferenza Stato-Regioni, 2003). The tasks that have been attributed to AGENAS in this field are two (Presidenza del Consiglio dei Ministri Conferenza Unificata, 2007): first, the agency had to support and coordinate regional and local HTA activities; second, it has to disseminate the national HTA results to encourage regions in adopting similar behaviors. Therefore, the Agency is not expected to be only an "HTA doer", but also to coordinate activities across Italian Regions and to disseminate results.

Second, the Italian Drugs Agency (AIFA) has been introduced in 2009 to undertake HTA activities related to drugs. In addition to the national role that is played by the agency, it is also part of the European Commission on HTA and Relative Effectiveness Assessment (REA) of Pharmaceuticals (EUnetHTA JA) (Agenzia Italiana del Farmaco, 2009; Goettsch *et al.*, 2011).

Additionally, a network for the exchange of HTA results has been established in 2010: the Italian Network for HTA (RiHTA). The main objective of the network was the possibility for all the Italian Regions to share their knowledge, experience, and data in order to support the systematic production of HTA reports (AGENAS, 2010). The indirect objective of the network is also to favor the development of a decentralized culture in HTA, by fulfilling the training gaps (Ciani, Tarricone and Torbica, 2012).

Additionally, the Italian Society of HTA (SIHTA) has been established in 2007 to share the mission and the objectives of the Association "Health Technology Assessment International" (HTAi). It is a multidisciplinary scientific company that shares the principles of the Italian Network of Health Technology Assessment established in the 2006 Charter of Trento and that is aimed at promoting training activities at different levels to guarantee the scientific and cultural development of HTA through the collaboration with different (e.g. scientific and technical) societies.

Additionally, the National Centre for the Health Technology Assessment was created on the 2nd March 2016 (Ministero della Salute, 2016) and it started to be operating from January 2017, as part of the Higher Institute of Health¹ ("Istituto Superiore di Sanità" – ISS). The main objective of the Centre is to improve the quality, the standards, and the value for money through the integration of the principles and methodologies of HTA in the programming of the health services and in the clinical practice at the different levels. Differently from the ISS, with which it is collaborating, the focus of the Centre is on the activities related to research, control, consulting, regulation, and training.

3.3.2 Lombardy

The welfare system of Lombardy Region provides health and social care services to more than 10 million citizens, including residents, and people coming from other Regions or Countries. It is based on the principles of patient care to people, efficiency and innovation (Regione Lombardia, 2019c). The actual program of HTA that is still in force in Lombardy Region is the one that has been introduced with the DGR X/5671 of 11.10.2016 (Regione Lombardia, 2016). It is composed of 27 Local Health and Social Authorities, and 19 Scientific Institutes for Research, Hospitalization and Health Care.

Evolution of the Lombard NHS and the development of HTA in Lombardy are described below.

¹ The ISS is public body that provides technical and scientific support to the Ministry of Health.
3.3.2.1 Lombard Social and Health System

The Lombard Social and Health System ("Sistema Sociosanitario Lombardo" - SSL) is aimed at promoting and protecting health and it is composed of different functions that guarantee the healthcare provision and its integration with the social responsibility of the local autonomies.

In particular, it is founded on the principles of freedom of choice of people and families, parity and competitiveness public-private, promotion and evaluation of the clinical, economic and organizational appropriateness, horizontal subsidiarity to guarantee equal access to citizens and warranty of universality of the SSL, and promotion of forms of operative and managerial integration between providers of health and social services of SSL (Regione Lombardia, 2014).

With the L.R. 23/2015, three different regional networks have been delineated (Regione Lombardia, 2015): the healthcare system with the aim to provide prevention, diagnosis, cure, and rehabilitation services; the social-health service aimed at providing services with an high social and health integration; and the social service for the care services for the support to the patient and her/his family. Within this reform, article 27 ter introduced the subjects that can operate in this system. First, the "Agenzie di Tutela della Salute" (ATS) are administrative divisions of the Region that are projected in the territories to implement the programming defined by the Region, through the provision of health and social-health services through accredited and contracted public and private subjects; second, the "Aziende Socio Sanitarie Territoriali" (ASST) are operating public entities that are composed of territorial networks and hospital centers. This has been done in order to separate the administrative structures (ATS) from the operative structures (ASST).

3.3.2.2 Health Technology Assessment in Lombardy

As previously stated, Italy is one of the decentralized countries in terms of NHS, and this has an impact on the ways in which the HTA process is managed. In particular, as supported by previous studies, the management of HTA is not only influenced by the culture of the country in which it is performed, but also by the ways in which the healthcare systems is organized in the country (Ciani, Tarricone and Torbica, 2012). This implies that the models that are used to perform the analysis are usually very different among them, not only because of the different stages of implementation, but also because there are different perceptions of the role of HTA in different Italian Regions (France, 2000; Favaretti *et al.*, 2009). Therefore, results of HTA performed in different contexts could be profoundly different (Ciani, Tarricone and Torbica, 2012).

At this purpose, Lombardy Region has actuated some programs aimed at diffusing the HTA, in a context of strong decentralization (Amigoni *et al.*, 2005). As supported by Favaretti et al., in 2009 Lombardy Region started approaching the assessment of health technologies, even if many evaluation criteria were not clearly defined (Favaretti *et al.*, 2009).

The first bases of the evaluation of the technological innovation were set by the DGR n. 7197 of 3/12/2001 with the establishment of a consumptive commission with the task to evaluate innovative health technologies which have passed their clinic trial phase (Regione Lombardia, 2001).

Subsequently, in the Healthcare and Social Plan 2007-2009 ("Piano Socio Sanitario") the topic of HTA has been extensively discussed by considering it as a priority for an excellence program (Regione Lombardia, 2006).

It is in 2008, with the DGR n. 7856 of 30/07/2008, that the Region introduced the Regional Program of HTA with an approach based on the evaluation of comparative efficacy, with a clinical and economic nature (Regione Lombardia, 2008). In particular, the entity that is devoted to perform the activity was configured in the Health General Direction ("Direzione Generale Sanità" – DG Sanità) in collaboration with the Core of Priority Evaluation and Conflicts of Interest ("Nucleo Valutazione Priorità e Conflitti di Interesse" – NVPCI), the Regional Technical Table for the Appropriateness in Medicine ("Tavolo Tecnico Regionale per l'Appropriatezza in Medicina" – TTRAM) and external experts (Regione Lombardia, 2009; Ciani, Tarricone and Torbica, 2012).

While the NVPCI is a collegiate body whose main task is to define the priorities of the Region in terms of evaluation to outline the work agenda, and the members have the task of participating in the preparation of the assessments, the TTRAM is a body that validates evaluation reports and impact analysis of health technologies, prepared by accredited experts; moreover the TTRAM supports the Health General Direction in the implementation of regulations aimed at the diffusion of innovative and cost-effective technologies to replace the less effective, safe and efficient ones (Ricciardi *et al.*, 2010; Ciani, Tarricone and Torbica, 2012).

Subsequently, the "Evaluation of Health Technologies" (Valutazione Tecnologie Sanitarie - VTS) framework has been introduced in order to regulate the introduction of new health technologies (Radaelli *et al.*, 2014). With the Regional Law N. 23/2015, Lombardy Region started an HTA program for supporting the conscious use of Medical Devices and other health technologies. In 2016, with the DGR X/4831 of 22.02.2016 the new evaluation process has been redefined. The process for assessing the appropriateness of the innovative technologies within the SSL is intended to spread the most effective, safe and efficient technology according to responsible, shared, transparent, and verifiable methods (Regione Lombardia, 2016). The program allows the systematic production of knowledge related to health technologies in order to allow the ex-ante verification of their value, and

the ex-post monitoring of the widespread technologies. The organization of the program is assigned to different operators. First, the General Welfare Directorate (DGW) has the responsibility of the management of all the phases of the program. It works in close collaboration with the Presidents and the Vice-Presidents of the two commissions responsible for the evaluation: Commission for the Emerging Technologies (CTE) and Commission for Technologies in Diffusion, Diffused or Obsolete (CTD).

In particular, it adopts a multidimensional approach, the multiple criteria decision analysis (MCDA). At this purpose, the collaboration with EVIDEM allowed the identification of an MCDA tool. More specifically, the VTS framework is adopted in the Region in order to allow the simultaneous consideration of multiple objectives of various stakeholders (Radaelli *et al.*, 2014). Both quantitative and qualitative dimensions are considered in the analysis and each of them is declined in different criteria. Dimensions and criteria adopted for the evaluation are presented in Table 3.1.

QUANTITATIVE		
Dimension	Criterium	
D1 – Health problem relevance	C01– Disease severity	
-	C02 – Size of affected population	
D2 – Technology solution relevance	C03 – Type of preventive benefit	
	C04 – Type of therapeutic benefit	
	C05 – Quality of evidence	
D3 - Safety	C06 – Comparative safety / tolerability	
D4 - Effectiveness	C07 – Efficacy and effectiveness advantages	
	C08 – Patient reported outcomes advantages	
	C09 – Unmet needs	
	C10 – Clinical practice guidelines and regulatory state	
D5 – Financial aspects	C11 – Direct financial impact on health care budget	
	C12 – Cost consequences on other medical costs	
	C13 – Cost consequences on non-medical costs	
D6 – Organizational aspects	C14 – System capacity and requisites for appropriate use	
QUALITATIVE		
D7 – Ethical aspects	C15 – Equitable opportunities for access and use	
D8 – Social aspects	C16 – Pressures and difficulties of stakeholders	
D9 – Legal aspects	C17 – Mandate and scope of National Healthcare System	

Table 3.1 - Evaluation dimensions and criteriaSource – Adapted from (Regione Lombardia, 2019a)

In this context, in 2017 the "Key Evidence Leaders" Program (KEL) was introduced with the aim of diffusing HTA culture in the Lombardy area and to actively involve healthcare professionals in conducting HTA to fulfill the constantly increasing demand of training for healthcare professionals about the concept and the role of health technology assessment (Regione Lombardia, 2019b). The project implies that healthcare professionals, after an adequate preparation and training, take part to

a KTE process to evaluate a selected healthcare technology at local level. In particular, since the project has been designed as a tailored implementation intervention, where training opportunities and educational activities have been customized after having identified the training needs of healthcare professionals, this allows the identification of factors affecting KTE process both at individual and organizational level. Based on that, a virtual learning platform, frontal and practical classes, and on-site practical training activities have been executed to fill up the information gaps identified and to actively involve healthcare professionals in the project by conducting an assessment on a selected health technology. In details, the project contributes to the education and the involvement of healthcare professionals in the best use of medical devices whose safety and efficacy can be systematically assessed through the health technology assessment process which expects the application of a rigorous comparative method. The project is structured with the final aim of obtaining a direct and measurable impact in Lombardy Region on the topic of HTA, and to acquire experiences and to produce new resources (instruments and formative and informative packages) that can be widespread in other regional contexts and at national level.

Given the difficulties encountered in conducting National/Regional HTA and given the strong regionalization of duties (and consequently, huge differences between regions), local HTA represents the way through which KTE process in HTA could be customized and results uptake increased in the area of Lombardy Region. Despite the potentiality of the HB-HTA in Lombardy, the examples of evaluations that have been conducted at local level is still limited.

However, different opportunities to stimulate the involvement of healthcare organizations in local evaluations emerged.

At this purpose, at the end of 2018, the DGR n. XI / 1046 of 17/12/2018 was amended with the aim of disseminating the systematic knowledge of the evaluation of the health technologies in the area for all the public and the accredited private organizations (Regione Lombardia, 2018). Within this context, the deliberation asked the above-mentioned organizations to organize training activities for diffusing the culture of HTA, to evaluate at least one health technology in the year 2019, and to collaborate to define the structure of the report that could be used to perform the analysis.

3.4 Data Collection Methods

3.4.1 Quantitative Data Collection

The quantitative portion of this study has been collected through a web-based survey that was delivered to healthcare professionals in the Lombardy Region. The objective of the survey is to identify the factors affecting HTA development and design a tailored implementation intervention accordingly.

3.4.1.1 Target Population and Sample

Concerning quantitative data, for the purposes described before, all the Local Health and Social Authorities, and the Scientific Institutes for Research, Hospitalization and Health Care in Lombardy Region have been included in the sample in order to represent the profiles of the whole population. In particular, the sample includes the different categorizations of healthcare organizations. The first categorization refers to the legal entity of the healthcare organizations. While a "public hospital" is conceived as government owned authority, which receives government funding, a "private hospital" is owned by a (non)profit organization, and it is mainly privately funded. As advocated by previous studies, the need of having both public and private hospitals in the sample is justified by the market incentives that guide them: while private hospitals are dependent on the income from clients, the quality of the services they provide could be higher in order to better meet patients' needs (Andaleeb, 2000; Cellini, Pignataro and Rizzo, 2000; Barbetta, Turati and Zago, 2007). The second categorization is related to the differentiation between Local Health and Social Authorities and Scientific Institutes for Research, Hospitalization and Health Care. The difference between these two categories is substantial: while the former are public hospitals aimed at providing care services, the latter are scientific public or private hospitals of excellence that, additionally to provide care services, have research purposes (Italian Ministry of Health, 2007). Since the different missions of these healthcare organizations could affect their approach to the process of HTA, they should be both included in the sample (Menon and Marshall, 1990).

Consistently with previous studies, following a precise schedule of contacts, different touch-points occurred with the components of the sample (Dillman, 2000).

First of all, the members of the Commission for the Emerging Technologies (CTE) and Commission for Technologies in Diffusion, Diffused or Obsolete (CTD)², the Assessment Network, and the General Directors of the Local Health and Social Authorities and of the Scientific Institutes for Research, Hospitalization and Health Care of the Lombardy Region received an email with the link to the survey and the explanation of the objectives of the project. The email was sent by the Welfare General Direction in Lombardy Region. In particular, the General Directors of the Local Health and Social Authorities and of the Scientific Institutes for Research, Hospitalization and Health Care were asked to make the survey circulate within their organizations. Subsequently, the survey was promoted during the Opening Conference of the "Key Evidence Leaders" (KEL) Project³, and a reminder was sent to all the groups in October 2017. The survey remained open online from September to December 2017.

According to Dillman, survey research could be affected by four possible sources of bias (Dillman, 2000).

First of all, sampling error "is a result of the measuring a characteristic in some, but not all, of the units or people in the population of interest" (Lindner, Murphy and Briers, 2001, p. 43). In order to deal with this possible bias, different touch-points with potential respondents occurred.

Second, survey research could be affected by the coverage error, when the researcher fails to include all the subjects in the population of interest in the sample. In order to overcome this potential bias, along with this study, different groups of potential respondents were created and reached differently. Measurement error represents the third potential bias of survey research. In order to avoid this potential bias, only items already used in the HTA research to conduct survey have been adopted.

Finally, the nonresponse error could occur when "people included in the sample fail to provide usable responses and are different than those who do on the characteristics of interest in the study" (Lindner, Murphy and Briers, 2001, p. 44). In order to control for this bias, previous studies compared the characteristics of early and late respondents of the survey (Miller and Smith, 1983; Connors and Elliot, 1994; Ary, Jacobs and Razavieh, 1996; Lindner, Murphy and Briers, 2001; Lewis, Hardy and Snaith, 2013). In this study, the same approach is adopted.

² CTE and CTD are the two Commissions that are in charge of supporting the evaluation activities related to the Health Technology Assessment Program at Regional level in Lombardy Region (DGR 5671 of 11.10.2016).

³ KEL is a Project of Lombardy Region that has been introduced with the aim of training and educating professionals on the basic principles of HTA and systematically involve them in the evaluation of medical devices. Additional information about the project are provided in Chapter 4.

3.4.1.2 Survey Design

According to previous studies, the use of a web-based survey can be legitimized by the various advantages that are related to that (Cobanoglu, Moreo and Warde, 2001; Solomon, 2001; Lefever, Dal and Matthiasdottir, 2007; Heiervang and Goodman, 2011), such as the lack of costs associated with its design and its speed in reaching potential respondents make it the dominant method for gathering data (Solomon, 2001).

Along with this study, the web-based survey was developed by reviewing the literature on factors affecting KTE process.

As advocated in the literature, the phase related to the choice of the survey instrument has to follow a clear definition of the objective of the survey. Once the objective is defined, it has to be converted into measurable factors (Salant, Dillman and Don, 1994). First of all, in order to design a proper survey, the researcher(s) has(have) to choose words that are consistent with the educational level of the potential respondents in order to avoid any kind of misinterpretation (Salant, Dillman and Don, 1994; Macintyre, 1999). In particular, debates about the typologies of questions to use in the survey emerged (Liu and Cernat, 2018). According to previous studies, surveys with a mix of typologies of questions, and, in particular, with the inclusion of matrices or row/column questions, are usually preferred (Dillman, 2000). At this purpose, different typologies of questions were adopted according to their objectives, among those proposed in the literature (Glasow, 2005).

- *Open-ended questions* have the advantage to allow respondents to answer in their own language and to explore ideas that would not incorporate in closed-ended questions, but, at the same time, they require more time and though to respondents and they are more difficult to be analyzed by the researcher (Glasow, 2005). For this reason and given the numerousness of the questions that are included in the survey, only few open-ended questions were envisaged;
- In *closed-ended* questions, instead, the respondent has to choose among different possible sets of responses (Macintyre, 1999). Different types of closed-ended questions were adopted in this study. First, closed-ended questions with ordered choices, adopting a Likert-scale, were adopted for the easiness in their completion from the respondent and in their analysis from the researcher(s). Second, matrix questions were introduced, when possible, in order to facilitate the comprehension and the compilation of the survey (Dillman, 2000). Finally, multiple choice questions were adopted in the other cases.

The literature related to the KTE process and previous surveys developed for analyzing the widespread of HTA across countries guided the development of the web-based survey of this study

(ISPOR Asia Consortium; Moharra et al., 2008; World Health Organization, 2015). More specifically, the survey designed for this study is grounded on the following previous questionnaires: ISPOR Asia Consortium designed for collecting information about HTA principles for analysing beliefs, awareness and attitudes towards HTA; 2015 Global Survey on Health Technology Assessment by National Authorities for capturing knowledge and previous experience, and the Survey designed by the EUnetHTA project in the Work Package 8 for detecting information about HTA organizations.

The survey is composed of 34 questions, comprising four different sections which allow the identification of part of the individual and organizational factors affecting HTA development identified in the previous Chapter (Appendix 1):

- Biographical information (7 questions: Q1-Q7). Socio-demographic information was collected at the beginning the of the questionnaire in order to identify the profiles of the respondents. Questions are related to (1) age; (2) sex; (3) organization of affiliation; (4) Professional Area; (5) Length of service; (6-7) Membership of an HTA network with the indication of which HTA network;
- Knowledge (12 questions: Q8-Q19). The second section of the survey aims at detecting the _ knowledge that respondents have about the concept of HTA. This would guide the design of the tailored implementation intervention and would allow the identification of the level of preparation on the topic of the respondents. Questions are related to (1) level of knowledge of HTA on a Likert scale: 1 (I don't know the topic), 2 (I know the topic, but I have never been involved in HTA processes), and 3 (Previous experience); (2) knowledge of guidelines for performing HTA; (3) knowledge of HTA agencies; (4) rate the importance of following issues on a Likert scale (1: Not important; 2: Slightly Important; 3: Important; 4: Very Important; 5: Extremely Important): Identification of clinical and technological innovation; identification of health needs; information related to the commercialization of drugs and technologies; (5) judgement of the access to the following information related to HTA on a Likert scale (1: Very easy; 2: Easy; 3: Adequate; 4: Difficult; 5: Very difficult): Identification of clinical and technological innovation; identification of health needs; information related to the commercialization of drugs and technologies; (6) existence of a scientific documentation service in the organization; (7) awareness of the publication of new HTA reports; (8) willingness to be informed about the publication of new HTA reports; (9) frequency in the consultation of the following sources on a Likert scale (1: Never; 2: Once a year or less; 3:

Once every six months; 4: Once a month; 5: Once a week or more): Governmental publications; University papers; consulting groups' reports; community organizations' reports; Professional Journals; Scientific Journals; Monographs and books; Documentation from the pharmaceutical industry; (10) existence of an explicit process for the identification of priorities in the organization; (11-12) knowledge and listing of the criteria used to identify priorities in the organization;

- *Experience* (10 questions: Q20-Q29). Previous experience of respondents would help the identification of involvement in HB-HTA activities. Questions are related to (1-2) participation (and number of times) in previous HTA processes; (3) technologies evaluated; (4-5) number and professional area of professionals involved; (6) HTA products produced; (7) use of available scientific documentation; (8) decisions supported; (9) use of reports produced; (10) activities of the organization of affiliation among the following: HTA activities; coordination; Reimbursement decision making on the basis of HTA reports; HTA activities;
- Beliefs, awareness and attitudes (5 questions: Q30-Q34). The last section of the survey is intended to capture the subjective perceptions of respondents about HTA, and their intention to be involved in HTA activities. Questions are related to (1) objective of HTA among the following: health needs assessment; guidelines definition; planning and budgeting; pricing; quality indicators of healthcare treatments definition; other; (2) relevance of the following typologies of knowledge on a Likert (0: I do not know; 1: Not useful; 2: Slightly useful; 3: Useful; 4: Very useful; 5: Extremely useful): Experts' opinions; professionals experiences (own and of colleagues); experiences of other organizations; opinions of specific individuals (patients, ..); analysis of political situation; scientific evidence; sociological and anthropological knowledge of the problem; market analysis; (3) barriers to production of HTA reports among the following: Resources availability; information availability; knowledge of methodologies; qualified human resources; other; (4) barriers to use of HTA reports among the following: Awareness of the importance of HTA; HTA institutionalization; political authorities mandates; political support; qualified human resources; other; (5) judgment of the following topics, on a Likert scale (1: Not relevant; 2: Scarcely relevant; 3: Partially relevant; 4: Quite relevant; 5: Extremely relevant): The objective and the aim of HTA should be explicit and relevant for their use; HTA should be a transparent and unconditional process; HTA should include all relevant technologies; a clear system for the definition of priorities for HTA should exist; HTA should include all the appropriate methods for the

evaluation of costs and benefits; HTA should consider a wide range of outcome and evidence; a complete social perspective should be included in HTA; uncertainty should be evaluated; transferability and generalizability of HTA products should be guaranteed; all the stakeholders should be actively involved; all the available data should be considered; the implementation of HTA results should be monitored; HTA should be timely; HTA results should be appropriately communicated to different decision makers; the connection between HTA and decision making process should be transparent and clearly defined.

The association between the typology of questions and its number and area is provided in Table 3.2.

Area	Question number	Typology
Biographical information	Q1	Multiple Choice - Ordered
	Q2	Multiple Choice
	Q3	Open-ended
	Q4	Multiple Choice
	Q5	Multiple Choice - Ordered
	Q6	Multiple Choice
	Q7	Multiple Choice
Knowledge	Q8	Multiple Choice - Ordered
	Q9	Multiple Choice
	Q10	Multiple Choice
	Q11	Matrix
	Q12	Matrix
	Q13	Multiple Choice
	Q14	Multiple Choice
	Q15	Multiple Choice
	Q16	Matrix
	Q17	Multiple Choice
	Q18	Multiple Choice
	Q19	Open-ended
Experience	Q20	Multiple Choice
	Q21	Multiple Choice – Ordered
	Q22	Multiple Choice
	Q23	Open-ended
	Q24	Multiple Choice
	Q25	Multiple Choice
	Q26	Multiple Choice
	Q27	Multiple Choice
	Q28	Multiple Choice
	Q29	Multiple Choice
Beliefs, awareness and attitudes	Q30	Multiple Choice
	Q31	Matrix
	Q32	Multiple Choice
	Q33	Multiple Choice
	Q34	Matrix

This study has been perfomed in accordance with the guidelines of the Declaration of Helsinki (World Medical Association, 1964). In particular, people decided to adhere to this study according to their own free will, by giving written informed consent. At this purpose, at the end of the survey, information about the objectives of the survey and the treatment of the data was provided. A section dedicated to the information related to the informed consent of participants has been included at the end of the survey. First, indications about the treatment of personal data are provided. Second, rights of respondents are illustrated. Finally, authorization for the use of the data for the purposes mentioned is asked.

As advocated in previous studies, the survey is done using HTML forms, and potential respondents are contacted via email with a cover letter for the specification of the objective of the survey and the treatment of data (Solomon, 2001). In particular, the survey was written in Italian in order to allow its comprehension by a wider range of healthcare professionals. The survey was developed using Google Forms. After the programming phase, consistently with previous studies, a pilot test was performed with a panel of experts in the field (the components of the Medical Devices Commissions for the evaluation of medical devices in Lombardy Region - 15 individuals) (Schleyer and Forrest, 2000). Different browsers (Safari, and Google Chrome) and different operating systems (Windows and Macintosh) were used to perform the technical test of the survey. Any technical problem was detected by the pilot test. The aim of the testing was also to make sure that the questions were understandable and clear for the target group of respondents, and to assess face validity and to measure duration (Litwin, 1995; Cobanoglu, Moreo and Warde, 2001; Couper, Traugott and Lamias, 2001). Since the pilot test detected some possible misunderstanding in the content of the survey, in order to avoid it, the wording of some questions was slightly modified in order to allow a better comprehension of the question(s). However, only minor adjustments that did not change the meaning of the questions were done. The final web-based survey took approximately 20 minutes to complete. Previous studies investigating the influence of survey length on response rate show mixed results (Sheehan, 2001). While some studies did not find any correlation between length and response rate (Mason, Dressel and Bain, 1961; Brown, 1965; Bruvold and Comer, 1988), according to other studies, a low response rate could be associated with longer surveys (Heberlein and Baumgartner, 1978; Yammarino, Skinner and Childers, 1991). In addition, when the survey is declared to last more than 20 minutes, the response rate is lower (Crawford, Couper, and Lamias, 2001). While an higher response rate is associated with surveys lasting for 10 minutes, when the survey took 30 minutes to compete, the respondents starting to answer are less (Galesic and Bosnjak, 2009). Therefore, an intermediate length was chosen in order to guarantee that all the questions were asked, but, at the same time, the respondents were not disincentivized to participate. However, as argued by previous studies, the length of the survey is not enough to predict the response rate (Sheehan, 2001).

3.4.2 Qualitative Data Collection

The second portion of this study has been flanked by a qualitative approach in order to identify concepts and understand phenomena related to the research problem (Bradley, Curry and Devers, 2007).

After having obtained information about the training needs of healthcare professionals through quantitative data, the main aim of qualitative data collection is to gauge the participants' experience and perspectives of healthcare professionals related to the introduction of the HTA process.

The semi-structured interviews were conducted with practitioners of healthcare organizations in Lombardy Region. An interview protocol has been followed in order to be consistent across interviews. The interviews have been conducted in Spring 2019 by a single researcher. All the participants have been interviewed once and recorded.

3.4.2.1 Target Population and Sample

The target population for qualitative data collection is represented by all the healthcare organizations that would be affected by the new Resolution. Therefore, healthcare professionals of both public and private healthcare organizations accredited in Lombardy Region are targeted for this study.

In this study, a purposeful sampling method is adopted to include only information-rich cases, as suggested by Palinkas et al. (Palinkas *et al.*, 2015). Many studies in the literature used the purposeful sampling technique in healthcare (e.g. Cohen *et al.*, 2014; Kash *et al.*, 2014; Nicol, Mohanna and Cowpe, 2014). The main benefit associated with the use of a purposeful sampling technique is that it can be adopted also in situation of scarcity of resources, since its aim is to identify participants who can contribute with new information to the study (Duan *et al.*, 2015).

Another important aspect to define when designing qualitative research is the sample size of the analysis. Different approaches can be found in the literature (Kelly, 2010; Robinson *et al.*, 2013). Some scholars pointed out that to capture the essence of the research problem a sample between four and ten interviews is adequate (Kelly, 2010), others give preference to a larger sample, from three to sixteen (Robinson *et al.*, 2013). Given that there is not a golden rule for the number of cases included in the sample in qualitative research (O'Reilly and Parker, 2013), along with this study the approach

of Marshall and colleagues is adopted: the size of the sample is determined by the lack of new informative data (Marshall *et al.*, 2013). In terms of study sample, the interviewees have been selected in order to represent the whole population, by taking into consideration the strategic positioning of the organization, its ownership structure and its regional relevance. According to Marshall and colleagues, data saturation, which occurs when no new information emerges from the data, is the point in which data start becoming redundant (Marshall *et al.*, 2013). Following this approach, the sample size of the qualitative portion of this study is determined by the point of data saturation.

3.4.2.2 Interview Design

The qualitative data have been collected by conducting semi-structured interviews. The semistructured interviews have been designed to be conversational and informal in tone to allow for open responses in the words of participants (Longhurst, 2003). The use of interviews allows researchers to obtain rich and detailed qualitative data in order to dig in the respondents' experiences (Rubin and Rubin, 2011).

Differently from quantitative methods, that are mainly used to test hypothesis, qualitative methods provide access to the subjective perceptions of participants, considering their experiences and the meaning they give to them (Moustakas, 1994; Denzin and Lincoln, 2011). For this reason, many authors argued that the use of semi-structured interviews can be useful in healthcare in order to gain access to experiences in this context (Low, 2013). The main advantage that is associated with the use of semi-structured interviews is the flexibility they allow, while ensuring enough exploration of the research question (Rowley, 2012). The researcher, by using semi-structured interviews, can guide the respondent through its own experience, by obtaining a complete answer (Kelly, 2010; Rowley, 2012; Saleem *et al.*, 2013). Additionally, more complex questions, and deeper clarifications can be achieved thanks to the use of interviews (Doody and Noonan, 2013). However, some disadvantages are also associated to the use of interviews, such as the time needed to collect data and the bias at which data are exposed (Doody and Noonan, 2013).

When designing semi-structured interviews, some elements should be clearly defined before conducing the interview itself. Previous studies in the literature identified the following elements as key aspects to be defined (Weiss, 1994; Rubin and Rubin, 2011; Seidman, 2013; Brinkmann and Kvale, 2015; Castillo-Montoya, 2016).

Environment, tone and duration of the interviews

The environment of the interview is an important aspect to be defined (Doody and Noonan, 2013). In order to ensure privacy and confidentiality, the semi-structured interviews have been conducted in a closed environment that has been jointly chosen by the researcher and the respondents, as suggested by previous studies (Kelly, 2010). The tone of the questions is informal and conversational. In fact, as suggested by Brinkmann and Kvale, it is important to keep research questions and interview question separate: the first uses a theoretical language, while the latter are expressed in every language of respondents to make them as much as understandable and accessible as possible (Brinkmann and Kvale, 2015). Each interview has been scheduled to last no more than one hour for each respondent.

Instruments for Data Collection

As supported by previous studies, the primary qualitative data collection instrument is represented by the researcher, since he/she annotates both verbal and nonverbal communication during the interview to explore respondents' thoughts (Hanson, Balmer and Giardino, 2011; Chan, Fung and Chien, 2013; Peredaryenko and Krauss, 2013). However, the researcher can make use of additional instruments to support data collection. In particular, the interviews have been recorded using a digital voice-recording device. The main organizational tool that has been used for the qualitative data collection and for the interview process is the interview protocol. The interview protocol allows the organization of data before, during and after the interview process in order to extract relevant information from respondents (Rabionet, 2011; Jacob and Furgerson, 2012; Doody and Noonan, 2013).

Before starting the interview, the respondents received a written copy of the interview protocol, that will be explained in the following section, and a written consent format has been sent to potential respondents. This agreement has to be signed by respondents in order to give the researcher the consent to record and use the interview.

Additionally, nonverbal cues have been documented as well. In order to detect them, the reflexive journaling has been used. According to previous studied, reflexive journaling can be used to detect experiences and beliefs of the researcher that may influence the research process (Tufford and Newman, 2012; Ward *et al.*, 2013; Berger, 2015). This can increase the trustworthiness of the study, ensuring that the data collected are representative of the researcher has to often refer back to personal writing while writing about his/her own feelings and thoughts in order to ensure that his/her perceptions are separated from the data collected from respondents (Dowden *et al.*, 2014).

Finally, emerging conclusions are drawn on a research log, which helps researchers to keep track of emerging thoughts and preliminary data interpretation (Yin, 2009; Ritchie *et al.*, 2013).

Interview Protocol

The interviews have been conducted following an interview protocol to provide uniformity. Jacob and Furgerson introduced the interview protocol as an instrument for keeping track of the statements before, during, and after the interviews (Jacob and Furgerson, 2012). Additionally, it can be also considered as a guide with cues and prompts to allow the researcher to remain on topic and to allow respondents to provide a more in-depth answer for an increased understanding of the research argument from the researcher (Rowley, 2012; Doody and Noonan, 2013).

The use of an interview protocol can strengthen the quality of the obtained data. In order to enhance the reliability of the interview protocol, it has been designed following the suggestions of previous literature (Jacob and Furgerson, 2012).

The review protocol is composed of three major areas:

- Pre-interview section provides prompts and statements for establishing the settings for the interview, for making contact with the respondents, and for preparing recording devices;
- In the interview section, questions, prompts and cues strictly related to the research project are provided. In particular, this section is composed of an initial part, in which the researcher explains the details of the research project to respondents, a central part, which contains the core questions of the interview, and a final part for expressing gratitude about respondents' participation;
- Post-interview section is dedicated to a follow-up phase: respondents will be contacted again after the interview by providing them first with the interpretation of data collected in order to obtain comments on that and, then, after further development, the main results and conclusions of the research project are sent to respondents.

As suggested by Castillo-Montoya, the review protocol helps the identification of the utility of the questions to be asked to respondents, ensuring that those included in the interview protocol are confirming the purpose of the research, and those unnecessary eliminated (Castillo-Montoya, 2016). Additionally, it can guide researcher in the sequence in which questions have to be asked, ideally locating the key questions in the middle of the interview (Rubin and Rubin, 2011; Castillo-Montoya, 2016).

Appendix 2 provides a distinction between four categories of questions, in line with previous studies (Merriam and Tisdell, 2009; Rubin and Rubin, 2011; Krueger and Casey, 2014; Lewis, 2015; Castillo-Montoya, 2016):

• Introductory questions are included to set the tone of the interview, to provide the respondents the opportunity to get used to describe experiences and to give more confidence to the respondents;

- Transition questions are used to slowly move from the introduction to the research problem;
- Key questions are those aimed at capturing the most relevant information. More specifically, consistently with previous studies, analytical categories are used in order to describe and explain the social phenomena under investigation (Pope, Ziebland and Mays, 2000). Semi-structured questions that are asked to respondents are grounded on the main key aspects delineated in implementation research. The categories analyzed by the interviews are related to the implementation outcomes that have been introduced by Proctor and colleagues in 2011 (Proctor *et al.*, 2011). As suggested by previous studies, the implementation outcomes are measured in terms of (Proctor *et al.*, 2011):
 - Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory;
 - Adoption is considered the intention, initial decision, or action to try or employ an innovation or evidence-based practice;
 - Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem;
 - Feasibility is the extent to which a treatment or an innovation can be successfully used or carried out within a given agency or setting (Karsh, 2004);
 - Fidelity represents the degree to which an intervention was implemented, or it was prescribed in the original protocol or as it was intended by the program developers (Dusenbury *et al.*, 2003; Rabin *et al.*, 2008);
 - Implementation cost is the cost impact of an implementation effort;
 - Penetration is the integration of a practice within a service setting and its subsystems;
 - Sustainability is the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations;
- Closing questions give the respondents the opportunity to raise new questions not yet addressed.

Along with this study, all the categories of questions listed above are asked to respondents, and the interview protocol is used to guide the order in which questions have to be asked. In particular, as advocated by Jacob and Furgerson, additional questions have been posed in order to deepen topics of interest of respondents (Jacob and Furgerson, 2012).

3.5 Data Analysis Methods

Data analysis is an essential step of a research project since it is the phase in which data are transformed from the descriptive process to a level of interpretation (Vaismoradi, Turunen and Bondas, 2013). In the following section the methods used for quantitative and qualitative data analysis are presented, such as the strategy adopted for results integration.

3.5.1 Quantitative Data Analysis

The web-based survey has been designed using Google Forms, that is one of the most used online survey program (Gehringer, 2010). Its dissemination is legitimized by the possibility to automatically collect the answers on Google spreadsheets and to use Google charts to visualize trends. After having collected all the answers, the data have been saved in Excel. The analysis has been conducted using the statistical software Stata 13.

Nonresponse bias represents a possible cause for misleading and/or inaccurate research findings (Lewis, Hardy and Snaith, 2013). For this reason, the assessment of this bias is of particular interest for survey researchers (Lewis, Hardy and Snaith, 2013). In particular, according to previous studies, response rate is considered a proxy for defining the representativeness of the survey sample, and, subsequently, a high response rate is associated with a low nonresponse bias (Draugalis and Plaza, 2009). On the contrary, when the nonresponse bias is a major concern, this is considered to reduce the quality of the survey responses (Lewis, Hardy and Snaith, 2013). Despite the response rate has been widely criticized in the literature as proxy for response quality (Cull *et al.*, 2005; McFarlane *et al.*, 2007; Halbesleben and Whitman, 2013), researchers have to adopt methods for ensuring the reliability of their results (Lewis, Hardy and Snaith, 2013).

Along with this study, the wave analysis has been adopted as measure to ensure the lack of nonresponse bias. In particular, nonresponse bias "occurs when a significant number of people in the survey sample do not respond to the questionnaire and have different characteristics from those who do respond, when these characteristics are important to the study" (Dillman, 2011, p. 10).

Consistently with previous studies, comparisons between late respondents and the rest of the respondents' group were performed (Lewis, Hardy and Snaith, 2013; Cohen, 2017). Indeed, the wave analysis starts from the assumption that people who respond less readily, or who need additional reminders (late respondents) are like nonrespondents (Armstrong and Overton, 1977).

Descriptive analyses were conducted in order to describe the sample of respondents. In particular, frequencies of demographic variables and organizational typology (teaching vs non-teaching hospitals) were used to differentiate the overall sample. This allows the researcher to better understand whether individual or organizational factors are affecting the approach of the respondent towards HTA. In particular, the differentiation between different typologies of healthcare organizations that participated at the survey has been made in order to investigate the role of organization in defining the approach of respondents towards HTA. Additionally, the Pearson Chi squared has been calculated to statistically compare subpopulations of level of knowledge within the sample of respondents in order to test whether the answers of the analyzed variables are differentially distributed over the different levels of knowledge of HTA by respondents (Rao and Scott, 1981; Plackett, 1983). In addition, adjusted p-values have been calculated with the application of the Bonferroni correction that is commonly implemented when testing multiple comparisons (Wright, 1992). In particular, the Bonferroni correction allows the identification of the critical value (alpha) for the individual test through the identification of the familywise error rate, defined as "the probability of even one false rejection" (Lehmann and Romano, 2012, p. 719).

The analysis conducted with the quantitative data allowed to have a better understanding of the profiles of potential adopters and the role played by the healthcare organizations. Instead, the perceptions about the implementation intervention are captured by qualitative data, whose analysis is described in the following section.

3.5.2 Qualitative Data Analysis

The Framework Method was adopted in the management and in the analysis of qualitative data (Gale *et al.*, 2013). Despite it has been used since the 1980s in large-scale social policy research (Ritchie *et al.*, 2013), its application is becoming particularly relevant in medical and health research (e.g. Heath et al., 2012; Rashidian, Eccles, & Russell, 2008; Sheard et al., 2013), and of particular interest in multi-disciplinary and mixed methods studies (Gale *et al.*, 2013). The framework allows to capture the key themes of the interview along with the whole data set through the in-depth analysis, and, at the same time, to keep the views of the researchers related to the context. This facilitates the comparison and the contrasting of the data, which is a crucial point in the qualitative analysis (Gale *et al.*, 2013). In addition, this model has been selected since it is particularly suitable for semi-structured interview transcripts in order to have a holistic and descriptive overview of the entire data set (Gale *et al.*, 2013; Ritchie *et al.*, 2013).

The procedure for analysis is delineated in seven different stages that are described and discussed below.

- Transcription: during this phase, the verbatim transcription of the interview is conducted in order to become completely immersed in the collected data. As argued by Oliver and colleagues, "transcription is a pivotal aspect of qualitative inquiry" (Oliver, Serovich and Mason, 2006, p. 1273). In particular, in order to provide a full and faithful transcription, the denaturalized approach has been adopted (Müller and Damico, 2002; Oliver, Serovich and Mason, 2006; Widodo, 2014). Differently from the naturalized approach, in which "utterances are transcribed in as much detail as possible" (Oliver, Serovich and Mason, 2006, p. 1275), this is in line with the purposes of this study and it is widely adopted "to get at emic pointsof-view, or insider meanings, that are attached to social phenomena" (Oliver, Serovich and Mason, 2006, p. 1278).
- 2. Familiarization: As suggested by Gale and colleagues, this is "a vital stage in interpretation" (Gale *et al.*, 2013, p. 4), since it is the phase in which the audio recordings are re-listened and the transcriptions of the interviews re-read. This process allows to achieve an extensive knowledge of the data, and, for this reason, it is also considered as the stage of "immersion" (Ritchie and Spencer, 1994, p. 179). In particular, following indications in previous studies, not all the material is reviewed in this stage, but only the relevant aspects (Srivastava and Thomson, 2009; Parkinson *et al.*, 2016). The main aim of this phase is to become familiar with the data, by listening to audio records, transcribing them, reviewing data, and annotating ideas while reading data (Bradley, Curry and Devers, 2007; Vaismoradi, Turunen and Bondas, 2013).
- 3. Coding: in this phase the different elements that emerge from the analysis are labelled with different codes, representing the important interpretation of the researcher (Weston *et al.*, 2001; Zhang and Wildemuth, 2009). The most important phase of qualitative data interpretation is the coding procedure (Yin, 2009). As suggested by previous studies, coding procedure has to follow a structured approach in order to enhance its validity (Elo *et al.*, 2014). In fact, according to Bradley and colleagues, coding procedure is the phase in which, after having familiarized with data, a formal system is used to organize data and link the concepts emerging from data (Bradley, Curry and Devers, 2007). Adopting a combination of deductive and inductive approach, first the passages related to pre-defined codes are labelled, while,

subsequently, the "open coding" is adopted in order to code anything that may be relevant and/or unexpected and that has not been already captured by the pre-defined codes. A combination of inductive and deductive coding procedure is adopted in this study. Codes are assigned when, while reading the data, a concept becomes clear (Thomas, 2006; Bradley, Curry and Devers, 2007). The concept becomes more and more defined once more lines are assigned to the same code. Additionally, along with this study, all the coding process is conducted by a single researcher. This is considered sufficient and preferred since, as stated before, the researcher is the main instrument of the analysis, and, therefore, he/she can collect additional information with respect to audio recording (e.g. feelings, perceptions) while collecting data, that would be lost in the case the analysis of the data is done by someone else (Bradley, Curry and Devers, 2007).

- 4. *Developing the analytical framework*: in this phase the analytical framework has been defined. As suggested by previous studies, codes are grouped into categories, and the analytical induction is adopted to define the pillars of the analysis, while themes included in these pillars have been detected by adopting an open coding approach.
- 5. *Applying the analytical framework*: in this phase codes and categories defined in the analytical framework are applied to the collected data. As suggested by previous studies the use of a Computer Assisted Qualitative Data Analysis Software (CAQDAS) is particularly helpful at this stage since it can speed up the process of data analysis, it can ensure retrievability of data and it can help the identification of the key themes of the research problem from the data, linking them with existing literature and conceptual framework (Gale et al., 2013). The software used at this stage is NVivo12 MAC. As suggested by Silverman "the main purpose of using NVivo was to code data into a broad brushstroke coding frame" (Silverman, 2013, p. 273). The benefits associated with the use of specific qualitative analysis software are largely identified in the literature (Barry, 1998; Gibbs, 2002; Bernauer et al., 2013; Houghton et al., 2013; Tesch, 2013; Zamawe, 2015). In particular, the possibility to aggregate codes and to auto-code based on set criteria are particularly relevant for the purposes of this study. The use of a CAQDAS can increase the accuracy and transparency of the data analysis process, by providing a reliable and general picture of the data (Richards & Richards, 1994; Welsh, 2002). In addition, it is particularly important to support the critical thoughts during data analysis process, since it can organize the data based on the different purposes. Despite the

use of a CAQDAS can be helpful for storing and organizing data in a way that they can be accessible for the analysis process, the analysis is conducted during the following stages.

- 6. *Charting data*: the management and the reduction of the volume of data is performed at this stage. At this purpose, a matrix is generated by considering the need to reduce data and to maintain the original meaning of the data. This phase reminds the description of the data analysis provided by Mason: "a range of techniques for sorting, organizing and indexing qualitative data" (Mason, 1996, p. 7). At this stage an overview of the data is provided with the aim of maintaining the original meaning of the interviewees. In addition, differences and similarities among cases are detected (Tuffrey-Wijne and Rose, 2017).
- 7. *Interpreting data*: the interpretation stage is supported by the use of a file where to note down "impressions, ideas and early interpretations of the data" (Gale *et al.*, 2013, p. 5). In addition to the identification of theoretical concepts, mapping of the connections between different categories of the analytical framework is desirable, such as the identification of the overall themes (Tuffrey-Wijne and Rose, 2017).

Assessing trustworthiness in qualitative research is an important aspect to enhance credibility of findings. Many strategies have been identified in previous studies to establish the credibility of findings (Thomas, 2006): independent parallel coding, check on the clarity of categories and stakeholder/member check. In this study, this last strategy is adopted. Member checking strategy for establishing credibility has been extensively legitimized in previous studied (Thomas, 2006; Harper and Cole, 2012; Burda *et al.*, 2016; Caretta, 2016). In fact, the adoption of member checking is used to allow respondents to verify the accuracy of the interpretation of the interviews (Caretta, 2016), to ensure that the meaning given to interview by the researcher is accurate and appropriate (Burda *et al.*, 2016), and, consequently, to reduce interpretations errors (Harper and Cole, 2012). After having analyzed data and obtained preliminary results, documents with a summary of data interpretation and findings were sent to respondents, so that those willing to collaborate had the chance to comment whether the interpretation of findings reflect their experiences (Thomas, 2006).

3.5.3 Integration of Quantitative and Qualitative Data

Despite the integration, defined as "the interaction or conversation between the qualitative and quantitative components of a study" (O'Cathain, Murphy and Nicholl, 2010, p. 1), is an essential part of the mixed methods research, there is a paucity of empirical studies performing such an integration (O'Cathain, Murphy and Nicholl, 2007a, 2010; Lewin, Glenton and Oxman, 2009).

According to Sandelowski, it is possible to link data coming from different qualitative and quantitative databases by treating each set of data with the common techniques used for that specific kind of data (Sandelowski, 2000). In order to provide clarity about the strategies to integrate different data, O'Cathain and colleagues identified different techniques (O'Cathain, Murphy and Nicholl, 2010). Consistent with the aims of this study, integration of quantitative and qualitative results will be done adopting the triangulation protocol strategy. This strategy encompasses the process of triangulation, intended as the process used to study a problem combining different methodologies to obtain a broader picture (O'Cathain, Murphy and Nicholl, 2010). This methodological approach is aimed at increasing the validity of the results when multiple methods are adopted (Flick, 1992, 2002; Erzberger and Prein, 1997; Farmer et al., 2006). In particular, the process of triangulation starts when, after having collected and analyzed qualitative and quantitative data separately, the findings obtained are combined. Therefore, triangulation happens at interpretation stage in order to detect convergence, complementarity or discrepancy between findings (Erzberger and Prein, 1997; Farmer et al., 2006; O'Cathain, Murphy and Nicholl, 2010). In order to perform the integration of qualitative and quantitative findings, the triangulation protocol is followed. The triangulation protocol is a document containing rules guiding the analysis of the findings coming from different methods (Farmer et al., 2006). It consists in creating a matrix in which findings emerging from both quantitative and qualitative data analysis are displayed and contraposed in order to find (dis)similarities among them (O'Cathain, Murphy and Nicholl, 2010). The integration is conducted by a single researcher, since he/she is responsible of both quantitative and qualitative data collection and analysis.

3.5.4 Theoretical framework

In particular, the integration of the quantitative and the qualitative portion of the data collection has been proposed by following the OMRU theoretical framework for guiding the collection and the analysis of data, such as the interpretation of the results (Graham and Logan, 1998; Hogan and Logan, 2004; Logan and Graham, 2010).

Despite a variety of frameworks exist for the implementation of evidence-based practices (Brownson, Colditz and Proctor, 2018), the OMRU has been selected because of the assumptions about KTE upon

which it is based (Graham and Logan, 2004). First, the processes between knowledge production and use are dynamic and interactive and they reflect the nature of knowledge translation, that is, by definition, complex. Second, health outcomes are at the center of all the processes, since they are the focus of the evidence-based practice. Finally, the environment has a potential influence on the knowledge translation processes.

The external validity of the OMRU was demonstrated by its implementation in previous studies in healthcare (Hogan and Logan, 2004; Gifford *et al.*, 2008; Zecevic *et al.*, 2017) in order to effectively explain the knowledge uptake by stakeholders (Logan and Graham, 1998; Graham and Logan, 2004). The model has been derived from planned action theories, research utilization, and physician behavior change literature (Boland *et al.*, 2019) in order to explain how the evidence can be implemented into practice.

In the framework, the key elements of knowledge translation are examined to explain the uptake of knowledge by stakeholders (Logan and Graham, 1998; Graham and Logan, 2004): practice environment, potential adopters, evidence-based innovation, transfer strategies, adoption and use, and outcomes. A more detailed explanation of the pillars upon which the model is based in provided in Chapter 6, during the discussion of the results. More specifically, since the components are strictly context-dependent, the first phase of this iterative process is to define the profile development, comprising the barriers and facilitators, the implementation interventions, and the evidence-based innovation (Graham and Logan, 2004; Boland *et al.*, 2019). According to the model, the research use is dependent on the innovation, the potential users, and the environment (Driedger *et al.*, 2010). Subsequently, it allows to monitor the adoption and the use of the innovation and to measure outcomes.

Despite some weaknesses have been detected in the literature (Estabrooks *et al.*, 2006; World Health Organization (WHO), 2012), along with this study some measures to overcome them have been adopted. More precisely, first, the model considers the implementation of a practice that can affect the health system in general, not only the clinical practice. Second, the model has been firstly developed by Logan and Graham in 1998 (Graham and Logan, 1998), and, since that time, it has been adopted and validated many times (Logan *et al.*, 1999; Hogan and Logan, 2004; Stacey *et al.*, 2006). Third, since tools are not provided in the model, and the theoretical pluralism is advocated by the model (Midgley, 2011), this approach has been adopted in order to face each element with the most appropriate instrument(s). Finally, as provided in the previous Chapters, the HTA process is considered as part of the KTE.

As suggested by the authors of the OMRU, the concept of "theoretical pluralism" has been embraced by adopting other theories, models, frameworks to the different components of the model (Graham and Logan, 2004). This allows to see the reality through different theoretical lenses that allow the simultaneous consideration of different assumptions (Midgley, 2011). In particular, the practical value of the theoretical pluralism has been recognized by previous studies since by seeing through different theoretical lenses, it is possible to achieve greater flexibility rather than adopting a single theoretical perspective (Churchman, 1970; Reason, 1988; Checkland, 1999; Midgley, 2011).

In particular, five different implications have been identified by Midgley:

"1) Knowledge cannot be regarded as universal and cumulative—when it appears to be so, it is still within a particular context and relevant to a particular community.

(2) Theories are more or less useful depending on the purposes of intervention that are being pursued.

(3) We can think pluralistically about the agency and choices of the researcher. (4) While it is impossible to produce universal standards for choice between theories, this does not mean that anything goes—standards of relevance to particular contexts can still obtain.

(5) Given that different theories inform different methodologies and methods, methodological pluralism (drawing upon methods from different paradigms) becomes philosophically justifiable alongside theoretical pluralism." (Midgley, 2011, p. 8).

According to the implications proposed by Midgley, the knowledge that is produced is highly dependent on the settings in which it is created, since "what is true today may be myth or falsehood tomorrow, and in another context on the very same day, that body of knowledge may simply be irrelevant" (Midgley, 2011, p. 9).

Previous studies argued that knowledge depends on the objectives of agents, who are, in turn, influenced by the system in which they are (Griffiths, 1997; Midgley, 2011; Jacobs, 2012). By being grounded on the agents' purposes, knowledge serves social roles, and, therefore, theory assumes always different meanings according to the activities pursued by the agents. Additionally, by embracing a plurality of theories, each of them is adopted for specific circumstances according to the meaning attributed by the agent.

Theoretical pluralism is usually combined with methodological pluralism, that consists in drawing upon various methods from different paradigms in the same study (Kaplan, 2001; Mingers, 2001). In particular, the use of methodological pluralism is particularly relevant in enhancing action research practice "by encouraging both the use of a wide range of methods and learning across methodological boundaries" (Midgley, 2011, p. 13).

Along with this study, the methodological pluralism has been followed by the theoretical pluralism that characterizes the discussion of each separate pillar of the OMRU. Adopting the pluralism proposed by Midgley, different theoretical approaches have been adopted along with this study and discussed separately for each element of the model.



Figure 3.2 - Alignment between OMRU, transfer strategies, and the study design Source - Adapted from (Graham et al., 1998)

The alignment between the OMRU, the transfer strategies, and the study design is provided in Figure 3.2. Along with this study a sequential explanatory mixed methods design has been employed, in which quantitative results from a knowledge, experience and attitudes towards HTA survey preintervention were collected first and then combined with qualitative results from semi-structured interviews post-intervention.

While the survey provided a snapshot of the state of the art of the diffusion of HTA across the healthcare organizations in Lombardy Region, analogous to the OMRU's profile development, the semi-structured interviews provided complementary information related to the OMRU pillars, after the intervention. The OMRU is applicable to the different levels of the health system (patients, professionals, organizations and health system), and, for the purposes of this study, it is applied first at the level of professionals in order to detect their perceptions about the introduction of the innovation, and, subsequently, the aggregation of the professionals' data allowed to perform analysis also at organizational level in order to better investigate the organizational change.

3.6 Conclusions

This Chapter is dedicated to the description of the methodology adopted in this study.

Mixed methods research is used in order to have a broader picture of the research problem by adopting quantitative and qualitative data to answer to two slightly different research questions of the same phenomenon. Quantitative data have been collected before the tailored implementation intervention through a web-based survey, written in Italian and with a duration of approximately 20 minutes, which allows the delineation of the profile development of the members' sample. Qualitative data have been collected after the tailored implementation intervention through semi-structured interviews, conducted in a conversational and informal tone, to capture healthcare professionals' perceptions. Finally, the integration of quantitative and qualitative data occurred using a triangulation protocol strategy guided by the OMRU theoretical framework, in which, at the interpretation stage, convergence, complementarity or discrepancy between findings are detected.

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Chapter 4: QUANTITATIVE RESULTS

ABSTRACT

The quantitative portion of this study is related to the analysis of the data that have been collected through a webbased survey that has been delivered in order to analyze the diffusion and awareness of Health Techology Assessment (HTA) concepts in Lombardy Region, in Italy. A total of 333 answers have been collected, of which 309 authorized for the treatment of their data.

Descriptive statistics are provided for four different areas: demographic characteristics, knowledge, experience, and attitudes, awareness, and beliefs. People from 41 health organizations took part in the survey, of which around 23% is aged less than 50. 34% are women, and 70% are from the medical area. The majority of respondents is not part of an HTA network, and 68% of them is aware of the existence of the HTA process for evaluating healthcare technologies. While some respondents already know some of the international associations relevant in the field, less awareness has been detected for national networks. Respondents with previous experience in HTA activities declared to be part of a group of, in the majority of cases, up to 10 components, predominantly from the medical field. People involved in HTA activities are mainly contributed at producing technical reports. Almost 40% of respondents declared that, according to them, the objective of HTA is to support planning and budgeting. Barriers to HTA have been investigated, as well. While for the production of HTA, the lack of resources (especially qualified human resources), and knowledge of the methodologies to adopt may prevent the involvement of professionals in HTA activities, respondents declared that to foster the use of HTA reports it is necessary to increase the awareness of the importance of HTA. For almost 68% of respondents the scientific evidence is an extremely relevant aspect that should be considered when performing HTA.

Additionally, after having divided the population in three different groups according to the level of knowledge of HTA of respondents ("Knowledge", "Experience", "Lack of Awareness"), the Pearson Chi squared has been calculated to analyze differences in the answers across different groups. Globally, 32 variables show statistically significant differences, of which 1 is significantly different for each level of knowledge.

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Chapter 4: QUANTITATIVE RESULTS

4.1 Introduction

Following a mixed methods design, both quantitative and qualitative data collection methods have been adopted in this study in order to analyze the factors affecting Health Technology Assessment (HTA) development.

The area of investigation is Lombardy Region, where a web-based survey was developed to determine the knowledge of HTA concepts, related experience, and attitudes, awareness and beliefs of healthcare professionals has been delivered (Appendix 1). More specifically, this survey is aimed at identifying the major determinants that allow the identification of the profile development of potential adopters, and to guide the design of the tailored implementation intervention. 34 questions, associated with 4 different areas of interest (demographic characteristics; knowledge; experience; and attitudes, awareness and beliefs towards HTA) were identified through a literature review and used as a basis for the questionnaire (Moharra *et al.*, 2008; ISPOR Asia Consortium, 2015; World Health Organization, 2015). The survey was distributed to the members of the Commission for the Emerging Technologies (CTE) and Commission for Technologies in Diffusion, Diffused or Obsolete (CTD)¹, the Assessment Network, and the General Directors of the Local Health and Social Authorities and of the Scientific Institutes for Research, Hospitalization and Health Care of the Lombardy Region. Answers from different organizations and different professional figures have been collected in the period September and December 2017.

The remainder of this Chapter is organized as follows: in the following Section the context of analysis is presented; in Section three results of the nonresponse bias test are discussed; descriptive statistics of the analyzed variables are presented in Section four for the four areas of investigation (demographic characteristics, knowledge, experience, and attitudes, awareness and beliefs); Section five presents the results of the bivariate analysis; finally, in Section six conclusions are discussed.

¹ CTE and CTD are the two Commissions that are in charge of supporting the evaluation activities related to the Health Technology Assessment Program at Regional level in Lombardy Region (DGR 5671 of 11.10.2016).

4.2 Nonresponse bias test

Nonresponse bias has been recognized in the literature as a possible cause for misleading and/or inaccurate research findings (Lewis, Hardy and Snaith, 2013). In oder to test for the presence of the nonresponse bias, the wave analysis has been adopted along with this study, by comparing late respondents to the rest of the respondents' group (Lewis, Hardy and Snaith, 2013; Cohen, 2017). In particular, the following steps for performing the wave analysis have been followed:

- first, the respondents' sample was split in two groups: early respondents are those people who answered before the reminder, while late respondent are the others;
- each group was consequently split in two: consistently with previous studies, the last 35% of respondents of each group are considered late respondents;
- consistently with previous studies (e.g. Lindner, Murphy and Briers, 2001; McColl *et al.*, 2001; Lewis, Hardy and Snaith, 2013), a ttest between characteristics of early and late respondents within each group has been performed in order to detect the presence of nonresponse bias.

Results are provided in Table 4.1.

		Early		Late		n values	
		Obs	Mean	Obs	Mean	p-values	
	Lack of		0.038		0.036	0.964	
Waya 1	awareness	52		28			
wave 1	Knowledge	33	0.453		0.571	0.316	
	Experience		0.509		0.393	0.323	
	Lack of		0.277		0.225	0.204	
Waya 2	awareness	140	0.277	80	0.223	0.394	
wave 2	Knowledge	148	0.486	00	0.575	0.204	
	Experience		0.236		0.200	0.530	

Table 4.1 – Wave analysis

As intelligible from the table, the analysis shows that nonresponse bias was not a major concern in this study. Indeed, no significant differences between the subsamples were detected since all the p-values are higher than 0.1. This implies that the nonresponse effect is not statistically significant to affect the data.

4.3 Descriptive statistics

Descriptive statistics are presented for the number of observations included in the univariate analysis, where the frequencies of all the research variables and items included in each variable are presented according to four different areas of investigation: demographic characteristics, level of knowledge, previous experience, and attitudes, awareness and beliefs. The survey was returned completed by 333 respondents, of which 309 authorized for the treatment of their data. According to previous studies, the authorization bias in the healthcare sector could be be influenced by the the authorization form (Beebe *et al.*, 2011; Bolcic-Jankovic *et al.*, 2015). In order to reduce the authorization bias, simple generic consent form was provided.

A total of 34 General Directors of the Local Health and Social Authorities and of the Scientific Institutes for Research, Hospitalization and Health Care of the Lombardy Region have been contacted by email and were asked to make the survey circulate within their organizations. A total of 41 healthcare organizations contributed to the survey: 31 of the healthcare organizations contacted by email (with a response rate of 91.18%) and additional answers were collected through the members of the Commission for the Emerging Technologies (CTE), the Commission for Technologies in Diffusion, Diffused or Obsolete (CTD), and the Assessment Network.

In the following sections the discussion of every area of the questionnaire is provided.

4.3.1 Demographic characteristics

Demographic questions investigate the following information of respondents: the age, the sex, the professional area, the years of service, the membership to an HTA association, and the organization of affiliation.

Table 4.2 presents descriptive statistics for the dichotomous variables related to demographic characteristics of respondents.

Research Variable	Attributes	Total Observations	Percentage
	30-39 years	309	7.12%
	40-49 years	309	16.50%
Age	50-59 years	309	45.31%
8	60-69 years	309	30.10%
	Not specified	309	0.97%
C	Female	309	33.98%
Sex	Male	309	66.02%
	Other Non-Health Professions	309	3.56%
	Other Health Professions	309	12.94%
Professional area	Economics and Management	309	4.85%
	Engineering	309	8.74%
	Medical	309	69.90%
	1-5 years	309	2.91%
	6-10 years	309	6.80%
Voors of somioo	11-15 years	309	8.41%
rears of service	16-20 years	309	14.56%
	21-25 years	309	13.92%
	> 25 years	309	53.40%
Membership to Yes		309	6.15%
HTA network	No	309	93.85%
	Local Health and Social Authorities	309	86.41%
Type of organization	Scientific Institutes for Research, Hospitalization and Health Care	309	11.97%
	Other	309	1.62%

 Table 4.2 - Frequencies of the dichotomous research variables related to demographic characteristics of respondents

In terms of age, almost half of respondents is aged between 50 and 59 years, while the least represented category is the one of people aged between 30 and 39 years.

In terms of sex, only one third of respondents is female, while the remaining respondents are males. While most of respondents are from the medical area, 13% of respondents is represented by other Health Professions. On average, the vast majority of respondents are from Health Professions, while only a small proportion represents people from other Non-Health Professions.

The most represented category in terms of years of service is the one of people employed from more than 25 years, while only 3% of respondents are in service from 1 to 5 years.

In terms of membership to an HTA network, almost the totality of respondents are not part of any network.



Figure 4.1 - Distribution of membership to HTA agencies among respondents

Among the respondents who are members of an HTA agency, Figure 4.1 represents the mostly recurrent associations. Among respondents, 13 of them are associated to Health Technology Assessment international (HTAi), 4 to Società Italiana di HTA (SIHTA), 1 to IHI National Forum, and 1 to both SIHTA and AIFM.

There is a huge variety in terms of affiliations. Respondents are from 41 different organizations. In particular, 267 are from Local Health and Social Authorities², 37 from Scientific Institutes for Research, Hospitalization and Health Care ³, and 5 from other types of organizations. 26 Local Health and Social Authorities have contributed with at least one respondent. Since the territory of Lombardy Region, after the Regional Law nr. 23/2015, is composed of 27 Local Health and Social Authorities

 $^{^2}$ According to the Regional Law nr. 33/2009, the Local Health and Social Authority is the term used to refer to those agencies, that, together with the other providers, is aimed at providing health services. In particular, they are articulated in two different corporate sectors: territorial coverage and hospital center (Regional Law nr. 33/2009).

³ The Scientific Institutes for Research, Hospitalization and Health Care is used in reference to authorities that, additionally to provide hospitalization and healthcare services, they perform research activities as well (Legislative Decree nr. 288/2003).

(Regional Law nr. 23/2015), this implies that almost the totality of Local Health and Social Authorities took part at the survey (26/27). The participation of Local Health and Social Authorities has been higher than the participation of the Scientific Institutes for Research, Hospitalization and Health Care , for which only 12 Scientific Institutes for Research, Hospitalization and Health Care on the territory of Lombardy Region took part at the survey. Additionally, despite there are some organizations that contributed with only one respondent, the first 12 organizations contributed with more than 70% of answers. In particular, the organizations that contributed the most provided more than 30 answers each.

4.3.2 Knowledge of the topic

The level of awareness of HTA among respondents has been analyzed by asking information related to their level of knowledge of HTA, of the existence of guidelines, or hospital library service in their organization, the awareness and the likelihood to be informed about the publication of new reports, and the knowledge of the process and the criteria that are used by the organization to evaluate health technologies (Moharra *et al.*, 2008; ISPOR Asia Consortium, 2015; World Health Organization, 2015).

Table 4.3 presents descriptive statistics for the dichotomous variables related to knowledge of HTA concepts of respondents.

The knowledge of HTA concepts has been investigated considering three different areas: knowledge, experience, and lack of awareness. In particular, a differentiation in the knowledge category has been made between respondents willing to participate in HTA processes in the future and those who are not willing to be involved in HTA processes in the future. The knowledge of HTA is well widespread among respondents in Lombardy Region, where more than the half of them are aware of the existence of HTA processes, and, almost one third who declared to have previous experience. However, there is still a big portion of people who does not have any knowledge of the topic.

Research Variable	Attributes	Total Observations	Percentage
	I know the topic and, maybe, I will use it in the future	309	49.51%
Level of knowledge	I know the topic but I won't use it in the future	309	1.62%
	I have participated to an HTA process	309	28.80%
	I do not know the topic	309	20.06%
Existence of	No	309	31.07%
Existence of guidelines	I do not know	309	6.15%
guidennes	Yes	309	62.78%
Existence of a	Yes	309	67.64%
hospital library	No	309	17.80%
service	I do not know	309	14.56%
Awareness of	Yes	309	50.81%
publication of new reports	No	309	49.19%
Likoly to bo	Yes	309	94.50%
informed	No	309	5.18%
intornieu	Other	309	0.32%
Explicit process	Yes	309	42.07%
used by the organization	No	309	57.93%
Knowledge of	Yes	309	66.34%
criteria used	No	309	33.66%

 Table 4.3 - Frequencies of the dichotomous research variables related to knowledge of HTA concepts of respondents



Figure 4.2 - Distribution of knowledge of HTA concepts among classes of age of respondents

In particular, by considering these responses together with the demographic characteristics of respondents, Figure 4.2 shows that youngest respondents are those that have already been mainly involved in HTA activities, since more than the half of them has already participated to an HTA process. On the contrary, half of respondents aged between 50 and 59 years has knowledge on the topic, but not experience. However, they also represent almost half of respondents who do not have any knowledge of the topic, followed by respondents aged between 60 and 69 years.



Figure 4.3 - Distribution of knowledge of HTA concepts among years of service of respondents

In terms of years of service, the majority of respondents who know the topic are in service from more than 25 years (Figure 4.3). More than half of respondents between 6 and 10 years of service has already participated to an HTA process, while among those people with 21-25 years of service, more than the half of them know the topic. Among those with more than 25 years of service, only a small portion of respondents has participated to an HTA process, while more than half has knowledge of the topic.

The knowledge of methodological guidelines has been analyzed in previous studies as a way to improve the quality of HTA implementation (Banta, 2003). In this survey, around two-thirds of respondents has knowledge of the existing guidelines, while the remaining does not. Together with the knowledge of guidelines, the awareness of the existence of agencies that are aimed at performing HTA activities at various level can increment the quality of HTA implementation (Kaló *et al.*, 2016).



Figure 4.4 - Distribution of knowledge of HTA concepts among sex of respondents

Figure 4.4 shows that, in terms of sex, there is a strong predominance of men with knowledge or experience in the field. On the contrary, only around half of female respondents are aware of the topic, and only few female respondents have already participated in HTA processes.



I know the topic and, maybe, I will use it in the future

Figure 4.5 - Distribution of knowledge of HTA concepts among professional area of respondents

Figure 4.5 shows that the majority of respondents who have a knowledge of the topic is in the medical area (70.59%). More than half of respondents from other Non-Health Professions, from other Health Professions and from medical area knows the topic, while the majority of respondents from the Economics and Management or Engineering areas has already participated in an HTA process.



Figure 4.6 - Distribution of knowledge of HTA agencies among respondents

Figure 4.6 shows that, even if the membership to national and international agencies is still very low, some of them are well known by a big portion of respondents. In particular, more than 120 respondents know the existence of EUROSCAN, while more than 80 are aware of the existence of HTAi. However, still more than 100 respondents are not aware of none of the listed or other HTA agencies.

At organizational level, the existence of a hospital library service in the organization has been analyzed. 209 respondents are aware of the existence of a hospital library service in their organization, 55 respondents declared that there is not a hospital library service in their organization, while 45 respondents do not know. However, when considering the answers for the different healthcare organizations, there are 18 cases in which some respondents declared that there is not the hospital library service, while others declared that there is. This implies that, in some circumstances, the existence of the hospital library service is not widespread within the organization to all its members. Additionally, only around the half of respondents are aware of the publication of new reports, which implies that a stronger communication is needed, since, on the contrary, 292 respondents are likely to be informed.

Always at organizational level, even if more than two-thirds of respondents know the criteria used by the organization to perform HTA, only 42% of respondents clearly knows the process upon which the HTA activity is based. Among the listed criteria, not only economic evaluations are recognized by respondents, but also multicriteria assessments. Some examples of the criteria that have been listed by respondents are provided in Appendix 3.

Table 4.4 presents descriptive statistics for the ordinal variables related to knowledge of HTA concepts of respondents.

Research	Attributos	Total		Frequencies					
Variable	Attributes	Observations	5	4	3	2	1		
			Extremely important	Very important	Important	Slightly important	Not important		
	Identification of clinical innovation and emerging technologies	309	95	155	56	2	1		
Importance	Identification of clinical needs	309	146	114	46	2	1		
	Information related to the commercialization of drugs and technologies	309	37	111	138	21	2		
			Very difficult	Difficult	Adequate	Easy	Very easy		
A	Identification of clinical innovation and emerging technologies	309	20	139	124	20	6		
Access	Identification of clinical needs	309	19	123	141	24	2		
judgement	Information related to the commercialization of drugs and technologies	309	25	112	138	28	6		
			Once a week or more	Once a month	Once every six months	Once a year or less	Never		
	Government publications	309	42	97	84	57	29		
	Research reports published by university groups	309	54	82	61	56	56		
	Research reports published by consulting firms	309	11	34	65	82	117		
Frequency	Community organizations' publications	309	16	59	76	85	73		
of access	Professional journals	309	143	106	34	16	10		
-	Scientific and/or clinical journals	309	176	84	22	18	9		
	Monographs/books	309	58	107	71	55	18		
	Documentation from the pharmaceutical and biomedical industries	309	54	99	72	62	22		

 Table 4.4 - Frequencies of the ordinal research variables related to knowledge of HTA concepts of respondents

The identification of respondents' preferences for and access to different types of information and knowledge has been analyzed since, according to previous studies, it has been assumed that different respondents are probably using different kinds of knowledge, and this could affect the final decision (Champagne and Lemieux-Charles, 2004).

Considering the typologies of information that could be relevant when performing HTA, according to the respondents the identification of clinical needs is among the extremely important aspects to be considered, while the identification of clinical innovation and emerging technologies is mainly considered very important. Slightly less importance is given to the information related to the commercialization of drugs and technologies.

Considering the access to the previous typologies of information, on average, respondents judged their access to the different information sources as or adequate or difficult. In particular, the majority of them have an adequate access to information related to the identification of clinical needs and to the commercialization of drugs and technologies, and a difficult access to the information related to the identification of clinical innovation and emerging technologies. However, there is still a small portion of respondents with a very difficult access to the information needed.

Additionally, in order to better define the spectrum of knowledge that is used by respondents, information about the types of documents they consult when seeking information have been identified. Results show that the reports of consulting agencies are the least bibliographic source accessed by respondents, with 117 respondents who declared that they never consult them. On the contrary, scientific journals are those mostly frequented, with 176 respondents who access them once a week or more. Overall, respondents are more incline to frequently consult professional or scientific journals, and books, rather than reports of consulting agencies or publications of community organizations.

4.3.3 Experience

Experience of respondents has been analyzed by asking information related to the previous involvement in HTA activities, number of times, technology(ies) evaluated, composition of the evaluation group, reports produced and their related use, use of scientific knowledge, decision supported, and involvement of the organization in HTA activities.

Table 4.5 presents descriptive statistics for the dichotomous variables related to experience characteristics of respondents.

Previous Experience Yes 309 55.66% No 309 44.34% 1 172 28.49% 2-5 172 44.19% 0 172 11.05% 6-10 172 11.05% +10 172 11.05% Number of times 172 52.3% Vaccinations 172 0.47% No 172 10.47% Modelad devices 172 10.47% Medical devices 172 13.95% Promotional and prevention 172 5.23% Models for service 172 14.53% Models for service 172 14.53% Models for service 172 4.07% More than 10 158 13.29% Not specified 158 43.67% Horiesions 172 57.56% Other Health Professions 172 57.56% Other Health Professions 172 11.65% Professionals involved*	Research Variable	Attributes	Total Observations	Percentage
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Reimbursement decisions made on the basis of HTA 133		Yes	239	38.49%
made on the basis of H1A 133		Reimbursement decisions	100	
		made on the basis of HTA	133	5 2 (0 /
HTA activities of the organization*	HTA activities of the organization*	reports	100	5.26%
HIA activities coordination 133 22.56%		HIA activities coordination	133	22.56%
HIA evaluation 133 76.69%		HIA evaluation	133	/6.69%
Other HTA activities 133 9.02%		Other HTA activities	133	9.02%

 Table 4.5 - Frequencies of the dichotomous research variables related to experience characteristics of respondents

In terms of previous experience, more than the half of respondents have already participated to HTA processes.

In order to better understand the practices and the experiences of respondents in terms of the use of knowledge related to technologies and, more in general, the health services that have been evaluated, questions related to the frequency of evaluation, group composition, and reports produced have been investigated.

In particular, while some respondents participated only once, and no specific information is provided for 9 respondents, the remaining two-thirds with previous experience has participated to HTA activities more than once. More specifically, less than the half of respondents has contributed to HTA activities between 2 and 5 times. However, only less than 10 people have participated between 6 and 10 times or more than 10 times.

In terms of technology evaluated, the majority of the evaluations has been done for medical devices (154 cases). Little experience, compared to the one for medical devices, has been registered for other health technologies.

The composition of the group has been investigated, as well. Almost half of participants with previous experience declared to be involved in a group with less than 5 components, while 54 respondents were part of a group with a number of evaluators between 5 and 10. Therefore, while it is not common to find a group of evaluators larger than 10 people, the majority of the groups are composed of less than 10 members.

In the majority of cases the evaluators were from the medical field, some were from other Health Professions, or from the field of economics and management. Additionally, the remaining respondents declared that the components of their group were from the field of other Non-Health Professions, engineering, research, or they did not specify their field.

While respondents have previous experience mainly in producing technical reports or economic evaluations, the production of systematic review, guidelines or other types of report is not common among people who took part in the survey. This reflects the current situation of HTA, according to which the growing number of HTA reports produced represents an indication of the growing importance of HTA (Hailey, 2003).

The 86% of respondents declared to have used scientific evidence for producing HTA reports. However, while only 4% of respondents with previous experience did not base their evaluation on scientific evidence, there is a 10% of respondents which does not know if the assessment was based on scientific evidence. In the majority of the cases, the HTA reports have been produced to support purchases decisions. However, almost half or respondents with previous experience does not know if the produced reports have been used by the organization, while the 14.64% declared that the organization did not use the reports produced.

Additionally, in order to detect differences among respondents in terms of organizational support, the HTA activities performed by the organization of affiliation have been investigated. The activity that is mainly executed by the organization is to perform HTA evaluations, followed by the coordination of HTA activities. Some respondents also declared that their organization is taking reimbursement decisions on the basis of HTA reports, or other activities that are not specified.

4.3.4 Beliefs, awareness and attitudes

Beliefs, awareness and attitudes have been investigated in terms of HTA objective, barriers to the production and to the use of HTA reports, and relevance and personal judgement of important topics associated with HTA (Moharra *et al.*, 2008; ISPOR Asia Consortium, 2015; World Health Organization, 2015).

Research Variable	Attributes	Total Obs	Percentage				
	Health needs assessment	309	24.27%				
	Guidelines definition	309	25.24%				
	Planning and budgeting	309	39.16%				
	Pricing	309	4.53%				
HTA objective*	Quality indicators of healthcare treatments definition	309	24.92%				
	Reimbursement decisions	309	1.94%				
	Other	309	4.53%				
	I do not know	309	0.97%				
	Resources availability	309	49.19%				
	Information availability	309	24.92%				
Barriers to production*	Knowledge of methodologies	309	38.19%				
	Qualified human resources	309	35.60%				
	Other	309	3.24%				
	Awareness of the importance of HTA	309	63.43%				
	HTA institutionalization	309	25.57%				
Damiana ta maa*	Political authorities' mandates	309	11.00%				
Barriers to use"	Political support	309	6.15%				
	Qualified human resources	309	27.83%				
	Other	309	1.62%				
	I do not know	309	2.91%				
*more than one answer accented							

 Table 4.6 - Frequencies of the dichotomous research variables related to beliefs, awareness and attitudes of respondents

Table 4.6 presents descriptive statistics for the dichotomous variables related to beliefs, awareness and attitudes of respondents.

The first variable that has been investigated in the area related to the beliefs, awareness, and attitudes area concerns the perceptions of respondents about the objective of HTA. According to 121 respondents the scope of HTA is to support planning and budgeting activities. The perceptions of the other objectives of HTA are quite heterogeneous among respondents, since 75 respondents declared that, for them, HTA supports the health needs assessment process, for 78 respondents HTA supports the guidelines definition, while for 77 respondents HTA is used for the definition of quality indicators of healthcare treatments. Only few respondents perceive the pricing of health production, the support for reimbursement decisions, or other objectives as the main scopes of HTA. Finally, there are 3 respondents who are not aware of what HTA is aimed at.

In terms of barriers to the production of HTA reports, the availability of resources is among the factors that are discouraging the involvement in HTA activities for 152 respondents. This is followed by the lack of knowledge of the methodologies that can be adopted, and the presence of qualified human resources that can undertake the assessment. Availability of information is not recognized as the leading barrier for the production of HTA reports. 10 respondents identified also additional barriers that can discourage the involvement in HTA activities, among which the lack of adequate procedures in the organization, difficulties in accessing relevant information, timing, complexity of the task, lack of interest, culture, lack of time and lack of diffusion and knowledge of what HTA is.

In terms of barriers for the use of HTA reports, instead, 196 respondents recognized the lack of awareness of the importance of HTA is among the major causes that can prevent the uptake HTA reports. Additionally, according to 86 respondents the lack of qualified human resources can discourage the HTA uptake, and, according to 79 respondents, the institutionalization of HTA could foster the HTA reports uptake. A lower number of respondents identified among the barriers for the use of HTA reports the political authorities' mandates, the political support, or other reasons. 9 respondents declared that they do not know what could be recognized as a barrier to the use of HTA products.

Table 4.7 presents descriptive statistics for the ordinal variables related to beliefs, awareness and attitudes of respondents.

Research	Attributos	Total	Frequencies					
Variable	Attributes	Observations	5	4	3	2	1	0
			Extremely useful	Very useful	Useful	Slightly useful	Not useful	I do not know
	Experts' opinions	309	94	105	95	10	4	1
	Professionals experiences	309	70	122	97	18	1	1
	Experiences of other organizations	309	53	134	111	9	0	2
D.1	Opinions of specific individuals	309	24	87	123	70	4	1
Relevance	Analysis of political situation	309	21	48	116	93	22	9
	Scientific evidence	309	210	63	11	0	0	25
	Sociological and anthropological knowledge of the problem	309	51	71	134	44	3	6
	Market analysis	309	48	108	121	25	2	5
			Extremely relevant	Quite relevant	Partially relevant	Scarcely relevant	Not relevant	
	The objective and the aim of HTA should be explicit and relevant for their use	309	103	169	35	1	1	
	HTA should be a transparent and unconditional process	309	142	138	28	1	0	
	HTA should include all relevant technologies	309	94	160	48	7	0	
	A clear system for the definition of priorities for HTA should exist	309	92	163	48	5	1	
	HTA should include all the appropriate methods for the evaluation of costs and benefits	309	106	163	48	5	1	
	HTA should consider a wide range of outcome and evidence	309	80	164	57	6	2	
	A complete social perspective should be included in HTA	309	25	138	109	37	0	
Personal	Uncertainty should be evaluated	309	32	135	112	27	3	
judgement	Transferability and generalizability of HTA products should be guaranteed	309	52	153	85	16	3	
	All the stakeholders should be actively involved	309	56	135	95	22	1	
	All the available data should be considered	309	86	158	60	5	0	
	The implementation of HTA results should be monitored	309	84	166	51	7	1	
	HTA should be timely	309	72	155	75	6	1	
	HTA results should be appropriately communicated to different decision makers	309	121	147	37	4	0	
	The connection between HTA and decision making process should be transparent and clearly defined	309	150	126	30	3	0	

Table 4.7 - Frequencies of the ordinal research variables related to beliefs, awareness and attitudes of respondents



Figure 4.7 - Distribution of judgments of relevant topics related to HTA concepts among respondents

In terms of relevance of the listed topics, the scientific evidence clearly emerged among the extremely useful aspects that should be considered when performing HTA activities by 210 respondents (Figure 4.7). Other aspects emerged among the very important features, like experiences of other organizations, professionals experiences, and experts' opinions. Sociological and anthropological knowledge of the problem, opinions of specific individuals, market analysis, and the analysis of political situation are mainly considered useful or very useful when performing HTA activities.

The attitudes of respondents towards HTA activities have been detected by investigating some of the relevant aspects associated with HTA. All the listed topics resulted to be mainly, extremely or quite relevant for the majority of respondents. In particular, two items have been judged to be extremely relevant for respondents: the transparent and clear definition of the connection between HTA and decision-making process, and the transparency and unconditionality through which HTA process is conducted. All the other listed topics are considered quite relevant by the majority of respondents. Only two aspects (inclusion of a complete social perspective in the process and the evaluation of uncertainty) present high values of partially relevant responses.

4.4 Bivariate analysis

After having completed basic descriptive statistics of the analyzed variables, this section presents the empirical results that have been obtained from the bivariate analysis for exploring the relationship between variables (Anderson, 1958).

More specifically, consistently with previous studies (e.g. Profetto-McGrath *et al.*, 2003, 2009; Boström *et al.*, 2009; Wallin *et al.*, 2012), Pearson Chi squared and related p-value have been used to statistically compare subpopulations of level of knowledge within the sample of respondents in order to test whether the answers of the analyzed variables are differentially distributed over the different levels of knowledge of HTA by respondents (Rao and Scott, 1981; Plackett, 1983). This advances some knowledge in relation to the first research question that has been stated in Chapter 2. According to previous studies, in order to analyze how implementation (in this particular case of HTA activities) should be guided, theories related to how change has to be executed need to be considered (Metz and Bartley, 2012; Hage *et al.*, 2013; Proctor *et al.*, 2013). More specifically, following and adapting the ADKAR model, answers were categorized according to three different levels of diffusion of HTA concepts: Knowledge, Experience, and Lack of Awareness (Hiatt, 2006). The group "Knowledge" represents those respondents who declared to have knowledge of the key concepts of HTA, while the group "Experience" represents those respondents who declared to have previous experience in HTA activities. Additionally, the group "Lack of Awareness" represents, instead, those respondents without any previous experience or knowledge of HTA activities.

Bivariate analysis of all independent variables was conducted for each of the three levels of knowledge separately to determine if a statistically significant relationship existed between the analyzed variable and the level of knowledge.

The Pearson Chi squared and the p-value of all the analyzed variables are provided in Appendix 4. A high value of the Pearson Chi squared test implies that the observed frequencies present significant differences from expected frequencies, and, therefore that there is dependency among variables (Plackett, 1983).

According to previous studies, both individual and organizational characteristics may influence results (Estabrooks *et al.*, 2003; Belkhodja *et al.*, 2007; Squires *et al.*, 2011). More specifically, for what it concerns the first group "Knowledge", results show significant differences in terms of individual demographic characteristics, and according to the organization they belong to. This is in line with previous studies, according to which the organizational interest towards a specific topic (HTA in this context) can influence individual processes (Belkhodja *et al.*, 2007). As for the group "Knowledge", results show significant differences in respondents

characteristics in terms of both individual and organizational characteristics. In particular, variables related to the organizational culture show significant results (Belkhodja *et al.*, 2007). Finally, for what it concerns the group "Lack of awareness", significant differences have been detected especially for individual characteristics, rather than organizational variables.

Research Variable	Lack of Awareness	Knowledge	Experience
Q1 - Age			Х
Q2 -Sex			Х
Q3- Organization			Х
Q4 - Professional Area	X		Х
Q5 - Length of service			Х
Q6 - Membership to HTA networks			Х
Q9 - Guidelines knowledge	Х		Х
Q10 - Agencies knowledge	X		Х
Q12(a) - Access 1	X		Х
Q12(b) - Access 2	X		
Q12(c) - Access 3	Х		
Q14 - Report publication	X		Х
Q16(c) - Frequentation 3	Х		
Q16(d) - Frequentation 4			Х
Q16(f) - Frequentation 6			Х
Q16(g) - Frequentation 7			Х
Q17 - Explicit process used by organization	X		Х
Q18 - Criteria used by organization	Х		Х
Q28 - Use of reports by organization	Х		Х
Q29 - Involvement of organization	Х		Х
Q29(c) - Activity 3	X	Х	Х
Q30(c) - Objective 3			Х
Q30(h) - Objective 8	Х		
Q31(b) - Knowledge 2			Х
Q31(f) - Knowledge 6	Х		
Q32(a) - Barriers production 1			Х
Q33(b) - Barriers use 2	Х		
Q33(c) - Barriers use 3			Х
Q33(g) - Barriers use 7	Х		
Q34 (g) - Judgement 7			Х
Q34 (1) - Judgement 10	Х		
Q34 (o) - Judgement 13			Х

Table 4.9 - List of the statistically significant variables for the different levels of knowledge

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Table 4.9 reports only statistically significant variables for the different levels of knowledge. A total of 32 variables were statistically significant at p<.05, of which only 1 variable was significant for each level of knowledge. Of them, 1 was statistically significant for the group "Knowledge", 24 for the group "Experience", and 18 for the group "Lack of awareness". The groups "Knowledge" and "Experience" had 1 significant variable in common, the groups "Knowledge" and "Lack of awareness" had 1 significant variable in common, and the groups "Lack of awareness" and "Experience" had 10 significant variables in common.

4.5 Conclusion

In this Chapter quantitative results of the survey have been presented according to four different areas of investigation: demographic characteristics, knowledge, experience and attitudes, awareness and beliefs of respondents.

Results show that, in terms of demographic characteristics of respondents, on average, surveyed people are from 41 health organizations. Around the 23% of respondents is aged less than 50. Female respondents are 34% and they are more represented in young age classes. Around 7 respondents over 10 are from the medical area and 1.3 are from other Health Professions (13%). Almost the totally of respondents is not part of an HTA network. In terms of knowledge of HTA processes of respondents, on average, only 20% of the respondents is not aware of the existence of the HTA process for evaluating healthcare technologies. While some international associations are already well-known, respondents are less familiar with national networks. In terms of past experience, more than a half of respondents has already participated in HTA processes. In particular, respondents declared to have participated for the 73% of cases between 1 and 5 times, mainly for the evaluation of medical devices (154 cases), in a group with maximum 10 components (78%), predominantly from the medical field (161 cases). The evaluation has been done in 122 cases for supporting purchase decisions, but respondents are not really aware of the extent to which the HTA reports produced are used by their organization to take decisions. As for attitudes, awareness and beliefs, 39% of respondents declared that they recognize the support for planning and budgeting activities as the major role of HTA. Among the barriers that have been declared by respondents, the lack of resources (in particular human resources) and knowledge of the methodologies to adopt have been recognized as important factors that can impede the production of HTA. Differently, the use of HTA is mainly prevented by the awareness of the importance of HTA. In terms of relevance of the topics associated with HTA activities, the use of scientific evidence emerged among the extremely useful aspects that should be considered when performing HTA activities. Additionally, the majority of respondents agree that the transparency in conducting HTA is extremely relevant.

Results of the bivariate analysis showed that the different levels of knowledge of respondents are associated with different features of respondents. While only 1 was statistically significantly different for each level of knowledge, a total of 32 variables were identified to be correlated with the different levels of knowledge.

These results advance some knowledge in answering the research questions stated in Chapter 2 related to the literature review and in designing an appropriate tailored implementation intervention. More specifically, the discussion of the results will be provided in Chapter 6 of this thesis, where both

quantitative and qualitative data will be analyzed in the lights of the OMRU framework. A concurrent embedded mixed methods design will be adopted, according to which the qualitative method is embedded within the predominant method, represented by the quantitative one, since they are used to complement answers to two slightly different questions.

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Chapter 5: QUALITATIVE RESULTS

ABSTRACT

The qualitative portion of this study presents the analysis of the data that have been collected through semistructured interviews, conducted on the period April-May 2019 in 15 healthcare organizations in Lombardy Region. The eight outcomes of implementation research proposed by Proctor and colleagues are investigated to analyze the intervention designed to promote the diffusion of Health Technology Assessment (HTA) in Lombardy Region. The first pillar, the adoption of the innovation, has been analyzed in terms of individual and organizational knowledge. At individual level, the majority of interviewees affirmed to have attended specific training courses on HTA, but only half of them are actively involved in HTA processes. At organizational level, instead, all the healthcare organizations have a commission that performs HTA activities, but not in all the cases this is already operating. In terms of acceptability, the interviewees recognized the importance of having proper tools that can be adapted to the peculiarities of different contexts in order to increase the positive perception about the HTA processes among implementation stakeholders. In addition, the supportive role of the regional level has been widely recognized. All the interviewees recognized the appropriateness of the HTA process for supporting the evaluation of new health technologies. Different elements for enhancing feasibility of HTA process in Lombardy Region have been identified. In particular, interviewees recognized features related to the mandate, the culture and competences, the resources, the networking activities, the obligation and monitoring, the process and the interactions among levels as supportive in enhancing the successful implementation of HTA process in local healthcare organizations. Additionally, benefits, limits and future directions of the implementation process are discussed, such as the perceived impact of interviewees in terms of cost. In terms of penetration, interviewees provide some insights related to the composition of the commission which performs HTA activities and the process that is followed in the healthcare organizations. Finally, elements for ensuring sustainability of the process are discussed in terms of training, culture and awareness, resources, process, and tools.
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Chapter 5: QUALITATIVE RESULTS

5.1 Introduction

In this Chapter qualitative results are presented. The qualitative research has been often criticized for lacking scientific rigour (e.g. Dickson-Swift, James, Kippen, & Liamputtong, 2007; Malterud, 2001; Mays & Pope, 1995). This is particularly true for health research, where it is considered as "an assembly of anecdote and personal impressions, strongly subject to researcher bias" (Mays and Pope, 1995, p. 109). However, guidance on how to improve quality of qualitative research has been extensively provided, especially in the last years (Mason, 1996; Seale, 1999; Merriam and Tisdell, 2015; Green and Thorogood, 2018). Quality of qualitative studies can be analyzed and expressed at different stages. While the requisites to ensure quality in the data collection phase have been already documented and presented in Chapter 3, where the methodology is discussed, in this section the strategies adopted to ensure a high level of quality of the data analysis are presented.

As supported by previous studies, the requisites for the qualitative data analysis, such as the strategies adopted to handle with them, are discussed below (Kitto, Chesters and Grbich, 2008; Gale *et al.*, 2013; Berger, 2015).

Drawing on previous studies (Mays and Pope, 1995; Hoddinott and Pill, 1997; Seale and Silverman, 1997; Mauthner, Parry and Backett-Milburn, 1998; Popay, Rogers and Williams, 1998; Kitto, Chesters and Grbich, 2008; Mauthner and Doucet, 2009), quality of the data analysis process can be measured by the *rigour* and the *reflexivity* of the study.

First, the recognition of the *rigour* in qualitative research, especially in the medical research, has been recognized as an important feature for the awareness of the respectability of qualitative research (Hoddinott and Pill, 1997; Seale and Silverman, 1997; Popay, Rogers and Williams, 1998). The strategies that can ensure rigour to a qualitative research are similar to those of quantitative research, since the systematic research design data collection and analysis is required (Mays and Pope, 1995). At this purpose, in practice, different strategies presented in previous studies have been adopted.

In terms of representativeness, since the objective of the qualitative research is, mainly, the reflection of the diversity within a given population (Kuzel, 1992), a purposive sampling has been selected in order to have a degree of control. By adopting this strategy, an initial selection of informants is

provided (Mays and Pope, 1995). In addition, in order to have illuminative views, "outliers" have been also included in the initial sampling (Barbour, 1999; Frankland and Bloor, 1999).

Moreover, as suggested by previous studies, reliability of the analysis has been ensured in different ways (Mays and Pope, 1995). The adoption of the Framework Method explained and presented below allows the researcher to classify and categorize data (Gale *et al.*, 2013). Furthermore, as suggested by previous studies, the content of the interview transcripts is analyzed with the support of a computer software (Seidel and Clark, 1984; Bringer, Johnston and Brackenridge, 2004; Rambaree, 2007; Foley and Timonen, 2015).

In order to ensure the right interpretation, the technique of respondents' validation was adopted, as well. This strategy refers to the opportunity given to the subjects interviewed to view and amend their transcripts as a way of ensuring rigour and validity (Lincoln and Guba, 1985). Indeed, according to previous studies, the sharing of the results of the analysis and interpretation process with the respondents could help in refine explanations of the researcher(s) (Barbour, 2001).

Second, the importance of the *reflexivity* is largely recognized in social sciences research (Mauthner, Parry and Backett-Milburn, 1998; Mauthner and Doucet, 2009). Indeed, through the process of reflexivity, the meanings of the data are made, rather than found (Mauthner, Parry and Backett-Milburn, 1998). It is intended as "the process of a continual internal dialogue and critical self-evaluation of researcher's positionality as well as active acknowledgement and explicit recognition that this position may affect the research process and outcome" (Berger, 2015, p. 220). Previous studies suggested that sharing experiences could be, from one side, beneficial because it can enable a better and a more in-depth understanding of the participants' perceptions, but, on the other side, the researcher should avoid that his/her own experience can influence the direction and interpretation of the research (Lietz, Langer and Furman, 2006; Berger, 2015). In order to ensure reflexivity of the study, and to avoid that the experience of the researcher affects the balance in the research process (Eppley, 2006), different strategies suggested by previous studies have been adopted.

First, in order to reduce as much as possible the impact of the bias, assumptions and personality of the research on the meanings of the research under investigation, a three-part log was used alongside the process of analysis (Berger, 2015). In particular, what is said, meant and interpreted is documented in different sections of the log.

Second, the transcripts of the interviews were reviewed after a couple of weeks after the first and initial analysis in order to be able to see the same data through different and new lens and to capture new and possible interpretations that were not captured in the first stage of analysis.

Third, both pre and post analysis are reported in a single matrix for identifying, comparing and contrasting discrepancies, changes and omissions.

Along with this study, the approach that has been adopted to analyze data is a combination of deductive and inductive. Each interview has been analyzed adopting a combination of analytic induction and grounded theory (Corbin and Strauss, 1990; Strauss and Corbin, 1994, 1997; Charmaz and Belgrave, 2007; Charmaz, 2014; Glaser and Strauss, 2017), in order to look for important and emerging themes and concepts. The analysis has started with the analytic induction, by considering the implementation outcomes proposed by Proctor and colleagues (Proctor *et al.*, 2011). These pillars were used to organize the framework for the subsequent analyses. In addition, the grounded theory approach was adopted in order to be open and reflective to new themes appearing in the data, by adding them into the initial framework provided by the analytical induction. An "open coding" approach was adopted in order to detect the emergent themes related to each of the pillars identified (Bohm, 2004; Moghaddam, 2006).

5.2 The process of data analysis

The target population for qualitative data collection is represented by all the healthcare organizations that would be affected by the new Resolution, thus, both public and private healthcare organizations accredited in Lombardy Region are targeted for this study. As suggested by previous studies, a purposeful sampling method is adopted to include only information-rich cases (Palinkas *et al.*, 2015). At this purpose, a total of 17 healthcare organizations (8 public and 9 private) have been contacted for the interview, of which 15 (7 public and 8 private) have contributed to this study.

Before drawing descriptive and explanatory conclusions clustered around themes identified through the analysis, the stages of data analysis reported in the Framework Method, and explained in Chapter 3, related to the Methodology, were implemented (Gale *et al.*, 2013). More specifically, along with this Chapter, the Framework Method, which consists in adopting seven stages for the management and the analysis of the qualitative data (transcription, familiarization, coding, developing the analytical framework, applying the analytical framework, charting data, and interpreting data), is adopted.

In particular, as described above, the analytical framework that has been adopted in the data analysis is the result of both inductive and deductive approaches. While the macro categories (adoption, acceptability, appropriateness, feasibility, fidelity, cost, penetration and sustainability) corresponds to the implementation outcomes of Proctor (Proctor *et al.*, 2011), the micro categories are derived from the coding procedure.

The analytical framework adopted in this study is presented in Figure 5.1.

- 1) Adoption
 - a) Individual
 - i) Awareness
 - ii) Specialized training
 - iii) Individual experience
 - b) Organizational
- 2) Acceptability
 - a) Tools
 - b) Differences of application
 - c) Regional level
- 3) Appropriateness
- 4) Feasibility
 - a) Mandate
 - b) Culture and competences
 - c) Resources
 - d) Networking activities
 - e) Obligation and monitoring
 - f) Process
 - i) Simplicity
 - ii) HTA as a project

- g) Interactions among levels
 - i) Regional support
 - ii) Centralization
- 5) Fidelity
 - a) Benefitsi) Awareness
 - ii) Acceptability
 - iii) Collaboration
 - b) Limits
 - i) Indirect effect
 - ii) Engagement
 - iii) Sharing of available knowledge
 - iv) Target of training
 - v) Production and decision-making gap
 - c) Future directions
 - i) Clarity and simplification
 - ii) Engagement
 - iii) Evaluation and decision link
 - iv) Ex-post operational research
 - v) Continuous training
- 6) Cost
- 7) Penetration
 - a) Commission
 - b) Process
 - i) Evaluation request form
 - ii) Commission
 - iii) Final report
- 8) Sustainability
 - a) Training
 - b) Culture and awareness
 - c) Resources
 - d) Process
 - e) Tools

Figure 5.1 - Analytical Framework

5.3 Results

A total of 23 healthcare professionals took part in the interview (Table 5.1), including professional figures from the following areas: General Direction (6 - 26.09%); Pharmacy (1 - 4.35%); Clinical Engineering (7 - 30.43%); Medical Direction (3 - 13.04%); Other (6 - 26.09%).

ID	N. of Interviewee(s)	Role of Interviewee(s)	Area	
1	2	General Director	General Direction	
1	2	Chief of Hospital Pharmacy	Pharmacy	
2	1	General Director	General Direction	
3	3	General Director	General Direction	
		Chief of Clinical Engineering	Clinical Engineering	
		Chief of Medical Devices Management Service	Other	
4	2	Medical Director	Medical Director	
4		Chief of Clinical Engineering	Clinical Engineering	
5	1	General Director	General Direction	
6	1	General Director	General Direction	
7	2	CEO	General Direction	
		Chief of HTA Commission	Other	
	2	Head of Management Control Unit	Other	
8		Head of Innovation and Clinical	Other	
		Governance Unit		
9	1	Chief of Clinical Engineering	Clinical Engineering	
10	1	Chief of Clinical Engineering	Clinical Engineering	
14	2	Administrative Manager of the Health Department	Other	
		Chief of Clinical Engineering	Clinical Engineering	
11	1	Chief of Clinical Engineering	Clinical Engineering	
12	1	Engineer	Other	
12	2	Assistant to the Medical Directorate	Medical Director	
13	2	Chief of Clinical Engineering	Clinical Engineering	
15	1	Deputy Medical Director	Medical Director	

Table 5.1 - Description of the interviewees

ID	Typology	Ownership	Area	Date of interview	Duration of interview
1	Local Health and Social Authority	Public	Brescia	09/05/2019	00:47:58
2	Local Health and Social Authority	Public	Varese	02/05/2019	00:36:23
3	Local Health and Social Authority	Public	Mantova	29/04/2019	01:12:22
4	Local Health and Social Authority	Public	Sondrio	18/04/2019	00:44:35
5	Local Health and Social Authority	Public	Milano	17/04/2019	00:35:39
6	Scientific Institute for Research, Hospitalization and Health Care	Public	Pavia	15/04/2019	00:29:44
7	Scientific Institute for Research, Hospitalization and Health Care	Private	Milano	03/05/2019	00:31:06
8	Local Health and Social Authority	Public	Lodi	09/05/2019	00:36:00
9	Scientific Institute for Research, Hospitalization and Health Care	Private	Milano	21/05/2019	00:21:33
10	Scientific Institute for Research, Hospitalization and Health Care	Private	Milano	21/05/2019	00:36:48
11	Scientific Institute for Research, Hospitalization and Health Care	Private	Sesto San Giovanni	22/05/2019	00:48:00
12	Scientific Institute for Research, Hospitalization and Health Care	Private	Milano	24/05/2019	00:20:46
13	Scientific Institute for Research, Hospitalization and Health Care	Private	Pavia	30/05/2019	00:11:07
14	Scientific Institute for Research, Hospitalization and Health Care	Private	Rozzano	27/05/2019	00:26:38
15	Scientific Institute for Research, Hospitalization and Health Care	Private	Monza	27/05/2019	00:19:22

Table 5.2 - Interview table

A total of 15 interviews were collected, with related case studies. All the interviews were conducted in a healthcare organization in Lombardy Region in the period April-May 2019.

Interviews lasted 34 min on average (range = 11 to 72 min).

Qualitative data from interviews are implemented with secondary data used also for cross-checking (Jick, 1979; Patton, 1999; Silverman, 2016). In Table 5.2 the interview list is presented.

Results of the discussion on the eight implementation outcomes discussed during the interviews (Adoption; Acceptability; Appropriateness; Feasibility; Fidelity; Cost; Penetration; Sustainability) are presented below.

5.3.1 Adoption

The first implementation outcome that was analyzed concerns the knowledge of the topic by the interviewees, both individually and at organizational level.

Results show that, at individual level, the majority of interviewees affirmed to have attended specific training courses on HTA, but only half of them are actively involved in HTA processes. In particular, the need to increase awareness and to have specialized training has been emphasized. At organization level, instead, all the healthcare organizations have a commission that performs HTA activities, but not in all the cases this is already operating.

Below the two levels are presented and discussed separately.

5.3.1.1 Individual

<u>5.3.1.1.1 Awareness</u>

The first step to be able to widespread the knowledge of a topic is to be aware of its existence. At this purpose, almost the totality of the interviewees stated that the awareness of the subject is currently widespread among the various professional figures.

"Currently we are aware that this is a very large system" (ID 11, PRIVATE)

"It seems, to me, that from the point of view of the suppliers of this service, there is now a lot of awareness, but we are there anyway. At the level of those who must provide the service, there is no continuity, an idea of continuity over time" (ID_3, PUBLIC)

In particular, it is particularly relevant, in this context, that knowledge and awareness are disseminated at all the different levels, both internal and external to the company, in order to allow to all potential stakeholders to be aware of the importance of the evaluation process.

"It is a culture, a virtuous circle, also towards producers and traders" (ID_3, PUBLIC), says one of the interviewees at this regard.

"Here, there is the need to return to a path that has the characteristics of scientificity, in a welldefined path, with well-defined steps, with the use of coded tools" (ID_2, PUBLIC) However, in line with what one of the interviewees said, "there is sensitivity on the subject even if we have room for improvement, it is something known and experienced. This regards general knowledge" (ID 5, PUBLIC).

Therefore, results suggest that the awareness of the topic is widespread among all the people interviewed and all the healthcare organizations they belong to.

5.3.1.1.2 Specialized training

Heterogeneity in terms of training received by the interviewees was found during the interviews. In particular, some of the interviewees reported the attendance of a specific course dedicated to HTA as a requirement to become part of the HTA commission: *"We did the HTA course at the LIUC is a post-graduate course on HTA"*, says one of the interviewees, which, below shows *"Everyone must have specific training on HTA for our procedure and so we all did the course of the LIUC on the HTA"* (*ID_8, PUBLIC*).

On the contrary, only few respondents received training on HTA directly in the healthcare organization in which they are currently working. In fact, internal courses have been adopted as a strategy for disseminating knowledge only in few structures, and, mainly, in the past years.

According to the results, a clear distinction between the various professional figures emerged: while in the majority of the cases the top management of the company has not received specific training in HTA and it is not always directly involved in the evaluation process, the other professional figures have (in most of the cases) undertaken a training course specifically tailored to the evaluation needs. In particular, one of the General Directors interviewed stated that *"personally I have never materially participated in the HTA, but I saw it, I know it as a user, so, briefly, I know the results, I appreciate its purpose" (ID_3, PUBLIC).*

In addition, several interviewees stated that they had received self-training in the sense that "There was no one else's idea of saying that "I have to build a class capable of HTA"" (ID_3, PUBLIC). According to this statement, the training on HTA is mainly derived from personal interest, rather than on external pressures. In particular, interviewees underlined that the self-training was done through different methodologies, among which, the e-learning courses emerged as particularly appropriate in providing training in this area. In particular, these courses are particularly relevant in order to have a general overview of what are "the concepts of HTA at an international level, therefore not only based on the Italian legislation" (ID 14, PRIVATE).

An additional element that was recognized as of great support for the diffusion of knowledge is represented by the meetings organized at regional level. Therefore, while the international overview of the topic can be obtained through the attendance of e-learning courses, the regional specificities can be learned at the regional meetings. As supported by one of the interviewees, "Yes, I have been a member of the regional group of HTA for some years now, and so I made a bit of knowledge on the field in that group and, in addition, last year I attended the distance learning course which was published by the Lombardy Region on the subject. I did a certain number of course hours, and the final questionnaires" (ID_15, PRIVATE). Therefore, regional support has been particularly relevant in the educational field.

In addition, although only in few cases, some of the interviewees attended HTA training courses during the academic studies. However, only younger respondents declared to have had a specific training on HTA during their university career.

"I had a smattering at university level, when I did my second-level master's degree in clinical engineering in Trieste" (ID 10, PRIVATE)

However, as outlined by one of the interviewees, the training at the university level does not always prove to be particularly effective because *"it is always a very high level, so mainly procedural, rather than at a more Ministerial than hospital level" (ID_14, PRIVATE).* Finally, an additional source of training is represented by the attendance at the conferences.

"As a personal experience I can say that I have approached HTA for 8 years now ... It was one of the SIHTA congresses, I had participated in Rome, when I was an intern at that time. It was a very interesting topic and so, briefly, this is the kind of individual experience I have" (ID_14, PRIVATE)

However, "personal interest in looking for things on the internet, experiences and deepening, perhaps also thanks to the experiences of other hospitals or other colleagues to understand what they do inside the structures and how to act" (ID_14, PRIVATE) turns out to be, in any case, particularly relevant in order to spread knowledge and culture.

"Then, at the individual level, it is a topic that I am quite sensitive to, in the sense that, during my previous experience, I was also the head of HTA in various organizations and I approached HTA in a specific way" (ID_5, PUBLIC)

"So, in terms of knowledge, I am sensitive to the subject, I have a good knowledge of what the context is at an individual level" (ID 5, PUBLIC)

5.3.1.1.3 Individual experience

In terms of previous individual experience, heterogeneity in responses was recorded. In particular, not all respondents are, or have been, directly involved in HTA processes. On the contrary, those who have had experience in terms of HTA, may have had it at different levels: within the company, at the regional level, or at both levels.

"[...] I think it was 2010-2012, the first regional experience when in fact we were talking about university figures, local figures, rather regional figures [...]" (ID_1, PUBLIC)

"I had the luck in 2004-2005 [...] to participate in one of the first technology assessment centers of the Lombardy Region - prehistory - in which new technologies and innovative procedures were evaluated to be subsequently admitted to the DRG" (ID_4, PUBLIC)

"Honestly, one of the processes we have done most actively is the one we followed this year [...] and, on that occasion, we have really made a multidisciplinary process, for which we have made us, as clinical engineering, the collectors of the information, and, also thanks to a group of students, we have involved the Medical Direction [...]; the medical and anesthetic part [...]; the surgeon [...]; the company, [...]; operational management [...]; management control, [...] and, on that occasion, we did a fairly comprehensive journey, which I can define a hospital HTA" (ID_14,

PRIVATE)

5.3.1.2 Organizational

At the company level, knowledge of the subject appears to be widespread in all the companies interviewed. However, there are large differences in terms of level of knowledge, previous experience and formalization of the activity.

In terms of previous organizational experience, large differences emerged between public and private organizations: while the majority of the former have already conducted at least one complete evaluation process, the majority of the latter have the intention to conduct the first HTA process this year, in order to comply with the Regional Regulation. Previous experiences are largely heterogeneous, and some examples of activities carried out at company level are shown below.

"There have been and have even been quite evolved. We did it within the scope of the request of the Region of 2017, they had asked us to perform three HTA studies [...] And then we did the evaluation of a drug. There was a device, a drug and a device" (ID 3, PUBLIC)

"We have been supporting a training done by LIUC and this internship, which was conducted in 2015-2016, allowed us to make a first glimpse of the Health Technology Assessment process, producing a mini-HTA model for internal company assessment of technologies. In order to take the first steps, some innovative technologies presented both by the clinical field, by the doctors, and by the Medical Direction were chosen. [...] Then, for example, the post-internship evaluation was done, but directly by us. [...] Then, at least I did, always at the company level, a training course in San Raffaele, always organized by LIUC to analyze, how to say, the principles of HTA" (ID_9, PRIVATE)

Regardless of the previous experience in conducting HTA processes, all the healthcare organizations interviewed stated that they had set up an HTA commission. In some cases, this has been operating for several years, while, in other cases, it has only been formalized and, therefore, it is expected to become operational in the near future.

"Yes, there is a reality that is the one of the commission. That is, the commission is still not established in a manner ... it is formally established, but this was one of the first experiences that was made. Even here, for organizational reasons, in my opinion, one thing that has been missing was seeing everyone together at the same time" (ID 14, PRIVATE)

Independently from the establishment of the commission, many interviewees highlighted that the evaluation process is not based on well-structured criteria and processes. In fact, as supported by one of the interviewee, "we say that formally there was not a path established according to the classical canons of the HTA process, informally this type of evaluation was done in a fairly familiar manner, trying to mediate the economic, the population, the geopolitics aspects and everything that is related with that, but, in fact, the basis was to allow to perform an evaluation according to the principles of the "orientation", rather than on the "evidence-based"" (ID 4, PUBLIC).

"Within our structure, this concept has been introduced for some years. A "Drug and Medical Devices Committee" is present from some years now, while the "HTA Committee" has been in place

from a few years less. We have tried to structure a complete evaluation process on HTA and to share a single committee" (ID_12, PRIVATE)

"Since 2005 there has been a Medical Devices Commission which involves several professionals, but which is not only dedicated to HTA and with which semiannual meetings are held" (ID_11, PRIVATE)

5.3.2 Acceptability

The second pillar of the interview has analyzed the acceptability of the innovation introduced, in order to identify whether the HTA is perceived as a valid instrument to support decision-making process. The interviewees recognized that having proper tools that can be adapted to the peculiarities of different contexts could increase the positive perception about the HTA processes among implementation stakeholders, which can also be enhanced thanks to the supportive role of the regional level.

All respondents agreed and acknowledged the acceptability of the process as useful for decision support, as reported in the interview excerpts below.

"It is a tool with which we are able to convey different competences of different functions of the company, each of which has its point of view, but which, in the end, in some way, must come together and collaborate on the final evaluation. So, I would say yes" (ID_15, PRIVATE)

"So, yes, and this response is also supported by the perception I have from the management and the administration. In the sense that our CEO is interested in raising this HTA culture in the structures he administers and, therefore, he asks us an opinion. [...] From an objective point of view of the requests by the medical personnel and, in any case, in the evaluation even of the purchase, it leaves a trace of all those that are the evaluation criteria, I think it is a more than valid tool" (ID_9, PRIVATE)

"I think the process must be implemented and we must capitalize and invest because in a world like the one we are in today, where we have great needs, technologies that increase daily, and resources that are limited, a solution like this allows us to make choices, and to understand what is appropriate and what is not, this is the first thing. And if it is appropriate, where to use that device, or the other device, because not all the structures are the same. It has always been necessary, but, a fortiori, in this situation, we need to make decisions and decisions must be supported not only by the feeling or reference of the clinician who presents you the technology, but by the scientific evidence. It is welcome, it is right that there is, and that it is increasingly important" (ID_5, PUBLIC)

"That is, a necessary summary document, in which we detach ourselves from the routine for a moment and analyze the problems, above all in this moment in which the resources are always

obviously scarce and the technology presses you, the technology, but also the new therapeutic pathways ... so having time to think about this, as yes, it is necessary to implement the whole theme of the outcomes, which are two important topics in my opinion inside the hospital, because if one never evaluates ... So, the concept of evaluation, for me, is an essential concept. It is part of this journey" (ID 7, PRIVATE)

However, despite the acceptability of HTA is widespread among interviewees, some peculiarities emerged. More specifically, features related to the tools adopted to conduct HTA, the differences among contexts in which HTA can be performed, and the regional support may affect the level of acceptability of the process. These features are discussed below.

5.3.2.1 Tools

Several interviewees addressed the link between the need for programming at company level, and the availability of the HTA process as a tool of support in this sense. Some interviewees pointed out that this is also dependent on the type of instrument/process being adopted.

"Surely. Of course, we have chosen a suitable tool for an Local Health and Social Authority, that is, that however it must be flexible, it must not require a large consumption of resources, it must be acceptable from the point of view of the scientific method, and, at the same time, it has to give answers quickly and quite comprehensively" (ID_8, PUBLIC)

This recalls that the acceptability of the process also depends on the tools used, pointing out the need for simplicity and flexibility. As stated before, the interviewees highlighted a lack of rigorous and structure in the evaluation process, and, therefore, the introduction of a well-structured tool could be of a great support in order to recognize the officiality of an activity that was carried out even before, but in a more informal manner.

Moreover, in some of the healthcare organizations interviewed, a high acceptability rate has been identified and it has helped to drastically reduce the resistance rate of potential adopters.

Furthermore, the acceptability rate was also supported by the recognition of the HTA process as a technical and non-strategic process. Therefore, the use of a clear and structured process is essential to ensure transparency, because *"the technical one must be correct, the strategic one is an assumption of a choice" (ID_4, PUBLIC)*. Therefore, the recognition of the HTA as a technical process is vital to support the acceptability of its introduction. Based on this principle, the HTA process is a technical

path based on the analysis and reorganization of scientific evidence, while the decision-making path, instead, turns out to be strategic.

5.3.2.2 Differences of application

The different applications of the HTA process have also emerged as factors that may affect the level of acceptability of the process.

"It is a valid support tool, but we need to see its usefulness for a private accredited structure. It currently has an impact on internal organizational procedures, but not on company practices" *(ID 11, PRIVATE)*

With this statement, the interviewee outlined the need to adapt the instrument/process to the local specificities. In particular, a different type of ownership (public or private) should be considering when designing an HTA process, because different logics and strategies can motivate the operativity of these two different entities.

Furthermore, every business entity, regardless of the ownership, may require more or less detailed processes depending on its complexity. Therefore, a more or less complete and detailed process can be structured and designed for a company according to its level of complexity. This has been also underlined by an interviewee, who pointed out that *"I think that an HTA process can hardly be done and taken for each, for all technologies. It is a heavy method, it would be too heavy to be applied to any acquisition that is going to be carried out" (ID_10, PRIVATE). Thus, the acceptability of the process also varies based on the technology being evaluated. Indeed, in some companies, in particular, especially in small organizations with few resources, the HTA is not used for investment decisions, but rather for disinvestments. In particular, in this context, some interviewees recall that when talking about disinvestment, not only elements related to efficacy and economic nature should be considered in the evaluation process, but rather, the social and environmental impacts are vital aspects to be taken into consideration.*

5.3.2.3 Regional level

Respondents also highlighted the possibility of centralization of the process in supporting its acceptability. In particular, it has been highlighted that it would be desirable to have a centralization

of the evaluation process, that could be at regional level, which can provide indication about health technologies that could be, subsequently, adopted by the healthcare organizations in the Region. In particular, an initial evaluation at regional level, related to, for example, the evaluation of the available scientific evidence, and, subsequently, adapted to the local level has been suggested. According to some interviewees, by providing the evaluation at the regional level, the level of trustworthiness of the quality of the evaluation would be increased. This would be beneficial also for helping the reduction of the duplication of efforts, as well as to address the problem of lack of sustainability in the long term of comprehensive and articulated assessments made at the local level.

Certainly, a regional planning and coordination of the HTA activities performed at local level is fundamental in order to help hospitals in having a clear understanding of the evaluations that are in place at different levels of analysis (e.g. regional and local).

"In my opinion, we need a new regional design. That is, the fact that the Region could strengthen a group at central level. Then, if it wants to strengthen it centrally, with people physically there or no, we do not care, but the important aspect is that there is a place with people who are interested in HTA at the regional level" (ID_5, PUBLIC)

In alternative to the opportunity of centralization, some of the interviewees highlighted the hypothesis that a strong group, or an important reality in a specific area of the Region, could perform the assessment for the entire Region. In this second case, the group is not stable, but it varies according to the competences and the knowledge needed to perform the evaluation process. This allows healthcare professionals and/or healthcare organizations which are expert in a specific field to provide an added value when an assessment is required in that specific field.

Independently from the proposal related to the centralization or to the specialization, respondents agree that the shared and desirable idea is that the Region standardizes the methodology and performs the evaluation for a specific set of health technologies, while hospitals can adopt the same methodology in order to adapt the existent regional evaluations. Indeed, this could be positively perceived by a number of healthcare organization, which, actually, do not have the competences and the resources to perform the activity locally.

"So, there may also be choices that may seem top down, but in regional structures and/or in organized structures that are not too large, [...] one could easily envisage a core group that carries out this type of activity, as long as there are skills (which are always the most difficult things). In my opinion, a good structure is able to ask for a series of very detailed and very punctual *information and, at that point, then the core group reaches some conclusions and these conclusions must help both the strategic and the operative choice" (ID 6, PUBLIC)*

"And then, even there, the choice to divide this whole activity is not good. We need to find a certain type of direction, or even similar companies that maybe get together" (ID 5, PUBLIC)

Some respondents are aligned with the idea of centralization since they consider it as a way to increase efficiency. Indeed, currently, the adoption of evaluations carried out in other settings (different level, different organization, or different country) is not commonly adopted in all the healthcare organization in Lombardy. This implies that, when an evaluation is needed at local level, all the HTA process should be conducted at local level. Although it has been given the opportunity to access assessments done outside the hospital, this has not always been implemented.

"In fact, there is certainly a need for regional planning" (ID_1, PUBLIC), recalls one of the interviewees. This affirmation reminds the need to have a direction and a coordination at a higher level than the local one, which can adopt and consider the logical framework in which the health system is located. The HTA process, therefore, should assess the adequacy of the health supply in relation to the needs of the population. To be able to do this, a possible solution could be represented by an initial regional assessment, for example an evaluation of the bibliography made at the regional level, followed by a local adaptation.

In this perspective, some interviewees have reported that participation in the HTA process at a regional level has also supported the local decision-making process, since the implementation of the evaluated technology is then performed at the local level. However, an analysis of the real local needs is necessary to be able to proceed with local adaptation.

5.3.3 Appropriateness

The third implementation outcome analyzed is the appropriateness, intended as the perceived fit, relevance, innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of innovation to address particular issue or problem.

The appropriateness of the HTA process for supporting the evaluation of new health technologies has been widely recognized.

The totality of the interviewees agrees in defining the HTA process as appropriate for the local development: "Absolutely. Relevant and very interesting, briefly. In the right direction to support the decision" (ID_3, PUBLIC).

The concept of appropriateness has been linked, by some interviewees, to the concept of necessity. *"The concept of necessity is something different than appropriateness. On which we are probably still far behind" (ID_2, PUBLIC)*, recalls one of the interviewees, reminding that the HTA process is only appropriate in relation to the need to adopt a specific health technology at local level.

In particular, the process turns out to be particularly appropriate in large companies and research companies, which certainly have "need of a tool like that of HTA, even with all the caveats, limits and local applications of we were talking about earlier" (ID_15, PRIVATE). Furthermore, another interviewee states that "it continues to be appropriate also at local level because, at the moment, it is true that we are not subject to particular legislation for the purchase of new instruments, but we have the requests" (ID_14, PRIVATE). However, according to another interviewee "It should be more adapted to the private context as there are different logics between public and private" (ID_11, PRIVATE). Consequently, even if the appropriateness of the process has been recognized also for private healthcare organizations, it should be properly designed to meet the requirements of the specific features of organizations with that type of ownership.

Exchanges between the local level and the regional level are also appropriate. Although some interviewees stress the need for a more stable and structured collaboration, *"the exchange with the Region is very useful. It also begins to consolidate a culture, even among doctors and among all the clinical and health personnel, an HTA culture, which perhaps in the past lacked a bit" (ID_12, PRIVATE).*

5.3.4 Feasibility

The fourth pillar analyzed refers to the feasibility, which is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or settings. Feasibility of HTA process in Lombardy Region could be enhanced by some features that characterize the activities, such as the mandate, the culture and competences, the resources, the networking activities, the obligation and monitoring, the process and the interactions among levels. Each factor that can foster the successfully implementation of the process is discussed separately below.

5.3.4.1 Mandate

The first fundamental element that has been recognized by the majority of the interviewees is the mandate. The importance of the recognition of the official nature of the process by the Management of the organizations is considered as a vital factor. *"That is the fundamental prerequisite for things to work" (ID_8, PUBLIC)*, suggested one of the interviewees, who perceives and represent the mandate as a preparatory element to those that will be presented and discussed later. A strong mandate from the top management could increase the trustworthiness that the stakeholders place on the process.

"Certainly, a mandate from the Top Management is important [...] it is a fundamental thing" " (ID 10, PRIVATE)

5.3.4.2 Culture and competences

Secondly, the mandate should be supported by the dissemination of culture and skills at various levels. "There is a mandate, but the training is for all the groups involved in the evaluation" (ID_11, PRIVATE), recalls one of the interviewees. However, "currently, there is sufficient training only for the Health Department and for Clinical Engineering" (ID_11, PRIVATE). This sentence outlines the need to widespread the HTA culture at various professional figures within the same organization, without concentrating knowledge and training activities only for a limited set of professional figures. Different peculiarities have been outlined between the various healthcare organizations. In fact, some of the interviewed organizations are already having the appropriate skills to perform the HTA process. For some of the others, instead, this represents a gap. In particular, an interviewee pointed out that

"Few people, in my opinion, are still trained on the concept of HTA. Many know what it is, but they have never had the opportunity to approach it in a concrete way" (ID_12, PRIVATE) to underline how, although it is a topic in the process of being disseminated, this is not always deeply perceived and it is not always possible to implement in practice what has been learned on a theoretical level.

Regardless of the level of skills within the company, everyone recognizes its importance. In fact, an interviewee reported that "everyone is used to look at his/her field and not to integrate, but, being a multi-professional process, it is always useful to better structure this part of the training" (ID_2, PUBLIC). In order to ensure the multidisciplinary of the process, it was therefore emphasized that the diffusion of competences should be addressed to the different professional figures, both in health-related activities and not, in order to guarantee an equitable diffusion of culture and knowledge. In particular, several interviewees pointed out that, while the majority of the training courses have been done on the basis of personal interest, a more structured planning of the diffusion of skills would be essential to be able to disseminate this knowledge. This would also allow to build "an idea of continuity over time" (ID_3, PUBLIC) that can guarantee the carrying out of the activity in the medium and long term. Training opportunities should be tailored to the needs of each professional figure, "at any level with different peculiarities, of course" (ID_14, PRIVATE).

The need to educate and spread skills is also demonstrated by the fact that, even in those healthcare organizations where skills are currently present, they are concentrated in a limited number of people, most of whom are aging rapidly.

"The fact of pulverizing this culture towards users forces companies to structure themselves and to give this information. It seems to me that having HTA studies is essential so that the use of the device and/or procedure can be accepted. [...] It is a culture, a virtuous circle, also towards producers and traders" (ID 3, PUBLIC)

Furthermore, some interviewees suggest supporting the dissemination of these skills and this culture not only at the company level, but also in the university training course.

"In my opinion, the culture of HTA, like any other innovative tool in the company, has its maturation times that concern, on the one hand, perhaps the implementation of a pilot project and then, perhaps, gradually, the habit of people who work within the company to structure their methods and formulate their thoughts according to specific standards; on the other, probably, it requires, especially at the clinical level, an awareness of the diffusion of the model" (ID_15, Respondents agree that it is possible to observe an acceleration of the process of knowledge diffusion when the dissemination of culture is not only imposed by the top management, or encouraged by the healthcare organization, but at the moment in which this *"is spread to the network over a region or a nation or, better, still, at international level" (ID 15, PRIVATE)*.

"I believe that more or less the road could be that. Unfortunately, the road that, due to the building of culture, takes years, it is not something that can be implemented within a few weeks or months" (ID 15, PRIVATE)

Therefore, training is necessary, and it is important to start practicing in the field and, in particular, to involve the "Champions" of a company, i.e. those who are seen by others as points of reference. In this regard, starting to train some "opinion leaders" is essential in order to guarantee high-levels training. Some interviewees have highlighted the need to have facilitators who can support the evaluation process, actively involving all the members who can be involved and acting with a role of coordination of activities. After the creation of reference points within each organization, culture and training should be disseminated to groups of people (not only to individuals) in order to be able to favor the exchange of ideas and information, both within the company and between healthcare organizations. In addition, some respondents highlighted the importance of training people on the key aspects related to the HTA, including also the ability to read and interpret scientific evidence, considered as a fundamental aspect in an HTA evaluation process.

Therefore, a wide-ranging training would be desirable, because, as reported by an interviewee "the multidisciplinary nature of the HTA must be translated also in the possibility of making these different professional figures talk to each other" (ID_14, PRIVATE), thus spreading competences that take into consideration the different background of the various figures involved in the evaluation process, offering them tools and a language that allows them to dialogue.

"So, the difficulty is, in structures, to make sure that this culture is not of a few, but that it is widespread." (ID_7, PRIVATE)

"That is, a culture that permeates the company, not only in the procedures, in the formal deeds, but also just to reach the single actors." (ID 7, PRIVATE)

5.3.4.3 Resources

The third fundamental factor to support feasibility is represented by the resources. Some respondents used the term "resources" to refer to the need to educate professionals, thus referring to training resources ("*Resources, the only way to apply them, is to educate professionals to start making requests in a certain way*" (*ID_3, PUBLIC*)). On the other hand, other respondents linked the term "resources" to the need for financial resources to be able to carry out the HTA process accurately, "because a complete Health Technology Assessment requires a fairly long period of time, because there are so many dimensions/topics to evaluate" (*ID_9, PRIVATE*). In particular, if the goal is to integrate HTA into the organization procedures, it is necessary to structure a commission or, in any case, a work group, that can be entirely devoted to the evaluation process, without considering the HTA as a transversal activity that is added to the standard ones, as commonly conceived in the current practices. In order to implement a structure of this type, however, it is necessary to have resources that can be entirely dedicated to this activity.

5.3.4.4 Networking activities

"First of all, to have skilled and trained professionals to be able to make the assessments and then, I repeat, in my opinion, the added value is to work not alone, but to work in a network" (ID_5, PUBLIC). This sentence, proposed by one of the interviewees, recognized the networking activity as an additional factor for fostering HTA dissemination. The totality of the interviewees recognized this as an important element in order to be able to support the feasibility of the HTA process.

Networking activities are already in place in an informal manner through the participation at the regional meetings. During these events, it is possible for the members to establish informal relationships with colleagues in other hospitals. However, despite these informal relationships are satisfactory for a part of the interviewees, the majority of them expressed their need for a strategy that can propose and coordinate the systematic involvement of the various healthcare organizations. In fact, although the informal relationship is necessary and supportive, in order to stimulate a faster and quicker collaboration and exchange of information between colleagues from various hospitals, the possibility to perform systematically joint HTA activities is desirable.

"So, from this point of view, the networking activity is welcome, the fact of being able to make contacts, and then carry them forward even in everyday life for a rapid exchange is welcome." *(ID 10, PRIVATE)*

Doing network activities could be stimulating not only to overcome the lack of time and resources at the organizational level, but also to be able to share experiences and knowledge.

"There are obviously, and this is good, realities that are pioneers, that were born before and that have, nevertheless, had the possibility of having resources that are perhaps more focused to start this methodology, so, briefly it is good that they can transfer some additional information to us" (ID 9, PRIVATE)

5.3.4.5 Obligation and monitoring

In addition to the previous elements, which have been recognized by almost all respondents, other ancillary elements have been proposed by some of the interviewees. Among these, the need for mandatory activity, both in terms of carrying out the activity, and in terms of monitoring, has been recognized in some healthcare organizations. In addition, boosting control activities would also be supportive.

"The moment in which the "a posteriori" control activities start, even the preventive information about which activity to perform in the future will work well" (ID 3, PUBLIC)

Therefore, compulsoriness should not be limited to the evaluation process, but respondents suggest extending it to the measurement and control feedback phases. At this regard, one of the interviewees acknowledged the importance of measurement in the following sentences.

"We could really evaluate and understand, if we measure, [...] to have the willingness to understand what we are doing, because we do it and the effects that our activity produces. Here is the question "what is effect produced by what I'm doing?" If this question is systematic, then the HTA might take root. If this question is not systematic, it is difficult that HTA might take root" (ID 1, PUBLIC)

"The precondition for HTA to become normal is that we pay attention to patients at three years. When we systematically put attention on patients at three years, then we will also pay attention to the HTA, that is, we want to understand the effect of the activity we are doing, so we really care" (ID 1, PUBLIC)

5.3.4.6 Process

Some indications to favor the feasibility of HTA have also emerged at the process level and are discussed below.

5.3.4.6.1 Simplicity

First, an interviewee reported that "One thing that, in my opinion, we must not lose sight of, is the simplicity of the processes, because the more complex and complex the processes are, the less people are willing to follow these methods" (ID_12, PRIVATE). Therefore, even the definition of a simple and clear process emerged among the fundamental elements that characterize the feasibility of the evaluation.

<u>5.3.4.6.2 HTA as a project</u>

Second, in addition, one respondent put forward the proposal to conceive HTA as a project. "If, instead, we face the problem as a project, of which the purchase is a phase, it means we need to establish first the needs, the organization that will manage them, to define how the training is done, for what purpose it must respond, what are the critical issues that occur when there are delays, rather than anything else ... I say, if we change the perspective from the purchase of something related to the project of providing a new service, the HTA could be perceived as a strength that comes from inside, it is not something that is concluded with the purchase, but it is really part of a project." (ID_13, PRIVATE). This systemic view would allow the evaluation activity to be allocated in a broader path with respect to the classical process in which HTA is normally conceived (that is the one that culminates with the purchase).

5.3.4.6.3 Common language

Based on the principle of multidisciplinary, that is at the basis of HTA, some interviewees recognized the importance of providing tools and instruments that allow different professional figures to communicate and collaborate. They recognized the need to create taxonomies and a common language that can be shared between different healthcare organizations and that can be understood by all the professional figures involved in the process. In fact, in support of what was stated, one of the

interviewees recognized the need to obtain a final outcome which is based on information (or categories of information/data) which is commonly shared among all the healthcare organizations in the area.

5.3.4.7 Interactions among levels

Another area that has been widely discussed during the interviews is represented by the interaction(s) between the various levels of evaluation. In particular, respondents discussed about the support provided at regional level and the possibility to centralize there the HTA activity.

5.3.4.7.1 Regional support

An additional relevant element to enhance feasibility is represented by the regional support. In fact, some of the interviewees expressed the need to have a strong reference at regional level, that could define clear paths, shared methodology and tools. This is particularly important because, in this field, the comparison with others is fundamental and, therefore, the availability of shared tools that can favor the dialogue and the comparison among hospitals is fundamental.

5.3.4.7.2 Centralization

In addition, some interviewees proposed a redesign of the interaction between the various levels of analysis, opting for a centralization of the activity. In fact, they have assessed the hypothesis that the evaluation activity (or, at least, part of it) can be done at regional level, allowing its possible adaptation at local needs.

"Then at this point I make a central group and I use the local professionalism that allows me to collect those professions that I need" (ID 6, PUBLIC)

Other respondents, always in agreement with the idea of centralizing the activity, proposed, instead, to centralize the activity in specialized realities. With the introduction of the idea of specialization, each group or healthcare organization is responsible for carrying out an assessment in which it is specialized, and then the results of the evaluation process are shared with all the healthcare organizations in the area, which can properly adopt and adapt them according to their own local needs.

5.3.5 Fidelity

The fifth implementation outcome analyzed is represented by the fidelity, which is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers (Proctor *et al.*, 2011).

Results show that the intervention contributed in raising awareness and acceptability of HTA, and it helped fostering collaboration among different healthcare organizations. However, some limits have been highlighted by the interviewees too. Indeed, the intervention generated only indirect effects, and the gap between production and decision making remains still huge. Indeed, the engagement of people within healthcare organizations is still a critical activity, such as the sharing of available knowledge within the organization and the Lombardy region. Interviewees underlined also the necessity to have more customized training courses. To conclude, possible future directions have been highlighted, such as the possibility to simplify the HTA process, to increase engagement, to improve the link between evaluation and decision, with a focus also on the ex-post operational research, and to adapt training courses to specific needs.

Benefits and limits of implementation of the intervention, such as the identification of future implementation avenues are identified and discussed below.

5.3.5.1 Benefits

The benefits of the implementation intervention, identified by the interviewees, are related to three main areas: Awareness; Acceptability; and Collaboration. The discussion of each area is presented below.

The discussion of each area is presented below

<u>5.3.5.1.1 Awareness</u>

All respondents described the indirect effect caused by the process carried out at regional level. In particular, this has had the function of *"carrying forward, and underlining a bit the concept. That is... it is known that HTA exists, that there is a central body, and which is a science that is developing" (ID_8, PUBLIC).* This benefit is recognized by the totality of the respondents, who share the idea that the benefit brought is relevant both for the awareness of the topic, and for the training. The pulverization of culture towards the various categories of users has allowed companies to structure themselves in order to be able to provide the information and data requested. In particular,

the increase in the awareness that has been generated by this process has been supportive in recognizing the importance of the discussion and evaluation phases with respect to specific topics and/or dimensions. This has certainly helped the shift of the paradigm from "key opinion leaders" to "key evidence leaders", recognizing the importance of making evidence-informed choices based on a solid scientific basis that goes beyond personal preferences. The widespread of a single tool that could be shared among the different healthcare organizations, and professional figures has accelerated the cultural diffusion, since it has allowed a structuring of the healthcare organizations that promotes the possibility to advance requests in an orderly manner, following a pattern shared between different local entities.

In addition, it helped the spread of the culture at different levels, among which, first and foremost, the top management. The interest does not appear to be concentrated in few and selected professional figures, but it has been widespread among the various healthcare organizations and also at the regional level. This has meant that the attention placed on the subject by the Lombardy Region has been transferred to the companies through a relapse mechanism. Therefore, the requests of the Lombardy Region to carry out certain activities at the local level, in almost all cases, was accepted as an opportunity to spread culture and knowledge of a subject that is still not totally integrated in the hospital practices. This process is considered as a "*process of contamination*" (*ID_6, PUBLIC*) by the Region, because some companies had "*the need to be contaminated in the strict sense of the term*" (*ID_6, PUBLIC*), because they had not yet been reached by the culture of the subject.

Even the HTA activities performed at regional level have stimulated interest within healthcare organizations. Despite in some hospitals this interest is still rather concentrated, in other companies the concept of multidisciplinary linked to HTA has stimulated the collaboration between different professional figures.

5.3.5.1.2 Acceptability

In addition to the widely accepted benefits in terms of knowledge of the subject, improvements have been suggested and pursued also in terms of acceptability. Indeed, by promoting the dissemination of culture, this has made it possible to reduce resistance by potential adopters and increase the rate of acceptance of innovation, understood as a practice that will enter into the daily activity and the tools to be used in practice. In particular, the engagement of the clinicians in the HTA activities would be particularly relevant in order to reduce their resistance to the innovation.

5.3.5.1.3 Collaboration

Another important advantage that has been generated by the tailored intervention implemented in Lombardy Region is the collaboration. The possibility of interacting, comparing and collaborating with other healthcare organizations was positively perceived as *"the synergy between companies, or at the regional level, can absolutely help decisions that are in an environment in which they are very difficult to make" (ID_1, PUBLIC)*. This is particularly relevant because the skills necessary to perform an evaluation process are not always widespread at the organizational level, and, therefore, the synergy between different local entities can increase the ability to decide and therefore improve the decision-making process.

5.3.5.2 *Limits*

The limits of implementation identified by the interviewees are related to five main areas: Indirect effect; Necessity to implement; Sharing of available knowledge; Target of training; Production and decision-making process gap.

The discussion of each area is presented below.

5.3.5.2.1 Indirect effect

Although the benefits have been widely recognized by the interviewees, the process carried out in the Lombardy Region appears to be *"still a process under construction" (ID_8, PUBLIC)*.

Some respondents have complained about the lack of the initial definition of a clear structure of how the HTA process can be applied in local realities. In fact, the spread of culture, despite being of vital importance, does not guarantee the integration of business practices. Therefore, a suggestion that emerged is that the process could have started by asking if and what assessments were being carried out in the different hospital structures, *"in a way to try to unify, to standardize the evaluations" (ID_8, PUBLIC)*. Therefore, despite the definition of the state of the art has been completed in terms of knowledge, a more specific request in terms of practical activities would have been desirable. On the contrary, imposing the involvement of healthcare organizations in new activities, regardless of those that were already in place in there, is negatively perceived. This recalls the need presented in the "Feasibility" section to create taxonomies and a common language that can be shared among healthcare organizations, in order to guarantee homogeneity. At this regard, a respondent stated that *"the process can be different from company to company, but the final outcome, the information that must be there, must be coded" (ID 8, PUBLIC)*.

Furthermore, the need to impose an evaluation was perceived by respondents as a sign of defeat of the path implemented years ago, testifying to the fact that, if you try to work in this area for years and still need to impose *"rules of behavior" (ID_6, PUBLIC)*, then there are great difficulties in taking the path forward.

<u>5.3.5.2.2 Engagement</u>

In particular, several respondents complain that this has had only an indirect effect, without tangible direct effects generated by this diffusion. In fact, the process has been recognized as *"still a bit confusing" (ID 8, PUBLIC)*, since it is not easy to perceive the directions that have been drawn.

"Therefore, as long as it is not structured at regional level, it is difficult to have effects also at the local level, if not the indirect one of making known" (ID_8, PUBLIC)

The lack of a direct effect, that could have been measured, for instance, by the presence of HTA reports produced at the end of the implementation phase, is perceived as particularly relevant by respondents. Despite the indirect effect that the intervention has generated is of vital importance, a direct effect was expected, as well.

5.3.5.2.2 Sharing of available knowledge

The knowledge of the activities that are being implemented in the various healthcare organizations in the area is extremely relevant not only for the Lombardy Region, but also for other hospitals. In fact, among the limits of implementation recognized during almost the totality of the interviews, the lack of knowledge of the ongoing activities in other healthcare organizations has emerged. The interviewees declared that the share of knowledge among organizations is mainly indirect and informal, and it takes place principally through word of mouth among colleagues from different healthcare organizations. Respondents stressed the lack of a "census" in the activities being carried out and the ways in which they are being implemented. Respondents recognized this necessity as a starting point for future improvement, since the possibility of having a single register in which this information is tracked allows the comparison and collaboration between healthcare organizations in terms of activities and methodologies used.

5.3.5.2.3 Target of training

Another limit that has been identified by some respondents is related to the target of the intervention. Indeed, respondents recognize the need to address training opportunities and dissemination of culture not only to the professionals who are directly involved in the evaluation process, but also to a range of stakeholders, which can be affected by the evaluation process. However, in the current practices, interviewees recognized that a gap in terms of training of the hospitals' management, which, paradoxically, should have the widest knowledge of the subject. Therefore, the results show that, while some of the key professional figures in the HTA process (such as engineering and pharmacy) had a proper education, more attention could have been paid to other figures, who, although in some cases not central, are directly or indirectly involved in the HTA process.

A different targeting could have happened also in terms of organizations. In fact, the intervention has characterized all the hospital companies in Lombardy. However, as previously highlighted, they are characterized by significant differences (e.g. size, property, purpose). Therefore, some interviewees suggested that, when an additional activity is requested to a healthcare organization of small dimensions, or with few resources, it is necessary to ensure the feasibility of this activity. This is justified by the contexts and realities in which some of the organizations operate, in which there is a lack of resources even for the performance of ordinary activities and, therefore, the imposition of an additional task could worsen the financial position of these entities.

5.3.5.2.4 Production and decision-making process gap

The last limit highlighted by some respondents concerns the gap between the evaluation process and the decision-making process. In fact, although some evaluations have been performed, these have not always supported the decision-making process. This testifies that the training and the education of the professional figures who are directly involved in the HTA process is not enough, but the culture of the topic should be disseminated at all levels, including, in particular, decision-making. Only through a close collaboration between the two realities, it would be possible to see practical implications of HTA activities. In particular, according to some respondents, it is important to identify the HTA process as a mere purely technical process, which includes the search and the analysis of the available evidence. Subsequently, and separately from the previous process, the political aspect at the various levels should intervene in order to take the decision. However, despite they are considered as two separate processes, they should be highly correlated in order to translate results of the HTA process into actions.

5.3.5.3 Future directions

The future directions of implementation were identified in order to overcome the limits highlighted in the previous paragraph and they are related to the five main areas: Clarity and simplification; Engagement; Evaluation and decision link; Ex-post Operational Research; and Continuous training. The discussion of each area is presented below.

5.3.5.3.1 Clarity and simplification

First of all, interviewees identified the necessity to increase the level of clarity that characterizes the evaluation process and, if possible, to simplify it.

Among the needs that have been felt, an interviewee stated that there is "that of definitely adopting a clear, structured and definitive path and, on the other hand, of starting to produce, that is, of starting to arrive at final results" (ID_8, PUBLIC).

This underlines and supports what was stated by another interviewee: "*implementing mechanisms to simplify the HTA evaluation mechanism, in my opinion, is fundamental, because it is indeed a complex process, and the mechanism of simplification of evaluation, as far as can be implemented, in my opinion it is to be favored*" (*ID_1, PUBLIC*).

The definition of guidelines or manuals could help in this sense, in order to be able to "describe the process from the beginning to the end" (ID_12, PRIVATE). This declines in the need for sustainability, both in terms of resources and timing, supported by the supply of valid and clear tools. From these two extracts, it is shown that simplification and clarity play a fundamental role. Furthermore, the simplification could help to overcome another limit previously identified, which is that related to the timing. "To do a complete HTA, you really need a lot of time, in addition to the skills" (ID_1, PUBLIC), says an interviewee who underlines the need for a simplification of the process that allows its execution and integration into business practices. This need arises precisely from the current difficulty of bringing the process into reality.

The possibility of "*being able to be more flexible and lean*" (*ID_5, PUBLIC*) could turn into a real support for healthcare organizations, something that, at the present time, *"has been lacking"*.

<u>5.3.5.3.2 Engagement</u>

Another fundamental aspect for the future development that emerged from the interviews is the need to "continue on this path of involvement of the structures. Maybe always bringing innovative elements

that bring companies to want to continue taking this path" (ID_12, PRIVATE). Therefore, some respondents stressed the importance of continuing to promote the activity, to organize courses that are increasingly focused on local needs. Furthermore, it is necessary to involve the various professional figures, both in clinical and non-clinical areas.

5.3.5.3.3 Evaluation and decision link

Third, the need to recognize a connection between evaluation activity and decision-making had already emerged among the limits of the implementation of this process. Therefore, among the suggested future developments, surely emerges the need to reduce the gap between these two realities in order to translate the evaluation path into final results. This could be facilitated by the possibility of collaboration between healthcare organizations, which could support the evaluation at both local and regional level.

The need to recognize the impact of the assessments on the economic value was also recognized.

"So, maybe, you demonstrate that technology is very important, you make the investment, you buy it and, then, in the end, you need to fight to demonstrate the benefits associated with it. Or maybe, there are technologies that prove they are totally useless, that instead benefit from attractive reimbursements" (ID 7, PRIVATE)

This underlines the missing link between evaluation activities and definition of tariffs and/or reimbursements. There is a lack of this translationality, which could hinder the effective recognition of the usefulness of the evaluation process.

5.3.5.3.4 Ex-post Operational Research

An additional theme that emerged from the interviews is that the HTA has the potential to become "a *functional regional control body, not an appendix*" (*ID_8, PUBLIC*). According to what has been previously stated, this would surely help when there are tender bids. The achievement of the recognition of the official status of the HTA activities would help, first of all, the company and, secondly, the definition of the activities useful for ex-post monitoring that would allow an operational verification of the choices and decisions taken. While in some realities this activity is already in place (although underlying under certain specific conditions), most of the interviewed hospitals are not aware of the impact that a decision (taken on the basis of an HTA evaluation) has made. In particular,
in some healthcare organizations, an ex-post operational research could help collecting data when they are not available or if they are not sufficient to support an evaluation study. However, an application to check "*How much the work is equal to the declared*" (*ID_8, PUBLIC*) would be desirable.

5.3.5.3.5 Continuous training

Moreover, the interviewees also recognized the importance of having continuous training on the subject.

"I graduated in 1981 ... the world has completely changed at least twice in terms of medical aspect. And it's changing extremely fast because they come out, I don't say every day, but almost, new research related to the improvements, the actions, the news. [...] But they're doing it now on incremental benefits that are around 1%, while, when we started, they were around tens of percentage points. Now if you improve, improve by a few percentage points" (ID 3, PUBLIC)

In these sentences, therefore, both the importance and the need to be able to access continuous training are recognized, as well as the necessity to develop a critical and careful thinking that is able to recognize a benefit, even if minimal compared to the benefits that could have been made years ago. In addition, innovative elements in the training course could be inserted in order to bring companies *"to want to continue taking this path" (ID_12, PRIVATE)*. The promotion of the activity, as well as the organization of courses increasingly aimed at local needs, is a need that has been widely perceived.

5.3.6 Cost

In terms of implementation cost, the healthcare organizations interviewed appeared to be deployed on two sides: about half of the health organizations stated that there will be no impact, while the remaining part stated that there could be financial and/or organizational impacts.

"In my opinion it will not lead to significant changes because, as you can see, we are already fairly structured. Given that, obviously, you always need to improve and do it better, but, from this point of view, for what I understand, it simply serves to consolidate something that already exists and eventually improve it" (ID 3, PUBLIC)

Therefore, in the case in which the HTA process is already integrated in the practices of the organization, no further cost and/or impact is foreseen by the interviewees. "All things substantially sustainable" (ID_2, PUBLIC), cites another interviewee. Indeed, "being integrated in the activity of the commission of the devices in a fairly structured way for years, it makes everything rather simpler" (ID_1, PUBLIC).

"I don't think they will have such a significant impact, neither from an economic point of view nor from the point of view of absorption of resources" (ID_10, PRIVATE), cites an interviewee, who, in turn, affirmed that it expects that the intervention has an impact on the perceptions and culture of the members of the HTA commission.

On the contrary, another group of healthcare organizations claimed that "Certainly it has a cost, because if I request more activities, even just in terms of hours of human resources, they have a cost" (ID_15, PRIVATE). The interviewees did not refer only to the economic but also to the organizational costs, as different professional figures will have to dedicate part of their working day to the performance of this activity.

"To fulfill the rules, the personnel must be sent to the training courses: this has an organizational, rather than economic impact" (ID 11, PRIVATE)

5.3.7 Penetration

The pillar "Penetration" measured the extent to which a practice is integrated within a service setting and its subsystems (Proctor *et al.*, 2011).

Results suggest that only in the half of the healthcare organizations interviewed the local HTA is integrated in the settings of the organization. In particular, differences emerged especially according to the ownership of the organization: public healthcare organizations show, on average, higher levels of integration of the HTA process in their practices with respect to private organizations, for which the diffusion and knowledge of the topic is still at its infancy. On average, in all the organizations interviewed the commission has been formalized, but not in all of them is already operating, as supported by one of the interviewed: *"Yes, and, in any case, we hope that it will become more and more operational because, in this moment, it is more a formal organism. Instead, we should make it grow both in terms of skills, but, above all, also as an activity in decision-making, why not? That it is really a used support and then that it is more integrated into the company's purchasing practices." (ID_14, PRIVATE). However, almost the totality of the organizations interviewed recognized the importance of having a multidisciplinary team in conducting HTA process.*

Differences and similarities emerged among organizations are discussed below and they are mainly related to two aspects: composition of the commission, and steps of the evaluation process.

5.3.7.1 Commission

The totality of the interviewees recognized the need to have a multidisciplinary commission, composed of different figures, both clinical and non-clinical.

As intelligible from Table 5.3, the three departments mostly represented are Clinical Engineering, Medical Direction and Pharmacy. However, heterogeneity among the various hospital structures surveyed has been outlined. In fact, always in Table 5.3, it is possible to see that there are some figures that are only involved in a specific organization and, therefore, their involvement does not appear to be systematic. Clinical engineering has been widely recognized as the fundamental element to conduct HTA: "We say that, at the company level, the entity that has to do the most with this aspect is the clinical engineering and therefore, that is fundamental. However, normally, it is much more connected to the purchase of the devices, rather than to the integration of the devices in a hospital information system, so, briefly, the two aspects must be strictly connected" (ID_13, PRIVATE). In addition, in some of the hospitals interviewed the necessity to have a specific training on HTA activities in order to be a part of the commission emerged.

Components	N. of healthcare organizations
Clinical Engineering	11
Medical Direction	11
Pharmacy	11
Clinical Unit	6
Purchasing Department	6
Nursing Department	5
Operational Direction/Management Control	5
Medical Supervision Office	5
Risk Manager	3
Quality Department	2
Information Systems	1
Training Office	1
Scientific Direction	1
Clinical governance	1
Administrative officer	1

Table 5.3 - Professional figures in the Commission(s)

"Everyone must have specific training on HTA for our procedure and therefore we have all taken the course of LIUC on HTA" (ID 8, PUBLIC)

In several healthcare organizations, the existence of more than one commission has emerged. In the mentioned cases, different commissions are created for the management of the different classes of medical devices¹. Therefore, the functioning and evaluation of these health technologies appears to be separate and independent even within the same hospital.

"Instead, this refers exactly to medical devices and therefore the modality of new equipment (whether medical devices or equipment connected) with regard to the introduction inside the hospital is quite structured" (ID_1, PUBLIC)

¹ According to the Legislative Decree n. 46 of 1997, different classes of medical devices exist. Medical devices are grouped into classes according to their complexity and potential risk to the patient (Legislative Decree nr. 46/1997, 1997). The class of risk is dependent upon the following features: Invasiveness of the device; Duration of contact with the body; Anatomical site affected by the medical device; Dependence on an energy source (active device). The classes are the following:

o Class I: less critical devices, such as most of the non-active and non-invasive ones;

[•] Class Is: Class I devices supplied sterile;

[•] Class IIa: medium risk devices, such as some non-active devices (invasive and non-invasive) and active devices that interact with the body in a non-dangerous manner;

[•] Class IIb: medium / high risk devices, such as some non-active devices (invasive species) and active devices that interact with the body in a dangerous way;

[•] Class III: high-risk devices, such as most implantable devices, those containing drugs or animal derivatives and some devices that interact on the functions of vital organs.

"A "Medicines and Medical Devices Committee" has been present for some years now, while the "HTA Committee" has been in place for a few years less. We have tried to structure a complete evaluation process on HTA and to share it in a single committee" (ID 12, PRIVATE)

In addition, in some cases, there is a commission that is entirely dedicated to HTA, while, in other cases, the activities related to HTA are performed by the "Medical Devices Commission", in which the HTA is one of the many activities that the commission carries out. In particular, when the commission is not entirely dedicated to carrying out HTA processes, some of the interviewees reported that the activities will be aimed at "*recall of safety notices, on, perhaps, improving device management procedures*" (*ID_10, PRIVATE*), and that "*the commission, however, it also deals with other activities, like recall, drugs, safety notices … the HTA is just a "referred to"*" (*ID_11, PRIVATE*). Finally, the possibility to engage in the evaluation process people who are not part nor of the commission, nor of the hospital has been discussed only in one case.

"We have this project, which will start soon, to also involve citizens, and therefore active citizenship (this is something we have already done in another structure that I manage) and, so, I want to bring this involvement here too, and, therefore also insert them in this type of evaluation (especially because it is an area to which they are particularly interested) and I believe that it is a value" (ID 7, PRIVATE)

5.3.7.2 Process

The evaluation process was widely described by the interviewees. Although some differences emerged from the interviews, an almost standard procedure, that is commonly adopted by all the healthcare organizations interviewed, is represented in Figure 5.2.



Figure 5.2 - Representation of the HTA process

In general, the process starts with the completion of an evaluation request form, more or less structured according to the level of penetration of the HTA concept in the healthcare organizations, it proceeds with the meeting(s) of the members of the commission, and it ends with the drafting of a final report containing the indication of the adoption (or not) of the evaluated technology. The different phases of the process are described and analyzed below.

5.3.7.2.1 Evaluation request form

The first step in the process shown in Figure 5.2 is represented by the completion of the evaluation request form.

Different paths have been identified during the interviews.

First, in some healthcare organizations, the evaluation request form is filled in directly by the clinician(s). The idea shared by almost all the interviewees is that *"the professional makes a request according to the rules of HTA" (ID_3, PUBLIC)*. The clinician(s), therefore, has(have) to be educated in order to be able to provide information in as much details as possible. The idea is precisely that of *"trying to get help from professionals" (ID_3, PUBLIC)*, in order to be able to respond to the specific needs of the organization.

"A procedure has been drawn up, which provides for the compilation of the mini HTA questionnaire, which is the Danish one, revisited by us (i.e. especially reduced) by anyone who intends to present a technological innovation that has a certain weight inside the company" (ID_8, PUBLIC)

"So, the entrance door is the HTA module" (ID_8, PUBLIC)

"The evolution is that the professional already compiles forms according to the HTA criteria and requires that the commission makes an evaluation and that they give evaluations" (ID_3, PUBLIC)

Second, in other cases, instead, the filling of the evaluation request form is accompanied by a preliminary evaluation of the request. In some organizations, the form should be requested to the members of the commission, who, in turn, can give indications to the clinician regarding the relevance of the technology proposed to evaluate. In other cases, instead, the request has to be approved by the applicant's Unit Director.

Third, in addition to the classic request that is proposed by the clinicians, some interviewees underlined the possibility for the Strategic Management of the hospital to propose the request.

In terms of the structure of the evaluation request form, despite differences emerged among hospitals concerning the module that is currently in use, the majority of the healthcare organizations have expressed their willingness to adopt the evaluation form currently being drawn up by the Lombardy Region as a basic starting model.

Differences between healthcare organizations have also been outlined in terms of evaluation requests: while in some situations it is possible to submit a request at any time, in other cases the requests are collected only at specific times.

The peculiarities that emerged from the interviews in this field are discussed below.

First, in more structured organizations, the model is not unique, but there are different models depending on the type of request. In fact, in one of the cases, in addition to the standard evaluation request model, there is also a model mainly used when the request is urgent, and another model to request the authorization to test a new medical device. While the first one aims at fulfilling the requirement of completeness, the other two models are much more flexible. In particular, the third one is particularly relevant in order to collect data and information by testing the health technology, which will be, subsequently, subject to a full HTA process when the trial period ends. In other cases, differences in the types of requests are detected according to the utility of the technology to be evaluated: therapy, diagnosis, prevention and screening.

Second, differences in the structure of the module have been underlined. Several healthcare organizations claimed to have adopted the Danish model of mini-HTA in their practices (Ehlers *et al.*, 2006), others are not adopting a structured module for the request, while almost the totality of interviewed are adopting a structured model which allows the identification of a detailed range of characteristics of the request. Additionally, all the respondents recognized the importance to complement the request with the available scientific evidence. Therefore, in addition to the completion of the evaluation request form, the bibliography that is supporting the request should be attached to the module.

Third, some interviewees highlighted significant differences in the assessment depending on the stage of development of the technology to be evaluated. In fact, as reported by one of the interviewees "If the technology is widespread, there is less attention. On the emerging technology, instead, there is clearly a more focused attention" (ID_3, PUBLIC). This is particularly true when an evaluation is performed for replacement purposes. In fact, as stated by one of the interviewees, a much more streamlined procedure can be adopted in these cases, since "there is not all the evaluation part related to the requirement, because the machine is there, I have to change it" (ID_15, PRIVATE).

"It takes a fair balance between the in-depth analysis of the topic and the output need, because you can't perform an analysis for too long, because, after a while, I'm not saying that the technology is already old, but then you must chase it" (ID_5, PUBLIC)

5.3.7.2.2 Commission

The second step of the process, once the evaluation request form has been presented, concerns the meetings of the commission described above. In most cases the commission meets periodically (indicatively once a month), although some interviewees have stated that, in their cases, the commission meets only when needed.

The deliberation can be concluded at the end of the first meeting of the commission, or additional elements and information could be required. In this second case, the members of the commission have (approximately) one month to integrate the current request with the additional information required and the deliberation would be concluded in the following meeting.

"Very often the device is not evaluated in a first session, but it needs further analysis of the bibliography, and, therefore, it needs further investigation because there are deficiencies in the request, which we do not believe are not explanatory of the real need, and, therefore, generally the answer we give in this case, is for a suspensive investigation" (ID 1, PUBLIC)

The process upon which the final indication of the commission is deliberated can vary according to the structure decided at local level. According to the results there is still heterogeneity in this sense. In particular, interviews showed that those healthcare organizations adopting the Danish mini-HTA model embrace the idea to structure the final indication based on a multiple criteria decision analysis approach (MCDA), since, at the end of the discussion, they are required to fill in "a weighing and evaluation form of the four dimensions of the HTA and from which a score is derived" (ID_8, PUBLIC). On the contrary, hospitals that have shown greater flexibility in the structure of the module, opt for flexibility also during the meeting phase, by adopting a discussion "around a table all together" (ID_3, PUBLIC).

5.3.7.2.3 Final report

The final step of the evaluation process concerns the drafting of a final report that contains the

indication of use (or not) of the evaluated health technology.

As for in the previous phases, there is a great difference between cases opting for flexibility, and those adopting a more structured approach.

Some organizations have defined a precise structure for the report, which is declined in the dimensions assessed in the discussion phase. On the contrary, other hospitals do not adopt a definitive report structure, but *"this relation, having no mandatory fields, can be done in any way, without having to respect a certain type of information, it can be done in any way" (ID_10, PRIVATE).* Therefore, healthcare organizations that do not follow a clear structure that allows a 360-degree view of the evaluated technology.

"In the field of procurement of medical devices and health technologies, for several years, we have been taking cues from the pillars of the HTA process. Basically, the first point is to have a 360degree overview of the health technology, from the budgeting phase to its introduction, and to what its introduction entails also in terms of adaptation to the structure" (ID 10, PRIVATE)

As recognized by the totality of the interviewees, the evaluation should go beyond the classical dimensions of cost and effectiveness, but it should include also other dimensions, such as, for example "the organizational impact; the impact of technological and plant adaptation, therefore in collaboration with the Technical Department; the fact of evaluating in the use of that technology if there is an impact of additional resources that must be destined or economic resources that are saved; the consideration in its life cycle of the maintenance activity that will underlie the equipment; the part of, how to say, an update that can result in machine obsolescence; how to say, they are all evaluations that we have, maybe not in such a codified way, started to do. It is more in a perspective, in economy, of total cost of ownership, than of a real HTA process, but which nevertheless also fall within a classic HTA flow" (ID_10, PRIVATE).

"No, it is not absolutely only economic, that is an attempt is made to perform an evaluation also of those that could be the clinical-assistance aspects, the benefits, the impact of the technology, the organizational relapses, the effects on the layout, or, rather than before, on consumption or saving of human resources. Then it is not just costs and revenues, as the costs of ceasing and emerging, but there is also the analysis of the processes" (ID_6, PUBLIC)

As previously stated, the report may contain indications that, in some of the cases analyzed, are based on "cut-offs, which for now are very mathematical, that is, depending on whether the technology is indifferent or negative or positive with respect to the opinion expressed" (ID_8, PUBLIC). The various indications may propose the adoption or use of the evaluated technology. In addition, in the event that the documentation on which the evaluation is based appears to be too scarce and, therefore, inadequate, the technology appears to be approved with reserve, "giving time for experimentation and, at the end of the trial, we redo the HTA with the collected data" (ID_8, PUBLIC). Therefore, in this specific case, the technology can be provisionally adopted and, subsequently, once the trial period is over, and once the necessary data have been collected, it is further subject to an evaluation process in order to have the final indication.

5.3.8 Sustainability

The last topic addressed during the interviews concerns the sustainability of the HTA process in the practices. Respondents expressed opinions on various factors that can favor and accelerate the sustainability of local HTA diffusion. In particular, the need for continuous training, and the necessity to widespread HTA culture at different levels, to raise awareness, to increase the amount of dedicated resources, and to better design process and tools for performing HTA emerged among the main factors for ensuring sustainability.

Each factor is discussed separately below.

5.3.8.1 Training

The need for continuous training has emerged as the main factor in order to support the widespread of local HTA over time. Therefore, interviewees suggested that the first step to be taken is to organize training courses. However, some interviewees have also highlighted the need to define which professional figures to train. The problem of the seniority of the (professional) population appears to be widespread among the interviewed hospitals, and, therefore, it is necessary to enroll young people who can be trained. Therefore, target training is needed in order to replace the professional figures who are close to retirement. However, some respondents pointed out that, although this could bring benefits in the long term, as once the culture of HTA is absorbed, it can be transmitted during all their career, current professional involvement is needed to exploit benefits in the short run. Therefore, the peculiarities of the process of recruiting new human resources within public healthcare organizations could represent an obstacle for the targeted training of resources. Therefore, training is certainly the fundamental and primary element in order to be able to guarantee sustainability in the dissemination of HTA, but a clear definition of the target of training process is equally important in order to have a benefit at both company and system level.

Furthermore, as stated by an interviewee "*we need the right professional profile*" (*ID_3, PUBLIC*), so it is clear that the training should be aimed at professionals who, even if they do not have specific technical skills in HTA, their background matches the request for multidisciplinary that the HTA process needs. Indeed, training is not necessary and indispensable only for those healthcare organizations that suffer from gaps in terms of competences at the present time, but also for those hospitals in which the previous training processes have not been outlined to allow long-term sustainability. Therefore, both the healthcare organizations that have a lack of current resources, and

those in which this shortcoming could become a future problem can benefit from training programs designed to support the spread of HTA in the long term.

In addition to the target professional figures, it is important to identify the topics being trained. Some interviewees stressed the need to go beyond the classic HTA technical and theoretical skills, by encouraging training also related to soft skills that can ensure the framing of the process in a strategic business context and coordinate this process within the business development plan of hospitals.

The need for training is also essential to "raise the level of knowledge" (ID_1, PUBLIC). This underlines the need to spread both quantity and quality. First of all, results suggest that the training should involve new professional figures and, therefore, contribute to increase the number of people and professional figures with specific training in the field. However, the quality of the training received should not be overlooked. For this reason, while spreading a superficial and generic knowledge of the subject is necessary at all levels and for all professional figures, a more detailed and in-depth training should be delineated for those professionals mostly and directly involved in the evaluation process. Therefore, in addition to a general course on the topic addressed to the various professional figures to widespread the basic knowledge of it, the need to organize and / or participate in "a course that will then be calibrated more on our needs" (ID_10, PRIVATE) has been expressed by different interviewees. This need emerged especially because, as emphasized by several interviewees, at the present time "It is a process of self-training" (ID_4, PUBLIC), and, therefore, there is not a clear and structured path for training in HTA of healthcare professionals.

Furthermore, some interviewees stressed the importance of being trained on the practical process, in addition to the diffusion of the basic knowledge of theoretical concepts.

Finally, almost all the interviewees reminded that training is not enough if it is not accompanied by a change in culture. In this regard, training could be considered as a useful tool for spreading culture and increasing awareness.

5.3.8.2 Culture and awareness

Secondly, as previously stated, training is not enough if it is not accompanied by a change in culture. In fact, given the multidisciplinary nature of the HTA process, different professional figures are expected to collaborate. In this regard, a culture that could be shared among different professionals is needed and it can be promoted by ensuring the use of a common vocabulary, as well as the pursuit of the same purpose. Therefore, it is necessary to promote the dissemination of the HTA culture in order to generate interest and support understanding of the process. The benefits that can be achieved are twofold. First, it can guarantee sustainability. Second, the resistance to the introduction of an innovation, which is a typical behavior of people who have not received adequate information on all aspects related to innovation, could be reduced.

The cultural dissemination could be relevant for a number of reasons.

First, this could be favored by the pursuit of a path "that has the characteristics of scientificity, in a well-defined path, with well-defined steps, with the use of coded instruments" (ID_2, PUBLIC). In fact, while the culture appears to be widespread both at the top management and among the professional roles directly involved in the evaluation process, awareness of the diffusion among clinicians is still at its infancy. Therefore, elements such as the participation and awareness of the clinicians are considered fundamental in the sustainability of the diffusion of HTA, so that HTA can be perceived as a tool that favors technological diffusion.

Second, it could also avoid, or, at least, marginalize situations of lack of governance of the introduction of technological innovation. This is particularly important in the health sector, where the results of innovation, regardless of the authorization phases, are always available many years later.

The cultural dissemination is necessary to guarantee sustainability for all the stakeholders of the HTA process, and, in particular, within committees and commissions, in order to promote a common and comprehensive vision of the expected results and of the objectives of the evaluation process. This could be favored also through a greater and continuous engagement of the different professional figures in the evaluation process.

Third, it could also have positive consequences on the evaluation request process, as the applicants would advance a request with a broader overview of the health technology for which the evaluation is requested, complemented by the relevant scientific available literature.

Fourth, it could and should be preparatory to the introduction of a shared tool that is promoted at regional level and adopted by the healthcare organizations in the area.

Finally, the diffusion of an HTA culture is certainly also in the interest of top management, especially in private hospitals with scientific nature. As previously stated, the mandate of top management is considered a useful precondition for spreading culture and fostering the sustainability over time. Additionally, the use of training as a tool through which culture can be disseminated can support the various contexts analyzed.

5.3.8.3 Resources

Another element that could favor the sustainability of the diffusion HTA in the long term is represented by the resources. As previously stated, many interviewees affirmed that difficulties in conducting HTA are related to the lack of time to be devoted to performing the assessment. Therefore,

the possibility of finding resources that could be entirely dedicated to the HTA process could support its institutionalization and, in turn, the sustainability of the activity in the long term.

5.3.8.4 Process features

According to the interviewees, there are also some features related to the HTA process that could contribute in enhancing its sustainability.

In particular, as reported by one of the interviewees "simplification is the need that everyone feels" (*ID_1*, *PUBLIC*). Simplification of the process may make it more easily integrated into the hospitals' practices. In order to be able to support its diffusion in the various contexts, with the various peculiarities, a simplification of the process could be desirable.

5.3.8.5 Tools

In terms of tools, a segmentation, as well as a clear definition of the purposes of HTA could be a relevant support for the sustainability of HTA at the local level. In particular, the differences in the contexts that have been previously outlined (e.g. different ownership structures) could be considered to define specific process features based on local characteristics and needs. Furthermore, regardless of the settings, recognizing the HTA as a tool to *"understand what is needed"* would be desirable according to the majority of respondents. Therefore, in order to guarantee sustainability in the diffusion of the HTA process, it is necessary that, at the regional level, the tools that can be used at local level are developed and provided to local entities.

5.4 Conclusions

This Chapter was aimed at presenting the qualitative results of the semi-structured interviews that have been conducted in the period April-May 2019 in healthcare organizations in Lombardy Region. Results are presented according to the implementation outcomes identified by Proctor and colleagues (Proctor et al., 2011) and reported below. In terms of adoption, the majority of the interviewees have attended courses on HTA, only some of them are directly involved in HTA activities and all the healthcare organizations interviewed have a commission which performs (also) HTA activities. The acceptability of the innovation has been widely recognized. Indeed, the importance of having proper tools that can be adapted to the peculiarities of different contexts in order to increase the positive perception about the HTA processes among implementation stakeholders, and the supportive role of the regional level have been widely recognized. The concept of appropriateness is supported by the majority of the interviewees. In terms of feasibility, features related to the mandate, the culture and competences, the resources, the networking activities, the obligation and monitoring, the process and the interactions among levels are supportive elements for enhancing the successful implementation of HTA process at local level. The fidelity has been measured in terms of benefits, limits, and future directions. The benefits that have been provided by the intervention has interested the culture and awareness, the acceptability and the collaboration, while the limits that have been detected refer to the indirect effect, the engagement, the sharing of available knowledge, the target of training, and the production and decision-making gap. Finally, future directions of the implementation process highlighted the necessity to have clarity and simplification, engagement, evaluation and decision link, ex-post operational research, and continuous training. For what it concerns cost, the impact of the intervention is mainly organizational, rather than economic. The analysis of the penetration allows to detect some insights related to the composition of the commission which perform HTA activities and the process that is followed in the healthcare organizations. In particular, the commission exists in all the healthcare organizations interviewed and the professional figures which are most commonly included are the Clinical Engineering the Medical Direction and the Pharmacy. The structure of the HTA process is shared among participants and it can be reconfigured in the following steps: evaluation module request, commission meetings, and final report. Finally, in order to ensure the sustainability of the process, training, culture and awareness, resources, identification of specific process features, and shared tools are needed.

The joint discussion of qualitative and quantitative results of this study are provided in the following Chapter.

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Chapter 6: DISCUSSION

ABSTRACT

The discussion of the qualitative and quantitative results, guided by the Ottawa Model of Research Use (OMRU) theoretical framework, is provided in this Chapter. Each element of the model is discussed separately. First, elements related to the external environment, that could have an influence on practitioners, researchers and policy makers, such as external pressures are discussed in the first element. Second, the analysis of potential adopters stimulates the dialogue related to the knowledge and the perception of potential stakeholders, with the objective of identifying barriers and enables that could have an impact on the diffusion of Health Technology Assessment (HTA). Third, features of the evidence-based innovation are discussed. Fourth, a description of the different transfer strategies adopted along with the implementation intervention is provided. Fifth, the results achieved are presented in the pillar related to the analysis of the adoption and use of the innovation. Sixth, in the Outcome pillar a model that consider the results emerged from the previous elements and that can be adopted for the monitoring of the factors that can have an impact on the diffusion of HTA is presented.

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Valentina Beretta PhD Student, Università degli Studi di Pavia Pavia, Italy valentina.beretta02@universitadipavia.it

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Chapter 6: DISCUSSION

6.1 Introduction

In this Chapter the discussion of both quantitative and the qualitative results is provided.

Data are integrated following the Ottawa Model of Research Use (OMRU) (Graham and Logan, 1998; Hogan and Logan, 2004; Logan and Graham, 2010). The theoretical framework adopted guided the researcher in the data collection phase, both in the interpretation phase.

The OMRU is composed of six different pillars that are closely related to each other during the implementation phase. Research is conceived along the model as a dynamic process in which the decision of one pillar affects all the others, in a multidirectional diagram (Graham and Logan, 1998). More specifically, the practice environment, the potential adopters, the evidence-based innovation, the transfer strategies, the adoption and use of evidence and the process outcomes are the elements that the models could help in assessing, monitoring and evaluating.

The remainder of the Chapter is organized as follows: in the following Section discussion of practice environment, potential adopters, evidence-based innovation, transfer strategies, adoption and use and outcomes is provided following the OMRU theoretical framework; Finally, conclusions are provided in Section 3.

6.2 The Ottawa Model of Research Use

In order to identify barriers and supports to research use, the Ottawa Model of Research Use (OMRU), as explained in Chapter Three, has been adopted as theoretical framework for guiding the collection and the analysis of data, such as the interpretation of the results (Graham and Logan, 1998; Hogan and Logan, 2004; Logan and Graham, 2010). In the framework, the following key elements of knowledge translation are examined to explain the uptake of knowledge by stakeholders (Logan and Graham, 1998; I. D. Graham and Logan, 2004): practice environment, potential adopters, evidence-based innovation, transfer strategies, adoption and use, and outcomes. The model is grounded on the following assumptions about the knowledge translation (I. Graham and Logan, 2004): dynamism and interaction between knowledge production and use; health outcomes centered; and potential influence of the environment.

Along with this this study, a sequential explanatory mixed methods design has been employed: quantitative results from the survey provided a snapshot of the diffusion of HTA in Lombardy Region, while the semi-structured interviews were used to provide a more in depth analysis of the research problem.

Each element of the OMRU theoretical framework is discussed separately below.

6.2.1 Practice Environment

The first element that is discussed in the framework is the practice environment. According to previous studies (Funk *et al.*, 1991; Haynes, 1993; Walczak *et al.*, 1994; Funk, Tornquist and Champagne, 1995; Lomas, 1997), this is particularly relevant since the external environment could exert a "set of influences on practitioners, researchers, and policymakers" (Logan and Graham, 1998, p. 231) which can impact the process of research transfer and use by encouraging and/or discouraging it. According to previous studies, since the environment could exert a variety of influences on stakeholders (Graham and Logan, 1998), its assessment is essential to identify the external pressures (I. D. Graham and Logan, 2004) which can encourage or discourage the KTE process (Funk *et al.*, 1991; Haynes, 1993; Walczak *et al.*, 1994).

The aim of this element in the model is to identify, describe and assess these pressures, by considering the different factors that may exert an influence on the process.

In particular, Damschroder and colleagues grouped the different factors that may influence the practice environment into outer and inner settings, where the former "includes the economic, political,

and social context within which an organization resides", while the latter "includes features of structural, political, and cultural contexts through which the implementation process will proceed" (Damschroder *et al.*, 2009, p. 5).

Table 6.1 summarizes the contributions of this study in terms of these elements and their detailed description is provided below.

Inner settings (implementation)		Outer settings (organization)	
Structural	Interactions among levels	Economic	Lack of resources
Political	Gap with the decision-making process	Political	Gap with the decision-making
			process
Cultural	Awareness, perceptions	Social	Organizational culture

Table 6.1 – Contribution of the study in terms of practice environment

6.2.1.1 Inner settings

This study advances some knowledge related to the context in which the implementation intervention is introduced. More specifically, inner settings are analyzed in terms of structural, political and cultural factors affecting innovation diffusion.

<u>6.2.1.1.1 Structural</u>

According to previous studies (Battista and Mickalide, 1990; Battista, 1992; Grol, 1992; Greco and Eisenberg, 1993; Nolan *et al.*, 1994; Elson and Connelly, 1995; Funk, Tornquist and Champagne, 1995; Graham, 1997), structural factors refer to the "settings' decision-making structure; rules, regulations, and official policies; physical structure; workload; available resources and supplies; and the system of incentives" (Logan and Graham, 1998, p. 231). Structural factors are discussed along with this study by providing evidence for the interactions among different HTA levels.

As widely supported by previous studies, the final objective of HTA is to "provide responses to the specific questions asked by the decision-makers on the likely value of health technologies" (Halmesmäki, Pasternack and Roine, 2016, p. 1). However, as stated before, HTA can be performed at different levels. More specifically, recently, national and regional levels are often combined and managed with the local level, in which the HTA process is performed by hospitals.

Even if the final objective is the same, the target audience varies. In fact, while the regional and national HTA provide responses to questions posed at regional or national level, the Hospital-based

HTA (HB-HTA) answers to the questions posed by managers of healthcare organizations for the adoption of new health technologies in their hospitals (Halmesmäki, Pasternack and Roine, 2016). In particular, HB-HTA is performed to support managerial decisions by considering the specific needs of organising work in hospitals, complying with their leadership and strategies, and adapting existing resources (Sampietro Colom *et al.*, 2015).

As provided in the study of Amigoni and colleagues, in Italy "there are at least two decisional levels related to the governance of healthcare system and the management of expenditure: the systemic one, i.e. national and regional, and the operating-unit related one, which refers to individual organizations supplying health assistance services (for example, hospitals)" (Amigoni et al., 2005, p. 9). This implies that communication between different levels should be good enough to guarantee the diffusion of HTA processes at systemic level. In particular, results of this study are aligned with previous literature suggesting that collaboration among different levels could be beneficial for a variety of reasons. More specifically, the collaboration among different levels could increase the HTA reports' uptake and the transparency of decisions, and it can promote innovation (Halmesmäki, Pasternack and Roine, 2016). The systemic approach would be particularly beneficial when expensive technologies are evaluated, since it allows the planning of research allocation at different levels (Halmesmäki, Pasternack and Roine, 2016). In addition, the sharing of available information and available reports produced would avoid the duplication of efforts of hospitals, especially when resources are limited. The creation of a shared database, where all the HTA reports produced in the area are shared, would be particularly relevant especially if hospitals have learnt how to use the work of others and customize it to its own necessities, considering local specificities (Halmesmäki, Pasternack and Roine, 2016). The national mini-HTA database represents a case in which the mini-HTA are shared among different healthcare organizations with the aim of improving the quality of the evaluation in practice (Kidholm et al., 2009).

In line with previous studies, the actual connections between different levels of HTA is mainly unofficial and informal (Sampietro-Colom *et al.*, 2015; Martelli *et al.*, 2017). As in other highly decentralized countries, the interconnections are mainly between the local and the regional level, while the exchanges between local and national levels are limited (Sampietro Colom *et al.*, 2015). Participants to this study reached a solid consensus concerning the need to encourage direct exchanges between local and regional level in Lombardy Region. However, while in other countries the distribution of tasks between the different levels is clearly defined (Martelli *et al.*, 2017), it is not the same in the area investigated in this study. However, healthcare organizations in Lombardy Region embraced the possibility to organize the HTA activity in two levels. This approach is similar to the one presented in the literature related to how the activity is organized in Finland: based on the

principle of fairness, the regional level would be responsible for the literature searches and evaluation methodology, and it would play a key role in organizing and coordinating the exchanges, while the local level is responsible for adapting it locally (Halmesmäki, Pasternack and Roine, 2016). Indeed, as provided in previous studies, the multidisciplinarity of the process implies that there is the need to create an HTA central point (regional level) that can coordinate activities and communicate with different stakeholders (local level) (World Health Organization (WHO), 2015).

6.2.1.1.2 Political

According to previous studies, political factors that may influence the KTE process are represented by "the nature of political systems, the role of institutional structures, and the political contestation of policy issues" (Liverani, Hawkins and Parkhurst, 2013, p. 1).

This study is in line with that stream of the literature according to which the KTA is still huge. This has been detected also in the field of HTA, where the HTA reports produced are rarely considered to support decision-making processes. As supported by previous studies, "if HTA does not improve its responsiveness to context-dependent issues, colloquial evidence will remain the main source of information for decision-makers and HTA will fail to establish a robust bridge over this particular knowledge-action gap" (Garrido et al., 2010, p. 199). This study supports that stream of the literature according to which the transfer of research findings into practice is a slow process (Graham et al., 2006). In particular, it supports the separation between technical process (Assessment phase) and decision-making process (Appraisal phase). Indeed, previous studies claimed that "the politicians remain responsible for implementing recommendations of HTA-studies and resolving possible tradeoffs among outcome measures." (Reuzel et al., 2004, p. 252). In addition, Reuzel and colleagues affirmed that "when HTA in the future should be able to retain its relevance and utility as a tool for informing health professionals and policy-makers, the scope of HTA definitely needs to be broadened" (Reuzel et al., 2004, p. 256). Decision making in healthcare is considered as the tradeoff between a wide range of elements (e.g. scientific, medical, economic, social, and ethical) (Goetghebeur et al., 2012) and the HTA can help achieving objective scientific judgement (PausJenssen, Singer and Detsky, 2003; Menon, Stafinski and Stuart, 2005) and value judgement (Eddy, 1990; PausJenssen, Singer and Detsky, 2003; Tunis, 2007; Sinclair et al., 2008).

This study is in line with previous studies according to which the "willingness at the policy level to integrate HTA in decision making" (Moharra *et al.*, 2017, p. 79) influences the success of the HTA implementation. According to previous studies, in fact, the collaboration between researchers and policymakers has been identified among the facilitators that can reduce the gap between knowledge

and action (Halmesmäki, Pasternack and Roine, 2016). Therefore, only if the HTA process and the decision-making process are aligned, practical implications of HTA could come out. This study is in line with previous studies according to which, given that HTA is a kind of policy research, it is linked to the policy-making decisions (Li *et al.*, 2017).

In addition, this study contributes in advancing some knowledge related to the theories focusing on the determinants of organizational change related to the political and economic context (Grol *et al.*, 2007). As affirmed by previous studies, despite changing determinants in this field is not in the interest of the implementation science studies, their identification is essential in the planning phase (Grol *et al.*, 2007). At this purpose, the OMRU model has been used as theoretical framework to identify factors affecting the adoption of the innovation.

6.2.1.1.3 Cultural

According to previous studies, some cultural aspects are considered among the contextual factors that can affect the acceptance of an evidence-based innovation (Aarons and Sawitzky, 2006), and they affirmed that a change in the culture could have an impact on the performance (Shortell, Bennett and Byck, 1998; Scott *et al.*, 2003).

In particular, factors that have been identified in previous literature as potential facilitators of HTA process (e.g. knowledge of methodological guidelines) are investigated in this study. The discussion of the most relevant contributions of this study in this field are provided below.

First, despite the knowledge of methodological guidelines has been analyzed in previous studies as a way to improve the quality of HTA implementation (Banta, 2003), their knowledge is not commonly widespread among healthcare professionals.

Second, together with the knowledge of guidelines, the awareness of the existence of agencies that are aimed at performing HTA activities at various level can increment the quality of HTA implementation (Kaló *et al.*, 2016). The external support provided by the HTA agencies is not widely recognized in Lombardy Region. Therefore, results of this study do not recognize the awareness of methodological guidelines and the existence of agencies among the fostering factors.

Finally, networking activities and external collaborations have been widely recognized in the literature to have an impact on the success of HTA implementation (Battista and Hodge, 2009; Moharra *et al.*, 2017). More specifically, the exchanges between national, regional and local level are vital. The regional meetings have been recognized as factors that can provide great support for the HTA development since they allow to achieve local knowledge of the topic.

6.2.1.2 Outer settings

In terms of outer settings, this study advances some knowledge to the theories related to the organizational context (Grol *et al.*, 2007).

In particular, this study provides support for the theories of organizational learning and knowledge management, according to which not only individuals can learn, but also organizations can (Garvin and Building, 1993; Grol *et al.*, 2007). In fact, while the knowledge of the individuals is stored in their memories, the knowledge of the organization can be retained even when the individuals leave (DiBella, Nevis and Gould, 1996; Garside, 1998). In addition to individual culture, also organizational culture could be relevant for changing performance (Scott *et al.*, 2003). Indeed, as advocated by previous studies, the receptiveness of the HTA process can be largely influenced by the management culture in which the evaluation is done and the decision has to be taken (Battista and Hodge, 2009).

Different healthcare organizations can embrace different typologies of culture, according to their features and the topics they stress the most (e.g. in a developmental culture, the emphasis is on the "growth, creativity, flexibility, and adaptation to the external environment"; a rational culture is "control oriented, emphasizing productivity and achievement and external competition", while an hierarchical culture stresses "stability especially in the internal organization, uniformity, and a close adherence to rules" (Grol et al., 2007, p. 122)). Therefore, the organizational culture of the healthcare organizations is dependent on the typology they rely on. Additionally, independently from the typology of organizational culture, quality improvements can be achieved when the culture of the organization emphasized the constant learning, the teamwork, and the focus on the customer (Ferlie and Shortell, 2001). This study supports the importance of the elements that have been recognized in previous studies for promoting a quality culture: leadership, engagement, learning (Boan and Funderburk, 2003). At this purpose, results of this study widely recognize the importance of building a strong structure in the organization for the acquisition, dissemination and integration of knowledge that could be both formal and/or informal (DiBella, Nevis and Gould, 1996; Grol et al., 2007). In addition, this study provides support for the idea that "only through individuals' learning are organizational routines changed" (Grol et al., 2007, p. 120), by highlighting again the importance of having trained professionals.

In addition, this study supports previous studies according to which the adoption of the innovation can vary according to the organizations' typology. More specifically, this study contributes to the classification proposed by Scott, according to which there is different emphasis on different types of innovation. Results of this study found that organizations have developed different types of

organizational culture, according to their legal status. In fact, while public organizations pursue mainly an hierarchical culture, in which the emphasis is based on the stability in the internal organization, the uniformity, and on the adherence to rules (Stock and McDermott, 2001). Furthermore, networking activities between different healthcare organizations can influence the extent to which the innovation is spread (Scott, 1990).

Outer settings are analyzed in terms of economic, political and social factors affecting innovation diffusion.

<u>6.2.1.2.1 Economic</u>

The economic burden of HTA activities has been widely discussed. As in previous studies, the lack of resources emerged among the most relevant and widespread barrier to the HTA production and use at the different levels. This is particularly true in the hospital settings, where the HTA is mainly an ancillary activity, without dedicated resources (Martelli *et al.*, 2017). However, this study is in line with that stream of the literature according to which the mandate of HTA without an adequate level of resources (both financial and human) could be associated with a negative impact on the quality of the HTA processes conducted (Kaló *et al.*, 2016).

<u>6.2.1.2.2 Political</u>

Despite the gap between production of HTA reports and the decision-making process is reduced in hospital settings, it is still observable. According to previous studies, HTA is conceived as an integral part of the planning and management processes at different levels in healthcare (Ehlers *et al.*, 2006). Based on the idea of the Danish Mini-HTA, the production and decision gap could be reduced by providing local decision makers with a tool that can incorporate local needs and that can be used to answer to them. The provision of a tool that can be used to perform local HTA has a variety of advantages, both at local and at regional/national level (Ehlers *et al.*, 2006). First, at local level, HTA can favor the dialogue between different stakeholders that contribute at the decision-making process, while ensuring transparency in the decision. Second, at regional and national level, local HTA can shed some lights on topics of interest that could be translated into national applications. Therefore, the provision of a valuable tool for performing HTA could reduce the gap between production and decision-making process, and, in turn, strengthen the implementation of the regional/national HTA strategy.

<u>6.2.1.2.3 Social</u>

Social factors are captured by the information related to "the politics and personalities involved, the presence of local champions or advocates of the evidence-based innovation, and the culture and belief systems operating within the setting" (Logan and Graham, 1998, p. 232).

Social aspects of the organizations involved in the analysis are represented by a variety of elements. First, networking activities are recognized among the important aspects to be considered. In particular, according to previous studies, "HTA is no longer conducted in national isolation" (Moharra et al., 2017, p. 79). This study embraces the need of networking among organizations as an important way to develop and share HTA activities, and better coordinate and communicate among different HTA programs. In particular, as suggested by Moharra and colleagues, when HTA is not institutionalized, the collaboration among different HTA organizations and levels is particularly relevant since it offers opportunities to learn from the experiences of others and benefit from HTA reports already done (Moharra *et al.*, 2017). In particular, "it can help reduce duplication, thereby enabling resources to be used more efficiently and assuring the timeliness of HTA reports" (Moharra et al., 2017, p. 79). This provides support for the social network and influence theories, according to which the structure of social networks largely influences the adoption of new ideas and technologies (Rogers, 2010). This study supports that, as delineated in previous studies for international collaborations, the willingness to be involved in networking activities is widespread, especially during formative stages (Chootipongchaivat et al., 2017), since they can enhance the diffusion of the awareness of the usefulness of HTA.

Second, in the literature few studies related to the description of the *sharing of information* among different healthcare organizations are provided (Martelli *et al.*, 2017). The sharing of available knowledge results to be among the barriers that are hindering the involvement in HTA activities. In fact, results claim that the access to internal and external newly issued HTA reports is rarely easy, and that, therefore, a stronger communication is needed, given the willingness of healthcare professionals to be informed about the publication of new HTA reports. Indeed, as advocated in previous studies, the access to relevant HTA research and its dissemination are among the barriers that limit HTA production and use (Cheung *et al.*, 2017). Limits in the knowledge of activities performed by other healthcare organizations were detected, as well. Word of mouth still plays an important role in the sharing of ongoing activities among healthcare organizations. Therefore, the recognition of the potential benefits associated with the sharing of available information is widespread, since it can prevent the duplication of activities and allow the sparing of resources among hospitals (Martelli *et al.*, 2017). More specifically, this study is in favor of both the solutions proposed in the literature: HTA networks for favoring the direct exchange of information among organizations

would avoid the duplication of efforts of hospitals, especially when resources are limited, and the creation of common databases for facilitating the sharing of HTA reports (Kidholm *et al.*, 2009; Gagnon *et al.*, 2014; Sampietro-Colom *et al.*, 2015), especially if hospitals have learnt how to use the work of others and customize it to its own necessities, considering local specificities (Halmesmäki, Pasternack and Roine, 2016).

6.2.2 Potential Adopters

Potential adopters are represented by all the people who could adopt research. This section of the model is particularly relevant in order to identify the features that characterize all the potential adopters or target audiences to which policymakers are intended to address and direct the innovation. At this purpose, this pillar allows researcher to describe them in terms of "attitudes, knowledge, motivation for adopting the evidence, skills, and current practices" (Logan and Graham, 1998, p. 232). The diffusion is intended as the process through which an innovation (that is an idea that is perceived as new) is shared with its potential adopters with different channels. The identification of features of potential adopters is particularly relevant since perceptions are important in the field. Notably, the adoption rate could be directly and/or indirectly influenced by the manner in which individuals perceived an idea and an innovation, especially with reference to "its relative advantage, compatibility, complexity, trialability, and observability" (Rogers, 2012, p. 37). The information that are collected on the potential adopters allow the researcher(s) to create a potential profile of adopters which is focused on the barriers that are perceived and on strategies that can be adopted to foster them (Graham and Logan, 1998). More specifically, various professional figures can be differently motivated in adopting evidence. For this reason, it is particularly relevant in order to include all the potential adopters' perspectives to identify and understand all the scientific and nonscientific considerations that may influence the adoption of evidence by potential adopters (Greer, 1977; Eveland, 1986; Kaegi, 1991).

Area	Items
	Individual level
Knowledge	Organizational level
	Previous experience
	External support
Dorcontions	• Knowledge
refceptions	• Objective
	Attitudes
	Resources
Barriers	• Lack of knowledge of availability of HTA reports
	HTA process features
	Culture and competences
	• Mandate
Enablers	Individual learning
	• Engagement
	Champions/Opinion Leaders

Table 6.1 – Contributions of this study in terms of Potential Adopters

Along with this study, considerations are made and detected at individual level. Furthermore, consistently with previous studies (e.g. Lukas *et al.*, 2008), the aggregation of the information to healthcare organizations allowed the researcher to perform the analysis at different levels. More specifically, in this study, knowledge diffusion at organizational level is detected.

Advancements in the knowledge related to individual theories are provided, as well. In particular the theories related to factors that may affect decisions of healthcare professionals focus on their knowledge, their skills, attitudes and motivation.

In order to detect information related to the profiles of potential adopters, four different areas were investigated: knowledge, perceptions, barriers and enablers.

A summary of the contribution provided by this study in the different areas is provided in Table 6.1 and each area is discussed below.

6.2.2.1 Knowledge

Initial knowledge of the topic is widespread among healthcare organizations of the Lombardy Region. However, some peculiarities were detected.

First, at *individual level*, difference among professional figures in the knowledge of the topic have been detected. This study is in line with that stream of the Literature according to which the educational theories may motivate individuals' changes. According to that stream of the Literature, change should be implemented according to the professionals' needs and motivation. In particular, this study extends the theories according to which people can learn better when they are motivated to change because they are experiencing problems in practices (Norman and Schmidt, 1992; Mann, 1994; Merriam, 1996; Holm, 1998). Finally, a gap between awareness and engagement has been detected. While the former is widespread, the latter rarely occurs. This gap is particularly relevant for respondents who are in service for more time. This testifies that the diffusion of the topic in the analyzed area is still at its infancy.

Second, at *organizational level*, context plays a significant role in diffusing knowledge since differences among organizations were detected. In particular, knowledge of the topic in public organizations is, on average, more advanced with respect to private organizations. This result provides support for previous studies according to which the adoption of the innovation can vary according to the organizations' typology. Results of this study found that organizations have developed different types of organizational culture, according to their legal status, with public organizations adopting mainly an hierarchical culture, in which the emphasis is based on the stability in the internal organization, the uniformity, and on the adherence to rules (Stock and McDermott,

2001).

Previous experience was analyzed, as well. Differences in terms of individual and organizational experiences were found. More specifically, at individual level, various experiences have been stated. A more systematic participation was detected at individual level, while a sporadic participation at organizational level. Experience has been detected especially in the field of medical devices, which are those mostly evaluated, while the production of systematic review, guidelines or other types of report is not commonly widespread. This reflects the current situation of HTA, according to which the growing number of HTA reports produced represents an indication of the growing importance of HTA (Hailey, 2003). Results suggest that the participation of individuals to the regional meetings could enhance their experience at individual level. On the other side, the HTA activities performed at organizational level do not follow a clear and shared HTA strategy. Subsequently, as stated before, reimbursement decisions are rarely taken on the basis of HTA activities, and the gap between HTA process and decision-making process remains huge.

6.2.2.2 Perceptions

External support has been recognized to be particularly relevant in previous studies (e.g. Banta, 2003; Kalo et al., 2016). However, this awareness was not particularly widespread at the beginning of this project (e.g. knowledge of methodological guidelines and/or awareness of the existence of agencies). The identification of respondents' preferences for and access to *different types of information and knowledge* has been analyzed since, according to previous studies, it has been assumed that different respondents are probably using different kinds of knowledge, and this could affect the final decision (Champagne and Lemieux-Charles, 2004). This study recognizes that the involvement in HTA activities should be mainly guided by the information related to the clinical needs identified in the investigation area, or by the clinical innovation and emerging technologies. Therefore, this study supports the relevance of HTA as an important tool for balancing health needs and technological advancements, when considering a variety of information sources.

At this regard, however, the *access to the information* needed could represent a barrier, when not easily available. More specifically, an adequate access to information related to clinical needs was recognized, while a difficult one for information related to clinical innovation. In terms of the typologies of evidence adopted to obtain information, the relevance of scientific knowledge has been widely observed. The most relevant channel to access to relevant information is represented by the scientific journals.

The objective of HTA that has been widely recognized is the support for planning and budgeting
activities. However, while the objective of HTA is clear and widely accepted, in practice it is rarely achieved since only few organizations adopt HTA report to support planning and budgeting decisions. Finally, in terms of *attitudes*, this study is in line with that stream of the literature according to which transparency and clarity are the two most relevant features that should be associated with the HTA process, and that the HTA process should clearly support the decision-making process. Therefore, this study supports the relevance of transparency and clarity as preconditions for supporting the decision-making process by HTA reports. Discussion of the implications of these two features is provided later in the Chapter.

6.2.2.3 Barriers

In line with previous studies, different barriers to the production and to the use of HTA reports have been identified.

First, this study supports that stream of the literature which identifies the lack of resources among the factors that discourage the involvement in HTA activities (Rajan, Gutierrez-Ibarluzea and Moharra, 2011). As provided in previous studies, the lack of resources represents an important barrier to change (Kajermo *et al.*, 2000; Gentile *et al.*, 2004; Representative *et al.*, 2010). In particular, the term "resources" is used with reference to a variety of items, like "time, Support, Costs/funding issues and Resources" (Representative *et al.*, 2010, p. 98). Therefore, investing in dedicated resources is necessary to implement a structure of HTA. The lack of resources imposes that the organizations develop gradually, starting with activities which do not require large amount of resources and going alongside with health policies which emphasize practices based on evidence and that can be measured (Kristensen, 2007).

Consistently with previous studies (e.g. Rajan, Gutierrez-Ibarluzea, & Moharra, 2011), not only financial resources are needed, but human resources are necessary, as well. Indeed, education and training strategies are needed in order to promote successful HTA programs (Moharra *et al.*, 2008). Finally, also features related to the HTA process (e.g. availability of adequate procedures) are stated among the barriers to the production of HTA reports. In terms of barriers for the use of HTA reports, the lack of awareness of the availability of HTA reports has been widely recognized among the most important barrier. Therefore, this implies that, even if the access to the information is not hindering the production of HTA reports, it is relevant when providing access to the use of the reports. The need for having qualified human resources as emerged also in the prevention of HTA reports uptake. This study supports previous studies according to which the information distributed is apparently not sufficient (Halmesmäki, Pasternack and Roine, 2016). Indeed, given the difficulties that are detected

in accessing to the knowledge of the publication of new reports, the need to adopt different communication strategies is largely stated.

6.2.2.4 Enablers

In line with previous studies, different enablers to the production and to the use of HTA reports have been identified and they are discussed below.

<u>6.2.2.4.1 Individual Learning</u>

First, the individual knowledge is relevant to sustain culture and awareness.

Indeed, when considering the hospitals as learning organizations, the knowledge of the individuals is stored in the memory of the organization, improving also its culture (Örtenblad, 2002). As promoted by Kuchenbecker and Polanczyk, "the current main efforts to institutionalize HTA [...] are dedicated fundamentally to instruct and train new personnel to perform HTA, which is an important but insufficient step" (Kuchenbecker and Polanczyk, 2012). Previous studies identified among the lack of awareness, the motivation, and the external factors, important barriers for the adoption of evidence-based practices (Schardt *et al.*, 2004). In particular, "Individual professionals need to be informed, motivated and perhaps trained to incorporate the latest evidence into their daily work" (Schardt *et al.*, 2004, p. S57). Educational theories are, therefore, supported by this study. In fact, as provided in the "stage of change" theory, which posits that, starting from the assumption that people do not change behaviors quickly and decisively, changes occur continuously through a cyclical process, that has to be sustained over time (Prochaska and Velicer, 1997). According to this theory, in fact, the change of behavior is an action that can occur over time through different stages of change. It also stresses the importance, after the preparation and action stages, to maintain the change in order to avoid the relapse (Prochaska and Velicer, 1997).

At this purpose, the Problem-Based Learning theories can justify the motivation of people to learn. Indeed, as provided by previous studies, people are more motivated to learn and to change when they have to face problems and they have pressures to find situations to solve them (Norman and Schmidt, 1992; Mann, 1994; Merriam, 1996; Holm, 1998). Personal interest emerged to be one of the most important aspects that drives knowledge of individuals. While this is relevant for diffusing the culture at the initial stages of diffusion of the innovation, this is not enough when the innovation has to be widespread across all the organizations, since huge variations across professional figures could be detected. Training, at the initial stages of diffusion of innovation, is, therefore, conceived as a proxy for the diffusion of the culture.

Support for motivational theories has been provided, as well. In fact, as suggested by previous studies, different target groups should be reached with different interventions, given their various motivations (Schardt *et al.*, 2004). This could be relevant both in terms of organizational features and individual characteristics. As provided in previous studies, Local Health and Social Authorities and Scientific Institutes for Research, Hospitalization and Health Care are different for a variety of things. Therefore, different motivations drive changes in these contexts.

Finally, customization of training for different professional figures is needed in order to let them perceive the benefits of the innovation in their operational contexts. This study suggests that different professional figures have had different training. More specifically, this study is in line with that stream of the literature suggesting that the top management, even if it is the category that is mainly involved and affected by HTA activities, is rarely targeted for training activities. This justifies the fact that initial involvement in HTA activities is mainly derived from personal interest. This is translated in a lack of structured and standardized training courses, where self-training is mostly adopted. In addition, HTA training courses are rarely included in academic studies, and, when it is the case, it did not always prove to be particularly effective because it deals with general topics. However, as provided by previous studies, "it is very important that HTA capacity is developed in HTA research organizations as well as in decision-making bodies and other relevant stakeholder groups using HTA" (Chootipongchaivat *et al.*, 2017, p. 15). In particular, this study is in line with that stream of the literature according to which individual training is an extremely important factor for the HTA institutionalization (Kuchenbecker and Polanczyk, 2012; Chootipongchaivat *et al.*, 2017).

6.2.2.4.2 Culture and Competences

While the training is a necessary condition to spread the knowledge of HTA at different levels, it is not enough if not combined with a diffusion of culture related to the topic (e.g. Kuchenbecker and Polanczyk, 2012). This study supports previous studies according to which HTA activity does not have to remain confidential, but it has to be widespread to the different levels of the organization (Bodeau-Livinec *et al.*, 2006; Gagnon, 2012).

At this purpose, theories of organizational culture have been extensively supported in this study. More specifically the use of this stream of theories in explaining the use and dissemination of evidence-based guidelines is justified by the assumption that a change in the organizational culture can impact performance (Scott *et al.*, 2003), and, subsequently, can have an impact on quality of care (Scott *et al.*, 2003). However, as provided by Schein, the organizational culture is not directly created with the creation of the company, but it is derived from the knowledge and the culture widespread among components of the company, and it is adapted according to the internal and external inputs (Schein, 2010). Therefore, a constant exchange between individual and organizational knowledge is needed.

In particular, this study advances some knowledge in defining which are the inputs that can be pursued in order to develop the organizational culture. Indeed, as provided in previous studies, the definition of a clear and well-structured process, with a transparent tool, is not enough for its successful implementation (Ehlers and Jensen, 2012; Halmesmäki, Pasternack and Roine, 2016). As occurred in Denmark, the information campaign to introduce the mini-HTA to support decision making processes was not enough, since it was not properly supplemented with diffusion of culture at local level (Ehlers and Jensen, 2012; Halmesmäki, Pasternack and Roine, 2016). Instead, in line with the study of Schein, the organizational culture is derived from the knowledge and the culture of its components (Schein, 2010). Therefore, developing an individual culture that can be widespread among components of the same organization/area is extremely relevant.

More specifically, this study advances some knowledge related to the diffusion of HTA culture across members of healthcare organizations in Lombardy Region, in Italy.

First, while the HTA culture appears to be widespread both at the top management and among the figures directly involved in the evaluation process, awareness of the diffusion among clinicians is still at its infancy. Therefore, elements such as the participation and awareness of the clinicians are considered fundamental in the sustainability of the diffusion of HTA, so that HTA can be perceived as a tool that favors technological diffusion.

Second, this study supports the necessity to avoid, or, at least, marginalize situations of lack of governance of the introduction of technological innovation. This is particularly important in the health sector, where the results of innovation, regardless of the authorization phases, are always available many years later.

Third, positive consequences on the evaluation request process, as the applicants would advance a request with a broader overview of the health technology for which the evaluation is requested, complemented by the relevant scientific available literature could derive from the definition of a clear HTA path.

Fourth, the introduction of a shared tool that could be promoted at regional level and adopted by the healthcare organizations in the area is of particular interest to the members of the healthcare organizations in Lombardy.

Fifth, the mandate of top management is considered a useful precondition for spreading culture and

fostering the sustainability over time. Additionally, the use of training as a tool through which culture can be disseminated can support the various contexts analyzed.

Sixth, the need to educate and spread skills is also demonstrated by the fact that, even in those healthcare organizations where skills are currently present, they are concentrated in a limited number of people, most of whom are aging rapidly.

Finally, it is possible to observe an acceleration of the process of knowledge diffusion when the dissemination of culture are not only imposed by the top management, or encouraged by the healthcare organization, but at the moment in which this is spread to a network in a region, nation, or at international level. In particular, the benefits that can be achieved through the diffusion of HTA culture are twofold. First, it can guarantee sustainability by diffusing the awareness of the importance of the evaluation process. Second, the resistance to the introduction of an innovation, which is a typical behavior of people who have not received adequate information on all aspects related to innovation, could be reduced.

<u>6.2.2.4.3 Mandate</u>

The promotion of the adoption of evidence-based practices is encouraged by the leadership (Boan and Funderburk, 2003; Grol *et al.*, 2007). Indeed, as provided by previous studies, the institutionalization of HTA "goes beyond training personnel and depends not only on context-dependent factors (i.e. social, economic, political, and cultural aspects) but also on political commitment, capacity for investment, the development and degree of maturity of the decision-making processes as well as the structure of the national health care systems, among others" (Kuchenbecker and Polanczyk, 2012). For this reason, the mandate of the top management results to be essential for increasing the trustworthiness that the stakeholders place on the process. This study supports that stream of the Literature according to which the institutionalization of HTA could foster the uptake of evidence-based practices (Kuchenbecker and Polanczyk, 2012).

According to previous studies, there are mainly three models that can be adopted for promoting the institutionalization of HTA: top-down, bottom-up and converging approach (Rajan, Gutierrez-Ibarluzea and Moharra, 2011). Interest in promoting HTA can start at political level by involving all relevant stakeholders (top-down approach), or by stimulating interest among the various actors through networking activities (bottom-up approach). The converging approach combines both of them, suggesting that the effort for diffusing HTA derives from both political players and different actors. This study is in line with that stream of the literature according to which a converging approach can be adopted to promote HTA diffusion, and, as supported by previous studies, the process of

institutionalization of HTA is largely dependent on a variety of actors (Kristensen, 2007; EUnetHTA, 2008). In particular, even if this approach is not the most widespread across countries, support for this approach has been provided in the study since it could be considered as "an essential key to sustainability of future HTA institutionalization" (Rajan, Gutierrez-Ibarluzea and Moharra, 2011). In particular, this approach could be particularly important since previous studies found that it minimizes the time taken to establish HTA compared to the other approaches. In particular, along with the study, the conceptualization of institutionalization provided by Leelahavarong and colleagues, intended as "the action or process of embedding a concept such as a belief, norm, social role, particular value, or mode of behavior into an organization, social system, or society" (Leelahavarong, Doungthipsirikul and Kumluang, 2019, p. 2) is adopted. Therefore, the institutionalization phase includes also the development of the structures that are needed for carrying out the HTA process (Rajan, Gutierrez-Ibarluzea and Moharra, 2011; Leelahavarong, Doungthipsirikul and Kumluang, 2019).

6.2.2.4.4 Engagement

This study is in line with that stream of the literature supporting that the engagement of people throughout the organization and the system is the first step to reduce the KTA gap (Boan and Funderburk, 2003). In addition to stimulate improvement in quality of care, this could also stimulate interest in continuous learning.

6.2.2.4.5 Champions/Opinion Leaders

Previous studies identified in the concept of the behavior change for the translation of evidence into practice the need to educate a figure that can promote the behavioral change (Gonzales *et al.*, 2012). According to Ovretveit, the engagement and the training of professionals, combined with strong systems, and the importance of leadership can consistently improve the quality (Ovretveit, 2004). This study is in line with that stream of the Literature according to which the involvement of Champions or Opinion Leaders, defined as those "people who influence the opinions, attitudes, beliefs, motivations, and behaviors of others" (Valente and Pumpuang, 2007, p. 881) is relevant in supporting behavioral change. Indeed, as supported by Rogers, the opinion leaders are not necessarily the early adopters, but they are those who embrace an innovation before the others do (Rogers, 2010). In particular, this study is in line with that stream of the literature according to which barriers to change can be removed and/or reduced by opinion leaders, and the rate of diffusion of innovations increased (Valente and Davis, 1999). In particular, "both formal and informal leaders can be very

influential in changing clinical practice or implementing new procedures or processes" (Grol *et al.*, 2007, p. 115). However, as supported by Donaldson, in order to be able to exert this influence, there are some conditions that should be respected: hold a formal authority, control the scarce resources, have the adequate information, expertise and/or skills, be part of a strong network of relationships or be part of a dominant culture (Donaldson, 1995). According to the social network and influence theories, opinion leaders are particularly important since they are considered respected people with a great influence in their field (Grol *et al.*, 2007). This study supports previous research, according to which the importance of these key people is recognized also in healthcare (Stross, 1996; Grimshaw *et al.*, 2006).

6.2.3 Evidence Based Innovation

In this pillar of the model the perceptions related to the innovation introduced ("the actual guideline") are discussed. In particular, this pillar is particularly relevant in order to understand how the perceptions of the attributes of the innovation could influence the decisions of potential adopters. This would also help identifying the attributes that should be considered when tailoring transfer strategies appropriately.

According to previous studies, "attributes of an innovation interact with potential adopters" (Logan and Graham, 1998, p. 233). In fact, as supported by Rogers, innovations with different attributes can show different diffusion patterns (Rogers, 1995).

In this context, different settings can affect the rate of diffusion because they alter the perceptions of potential adopters. Therefore, ideally, the attributes that can positively impact the diffusion of the innovation should be strengthen, while those with a negative impact on the adoption of the innovation should be mitigated.

The need of obtaining information related to perceptions about the innovation is justified by the possibility for implementation strategy developers and/or policy makers to proactively respond to the identified perceptions by delineating the appropriate transfer strategies (Graham and Logan, 1998).

Area	Items
Acceptability	 Multidisciplinarity Necessity vs appropriateness Need to invest – scarcity of resources Scientific evidence Differences among contexts Recognition as a technical rather than a political process
Requirements	 Clarity Simplicity Flexibility Transparency HTA as a project Vocabulary Engagement Programming Monitoring

Table 6.3 – Contributions of this study in terms of Evidence-based Innovation

The evidence-based innovation is described in terms of the following features that have been delineated during the data collection phase. First, the acceptability refers to the extent to which the innovation is considered acceptable by the stakeholders. Second, in the section related to the requirements, features that could increase the adoption of innovation are discussed.

A summary of the contribution provided by this study in the different areas is presented in Table 6.3 and each feature is described below.

6.2.3.1 Acceptability

The acceptability of the process as a useful tool for supporting the decision-making process has been widely recognized in this study. In particular, some aspects have been associated with the acceptability of the HTA process.

First, as supported in previous studies "HTA requires a *multidisciplinarity* team of professional profiles" (Sampietro-Colom *et al.*, 2015, p. 49). This requirement has been widely accepted and shared among healthcare organizations within Lombardy Region. This provides support for the stream of the literature according to which effective management of care should rely on multidisciplinary teams (Wagner, 2000).

Second, this study introduces the differentiation between *necessity and appropriateness*. In fact, even if the process is considered appropriate to evaluate health technologies, involvement in it should be guided and motivated by the necessity to conduct the assessment.

Third, this study recognizes the need to invest *dedicated resources* for performing the HTA activity, since the scarcity of resources could prevent the appropriate execution of the HTA process.

Fourth, the appropriateness of the HTA has been particularly relevant given the necessity to consider *scientific evidence* in improving quality of care. Therefore, the acceptability of the HTA process is strengthen when the process is conducted considering a strong scientific evidence basis.

Fifth, differently from what was stated in the literature (Sampietro-Colom *et al.*, 2015), the *legal status* of the healthcare organizations can exert some influences in defining the ways in which HTA is conducted. In particular, higher motivation has been detected in public organizations.

Finally, despite the political considerations are included as a domain in the HTA process, this study stressed the importance of considering the *HTA as a mere technical process*, rather than a political one. In particular, a clear differentiation between the technical HTA and the political decision is expected.

6.2.3.2 Requirements

Requirement	Discussion
1 - Clarity	Consistently with previous studies, clarity of the HTA process can facilitate the
-	adoption of the innovation (Sampietro-Colom et al., 2015). In order to increase
	clarity of the process, as advocated in previous studies (e.g. Marsh et al., 2016), the
	scope needs to be clearly stated at the very beginning of the assessment process.
2 - Simplicity	This study is in line with previous research, according to which when the innovation
	is not considered difficult to perform, it has a positive impact on the adoption rate
	(Tornatzky and Klein, 1982; Grilli and Lomas, 1994). Therefore, simplification of
	the process is needed in order to more easily integrate the innovation into the
	hospitals' practices.
3 - Flexibility	Flexibility is required in order to be able to adapt the innovation to the various
	context in which it is expected to be widespread. Since features of the healthcare
	organizations, such as typologies of health technologies can impact the evaluation
	phase, a tool that can be easily adopted is required.
4 – Transparency	The need for transparency has been widely recognized, such as the importance of
	the searching of the literature to incorporate objective methods that can be used to
	synthetize the evidence (Auston, Cahn and Selden, 1992; Hayward and Laupacis,
	1993; Shiffman and Greenes, 1994; Oortwijn et al., 2017).
5 - HTA as a project	This study supports the conception of HTA as a project, with the adoption of a
	holistic view of all the activities. This approach could have a double effect: first, it
	helps reducing the HTA process and decision-making gap since the decision is
	considered a phase of the entire process; and, second, it could enhance the
	monitoring phase, that could be directly included as a phase of the project.
6 - Common	Based on the principle of multidisciplinarity that is at the basis of HTA, the
language/Vocabulary	importance of proving tools and instruments that allow the communication among
	different professional figures has been extensively supported by this study. This
	study is aligned with that stream of the literature according to which language of
	research evidence could prevent its use (Morton and Seditas, 2018).
7 - Engagement	This study supports the relevance of the involvement of potential adopters in the
	implementation process and the inclusion of credible developers as two important
	aspects that can positively influence the translation process (Grol, 1993; Brown,
	Shye and McFarland, 1995; Conroy and Shannon, 1995). In fact, there has been a
	wide recognition of the need to always present innovative elements, which can
	motivate companies to continue adopting the innovation.
8 – Programming	Since the local HTA has been introduced with the idea that it "can be considered as
	one possible approach to enhance the use of HTA for managerial decision-making
	in hospitals and other healthcare organizations and to improve the use of evidence,
	complemented with local information, to inform clinical practice in the "real
	world"" (Sampietro-Colom and Martin, 2017, p. 371), it is strictly linked to the need
	for programming at company level. In particular, this study is in line with previous
	studies according to which the objective of the HB-HTA is to support managerial
	decisions (Sampietro-Colom and Martin, 2017).
9 – Obligation and	This study advances some knowledge related to the importance of having a
monitoring	monitoring of the HTA activity. In particular, this study supports the idea that
_	having a mandatory monitoring phase after the decision-making step could be
	relevant in assessing the appropriateness of the choice made and it could help having
	a more precise idea of what are the effects of the healthcare organizations' activities.

 Table 6.4 – Requirements for local HTA

This study allows the identification of a set of requirements that are needed in order to foster and promote diffusion of HTA at local level.

The list of the requirements and their discussion are provided in Table 6.4.

6.2.4 Transfer Strategies

In this pillar of the model, the process by which the research evidence is translated into evidencebased innovation ("the process by which a practice guideline was developed" (Graham and Logan, 1998, p. 233)) is discussed (Logan and Graham, 1998). In particular, this pillar is relevant for the understanding of the influences of transfer strategies on the decisions of potential adopters. This would also help identifying the attributes that could be considered when tailoring transfer strategies appropriately.

As provided in Chapter 2, related to the Literature Review, the diffusion of an innovation could range from passive unplanned efforts to the systemic efforts to encourage the adoption (Lomas, 1997), and different settings and disciplines could have different and more appropriate strategies (Hodnett *et al.*, 1996).

As advocated in the literature, in order to promote effective implementation strategies, intended as techniques adopted for enhancing the adoption, implementation and/or sustainability of an evidence-based practice (Curran *et al.*, 2012; Proctor, Powell and McMillen, 2013), the implementation interventions should be designed.

In particular, in previous studies, the terms "implementation strategies" and "implementation interventions" have been used interchangeably with reference to the multiple components that are used in an implementation effort (Stetler, Mittman and Francis, 2008; Curran *et al.*, 2012). Along with this study, the definition of Powell and colleagues of implementation interventions is adopted, according to which they are considered as "a systematic intervention process to adopt and integrate evidence-based health innovations into usual care" (Powell *et al.*, 2012, p. 124).

More specifically, as suggested by Proctor and colleagues, the approach to the study of the implementation strategies should be similar to the one of evidence-based interventions, considering the strategies as types of interventions (Proctor, Powell and McMillen, 2013).

In particular, along with this study, a tailored implementation intervention, intended as a strategy that is designed to promote changes in clinical practices that are based on the assessment of their determinants (Baker *et al.*, 2015), is adopted.

The design of the implementation strategy adopted in the study follows the Replicating Effective Programs (REP) process, according to which four phases characterize the intervention (Kilbourne *et*

al., 2007): first, the Pre-Conditions phase is devoted to the collection of information related to the environment in which the intervention is planned; second, in the Pre-Implementation phase the intervention is prepared for the implementation; third, during the Implementation phase the intervention is executed; finally, the Maintenance and Evolution phase favors the sustainability of the innovation in the long term.

The implementation strategies that have been adopted are presented in Table 6.5.

Pre-Conditions	Pre-Implementation	Implementation	Maintenance and Evolution	
Gather Info	Select Strategies	Initiate Leadership	Develop Relationships	
	Develop Meterials	Educate	Destroyeture Stretegies	
	Develop Materials	Educate through Peers	Kestructure Strategies	

Table 6.5 - Mapping of strategies adopted in this study following the REP process Source – Adapted from (Kilbourne et al., 2007)

Each phase of the REP process is executed by a variety of actions. More specifically, the available strategies that have been identified by Powell and colleagues and that are adopted in the study are allocated in the phases of the REP process (Kilbourne *et al.*, 2007; Powell *et al.*, 2012). The multidimensional aspect associated with the different implementation strategies has been positively perceived along with this study. In particular, this study supports that stream of the literature according to which the use of multiple implementation strategies is perceived more effective than the use of a single strategy (Graham and Logan, 1998).

The definition of the strategies adopted is grounded on the guidance provided by Proctor and colleagues (Proctor, Powell and McMillen, 2013). More specifically, according to the Authors, the strategies adopted have to be defined operationally. At this purpose, they provided a list of attributes that should be discussed in order to specify the intervention in a granular way:

- the actor is the person/institution who delivers the implementation intervention;
- the action is represented by the steps performed;
- the action target represents the people/institutions at which the intervention is directed;
- the temporality is used to define the sequence of the strategy in use;
- the dose represents the dosage/intensity;
- the implementation outcome affected represents the feature(s) on which the implementation intervention has an impact;

- the justification represents the rationale behind the intervention.

The categories, the names, the definitions and the specifications of the transfer strategies adopted are presented in Table 6.6.

Category	Name	Definition	Specification
Pre-Conditions	Gather Info	Conduct local needs	Actor: Regional level
		assessment through the barriers and facilitators	Action: Develop a survey to assess local need through the identification of barriers and facilitators
			Action target: Professionals in the healthcare organizations in Lombardy Region
			Temporality: Before the Pre-Implementation phase
		(Powell <i>et al</i> 2012)	Dose: NA
		(10well <i>et al.</i> , 2012)	Implementation outcome affected: Acceptability, Adoption, Appropriateness, Feasibility
			Justification: Need to understand the state of the art
Pre-	Select	Develop a formal	Actor: Regional level
Implementation	Strategies	implementation roadmap by	Action: Identify methodologies that can be adopted to diffuse awareness and knowledge of the topic
			Action target: NA
		integrating multiple	Temporality: After the Pre-Conditions phase
		overcome identified	Dose: NA
		barriers (Powell <i>et</i>	Implementation outcome affected: Fidelity
		al., 2012)	Justification: Need to identify the most appropriate strategies for the purposes of the intervention
	Develop	Develop educational	Actor: Regional Level
	Materials	material (Powell et	Action: Design and formulate the materials that can be used for education purposes
		al., 2012)	Action target: NA
			Temporality: After the Pre-Conditions phase
			Dose: Once a month
			Implementation outcome affected: Acceptability, Adoption, Appropriateness, Feasibility,
			Penetration, Sustainability
T L ((*	T '.' .	T 1 1 C	Justification: Need to have detailed material for educational purposes
Implementation	Initiate	attate Train champions for	Actor: Regional level
	Leadership	various healthcare	Action: Organize regular meetings for the various healthcare organizations
		organizations	Action target: Professionals in the healthcare organizations in Lombardy Region
		(Powell <i>et al.</i> , 2012)	Desce Ones a month
			Dose. Once a monute Implementation outcome affected: Accentability Adaption Appropriateness Ecosibility
			Penetration Sustainability
			Justification: Need to disseminate awareness and knowledge of the topic through peers
	Educate	Distribute the	Actor: Regional level
		educational material	Action: Administration of the educational material prepared

		prepared (Powell <i>et al.</i> , 2012)	Action target: Professionals in the healthcare organizations in Lombardy Region
			Temporality: After the Pre-Implementation phase
			Dose: Once a month
			Implementation outcome affected: Acceptability, Adoption, Appropriateness, Feasibility, Penetration, Sustainability
			Justification: Need to disseminate awareness and knowledge through educational activities
	Educate	Influence	Actor: Champions/Leaders in the various healthcare organizations
	through	stakeholders through trained champions (Powell <i>et al.</i> , 2012)	Action: Indirect influence of stakeholders by champions
	Peers		Action target: Professionals in the healthcare organizations in Lombardy Region
			Temporality: After the Pre-Implementation phase
			Dose: NA
			Implementation outcome affected: Acceptability, Adoption, Appropriateness, Feasibility, Penetration, Sustainability
			Justification: Need to disseminate awareness and knowledge through peers
Maintenance	Develop	Build a network	Actor: Regional level
and Evolution	Relationships	(Powell <i>et al.</i> , 2012)	Action: Create opportunities for professionals in the healthcare organizations to share ideas and information
			Action target: Professionals in the healthcare organizations in Lombardy Region
			Temporality: During and after the Implementation phase
			Dose: Once a month
			Implementation outcome affected: Acceptability, Adoption, Appropriateness, Feasibility, Penetration, Sustainability
R			Justification: Collaboration could enhance sustainability of the innovation
	Restructure Strategies	Influence and modify implementation environment (Powell <i>et al.</i> , 2012)	Actor: Regional level
			Action: Issue a deliberation that could foster the diffusion of HTA in the territory
			Action target: HTA structure in the Region
			Temporality: NA
			Dose: NA
			Implementation outcome affected: Penetration, Sustainability
			Justification: Need to establish a context in which HTA can be easily performed

 Table 6.6 - Categories, names, definitions and specifications of transfer strategies adopted (Regione Lombardia, 2019)

6.2.5 Adoption and Use

The pillar "Adoption" refers to the results of the actions that are implemented to employ the innovation (Graham and Logan, 1998). The determination of the use of the innovation could be relevant for assessing the success of the transfer strategy. In particular, monitoring the adoption of the innovation could provide information about the ways through which the innovation has been adopted and/or adapted to local specificities. This information could help the modification of the existing transfer strategies or to select new ones in the future to maximize the transfer of the research. The implementation intervention strategy had two important outcomes in terms of adoption of the innovation. First, at individual level, awareness and knowledge of the topic were stimulated by the intervention. Second, at organizational level, the healthcare organizations established a committee for performing HTA activities.

6.2.5.1 Individual level

Awareness around the topic has been extensively expanded. The need to share the knowledge to the different levels of the healthcare system was recognized. In fact, all the potential stakeholders need to be informed and aware of the purpose and objectives of HTA activities. However, while awareness and knowledge are concepts in development, the engagement of people in performing HTA activities has to be forced. In fact, actually, the HTA activities are performed by a small range of people.

6.2.5.2 Organizational level

Adoption of the innovation at organizational level is represented by the extent to which the current practice has changed.

In line with previous studies, the structures of HB-HTA are heterogenous across healthcare organizations (Martelli *et al.*, 2017). However, a standard process is adopted in the area. More specifically, consistently with previous studies, HB-HTA process is performed in three different stages: the evaluation request form, the commission, and the final report.

6.2.5.2.1 Evaluation request form

As in other countries (e.g. France), the request of performing an HTA comes in the majority of the cases from a clinical practitioner (Martelli *et al.*, 2017). This is particularly relevant to ensure that the requested technology is based on a strong medical need. At the same time, the introduction of a new technology could affect the medical activity of the clinical practitioner, who needs to be trained in order to guarantee his/her engagement.

Therefore, the availability of having "well-defined profiles and skills for human resources, recruitment policies and career development plans are established" is among the guiding principles that can foster HB-HTA (Sampietro-Colom *et al.*, 2015, p. 102).

In addition, even if the practitioner is normally considered the initiator of the process, when the resources are insufficient, the Commission, or the Director of the Unit of the initiator should control the quality and the feasibility of the request made. In fact, as supported by previous studies, "the presence of an HB-HTA unit at a hospital tends to foster the formalisation of the process of adoption of health technologies. Consequently, hospitals with an HB-HTA unit usually have a better organised process of adoption of innovations. In this case, the clinician is recognised as the main initiator of the process of adoption" (Sampietro-Colom *et al.*, 2015, p. 45)

In addition, the initiator of the HTA process could be also represented by the Top Management team. Indeed, differently from previous studies (Sampietro-Colom *et al.*, 2015), high importance has been recognized for the alignment between the HB-HTA and the hospital's strategy. This implies that additional elements (e.g. the political and the strategic aspects) with respect to those widely recognized in the Literature (e.g. EUnetHTA Core Model) should be taken into consideration when developing HTA strategies at local level.

6.2.5.2.2 Commission

Despite the importance of the multidisciplinary aspect of the HTA process has been widely recognized in this study, in line with previous studies, some professional figures are mostly represented in the commission with respect to the others. More specifically, the Clinical Engineering, Medical Direction and Pharmacy represent the major figures that are involved in the commission. However, in line with previous studies, even if the "medical and clinical competencies are perceived as the most relevant" (Sampietro-Colom *et al.*, 2015, p. 49), there is a lack of training activities devoted to medical practitioners. Additionally, the nursing area, despite being considered among the factors that can foster collaboration between HB-HTA units and national or regional HTA agencies (Sampietro-Colom *et al.*, 2015), it is rarely included in the commission.

<u>6.2.5.2.3 Final report</u>

Consistently with previous studies, the features of the reports produced can vary according to a variety of issues. However, the type and the structure of the report do not vary according to the culture of the hospitals, as expected in previous studies (Sampietro-Colom *et al.*, 2015). Indeed, there is a strong recognition of the need of having the same structure in all the different healthcare organizations in order to be able to compare and contrast results and to, eventually, be able to adopt the evaluation conducted elsewhere.

In terms of dimensions evaluated, support is provided for methodologies allowing a 360-degree overview of the health technology, which are able, therefore, to consider different dimensions at the same time. The MCDA approach is adopted in Lombardy at regional level. However, the process has not been directly transferred to the hospital level since the development of the tool is currently ongoing.

The production of HTA reports emerged as a necessity to provide high quality tailored information to support decision-making process (Sampietro-Colom *et al.*, 2012). However, in order to be able to support decision-making, quality of the information should be controlled. According to previous studies, the quality of HB-HTA could be different and lower with respect to the one of HTA conducted at regional/national level (Sampietro-Colom *et al.*, 2012, 2015). On the other hand, at the same time, additional elements reflecting the context and the environment in which HTA is conducted should be possibly introduced in the model (Sampietro-Colom *et al.*, 2015). This study introduces discussion around quality and flexibility. Indeed, as for the composition of the commission, a tradeoff between these two concepts is introduced in order to simulate discussion on whether local HTA needs higher quality or flexibility. Despite the provision of high quality reports could contribute at the "improvement of transparency and consistency of HB-HTA reports" (Sampietro-Colom *et al.*, 2015, p. 76), it should be combined with the possible customization of the tool used.

Finally, no consensus has been achieved in terms of the typology of approach that can be adopted to finalize the report. While in unstructured healthcare organizations, a deliberative approach is mainly adopted, more structured healthcare organizations are adopting a tool with a mathematical approach. However, independently from the approach adopted, there is a consensus on the necessity to adopt a tool/process that could allow and promote deliberation but following a structured process.

6.2.6 Outcomes

The final element of the model is represented by the outcomes. In particular, it refers to the effects of using the evidence-based innovation (Graham and Logan, 1998), which, as advocated by previous studies, are not always expected and direct (Greer, 1988). Implementation outcomes are defined as "the effects of deliberate and purposive actions to implement new treatments, practices, and services" (Proctor *et al.*, 2011), and they are associated with three different functions: they are indicators for the success of the implementation, for the progress of the process, and of quality of research. Since the OMRU is based on the assumption that the objective of research use in healthcare is to improve outcomes for patients, the identification of strategies for improving the adoption is needed (Basinski, 1995; Davis and Taylor-Vaisey, 1997). At this purpose, the discussion of the previous elements allows the researcher to delineate and design a model that could be adopted in order to promote the diffusion of HB-HTA in different countries. Bases on the results that emerged from the analysis, the main outcome derived from this study is the elaboration of the model that is provided in Figure 6.1.



Figure 6.1 – Model for the diffusion of HTA

The model is intended to guide the diffusion of HTA on the basis of the results that emerged from this study.

More specifically, according to the results of this study, six different elements could impact the HTA development in the context of analysis. The discussion of each of the components of the model is provided below.

1 - Barriers

The barriers represent the element that could prevent the involvement of organizations in HTA activities. Based on the results of this study, the main barrier that should be faced by the organizations are related to the lack of resources (financial and human), specific HTA features that could undermine the appropriateness of the HB-HTA in specific settings, and the lack of knowledge.

2 – Perceptions

The perceptions represent the elements that should be considered before the involvement in HTA activities. They can affect the way in which HTA is perceived, and, consequently, the willingness of potential adopters to be involved in HTA activities.

According to the results of this study, the objective of HTA, the external support, the attitudes, and the acceptability are all factors that could affect perceptions of HTA.

3 – Enablers

Among the enablers there are the factors that are facilitating the involvement of organizations in HTA activities. More specifically, the factors that have been recognized as potentially being able to enhance involvement are the following: culture, training, mandate, engagement, opinion leaders/networking.

The enablers have the role to overcome the barriers, and to change the perceptions of potential adopters in order to favor the involvement in HTA activities.

4 – HTA Project

The fourth element is represented by the HTA Project. This pillar is grounded on the idea that HTA is a mere technical process, while the decision-making is a political process. Despite they are considered as two separate entities, with different purposes and requirements, they should be strictly connected in order to reduce the KTE gap. Therefore, each single HTA activity should be considered as part of a project, that is composed of two elements. First, the HTA process represents the steps through which the HTA activity is conducted. Results of this study affirmed that the classical process that is adopted in Lombardy is composed of three phases: the evaluation request form, the

commission, and the final report. In addition, the decision-making process is the process through which the (managerial) decision is taken based on the results of the HTA process.

5 – Requirements

The requirements represent the features that are requested for the HTA process to be more easily implemented. Those that have been recognized in this study are the following: clarity, simplicity, flexibility, transparency, vocabulary, monitoring, programming. Results of this study affirmed that if the HTA process possess these features, its acceptability and feasibility could be enhanced.

6 – Interactions

Interactions among different levels of analysis emerged as essential elements to be considered when developing a strategy for the diffusion of HTA. More specifically, the success of the implementation strategy is impacted by the networking activities and external collaborations. Interactions are expected between different levels (e.g. regional and local level) and between different entities of the same level (e.g. different healthcare organizations).

6.2.3 Conclusions of the OMRU

Results of this study demonstrated that there has been a growing interest towards HTA in the last years. As presented in Figure 6.2, three different stages for HTA development have been proposed in the development model of Battista and Hodge (Battista and Hodge, 2009).

The tailored implementation intervention has been initiated in the phase of emergence of HTA in Lombardy Region. This represents the phase in which needs are collected, champions identified, and focus on specific typologies of medical devices is performed. In addition, the scarcity of resources emerged also from the interview, such as the limited capacity. Consistently with previous studies, this is the phase in which the translation of knowledge produced is limited, and mainly personal communication is adopted to disseminate results. Therefore, relevance of the results obtained is provided for the specific settings of the emergence stage of HTA development.



Figure 6.2 - HTA developmental phases in Lombardy Region Source: Adapted from (Battista and Hodge, 1999, 2009)

HTA in Lombardy Region is now achieving a new level of maturity given the recent developments. This testifies the shift from the emergence phase to the consolidation one. As advocated by Battista and Hodge, this phase "marks the transition from HTA as a "venture investment" by health systems to an "operational feature"" (Battista and Hodge, 2009, p. 283). A more widespread recognition of the importance of the relevance of HTA, combined with a sign of success of the initial investments in HTA can justify the shift towards this second phase. The development of HTA tools, the expansion of the research team with the consolidation of expertise, and the reinforcement of the interdisciplinary nature of HTA characterize this phase.

The third phase represented in the model is the consolidation one. However, since it is characterized by a substantial increase in resources, diversification of products, and enlargement of the HTA scope, and Lombardy Region is not already prepared for that, this represents only a future development.

6.3 Conclusion

In this Chapter the discussion of the qualitative and quantitative results is provided. The discussion is guided by the OMRU theoretical framework, which has been used in previous studies to provide guidance for the implementation intervention.

Each element of the model is discussed separately.

First, practice environment was discussed to identify the elements of the external environment that could have influences on practitioners, researchers and policy makers, such as external pressures. In terms of inner settings, the structural, political, and cultural influences have been analyzed. First, this study provides support for the importance of the interactions among different levels of HTA. This is particularly relevant especially in countries with a decentralized healthcare system, where power to lower levels is enhanced (Saltman, Busse and Figueras, 2006). Second, the gap between the HTA process and the decision-making process is recognized as a limit in the implementation of HTA processes. Finally, the sharing of available knowledge and networking activities emerged as main activities for fostering cultural flourishment at individual level, while leadership, engagement, learning could be relevant in fostering organizational culture. The analysis of outer settings confirmed the presence of the lack of resources among the barriers that could prevent the involvement in HTA activities; it recognized the gap between HTA and decision-making process also at local level; and it stressed the importance of the establishment and the diffusion of an organizational culture on HTA. Second, the pillar related to the Potential Adopters stimulated dialogue on the knowledge and perceptions of potential adopters, and it allowed the identification of barriers and enablers that could affect the diffusion of HTA. The initial phase of the diffusion of HTA in Lombardy Region has been testified by the level of knowledge that has been observed both at individual and at organizational level. Lack of resources, lack of knowledge of the availability of HTA reports, and some of the HTA features are recognized among the barriers that could prevent the diffusion of HTA, while the building of a strong culture and competences, the mandate, the individual learning, the engagement and the availability of Champions/Opinion Leaders could help the involvement in HTA activities.

Third, with reference to the innovation, the analysis of the diffusion of its acceptability demonstrated that the multidisciplinarity has been widely recognized as an important feature of the HTA. In addition, the HTA process, mainly recognized as a technical process rather than political, should be grounded on scientific knowledge, and adapted to the different contexts. Additionally, the requirements that have been identified as factors needed to promote the HTA process are the following: clarity; simplicity; flexibility; transparency; HTA as a project; vocabulary; engagement; programming; and monitoring.

Fourth, different transfer strategies are adopted along with the intervention. Consistently with previous studies, strategies from four different stages have been implemented. First, the Pre-Conditions category allowed the identification of the information needed. Second, in the Pre-Implementation phase the strategies have been selected, and the material developed. Third, the Implementation phase is the stage in which the leadership is initiated, and professionals educated. Finally, the Maintenance and Evolution phase is aimed at developing relationships and restructuring strategies.

Fifth, in terms of Adoption and Use, the intervention helped for the enhancement of the culture and awareness of HTA both at individual and organizational level. More specifically, healthcare organizations adopted an HTA process that is composed of three phases: first, the evaluation request form is compiled in order to start the evaluation process; second, the commission discusses on the topic of interest; third, the final report with the recommendation is produced. However, the need to include this process in a bigger project, that could help the reduction of the KTE gap, has been widely recognized.

Sixth, the Outcome pillar allows the researcher to delineate a model that consider the results emerged from previous pillars and that can be adopted for the monitoring of the elements that can have an impact on the diffusion of HTA. At this purpose, six items have been identified: first, the barriers are the elements that could prevent the involvement of organizations in HTA activities; second, perceptions should be considered in order to understand the acceptability of the HTA in the settings in which it would be introduced/developed; third, the elements that could facilitate the involvement of organizations in HTA activities are discussed among the enablers; the features associated with the HTA Project are presented in the fourth pillar; fifth, requirements of the HTA process are relevant in order to increase the ease with which the process is implemented; sixth, interactions are vital to stimulate interest and sustain the adoption.

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Chapter 7: CONCLUSIONS

ABSTRACT

In this study, a mixed methods approach is adopted to analyze the factors that can affect the diffusion of HTA at different levels of analysis in Lombardy Region, in Italy. The Ottawa Model of Research Use (OMRU) is adopted as theoretical framework for guiding the discussion of the results emerging from the collection of quantitative and qualitative data. The aim of this Chapter is to present contributions in different streams of research, theoretical, policy, and practical implications that can be derived, and limitations and future research avenues that are associated with this study.

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7.1 Introduction

This study adopts a mixed methods approach (MMA) to analyze the factors affecting the diffusion of the HTA development in decentralized countries and to identify possible successful HTA designs at different levels of analysis. More specifically, the analysis is conducted in Lombardy Region, in Italy, where implementation strategies to diffuse HTA at different levels (regional and local) have been adopted. The theoretical framework that guides the analysis is the Ottawa Model of Research Use (OMRU), which allows the researcher to identify the barriers for the diffusion of the innovation, to design appropriate tailored strategies to overcome the barriers, and to monitor the implementation intervention. Despite many advancements have been done in the literature in the field of HTA, there are still areas which need further investigation. In particular, while the literature related to the description of the barriers and enablers of HTA is growing (e.g. Ehlers and Jensen, 2012; Oliver et al., 2014; Merlo et al., 2015), factors affecting the HTA development needs to be further investigated. More precisely, the perceptions of practitioners related to HTA development are rarely captured, even if they play a crucial role, especially when the analysis is conducted at local level (Hurst and Mickan, 2017). Previous studies identified a significant gap also in the analysis of the establishment of evidence advisory systems at national or sub-national levels by comparing countries according to their system (Parkhurst, Ettelt and Peters, 2018). More specifically, current literature lacks an indepth analysis of how evidence analysis activities can be implemented in healthcare systems characterized by decentralization (Ciani, Tarricone and Torbica, 2012). For the reasons aforementioned, this study is aimed at investigating factors that are affecting the development of HTA activities in decentralized countries. More specifically, perceptions of healthcare professionals are captured to identify possible HTA designs at local level. In common with applied research, contributions, implications, limitations, and future research avenues can be derived from this study. In order to discuss all of them, the remainder of this Chapter is organized as follows: Section two presents the contributions that this study has generated; in Section three the implications that can be derived by this study are discussed; Section four highlights the limitations and the future research avenues that can be derived from this study.

7.2 Contributions

Given the multidisciplinarity of the topic, this study provides contributions in different streams of literature.

This study contributes in advancing some knowledge in the HTA literature.

First, since there is still a lack of clarity in defining the concept of HTA and its objective, and this can cause situations of miscommunication and confusion, and that can lead to poor decision-making (Luce *et al.*, 2010), this study provides some insights in this sense. In particular, results of this study demonstrated that HTA objective is largely identified as a support tool for planning and budgeting decisions.

Second, this study advances some knowledge related to the identification of the requirements of the process of HTA (Hutton, Trueman and Facey, 2008; Kamae, 2010). In particular, HTA has been introduced as an innovation which allows the researcher to identify the (un-)acceptable features of the process. More specifically, it allows the identification of the specific features of the process that allow people involved in HTA to accept it more easily.

Third, this study advances some knowledge related to the identification of the barriers that are faced by HTA doers. The identification of the factors that prevent the involvement of HTA activities is particularly relevant to have the possibility to design a strategy to overcome the identified issues (Gagnon *et al.*, 2014).

Fourth, it contributes in advancing some knowledge related to the enablers that can foster the involvement in HTA activities. In particular, this allows to design strategies that can emphasize the relevance of the identified features (Cheung *et al.*, 2018).

Fourth, this study advances some knowledge related to the conceptualization of the HTA activities. In particular, the inclusion of HTA activities in a bigger project is desirable, according to this study, in order to shorten the gap between HTA and decision-making process. More specifically, results of this study suggest considering the HTA process as a project, in which the purchase is considered only a phase between the analysis of the organizational needs and the control feedback activities.

Finally, this study advances some knowledge related to the organizational and individual factors that can affect involvement in HTA activities (Drummond *et al.*, 2012). In addition to the need of wide-spreading culture and knowledge at individual level, mandate and resources are essential at organizational level.

This study contributes also to the HB-HTA literature.

First, it provides an in-depth analysis of the relationships between different levels of analysis of HTA. Indeed, according to previous research, there are benefits and drawbacks associated to both the sharing of ideas, methods, and data between different organizations and to the stand-alone conduction of the HTA process (Hutton, Trueman and Facey, 2008). At this purpose, it advances some knowledge related to the extent to which collaboration between different levels is embraced. Second, through the direct investigation with the healthcare organizations in the area of investigation, this study advances some knowledge related to the process of HTA performed at local level. Third, this allows also to capture the perceptions of healthcare professionals at local level. This is useful in order to advance some knowledge related to how HB-HTA is perceived and how it could be successfully implemented at local level (Hurst and Mickan, 2017). This study contributes also to the stream of literature related to the Knowledge Management. First, it allows to have a deeper understanding of the KTE in healthcare, and, more specifically, on how the knowledge is generated and used in the context of HTA. More specifically, it contributes in

advancing some knowledge related to the research uptake in the context of analysis.

Second, it advances some knowledge related to the identification of features that can reduce the KTA gap in healthcare.

Finally, this study contributes to the implementation research literature. Indeed, it provides some insights related to the application of implementation science in the context of healthcare, and, more specifically, in the field of HTA.

7.3 Implications

Theoretical, policy and practical implications can be derived by this study.

First, theoretical implications are discussed below.

This study contributes in supporting the relevance of the Mode 2 Knowledge production theory, in the context of healthcare, and, more specifically, in designing HTA processes. In particular, in this study, the principles of the theory (context of application, transdisciplinary, heterogeneity, heterarchical and transient, and socially accountable and reflexive) are emphasized (Gibbons *et al.*, 1994).

This study provides also support for the theories of organizational learning and knowledge management, since it provides support for the organizational learning as a different concept with respect to the sum of the individuals' knowledge (Garvin and Building, 1993; Grol *et al.*, 2007).

In addition, social network and influence theories are supported by this study (Grol *et al.*, 2007; Rogers, 2010). This implies that the relevance of becoming part of a network is particularly important for the adoption and new ideas and technologies, also in the field of HTA, and, therefore, it could be beneficial for the diffusion of the awareness of the usefulness of HTA.

Educational theories are supported by this study, as well (Norman and Schmidt, 1992; Mann, 1994; Merriam, 1996; Holm, 1998). In particular, according to the motivational theories, the attitudes to change are more positive when there is the necessity to change motivated by problems experienced in practices. Therefore, the introduction of an HTA process can be more positively approached when problems are faced in practice.

Finally, this study supports the "stage of change" theory, according to which changes occur continuously through a cyclical process, that has to be sustained over time (Prochaska and Velicer, 1997). This implies that long term interventions should be designed in order to sustain change and avoid the relapse.

Second, policy implications can be derived from this study, as well.

First of all, the relevance of the relationships between different levels of analysis (e.g. regional and local) implies the need for a design of an HTA system that foresees collaborations among them.

In addition, this study provides support for the demand for constant learning and engagement (Ferlie and Shortell, 2001). This implies that policies aimed at constantly training and educating professionals involved in the evaluation process could sustain the diffusion of HTA in the long term. Finally, the gap between HTA process and decision-making process has been observed in the study. This underlines the need to have policies that could combine the HTA and the decision-making process in a single project in order to reduce the gap. Third, practical implications that are derived from this study are discussed below.

By investigating the perceptions of the healthcare professionals, this study advances some knowledge related to the requirements of the HTA process. More specifically, this implies that the elements that have been identified as supportive for the widespread of HTA should be included in the daily practices.

The relevance of local needs has been largely supported by the study. This implies that the process of HTA should be adapted to the local requirements.

This study underlines the importance of the identification of the barriers and the enablers. Therefore, before starting a new implementation intervention, it is particularly relevant to identify the barriers that can prevent the involvement in HTA process in defined settings, and the factors that can overcome these barriers.

Finally, the collaboration has emerged as important feature to reduce the knowledge waste (Moharra *et al.*, 2017). Therefore, fostering the involvement in networks is important in order to share knowledge and experiences, from which other individuals and/or organization can benefit.

7.4 Limitations and Future Research

In common with applied research more generally, this study is not without limitations, which can open interesting avenues for future research.

First, this study has been conducted in Lombardy Region, in Italy. Despite the peculiarities of the area are notably relevant for analyzing the diffusion of HTA, and factors affecting it, this allows to have a view of the research problem limited to the area of investigation. It would be fruitful, for future research, to explore the same research problem in different contexts. More specifically, the focus of the analysis is on a country with a decentralized healthcare system. Therefore, future research could also extend the analysis to other types of countries, in order to analyze whether similar results could be found in settings different from those of Lombardy Region.

In addition, despite previous studies called for research in decentralized countries (e.g. Ciani et al., 2012), a comparison between centralized and decentralized countries could be interesting for future studies in order to analyze whether the HTA requirements are dis(similar) in different settings.

Third, different typologies of healthcare organizations are included in the study. Since the specific items and issues that can drive HTA decisions across different typologies of healthcare organizations can considerably vary, these differences should be addressed when implementing HTA processes in different realities. A more in-depth analysis of the reasons that could drive the involvement in HTA activities, by focusing of the different features of healthcare organizations, could be interesting for future research avenues.

Fourth, this study suffers from the limited knowledge of the relative effectiveness of using conceptual frameworks in KTE interventions, such as the OMRU. Indeed, given the theoretical pluralism advocated by this framework (Midgley, 2011), this is related to the limited ability to compare published literature because of the limited availability of methodological comparison (LaRocca *et al.*, 2012).

Fifth, a further limitation of this study is related to the missing perspective of perceptions of regional level through direct interviews. Indeed, the management of HTA process at regional level has been detected only indirectly, through the analysis of the deliberations upon which the healthcare system is based. Direct interviews of the people operating at regional level may have been able to offer a different view of the research problem.

Sixth, additional perspectives of perceptions at local level could have been included in the analysis, too. Indeed, since some people refused to take part at the survey, perceptions of some relevant stakeholders have been not been captured in this study. Further research could be conducted in order to better investigate the research problem considering additional perspectives.

Seventh, some limitations related to the quantitative portion of this study can be detected, too. In particular, despite the nonresponse bias has been tested, other bias could characterize the results to the survey. More specifically, quantitative data have been collected through a mechanism that allows for privacy in order to reduce the "tendency of research subjects to choose responses they believe are more socially desirable or acceptable rather than choosing responses that are reflective of their true thoughts or feelings" (Grimm, 2010, p. 1), but the possibility of a social desirability bias could not be totally excluded.

Furthermore, this study does not perform a multilevel analysis. Further research could pursue this line of research by using data at individual and organizational level in order to check for independent effects of the organization of the outcome variable, over and above the individual effect. This would be particularly relevant to estimate intra-class correlation coefficient.

Finally, since part of the study is partially based on qualitative data, common limitations of the qualitative studies can be associated with this study. In particular, along with this study, despite triangulation of different sources has been performed, investigator triangulation was not possible since the research has been conducted by a single researcher. More specifically, all the coding process has been conducted by a single researcher and, therefore, limitations related to the possible interpretations are associated to this study. However, previous research affirmed that this is considered sufficient and preferred because the researcher acts as the main instrument of the analysis (Bradley, Curry and Devers, 2007).

Furthermore, despite this study includes also quantitative results, it is complemented with qualitative data, which emphasizes an in-depth investigation of a limited number of cases. Therefore, the purpose of this study is not the generalizability of the findings, but, instead, the perception of the interviewees about the research problem. The lack of generalizability is also demonstrated by the fact that perceptions of respondents are related to the implementation intervention occurred, and, therefore, highly context- and experiences- dependent. Therefore, this study heavy relies on the experiences, opinions and perceptions of people who took part at the survey. This implies that they could be biased by the situation in which respondents rely and by the way in which they experienced and observed the events. However, drawing on previous research (Mays and Pope, 1995; Hoddinott and Pill, 1997; Seale and Silverman, 1997; Mauthner, Parry and Backett-Milburn, 1998; Popay, Rogers and Williams, 1998; Kitto, Chesters and Grbich, 2008; Mauthner and Doucet, 2009), different methods have been adopted to ensure rigour and reflexivity of the study.

An additional limitation is represented by the lack of consideration of political influences that can be exerted at different levels of analysis. Indeed, as supported by previous studies, it is "not possible to separate policymaking from politics" (Parkhurst, Ettelt and Peters, 2018, p. 8). Therefore, future

research can be conducted in order to have a better understanding of if and how politics can influence HTA process.

7.5 References

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APPENDIX

Appendix 1 – Survey questions

AREA	ID	QUESTION					
	Q1	Age					
Diagraphical	Q2	Sex					
	Q3	Organization of affiliation					
biographical	Q4	Professional Area					
mormation	Q5	Length of service					
	Q6	Membership of an HTA network					
	Q7	Which HTA network?					
	Q8	Which is your level of knowledge of HTA?					
	Q9	Are you aware of the availability of guidelines for performing HTA?					
	Q10	Are you aware of the existence of the following HTA agencies?					
	Q10(a)	EUnetHTA					
	Q10(b)	EUROSCAN					
	Q10(c)	HTAi					
	Q10(d)	INAHTA					
	Q10(e)	SIHTA					
	Q11	According to you. how important are the following issues related to the					
		health technologies?					
	Q11(a)	Identification of clinical and technological innovation					
	Q11(b)	Identification of health needs					
	Q11(c)	Information related to the commercialization of drugs and technologies					
	Q12	How do you judge your access to the following information related to					
		HTA?					
	Q12(a)	Identification of clinical and technological innovation					
	Q12(b)	Identification of health needs					
Knowledge	Q12(c)	Information related to the commercialization of drugs and technologies					
itilowicuge	Q13	Is there in your organization a hospital library service?					
	Q14	Are you aware of the publication of new reports?					
	Q15	Would you be informed about the publication of new reports?					
	Q16	How frequently do you consult the following sources?					
	Q16(a)	Governmental publications					
	Q16(b)	University papers					
	Q16(c)	Consulting groups' reports					
	Q16(d)	Community organizations' reports					
	Q16(e)	Professional Journals					
	Q16(f)	Scientific Journals					
	Q16(g)	Monographies and books					
	Q16(h)	Documentation from the pharmaceutical industry					
	Q17	Do you know if your organization uses an explicit process for the					
		identification of priorities?					
	Q18	Do you know the criteria that your organization uses to identify the					
		priorities?					
	Q19	Which are the criteria used by your organization to identify the					
		priorities?					

	Q20	Have you ever participated to HTA processes?				
	Q21	How many times?				
	Q22	Which kind of technology have you evaluated?				
	Q23	How many professionals were involved?				
	Q24	At which professional area did the involved professionals belong to?				
	Q25	Which kind of HTA products have you contributed to produce?				
	Q26	The assessment of comparative efficacy was based on the available				
Experience		scientific documentation?				
	Q27	For which kind of decision have been used the HTA reports produced?				
	Q28	Does your organization use the HTA reports produced?				
	Q29	Does your organization one of the following activities?				
	Q29(a)	HTA activities coordination				
	Q29(b)	Reimbursement decision making on the basis of HTA reports				
	Q29(c)	HTA activities				
	Q29(d)	Other				
	Q30	According to you. which is the objective of HTA?				
	Q30(a)	Health needs assessment				
	Q30(b)	Guidelines definition				
	Q30(c)	Planning and budgeting				
	Q30(d)	Pricing				
	Q30(e)	Quality indicators of healthcare treatments definition				
	Q30(f)	Other				
	Q30(g)	I do not know				
	Q31	Do you think that the following typologies of knowledge are relevant				
		in taking decisions?				
	Q31(a)	Experts' opinions				
	Q31(b)	Professionals experiences (own and of colleagues)				
	Q31(c)	Experiences of other organizations				
	Q31(d)	Opinions of specific individuals (patients)				
	Q31(e)	Analysis of political situation				
Beliefs.	Q31(f)	Scientific evidence				
awareness	Q31(g)	Sociological and anthropological knowledge of the problem				
and	Q31(h)	Market analysis				
attitudes	Q32	Which are. according to you. the main barriers to the production of				
		HTA reports?				
	Q32(a)	Resources availability				
	Q32(b)	Information availability				
	Q32(c)	Knowledge of methodologies				
	Q32(d)	Qualified human resources				
	Q32(e)	Other				
	Q33	Which are. according to you. the main barriers to the use of HTA				
		reports?				
	Q33(a)	Awareness of the importance of HTA				
	Q33(b)	HTA institutionalization				
	Q33(c)	Political authorities mandates				
	Q33(d)	Political support				
	Q33(e)	Qualified human resources				
	Q33(f)	Other				
	Q33(g)	I do not know				

Q34	Which is your judgement about the following topics?
Q34(a) The objective and the aim of HTA should be explicit and relevant for
	their use
Q34(b) HTA should be a transparent and unconditional process
Q34(c) HTA should include all relevant technologies
Q34(d) A clear system for the definition of priorities for HTA should exist
Q34(e) HTA should include all the appropriate methods for the evaluation of
	costs and benefits
Q34(f	HTA should consider a wide range of outcome and evidence
Q34(g) A complete social perspective should be included in HTA
Q34(h) Uncertainty should be evaluated
Q34(i)	Transferability and generalizability of HTA products should be
	guaranteed
Q34(1)	All the stakeholders should be actively involved
Q34(n	h) All the available data should be considered
Q34(n) The implementation of HTA results should be monitored
Q34(o) HTA should be timely
Q34(p) HTA results should be appropriately communicated to different
	decision makers
Q34(q) The connection between HTA and decision making process should be
	transparent and clearly defined

Appendix 2 – Interview Protocol

	PRE-INTERVIEW						
	Select potential respondents						
	Identify each potential respondent with a code. called Respondent Identified						
Contact with potential respondents via email or phone							
Select time and place for the interview with those potential respondents willing to participate							
	Share the questions of the interview with the potential respondents willing to participate						
	INTERVIEW						
Introductory	I would like to thank you for agreeing to participate in this research study.						
Questions	Before starting the interview. I would kindly ask you to complete this Written Consent for the treatment of data. If during the interview you would like me						
Questions	to turn off the recorder. just let me know. please.						
	Please feel free to stop me and ask me any questions at any time during the interview. It will be a pleasure for me to answer your questions.						
	As I already mentioned to you. the aim of my study is to have a better understanding of factors affecting HTA development. with a particular focus on the						
	interactions between different levels of analysis.						
Transitory	At this purpose. this interview is designed to capture your experiences and feelings about local HTA in Lombardy and. more specifically. in your						
Questions	organization. The semi-structured questions allow you to elaborate on how you experienced the implementation intervention proposed in the Region. and						
Questions	how future interventions can be designed.						
	As you may know. the interview is outlined on the basis of questions related to the implementation outcomes identified by Proctor and colleagues as						
	elements to be monitored in order to have a better understanding of implementation intervention introduced in the context of analysis.						
	KNOWLEDGE - ADOPTION						
	o First of all. I would like to ask you a few questions about your previous experience: what level of HTA knowledge do you have? If you have had previous						
	experience. can you tell me about it?						
	o For what it concerns your company. can you tell me if there is a unit that deals with health assessments? How is the assessment performed locally? What						
	are the links between the various levels of evaluation: local. regional and national?						
	ACCEPTABILITY						
Kan Ou actions	• Do you think that the health technology assessment process, carried out at various levels of analysis (national, regional and local), can be considered as a valid suggest tool?						
Key Questions	valid support tool?						
	• Are you aware of an ITTA assessment, carried out at national. regional of company level, that was used in your organization for the purchase of an nearth the decision making process?						
-	• Can you provide me with an example of an evaluation that modified the practical process in the clinic, such as, for example, reviewing an assisted						
	diagnostic-therapeutic pathway ("Percorso diagnostico-terapeutico assistenziale" (PDTA))?						
	APPROPRIATENESS						
	• What do you think about carrying out this activity in your organization?						
	• What do you think about the collaboration established with the Lombardy Region and / or at national level?						
	FEASIBILITY						
	• How can the health technology assessment process be successfully implemented in your organization?						

	 What are the predisposing factors you need? 					
	• Did you. or your company. participate in network activities? Do you think your company is ready to participate? Is it an activity of your interest?					
	LOYALTY					
	• In the Lombardy Region. the assessment of health technology is regulated by Law 23 of 2014. Subsequently. commissions were appointed for the					
	authorization of investments in large equipments and for the preparation of regional decisions on the use of diagnostic and interventional devices.					
	Subsequently a network of evaluators was composed. In your experience, has this path carried out in the Lombardy Region provided (or will provide) any					
	benefit to your company? If yes. in which cases? Otherwise. do you believe that this can damage or reduce the ability to take informed decisions? If so.					
	how can it help to improve the process? What kind of changes could the Region suggest for an implementation in the near future?					
	COST OF IMPLEMENTATION					
	• Regarding the economic impact: do you believe that the introduction of the Deliberation of 2019. limited to the indications related to the HTA topic. will					
	provide any change in your company and/or at the different levels of analysis?					
	PENETRATION					
	• Has the HTA assessment of medical devices and equipment been integrated into your organization's practices?					
	How does your organization's medical device commission work. if any?					
	SUSTAINABILITY					
	• Has any activity been implemented to support the development of the evaluation process in your company? Do you think it could be institutionalized in					
	the future?					
Classics	Before concluding this interview. is there something about your experience that you think would be relevant in identifying factors affecting local HTA that we had not discussed yet?					
Closing	Thank you again for the time you dedicated to complete this interview.					
Questions	Your experience and feelings are important for encouraging and supporting the rise of local HTA in the context we are living. The interview will be					
	transcribed and analyzed. I will contact you after the analysis of the results of this study to inform you about the conclusions of the study.					
	POST-INTERVIEW					
	Contact respondents to express gratitude for their participation					
	Send a reduced version of the interpretation of collected data to respondents. giving them the opportunity to comment (Member checking)					
	Collect comments from respondents willing to give a feedback on the interpretation of the collected data by the researcher					
	Adjust results and conclusions according to the comments received					
	Send a reduced version of results and conclusions to respondents					

Appendix 3 - Most recurrent criteria listed by respondents

Most recurrent criteria listed by respondents				
Multiple criteria decision analysis				
Cost-effectiveness analysis				
Cost-benefit analysis				
Economic evaluation				
Safety				
Obsolescence				
Clinical need				
Appropriateness				
Urgency				

	Knowledge		Experience		Lack of Awareness	
Research Variable	Pearson	Adjusted	Pearson	Adjusted	Pearson	Adjusted
01 Age	<i>Chi2</i>	<i>p-value</i>	<i>Chi2</i>	<i>p-value</i>	<i>Chi2</i> 5 5420	<i>p-value</i>
QI - Age	/./034	0.3090	70.0635	0.0030***	3.3420	2.4000
Q2 -Sex	49.2401	0.4300	10.9509	0.0000***	52.2475	2.4090
Q3- Organization	4.6661	0.2910	19.8508	0.0000***	5.6453	0.1//0
Q3 - Type of Organization	5.0048	0.0750	3.6902	0.1650	0.3846	1.6050
Q4 - Professional Area	7.4847	0.3360	27.1261	0.0000***	19.0732	0.0030**
Q5 - Length of service	11.1344	0.1470	15.3797	0.0270*	3.2050	2.0040
Q6 - Membership to HTA networks	4.2011	0.3660	18.1604	0.0000***	5.3677	0.2040
Q9 - Guidelines knowledge	6.4099	0.1230	61.3612	0.0000***	116.9752	0.0000***
Q10 - Agencies knowledge	42.6899	0.0840	91.1269	0.0000***	69.4619	0.0000***
Q11(a) - Importance 1	3.1126	1.6170	3.8065	1.2990	9.4564	0.1530
Q11(b) - Importance 2	3.0846	1.6320	1.4835	2.4900	11.2678	0.0720
Q11(c) - Importance 3	5.3121	0.7710	3.2464	1.5510	5.1505	0.8160
Q12(a) - Access 1	4.5886	0.9960	15.9543	0.0090**	30.4993	0.0000***
Q12(b) - Access 2	8.0874	0.2640	4.3089	1.0980	32.6510	0.0000***
Q12(c) - Access 3	6.5366	0.4860	4.4751	1.0380	27.3962	0.0000***
Q13 – Hospital library service	2.4142	0.8970	3.6276	0.4890	5.2959	0.2130
Q14 - Report publication	1.4437	0.6900	29.9525	0.0000***	21.9835	0.0000***
Q15 - Report publication awareness	1.0611	1.7640	2.6183	0.8100	7.2914	0.0780
Q16(a) - Frequentation 1	1.1652	2.6520	6.1877	0.5580	10.9723	0.0810
Q16(b) - Frequentation 2	2.8487	1.7490	3.3838	1.4880	7.2131	0.3750
Q16(c) - Frequentation 3	3.2003	1.5750	6.8454	0.4320	13.0931	0.0330*
Q16(d) - Frequentation 4	3.4812	1.4430	14.2288	0.0210*	9.7767	0.1320
Q16(e) - Frequentation 5	3.1426	1.6020	6.5681	0.4830	7.4637	0.3390
Q16(f) - Frequentation 6	4.8006	0.9240	17.1814	0.0060**	5.5443	0.7080
Q16(g) - Frequentation 7	4.0907	1.1820	18.5300	0.0030**	7.3750	0.3510
Q16(h) - Frequentation 8	1.2433	2.6130	3.0713	1.6380	3.3322	1.5120
Q17 - Explicit process used by organization	0.0119	2.7390	8.6483	0.0090**	10.1717	0.0030**
Q18 - Criteria used by organization	0.5858	1.3320	23.0146	0.0000***	19.9740	0.0000***
Q28 - Use of reports by organization	2.9970	0.6690	17.4641	0.0000***	14.0163	0.0030**
Q29 - Involvement of organization	5.2898	0.0630	45.8647	0.0000***	22.9156	0.0000***
Q29(a) - Activity 1	0.2652	1.8210	3.4210	0.1920	2.0985	0.4410
Q29(b) - Activity 2	0.1035	2.2440	0.0002	2.9670	0.1491	2.0970
Q29(c) - Activity 3	8.6538	0.0090**	43.2630	0.0000***	14.1799	0.0000***

Q29(d) - Activity 4	12.0126	1.3350	17.3650	0.4080	3.1338	2.9850
Q30(a) - Objective 1	1.5239	0.6510	2.6944	0.3030	0.0994	2.2590
Q30(b) - Objective 2	0.3074	1.7370	4.6616	0.0930	3.0599	0.2400
Q30(c) - Objective 3	2.5661	0.3270	11.4524	0.0030**	3.3383	0.2040
Q30(d) - Objective 4	0.4019	1.5780	0.3889	1.5990	2.2392	0.4050
Q30(e) - Objective 5	0.4780	1.4670	0.8519	1.0680	0.0326	2.5710
Q30(f) - Objective 6	0.0031	2.8650	0.0613	2.4150	0.0441	2.5020
Q30(g) - Objective 7	12.1222	1.5540	20.0245	0.2850	3.6809	2.9820
Q30(h) - Objective 8	3.1698	0.2250	1.2255	0.8040	12.0688	0.0030**
Q31(a) - Knowledge 1	4.7919	1.3260	3.3667	1.9320	4.3324	1.5090
Q31(b) - Knowledge 2	8.8077	0.3510	14.5387	0.0390*	9.6115	0.2610
Q31(c) - Knowledge 3	4.2781	1.1100	5.8110	0.6420	1.2000	2.6340
Q31(d) - Knowledge 4	8.8401	0.3480	9.9196	0.2340	9.9034	0.2340
Q31(e) - Knowledge 5	6.7087	0.7290	7.2310	0.6120	1.7476	2.6490
Q31(f) - Knowledge 6	3.3489	1.0230	3.6479	0.9060	11.2009	0.0330*
Q31(g) - Knowledge 7	2.6090	2.2800	4.4612	1.4550	6.0665	0.9000
Q31(h) - Knowledge 8	6.0206	0.9120	2.6013	2.2830	6.5517	0.7680
Q32(a) - Barriers production 1	1.1553	0.8460	7.9490	0.0150*	3.4092	0.1950
Q32(b) - Barriers production 2	0.0096	2.7660	0.0570	2.4330	0.0218	2.6490
Q32(c) - Barriers production 3	0.3892	1.5990	0.2709	1.8090	1.8693	0.5160
Q32(d) - Barriers production 4	0.1738	2.0310	0.0069	2.8020	0.3776	1.6170
Q32(e) - Barriers production 5	10.1175	1.2900	14.4556	0.4590	6.2641	2.3790
Q33(a) - Barriers use 1	0.4315	1.5330	3.7792	0.1560	1.8996	0.5040
Q33(b) - Barriers use 2	0.1754	2.0250	3.2352	0.2160	6.5358	0.0330*
Q33(c) - Barriers use 3	0.2537	1.8420	6.2091	0.0390*	4.7911	0.0870
Q33(d) - Barriers use 4	3.0978	0.2340	3.4029	0.1950	0.0123	2.7360
Q33(e) - Barriers use 5	1.6288	0.6060	2.6160	0.3180	0.0557	2.4390
Q33(f) - Barriers use 6	4.9624	1.2600	4.0932	1.6080	4.9879	1.2510
Q33(g) - Barriers use 7	3.1008	0.2340	0.1957	1.9674	7.2802	0.0210*
Q34 (a) - Judgement 1	2.1064	2.1480	6.6530	0.4650	4.4039	1.0620
Q34 (b) - Judgement 2	2.1564	1.6230	1.4968	2.0490	4.5828	0.6150
Q34 (c) - Judgement 3	1.0737	2.3490	4.6626	0.5940	3.2492	1.0650
Q34 (d) - Judgement 4	1.6225	2.4150	1.8499	2.2890	1.9817	2.2170
Q34 (e) - Judgement 5	4.1554	1.1550	1.2009	2.6340	2.8587	1.7460
Q34 (f) - Judgement 6	3.7892	1.3050	0.1174	0.5730	1.4322	2.5170
Q34 (g) - Judgement 7	7.4200	0.1800	13.5471	0.0120*	0.9832	2.4150
Q34 (h) - Judgement 8	3.2260	1.5630	2.8978	1.7250	2.7064	1.8240
Q34 (i) - Judgement 9	5.3100	0.7710	4.4038	1.0620	3.0259	1.6620

Q34 (1) - Judgement 10	3.0356	1.6560	4.9245	0.8850	12.5524	0.0420*
Q34 (m) - Judgement 11	2.9053	1.2180	3.1655	1.1010	2.4649	1.4460
Q34 (n) - Judgement 12	2.4545	1.9590	3.9492	1.2390	1.4505	2.5050
Q34 (o) - Judgement 13	12.0975	0.0510	15.7327	0.0090**	1.7846	2.3250
Q34 (p) - Judgement 14	4.0840	0.7590	6.0970	0.3210	9.3277	0.0750
Q34 (q) - Judgement 15	1.1010	2.3310	4.7107	0.5820	7.0317	0.2130
***p<.001. **p<.01. *p<.05.						