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An investigation of the use of ICT in the modernization of the health care sector: a comparative analysis

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To my Mum…

She always encouraged me,
throughout these years, recalling
"Volli, sempre volli, fortissimamente volli"
(V.Alfieri,1783)

ACKNOWLEDGEMENT

DECLARATION

I declare that this is my own work

Signed:………………………….

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ABSTRACT

This Ph.D project started from a broad analysis aiming at investigating the key issues in the development of Information and Communication Technologies (ICT) in the health care sector, with the aim of making an in depth investigation to evaluate the effects of Electronic Medical Record (EMR) implementation on the organizations adopting them. Furthermore the study examined two study settings which have adopted the same EMR system produced by the same provider. This comparative study aims, in particular, to analyse how EMR systems are adopted by different health organizations focusing on the antecedents of the EMR project, on the implementation processes used and on the impacts produced. Diffusion theory, through the lens of socio-technical approach, represents the theoretical framework of the analysis.

The research results are based on policy evaluation and case studies. The two hospitals selected for the case study analysis are the Regional Hospital of Local Health Authority in Aosta, Italy and the Royal Infirmary of Edinburgh, Scotland. In conducting the data collection several strategies have been used: documentary analysis, interviews and observations have been carried out.

This work provides an overview of the key issues arising over e-health policy development through a comparative analysis of the UK and Italy and provides an insight into how EMR systems are adopted, implemented and evaluated within acute care organizations. The thesis is a comparative international research about the development of e-health and the use of ICT in health care sector. This approach makes a both a theoretical and methodological contribution. By

focusing, in particular, on EMR systems, it offers to practitioners and policy makers a better basis of analysing ICT usage and its impacts on health care service delivery.

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"Developing a comprehensive medical information system is a more complex task than putting a man on the moon had been"

(Morris Collen, 1995 1: 464)

CHAPTER 1

INTRODUCTION

Information and Communication Technology (ICT) has improved efficiency and quality in many sectors of the economy and made a considerable contribution to the modernization of public administration at all levels (Hendrick 1994; Heeks, 1999). This is also true in the case of health care, where technologies are helping to transform the sector with the introduction of new medical technologies, evidence-based medicine and new financial models (Vikkelsø, 2007). Electronic medical and patient record systems, in particular, are "predicted to change and improve health care" (Kazley and Ozcan, 2007). Some literature on the adoption and the impact of technology on service delivery by public organizations (Kraemer and King, 1977; Griessemer, 1983; Klay, 1988; West, 2005) has shown that the effective adoption of ICT has changed over the years, as technology has evolved, and its incidence among organizations has grown and become more pervasive (Hendrick, 1994).

However, health care professionals and organizations have found that they do not always have adequate systems to deliver strategic change. To remain competitive, health care professionals and organizations are looking to information technologies for help. According to Eng (2001), the adoption and implementation of ICT in the health care sector is developing much more slowly compared to other sectors, such as finance and commerce. This is due to several impediments observed by Ganesh (2004). These include the continuing lack of awareness

among patients of the availability of online access to specialist knowledge or the legal issues implicated by the use of electronic communications in medicine. In practical terms, although some ICT systems are already in place in the healthcare sector for the execution of administrative tasks, such as billing, scheduling and inventory management, there is scant adoption of extensive integrated clinical information systems. Although some of these factors persist to a certain extent, greater computer literacy (Norris and Moon, 2005) in the general population, the availability of communication infrastructures and changes in government policies and increased support for clinical computing in particular, suggest that this trend is changing and will continue to do so in the coming decade.

Such considerations are substantiated by previous studies focusing on the level of adoption of ICT tools by the health care systems in different EU countries, both at general practice level and at acute hospital level. Continuity of care and effectiveness of health care policies can be achieved at regional and European levels if the main actors of the care processes share information on their patients' history. Hospitals around Europe have been introducing electronic medical record systems, to keep track of their patients' records and to facilitate the administration of prescriptions. Assessing the diffusion of ICT among the latter becomes paramount for stimulating the creation of longitudinal patient summaries that might contribute to more efficient health care processes for individuals and more effective health policies. To this end, understanding the use, diffusion and degree of pervasiveness of ICT among acute care organizations sets the grounds for depicting the nature and direction of new trajectories in health care practices based on a more comprehensive and informed basis for decision making.

1.1 The aim and scope of this research

The main purpose of the study is to *identify* the key issues in the development and implementation of e health and to *evaluate* how the adoption of EMRs influences delivery of health care services in hospitals, analysing how these systems affect the organization and the operations of its main users and stakeholders.

This purpose is addressed by two types of motives: *academic* and *social.*

- the primary reason is the desire to fill a gap in literature in terms of systematic comparative international research into the evaluation of the impacts of IT, EMRs in particular, by making a theoretical and methodological contribution;
- the study also aims to contribute to the development of advice for public decision makers by offering a better basis for practitioners and the policy makers involved in the health care sector for an analysis of IT usage and its impacts on service delivery.

1.2 Structure of the thesis

This thesis is divided in 10 chapters. Chapters 2 to 5 illustrate the background of the research in terms of literature, the theoretical framework and methodological perspective.

Chapters 2 and 3 provide an overview of literature and past studies focusing on the relevance and use of Information and Communication Technologies. Chapter 2 looks specifically at issues relating to the adoption of ICT within the public

sector and the health care sector. Chapter 3 examines specific ICT use within health care organizations: Electronic Medical Record systems and the impacts produced by them.

Chapter 4 provides an overview of the theoretical framework of the study. It looks at innovation and the Diffusion Theory in greater detail and how it may help us interpret and understand the spread of innovations within the health care sector. We also applied the lens of the social-technical approach for this analysis in order to identify all the relevant aspects associated with this study: "technical aspects" that have to be balanced with the "social aspects" of the development of a system (Berg, 2003).

Chapter 5 illustrates and discusses the research methodology adopted and the data collection methods selected for the analysis, to answer the research questions identified and to address the research aims of the study. This includes especially the use of Actor Network Theory (ANT) as an analytical technique where the researcher follows actors and seeks to understand what they do. This represents a valuable means of understanding and recognizing complex realities.

Chapters 6 to 8 present our findings. Chapter six presents the results of the documentary analysis of publicly available data aimed at identifying the policies and acts marking the development of e-Health over the last 10 years in different geographical and cultural contexts. The analysis moved from the broadest, or supranational level represented by the European Union and then analyzed both the national (UK and Italy) and local contexts (Scotland and the Aosta Valley).

Chapters 7 and 8 present the case study results. These are the of Valle D'Aosta Regional Hospital and the analysis of the case study setting of Royal Infirmary of Edinburgh .

Chapter 9 discusses some ethical and privacy issues related to EMR adoption recurring at both study sites.

Chapter 10 draws the findings of this study together and considers the policy and managerial implications concerning the promotion of e-health and relating to the adoption, implementation and evaluation of EMR systems in particular, and then presents the contributions of this thesis in terms of its theoretical, methodological and practical contribution and also highlights any limitations of the study and how they have been addressed.

The thesis, in fact, contributes in several ways:

- Firstly, it contributes to existing literature on e-health with regard to the research context and the specific focus of the adoption, implementation and evaluation of EMRs.

- Secondly this work makes a *theoretical contribution* in relation to the use of the social-technical approach to the investigation of the diffusion of innovation through the different stages of adoption, implementation and evaluation by studying how two different organizations went about introducing the same EMR system.

- Thirdly the *research perspective* that marks this research project from a methodological point of view, draws on the Actor Network theory, while the dominant perspective of information and communication technology studies has generally been marked by the positivist tradition (Kauber, 1986), which stresses the adoption of previously defined model -

controlling variables and testing hypothesis.

- Lastly, this research contributed to the development of advice for public decision makers since it helped identify which processes are most valuable for the implementation of innovation within health care organizations and how the processes may be enhanced.

CHAPTER 2

E-HEALTH: FROM VISION TO PRACTICE.

A critical examination of literature on the adoption and implementation of ICT in the healthcare sector.

This chapter conducts a review of recent academic literature on e-health, in terms of both *formulation* and *implementation*. It initially explores the concept of "innovation" in the public sector in the broadest sense and subsequently examines literature on the formulation and implementation of e-government policies, focusing on the e-health adoption and implementation process in particular.

2.1 Introduction

No analysis of the innovation process in the public sector can be conducted without considering the framework within which they have taken place. In recent years, the importance of information technology has gradually increased and attention has shifted to the role it plays in modernizing the public sector. The need for a new model of public administration and a new way of governing, connected with the growing role of ICT, has even led some scholars to support the American concept of a "Virtual State" where "the internet and a growing array of information and communications technologies fundamentally modify possibilities for organizing, work, business and government. As a revolutionary technology, the internet provides the technological potential to influence the

structure of the State as well as the relationship between state and citizens" (Fountain, 2001). Historically speaking, public agencies operated in an environment characterized by high regulatory restrictions and political "must-dos" (Greenhalgh, Robert et al. 2004) enforced by external institutions (such as higher levels of government and supra-national organizations). Their fiscal capacity has been limited and their resources greatly dependent on the transfer of funds from other public institutions (e.g. the federal or state government, regional governments or other agencies). In such an environment, public agencies focused on *internal* processes, establishing formal rules to guide their activities and controlling inputs. This led to the introduction of layers of specialized roles and positions, and formal and strict coordination mechanisms. Conversely, little attention was paid to innovation. For all these reasons, Governments around the world have been considered inefficient, ineffective and unresponsive for several decades. Barton (1979, p.28-29) commented on the causes of these "bureaucratic maladies" in the public sector and identified several challenges:

- the adoption of rigid rules and a lack of managerial discretion;

- the impossibility to dismiss incompetent staff and develop more efficient resources;

- perverse incentive systems, with rewards being given for growth in budgets and staff, regardless of benefits to the public;

- "irrational" decision processes, not linked to any "cost/benefit" analysis.

However, as according to many authors (Osborne and Brown, 2005; Hughes 2009; Pollitt and Bouckaert, 2005) , there has been a series of reforms in the public sector in a number of countries over the last two decades. These reforms

tried to apply the principles of business models to the public sector, under the assumption that the application of these principles would automatically lead to improvements in the efficiency and effectiveness of these services (Thatcher, 1995). According to Hood (1991), the rise of "New Public Management" (NPM) over the past 10 years is one of the most striking international trends in public administration. Connected to this approach is the viewpoint that there needs to be greater emphasis on "results" in the public sector and that market competition and outsourcing to private sector contractors will improve government responsiveness (West, 2005). Christensen and Laegreid (1999), Ferlie et al (2001), Fortin and Van Hassel (2000), Lane (2000) and Larbi (1999), Lapsley (2008, 2009) explore these ideas even further, creating a large amount of literature centred on NPM. NPM literature is now quite extensive and includes official campaigns to adopt various elements of NPM, academic considerations of the advantages and disadvantages of NPM and various texts dealing with specific elements of NPM techniques (Christensen and Yoshimi, 2001). Osborne (2006) summarized the key elements of NPM as:

(1) attention to lessons from private sector management;

(2) a focus upon entrepreneurial leadership within public service organizations;

(3) an emphasis on control of inputs and outputs and on performance management and auditing;

(4) the disaggregation of public services and the growth of the use of market, competition and contracts within public organizations.

Nevertheless, many authors have recently questioned the nature and success of NPM with regard to several aspects (Ferlie et al, 1996; Lapsley, 2008) For example, some authors found that NPM is a kind of sub-school of PA whose impact has been limited by the lack of a true theoretical base and conceptual

rigour (Frederickson and Smith, 2003) or that NPM is a failed paradigm. Furthermore, even if the NPM agenda for change has been extremely influential in recent decades, the evaluation of the future of NPM is a very complex matter. According to Lapsley (2008), the NPM phenomena cannot be analyzed without considering the progress as well as the obstacles encountered during its development. In particular, there are three major constraints for NPM implementation: the *existence of an audit society* (which may appear to be a facilitating factor for the adoption of NPM but could also be considered an element reducing the effectiveness of NPM); the embedded *nature of professional boundaries* in public services; the way that certain *public service organisations* behave like social institutions. Consequently, after a period of enthusiasm and "political rhetoric", when both policy makers and practitioners believed that private sector principles can solve the problems of efficiency and effectiveness in the public sector, came the awareness that a finer balance was needed between the public and private sectors also in view of the increase in non-profit organizations and cooperatives, which do not fall under the traditional classifications of public and private sector. Mintzberg (1996) discussed another critical aspect that distinguishes the public and private sectors: he maintains that the public sector has to consider many stakeholders, including other public administrations, business, and various categories of citizens with different needs. As a result, we can conclude that the NPM evolution will continue to be severely contested, even if the push towards NPM does not abate (Lapsley, 2008).

Literature considering the implications of NPM in public sector organizations suggests that it has influenced many reform programmes in the western world (Weiss & Barton, 1979; Hodge, 1996). These reforms have facilitated the spread of *Information and Communication technologies* (ICT) in the public sector for

the delivery of products and services and to enhance relationships with the public. IT has been used in government as a method for improving efficiency and effectiveness (Norris and Kraemer, 1996; Kraemer and King, 1977); prior to the advent of the internet, IT was used for mass data transaction through mainframe computers (Schelin, 2003). In recent years, ICT developments changed interpersonal communications, eliminating the constraints of geography and space, with great organizational consequences (Rahm, 1999) and contributing to the creation of the so called "Information Society" where economic and political behaviours are enabled by large-scale use of digital networks. The benefits linked to the use of ICT to cater for demands made on the public sector include less time needed for transactions and the ability to access services with no time and space constraints, as in private business. Therefore, the application of IT for the delivery of public services is considered a promising way to meet public expectations for "better public services". This perspective was largely expounded by Osborne and Gaebler (1993) in their work entitled "Reinventing Government in the Information Age". They offer empirical support for this line of reasoning, with evidence that reforms aiming at the innovation of the public sector will reap benefits when associated with the use of ICT. Rose and Miller (1992) emphasise the importance of the use of ICT in the public sector as a way of creating networks between different inter institutional actors. Heeks (1999) observed that the delivery of such reforms depends critically on a more overt role for information and a greater use of ICT, since the most tangible evidence of the passage from NPM to "information age reforms" comes from the increasing use of IT within government.

2.2 Literature review: method and structure

This chapter is divided into 2 sections. Section 1 provides a brief summary of the literature on e-government concerning both the adoption and the implementation of ICT in the public sector. Section 2 provides a critical discussion of e-health literature produced by scholars in terms of the adoption and implementation process.

In this and the following chapter, we conducted a *systematic review,* namely a review of literature according to explicit, rigorous, and transparent methodology (Greenhagh et al 2005). In particular, the process of literature review was conducted following a precise methodology, a structured and transparently defined "metanarratives approach" as proposed at the international level by Greenhalgh and others (2004).

This approach organizes the analysis into 6 steps:

1. Planning Phase;

2. Search Phase;

3. Mapping Phase;

4. Appraisal Phase Using appropriate critical appraisal techniques:

5. Synthesis Phase;

6. Recommendations Phase Through reflection, multidisciplinary dialogue, and consultation with the intended users of the review.

During the *planning phase* the inclusion criteria were defined with the aim of including in the analysis:

a. Studies concerning the public sector;

b. Studies that address innovation within the public and health care sector.

c. Studies that analyze egovernment and ehealth.

During the *Search Phase* several activities were carried out:

- Searching for seminal conceptual papers by tracking references of references.

- Evaluating of these by the generic criteria, such as "scholarship, comprehensiveness, and contribution to subsequent work within the topic" (Greenhalgh et al. 2005)

- Searching for empirical papers by electronically searching key databases, handsearching key journals, and "snowballing".

This lead to the identification of the keywords related to the macro-themes of research that drive the "navigation" between databases and journals;

During the *Mapping Phase* we proceeded in identifying items that, according to the criteria previously identified, can be considered particularly relevant; then we defined conceptual maps able to show connections and relationships between various articles.

Later in the *Appraisal Phase* , each paper was examined under a scheme of analysis aimed at mapping:

      i. The key elements of the research paradigm;

     ii. The context of the study;

   iii. The research methodology adopted;

   iv. The sample analyzed (in the case of empirical studies);

    v. The main results emerged.

In this phase, each paper was evaluated for its validity and relevance to the study we were carrying out; then, according to the main findings, comparable studies were identified .

The next step *Synthesis Phase* involved the synthesis of the results by identification of key dimensions related to the issues of egovernment and ehealth

in the public sector (in terms of features specifications and input methods) and identification of the main factors affecting the adoption of egovernment and ehealth in the public sector.

Finally the *Recommendation Phase* aimed "to summarize the overall messages from the research literature along with other relevant evidence (budget, policy making priorities, competing or aligning initiatives) and to distill and discuss recommendations for practice, policy, and further research" (Greenhalgh et al., 2005).

The purpose of this method is:

- To ensure comprehensive coverage of the topic under investigation;

- Make transparent the process of analysis and selection of sources;

- To ensure the reliability of the results of the review from the scientific. and academic perspective

Figure 2.1 Lists the sources analyzed in this review
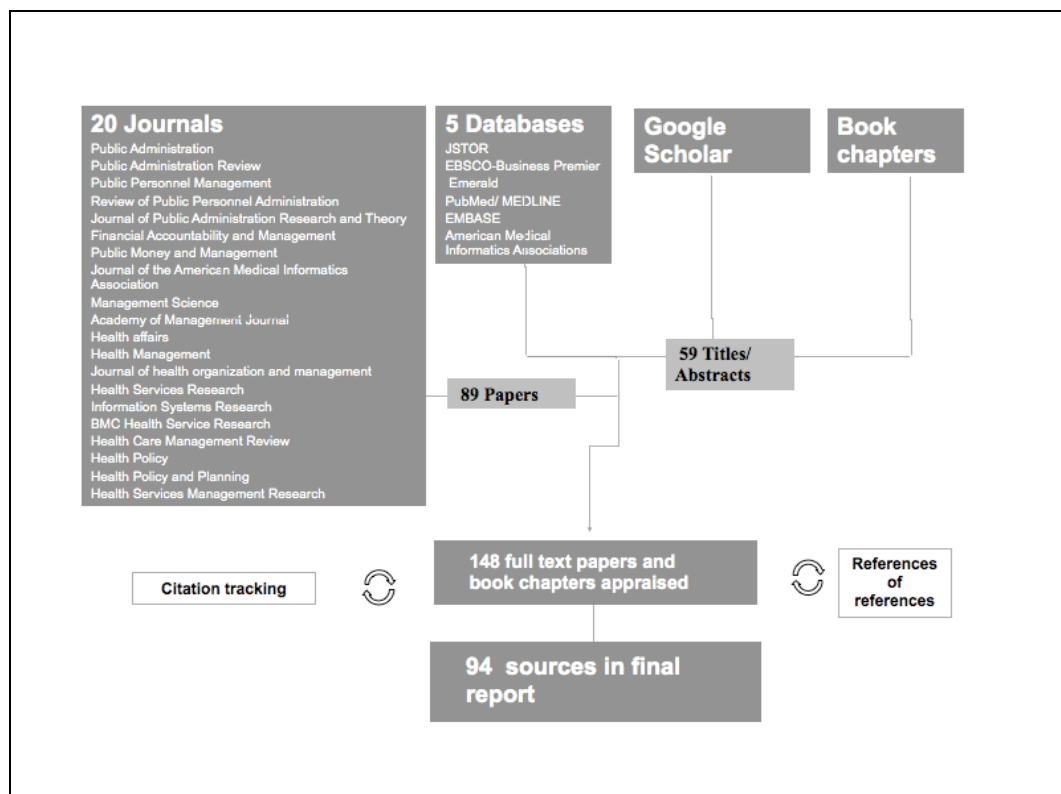
2.3 E-government: review of previous studies

The policy formulation process is the starting point for the analysis of the use of ICT in the public sector and the adoption of e-government, in particular. Focusing on this concept, current literature contains numerous studies discussing the adoption of ICT with the aim of modernizing the public sector. As stated by Huff and Munro (1985), "e-government policy formulation has different dimensions and it refers to the organizational *strategies*, *policies* and *processes* employed by an organization in its effort to acquire and diffuse appropriate ICT to support its objectives". ICT has been implemented by public agencies since the early diffusion of computer technology (Stevens and McGowan, 1985) to automate repetitive activities as well as complex tasks in certain organizational areas. According to Simon (1976, page 286), "technology was seen as a means to manage the limitations of bounded-rationality and provide the infrastructure for better decision making". In particular, early studies into the adoption of technology by public agencies refer to the usage (or non-usage) of computer-based technology (Brudney, Selden and Coleman, 1995) and measure it by way of computer applications (such as payroll preparation, word processing, geographical information systems, tax billing) and the number of types of technology (Heintze and Bretschneider , 2000) implemented by the organization by way of actual equipment (i.e. scanners, printers, fax machines), telecommunications and storage technologies and the configuration of the information systems.

Throughout the years, ICT diffusion and its pervasiveness have facilitated the evolution of technologies to cater for shifts in organizational needs and

managerial tools; today, e-Government policies aim to use ICT to support any level and type of activity of a public agency (Hendrick R. 1994): from operative tasks to decision making and public service delivery. Since the diffusion of web technologies in the late nineties, governments have also been developing their websites: initially, their goal was to establish a virtual presence, but they eventually aimed to promote on-line interaction between the public and government agencies.

Much research into e-government policy formulation has attempted to focus on factors that determine ICT adoption by public agencies and they are generally influenced by literature on the availability of innovation (Bingham 1978; Damanpour 1996; Rogers, 1995; Greenhalg, Robert et al. 2004). Most of these studies have been presented by Norris and Moon (2005) in their exploratory framework, where they discuss the associated environmental and organizational factors. A common claim made is that e-government policy formulation is influenced by *environmental factors* representing the basis for understanding the community and the needs of the public. They influence decisions relating to the adoption of ICT and its actual use in public sector organizations. Furthermore, a large body of literature discusses external factors affecting innovation in the public sector. These include the demographic (for example social and economic background) and cultural nature of the community (Coleman 1995), the form and functions of the government (Greenhalgh, Robert et al. 2004), the specific area of the country and metropolitan status (Norris and Moon 2005), the demand for services, political stability (Bingham 1978) and regulatory influences (Bingham 1978; Moon, 2002; Walker, 2006).

Other studies examining the adoption of e-government by public organizations have demonstrated that it is also affected by the *organizational characteristics*,

including the culture of the organization, human factors and the structure of the organization and government. A strong organizational vision is said to facilitate the generation of clear organizational goals (Kanter, Stein et al., 1992). Similarly, this affects the degree of their successful implementation, stimulates a collective culture and facilitates the development of a sense of involvement among personnel. Furthermore, empirical studies, such as the work by Nedovic-Budic and Godschalk (1996) and Heintze and Bretschneider (2000), emphasize that the perception of specific needs and the perceived benefits offered by an innovation to individuals also affects innovation in public service provision. In turn, acceptance of an innovation by the organization and its members, such as the use of web technology to deliver services, affects the extent to which it is implemented. Accordingly, the structural characteristics of public agencies somehow reflect these soft factors since they are designed by the individuals and managers (Leonard-Barton and Deschamps; 1988) that manage and govern them and are shaped by the culture and vision of the organization.

Table 2.1 Factors influencing e government adoption

Dimension	Theories	Selected related studies
Organizational factors		
Organization's perceptions of particular needs	Adoption/ Diffusion Model; Technological acceptance model	Colesca and Dobrica, 2008
Organization size		Brudney,Selden and Coleman 1995; Moon 2002; Hage 1980; Norris and Kraemer 1996; Demanpour 1987
Perceived relative advantage of innovation, computer experience, attitude towards work-related change		Nedovic, Dudic, Godschalk 1996; Verkatesh and Davis 2000; Heintze and Bretschneider (2000) Belanger and Carter, 2008

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External/Environmental Factors		
Demographic factors	Adoption/ Diffusion Model; Technological acceptance model	Brudney,Selden and Coleman 1995; Bingham 1978; Steccolini and Nasi 2008
Form and function of e-government		Greenhalgh, Robert et al, 2004 Aicholzer and Schumtzer, 2000
Region and country and metropolitan status		Norris and Moon, 2005 Coursey and Norris, 2008 Sang et al 2009
Regulatory influence		Bingham 1978; Moon 2002; Walker 2006 Teo et al, 2008

Adapted from Norris and Moon 2005

As stated above, ICT adoption has shifted over the years with the evolution of technology and its incidence among organizational processes; consequently, many scholars and authors have tried to differentiate e-government evolution in different ways (Hiller and Bèlanger, 2001; Layne and Lee, 2001), since Governments increasingly use information and communication technologies in their daily business (Gil-García and Luna-Reyes 2003; Schelin 2003). Ridley (2006) notes that many models and frameworks attempting to explain the development and implementation of e-government have been proposed in recent years as a result. Aicholzer and Schumtzer (2000) maintain that "e-government covers changes of governance in a twofold manner: transformation of the administrative process and transformation of governance itself". Furthermore, Holden, Norris and Fletcher (2003) found that each of the e-government stages represents different levels of technological sophistication, citizen orientation and administrative change. The paper by Coursey and Norris (2008) offers a more work on this topic where they try to explore and systematize publications that proposed e-government development models. Coursey and Norris found that

these works, all published between 2000 and 2001, depicted e-government as a linear development process that progressed through a series of phases. Despite noting a number of differences in the models, the authors underlined that all five publications they studied, started with the establishment of web presence and the providing of information before offering interaction with citizens, transactions and ultimately integration. The models portrayed e-government as reaching "the seamless delivery of governmental information and services, e-participation, e-democracy, governmental transformation or some combination of the above" (Coursey and Norris 2008, 258). Figure 2 shows the five models considered in their analysis: Baum and Di Maio (2000), Ronaghan (2001), Wescott (2001), Layne and Lee (2001), and Hiller and Belanger (2001) and offers some interesting arguments for each model.

Table 2.2 e-government development models

	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
Baum and Di Maio (2000)		Presence	Interaction	Transaction	Transformation	
Ronaghan (2001)	Emerging presence	Enhanced presence	Interactive	Transactional government	Seamless	
Wescott (2001)	E-mail and internal network	Enable interorganizational and public access to information	Two-way communication	Exchange of value	Digital democracy	Joined-up government
Layne and Lee (2001)		Catalogue	Transaction	Vertical integration	Horizontal integration	
Hiller and Bélanger (2001)		Information dissemination	Enable intero	Integration	Transaction	Participation

Adapted from Coursey and Norris (2008)

Baum and Di Maio's model (2000) predicts that e-government development will be divided into 4 different steps starting from *"web presence",* aiming to provide

basic information, a second step called *"interaction"* where citizens can interact on line with governmental organizations. The third step is called *"Transaction"* since it enables people to conduct business on line with governments. The fourth and final stage is *"transformation"*: at this stage, the relationship between governmental organizations and the public is enhanced owing to the use of ICT for the delivery of services and information and also as a communications tool between the public sector and its stakeholders.

In *Ronaghan's model* (2001), the first stage is called *"emerging presence",* namely a web "presence" that is simply available at this stage but does not offer any useful information. In stage two, called "*enhanced presence*", governmental information is available on an official website 24 hours a day, 7 days a week. The third stage is the "*interactive*" stage and the fourth stage is "*transactional government*": both are quite similar to Baume and Di Maio's model. The last, *"seamless"* stage is the most interesting, marked by the horizontal and vertical integration of information and services, enabling citizens to have better and faster access to the services they require.

Westcott's model also considers the first stage to be a basic phase where only *e-mail and an internal network* are available. The second stage enables inter-organizational and public access to information, the third stage promotes *two way communications* between government organizations and the public. Wescott defined the fourth stage as allowing the "*exchange of value"* meaning the enhancement of transactions between government and the public. The fifth stage is *"digital democracy"* whereby citizens will be able to play an active role in political activities at this level of development by using the government's website. In the last stage, e-government enables the public to participate in

"joined up" government, namely complete integration of services and information so people can get what they need in less time, spending less than for using traditional services.

According to Coursey and Norris (2008), Layne and Lee's model is quite similar in the first two stages to the others models described above, as e-government is initially used simply to *"catalogue"* before progressing to a *"transaction"* stage. They find that the difference to other models lies in the third stage, since there will be *vertical integration* at this point, involving the sharing of data and information online by upper and lower levels of government. The final step in Layne and Lee's model is *horizontal integration*, where e-government enhances the sharing of data and information online across departments within the government.

However, one of most important contributions to the operalization of e-government policy implementation in recent times was made by Hiller and Bélanger (2001). They contributed to the conceptualization of the use and sharing of information systems in public administration based on web technologies. Their proposed model includes two dimensions: the degree of technological sophistication in the delivery of online services and the types of stakeholders who interact with public administrations. This model can be used to analyze the actual rate of penetration of technological innovation in public administration.

The measure of technological sophistication is based the use of internet, the functionality of the institution's website for the provision of information and services and the level of technological integration between web applications and back office information management.

Hiller and Bélanger divided the level of sophistication of ICT into five stages: information, two-way communication, transaction, integration and political participation. The first four stages have been discussed in many studies, including research by Capocchi (2003) and Layne and Lee (2001), and represent *incremental* levels of e-government for the delivery of information and services (administrative arena), moving from the lowest (information) to the most advanced (integration).

The lowest level of sophistication (information) is when public administration and local authorities in particular, establish an online presence to provide the public with information via the portal of the institution. This stage ensures the online presence of the organization. The site can also be considered like an electronic bulletin board used to provide information to stakeholders, without requiring a high degree of technological sophistication or special integration with existing computer applications.

The second level (two-way communication) typically includes the use of communication technologies, such as electronic mail and virtual forums, promoting two-way interaction, albeit often asynchronously, between the government and its users. This layer helps to strengthen the relationship with the institution and its members are able to respond quickly. From a technical point of view, providing e-mail administrators, managers, executives and members of the organization with a procedure to start a discussion forum on the institutional website is not a complex matter; from an organizational perspective, it requires some amendments to how work is organized, for example by providing guidelines to define criteria and response times and adjustments to the workload.

The third level (transaction) concerns the possibility of actions associated with the obtaining of a service on the website, such as applying for a license, concession or permit, submitting tax returns by sending the required documentation on line, or paying stamp duty and other taxes via the Internet using a credit card or other method of payment. This level of sophistication offers the user on-line access to services, and often replaces part of the activities required for the delivery of services by specialist front-office officials.

Offering online services at this level implies the achievement of a degree of technological sophistication going beyond the bulletin board (Layne and Lee, 2001) and requires the creation of appropriate interfaces so the website can make the request; it is an online catalogue with the possibility to download forms and documents and upload them after completion.

Adaptation of technology also demands substantial support at organizational level because offering such services over the web can have a potential impact on the workload of the official reference staff, depending on the number of applications received via the website, and has an impact on the activities involved in the service delivery process and the response timeframe.

The fourth level, or integration, is the establishment of integrated processes between the government and its users, production-oriented services with lower costs and increased effectiveness and efficiency of public actions, such as the ability to submit applications online for subsidies and social services, the ability to view the progress of an application and consult maps, photographic surveys and plans etc. Governments which provides web-based services with this level of technological sophistication have reached a high level of integration of inter-and intra-organizational information systems and safeguard the consistent flow of information needed for to support decision making.

The site used to access services is the back-office access interface. The degree of sophistication of the information system is very complex in terms of both the organizational and technical demands. Literature distinguishes this type of technological change by referring to "soft" and "hard" levels (Osborne and Brown, 2005).

"Soft" implementation is encouraged for increased efficiency within the organization (e.g. the adoption of software in order to automate repetitive tasks) or for the service delivery process (e.g. the adoption of multiple high-tech channels, possibly a website, in order to ensure greater accessibility to the town council and to exploit the convenience of operating on-line), similar to the level of sophistication called "transaction". However, as mentioned above, "soft" technological innovation does not involve complex organizational change or the substantial re-design of processes. On the other hand, the implementation of "hard" technological innovations, like those relating to the fourth level of sophistication (integration) in the Hiller and Belanger matrix, involves the adoption of management applications that facilitate a systematic updating of the structures and organizational processes involved in service delivery.

This level of sophistication in the use of technology by public administrations has a strong impact on the organization's structure, the system of delegation, the content of professional activities (Kraemer and Pinsonneault, 2003, Holden, Norris et al., 2003) and the effectiveness of public actions. Providing more reliable, transparent and shared information (Fountain, 2001) to the officials involved in the process can also help reduce the number of tiers in the chain of command.

Although the fifth level should not to be considered the "pinnacle" of technological sophistication, as explained above, it focuses on political

participation with political activities conducted primarily on-line by citizens. It aims to encourage public participation in political activities.

Although there are examples of interaction at all levels of sophistication with many of the stakeholders identified above, some authors (Moon, 2002; West, 2004) find that local authorities do not necessarily adopt technological innovations in order to manage this level of sophistication in an incremental manner or implement them in a particular order. However, the dimensions outlined above provide a useful conceptual tool for discussing the evolutionary nature of technological innovation within local authorities.

The new element studied by Hiller and Bélanger is the shift from the concept of the public sector as a *function-centred approach*, whereby ICT is used to enhance the final outcome of the service delivery process, to a user or *citizen-centred approach*, putting the focus on the overall results of the service delivery process, achieved by managing and coordinating all the functions and activities involved.

They, in fact, present an e-government framework that incorporates two dimensions: the level of sophistication of ICT for providing on line services and the types of stakeholders involved. The fifth stage (political participation) is associated with the political arena. It incorporates different technologies at different levels of sophistication that serve mainly as communication- and public relations tools (the two-way communication stage) to promote democratic participation in policy-making processes, but also supporting online voting in countries where this is allowed.

However, as Moon (2002) points out, governments do not necessarily make use of all these levels of sophistication of technology or apply them in any particular order: these frameworks are useful for providing conceptual instruments for discussing the choices made by governments for the implementation of e-

government for supporting interaction with constituents. Some studies have found that the trend of e-government initiatives apparently pursues a different trajectory from national and state to local government (Edmiston 2003; Holden et al 2003; Moon 2002; Stowers 1999; West 2005). However, although several studies have been conducted on the implementation of e-government, their scope is mainly descriptive and more analytical research and theoretical frameworks are needed in order to explain how this evolution has taken place.

2. 4. E-health policy formulation and policy implementation

Innovations in ICT have improved efficiency and quality in many sectors of the economy but there is still a distinctive need for IT enhancement in the delivery of health care, since health care organizations have found that they do not have adequate systems in order to deliver strategic change. According to Eng (2001), the adoption and implementation of ICT in the health care sector is developing much more slowly compared to other sectors, such as finance and commerce. This is due to several impediments observed by Ganesh (2004). These include the continuing lack of awareness among consumers of the availability of online access to specialist knowledge or the legal issues implicated by the use of electronic communications in medicine. In recent years, traditional health care corporations, which were initially slow to embrace the Internet, have become increasingly active in the adoption of ICT since public health organizations are looking to adopt information technology to remain "up to date", even if building an electronic health information infrastructure requires an immense amount of effort and resources. As a result, Government intervention has been called on in order to accelerate the adoption process for Health Information Technology (HIT) because of the widespread belief that its adoption and implementation are

still too slow to be socially optimal. In practical terms, although some ICT systems are already in place in the healthcare sector for the execution of administrative tasks, such as billing, scheduling and inventory management, there is scant adoption of clinical HIT. According to Berner and collegues (2005), the immaturity of the technology, the focus of health care administrators on financial systems, the ''unfriendliness'' of applications and resistance among physicians were all barriers to acceptance after the 1950's. Although these factors persist, "more computer literacy in the general population and changes in government policies and increased support for clinical computing in particular, suggest that this trend may change in the next decade"(Berner et al. 2005). Nevertheless, it is hard to imagine the health care sector without ICT. Oh et al (2005) offer support for this line of reasoning with a systematic review of e-health studies. They sustain that the term "e-health" encompasses a set of disparate concepts including health, technology and commerce. They examined 51 definitions and found that all include these concepts with different degrees of emphasis but failed to find a clear consensus with regard to the meaning of e-health. They did note two universal themes: 'health' and 'technology'. The definition by the World Health Organization simplifies matters and incorporates these themes: "e-health is the combined use of electronic communication and information technology in the health sector."

Pagliari et al (2005) identified 36 definitions of e-Health appearing in published scientific abstracts and web-based systems, with the aim of grouping the most salient and easily accessible examples. They state that articles referring to "e-Health" exist since 2000 and almost all are indexed by Medline. They conclude their research with a definition that maintains that e-health "demonstrates a broad variation of alternative conceptualizations….most of these address medical

informatics applications for facilitating the management and delivery of healthcare".

As regards recent e-government policy, the health care sector is also trying to align its information technology strategy with organizational goals designed to respond to environmental pressures. However, although existing literature is helpful for an analysis of hospital adoption of high-tech equipment for administrative use, little is known about the policies and factors that contribute to the formulation of policies for e-health adoption in terms of clinical and managerial-strategic applications in the health care information system (Wang et al, 2002). Many authors (Kim, Lee et al. 2005; Chung and Snyder 1999; Davenport 2000; Stefanou 2001) agree that a particular challenge lies in defining the factors that are linked to Health Information Technologies (HIT) adoption and the incentives that are driving the policy formulation process. In particular, some models, such as the the Technology Acceptance Model (TAM) examines the individual and *organizational determinants* of ICT acceptance and use (Kanter, Stein et al. 1992). Other studies focus on *environmental factors* (Schaper and Pervan, 2007; Brandyberry, 2003), *technological characteristics* (Hwa Hu, Chau, and Liu Sheng, 2000; Tornatzky and Fleischer, 1990) and *financial factors* (Wang, Burke and Wan, 2002; Borzekowski, 2003).

Table 2.3 Models depicting factors affecting e-health adoption

Dimension	Theories	Selected studies
Organizational Factors		
Organizational context Internal Communication	Technological Acceptance Model	Kanter, Stein et al. 1992 Tornatzky and Fleischer,1990 Brandyberry, 2003
Characteristics of the individual		Fichman et al., 2008 Venkatesh et al., 2008
User needs		Au et al, 2008

External/Environmental factors		
External environment	Adoption/Innovation diffusion model	Tornatzky and Fleischer (1990) Hwa Hu, Chau and Sheng (2000) Green and Kreuter, 2005
External Communication		Brandyberry (2003)
Characteristics of implementation context		Schaper and Pervan (2007)
Technological Factors		
Technological context	Adoption/Innovation diffusion model	Tornatzky and Fleischer (1990) Hwu Hu, Chau and Liu Sheng (2000)
Technological attributes		Tornatzky and Fleischer (1990) Hwa Hu, Chau and Liu Sheng (2000)
Financial factors		
Financial capabilities	Adoption/Innovation diffusion model	Wang, Burke and Wan (2002)
Source of financing		Borzekowski (2003)

In this context, one of the most relevant theories concerning the process of innovation, adoption and diffusion the Diffusion Theory pioneered by Rogers (1995). However this will be largely discussed in chapter 4.

Additionally, strategic contingency theory suggests management plays an influential role in determining the organizational structure and also helps to understand the reasoning behind the determinants of diffusion (Wang et al. 2002). Brandyberry (2003) also sustains that the adoption of information technology in health care is affected by *bureaucratic control*, *internal communication* and *external communication*, whereas the size and innovation of the organization do not influence it. Tornatzky and Fleischer (1990) and Hwa Hu, Chau and Liu Sheng (2000) claim that the formulation of e-health policy in an organization is influenced by factors pertaining to *technological context*, *technological attributes* (such as the perceived easy of use, the perceived safety of the technology), the

outcome of the use of technology (including perceived benefits and perceived risks), the *organizational context* (e.g. the collective attitude of medical staff) and the *external environment* (such as services demanded).

In considering the factors that can influence e-health policy formulation, literature also suggests that the *financial capabilities* of the organization may influence strategic decisions. From a financial perspective, organizations with excess revenue or cash flow might use these funds to finance projects that are not directly implicated in reaching the organization's primary mission. Lapsley offers more arguments, sustaining that costs can be linked to clinical effectiveness and the quality of care (Lapsley, 2001). Also Borzekowski's examination of e-health policy formulation (2003) finds that the adoption of HIT is strictly connected to the *source of financing*. The author suggests an explanation for his findings: "in the early years, these systems did not have the ability to save sufficient funds to justify their expense, and adopters, in particular non-profit hospitals, were motivated by factors other than cost. By the early 1980s, this situation had changed: hospitals with the greatest incentives to lower costs were now more likely to adopt such technologies".

Consequently, e-health *policy implementation* can also be viewed in different ways. As seen above, modern health care is undergoing a phase of "transformation with the introduction of new medical technology, evidence-based medicine, quality indicators, private healthcare providers and new financial models" (Vikkelsø, 2007) and health care systems are becoming increasingly dependent on ICT.

Many authors have tried to identify models in order to explain IT implementation in the health sector. Scott et al (2002), for example, argue that health care policy can be defined as a set of statements, directives, regulations, laws and judicial

interpretations that direct and manage the life cycle of e-health. Scott (2003) explores these ideas based on this definition, describing 4 categories of policy maturity:

- Stage 1: Regulations and laws *governing* e-health activity;

- Stage 2: Statements, directives, guidelines, *defining and delimiting* e-health activity;

- Stage 3: Evidence of *pro-active consideration* of e-health activity.

- Stage 4: Broad suggestions of *intended directions* encompassing e-health activity

(Adapted from Scott, 2003)

The first stage represents the development of policy formally embedded into the administration of the specific level of government. The second stage shows clear evidence of formal, written material that governs at least some e-health activity. Stage number three considers jurisdiction mechanisms and/or funding programmes to move e-health initiatives forward. The last stage is the weakest "policy statement" for any jurisdiction.

Nolan (1979) defined a model known as "maturity models" or "stages of growth model" and Galliers and Sutherland (1991) reviewed the evolution of Nolan's maturity model (1979). Galliers (1994) suggested the use of the information system maturity model in its modified form to facilitate a more effective formulation of ICT strategy within the health care sector and the National Health Service in particular (Wainwright and Waring 2000).

The revised maturity model proposed encompasses 4 different stages:

- *Initiation* : IT is introduced into organizations in this phase;

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- *Contagion*: this phase typically sees widespread proliferation of systems, technology and infrastructure to support the implementation of innovation processes in health care sector;

- *Control*: this phase arises when organizations regain control of IT spending by cutting budgets and introducing stricter procedures for purchasing and developing systems, even putting the IT department under the direct control of the finance director;

- *Integration*: this phase represents the "maturity" stage, implying that the organization is beginning to address its difficulties and become more comfortable with IT and the system in general.

As seen above, the HIT implementation process in the health care sector can produce many relevant effects both for healthcare professionals and patients. However, there are many steps involved in achieving improvements in the health care sector: "institutional and (inter-national) HIS strategies, more education in health informatics and new trans-institutional HIS architectural styles" (Haux, 2006).

2.5 Conclusion

This chapter provided a review of recent literature focused on the adoption and implementation of ICT both in public organizations and the health care sector.

Today's information technology is able to support all of the objectives and activities of public agencies. E-government represents a real opportunity for developing a new mode of communication and collaboration with other

organizations, but is also a mean for increasing interaction with citizens. The success of completed e-government adoption and implementation provides increased legitimacy for further adoption of information technology (Norris, 2009).

Many models have been presented in this chapter. In particular Hiller and Bélanger (2001) concept of innovation within the public sector and their framework captured our attention. They highlight the need to move from a *function-centred approach* that characterizes public sector activities, emphasizing just the final outcome of the service delivery process, to a user or *citizen-centred approach*, focusing on the overall results of the service delivery process, achieved by managing and coordinating all the functions and activities involved. This represents an important goal to be addressed by public but also by health care organizations.

However, there are still many barriers to adoption and the development of e-government policy today that may block or restrict the progress of e-government, such as a lack of political resolve, the high costs for developing, implementing and maintaining ICT systems and scant motivation of the public to use e-Government services (Conklin, 2007).

Consensus is also growing with regard to the role of ICT in the health care sector, due to the evidence of its efficiency and effectiveness in recent years. Furthermore, it might be expected that e-health will have the potential to change the clinical relationship with patients by providing greater access to personal data and health information, and communications tools, which may aid self care,

shared decision making and clinical outcomes (Pagliari, Detmer, and Singleton, 2009).

Many factors can influence and affect the adoption of HIT: *organizational determinants* of ICT acceptance and use (Kanter, Stein et al. 1992) *technological characteristics* (Hwa Hu, Chau, and Liu Sheng, 2000; Tornatzky and Fleischer, 1990) *environmental factors* (Schaper and Pervan, 2007; Brandyberry, 2003), and *financial factors* (Wang, Burke and Wan, 2002; Borzekowski, 2003).

Some of these are related to the "inner context", some others to the "outer context" (Greenhalgh et. al 2005). With the term "inner context" we refer to the hospital context and it includes both the hospital's structure, culture and the way of working within a service organization (Fitzegerald et al. 2002). The "outer context" includes all the factors that are related to a "wider environmental context" (Wejnert, 2002; Baldridge et al. 1975; Di Maggio and Powell, 1983). We will analyse these characteristics and how they can affect and influence, in a positive or negative way, the adoption and implementation of innovations within a health care organization through the two case studies carried out (see chapter 10).

However there are many barriers, including a lack of trust in technology, the cost of systems and the risk of unsecured patient health (Smith, 2006) that need to be overcome in the near future.

The next chapter will focus on a specific type of HIT, specifically electronic medical records (EMR) are information systems that manage both the "distribution and processing of information" (Lærum and Faxvaag 2004) that are necessary in the patient delivery process.

In fact, the introduction of EMRs is potentially one of the main innovations capable of safeguarding clinical processes and facilitating improvements in health care performance and service delivery.

CHAPTER 3

ELECTRONIC MEDICAL RECORDS: STRATEGY AND

BENEFITS

Chapter 2 introduced the main issues related to the adoption and implementation of egovernment and ehealth. This chapter discusses the usage of a specific HIT within Health care sector: the electronic medical record systems, in terms of main impact delivered by these systems. It highlights the broader importance of these issues by reflecting on the relevance of the adoption of EMR on the organizational performance in terms of efficiency, effectiveness, clinical governance, patient safety and empowerment.

In particular the chapter is organized into 3 sections: the first one offers an overview of different definitions of Electronic Medical Records (EMR). Section 2 presents some models produced in the literature to describe the *adoption* and *implementation* of EMR within healthcare organizations and finally section 3 discusses some previous studies that analyzed the *impacts* of EMR.

Electronic medical records are claimed to have the potential to transform health care delivery by means of increased efficiency and productivity, by enhancing the quality of service and enabling patients to be more involved in their care (Hillestad et al., 2005). The effects that technological innovation has on the performance of an organization have been proved in many sectors of the economy (Chen et al. 2004) but there is still a lack of extensive evidence of the actual

impacts of EMRs in the health care sector. The few studies that have focused on this area present isolated projects or discuss single types of impacts.

3.1 Introduction

The recent focus on improvements to the quality of health care and the containment of costs has led many scholars, practitioners and policy makers to advocate the adoption of health care information technology (HIT). In particular, the current information strategy (Burns, 1998) is based on integrated systems being in place in order to underpin the new initiative of EMR "which is predicted to change and improve health care" (Kazley and Ozcan, 2007). Policy makers within the health care sector are emphasizing the importance of both technical and organizational integration. As Wainwright and Waring (2000) state, "the new strategic HIT objectives are based around the vision that information will be available at any place, at any time, in multimedia form if relevant, by those who need it - serving health care professionals, patients the public and health care sector managers and planners". Kazley and Ozcan (2007) maintain that "Hospital EMR adoption is significantly associated with environmental uncertainty, the type of system affiliation, size, and whereas the effects of competition, ownership, teaching status, operating margin were not statistically significant". Haux, Ammenwerth et al. (2003) also assert that e-health policy will be focused on patient-centred recording and the use of medical data for cooperative care within the near future. In their view, the use of IT regardless of location, time and person, will only be achieved via EMRs. This is especially important in a unified Europe, since EMRs represent the easiest way to handle the storing and use of data for organizational support within the same and between different health care organizations.

3.2 Electronic Medical Records: a definition

First of all, it may be useful to explain that many different acronyms and different definitions have been used to denote electronic medical records, such as ePHR (Electronic Patient Health Record), EPR (Electronic Patient Record), CPR (Computer based Patient Record), EHR (Electronic Health Record). However, as Waegemann said (2002), "Whatever you call it, the vision is of superior care through uniform, accessible health records". According to Anderson and Aydin (2005), "these applications are referred to generally as medical or clinical information systems or electronic medical records" (EMRs).

More specifically, the term ePHR "indicates an electronic application through which individuals can access, manage and share their health information and that of others for whom they are authorized in private, secure and confidential environments"(Pagliari, Detmer and Singleton, 2007).

According to Waegemann (2002), the term electronic patient record (EPR) is similar to computer-based patient record (CPR), which refers to a lifelong patient record of all information from all spheres and requires full interoperability but does not necessarily contain a lifetime record focusing on relevant information. In contrast to EPR, the EHR provides a longitudinal record of a patient's care carried out across different institutions and sectors. However according to Waegmann (2003) such differentiations are not consistently observed in discussion.

The Patient Safety Report (IOM 2003) offers a comprehensive definition of EMRs, describing these systems as "a longitudinal collection of electronic health information for and about persons [immediate] electronic access to person- and population-level information by authorized users; provision of knowledge and

decision-support systems that enhance the quality, safety, and efficiency of patient care and support for efficient processes for health care delivery".

In more general terms, EMRs can be described as information systems that manage both the "distribution and processing of information" (Lærum and Faxvaag 2004) necessary for the health delivery process.

3.3 EMR implementation and evaluation processes within health care organizations

The introduction of EMRs is potentially one of the main innovations capable of securing the clinical process and of facilitating improvements in health care performance and service delivery. The main goal of the EMR system is to ensure continuity of care, even if performed by different practitioners, at different times and places. According to some scholars (Burns, 1998; Caccia, 2008), hospitals will develop it through increasingly sophisticated levels of integration starting from:

(1)   Clinical administrative data;

(2)   Integrated clinical diagnosis and treatment support;

(3)   Clinical activity support;

(4)   Clinical knowledge and decision support;

(5)   Specialist support

(6)   Advanced multimedia and telematics.

(Adapted from Van Den Branden, 2011)

At the first level, each department has its own patient administration and independent system. At the second level, each department has its own integrated master patient index, which is a database that maintains a unique index for every patient registered at health care organization (American Health Information Management Association- AHIMA 2005). The third level is based on the adoption of electronic clinical orders, reporting of results and prescriptions, and multi-professional care paths. The fourth level represents a higher level of sophistication: at this stage, EMRs guarantee electronic access to knowledge databases, they provide electronic alerts, have specific guidelines and rules and also offer specialist system support. At the fifth level, EMRs are used for special clinical models and for document imaging. The last level represents the *highest level* of integration that can be reached by EMRs and implies the use of telemedicine and other multimedia applications. Implementing a clinical information system of this type can promote the alignment of administrative processes and clinical information. Both the case studies included in this work aim at the highest level of integration even if at the time of our data collection they have reached different level of integration as we will see further in chapters 7 and 8.

As De Moore points out (1993), "the necessity for the integration of systems and communication of information in the health care sector becomes evident when studying the variety of interested parties, the multitude of applications and their importance".

The emergence of this scenario, where clinical information is considered a strategic variable in managing daily care activities, has focused attention on theoretical models described in the literature (Buccoliero, Caccia, Nasi, 2002;

Waegemann, 2002) leading to the practical study and design (Berg, 2004; Berg, 1999; Walker, 2005) of clinical information systems and actual implementation, even if there has been little investment in the field of clinical information systems in recent years due to numerous issues, including institutional or organizational constraints, such as the lack of a corporate information system, failure to involve management and scant opportunities to invest in IT projects (Hunt, 1998).

Many studies have analysed the adoption of technological innovations in health care and suggest factors focusing on the methods of adoption and implementation and discuss the extent of any impacts. Some studies discuss the dimension of business impacts following the adoption of electronic medical records but there are few studies which have measured the actual occurrence of outcomes of such systems and that have examined the role of professionals in the implementation and evaluation processes.

3.4 EMR impacts: analysis of previous studies

Although health care providers recognize the potential, they want proof of the effects of EMRs before they commit to such innovation, for example Anderson and Aysin (2005, page 7) made the following observation: today, there is a need for an evaluation of health care information systems which "requires not only an understanding of computer technology, but also an understanding of the social behavioural processes that affect and are affected by the introduction of the technology into the practice setting" (Anderson and Aydin, 1995)

A first step towards assessing how EMRs contribute to the performance of health care delivery is to move beyond a list of efficiency and effectiveness impacts that technological innovation might produce, and identify those that are most relevant

to the healthcare organizations. In this regard, some studies (Hitt and Brynjolfsson 1996; Dameri, 2005) have shown that a purely economic evaluation of the impact of technological innovations is not appropriate in contexts like the healthcare sector, since this does not take certain effects into account such as higher quality of health care processes and the increased value for patients, as well as social effects on public health. A second step towards the assessment of the effects of EMR is to recognize that different contexts and institutional systems, distinctive organizational cultures and existing situations may mitigate some of the expected impacts.

We started our review of literature based on an "explicit, rigorous and transparent methodology" (Greenhalgh, et al. 2004) by using also in this part of the study the *metanarrative approach* described in the previous chapter. According to this methodology, our selection started with a formal search of electronic databases (EbSCO, Business Source Complete, Jstore) and then continued using the snowball method, pursuing references of references in order to select more relevant papers.

We defined a *systematic review* to be a review of literature using explicit, rigorous, and transparent methodology.

We established some criteria to guide our search:

(i)   journal articles, book reviews and comments about the use of ICT in the health care sector.

We then narrowed down our research, focusing on

(ii)   reports looking into the use of Electronic Medical Records and, more specifically, those with evaluation or assessment models.

It is evident form this review that many scholars have highlighted the potential benefits deriving from the adoption of EMR systems, assessing different dimensions of impacts, either in theoretical terms or supporting their discussion with empirical evidence.

In this regard, some authors and some studies (Hitt and Brynjolfsson, 1996; Dameri, 2005) have shown that a purely economic evaluation of the impact of information systems, which contrasts projected revenues and costs, is not only not always reliable, for example by justifying the investment made in relation to the economic benefits achieved. This method of measuring the value of ICT is not appropriate, since it does not take certain factors into account, including the strategic increase in efficiency and company performance, higher quality of processes/business services and the increase in value for patients. Other authors (including Van Gremberg et Al. 2001, 2003; Pasini et Al. 2005), highlight the need for a model to evaluate information systems where the financial perspective is replaced by the perspective of the "contribution of the information system to business and business value." It is clear that this approach is determined theoretically, starting from the assumption that the information system is not intended as a "commodity business" with the sole objective of achieving operating efficiency with a predefined budget based on industry benchmarking, but is a "strategic resource" with business-like goals whose results are not separable from business results (Hunt, 1998).

One type of benefit that has often been investigated refers to *time* and *cost savings*. Van Der Loo and colleagues (1994) argue that EMRs could reduce the time for collecting information since data is not collected and recorded on multiple occasions and patient health information can be shared more quickly

(Thompson et al. 2009). Furthermore, "sharing EMR information between different health care providers may also reduce geographical barriers and serve as a point of record integration, particularly in fragmented health systems, and consequently improving the continuity of care" (Pagliari et al., 2007). This could also lead to potential cost savings via the reduction of superfluous prescriptions or duplicated testing (Protti and Peel, 1998). An empirical study on clinicians by Joos and colleagues (Joos and al., 2006), found that "they either agreed or strongly agreed that EMRs resulted in gains compared to the pre-EMR environment due to features such as computer-retrievable lab results, chart-stored notes and other documents". This study also found evidence of another type of gain: less time needed to develop a patient synopsis and improved communications, which could lead to potential cost savings. The study by Keshavjee, Troyan et al. (2001) focused on the success of EMR implementation was based on analysis conducted at 2 different times: six months and 18 months after EMR adoption. The findings show that the time required for administrative tasks decreased within six months, but the time spent by staff for charting increased, especially nurses (who were assigned more responsibility for charting in different offices). The time spent by clinicians for charting, meaning the tracking activities if the illness of patient encounters, increased during the first six months but then returned to its original levels. Likourezos et al. (2004), found that nurses were able to finish tasks much faster than before when using EMR systems, but this finding was not valid for clinicians, who perform less repetitive activities.

Some studies (Smith, 1996; Kelly, 1998; Goodman, 2000) have shown that the adoption of EMRs can facilitate *clinical decision making*. According to Neame and Olson (1998), "there is a recognized need to share clinical information in

order to improve the integrity, continuity, safety and speed of delivering patient care. The evolution of EMRs supports the more widespread use of clinical data exchange, underlining the importance of web technology as a key element in the communications strategy and as an adjunct (or alternative) to more structured messaging environments". Furthermore, according to Laing (2002), the use of aggregated data can support decision analysis, facilitate the clinical decision making process and guide improvements in professional and organization performance in more general terms.

Some authors (Abdelhak, 1996; Bates et al. 1999; Shojania, 2009) found the adoption of EMRs can improve *patient safety*, avoiding potential errors in drug prescriptions. Cannon and Allen (2000) and Henry and colleagues (1998), explored these ideas further, observing that EMRs used to automatically generate alarms, alerts and reminders have a positive effect on the quality of patient care. Laing (2002) questioned the benefits of EMRs from the nurse's point of view and found that the use of standardized nursing language, an extensive integrated database and information management processes, provide specific data that can facilitate patient care. In contrast to these findings, the survey by Likourezos et al. (2004) on EMRs in an Accident and Emergency Ward, found that clinicians believe that EMRs do not have a positive effect on patient care since the system may produce some confusion and the time required to use it, even if EMRs are considered easy to use and they appear to be generally satisfied with the impact on their own work.

Many authors have studied a variety of effects related to *patient empowerment*. Tsai and Starren (2001) stated that "patient interaction with EMRs has the potential to reduce the frequency of clinical visits and improve health care

outcomes". Chin (1995) and Wright (1997) argued that the introduction of new communications technologies offer different ways to interact with patients and for the provision of higher quality care. Another study conducted by Littlejohns and colleagues (2003) used an evaluation programme to demonstrate that EMRs can improve the accessibility of patient-related information. Improved handling of medical records can have positive impacts on patient administration procedures, resulting in shorter waiting times and better service. This may also improve the efficiency of hospital management by facilitating decision making and productivity. However some studies (Essin et al. 1998; Makoul et al. 2001) maintain that EMR systems do not affect interaction between patients and clinicians.

All the types of impacts described either refer to effects on internal processes or organizational outputs and outcomes. The former refers mainly to managerial and organizational changes in terms of decreased transaction time and costs, reduction of the size of the organization and effects leading to structural, cultural, and procedural changes in health care organizations in the long run. Evidence on these dimensions from other sectors varies greatly (Fountain, 2001) and some authors conclude that information technology contributes very little to organizational change and instead supports the status quo (Kraemer, 2001). The impacts on organizational outputs and outcomes focus on productivity, efficiency and effectiveness (Norris and Moon, 2005). Although it is hard to measure return on investment for health care information technology in economic terms, some studies have found a positive relationship between the use of information technology and productivity (Kraemer and Dedrick, 1997).

Smith (1996), Kelly (1998) and Goodman (2000) conducted research specifically focusing on *clinical governance* and showed that the adoption of EMRs can facilitate and support clinical decisions. Neame and Olson (1998) claimed for the need to share clinical information in order to improve the integrity, continuity, safety and speed of delivery of patient care.

According to some authors (Haux, Ammenwerth et al, 2002), e-health policies will soon be focused on patient-centred recording and the use of medical data for cooperative care. In their view, this kind of process (independent of location, time and person) can only be achieved by EMRs. It is especially important in a unified Europe, since EMRs should promote ways for storing and using data for organizational support within the same and between different healthcare organizations. Introducing EMR systems within Hospitals, in fact, might help to keep track of their patients' records and to facilitate the sharing of information and clinical data at different levels (regional, national and supranational level). This stimulates the creation of longitudinal patient summaries and the definition of more efficient health care processes for individuals and more effective health policies. To recapitulate, many authors describe a variety of potential benefits of EMR implementation, providing evidence that sometimes offers counterintuitive results (Øvretveit et al., 2007). However, they also state that it is actually very difficult to measure EMR impacts because of the complexity of the subject observed, the implementation of the project and the motivation of the healthcare provider to perform an evaluation study (Ammenwerth et al., 2003).

The figure below summarize the key dimensions of impact we have identified based on the literature and that we have used in defining the interview scheme concerning the evaluation process (figure 3.1) . Then at the end of the chapter, we

drafted a table organized in three columns: for each dimension of impacts we identified the main relevant types of impacts and the related relevant literature, adding more references to those previously mentioned in paragraph 3.3 (Table 3.1).

Figure 3.1 Impact Dimensions
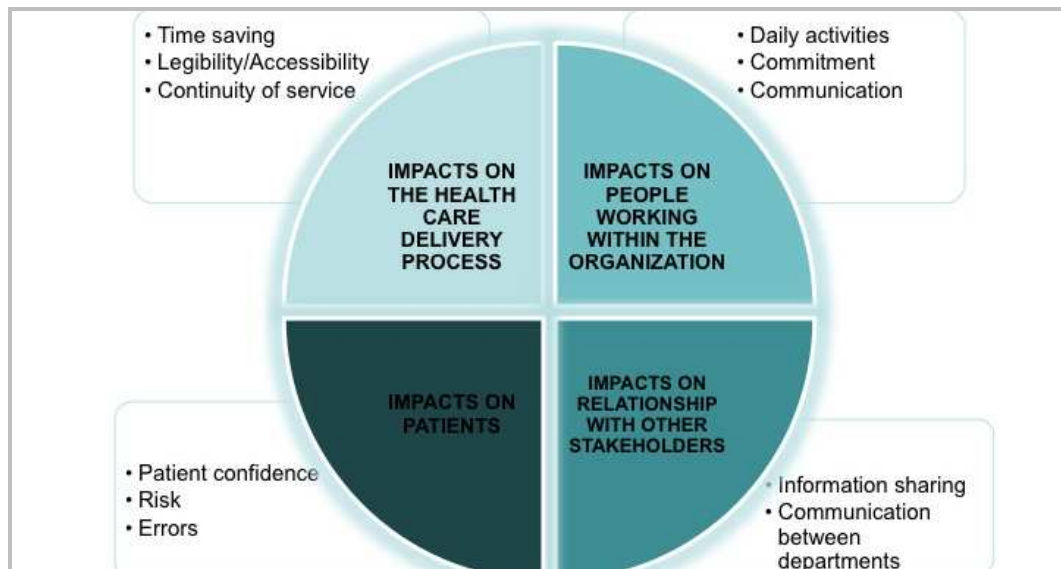
Furthermore, risks related to EMR usage within healthcare organization were largely ignored. Some papers (Jamal,2009; Thompson, 2009) refer to theincreased time associated with recording data and increased costs of EMR and also to privacy issues related to patient data, which is becoming a very topical issue. We will focus on ethical and privacy issues later in this work (see chapter 9).

Very often, health care providers are still wondering to what extent a large investment in terms of economic resources and human capital aimed at introducing complex healthcare information technology systems, such as EMRs, can effectively contribute to improvements in corporate performance. This includes outcomes both in terms of efficiency and cost savings and in terms of the

effectiveness of patient care, which in turn might have effects on public health overall.

3.5 Conclusion

Based on our analysis, we found 2 main points. Firstly, the importance of introducing EMR systems as a tool to achieve higher levels of productivity, efficiency and effectiveness. Secondly, despite the presence of a wide range of ideas and viewpoints based on theoretical considerations about the impact of EMRs (Hunt, 1998; Hillestad et al, 2005; Himmelstein and Woolhandler, 2005), there is a need to rationalize and classify the different types of impacts described in literature, putting them into a framework that can be used for assessing the impacts of EMR systems on the overall performance of health care providers. These differ due to a variety of reasons, such as the context and type of healthcare provider, the time since the implementation of the EMR system, the functions offered by the EMR systems and the main reasons for the implementation of the EMR system.

It is necessary to go beyond a list of impacts on efficiency and effectiveness that technological innovation may produce and to identify those most applicable to the healthcare organizations in order to assess how EMR systems contribute to healthcare performance. In this regard, many authors (Hillestad et al., 2005; Chen et al., 2004; Berner et al., 2005; Øvretveit et al., 2007; Pagliari et al., 2011) have shown that a purely economic evaluation is not appropriate in contexts like healthcare, since it fails to take more "social" effects into account (Berg, 2003; Kaplan, 2001) such as better quality of healthcare processes, the increasing value of these processes for patients and their overall effects on public health.

Furthermore, impacts on different healthcare organizations should be compared and how EMRs affect the performance of an organization in terms of speed and extent, whilst recognizing that different contexts and the strategies of individual organizations may mitigate or enhance some of the expected impacts.

The next chapter will set out the conceptual framework of the thesis. As mentioned previously, diffusion theory, through the lens of socio-technical approach, represents the theoretical framework of the analysis.

The thesis refers essentially to Rogers' definition of the "diffusion theory" since it aims to analyse a process of innovation diffusion and Rogers' framework can be considered as one of the most powerful framework to investigate the overall introduction of innovation, split into different phases, within an organization (Greenhalgh et al., 2005). Furthermore, it has been adopted the lens of socio-technical approach since we are interested not only to "technical aspects" but also to the "social aspects" of the development of a system (Berg, 2003).

Table 3.1 Impacts on the health care delivery process

IMPACT DIMENSIONS	Types of impacts	Selected related studies (Lead Authors and Year)
IMPACTS ON THE HEALTH CARE DELIVERY PROCESS	**Prescription writing speed**	Eslami, 2009 Niyazkham, 2009
	Image arrival speed	Maass et Suomi 2004 Baorto Cimino , Parvin, Kahn, 1997
	Report arrival speed	Van Rosse, 2009
	Time changes in logistical processes	Goraya, 2000 Zdon and Middleton, 1999
	Time changes for personnel (for example faster images results and referrals)	Wager, Lee, White, Ward and Ornstein, 2000 Jamal, 2009 Tan, 2009 Keshavjee, Troyan et al. 2001
	Time changes for personnel (for example waiting time)	Van der Loo, Van Gennip, Bakker, Hasman, Rutten, 1995 Benson and Naeme, 1994 Lambeth, Southwork and Lewisham, 2001 Niyazkhani, 2009; Thompson, 2009 Likourezos et al, 2004
	Initial costs	Terry, 2001
	Cost savings	Barlow, Johnson, Steck, 2004 Zdon, Middleton, 1999 Birkmeyer, Bates, Birkmeyer, 1999 Protti and Peel, 1998
	Dematerialization	Protti and Peel, 1998 Birkmeyer , Bates, Birkmeyer , 2002 Couch J 2000 Van der Loo, Van Gennip, Bakker, Hasman, Rutten, 1995
	Process integration	Wager, Ornestein , Jenkins, 1997
	Expenses for legal tasks /requirements	Kalra D (1990) Lambeth, Southwork and Lewisham, 2001
	Accuracy	Birkmeyer CM, Bates DW, Birkmeyer JD (2002) Delone, McLean, 1992 Hippley, Cox et al. 2003
	Completeness	Delone WH, McLean ER (2003) Jamal, 2009 Mitchel, 2001 Shachak, 2009
	Understandability	Shekelle, 2009
	Reliability	Mitchel, 2001 Shacak, 2009
	Effects on care processes	Delone, McLean, 2003 Abdelhank, 2000 Mc Shame, 1999

Table 3.2 Impacts on the people working within the organization

IMPACTS ON PEOPLE WORKING WITHIN THE ORGANIZATION	**Speed of clinical decision making**	Naeme and Olsen. 1998 Abdelhak 1996 Bates , Pappius , Kuperman , Sittig , Burstin , Fairchild ,1999; Bates, 2000 Menke, Broner, Campbell, McKissick, Becckett ,2000 Shojanie, 2009
	Transcription errors	Doran B. DePalma,1996 Bates, Leape, Cullen, Laird, Petersen, Teich, Burdick,Hickley, Kleefield,Shea, Vander,Vliet, Seger, 1998
	Decision effectiveness	Hadler, 2005
	Availability of information for the decision process	Hadler , 2005 Balas, 2001
	Patient care benefits **Care becomes more patient-centred**	Ralston, Revere, Robins, Goldberg, 2004 Kaplan and Lundsgaarde, 1996
	Changes in clinical work patterns	Pabst et al. 1996 Pizziferri et al. 2005 Kremer, 2001 Norris and Moon, 2005 Kraemer and Dedrick, 1997
	Improved communication between physicians and residents	Cooke e Peterson 1998; Keller e Teufel 1998 Rick 1997
	User friendliness for nurses and clinicians using EMR	Kaplan and Lundsgaarde, 1996 Darbyshire, 2000 Delpierre et al. 2004
	Clinician- and nurse duties	Saarinen and Aho, 2005
	Educational benefits for nurses and clinicians	Saarinen and Aho, 2005
	Improved medical record keeping	Darbyshire, 2000 Gustfson et al., 2004
	User satisfaction	Marill, Gauharou, Nelesen, Peterson, Curtis, Gonzalez, 1999
	Training time	Kovner, Schuchman, Mallard, 1997
	Information management technical courses	Gorman et al. 1996 Kaplan and Lundsgaarde, 1996
	Strategic information management courses	Schneider and Eisenberg ,1998 Mc Shame, 1999 Roscoe, 2000 Hannan, 1999

Table 3.3 Impacts on patients

IMPACTS ON PATIENTS	Patient commitment/ Patient empowerment	Tsai and Sterren, 2001 Chin, 1995 Wright 1997 Littlejohns et al. 2003 Freeman e Soete , 1994 Rikfin, 1995
	Patient safety	Cannon and Allen, 2000 Henry et al. 1998 Laing, 2002 Likourezos et al., 2004
	Measurement of patient satisfaction	Levinson, 2006 Gustafson, 2003 Bryan 2008 Eslami, 2008 Eslami, 2009
	Level of transparency in information management and documentation - patient record security	Smith, 1996 Gritzalis, 1998 Kelly, 1998 Goodman, 2000 Jamal, 2009 Thompson, 2009
	Physician and patient interaction	Essin et al. 1998 Makoul, Karry, Tang, 2001 Wager et al., 2000 Cimino, 2002 Makoul et al., 2001
	Claims from patients about clinician performance	Simon, 2007

Table 3.4 Impacts on impacts on relationship with other stakeholders

IMPACTS ON RELATIONSHIP WITH OTHER STAKEHOLDERS	Territorial integration	Abdelhank. 2000 Pagliari et al. 2007
	Information sharing with GPs	Porteous, Bond , Robertson Hannaford, Reiter 2003
	Improved communication among different department/hospital sites	Cooke and Peterson, 1998 Keller and Teufel, 1998 Rick 1997 Canfield, 1994 Gadd et al. 2001 Doolan, Bates et al. 2003

CHAPTER 4

CONCEPTUAL FRAMEWORK

The previous two chapters set the context for this work by illustrating the precedents and discussing current works on the public and healthcare sectors, focusing on the Electronic Medical Record system in particular.

The purpose of this chapter is to offer a critical analysis of literature on innovation diffusion theory. It reviews the following issues in particular: i) what is diffusion theory; ii) how it has been used; iii) how it has been adopted in other fields of research, especially the adoption of information technology in the health care sector; iv) how other approaches, such as the social-technical approach, can help us get a better vision of the organizational context.

This chapter looks at innovation and Diffusion Theory in greater detail and how it may help us interpret and understand the spread of innovation within the health care sector. We also applied the lens of the social-technical approach for this analysis to identify all the relevant aspects that are associated with this study: "technical aspects" that have to be balanced with the "social aspects" of the development of a system (Berg, 2003).

4.1 Introduction

Innovation is essential for the effective operation of any system. In the private sector, innovation is mainly driven by the need to stay ahead of the competition

(Leonard-Barton, 1988; Zander and Kogut, 1995). For example, in contrast to the private sector, innovation in the public sector does not necessarily aim at the economic improvement of the organization, even if its main goal is to enhance its efficiency and effectiveness.

Althsuler and Behn (1997) argue that the "need" for innovation can be attributed to the influence of the notion that was widespread in the 1980's whereby innovation in the private sector can be considered a "*positive*" factor. It follows that this must also be true in the public sector; according to Donahue (2000), innovation in public administration is considered a fundamental process in order to accomplish and satisfy public interest and to provide more services with a high impact on society.

Furthermore, we need to analyze different approaches to innovation for a better understanding of how public organizations can be transformed so they can investigate and fulfil the needs of stakeholders. Such considerations are useful for providing theoretical and practical guidelines on how the introduction of processes of innovation can effectively improve the performance of public administration and the public sector as a whole.

4.2 Innovation: the broad concept

A great deal of discussion on the diffusion theory has appeared in innovation literature by academics and practitioners in recent years due to the extensive adoption of innovation in the public sector. According to Drazin and Schoonhoven (1996) "the growing importance of *innovation* for organizations is reflected in the dramatic increase in literature that addresses the role and nature of innovation".

The subject of innovation has been a longstanding matter for many scholars and disciplines. Schumpeter (1939) argues that innovation is totally different from invention, which "occurred in isolation and which could not be coupled with innovation". Barnett (1953) maintains that innovation represents the basis of change and he gives a broader definition with his suggestion that innovation is "any thought, behaviour or thing that is new because it is qualitatively different from existing forms". Usher (1954), the economist, reflects on sociological thought and argues that innovation is the combination of many "individual items of novelty as well as many familiar elements": Usher's definition emphasises that innovation is not an accidental or mechanistic affair and he suggests a cumulative synthesis approach in which the "act of insight" represents a crucial stage.

Furthermore, many *empirical studies* have investigated innovation processes. Brown (1957), for example, studied a machine-tool industry and reveals that in this kind of organization "innovation has been planned to increase demand for machine tools", highlighting the principle that innovation processes can be programmed and they do not need to be discontinuous.

Rogers (1962) focused on this concept in a seminal contribution on the diffusion of innovation, by examining the *"unit of adoption"* and considering innovation to be any idea, practice or object that is perceived to be new by an individual or other unit of adoption. This definition can be applied to the behaviour of individuals and may be useful in this case, but it is less useful at an organizational level.

Other authors have discussed the relationship between innovation and the unit of adoption. According to Bradford and Kent (1977), innovation is "the successful introduction of ideas, perceived as new, into a given social system", emphasizing

the concept that anything that is acknowledged as new by a social group may be considered an innovation. Osborne (1998) identified the 4 main characteristics of "innovation" based on organizations studies:

- Newness;

- It differs from an "invention, namely the discovery of new ideas or approaches, whereas innovation is concerned with their application;

- It can be considered a process and also an outcome;

- It involves discontinuous change.

This last attribute represents the difference between innovation and incremental development in an organizational context (Tushman and Anderson, 2003).

Many authors have recently emphasised that *innovation* is more than an idea (Moore and Hartley, 2008): innovation is "new ideas and practices brought into implementation" (Tidd et al., 2005). Lyin (1997) maintains that "innovation must not simply be another name for change, or for improvement, or even for doing something new: innovation is properly defined as an original, disruptive and fundamental transformation of an organization's core tasks". Nohria and Gulati (1996) consider the organizational context of private business more specifically and define innovation to be "any policy, structure, method or process, or any product or market opportunity that the manager of an innovating unit perceives to be new". Damanpour (1991) describes innovation as "the generation, development, and adaptation of novel ideas on the part of the firm".

The modernization of the public sector is no recent phenomenon, although the approaches to the adoption and implementation of innovation have only recently

been extended at a more organic and systemic level.

There are several practical and theoretical studies that investigate the development of innovation processes in the public sector.

In particular, there is abundant literature describing the approaches to the adoption of technological innovations in the public sector and it has driven the debate on the nature of technological innovation since the 1970s, meaning the process of the introduction of new tools (including physical equipment, such as personal computers) and new logic and set ups in government (Walker, 2006). Some authors (Mele, 2008; Osborne and Brown, 2005) argue that different theoretical perspectives can be applied: the transformation, the continuity and the structural approach.

The "*transformation perspective*" finds that technological innovation contributes directly to the creation of a revolutionary shift from the "industrial society" to the "information society". Analyzing the context of the public sector, it arises that the logic and mechanisms introduced by this kind of innovation facilitated the transformation of relationships within different types and levels of governments and with their stakeholders. For example, the introduction of information and communication technology improved the accessibility to public services, reducing the time and cost involved to access them.

The second perspective is called "*continuity*". According to this school of thought, the technological innovations that exist today are the incremental evolution of those implemented in the past. They make a marginal contribution to the transformation of the public sector: the process of change and adoption of innovation in the public sector is a long-term development and the ability to contribute to its overall performance is mediated by failures, delays, resistance to

change and inertia. This view was widely shared in the past, since many authors argued that the adoption of technological innovation did not lead to a real transformation of the public sector, just as the adoption of technological innovation did not actually lead to a real transformation of the private sector. The changes that occurred affected the activities of a handful of organizations and have often been traced to effects produced on individual areas.

The third perspective is "*structuralism*". It shares some principles with the transformation viewpoint. In particular, it accepts the potential resulting from the adoption of technological innovation, but rejects the cause-effect relationship linking social evolution to such innovation. Structuralism does not accept technological determinism and emphasizes the concept of exchange and mutual influence between the development of technological innovation and social institutions.

This last perspective is the most closer to the approach adopted in this study, since our aim is to investigate the interactions between technical and social aspects in such a process.

In this line of reasoning Damanpour and Euan (1984) previously, have also offered a definition of organizational innovation that can be considered crucial for the programme of modernization in the NHS in Britain: "innovation is the implementation of an internally generated or a borrowed idea - whether pertaining to a product, device, system, process, policy, program or service, that was new to the organization at the time of adoption… Innovation is a practice, distinguished from invention by its readiness for mass consumption and from other practices by its novelty" (Damanpour and Euan, 1984).

Furthermore, Greenhalgh et al. (2005) offer a specific definition referring to

innovation in the health care sector, whereby it is "a set of behaviors, routines and ways of working, along with any associated administrative technologies and systems", which are:

- Perceived as new by a proportion of key stakeholders;

- Linked to the provision or support of health care;

- Discontinuous with previous practice;

- Directed at improving health care, administrative efficiency, cost effectiveness or user experience;

- Implemented by means of planned and coordinated action by individuals, teams or organizations.

(Adapted from Greenhalgh et al., 2005)

The innovation processes analyzed and discussed in this work can be considered consistent with the above definition, as we will see in more details in the next chapters.

4.3 Diffusion theory: theoretical framework and previous studies

Having ascertained the phenomenon of innovation, the challenge then becomes its diffusion. As stated above, many authors discuss innovation in the private sector and consequently most studies of its diffusion have been focused on this (Lapsley and Wright, 2004). However, these studies contain some useful suggestions that can be adapted to the public sector for the analysis of the diffusion of innovation at management level.

Before starting to analyse the diffusion of the innovation theory in managerial

practices in health care research in particular, it will be useful to establish a broad definition of the "diffusion theory". Many authors have tried to explore this concept by developing several models, each with a different approach towards the diffusion of innovation in an attempt to explain this concept as a process consisting of mutually dependent and consecutive stages.

The chapter analyses some earlier models, which we consider influential and that have been adopted in many subsequent studies. Firstly, the "classic diffusion theory" is associated with Rogers' diffusion model presented in 1962 in the first version of his book "Diffusion of innovation". Rogers explains that communication is "a process in which participants create and share information with one another in order to reach a mutual understanding". More specifically, the diffusion process involves 4 elements:

- *An innovation*, namely something perceived as new. According to Rogers, new ideas are often technological innovations and we often use the word "innovation" and "technology" as synonyms.

- *A communication system*, namely a transmission system from one individual, group or society to another. The essence of the diffusion process is the exchange of information, when one individual communicates a new idea to another or several others.

- *A social system*, namely a set of interrelated units that are engaged in joint problem solving to accomplish a common goal, providing the domain for the diffusion process. The social system can consist of individuals, informal groups, organizations or other subsystems.

- *Time*, from the initial awareness of innovation to saturation of its adoption in the social system.It includes: the innovation-decision process, the innovativeness of an individual or other unit of adoption compared to

other members of a system and the rate of adoption of the innovation by a system.

Subsequently, Rogers distinguishes five key stages in the innovation diffusion process. He defines the innovation diffusion process as "the process through which an individual or other decision-making unit, passes from gaining initial knowledge of an innovation, to forming an attitude toward the innovation, to making a decision to adopt or reject, to implementation a new idea, and to confirmation of this decision" (Rogers, 2003, page 168).

In particular he refers to:

(1) Knowledge, in which the agent becomes aware of the existence of the innovation;

(2) Persuasion, characterized by the agent that becomes progressively interested by the innovation;

(3) Decision, in which the agent tests the innovation on a small scale;

(4) Implementation, in which the decision for adoption is taken;

(5) Confirmation, when the agent seeks reinforcement of his decision or rejects it.

Table 4.1 Rogers' Stages of the Innovation Decision Process

Knowledge Stage
Comprehension of messages
Knowlege or skill for effective adoption of innovation
Persuasion Stage
Discussion of new behaviour with others
Acceptance of the message
Formation of positive image of the message and innovation
Support for the innovative behaviour from the system
Decision Stage
Intention to seek additional information about the innovation
Intention to try innovation
Implementation
Acquisition of additional info about innovation
Use of innovation on regular basis
Continued use of innovation
Confirmation Stage
Recognition of the benefits of using the innovation.
Integration of the innovation into ongoing routine
Promotion of innovation to others

Adapted from Everett Rogers, Diffusion of Innovations, 4th ed. (New York: Freepress), 1995, p. 190.

Each of these steps involves interaction and fine tuning with the others and so they are never really separate. Moreover, many studies have discussed how the degree of diffusion and transformation inherent to innovation processes follows a line or curve (regular or S). The various diffusion models have limitations and each one focuses on different aspects. Regardless of this, it is important to note how they are influenced by factors that determine innovation, since the nature and direction of effects obtained through the process of change will depend on the levels of innovation pursued.

Another central concept in the Rogers modelconsists of five relevant *innovation characteristics*:

- Relative advantage;
- Compatibility;
- Complexity;
- Trialability;
- Observability.

Rogers argues that those attibutes can directly influence the level of innovations' adoption.

Table 4.2 Attributes of innovations that have been shown by Rogers to influence the adoption and implementation of ICT within organizations.

Attributes	Explanation
Relative advantage	The degree to which an innovation is perceived as being better than the idea it supersedes.
Compatibility	The degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters
Complexity	The degree to which an innovation is perceived as relatively difficult to understand and use.
Trialibility	The degree to which an innovation may be experimented with on a limited basis-possibility of experimentation)
Observability	The degree to which the results of an innovation are visible to others

In this study we tried to observe and verify the presence of this charactiristics in the two case studies analyzed to discuss the applicability of this model to our specifc settings.

Other scholars have tried to explain the concept of the diffusion of innovation by focusing on different contexts or different aspects.

Abrahamson (1991) offers a framework to understand the notion of innovation diffusion, since he maintains that there are three possible perspectives in addition to the efficient choice perspective (whereby innovation diffusion occurs because of the benefits it offers the organization): the *forced,* the *fashion* and the *fad* perspective. With regard to the *forced* perspective, many authors (Carroll et al., 1989; Scott, 1987) argued that a number of organizations authorised by government agencies, can *force* the diffusion of innovation within an organization and the adopting organisation does not play any part in the implementation process. The *fashion* perspective assumes that innovation is taken on by potential

adopters in conditions of uncertainty in order to imitate administrative models prompted by "fashion setting-organizations" (Abrahamson, 1991), such as management consulting firms, without taking any specific decision about the implementation process. The *fad* perspective assumes that the diffusion of innovation occurs when organizations within a group imitate other organizations with no other rational reason (Abrahamson and Rosenkpof, 1990; Arthur, 1988).

Johannessen et al. (2001) took these models and drew on the analysis offered by innovation literature in order to identify 4 approaches to the diffusion of innovation:

1. *individual-oriented*, emphasizing the role of individual factors, for example level of educational age and gender in the innovation process (Scott and Bruce, 1994);
2. *structure-oriented*, focusing on organizational characteristics such as the interactions between the organization external environment (Slappendel, 1996);
3. *interactive-oriented*, pointing out on how action affects structure in the innovation process(Van de Ven and Poole, 1988; Pettigrew, 1985);
4. *systems of innovation-oriented*, where the main focus is represented by the organization considered within "the environment", focusing on knowledge infrastructures and networks (Nelson and Winter, 1982)

This framework attempts to expand the focus from individual factors to the organizational and external environment in the broadest sense. For these reasons, his work was very influential for the creation of the modern field of diffusion theory.

However the present work of this thesis refers essentially to Rogers' definition of the "diffusion theory" since it aims to analyse a process of innovation diffusion and Rogers' framework can be considered as one of the most powerful frameworks to investigate the overall introduction of innovation, split into

different phases, within an organization (Greenhalgh et al., 2005).

Furthermore, the five innovation characteristics identified by Rogers provide a better understanding for the adoption and decision making process and also help to evaluate the implementation of new technological innovation and to illustrate how these variables interact with one another (Wu et al., 2005).

4.4 Diffusion of Innovation: criticism of previous approaches and further study

Although all the models and frameworks discussed above provide a very attractive base to study the diffusion of innovation and despite producing some interesting empirical findings on innovation, many authors argue that these theories must be modified and extended in order to enhance their usefulness in the contemporary society (Chua, 1995; Briers an Chua, 2002). The previous models do not capture the complexity of the process that involves the *individual* and the *organizations* that have to adopt an innovation and present a number of theoretical limitations:

- innovations are considered **transferable** to new contexts and settings;
- **interaction**s between various social and technical systems is not taken into consideration;

The beginnings of diffusion research left an indelible stamp on the approaches, concepts, methods and assumptions in the field due to several reasons. First of all, the diffusion model is a paradigm that can be applied to many fields. The multidisciplinary nature of diffusion research cuts across various scientific fields and its most important strength is to consider **time** as an essential element in the analysis of changes in human behavior. Second, the diffusion approach enables solutions to be suggested to individuals and organizations that have invested in

research on a topic and hope to get their scientific findings applied and those who want to use the results of research by others to solve a particular social problem or to fulfil a need. Furthermore the methods implied by the classical diffusion model are relatively straightforward to apply and replicate.

Nevertheless, there is ample criticism of research into diffusion:

- The *pro-innovation bias*: namely innovation should be spread among and adopted by all members of a social system; it should be spread rapidly and the innovation should be neither re-invented nor rejected. Other attempts to understand "why does innovation appear or disappear" have demonstrated that the early diffusion theory was characterized by pro-innovation biases (Rogers 1962, 1983; Van De Ven, 1986; Zaltman, Duncan and Holbeck, 1973). According to Kimberly and Evanisko (1981), pro-innovation biases imply that innovation will benefit organizations: in this sense, innovation only spreads when it benefits the organizations adopting them, and disappears when it does not. According to this definition, the diffusion process depends on the "benefits" that an organization can have after its adoption, de-emphasizing the importance of inter- and intra-organizational decision making in the design of new technologies (Lapsley and Jackson, 2003).

- The *individual-blame bias*: the tendency to focus the attention on an individual rather than on the system that the individual belongs to.

- The *recall problem* in diffusion research, which may lead to inaccuracies when respondents are asked to remember the time when they adopted a new idea.

- The issue of *equality* in the diffusion of innovation, as social and economic gaps between the members of a social system are often expanded as a result of the spread of new ideas.

Other authors have provided other frameworks in an attempt to review Rogers' theory of the diffusion of innovation. Dubin (1978), for example, points out that Rogers' diffusion of innovation theory focuses on diffusion and adoption by individuals and not within an organization. Dubin analyses Rogers' diffusion model and argues that there is a need for a better description of the interaction between the innovation, the adopter, the social system and the other influencers of adoption, and above all of how these units relate to the diffusion of innovation within an organization. Finally, Rogers' model focuses on the diffusion of innovation within an organization and he does not investigate the diffusion across organizations.

However, different ways of describing the innovation process within organizations have been developed over the years. Van de Ven (1986) argued that "there are two cycles in the implementation of innovation stemming from the external context: two cycles are shown to exist in companies when implementing *externally-induced innovation*: 1) a vicious cycle during which poorly performing organizations respond with rule bound behavior and this response perpetuates their poor performance; 2) a beneficiary cycle during which better performing organizations are autonomous and this response reinforces their strong performance". This may be a different way of describing Rogers' innovation-decision processes within organizations: namely, the vicious cycle may be related to authority in the innovation-decision process and the beneficiary cycle related to collective innovation-decision.

Marcus and Weber (1989) applied the vicious and beneficiary cycles to the nuclear safety standards industry to test them empirically. Results of the study showed that the autonomy approach was linked to fewer safety events and fewer human error events. Their study supports the hypothesis that autonomy is likely to be associated with fewer human error events. Marcus and Weber (1989) looked at evidence from other studies of externally-induced innovation to support their nuclear study findings. Five studies on naval systems, and medical devices, either involving a process innovation, a product innovation or both, showed similar results supporting the hypothesis that autonomy is key to the successful adoption of externally-induced innovation.

Lindquist and Mauriel (1989) conducted a case study to test the importance of breadth versus depth in diffusing innovation within schools. In their study, breadth was indicated by the number of organizational lines or departments crossed horizontally during the innovation adoption process. Depth, on the other hand, was an innovation effort focusing on a specific work group or organizational unit. They concluded that there is greater sustainability of the breadth approach, that depth approaches are slower to launch and that the depth approach is more challenging because of multiple stakeholders. However, they found no conclusive answer to their central research question (which approach is more productive in facilitating smooth and effective adoption of the innovation). The distinction between breadth and depth provides a useful extension of Rogers' work regarding communication channels and their particular role in diffusion within organizations.

Other research substantiates and extends parts of Rogers' theory and provides more specific elements. Damanpour (1992) conducted a meta-analytic review of

innovation diffusion looking at the relationship between organizational size and innovation. His findings confirmed that size is a key factor in the structure of an organization for the diffusion of innovation, as suggested by Rogers, but Damanpour found that size was related more strongly to the *implementation phase* than the *adoption decision phase*. The meta-analysis also showed that size is a more important factor for manufacturing organizations than service organizations and for profit making organizations than for not-for-profit settings (Damanpour, 1992).

Areas of research developed and sometimes broke away from such conceptual models, in the attempt to emphasize the role of "social process" in innovation diffusion.

Greenhalgh et al. (2005) also conducted a systematic review of literature on the diffusion of innovation in the organization and delivery of health care services. Based on this review, classical diffusion of innovation can be considered a body of knowledge built around empirical work, demonstrating a consistent pattern of adoption of new ideas over time by people in a social system. In developing this view they emphasized the existence of limitations related to classical diffusion theory models. "These early research traditions were all characterized by pro-individual[1], pro- innovation bias[2] and took little account of the wider context (historical, political, ideological, organizational) in which adoption decisions were made or of the unintended consequences of innovation" (Greenhalgh et al. 2005 p.

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[1] "Pro-individual bias" refers to the focus of classical diffusion studies which emphasize the existence of particular categories of individuals such as for example "early adopters" and so on, focusing less on the relevance system variables.
[2] With the term "pro-innovation bias" the authors refer to classical diffusion models which were characterised by a huge amount of descriptions related to some aspects of innovation process, since "it is easier to study some phenomena than others" (Greenhalgh et al. 2005 p 58), as happened for example with studies who describes adoption compared to the number of studies related to non adoption or rejection of innovation.

48).

From an organizational perspective, the diffusion of innovation depends on ideas and information collected from outside, on "what other organizations in the social network are perceived to be doing, and on mutual sense that occurs between organizations in relation to an innovation" (Greenhalgh et al. 2005). In fact, "the ability to exchange information about innovation and related experience among members of a network is related to the degree of association between organizations by an *interpersonal network*" (Korteland and Bekkers, 2008).

Also Greenhalgh et al. (2005) analysed a broader range of literature and found that social networks influence the diffusion of innovation since they represent the channels through which interpersonal communication takes place. They have the added benefit of increasing the "adoptability" of an innovation by increasing its observability.

Some studies focus specifically on *interpersonal influence* within social network of health professionals. Fornell and Warnecke (1988) conducted a study into the diffusion of cancer patient management strategies between networks of clinicians, discovering that informal and formal interaction between the members of the organization might stimulate the transfer of knowledge and its dissemination inside the agency.

In conclusion, these authors find that *networks* represent a crucial element for stimulating the diffusion of innovation. This dimension of the diffusion process is discussed in further detail below.

4.5 The innovation diffusion theory and ICT adoption within organizations

According to Fichman (1992), the innovation diffusion theory "provides well-developed concepts and a large body of empirical results applicable to others fields, such as study of technology evaluation, adoption and implementation". The diffusion theory provides tools that enable the evaluation of the "diffusion" of a technology and the identification of the factors that facilitate the adoption and implementation of Information and Communication Technology (ICT). These factors include the "characteristics of the technology, characteristics of adopters, and the means by which adopters learn about and are persuaded to adopt the technology" (Rogers, 1995). Likewise, most micro-level research has tried to identify the relevant factors of ICT diffusion at organizational level (Zmund, 1982) without considering the external environment.

However, some authors focus on the relationship between internal and external factors, arguing that "ICT systems are global networks that link organizations, customers and business partners around the world" (Kim and Galliers, 2001). They used empirical evidence to show that ICT diffusion is determined by the interaction between these 4 dimensions and the pervasiveness of Internet systems, showing that ICT diffusion cannot take place without considering both the internal and external context.

In particular, some scholars focused on the role of networks in the diffusion of ICT innovation. Korteland and Bekkers (2008), for example, examined the diffusion process of electronic service delivery to Dutch policy forces, noting that organizational, political and network characteristics have gained great importance. In fact, the diffusion of innovation among the different organizations is influenced by the degree to which organizations are linked by an interdependent network.

In most cases ICT support these processes, overcoming geographical barriers and stimulating team working and the formation of intergovernmental relationships and ultimately networks. Fountain (2001) states that ICT has the potential to reframe the set up of an organization, redistributing power and responsibilities by providing transparent, reliable and shared information, even if this does not happen in all the cases (West, 2005; Norris and Moon,2005) .

4.6 The use of Diffusion Theory in health care organizations

Although what may appear to be the strongest papers on diffusion theory fall outside the field of healthcare IT, the key papers in healthcare IT diffusion lead us to believe that the general diffusion theory is applicable to HIT and to EMRs in particular (Bowers, 1995), and some papers exists that link the diffusion theory to healthcare IT. England, Stewart and Walker (2000) put the diffusion of healthcare information technology into Rogers' (1995) diffusion framework.

England et al. (2000) found that the slow pace of HIT diffusion is due to the fragmented structure of providers, the immature status of strategic HIT, limited financial resources and the complexity of HIT systems. Both organizational and technological factors lead to the slow adoption of strategic IT. Anderson and Jay (1985) find that "informal communication networks, in this case physician networks, are very important for the process of diffusion".

Researchers, theorists, and practitioners from many fields are interested in and affected by the diffusion of innovation within and across organizations and today more 6000 papers and pieces of work have used Diffusion Theory as theoretical framework, in more than 14 different fields of research (Greenhalgh et al., 2005), including organization development, education, management, health care and public health, information technology, and sociology (Damanpour, 1992; Johns,

1993; O'Neill, Pouder, & Buchholtz, 1998; Premkumar & Ramamurthy, 1994; Wright, Palmar, & Kavanaugh, 1995; Van de Ven & Poole, 1988).

4.7 The Socio-technical approach

In health care studies focusing on the adoption and evaluation of innovation technologies, it has become increasingly important to take elements into consideration originating from social science and the social world (Kaplan, 1997; Lorenzi et al. 1997).

According to Kaplan, 2001, "social interaction models" are based on Roger's classic diffusion theory and thus emphasize how an innovation like an information system is communicated through channels over time.

> "*Sociotechnical approach aims to do just this: increase our understanding of how information systems or novel electronic communication techniques are developed, introduced and become a part of social practices. With this aim comes a concurrent ambition to improve these systems. When insights from the social sciences can help us better understand these phenomena, after all they may also help us to make better systems - or to make systems function better*"(Berg et al. 2003, p. 297)

This approach to the diffusion of innovation emphasizes the importance of interactions between individuals and social elements.

In Rogers' work (2003) on the diffusion of innovation, he measures the attitude of an individual toward an innovation itself (Wu et al., 2005) but he does not explain the role of organization as a whole within the innovation process. According to Kaplan (2001) and Berg (1999), the adoption and introduction of ICT in the health care sector involves a variety of people, organizational and

social issues including human-computer interaction, socio-technical, cultural and ethical concerns. Berg (2003), in particular, considers organizations and the work practices within them, as networks of various related elements, such as people, tools, organizational acts and documents.

In particular, the introduction of EMRs by healthcare organizations may be accompanied by changes at several different levels (Anderson and Aydin, 2005):

1) Individuals and their jobs;

2) A department as a whole and how each department performs its tasks;

3) The structure and operation of the entire organization:

4) The quality of both the service received by patients and the medical care delivered.

(Adapted from Anderson and Aydin, 2005)

In such a context, the socio-technical approach "seeks to identify the dynamics between technology and the social professional and cultural environment in which it is used" (Li, 2010). Technology and organizations are elements that constitute an assembly that should be dealt with as a whole rather than a "technical subpart for the engineers and a social subpart for the social scientists" (Berg, 1999). The introduction of electronic medical records, for example, in a context where paper-based records were previously used can have "huge consequences in terms of relations among professionals within the hospital (Bowers 1995; Egger, 1993).

In particular, Kaplan (2001) in order to explain the diffusion of innovation systems within health care organizations and the spread of EMR systems,

developed the "4 Cs" model, name after the initial letter of the main elements she considered relevant for drafting her framework: *Communication,* meaning the interaction process within the department; *Care*, referring to the delivery of health care services; *Control* over the organization; and *Context,* referring to the clinical context in which innovation technologies are adopted. She found that a combination of both social and technical elements can help to define a valuable implementation process that may also be helpful for its subsequent evaluation.

In a more specific way, Berg (2003) stated that the adoption of the socio-technical approach to explain the introduction and implementation ICT within the health care sector, typically has 3 main elements. Firstly, the nature of the *context* of the healthcare organization, which has to be seen as a "heterogeneous network of people, tools and organization routines" (Kling and Scacchi, 1996; Bijker and Law, 1992). Berg (1999) suggests that a second element to take into consideration is the *nature of the work*, as the core activity is managing patient trajectories and this implies working in a context marked by regular emergencies. Furthermore, all the activities at the hospital are marked by *continuous negotiations* between the different members of staff involved in the health care delivery process. The last element that Berg considers to be relevant for adopting a sociotechnical approach is the importance of *qualitative methods*, since it is fundamental to observe and get closer to the grasp on the flows and forms of information (Berg, 1999; Berg 2003).

We should also consider that "health care organizations are complex" (Braithwate et al, 2009) and that ICT is "a potentially disruptive innovation that challenges the way in which health care is delivered" (Westbrook et al.2009).

For this reason the approaches to ICT implementation used in other industries

have had limited success in the health care sector for these reasons (Westbrook et al 2009) and between 50% and 80 % of EMR projects still fail today (Greenhalgh et al, 2009).

"..Many systems fail. Not because of hard- or software problems, or of fundamental limitations to the technologies being used. But since they are built upon the wrong assumptions they incorporate problematic models of medical work or they fail to see 'implementation' as organizational change. One additional important reason for system failure is the omission of evaluation studies during system development. This might be the largest challenge for the sociotechnical approach: finding out just how to interrelate the nature of health care work with the characteristics of formal tools." (Berg et al. 2003, p. 300)

As pointed out by Berg systems' failures are not only due to technical problems: in most cases they are related to lack of people involvement within the project since the initial phase, to absence of communication and training plans, to lack of evaluation and monitoring tools. These are all key "social" elements and aspects to take into account in the adoption and implementation of technologies within such complex organizations, like health care organizations.

4.8 Conclusion

This chapter aimed to provide an analysis of the innovation diffusion theory and its application to the diffusion of innovation and communication technologies in the health care sector. It also aimed to explore other research fields where it has been adopted. After illustrating the "innovation" concept, the chapter analyzes studies of "diffusion theory". Since published materials cover innovation in the private sector, most studies into diffusion have also been focused on the context of the private sector. However, there are some useful lessons that can be learnt from these studies and that are readily adapted to the public sector for the analysis of innovation diffusion at management level. Some authors argue that the diffusion theory has been marked by pro-innovation biases (Rogers 1962, 1983; Zaltman, Duncan and Holbeck, 1973), whilst others emphasize the role of the

"social process" in innovation diffusion, introducing the concept of *internal* and *external networks* (Jackson and Lapsley, 2003) and also of *informal networks*

The chapter describes several empirical studies that have applied a diffusion theory to the private sector and the public sector. It also explores how the innovation diffusion theory might be adopted in other research fields, introducing studies into the diffusion of innovation of new technologies (ICT) and finds that the diffusion theory helped explain the adoption of different types of new ICT.

Then the chapter highlights the diffusion of innovation in the particular context, such as the healthcare sector and concludes with a remark on the relevance of interaction between technical and social aspects (Berg, 2003; Kaplan 2009).

Consequently, a socio-technical lens has been adopted in this work in order to explain the diffusion of innovation within the health care sector. Social-technical approaches favour a central role of the users throughout the development process, even if defining how to involve the users is not easy (Faber, 2003 Hartswood et al, 2003). In fact, it often happens that users are only consulted a few times in meetings whose setup mitigates any real involvement of users or any real openness of the designers (Markussen, 1994).

The theory proposed by Berg and Bergen (2004) identified user-involvement as a being important to foster the ownership of the systems that will actually match work processes. All these key elements will be further discussed by analysing the case studies results.

CHAPTER 5

METHODOLOGY

Chapters 1-4 offered a detailed discussion centred on the context of ICT adoption within the health care sector based on previous studies and empirical research. They also introduced the theoretical arguments underpinning the adoption and development of e-health. This chapter sets out the research questions presented by this study and the methodology adopted.

After the introduction, section 2 sets out the research questions of the study , section 3 provides an explanation of the *empirical work* that has been conducted, starting from the bearing of the research perspective adopted for this study.

Section 4 discusses the *method* chosen for the research, while section 5 focus the case study approach used in the study, the strategy of data collection and the analysis of the data,.

Section 6 then analyses *other relevant issues* stemming from the project in terms of limitation of the research.

5.1 Introduction

It is evident from these previous chapters that there are several research gaps in literature in terms of systematic comparative international research into the adoption, implementation and evaluation of IT in the healthcare sector and in

particular there is a lack of studies focusing on EMR systems within Acute Care providers.

When this research commenced, there was a clear lack of cross national studies, since much research into EMR is currently country based. This substantiate a need for a common basis of comparison, since previous research uses different sources of data, methods of research and metrics. It also identified the need to focus on the overall introduction of EMR systems within acute care, since previous studies attempted to make a quantitative evaluation

Furthermore, this thesis seeks to contribute to a deeper understanding of the roles played by the various actors (humans and non-human actors) within the hospital and the interaction between people and IT systems, in the introduction of EMR.

5.2 Research questions

The framework for this study is the e-Health stream of research with a particular focus on Electronic Medical Record (EMR) systems. The definition of e-health embraced for this project is "is *e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology"(Pagliari et al, 2005)*.

In this context, EMRs are information systems that manage both the "distribution and processing of information" (Lærum and Faxvaag 2004) necessary for the patient care delivery process.

The main purpose of the study is *to identify* the key issues in the development and implementation of e health and to *evaluate* how the adoption of EMRs influences health care service provision in hospitals, analysing how these systems affect the organization and the operations of its main users and stakeholders.

This purpose is steered by two types of motives: a*cademic* and s*ocial*:

- the primary reason is the desire to fill a gap in the literature in terms of the lack of systematic comparative international research offering an evaluation of the impact of IT (and EMRs in particular), by making a theoretical and methodological contribution;

- the study also aims to contribute to the development of guidelines for public decision makers by offering a better basis of analysis relating to the use of IT and its impact on service delivery for practitioners and policy makers involved in the health care sector.

Based on these objectives, the project aims to address the following research questions:

- *RQ1: What are the key issues in the implementation of e-health?*

- *RQ2: How are EMR systems adopted by different health organizations and what are their main impacts?*

5.3 The research design and ANT approach (description and justification of method)

The research perspective featuring in this research project draws on the "Actor Network Theory" (ANT) approach pioneered by Latour (2005). This approach has been used in several fields of research to examine the "innovation diffusion

process". According to the ANT, the "diffusion of innovation happens due to networks formed by interconnections between human and non human actants" (Law, 1986). Consequently, this research project opted to analyze the development of e-health policies and the implementation of information systems, especially EMRs, and the resulting effects at health care organizations through the lens of "actor networks theory", considering these systems "within the context in which they evolve" (Callon, 1986) since we are interested in analysing how these systems affect the organizations adopting them, the people involved and the way they operate, rather than restricting the investigation to a mere evaluation of the performance of the system.

In recent decades, the dominant theoretical approach to information and communication technology studies has been generally marked by *positivist* traditions (Kauber, 1986) and objectivism has been the epistemological assumption underlying them (Crotty, 1998) The positivist approach emphasises the adoption of models which demonstrate causality and the testing of previously established hypotheses. Most of these studies were actually based on methods that "neglect aspects of cultural environment, social interactions and negotiation" (Lyytinen,1987). However, sociologists and psychologists criticized this approach, since they maintain that studies on IT evaluation cannot be only based on "continuously statistical hypothesis testing" (Galser and Strauss 1967) without considering the effect of context. Many studies have demonstrated that the development of information systems is also affected by the organization's characteristics, including "soft aspects" such as social, cultural and individual factors (Damonpour 1991, Norris and Moon, 2005). As a result, great importance has been delegated to the meaning of the context since it is considered to be socially constructed by people in their environment.

Consequently, the view was adopted for this research project that originated in the "Actor Network Theory". Through the ANT lens, material objects are not considered merely passive resources that only become important when activated by human actors; instead, they play a key role in social configuration in their own right. Once an object participates in human action it becomes an actor. It is the job of the researcher to identify these objects in a network and find a way "to make them talk" (Latour, 2005).

"Approaches to ICT implementation used in other industries have had limited success in the health care sector" (Westbrook, 2009). In fact, compared to other settings, health care organisations "are complex organizations" (Braithwaite, 2009). Unlike some industries, "ICT in health can increase the complexity and intellectual content of the world, rather than simplify it" (Westbrook, 2009).

In such a complex context, ANT can represent a useful tool for gaining a deeper understanding of how the power change relationship happens in relation to the introduction of information systems within a health organization (Mc Lean & Hassard, 2004).

The ANT approach can also offer an interesting insight into the role of objects within specific contexts. Again, objects are not considered "black boxes" or containers of information, data or words and so on, but they become real actors.

According to Doolin and Lowe 2002 "ANT's main shortcoming is its being everything *but a theory*". However, its use in combination with multi-sited ethnography can be useful for proceeding with data collection. Its use with other theories- such as diffusion- offers a powerful means of exploring new social processes.

The ANT approach can help to follow and shadow objects within a certain context and aid our understanding of the relationship between IT and other stakeholders.

ANT can also be useful for identifying the key persons involved in the research process by examining different perspectives and analyzing how things (items such as IT systems) and persons (such as clinicians and nurses) are connected. For example, Cresswell et al. (2010) found it "helpful to view ANT as a something between a theory and a method, or more exactly as an analytical technique where the researcher follows actors and tries to understand what they do".

For all the above reasons, some scholars find the ANT approach can be a valuable method for understanding and recognizing the value of the complexity of reality, which may neglected or completely ignored by more positivistic and cause-effective approaches (Tantall and Gilding, 1999).

By way of contrast, ANT offers a lens to investigate the role of ICTs in different realities, enacted by different actors inside complex settings.

Based on all these observations, we decided to conduct our research using the ANT perspective that embraces the entire research design and data collection process.

5.4 Research Method

The study proceeded in 2 main stages in order to answer the two research questions outlined above.

5.4.1 The location of the study: a cross-national comparison

In order to answer the first research question and to identify the key issues in the development and implementation of e-health policy, the study focused on an

international comparative analysis between Italy and the UK, focusing on the two national health systems. The idea of conducting a comparative analysis was the outcome of several considerations:

- Firstly, the assumption that the "Kohll/ Decker judgments of the European Court of Justice have demonstrated that health services can no longer be regarded as operating in isolation from other EU member states" (Schreyögg, Stargardt, Velasco-Garrido and Busse, 2005).

- Secondly, both Italy and UK are members of the European Union and their level of comparison is stronger since their "Governments are directly represented on the Union's Supreme decision-making body" (Haintrais 1999).

- Thirdly, both Italy and UK have a National Health Services (NHS), making these two nations different from Social Health Insurance (SHI) nations.

- Finally, "the Italian NHS was established in 1978 and was modelled after the British National Health Service" (Anessi Pessina, Cantù and Jommi, 2004).

However, if these aspects represent the principal strengths enabling this comparative analysis, there are also several weaknesses which should be taken into consideration and overcome. There are various constraints relating to linguistic and cultural factors in this comparative study that influence tradition and administrative structure (Haintrais, 1995). However, with reference to the problems resulting from the cultural differences between the two countries selected for the analysis, we should note that one of the countries is the native country of the author and, as a result, she has substantial knowledge of the Italian

National Health System and use of IT in the health care sector, having conducted several research projects focused on these subjects. As far as the UK context is concerned, the problem of language was minimal, as the researcher has a very good knowledge of both spoken and written English and the Ph.D course offered the researcher the possibility to acquire extensive and comprehensive knowledge of cultural issues.

5.4.2 The documentary analysis

In order to answer the <u>first research question</u>, a detailed *analysis of publicly available data* was conducted in order to identify the policies and acts defined to promote the adoption of e-health in two different geographical and cultural contexts: the United Kingdom and Italy. This part of the chapter specifically aims to assess the following issues:

1) the approach used for analysing documents;

2) the preliminary findings from the European, the Italian and UK contexts;

3) an in-depth analysis of the development of e-health policy in Scotland and the Valle d'Aosta Region. These regions represent the geographical setting of the second part of the empirical work conducted, since the hospitals selected for the case study are located there. Consequently, the focus of the research shifted from a broader assessment to a more in depth analysis that also investigated the e-health development process in these two regions to gain a better understanding of the policy context affecting the case studies.

The research moved from a general analysis of documents produced by the European Commission, especially the Directorate General for 'Health and Consumers' (such as the Health Strategy Plan and Health Programs), and then

proceeded to a focused analysis of the policy priorities identified by the Ministries of Health in the Countries selected in order to investigate how are they moving towards the development of innovation technologies in the health care sector.

5.4.3 The approach used for documentary analysis

In this study public documents were examined "not only as containers of words, images, information and instructions, but also for the way they can influence episodes of social interaction and schemes for social organization, and for the way they may be involved in the analysis of such interaction and organization as a means of tracing the evolution of government policy and the involvement of political actors" (Prior, 2003). This approach recognises the potential of such documents of being key actors (Latour, 2005) in the unfolding of health policy development.

Recently, key research questions have been focused on the ways that documents are used and integrated into various kinds of knowledge networks, as well as how documents are exchanged and circulated within such networks. "Documents and other objects can be conceptualized as actors and can be regarded as members of a network; they can be recruited into schemes of organized activity and regarded by others as allies, enemies or simply as instigators of further action" (Prior, 2008).

Based on this approach, members of the health care community, such as practitioners, representatives, clinicians and so on, can be considered actors needed for the creation of durable interaction in a network but as insufficient to safeguard a robust network. Documents, reports and statistics play a relevant role within the organization. According to these considerations, this study aims to

investigate "*how documents can drive and shape political, economic, medical and scientific activities to the same extent as humans*"(Prior, 2008).

To fulfil all of the above considerations, the study analyzed public documents, including reports by government agencies concerning e-health focusing on:

• the *functions* rather than the contents of the document: "what documents do rather than what they say" (Prior, 2008);

• *networks*: examining the relational properties of things, such as documents, rather than just their attributes;

• *visualizing* the links between the network to "reticulate" the field as it is, examining the traces that documentation generates and visualizing the links within networks that exist between documents, institutions and concepts" (Prior, 2008).

5.4.4 Assessing documents: method used

The analysis initially involved publicly available data on the websites of the main institutions and organizations involved in the development of e-health policy in the countries selected.

The analysis of these documents aimed to outline an answer to the various questions and identify the main relationships and links between documents, people, things, institutions and concepts and then identify the key issues in policy development based on a specific assessment scheme (Freeman, 2009).

5.5 Case Study

As mentioned above, the study focused on an international comparative analysis between the UK and Italy. In order to answer <u>the second research question</u> and analyse how EMR systems are adopted by different health care organizations and their impacts, 2 hospitals were selected because they have adopted the same EMR system:

- the Regional Hospital of Aosta Local Health Authority.

- the Royal Infirmary of Edinburgh;

These hospitals adopted the **TrakCare System** made by Intersystems Snc. It is a "connected healthcare information system" with EMRs that integrate clinical and administrative modules, which are interoperable with legacy and future applications (http://www.intersystems.com).

Here is a brief overview of the cases (more details in Table 5.1):

- **Context**: Italian and UK health care organizations are subject to different institutional frameworks. Furthermore the Italian Hospital is a Regional Hospital related to the regional health authority. As mentioned in chapter 6, in the Italian context, healthcare is a regional function and the organization selected is located in an autonomous Region with specific healthcare strategies and governance structures. The UK hospital, The *Royal Infirmary of Edinburgh* , is located in Scotland, that endorses an overall strategy for continuity of care and ehealth;

- **Types of organizations**: the health care providers have different corporate characteristics and degrees of complexity: the Italian

regional health authority provides acute hospital; the Scottish hospital is an acute care centre and a teaching Hospital.

- **Status of EMR adoption**: at the time of assessment, the italian regional Hospital had been using EMRs for one year and were still implementing some features, whereas the three Royal Infirmary of Edinburgh had been using EMRs for more than 6 years.

Table 5. 1 An overview of the characteristics of the cases analyzed

Organization	Valle d'Aosta Regional Hospital	Royal Infirmary of Edinburgh
Structures	3	1
Number of beds	500	872
Number of workers	3690	6000
Number of wards using EMR	29	25
Number of total wards	34	25
Number of authorized users	2000	5800
Average of daily access	1150	2850
Patient Workflow phases supported	Acceptance; Integrated scheduling and order management; Discharge phase and patient follow up	Acceptance; Integrated scheduling and order management; Diaries - physician, nurse, pharmaceutical therapy; Discharge phase and patient follow up; Continuity of care

5.5.1 Case Study and Data Collection Method: the suitability of the selected method for this study.

Having identified the main research questions that the two case studies intended to answer, the best method of data collection had to be defined. Previous studies found frequent recourse to the qualitative evaluation method of medical informatics. According to Shortell (1999) and Sofaer (1999), "Qualitative research is increasingly common in health service research". Furthermore, qualitative research could help in "understanding phenomena within their context uncovering links among concepts and behaviours and generating and refining theory" (Bradley, 2007).

A "multiple method" strategy was selected as the research method for the analysis of these 2 case studies for several reasons:

- it offers greater validity of the research by using different methods to check findings (Read and Marsh, 2002);
- it is "capable of providing a more integrated picture of a phenomenon" (Hantrais, 2005);
- it enables "a deeper understanding of complex social phenomena and produces much more accounts of social reality" (Bryman, 2008).

The *"triangulation method"* of using multiple, independent measures of one object for 'cross-checking' or validity was selected from the various multiple-method strategies. According to Denzin (1983), the triangulation method means that "various methods for data collection and analysis are applied" (Ammenwerth, Iller and Mansmann, 2003).

Two types of triangulation methods "within method" triangulation, that combines approaches from the same research tradition and "between-methods" triangulation, that means combining approaches from both quantitative and qualitative traditions can be used.(Kimchi et al., 1991) .

Triangulation within methods was adopted in this project, since it has several strengths:

1) it provides several important opportunities in terms of avoiding the possible limitations that could be encountered by using one method alone: "multiple and independent measures do not share the same weaknesses of potential bias" (Ronher, 1977).

2) "it allows researchers to be more confident of their results" (Jick, 1979): by using different data collection procedures, the researcher is able to increase the validity and robustness of results because the findings can be strengthened by cross validation achieved by using data obtained through different strategies (Thurmond, 2001).

3) it gives a much more rounded picture of someone's life and behaviour, enabling the researcher "to get inside the process" underlying the decision outcomes (Tarrow, 1995).

As Czarniawska noted (1998), studies of networks must involve multiple access situations and also multiple cover stories. Hearing and eliciting stories from the field enhances the understanding of the cases analyzed. By hearing how different actors make sense of situations, we can create a more comprehensive picture of which actors are more affected by the adoption and impacts of these EMR

systems. Interviews represent an essential tool for understanding the frames individual actors create about situations.

Data will be collected in several ways (Bryman, 2008) in order to identify the multifaceted nature of these realities as they enfold and involve different actors:

- by analysing documents produced within the two hospitals ;

- by interviewing the key actors at both study sites;

- by observation.

5.5.2   Documentary analysis

As mentioned above, documents can represent a useful source of data that can be used qualitatively "as identifying phenomena among which patterns of relationship are established" (Blaikie, 2000). Therefore, the documentary analysis was based on organizational acts, reports and documents related to the adoption and implementation phase in order to identify the (declared) reasons for the adoption of the system and its role. In this study, public documents were not only examined as containers of words, images, information and instructions, but also for the way they can influence social interactions within the organization as a means of tracing the involvement of actors, their relations and the way their work affect and/or is affected by IT systems(Prior, 2003).

5.5.3 Interviews

Semi-structured in depth interviews were held as a second method of data collection in the case study setting, since they "can get close to the social actors' meanings and interpretation, to their accounts of the social interaction in which they have been involved." (Blaikie, 2000).

The interview process started with an introductory, themed interview designed to get a general idea about the hospital environment and its context in terms of activities and the types of interaction and in order to investigate the roles of the actors (head clinicians, head nurses, clinicians, nursing staff, head of IT services, head of finance and control) and ascertain which human and non-human actors were involved in the process of EMR adoption and were impacted by EMRs.

Several interviews were conducted with the General Director, the Medical Director and the Information System Director before starting the case study. All of these interviews were conducted in a "conversational" style (Bryman, 2008), since they were designed to achieve an overview and a general picture both of the hospital environment and the adoption and use of EMRs.

Further interviews were conducted with a more structured approach and the interview scheme was divided into several parts based on findings in literature (Rogers, 1995) clearly stating that an innovation process is organized into different stages, described by Rogers as the 5-step process (Rogers, 1995, p.162)

1. The Knowledge stage, when a person becomes aware of an innovation and has some idea of how it functions;

2. The Persuasion stage, when a person forms a favourable or unfavourable attitude toward the innovation;

3. The Decision stage, when the intention to introduce an innovation becomes clear: the person engages in activities leading to the decision to adopt or reject the innovation;

4. The Implementation stage, when the innovation enters regular use by the people working for the organization;

5. Confirmation – when the person evaluates the results of an innovation-decision already made.

The interview scheme was organized with different parts based on Rogers' framework and in order to adapt it to the case study analyzed, taking into consideration the relevance of the social actors and their links with ICT systems (Kaplan, 2000),:

- Antecedents of the EMR project

- Implementation processes used

- Impacts produced

5.5.3.1 Interviews Analysis

As pointed out by Gibbs (2007) qualitative analysis of data may be very different, but they have in common "forms of human communication and production of shared meanings". For this reason, the purpose of qualitative research is to codify these meanings. Another feature of the qualitative analysis is identified by the same author on the volume of data it produces: qualitative analysis produces volumes of data that consists mostly of transcripts or documents that can not be synthesized by the use of mathematical formulas, as a large database. These features require massive amounts of time analyzing qualitative data and the use of meticulous and consistent protocols (Silverman, 2000).

For the analysis of interviews, we proceeded by audio recording all meetings with stakeholders. Each interview took an average time of 45 minutes. Some lasted more than an hour, the shortest lasted 40 minutes. Each interview was transcribed and, therefore, the objects of analysis were the transcripts of the interviews. The

transcripts were made anonymous and each interview was given a code formed by the initials of the role of the interviewees.The data was then analysed.

According to Miles and Huberman (1994), qualitative data analysis involves three procedures:

1. *Data reduction*, referring to the process whereby data is reduced and organised. Examples include coding, writing summaries, discarding irrelevant data .

2. *Data display*, namely the process to display and show the data and information collected in the most appropriate and understandable format;

3. *Conclusion drawing/verification* by referring to existing field notes.

First of all, coding was carried out. As Miles and Huberman (1994, p.56) note: "*Codes are tags or labels for assigning units of meaning to the descriptive or inferential information compiled during a study. Codes are usually attached to 'chunks' of varying size – words, phrases, sentences or whole paragraph*".

Data was analysed according to the framework analysis method (Ritchie et al, 2003). After familiarisation, recurring themes and ideas were identified and a coding index was then developed with themes subsequently sorted into broader categories and key themes. In a first phase, the transcripts of interviews were manually analyzed: this step is considered by some authors (Bryman, 2008; Gibbs, 2007) necessary to familiarize the researcher with the text and start to develop lists of codes for analysis. The analysis primarily coded types of response of the respondents in order to highlight some common concepts proceeding in an inductive way. Subsequently the codes generated, were analyzed in the light of a more detailed analysis of the literature and theory, and brought back into macro-

categories, according to a concept-driven approach and to main findings arising from the literature review (Gibbs, 2007).

That the analysis was inductive means in this case that themes (or nodes in NVivo terminology) were identified in the transcripts regardless of their occurrence in the interview guide, very much influenced by an ANT approach.

Furthermore, while it has been argued that it is not necessary to use specialised software with a small dataset, since a word processor may be adequate, (Haddow, 2009), in this study NVIVO 8 as software packages was used to improve access to data and, above all, to increase transparency and consistency.

5.5.4 Observations

As third method of collecting information and identifying all the actors, their role and their reactions using EMR systems, there was a period of observation. The observation process started from general observation of the hospital environment. Furthermore, some of this data collection took the form of participant observations. It entailed observing interactions between clinicians, nurses and other staff, and between these and patients. This facilitated the observations of different situations in several department,s since according to Czarniawska (1998) modern organization "takes place in multiple fragmented context". For these reasons one of the possible ways to observe and get information can be represented by "shadowing". In this approach the researcher can move from one point in a context to another, with the shadowed system in order to "see" and understand if in this case the adoption of EMR systems has affected the operation of its main users and stakeholders.

Observation as a method of inquiring is a valuable means of studying relationships among people, facts and the organisational context – both at the micro and macro level- (Jorgensen, 1989). Many researchers have highlighted that participant observations can present some difficulties of access (Strauss 1987, Jorgensen, 1989). However in this study we focused on the idea that humans and non humans are involved in the making of the social world. The observations were overt to the medical, nursing and administrative staff and covert to the patient. In particular, the interview phase gave the opportunity to develop the necessary rapport with interviewees to facilitate both access and the observation process.

5.6 Limitations of the study

The use of the triangulation method in the case study was subject to some constraints. It is difficult to "replicate" research that adopts different data collection strategies, especially because observations used as the data collection method are tricky to replicate (Jick, 1979). By using this method, is possible that only those elements that are considered relevant by the researcher are noted, and therefore the data analysis may be affected by the researcher's point of view.

Furthermore, other issues are related to the validity and reliability of the findings. "The problems of validity in field research concerns the difficulty of gaining an accurate or true impression of the phenomenon under study"(Shaffin and Stebbins 1191:12) and the problem of reliability is closely related to the replicability of observations. In fact, according to Hammersley, reliability refers to the "degree of consistency with which instances are assigned to the same category by different abservers or by the same observer on the different occasions" (1992, 67).

To mitigate against these possibilities, analysis of interviews and observations findings were supported by feedback from academics and practitioners not only during the data collection phase but also later. The research design, the data collection methods and the preliminary findings from the case studies were presented in several conferences and public presentations, such as at the World eHealth Conference 2010, in Barcelona, at ICT & Care meeting in Grenoble-2010, at the Scottish Doctoral Forum in Sterling, at NPS Seminar 2010 in Edinburgh, at HORNET Meetings research workshops both in 2009 (St. Andrews) and 2011 (Edinburgh). Furthermore preliminary findings arising from the Aosta case study were discussed during a workshop organized with some of the interviewees, at Aosta Regional Hospital and during a meeting organized by the CeRGAS Bocconi, the Centre for Research on Health and Social Care Management at Bocconi University,

These presentations offered an opportunity for further discussions on the validity of the findings and testing ideas against the experiences of external experts and practitioners and this helped to increase the validity of the study.

5.7 Conclusions

This chapter has considered the research design of the study. It has outlined the research questions which will be addressed in this thesis, the research methods and the data collection and has outlined how the Actor Network Theory (ANT) approach has been used as an "analytical technique" in conducting the study.

The study, which is an international comparative research, employed a multi-method approach. In conducting the data collection several strategies have been

used: documentary analysis interviews and observations through the comparison of two different case studies.

a) The documentary analysis was based on organizational acts, reports and documents related to the adoption and implementation phase in order to identify the (declared) reasons for the adoption of the system and its role. As mentioned above, in this study, public documents were not only examined as containers of words, images, information and instructions, but also for the way they can influence social interactions within the organization as a means of tracing the involvement of actors, their relations and the way their work affect and/or is affected by IT systems (Prior, 2003).

b) Semi-structured in depth interviews were held since they can get close to the social actors' meanings and interpretation, to their accounts of the social interaction in which they have been involved. (Blaikie, 2000).

c) There was also a period of observation. The observation process started from general observation of the hospital environment. Furthermore, some of this data collection took the form of participant observations. It entailed observing interactions between clinicians, nurses and other staff, and between these and patients.

The use of multiple methods in conducting the case studies helped to get a much more rounded picture of the context, enabling the researcher "to get inside the process" underlying the decision outcomes (Tarrow, 1995) and in our case, the innovation processes.

The following chapters will outline the findings of this study. In chapter 6 the results from the documentary analysis about the ehealth policy development process will be outlined followed by the results from the two case studies (chapters 7 and 8).

CHAPTER 6

KEY ISSUES IN E-HEALTH POLICY DEVELOPMENT.

Evidence taken from a documentary analysis of the situations in the

UK and Italy.

The purpose of this chapter is to conduct a detailed *analysis of publicly available data* and identify which policies and actions were implemented in order to promote the adoption of Health Information Systems (HIS) in two geographical and cultural contexts: the United Kingdom and Italy. More specifically, this chapter reviews the following issues: i) the approach used to analyse documents; ii) the findings in the European, Italian and UK context; iii) an in depth analysis of the development of e-health policies in Valle D'Aosta region and Scotland.

6.1 Introduction

"Modern healthcare is in transformation with the introduction of new medical technologies, evidence-based medicine…and new financial models", (Vikkelsø, 2007) and healthcare systems are becoming increasingly dependent on IT. Many studies have demonstrated that there are several potential benefits deriving from the adoption of ICT in the health care sector (Caccia et al. 2009; Hillestad et al. 2005) in relation to *efficiency gains*, *improvements to patient safety*, *clinical governance* and *patient empowerment*. These effects are especially important in a "unified Europe", since ICT should promote integration and data sharing between

different health care organizations. However, there is still scant evidence of extensive adoption of health information technology systems in most countries. According to some studies (Berner et al., 2005; Norris and Moon 2005), the immaturity of the technology, its "unfriendliness" and human resistance are among the barriers preventing its adoption. Despite these factors, changes in government policies and increased support for the implementation of health care information technology systems suggest that successful implementation may be feasible in the near future.

This chapter focuses on the key issues in the development of ICT in the health care sector. In particular, it aims to conduct a detailed *analysis of publicly available data* and identify the policies and actions implemented to promote the adoption of Healthcare Information Systems (HIS) in two geographical and cultural contexts: the United Kingdom and Italy.

The research started with a broad analysis of documents produced by the European Commission, especially those issued by the Directorate General for 'Health and Consumers' (such as Health Strategy Plans and Health Programs). It then conducted a focused analysis of the policy priorities identified by the Ministries of Health in the two countries selected in order to investigate how they are moving towards the development of innovation technologies in the health care sector.

This part of the study aims to address three main goals:

- to fill a gap by providing a systematic, comparative international analysis of developments in e-Health policies in the health care sector;

- to identify the actors (human and non human actors: documents, events and persons) who contributes to the development of e-health policy in the countries analyzed ;
- to provide recommendations for decision makers in the public health care sector who are interested in applying ICT to healthcare.

6.2 Why documentary analysis

Documentary analysis has been widely used for comparative analysis of the implementation of health care policies. However, the merits of this method are rarely debated and the process used to carry it out is rarely described in detail or justified. Documentary analysis in policy development studies has obvious appeal for several reasons (Abbott et al. 2004; Bryman, 2008).

Firstly, they are available since an early stage of policy innovation.

Secondly, documents are usually readily available and inexpensive to collect;

Futhermore, documents have a broad extension in terms of time coverage and they keep the researcher in touch with the specialized expression and language used in the selected context, in this case the health care sector;

Finally, documents are available to the researcher for further consultation.

Nevertheless, official documents may be incomplete or superficial, and they may represent aspirations rather than reality, especially if our analysis of them adopts an approach aimed exclusively at extracting basic descriptive information, such as content analysis.

6.2.1 The approach to documentary analysis

For the above reasons, and in consideration of the potential advantages offered by documentary analysis when investigating the policy implementation process, the public documents examined for this study were not only considered containers of words, images, information and instructions, but for the way "they can influence episodes of social interaction, and schemes of social organization, and in the way they might enter into the analysis of such interactions and organization as a means of tracing the evolution of government policy and the involvement of political actors" (Prior, 2003). This approach recognises the potential of such documents to act as *key actors* (Latour, 2005) in the unfolding of health policy developments.

Based on the history of sociology, documents can fulfil a DUAL role: they can be considered receptacles of content or active agents in networks of action. Unfortunately, only the former role has been regularly acknowledged in the past. A focus on documents considered mere containers of data is well established in social science research texts starting from the work of Goode and Hatt (1952). Other studies, such as Glaser and Strauss (1967), recommended treating documents like informants or interviewees. Furthermore, it is generally recommended that document content, as a key source of data, has to be screened, counted, and coded in case of any appropriate evidence in support or refutation of relevant hypotheses (Krippendorf, 2004). Hodder (1994), the author of a chapter on documents and material culture, also states: "this chapter is concerned with the interpretation of mute evidence. Such evidence, unlike the spoken word, endures physically and thus can be separated across space and time from its author, producer and user".

According to these authors, documents exist as a mute, inert, non-reactive, isolated source of evidence that is particularly well-suited to styles of unobtrusive research (Lee, 2000). However, the potential for some new approaches to the study of documents has come about in recent years. Key research questions have recently focused on "how documents are used and integrated into various kinds of knowledge networks, as well as how documents are exchanged and circulate within such networks" (Prior, 2008). According to Callon (1986) and Latour (2005), documents and other objects can be conceptualized as actors and can be regarded as members of a network; they can be recruited into schemes of organized activity and regarded "as allies, as enemies, or simply as instigators of further actions" (Prior, 2008) by others.

The "actor-network theory" approach lets social scientists look beyond the actions of humans by defining 'actor' in broader terms on the basis that humans are limited by their social skills, when, in fact, there are many more types of association present in the world (Latour, 2005:69).

An object becomes an actor when it makes a detectable difference to the action taken by another agent; the object must leave its mark on human actors. Once an object participates in human action, it becomes an actor. It is the job of the researcher to identify these objects in a network and to find a way to '*make them talk*' (Latour 2005:79, emphasis in original)**.**

Actors and actants are central elements in actor network theory.

If we consider members of the health community, such as practitioners, representatives and clinicians, they are important actors for the creation of a durable interaction in a network, but the ANT says they are necessary but not

sufficient for the robustness of the network. ANT makes us also look for the documents, reports and statistics that are incorporated into the organizational structures of the international organizations involved as well as other, non human actants. According to the ANT, networks challenge the divide between local and global and, therefore, there is no difference between "macro" and "micro" or "global" and "local" actors. However, networks are flexible and impermanent and can only be maintained through the efforts of the actors.

Given the above considerations from a theoretical insight into the ANT, this study attempts to investigate *how documents, considered as vital objects, can drive and shape political, economic, medical and scientific activities just as much as humans.* Since the ANT approach maintains that non-human agents can be considered to be actors, it means that such actors or hybrids may be conceived to be components of an actor-network. Michel Callon (1986), for example, linked the fishermen of Saint Brieuc Bay to the scallops that supported their livelihoods and spoke of the scallops very much as actors. Other actors or 'actants' included a group of researchers, visitors to the bay, starfish, larvae and sea currents. Consequently, this allows us to consider documents as members of a network; actors that can be recruited into schemes of organized activity, enabling the identification of the main actors and the mapping of the relationship between them.

This study makes use of official documents, such as reports concerning e-health issued by government agencies, and analyses how documents come to be integrated into networks and their influence on the development of the network itself.

6.2.2 Assessing documents: method

We decided to investigate the last ten years because the EU undertook its greatest expansion in 2004 when 8 new countries joined out of a total of 25, and this influenced the e-health policy development process. In Italy, the Constitutional Reform of 2001 also determined great changes in the e-health development process. In the UK, one consequence of devolution in 1998 was to detach the health care service in Scotland, Wales and Northern Ireland from the English *"mother ship"*: as a result, the e-health policy can be defined in terms of each nation rather than the UK as a whole. The new status influenced e-health policy developments over the last 10 years.

6.3 The e-health policy development process in the European Union.

We started the analysis of EU documents by selecting documents available on the EU Commission's website, issued by the DG Health and Consumers Protection and by the DG Information Society. We focused on 5 specific documents since they can be considered the most relevant and influential of those produced by the EU Commission about health policy, and e-health in particular, in the last 10 years.

These documents are:

1. The new health care strategy "Together for Health - A strategic Approach for the EU 2008-2013" adopted by the Commission on 23 October 2007

2. The Community Action programme for Public Health 2008-2013 (second programme of Community action affecting health care, which came into force on 1 January 2008)

3. The Community Action programme for Public Health 2003-2008 (first programme of Community action affecting health care, which ran from 1 January 2003 to 31 December 2007)

4. e-health Action Plan: e-Health-making healthcare better for European citizens: an action plan for a European e-Health Area (2004)

5. Communication on the Health strategy of the European Community (2000)

The aim of the analysis of these documents was to answer different questions and identify the main relationships and links between documents, people, items, institutions and concepts and ultimately to identify the key issues for policy development based on a specific assessment scheme (Freeman, 2009). This analysis proceede on the following basis:

1. Origins

– Why was the document produced?

– What claims are made about health policy development?

2. Purpose

– What purpose does it serve?

3. Authorial/other documents relations

– Who are the producers of the text?

– Which actors are mentioned in the text?

– What sources or other documents are mentioned in the text?

6.3.1 EU Documentary analysis: results

The European Union plays a vital role in the development of e-health policy. Community actions actually complement the national health policies of Member States while lending added European value at the same time: issues such as cross-

border health threats or the free movement of patients and medical personnel need a response at European level.

This below diagram shows the 5 main documents selected which contributed to the development of the latest health care strategy entitled "Together for health", containing the guidelines for future e-health actions in EU countries. The analysis of these documents has shown that they are interrelated: there are many links among documents, events (the Treaty of Nice), institutions (such as the WHO) or specific organizations (like the EU Forum) separate from EU institutional and political bodies (the Council, the European Parliament and The European Commission).

Figure 6.1 European Union policy documents related to the eHealth
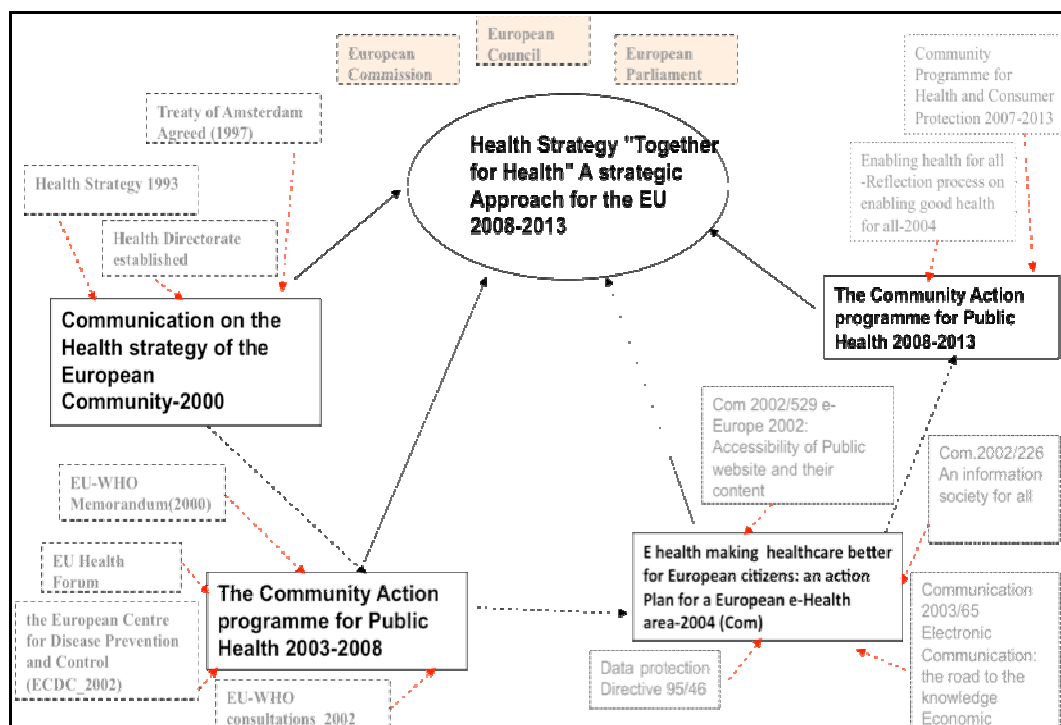
For example, the **Communication on health strategy at EU level** adopted in May 2000, calling for the concentration of resources where the Community can provide real added value without duplicating work that can be done better by the

Member States or international organisations, derives from the *Health Framework* published in 1993, which identified the priority areas for Community Action in terms of Health. Furthermore, an important event in 1997 was a landmark in the history of the EU and acquired great relevance for the definition of the Health strategy in 2000: the *Treaty of Amsterdam.* This amended the Treaty of the European Union, put more emphasis on citizenship and the rights of individuals, but above all gave the EU the mandate to ensure a "high level of health protection shall be ensured in the definition and implementation of all Community policies and activities" by way of article 152. Another significant event, which influenced the definition of this Communication, was the establishment of the *Directorate of Health and Consumer Protection*. Supported by the public health care programme, it led to the development of public health activities and the strengthening of links with other health care-related policies.

The general outlines of a health care policy were set out in the concept of a "Europe of Health" in 2002, which set out the **The Community Action Programme for Public Health 2003-2008**. Work was undertaken to address public health threats, including the creation of the *European Centre for Disease Prevention and Control* (ECDC). In December 2000, the Commission signed a *Memorandum of Agreement with WHO*. In May 2002, high-level EU-WHO consultations took place in Brussels. New areas for collaboration were identified, including poverty, EU expansion and children's health.

 Networks, coordinated responses, sharing experiences, training and dissemination of information and knowledge were to be inter-linked and mutually reinforcing.

The aim was to embody an integrated approach towards protecting and improving health. The *EU Health Forum* brings together organisations that operate in health

care and guides the European Commission for its health care policy and is also a key element in the EU Health policy development process. The Forum enables the health care community to participate in the stipulation of health care policies from the beginning. It was set up in September 2001 and revolves around co-operation with Member States, especially for cross-border issues such as patient mobility. Healthcare systems are also becoming increasingly dependent on Information and Communication Technologies (ICTs) to deliver top-quality care to European citizens.

The EU's **e-Health action plan**, adopted by the Commission in 2004, sets out a clear road map for this sector. The action Plan covers all aspects in order to facilitate a more harmonious and complementary European approach to e-Health. The plan sets out the steps needed for widespread adoption of e-Health technologies across the EU by 2010. eHealth is an integral component of the EU's i2010 policy framework, which seeks to promote an open and competitive digital economy, ICT-related research, as well as applications to improve social inclusion, public services and quality of life. Major documents contributing to the definition of this Action plan include *Communication 2002/529 e-Europe 2002*: Accessibility of Public websites and their content; *Communication 2002/226* An information society for all; *Communication 2003/65* Electronic Communications: the Road to the Knowledge Economy; and *Data Protection Directive 95/46*

Another relevant document is **The Community Action programme for Public Health 2008-2013.** The Commission adopted a proposal on 24 May 2006 for a European Parliament and Council Decision creating the Programme for Community Action in the field of Health 2007-2013. This proposal provides the framework for the Commission's funding of projects relating to health from 2007-

13 and will be part of a strategy bringing together the broad range of Community health actions to define goals and priorities to help improve the health of European citizens. It replaced the proposal dated 6 April 2005 for a Community Programme for Health and Consumer Protection 2007-2013 and was done further to the European Parliament's first reading and in light of the final decision on the budget for 2007-13. The Action Programme was preceded by a process of reflection, characterised by meeting and discussions among the stakeholders form other international organizations and European country's representatives, on how to enable good health for everyone, aiming to revise the May 2000 Health Strategy and consider whether and how it needed to be revised in light of developments. Furthermore, the results of this reflection process played a part in developing the new Health Strategy.

The New Health Strategy, '**Together for Health: A Strategic Approach for the EU 2008-2013**'was adopted by the European Commission on 23 October 2007. This strategy builds on previous documents, act and events and is the outcome of collaboration between several international organizations. It aims to provide a sweeping strategic framework for the first time, spanning core health issues as well as health policies and global health issues. The strategy aims to set clear objectives to guide future work on health at European level and put an implementation mechanism in place to achieve these objectives, working in partnership with Member States.

All the above gaols identified may be achieved at European level if the main actors of the care processes share information on their patients' history. Hospitals around Europe have been introducing HIT, to keep track of their patients' records and to facilitate the administration of prescriptions. Assessing the diffusion of ICT

among the latter becomes paramount for stimulating the creation of longitudinal patient summaries that might contribute to more efficient health care processes for individuals and more effective health policies at EU level.

However, while health-related challenges are increasing at European level, the proposed programme has been dramatically reduced.

6.3.2 Preliminary Considerations: EU context

The EU policy development process is based on documents referring to other documents, such as reports and recommendations arising from discussions during meetings organized by the EU Commission, as well as a range of similar documents produced by other organizations.

- This cross citation of key policy and instruments, goes beyond mere intertextuality and constitutes a distinct means of constructing authority, which we can call INTERINSTRUMENTALITY (Freeman, Smith and Sturdy, 2008)
- By describing and invoking a web of interrelated text, instruments and events, the main documents analyzed envisaged a dynamic policy development process that would culminate in the definition of the New EU health Strategy.

6.4 The e-health policy development process in Italy

In building an inclusive European health information space for all citizens, there is complexity and diversity in the approaches taken. Each country has a different approach, reflecting the diversity of the national health systems in the Union. The

challenge is not only to ensure interoperability among local and regional e-Health systems, but also among Member States.

The policy process of the Italian eHealth strategy has been strongly influenced by the Constitutuional Reform of 2001, which gave to Regions legislative authority within the context of essential principles determined by the state.

The below diagram clearly shows that the Italian strategy is divided into three distinct programmes – the national, semantic and territorial areas – with common objectives:

- to promote the efficiency and effectiveness of the healthcare system;
- to defend the Fundamental Levels of Healthcare Services throughout the territorial areas;
- to enhance the processes of technological innovation of healthcare services..

Figure 6.2 Italian policy documents related to eHealth
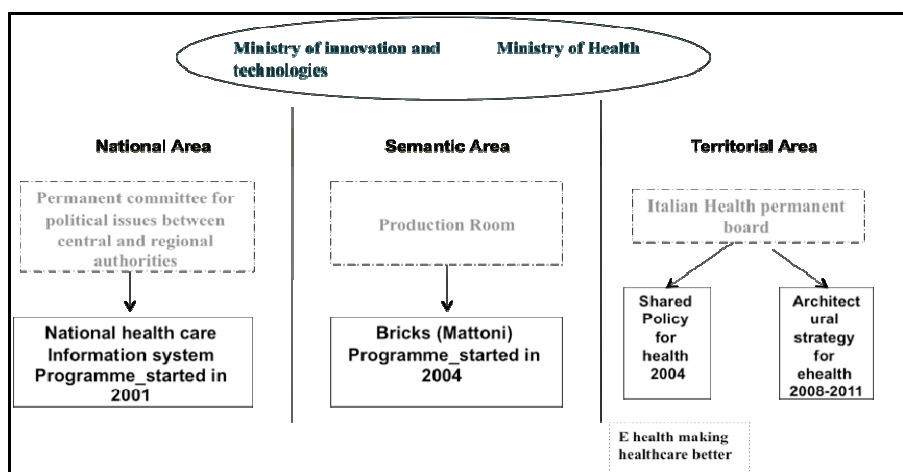
a.The National area: the New Healthcare Information System (*NSIS*)

In February 2001, the Permanent Committee for political issues between central and regional authorities (*Conferenza Stato-Regioni*) developed the New National Healthcare Information System (*NSIS*) – in order to identify governance

objectives taking into accont the LAE (Fundamental Levels of Healthcare Services).

The strategic framework of NSIS delineates the common lines and the progressive steps that characterize the development of the system's various components and the patient and the care delivery structure are identified as central information entities in this context.

b. Semantic area: the "Bricks" in the National Healthcare Service (Mattoni)

This second programme has the responsibility to ensure that all the information systems available both at the National and territorial level, share a common language that makes it possible to adopt methodologies and approaches that are uniform and that promote the managing of Fundamental Levels of Healthcare Services.

This Programmne, which is also named *Mattoni (Bricks)* programme, has to guarantee semantic interoperability among regional information systems and between the regional and national information systems, started in 2004 and is divided into 15 thematic sub-projects, and each subproject is managed by one Region.

It has been defined a body in charge of the governance of the overall programme: the "*Cabina di Regia*".

c. Territorial area: the e-Health Board

The *Ministry of Innovation and Technologies* and the *Ministry of Health* in 2004 created a permanent "e-Health Board" (*Tavolo di lavoro permanente per la Sanità Elettronica*). It is responsible for managing the discussion and consultation

between the Regions and the two Ministries, and for the coordination of e-health policies at both national and regional level.

The first goal realized by the e-Health Bord was the delivery of the documents "Shared policy for e-Health" (*Politica condivisa per la Sanità Elettronica*). Based

on the strategic objectives defined in the 2004 e-Health Action Plan, this document identified the main guidelines for the adoption and implementation of ICT within the healthcare sector. It represents the "Italian National Electronic Health Programme". An initial investment of 44 million Euros seed funding has been made

In March 2006, the e-health Board published the document "Architectural strategy for e-Health " (*Strategia architetturale per la Sanità Elettronica*), that contributed to define a "benchmark architectural strategy" for the national e-Health system. In this context and based on previous activities and documents produced, the Ministry of Health produced the National Health Plan 2011-2013 with the intention of continuing to support the development of e-health at different levels of the NHS. This will be achieved by defining and developing an overall strategy for e-health nationally within the context of a shared Control room (Cabina di Regia) with the NSIS with regard to direct line of the e-health project initiatives at regional and local levels to implement the health care network and the necessary process of modernization of the NHS.

6.4.1 Preliminary Considerations: Italian context

To conclude, we can state that the Italian e-health strategy is divided into 3 interconnected programmes: the national, semantic and territorial areas. What's more, specific bodies have been created and are responsible for governing each programme. The Italian e-Health strategy is strongly influenced by the constitutional reform of 2001 (Constitutional Law n° 3 of 18th October 2001), which gave the Regions legislative authority over health care protection within the context of basic principles set down by the State.

Based on this analysis, the first results show that policy development and the definition of an e-Health strategy in the Italian context occur in a different way to the European context. Interaction and interrelation among different human and non-human actors appears less relevant in the development of e-health policy and the process seems to be more structured, whereby each body has its own, detailed responsibilities and defines "its strategy *per se* within the context of the basic principles laid down by the State".

Our documentary analysis showed that the process of developing a e-health policy in Italy was marked by a "multilevel approach" over the last 10 years: the definition of the e-health policy in Italy can be explained by way of a "system of continuous negotiations among nested governments at several territorial ties" (Marks, 1993) and it describes "how national, regional and local governments are enmeshed in territorially overarching policy networks" (Bache 2005).

6.5 The e-health policy development process in the British NHS

Today, the four constituent countries of the United Kingdom: England, Scotland, Wales and Northern Ireland, each have their own, separately-administered health service. We initially examine the UK e-Health Policy and then focus on the Scottish context. £The implementation of ICT has been a vital component in the UK Government's strategy for the National Health Service (NHS) for at least a decade" (Brennan, 2005).

The vision of an entirely information-led health service is appealing on clinical, economic, social and political grounds (Berg, 2004). Nevertheless, it has not been an easy process for several reasons, such as "the gap between the government's vision and the scant availability of adequate resources (e.g. skills and technologies), the attitudes to ICT and reforms in general as well as the complexity of the systems needed"(MC Grath, 2008).

Prior to devolution, divergence was only possible at peripheral level: although each of the four nations had administrative autonomy over the NHS, this was heavily constrained by policies issued by Westminster and the dominating principle of collective ministerial responsibility. The Secretaries of State for Scotland and Wales were members of the UK Cabinet and so were subject to the collective responsibility for any decisions taken and could not take a different tack with regard to health care policies (Woods, 2004).

As a consequence of the devolution, the health care services in Scotland, Wales and Northern Ireland broke away from the English mother ship: this means that each nation procures its own IT instead of IT being procured for all of the United Kingdom. All four healthcare services are publicly funded and operate independently, even if there is close cooperation to ensure that the public receives the same quality of care.

For this study of the development process of UK e-Health policies, we decided to analyze documents, acts and reports produced by the English NHS, for several reasons.

The NHS, in fact, in England is the responsibility of the Department of Health and 'NHS Connecting for Health' is an agency under the Department of Health that is responsible for delivering the National Programme for IT to the NHS in England. The Department of Health is also part of the UK Government and is responsible for representing the *UK internationally in healthcare matters, liaising with the other "home countries" as appropriate*. The UK Department of Health answers to the Ministry of Health for the overall e-Health policy of England. Regional Strategic Health Authorities are responsible for coordinating the progress of local National Health Service bodies and managing their performance.

The government first set out its vision of IT as a tool to support the implementation of the NHS Plan in the Department of Health's strategic document "***Delivering 21st Century IT Support for the NHS"***, a national strategic programme launched in 2002. This document was built on previous work programmes, including documents such as:

- Information for health: an information strategy for the modern NHS published in 1998

- The NHS Plan: a plan for investment, a plan for reform edited in 2000

- Building the information core implementing the NHS Plan published in 2001)

- Securing our future health: taking a long-term view - the Wanless Report edited in 2002

- Delivering the NHS Plan: next steps on investment, next steps on reform published in 2002.

The development of this Programme was preceded by public debate and extensive input from a range of health informatics practitioners, leading to a number of updates.

The *NHS Plan-a plan for investment, a plan for reform-* (2000) can be seen as the Government's first comprehensive attempt to reshape the NHS around the needs of the patient and more effective use of ICT has the potential to contribute to realising this goal.

 The foreword to *Building the Information Core – Delivering the NHS Plan* (2001), published six months after the Plan itself, makes this clear. This document builds on and updates the document named *"Information for Health"*, the information strategy for the NHS developed in 1998, whose purpose was to ensure that information is used to help patients receive the best possible care, provides a clearer focus on the delivery needs. Whilst the e-government strategic framework requires "building services around citizens' choices", the NHS Plan requires an "NHS designed around the patient".

Furthermore, a crucial moment in the recent history of ICT in the NHS was the publication of the *Wanless Report in April 2002* (Wanless 2002). Wanless' purpose was to assess the resources necessary, "to ensure the NHS can provide a publicly-funded, comprehensive, high-quality service available on the basis of clinical need and not ability to pay" (Wanless 2002 p. 2). Wanless' criticisms stimulated the response of the Government, which stated its own commitment to improve ICT use in Delivering the NHS Plan (Department of Health 2002a). This

led to the publication of the policy paper ***Delivering 21st Century ICT Support for the NHS*** (Department of Health 2002b) in June 2002. This document shed light on the principles behind Information for Health and stated the development of the use of IT in the NHS.

However, in spite of this vision for IT transformation in the NHS, the adoption of ICT in the U.K., costing the government approximately £2.3 billion per annum over the last 10 years, has led the government to acknowledge that "there is a history of failure of major IT-enabled projects, characterized by delay, overspend, poor performance and abandonment" (National Audit Office, 2004, p. 3).

Yet, despite the disappointing outcome of IT investments in the past, the U.K. NHS is now embarking on the largest public IT programme in the world. "This initiative has been made possible by the development of Web-based service architecture, which will provide an IT platform to facilitate inter- and intra-organizational data networks" (Currie, 2006).

A new Coalition Government took office in 2010 and is carrying out a comprehensive spending review. The current situation of the English e-Health strategy is also under review due to these changes in government. The newly elected Coalition Government is expected to indicate a new direction for the main IT programmes and develop a new Information Strategy towards the end of 2010, which will be subject to public consultation exercise before finalisation.

Following the elections in the UK in May 2010, the set-up of the National Health Service (NHS) is undergoing an important review. The policy changes will impact on the e-Health policy in NHS England.

The first available document produced at the date of the documentary analysis (May 2011) is the Government document published on 12 July 2010, namely a White Paper entitled "Equity and Excellence: Liberating the NHS".

The new Coalition Government is expected to carry out a public consultation on a proposed Information Strategy and indicate a new direction for the main IT programmes during the latter part of 2010.

> Mr. Simon Burns, Minister of State for Health, declared in September 2010:
> *"The National Programme for IT is being reconfigured to reflect the changes described in the White Paper "Equity and Excellence: Liberating the NHS" and the outcome of the cross-Government review of ICT projects initiated inMay. A departmental review of the National Programme for IT has concluded that we deliver best value for taxpayers by retaining a national infrastructure and applications whilst devolving leadership of IT development to NHS organisations on the principle of connected systems and interoperability with a plural system of suppliers. The programme has delivered a national infrastructure for the NHS, and a*
> *number of successful national applications such as choose and book, the picture archiving and communications (digital imaging) system, and the electronic prescription service should now be integrated with the running of current health services. The remaining work of the programme largely involves local systems and services, and the Government believes these should now be driven by local NHS organisations. Localised decision making and responsibility will create fresh ways of ensuring that clinicians and patients are involved in planning and delivering front line care and driving change. This reflects the coalition*
> *Government's commitment to ending top-down government."*

It is understood that certain commitments under the National Programme will continue until their completion in 2012. From then on, it is envisaged that most future applications will be *locally driven* and delivered provided they remain consistent with national information standards.

6.5.1 Preliminary consideration: UK context

Based on the documents analysed, the e-health policy development process in England appears to have the mark of a centrally dominated model and a lack of communication between separate but complementary initiatives.

The National Programme for IT faces a huge array of challenges, including patient expectations, demographic change and the constant advances in technology and medicine.

Based on the preliminary analysis, we can define the English approach to e-health policy development as a **"transformational approach"** (Lewis, 2004). "One of the most relevant characteristics shown in the documentary analysis is that the process of e-health policy development was defined without a clear strategy for its implementation and can be considered a collection of responses to individual policies subject to rapid change" (Parry, 2002). "The documents analysed show that there was no attempt to integrate policies in England and there was no obvious unifying objective that could be used to fit policies together: in these documents, words such as collaboration, and trust do not appear and this is indicative of the absence of a clear, managed development strategy. The e-health policy development process seems to be the result of a fragmentation of voices at the centre, a lack of clear policies for the growth of collaboration between professionals and failure to tackle the problems of information decisively" (Keen, 1994).

The table below summarizes the key issues arising from the documentary analysis, representing the starting point for further analysis.

Figure 6.3 Preliminary findings - Key issues in e-health policy development at Supranational and National level

European Union
- active agent of change which has the responsibility about the way e-health policy function in Europe and the directions in which these policies should head (Freeman, Smith and Sturdy, 2009);
- Policy development process is characterized by a strong relation between people but also documents developed by the EU Commission and documents produced by other organizations (WHO, European Parliament);

England
- centrally dominated model characterized by lack of communication between separate but complementary e-health initiatives;
- frenetic reform of e-health policy characterized by huge production of programs and strategies (Greener 2004)
- e-health policy development process defined without a clear implementation strategy, as a collection of responses to individual policies (Keen,1994)
- lack of collaboration between professionals (especially medicine and policy makers (Parry 2002): the Department of Health "does not listen enough"stakeholders and health users needs (Alvarez-Rosete, 2007 Cabinet Office; 2007)

Italy
- e-health policy strongly influenced by the constitutional reform of 2001;
- Regions have a legislative authority over health protection, within the context of the essential principles determined by the State;
- e-health policy development characterized by a "continuous negotiations among nested governments at several territorial ties" (Marks, 1993);
- "national, regional and local governments are enmeshed in territorially overarching policy networks" (Bache 2005)

6.6 The e-health policy development process in Valle d'Aosta Region

The Aosta Valley is a region located in the North West of Italy. The geography of the area marked by deep valleys characterizes and influences the healthcare service delivery. From an administrative point of view, Valle d'Aosta is an autonomous region with legislative authority over health care issues and is marked by the close relationship between the Regional Government and the Local Health Authority (the only one in the Region)

Our documentary analysis highlighted the slow production of policy documents mentioning *e-health* and concerning *e-health strategies and projects*. In fact, we did not find any specific e-health document containing the guidelines for the development of e-health strategy at regional level and all the documents included in this review consider general aspects of health care and social programmes and

plans. Furthermore, only 3 Healthcare plans were developed and published at Regional level over the last 10 years:

- the Regional Plan for Healthcare and Social Welfare 2002- 2004;

- the Regional Plan for Healthcare and Social Welfare 2006-2008;

- the most recent plan for 2011-2013.

It is evident, in particular, when analysing these documents, that the Regional Council replaced and updated the earlier "*Regional Plan for HealthCare and Social Welfare 2002- 2004*" when it produced its 2006-2008 Healthcare plan and added a part on the development of the regional information system. As mentioned above, the term *e-health* does not appear in any of these documents but they sometimes mention the "regional information system" as a way to support and improve the delivery of healthcare within the regional context, marked by several constrictions.

The "*Regional Plan for Healthcare and Social Welfare 2006-2008*", in line with the National Healthcare Plan 2006-2008 focusing attention on the strategic role of organizational communication, stresses the importance of programmes of communication to promote health (e.g. healthy lifestyles) and achieve the "*development of a regional plan of social communication to reduce barriers to access services, through the activation of an information strategy in a logical network.* "

Consequently, the *"Gaining Health Policy"* law issued on May 4th 2007 contains activities and actions to promote healthy lifestyles (stopping smoking, reducing alcohol abuse, facilitating the practice of sports, etc). The law says: "*Communication is an integrated component of prevention and is an important tool of information and knowledge for people. This is achieved through specific*

communication plans for each intervention and information campaigns that put the citizen at the heart of the choices for their health. "

The guiding principles set out to promote communication are based on several key points:

- Infrastructures safeguarding interconnection and interoperability of public facilities in a broad sense

- Technical cooperation, focusing on the process and interchange of information between different public facilities,

- on-line service delivery, with precedence for those considered a priority for citizens and businesses.

Within this context, the Regional Department of Health and the Department of Information Systems allocated 120 projects aimed at contributing to the implementation of Healthcare information systems, improving both the efficiency and effectiveness of the health service delivery.

The latest health care plan, the *"Regional Plan for Health and Social Welfare 2011-2013"* issued by the Regional Government, clarifies that the Plan will promote the *"dissemination of information and communication technology (ICT) to pursue policies of e-inclusion and to reduce social isolation to combat the loneliness and social isolation"* via electronic data management and the flow of information.

All these documents were produced by the Regional Government with the collaboration of external consultants to support the health care policy development process.

The Regional Government has also embarked upon an important investment plan for a new technology infrastructure in recent years, aiming to cut the digital divide. For this reason, the Regional Government and the Local Health Authority launched the "Telemedicine Health-Partout" project, which is supposed to promote the integration of all information systems used in health care and social welfare in order to

- Enhance the construction of "electronic health records"

- Improve the public system of regional connectivity

- Extend the technical coverage of IT systems throughout the Regional context.

6.6.1 Preliminary considerations: Valle d'Aosta Region

This documentary analysis clearly demonstrates that the e-health development process in Valle d'Aosta is marked by the slow production of policy documents mentioning e-health and concerning e-health strategies and projects. Furthermore, compared to Scotland, the production of documents lacks the involvement of professionals within the development process of e-health plans with technically proficient external consultants playing a greater role.

The overall policy development process seems led by a **functional approach** to the introduction and development of an e-health strategy: any established policies aim essentially to guide the purchase and technical development of IT systems. The documents analyzed consider health and social issues in general terms and the adoption of technology is considered a technical support tool, but not in a strategic or comprehensive way.

6.7 The e-health policy development process in Scotland

Scotland has its own Parliament and Executive, formally drawing its powers from the UK Parliament, and with devolved responsibility for health care and other matters. Scotland has its own e-Health strategy implemented by the Scottish Executive Health Department.

One of the most significant documents in the Health Scotland Policy after devolution was *"Our National Health- A plan for action, a Plan for change"* (2000). This health plan refers to the need for "innovation" in the health care sector in Scotland and it aimed to encourage local innovation within rational standards and to promote innovation and creativity (page 79). In particular, the document says: *"we will establish the NHS centre for Change and Innovation which will provide a framework for the development programme."*

Afterwards, a **Health White Paper** was produced in 2003 with a section called "Change and Innovation". This stated that a "NHS Board will be required to develop change and Innovation Plans, that are specific, prioritised and resourced to support local redesign". It says in particular that Plans must: *"ensure information systems support changing patterns of care"*.

The *"Building a health service - Fit for the future"* plan was developed in May 2005: the documents highlights tha the use of ICT in the Scottish context is similar to the situation described in the Wanless Report, with low levels of spending compared to other sectors. In response to this document, the Scottish Executive produced the report *"Delivering for health"* (2005), which stated that the "*adoption of a common information system is essential for NHS Scotland to deliver an integrated care service"*(*Scottish* Governemnt, 2005). Health care

providers around the world recognise the potential offered by ICT for faster, safer, more efficient and more patient centred services" (Hillestad et al., 2005).

The *"Better health, Better care"* plan was launched in 2007, as consequence of a change of government. This highlights the importance and relevance for NHS Scotland to invest in innovation, arguing that "*high quality information is crucial to the delivery of safe and effective health care. We will build on our work to put in place a modern and efficient information and communication system"*. This action plan enphasizes the role of ICT in the Scottish health care sector as a way to improve the efficiency, to promote better access to health services and to reduce the waiting time for care services.

All of the above documents played a part in defining the overall e-health strategy produced in June 2008 and called *"e-health strategy 2008-2011".* This contains a strategy that will support NHS Scotland's goals in general as set out in the "Better Health, Better Care" action plan. It focuses on exploiting the power of electronic information to help ensure that patients get the right care, involving the right clinicians, at the right time, with the right outcome.

It is based on an *incremental and pragmatic approach*, collaborative at all levels and closely aligned to NHS Scotland's delivery priorities. The cornerstone of delivering the strategy is to be a nationally co-ordinated approach, collaborative at all levels and closely aligned to deliver NHS Scotland's priorities.

The current strategy runs until June 2011. At the time of the termination of the documentary analysis, the available information stated that the new strategy for 2011–14 will not be finalised prior to the start of the new administration after the May 2011 Scottish Parliament elections.

However, the current strategy has demonstrated a fresh approach to governance and delivery based on 3 main points:

- clear and effective governance arrangements

- national- local clinical IT partnership

- devolving delivery to NHS Boards within a national framework

The challenges for the next strategy are represented by:

- clinical expectations;

- advances in technology;

- the need for IT-enabled support for business processes as the workforce shrinks.

6.7.1 Preliminary considerations: the Scottish context

Compared to England's policy discussed earlier, the documents analysed seem to show a closer relationship between the clinical professions, leading to a more consensual style of decision making (Jervis and Plowden, 2003). Our documentary analysis has shown that e-health policy development in Scotland has been marked by an **"incremental and pragmatic approach"** over the last ten years since both the definition of the programme and its contents have always been aligned with NHS Scotland's delivery priorities, building on what is already working well and making targeted investments to fill the gaps and ensure a collaborative approach.

As stated in the most recent e-health strategy for 2008-2011 developed by NHS Scotland (2007), "the incremental and pragmatic approach Scotland has taken to date is the right one, building on what exists and filling gaps where necessary. We want a programme that is focused on the priorities for NHS Scotland and for each

NHS Board, meaning we can see the benefits of our efforts as we progress and therefore help build confidence of the public, patients and healthcare professionals that we are on the right track."

Figure 6.4 Preliminary findings - Key issues in e-health policy development at Local level
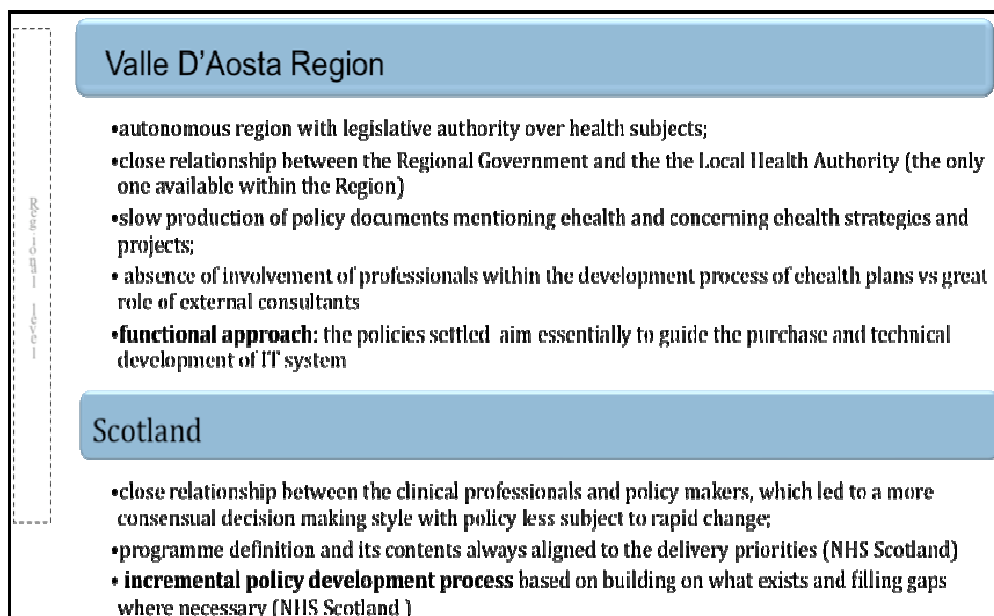
6.8 Conclusion

This chapter submitted the main findings of the documentary analysis of *publicly available data* aimed at identifying the policies and acts marking the development of e-Health over the last 10 years in different geographical and cultural contexts. The analysis went from a more general level, namely a supranational level represented by the European Union, and then analyzed both national (UK and Italy) and local contexts (Scotland and Valle D'Aosta Region).

The chapter identified five different approaches to the development of e-health strategies that will be discussed further in chapter 10, which matches the

preliminary considerations from the documentary analysis with the findings from the case studies.

In particular, approaches were illustrated taking into consideration the different actors (human and non human actors - Latour 2005), and considering documents "as a means of tracing the evolution of government policy and the involvement of political actors" (Prior, 2003). This form of analysis recognises the potential of such documents being key actors (Latour, 2005) in the unfolding process of e-health policy development. In fact, in this study we did not list and comment documents and acts according to the chronological order they were produced and delivered. We tried to identify the Governmental and organizational bodies that worked on it, and where possible, we investigated the relationships existing between one document and the others produced before it and also how it may affect the further ones. We highlighted the key themes in each document and we tried to understand the role of ICT achieving goals that these policy acts aim to address.

Based on this analysis we found that all the documents express different relationships and systems of hierarchy, that we tried to highlight. Their circulation and dissemination may shape patterns of everyday activities, may influence policy definition process and its implementation.

Furthermore, we tried to identify different approaches to the development of e-health policy by considering the different bodies in charge of editing and publishing the policy acts, plans and strategy, the stakeholders involved in the definition and development process (such as policy makers, clinical professionals and external consultants). Our analysis shows that the different levels of governments have different starting points, resources and goals. Government may

play a key role in defining policies or have a more pragmatic approach led by strong communication between clinical professionals and policy makers. The policy development process is strictly related to the context and to the people who work within the organization. We need to move toward an approach that combines local consultation with professionals and agreed standards and goals at local, regional, national and supranational level for the exchange of information at different levels. The policy development process has to combine elements of all of the above approaches in a comprehensive way, taking 2 main points into consideration: (i) the need for cooperation between professionals and policy makers and (ii) the continuous interaction with contingent circumstances that make up the situation for the development of policies in terms of former policies and actions delivered and in terms of the needs of the public.

Having reviewed the purpose and development of e-health policy and highlighted the approaches used in the different contexts, chapter 7 proceeds with the presentation of the Italian case study.

THE VALLE D'AOSTA REGIONAL HOSPITAL CASE STUDY

This chapter presents the results arising from the case study analysis carried out in an Italian Hospital, the Valle d'Aosta Regional Hospital. It starts by introducing TRAKCARE S.n.c, the EMR system adopted in the hospital. Then it outlines the results arising from the analysis of key organizational documents and act analyzed and considers the main findings from the interviews and the observation process, related to the adoption, implementation and evaluation of the EMR system.

7.1 Introduction

The study is focused on an international comparative analysis between the UK and Italy. Two hospitals were selected, which have adopted the same EMR system, in order to suggest an answer to the second research question, as outlined in the methodology chapter, and to evaluate the effects of EMRs on the organizations adopting them:

- Royal Infirmary of Edinburgh (a major acute teaching hospital with 872 beds);

- The Regional Hospital in Aosta run by the Local Health Authority (with 500 beds).

Recently, most reforms affecting the healthcare system have focused on improving the quality of care and containing costs. This has led many scholars (Caccia, 2008; Hillestad et al, 2005; Himmelstein and Woodlhander, 2005; Pagliari et al, 2007) to advocate the adoption of EMR systems by highlighting the potential benefits deriving from their adoption. To date, most studies have assessed single dimensions of impacts, either in theoretical terms or supporting their discussion with single-case empirical evidence.

This study used documentary analysis and interviews, as explained above, and aims to establish to what extent each hospital had a clear vision of the role and impacts of technology and explicitly or implicitly incorporated evaluation into their plans, for example by base lining key indicators and measuring their progress. Furthermore, the study explores and describes how EMRs were integrated to understand how the adoption and implementation of such complex, adaptive social - technical systems unfolds.

The comparison will help to answer to several sub-questions, including:

a) Does the same system produce the same impacts in different organizational and institutional contexts?

b) Does the organizational/institutional context affect the way the system works?

In order to answer these, it is important to consider how these systems gradually evolved in the two different contexts as the systems, the formal implementation processes and the users interacted with one another.

7.2 Trakcare S.n.c.: the EMR system used in the Hospital

These hospitals have chosen the **TrakCare System** produced by Intersystems Snc. It is a "connected healthcare information system" with EMRs integrating clinical and administrative modules that are interoperable with legacy and future applications (http://www.intersystems.com).

TrakCare, the EMR system designed by Intersystem Snc, enables the full scope of the clinical and administrative information about a patient to be collected together. The record contains patient demographics, medical history, information on any previous admissions and surgery and obstetrical details. The medical history includes details of any allergy, disease, family- and social history. Patient information can be sourced from legacy systems linked via the TrakCare Connectivity Module or can be obtained directly from any of the TrakCare modules. The type of data available depends on the data sources connected but may include prescribed laboratory tests and results, X-rays, prescriptions, or produce a post-discharge summary associated with a specific or connected episode. In order to access an EMR, a patient is identified by a unique identification code or name, or can be selected from an optional "favourites" list if seen frequently by a clinician. The EMR provides a patient-centric display of all available information.

Trakcare can also be integrated with other modules, such as the administrative and control module, and can also be integrated to cover the full patient history.

Table 7.1 Information and data provided by the EMR system

Allergies and Alerts	Shows previously recorded allergies and alerts and recording any newly identified cases;
Clinical Summary History	To consult previous clinical summaries (including discharge) generated for a patient;
Diagnosis Entry	To fill in patient diagnosis and the current status for each episode, including diagnosis on admission, suspected diagnosis, final diagnosis and diagnosis at the time of discharge ;
Episode List and Time Line	Shows the patient's EMR in chart format.
Orders and Results History	Presents the results and order history of diagnostic and investigative procedures.
Patient/Clinical Notes	To enter and view patient conditions.
Patient History	To view, amend or add information on the patient's medical, social or family history.

The figure below (figure 7.1) shows a screen view of Trakcare system, on the page which contains the patient's medical episodes.

Figure 7.1 Patient's medical episodes- screen view on Trakcare (Italian version)
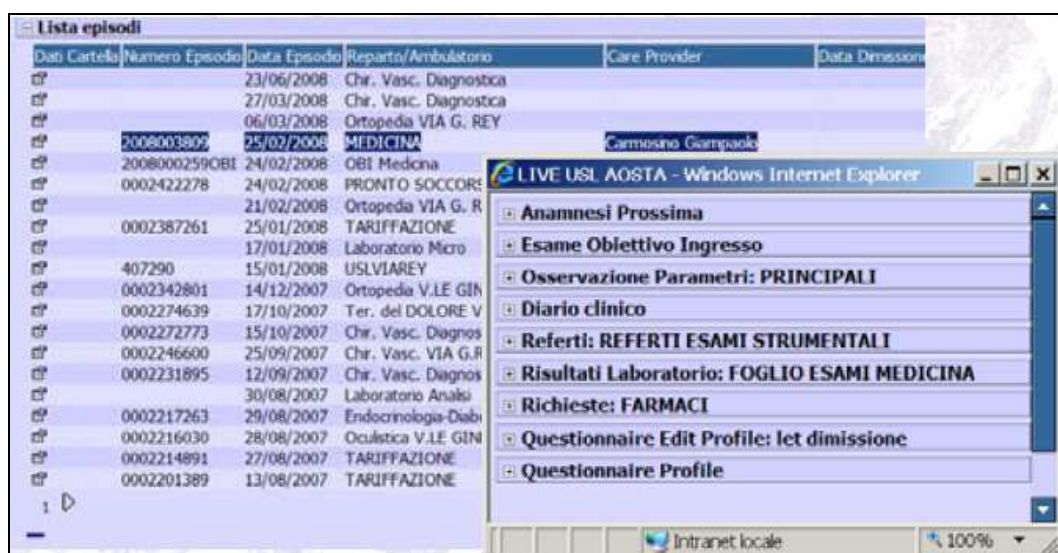
Adapted from http://www.intersystems.com

The figure 7.2 shows a view of list of patients admitted within a ward. It seems quite intuitive and simple to understand, thanks to specific symbols and colour used to categorize the different situations.

Figure 7.2 List of Patient admitted within a ward-screen view on Trakcare (Italian version)

Adapted from <ins>http://www.intersystems.com</ins>

The last figure (fig. 7.3) shows the view of Patient allergy list and Patient alert list on Trakcare system (English version).

Figure 7.3 Patient allergy list and patient alert list- screen view on Trakcare
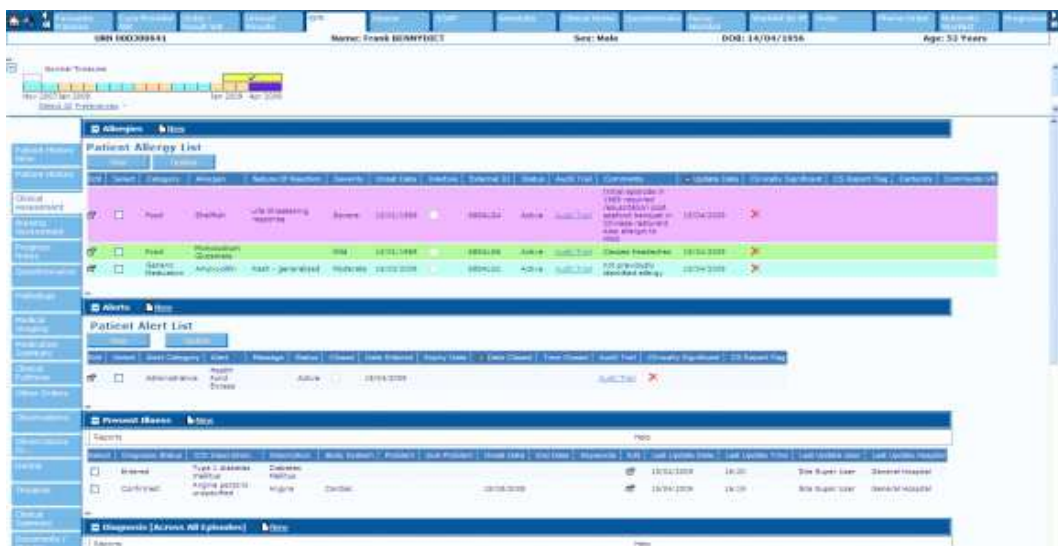
Adapted from http://www.intersystems.com

7.3 The Valle d'Aosta regional Hospital case study: the study setting

The region of Valle d'Aosta (the Aosta Valley) sits in a completely mountainous area, featuring deep valleys and some of Europe's highest mountains, including Mont Blanc and the Matterhorn. The extreme geography of the area (for example, one town can only be reached by cable car) presents unique challenges to the healthcare system. The Aosta Valley has a special legal status with its own legislation in addition to National law.

The Region is remarkable for several peculiarities. First of all, 20.2% of the total population is aged over 64: a huge amount. Despite the older age of the population, it is one of the regions with the highest level of income per capita (+19.5% above the Italian average in 2008-2010). Consequently, per capita spending levels are high, so that Valle d'Aosta ranks among the top spenders in the Italy in terms of per capita expenditure (€22,186 compared to the national average of €15,525).

Figure 7.4 Valle d'Aosta Region-The geographical setting
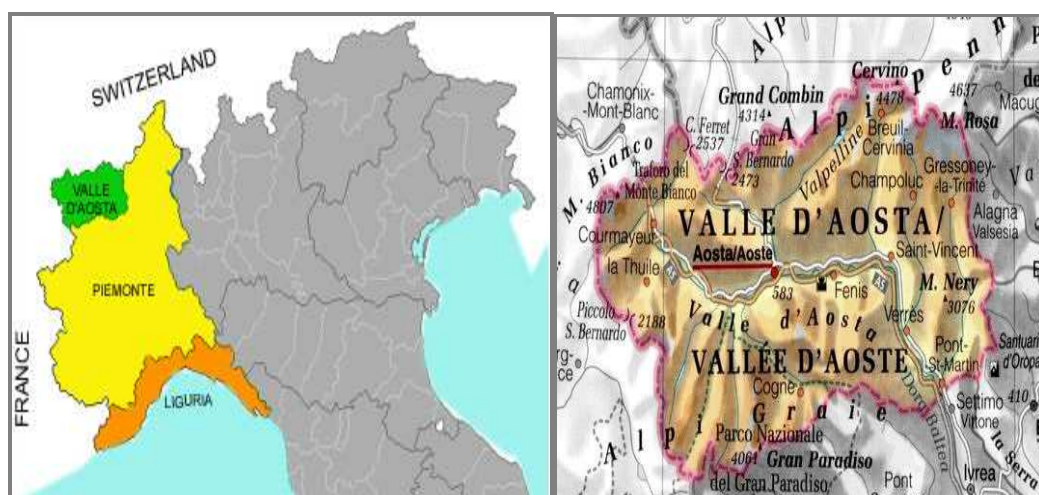
There is only one Local Health Authority (LHA) in Valle d'Aosta, as well as one main Regional Hospital based in three separate locations:

1. "Viale Ginevra" Hospital Centre

2. "Via Beauregard" Hospital Centre

3. "Via Saint-Martin de Corleans" Hospital Centre

The Regional Hospital covers all 74 municipalities in the Region with a catchment area of over 122,000 people. Valle D'Aosta Regional Hospitalprovides health care services to 120,000 residents in the 74 towns each year. In particular, each year the Hospital registers:

• 50,000 emergency room episodes;

• 22,000 hospitals admissions;

• 220,000 outpatient visits;

• 500 patient beds (449 ordinary beds and 51 day hospital beds)

The Hospital has a total of 2411 employees and has 34 Departments.

The *mission* of the Local Health Unit and its regional Hospital is: (i) to guarantee adequate and uniform levels of health care for the citizens who live in the Region; (ii) to coordinate activities for service delivery, monitoring supply and demand and the quality of services delivered to patients; (iii) to promote health among the local population by means of projects, activities and specific tools in collaboration with the Regional Department of Health and other public and private institutions. In particular, it seeks to promote the adoption of a healthy lifestyle.

From an organizational and strategic point of view, the Regional Hospital has a Strategy Board with a General Director (who is in charge of running the LHA), a Medical Director and an Administrative Director.

The Strategy Board is responsible for the strategic planning, the directional control and the negotiation and budget control.

The main responsibilities of the General Director are to perform any duties and implement any measures to safeguard the correct running of the LH, to verify the correct management of allocated resources and revenue, to safeguard impartiality and the proper administrative practices.

The General Director is also is the legal representative of the LHA.   The Administrative Director manages the administrative services of the LHA and supports the General Director for any actions related to matters falling under his remit. The Medical Director is in charge of organizing the health care services provided by the LHA and advises the General Director for any actions related to matters falling under his remit.

The data for the study was collected between May and December 2010.   The General Director had not been appointed at that time. As a result, the Medical Director was also the acting General Director. A total of 15 semi-structured interviews were conducted; all were recorded on tape and then transcribed. In addition, several informal conversations were held. Substantial documentary evidence was collected and any interaction between participants and within wards was observed.

7.4 Documentary analysis

The analysis is based on organizational acts, report and documents related to the adoption and implementation phase and aims to identify the declared reasons for the adoption of the system and its intended role.

In this study, public documents were not only examined as containers of words,

images, information and instructions, but for the way they are able to influence episodes of social interaction and schemes of social organization.

7.4.1 Documents analyzed

The analysis started by selecting documents considered relevant for the adoption and implementation process. Documentation on the EMR system was produced by the Hospital Strategy Board (General Directorate), mostly in the form of information pamphlets, strategy reports and information bulletins, much of which was available to the researcher for analysis. In particular, the documents analyzed were:

-the <u>motion to adopt the system</u>;

 -the <u>technical presentation of the project</u>;

The official documents discussing the decision to adopt the EMR system were all interconnected and linked to each other, since each one mentions and quotes the others.

The main points emerging from the analysis of the <u>motion to adopt</u> are:

- the project was first submitted on August 4th 2006 and was approved after only 4 months on December 28th, 2006 (quite a short period of time);
- the Regional Government was involved in the project and financed 50% of the total cost of the project (allocated over two years);
- the total cost of the project was €392,000, co-financed by the Regional Government and Aosta Regional Hospital;

The technical project, signed and approved by the Hospital Strategy Board on September 29th 2006, before the adoption of the system itself, contains a clear description of the project, including:

- Section 1: general aspects of the project ;

- Section 2: motivation for the project ;

- Section 3: strategic goals of the project: actions and tools required to implement the project.

Section 1, entitled general aspects of the project, generally highlighted the project timeline: the starting date was 01/12/2006 and the date for completion was 31/12/2007. The date for the initial delivery of the project was scheduled for 10-01-2008. Nothing is mentioned about the general delivery process of the project or further monitoring actions.

This section also contains the description of the project, clarifying that the project aims to equip all wards with electronic medical records capable of recording all the patient episodes and information by implementing an integrated system of information and the use of mobile technologies.

As regards project motivation, described in section 2, the technical proposal states the following as the official reasons for adoption:

- To improve patient safety and the quality of care in general;

- To get quick and reliable access to patient data;

- To obtain an integrated view of all reports for all patients;

- To have patient-centred documentation stored in a structured way;

- To delete handwritten reports, improving the quality of information available to those involved in providing health care;

- To get an alert message in case of direct clinical application, thus reducing the risk to the patient

In section 3, the <u>technical project</u> outlines the main goals for the system:

1. Provision of facilities needed for diagnosis and treatment;

2. Integration of management tools episodes between the main Hospital and primary care facilities;

3. Ensuring integration and movement of health care information within the Regional Health Service network.

Our analysis of these documents clearly shows that <u>a clear implementation plan was not defined and was not included in the technical proposal</u>; instead, information was added with reference to the potential benefits offered by the system and the potential goals in the short and medium term.

It would have been helpful if the team had planned the project and the implementation of the new system with a clear schedule before going ahead in order to avoid potential problems when the actual implementation starts.

It also seems clear that no monitoring actions were defined prior to the adoption of the system and before the project's "go-live" phase, such as a plan or a tool designed to monitor elements such as progress, impact and costs. Furthermore, the documents lack an incorporated evaluation plan, for example allocating key indicators for measuring project progress. These are all crucial elements for the adoption and implementation of a process of innovation. Øvretveit (2004), for example, referred to projects for the implementation of innovation as 'actions to select, plan, introduce and achieve 'reasonable use' of the new EMR by 90% of the personnel for 90% of patients intended". Successful implementation needs strong monitoring prior to adoption, but also *in itinere* and *ex post*, namely during

and after the implementation process. This can be evidently done by establishing a precise timeline and promoting the participation of personnel (clinicians and nurses) in the process starting from its initial phase (Øvretveit et al 2007).

7.5 Interviews

As mentioned in the previous chapter, the interview process aimed to:

- compare the expected role and impacts of the system with its actual role and impacts experienced by the users;

- consider how these impacts evolved over time;

- analyze how the system and the users interacted with one another.

In particular, the subjective accounts of people working in the organization were explored with regard to: (a) background to the EMR project; (b) implementation processes used (c) impacts produced .

7.5.1 The interview sample

Several studies (Lapsley & Llewellyn, 1998) have found that there are many powerful stakeholder groups within healthcare organizations and each of these can influence the ultimate success or failure of a system. This study took a purposive sample, helping to pick subjects on the basis of specific characteristics (Bryman, 2008) in order to include a diversity of roles and responsibilities. We selected the key actors for the interviews based on certain specific characteristics:

> - staff profile: Head of Clinicians - Head of Nurses – Clinicians - Nurses, Managers, CIO, in house Information System staff (clinicians, nurses, General Director, Medical Director, CIO)

- number of years working at the organization: at the very least, after the adoption of the EMR system

Clinicians and Nurses were interviewed from the 4 departments included in the study. The four departments were selected because each of them is representative of a specific "Area" inside the Hospital. From an organizational point of view, the Hospital is divided in 4 main areas that have adopted Electronic Medical Records. In a fifth area, the Emergency Area, the system still has to be fully implemented. As a result, the Emergency ward was not included in this study sample, which includes:

• Medical Area: includes all wards involved in providing general health care;

• Surgery Area: includes wards involved in providing surgery-based treatment;

• Specialist Medicine Area: includes wards that deliver specialist health care, mainly on an acute admission basis for inpatients or day patients;

• Maternal and Infant Area: includes wards that integrate different aspects of patient care (such as the maternity ward and Paediatrics).

We selected one ward for each area as each ward can be considered as representing the overall Area in scale in terms of beds, patients and number of employees.

Table 7.2 The study sample

AREA within the Hospital	WARDS
Medical Area	General Medicine Ward
Surgery Area	General Surgery Ward
Specialist Medicine Area	Gastroenterology Ward
Maternal and Infant Area	Paediatric Ward

These 4 wards were also initially selected by the Hospital Strategy Board and were included in a "steering group" formed in the initial phase of the project. As

mentioned above, a total of 15 semi-structured interviews were conducted, all

recorded on audio-tape and transcribed. We interviewed the Head of Clinicians, a

General Clinician and the Head of Nurses in each of the selected departments. As

regards Administration, we also asked the CIO to answer some questions; the

CFO (who is also the Controller) and some members of the Directorates of

Medical Services were also involved in the interview process.

Table 7.3 The interview sample

Participant role	Key	Number
Head of Clinicians	HD	4
Head of Nurses	HN	4
Clinicians	C	4
Chief Information Officer	CIO	1
Chief Financial Officer	CFO	1
Medical Director	MD	1

Initially, interview transcriptions were handled manually to become more familiar

with the data; they were subsequently analyzed using NVIVO 8, a qualitative data

analysis software.

Figure 7.5 Stakeholders involved in the case study
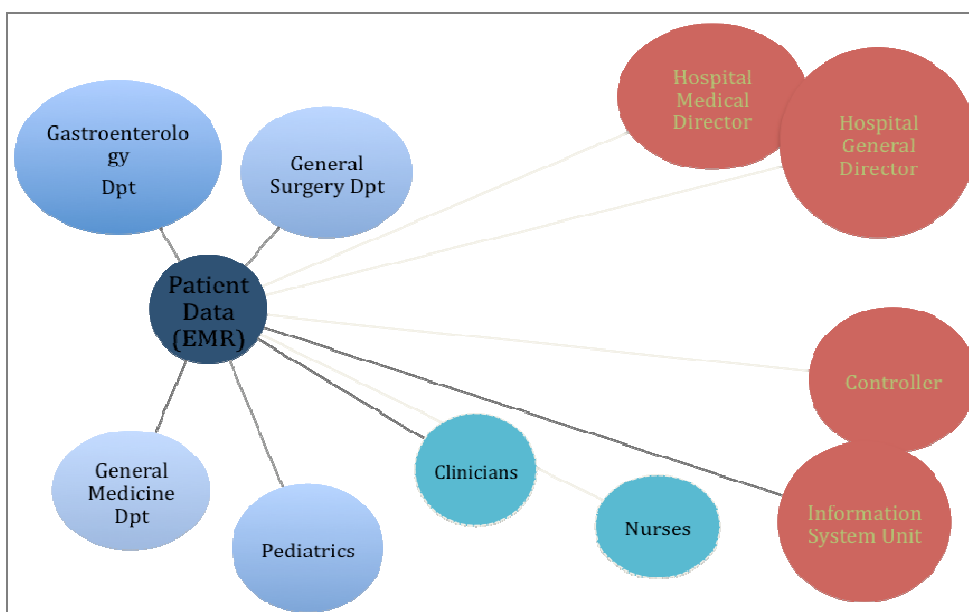
The data was then analysed. According to Miles and Huberman (1994), qualitative data analysis consists of three procedures:

1. *Data reduction:* the process whereby data is reduced and organised, for example by coding, writing summaries, discarding irrelevant data and so on.

2. *Data display:* the process of displaying and showing the collected data and information in the most appropriate and understandable way;

3. *Conclusion drawing/verification*: by referring to existing field notes.

The first process involved coding.

As Miles and Huberman (1994, p.56) note: *Codes are tags or labels for assigning units of meaning to the descriptive or inferential information compiled during a study. Codes are usually attached to 'chunks' of varying size – words, phrases, sentences or whole paragraph.*

As mentioned in chapter 5, although many researchers have stated that it is not necessary to use a specialised software with a small dataset as a word processor may be adequate, (Haddow, 2009), we used the NVIVO 8 software package for improved access to data and, above all, for increased transparency and consistency.

In highlighting the results and discussing them, it is important to understand that the stories were not told in their entirety by each interviewee. The researcher went from the individual description given by the interviewees to construct these stories, also by selecting specific and relevant pieces of information in order to highlight a particular story line and emphasize the most relevant results emerging from the analysis. (Mills, 1979, Watson, 1994).

Table 7.4 The coding procedure

Macro categories	Inductive categories	Participant Responses
Impacts on the health care delivery process	Time savings	It has cut the waiting time for laboratory test results
		It has helped save time when searching, editing and storing documentation
	Cost Savings	The system is paperless
		It cuts the need for further exams and investigation
	Information quality	More reliable information
		The adoption of the system has improved the accuracy and completeness of data
	Accessibility	The system lets you check images or reposts at any place and at any time

1. As explained in the methodology chapter, the interview plan was divided into several distinct parts based on literature (Rogers, 1995), clearly stating that an innovation process is organized with different stages, and is described by Rogers (1995) as the "5 step process" (see chapter 5) The interview plan was divided into different parts based on Rogers' framework while trying to adapt it to the case study analyzed:

1) Antecedents of the EMR project (which includes the knowledge, the persuasions and decision stages);

2) Implementation processes used;

3) Impacts produced.

7.6 The interview results

7.6.1 The Antecedents of the EMR project - origins of this EMR project

First of all, we need to clarify that there was a change in General Director just after the adoption of the EMR system, so the implementation process and the initial monitoring of the system was done by others. After the General Director left, the Medical Director became the Acting General Director.

We should mention, at this point, that the General Director in charge at the time of the adoption declined our request for interview, as he said:

> *"I am no longer involved with that Hospital now and so I cannot pass comment on what has been done in that organization." (Former General Director)*

We therefore tried to trace the origins of the EMR project by talking with other people involved in the actual process, including the new General Director, clinical staff members working on the wards selected, the CIO and the CFO.

The Medical Director, who was also Acting General Director at the time of data collection, had an interesting point of view that differed considerably from other opinions analyzed. She listed the following as motives leading to the adoption of the system:

• *adoption of a standardized model for patient data;*

• *greater accessibility to patient information;*

• *integration of clinical patient data*

According to the Medical Director, the General Director made the decision to adopt the system, deciding to start a pilot programme in line with the Regional strategy for Innovation in Health care. This could be due to the fact that the

Region funded half of the total investment (stated in the proposal document).

> *" The decision to adopt the system wasn't a collaborative one it just happened top down and then ..a proposal was made that some wards should be considered for a pilot programme during the initial period of the implementation process. However the decision was strongly supported by the Regional Programme....there was "ad hoc"funding" (MD/1)*

This may be due to the fact that this is the only hospital in the Region, resulting in the strong relationship between the Hospital Strategy Board and the Regional Government. It must be observed this is a peculiar aspects.

Also according to all of the interviewees, there was no participation at this stage of the decision process. One clinician, in particular, said:

> *"....the selection of the system and the decision to adopt it was taken by the General Director, without a consultation process to clearly state whether to adopt an EMR system or not and in the case the decision was positive to proceed with the selection of the system among the several packages available today on the market. We do not know if any information was sourced from vendors about EMR system packages or if it was analyzed or if a group of consultants suggested the Trakcare system due to any specific characteristics...We just know that the system has been adopted and they told us we have to start to using it".... (HC/2)*

In a similar way, another clinician said:

> *"We were just informed that we would shortly have to start using a new system that would help us improve hospital activities and the relationship between staff and patients. (C/2)*

It appears clear that the decision was only notified to clinicians and nurses *after* the selection process and then, according to the information we collected, a steering group was defined including the 4 wards listed above.

These wards were mainly selected by the General Directorate and by the Strategic Board even if some Heads of Clinicians had confirmed their interest in being used as the pilot ward. In fact, the Head of one ward stated:

> *"I just offered my ward...I mean I suggested my ward should be included in the pilot group...I know that most of my staff were bored with using paper records ... they were looking for something faster to use, smarter...However I must confess that there was some resistance, some people originally refused to go along with the new system...." (HC/1)*

All the people interviewed appeared generally well informed about EMR technologies. However according to all the interviewees, the adoption of the system and the decision to go ahead was taken by the General Medical Director of the Hospital.

7.6.2 The Implementation Process

The data revealed two distinct accounts in relation to the implementation process: one associated with clinicians and the other with nurses. Clinicians maintain there was effective training on the use of the systems in technical terms.

One junior clinician stated:

> *"The initial training and the operational support during the implementation has been excellent... we do not feel alone with the help desk available 24 hours a day, 7 days a week "(C/1)*

However, it seems clear they refer to operational support since they clearly stated that there were no courses on the strategic relevance of adopting integrated information systems.

On the other hand, nurses maintained that few events were held to introduce the new system and no technical courses were organized to support the implementation phase.

> *"I took part in a one-day seminar, in which some people, two to be precise, introduced us the system. They showed some colleagues and me how the system works and they gave us instructions on carrying out some of the most common activities with it. Then they said we could contact the HELP CENTER for any more information we needed when using it. However, one of the two trainers came along to the Department a few times, let's say twice, over the last year to check if I and the other nursing staff needed anything and if*

everything was clear....However I think we should have had some more help and training before starting to use the system" (HN/4)

Furthermore, the interview process showed that they did not perceive the difference between strategic management courses and technical courses; they simply stated that they needed more training.

7.6.3 The evaluation process

As mentioned in the chapter on methodology, we attempted to achieve an in depth understanding of the role of the system within the organization and how it affects people's working conditions.

Based on the literature we reviewed concerning the impacts of EMR (Bates et al., 2000; Protti et al, 1998; Pagliari et al, 2008), we identified 4 macro-categories of impacts:

a. Impacts on the health care delivery process;

b. Impacts on people working within the organization;

c. Impacts on patients

d. Impacts on relationships with other stakeholders, Institutional and others

The interview scheme contained some prompts to encourage respondents to go into detail on each of the categories identified.

A clinician talking about his own evaluation of EMR gave an interesting answer. He sums up his own usage of the system as follows:

> ….*"first of all, I think that the adoption of the system has improved the <u>accuracy</u> and <u>completeness</u> of data. This means that I can have access to more complete information in terms of laboratory test results, X-rays and I get them <u>more rapidly</u> compared to before the adoption... I can display them <u>at any time and at any place</u>…… Furthermore it has helped <u>save time</u> when searching, editing and storing documents. ....The system*

enabled fewer <u>documents to be printed</u>. It also reduced the need for <u>further exams and investigation</u>... (C/4)

By analysing and coding this statement, we found that several relevant impact categories were mentioned, such as time savings, cost savings, information quality, accessibility.

a) Impacts on the health care delivery process

The Medical Director found that efficiency gains were the main impact. "The system produced better efficiency within each ward". However she added that there were no clear results regarding these improvements. *"There wasn't a great perception"* she said. This may be due to the fact that the hospital management did not opt to monitor these types of impacts at organizational level using an evaluation model based on certain indicators and variables, starting monitoring prior to adoption, during the implementation process, and continuing after the adoption of the EMR system.

According to the Medical Director:

> *"... more evident benefits were revealed in terms of error reduction, according to the statistics produced by the quality service office"* (MD/1)

The majority of clinicians agreed that the adoption of EMRs helps save time, for instance by reducing the waiting time for lab test results and enabling diagnosis images to be viewed in real time.

> *"Before the adoption of the system, it took hours before we were able to get results, and we also had to wait for nurses who had to go pick up the results from the laboratory. Now I can display the results close to the patient's bedside or wherever I want in my office....so I have also the time to reflect and review if I'm reconsidering a patient's condition at the end of the day "* (C/2).

In terms of saving time, the respondents (clinicians and nurses) stated they take it for granted that EMRs produce information in real time.

The majority of clinicians affirmed that as a result of the adoption of the system, they perceived a cut in paper medical records, which may lead to cost savings, even if they do not have any data to confirm this perception. They also presume the system may produce cost savings through better information sharing leading to savings in terms of printing costs. However when asked to quantify the amount cost saving they were not able to offer an answer.

Nurses in particular emphasize the EMR system produced relevant results in terms of accuracy, completeness, ease of understanding and reliability of the information. One nurse said

> *"Now, it is easier to understand what clinicians write, without the need to interpret their handwriting. This makes me feel more comfortable when doing my job"* (HN/3)

The Chief Financial Officer, who is also responsible for Controller activities, was also interviewed. He stated that there is no actual integration between the clinical information system and the administrative system. The administrative system they use is called OLIAMM and is produced by another provider.

He said:

> *"The clinical part seems to be more relevant than the administrative one in the thoughts of the Hospital Direction and Strategy Board. From an accounting viewpoint, the introduction of the EMR system is not perceived as being relevant since the two systems (administrative and clinical one) are not currently integrated."* (CFO/1)

The Oliamm system helps with drugs management in terms of costs, delivery, usage and so on. Furthermore, the CFO explained

> *"When this system needs information about patients in terms of number of days or the type of surgery, it gets its information from the TRACKCARE EMR system"* (CFO/1)

He emphasized that information sharing does not happen automatically since the two systems do not have fully integrated information. This means that the EMR system is used only partially at the moment instead of using all the features offered by the system itself.

b) Impacts on people working within the organization

Based on the answers of respondents, results in terms of impacts on organizational aspects are mainly linked to risk management due to the presence of alerts in the Italian case. This comprehensive medical information system not only provides the healthcare provider with alerts, but also information for reducing different types of errors and avoiding unnecessary, or redundant, invasive clinical tests. Interviewees found that the adoption of EMRs ensured the temporal continuity of the service and an effective response to the needs of clinician and nurses. Furthermore, it guaranteed access to the full patient history even if they found that the system initially increased their daily workload. For example, one of junioir clinicians interviewed stated:

> *"At the start, it was quite time consuming to use the system and to enter the data for each patient during the daily rounds. However, after a while, let's say 6/8 months after adoption, I can say the system helped to cut the time needed to work on their daily activities".* (C/3)

Furthermore, the system increased communications between clinicians and nurses, since nurses have access to more reliable patient data. However, according to the clinicians interviewed, the system did not produce any changes in terms of the commitment of clinicians and nurses to the organization's mission. In particular the Medical Director said:

> *"I think the system did not produce impacts on the relationships between clinicians and nurses : they were already coherent and effective prior to adoption."(MD/1)*

However based on her view, the system produced greater attention on who has access to patient data by *"offering the possibility to identify the person responsible for a single act".(MD/1)* She also said :

> *the EMR system may have improved the effectiveness of the diagnostic process, since now "it offers the possibility to check if data is updated each day."*

This is apparently a method of using the system as a top down tool to control what happens within wards.

As expected, the results did not find much evidence in terms of impacts on organizational effectiveness. According to literature, this type of effect is revealed in the medium to long term (Cooke&Peterson 1998; Keller&Teufel1998; Rick 1997). Some interviewees mentioned that people's reluctance to change to new ways of working might affect the implementation of the EMR system in some way. Some nurses apparently felt there was no need to change because they could not see the benefits of using EMR technology, above all in terms of the time saved to do their own job. One interviewee explained that they believe the adoption of the system will determine an increase in their workload, as they are sceptical about its usage and they do not know enough about the system's potential.

The introduction of an EMR system should be phased in and be fully-supported by service staff and custom-tailored to meet specific needs, so that employees can begin to appreciate the real benefits. For the successful implementation of an integrated EMR system, it is imperative that doctors, nurses and administrative staff "buy in" to the concept. In particular, a serious impediment to the roll-out of

EMR technology is the belief, shared by a considerable group of healthcare workers, that such technology might be more of a hindrance than a help because it puts more administrative weight on healthcare professionals.

c) Impacts on patients

Some clinicians perceived an improvement in terms of better interaction between physicians and patients and in terms of the impacts on healthcare processes, as saving time helps the decision making process (especially at diagnosis level). This leads to the perception of a potential impact on the overall effectiveness of the quality of care.

A clinician clearly stated:

> *"I think that the EMR may lead to more awareness of patient empowerment, particularly the possibility of further patient involvement in processes due to the increased availability of information. " (C/2)*

According to some clinicians, the adoption of the EMR system improved patient's confidence and trust in the services provided.

It also produced a reduction in the risks for patients: minimizing the issues of incorrect and conflicting drug prescription and reducing the duplication of invasive medical examinations.

However both clinicians and nurses raised some concerns about ethical issues related to the use of the EMR system. Some of them declared to be worried about the possibility that someone else could access patients' data or that external unauthorised people could attack the system. This matter is discussed, in detail, at the end of this thesis.

d) Impacts on relationships with other stakeholders - Institutional and others

The most significant effect on clinical governance refers mainly to the opportunity offered by EMRs to clearly identify who is accessing, managing and exchanging medical information about patients at all times. This also has a positive effect on the degree of accountability of clinical personnel, considered a fundamental component of high-quality healthcare organizations.

According to the interviewees, both clinicians and nurses, the adoption of the EMR system improved communication between wards: in the case of Aosta Regional Hospital, these are located at different sites due to territorial constraints. Furthermore, the EMR system allows information sharing between Acute Care Providers and Primary Care Providers (although this is still in the initial stages): GPs automatically receive the patient's discharge letter and have the opportunity to access a patient's full history. Conversely, patients do not need to physically take their X-rays, lab reports or other information to the doctor and physicians can choose when to analyze images or reports and can check them at any time.

The Medical Director, in charge at the time of data collection and also the Acting General Director) stated clearly:

> *"Territorial integration was not considered a priority and the Directorate doesn't consider it to be a potential benefit of EMR technology at the moment of adoption"* (MD/1)

This is quite a surprising statement, since the interviews with clinicians and nurses made it clear that the adoption of the EMR system helped communications between different wards located in different parts of the Region and helped to reduce territorial limitations. It would seem that this is an "unintended and unplanned consequence" of system adoption .

7.7 Observations

As, mentioned above, a period of observation represents the third method of information gathering and is used to identify all the actors, their roles and their reactions to use of EMR systems. The main purpose the observation was to identify the relevant actors, humans or non-human, their roles and their relationships. The observation process started with general observation of the hospital environment. Some observation took the form of participant observation and took place during meetings between clinicians, nurses and other staff, and between staff and patients. Different situations were observed in several wards, according to Czarniawska (1998) who says that "modern organization" takes place in multiple fragmented contexts. As a result, "shadowing" is one method of observation and information gathering, since the researcher is able to move from one point in a context and network to another with the shadowed person.

We were allowed to conduct the interviews directly in each ward, offering the researcher the opportunity to interview people in the place where they work. Clinicians and nurses were generally approached while they were working and the researcher had the unique opportunity to observe how they use the system and note if they appear to be confident with it; this helped to gain a better understanding and clearer vision of the context and so understand what people say during the interviews. Participants in the study were also asked "to recall critical incidents or examples of system use" as suggested by Kaplan in her work on the evaluation of medical systems (1997).

Based on the observations we carried out, some actors showed a great confidence in using the system while others appears less experienced. The doctors have tablet PCs to go around the ward during the daily visits. Then there are several

computers and printers locate in some spaces within each ward. The fact that clinicians and nurses used laptops during the field visits appeared to have influenced in some way patients' perception about the system: they are aware that the system is used within the hospital. It to them that they noticed the organization as more "integrated".

Furthermore, when patients move around the hospital they are not asked several times for the same information. This seems to have produced a "safer feeling" in patients: they know all their data are stored together and easily accessible and this gives the impression to help them to fell better.

7.8 Conclusion

The first part of the chapter presented the main characteristics of the case studies included in this research and introduced the EMR system under analysis. Then the chapter focused on the first case study, presenting the the findings from the case study carried out at Aosta Regional Hospital. Results from (i)documentary analysis, (ii) interviews and (iii) observations were illustrated and discussed.

(i)The motion to adopt the system and the technical presentation of the project were analyzed. These documents clearly shows that a clear implementation plan was not included in the technical proposal, and only the potential benefits offered by the system and the potential goals in the short and medium term were listed in these documents. Furthermore no monitoring actions were defined prior to the adoption of the system and before the project's "go-live" phase as show the documents that did not contains an evaluation plan. These are all crucial elements for the adoption and implementation of a process of innovation, and this case show a lack of them.

(ii) The interview process offered the possibility to get an in depth knowledge of people views about the different stages that characterize the introduction of innovation process. The results related to each stage- selection and adoption, implementation, evaluation- were discussed. Some broad considerations arise concerning this case study: a) the selection and adoption process was characterized by a *top down approach*, without promoting personnel participation in the process from the selection phase (Øvretveit et al 2007); b) the implementation phase was characterized by an initial resistance toward the system implementation and the training delivered was basically technical and this dis not promote the committment and involvement of staff member (both clinicians and nurses). b) The interviews findings about the evaluation phase identify some benefits produced by the EMR system, above all in terms of better health care delivery processes, meaning time savings and quality of information improvement with respect to its completeness and accuracy. However it should be clarified that these are "perceptions" of clinical staffs and administrative people, since the analysis highlighted the lack of systematic assessment and tools to monitor EMR impacts at Aosta Hospital.

(iii) The observations offered the possibility to observe interactions between the EMR systems and clinicians, nurses and other staff, and between these and patients in several departments and allowed also the opportunity to verify staff confidentiality in using the system, offering us some very interesting insights for this study that the interviews may not provide.

Based on this first case study we can identify some emerging lessons:

- EMR contributes to **enhancing organization communication and information sharing at multiple levels;**

- A **participative approach** promoting personnel participation within the process since the selection phase **might reduce initial resistance** toward the system implementation;

- Sharing the **vision and goals** versus training for the software might enhance key actors' commitment;

- A **systematic assessment and monitoring** of EMR impacts might suggest the nature and direction of Hospital's priorities and future strategies.

Many other interesting results and lessons to share will arise from case study number two, that will be presented in the next chapter.

THE ROYAL INFIRMARY OF EDINBURGH CASE STUDY

This chapter presents the results from the second case study analysed: the Royal Infirmary of Edinburgh (RIE).

After briefly describing the background of the organization, the chapter focuses on an analysis of the results of the data collection. Some documents were obtained from the organization for analysis and interviews with key actors were conducted within the hospital. Observations around the hospital and on the wards were also carried out. Key findings arising from the data collection and Royal Infirmary of Edinburgh study settings will be presented and discussed.

8.1 Introduction

The Royal Infirmary of Edinburgh (RIE) is a major acute teaching hospital providing acute care and surgical services to patients across the Lothian area (South East Scotland and beyond). NHS Lothian (Lothian) runs four main acute hospitals – the Royal Infirmary of Edinburgh, the Western General Hospital, the Royal Hospital for Sick Children, and St. John's Hospital – in addition to providing primary and community services.

The RIE handles:

• 111,000 inpatients per year

• 575,000 outpatient attendances per year

• 90,000 A&E presentations per year

The hospital has a total of 6,000 employees and 25 units.

8.2 Documentary analysis

The following section outlines the main results found from the analysis of documents during data collection. The analysis was based on hospital reports and acts related to the adoption, implementation and evaluation phase.

The documents made available for analysis were:

- A report on the adoption of the system containing the project objectives;

- An evaluation report, containing data related to the results delivered by the system.

The first document, dated December 2004, was prepared for submission to the Scottish Government and contains several sections: (i) a description of the background situation; (ii) the Project Objectives; (iii) the Scope of Proposed Services within the RIE; (iv) the results and benefits addressed by the adoption of the system.

The first part of the document describes the situation prior to adoption.

The RIE entered into a Private Finance Initiative contract in November 1999 to provide a Hospital Information System (HIS), whose key element consisted of Electronic Medical Records. The main drive for this project was the need to fully support the Royal Infirmary of Edinburgh (RIE) with the implementation of a HIS and a Picture Archive Communication System (PACS). The initial results of this initiative, in terms of a Patient Administration and Order Communication System, which includes electronic ordering and reporting of Laboratory and Radiology

tests, were expected for the end of 2003. However, such results were not delivered and the contract was terminated at the end of spring 2004.

Several years passed since the initial decision was made in 1999 to give the hospital a HIS system and the need for an electronic medical record system became urgent.

At the time when the document was defined, the situation was marked by the subsequent issues: first of all there was a lack of functionality when ordering test results; the process was still paper-based. Three separate Radiology systems existed which did not support the integration of PAC and there was also a lack of a single Master Patient Index for covering these services. Furthermore eight different patient databases were in use, based on a variety of patient numbering systems. This meant that patient information was entered into multiple systems for each patient episode and could not be linked or shared electronically.

The RIE was characterized by the presence of three separate Patient Administration systems, - with the majority of patient's clinical letters being produced using MS WORD and so they were not linked to any electronic patient record,- and two unrelated A&E systems, that were not integrated with the rest of the hospital. For this reason, much of the relevant clinical information was available only to A&E and was not available to other parts of the hospital unless in the form of case-notes on paper. Furthermore, clinicians had a basic Results Reporting facility hampered by huge clinical weaknesses that reduced its usefulness and support for clinical governance and the hospital was unable to provide patient's clinical letters (e.g. discharge letters) and radiology reports throughout NHS Lothian.

In order to address these issues and improve the efficiency and effectiveness of the health care delivery process, section 2 of the document presented the project's objectives for the adoption (Table 8.1) .

Table 8.1 EMR Project objectives at RIE

Objective 1 To support the only laboratory reception area at RIE with electronic ordering of tests;
Objective 2 To support the implementation of PACS to enable communication of digital Radiology images across NHS Lothian;
Objective 3 To support the delivering of patient care by staff to the large volume of emergency patients with electronic ordering and reporting of laboratory and radiology tests, and with integration of key clinical information (patient's letters such as discharge notes, radiology reports, laboratory test results) for all patient episodes.
Objective 4 To support the single system in place at NHS Lothian and improve access to key clinical patient information with a single electronic source of clinical letters for patients (e.g. discharge notes), radiology and laboratory test results.

Section 3 of the report highlights the importance of the project for reaching NHS Lothian's strategic goals, set out in the *Scottish Health Plan* (National Health Plan - A plan for action, a plan for change 2003 - discussed in chapter 6). The project's aims at supporting a single-system working throughout the hospital and the implementation of a single system and database for Patient Administration Radiology, A&E and Order Communication/Results Reporting functions. It looks also at providing a single source of patient information - in particular clinical letters (e.g. discharge letters), radiology results and laboratory test results - made available electronically across NHS Lothian. Finally it was supposed to help in reducing clinical risks and improving the quality of care by providing key clinical patient information to all staff in a timely, legible and standardised way.

Lastly, section 4 of the document claimed the results and benefits addressed by the adoption of the system, in terms of efficiency, reduction of clinical risk, increased time spent with on patient care- compared to that spent in filling sheets- reduction of repetitive and invasive examinations due to lost paper results.

The document clearly indicates that the adoption of the system was not only supposed *to assist staff* (clinicians, nurses and administrative personnel) in a technical manner, it was also intended *to address strategic purposes* and goals in order to guarantee the *implementation of a single, fully-integrated patient system* and so support the delivery of health care services throughout the hospital and across NHS Lothian in general.

The document also contains the vision statement: "Sharing healthcare information to help our staff deliver improved patient care throughout Lothian". Furthermore, the Director of the Lothian eHealth Board stated at the time of adoption: "The solution needed to capture and present all information relating to an individual patient – referral and attendance details, diagnostic test requests and results, treatment details, and comprehensive discharge information."

The structure and content of this document are consistent with the characteristics of a mission statement, namely a written, formal document which attempts to capture an organization's unique and enduring purpose and practices (Byars, 1984; Bart, 1996; Collins and Porras, 1991); it also has to be concise, convey the overall goal and be memorable.

The second document made available for analysis is a report dated September 2010, containing data and information about the results produced by the system several years after its introduction. This document provides statistics on the different types of results produced during the last 5 years by the system. The data

in this document will be discussed in detail in paragraph 3 together with the analysis of the impacts produced by the system. Nevertheless, this document is indicative of the attention and relevance assigned to the evaluation process as part of the introduction of the EMR project as a whole. According to several studies, successful implementation needs strong monitoring and rigorous evaluation before the adoption, *in itinere* and *ex post*, using indicators of safety, quality, accessibility and impact on workflow (Pagliari et al., 2008).

8.3 Interviews

As broadly discussed in the chapter on methodology and mentioned in the previous chapter on the Italian case study, the interview process aims to explore the subjective accounts of people working in the organization with regard to three main phases:

1. The selection and adoption of the EMR system;

2. The implementation process used;

3. The evaluation process.

8.3.1 The interview sample

As for the Italian case study, we selected a purposive sample (Bryman, 208) including each type of staff profile (medical, clinicians and nurses, and administrative profiles). Some interviewees were selected specifically for their ability "to shed light on a particular aspect of the behaviour under investigation" (Cassell and Symon, 1994). These included the General Director and the Project Manager. Other interviewees were selected using the snowball technique: the initial respondents were used as informants to identify others with the previously defined characteristics:

- staff profile;

- number of years working for the organization: at least since the adoption of the EMR system;

Four departments were selected to pick clinicians and nurses for interviews (see table 8.2).

As with the Italian study setting, these departments were selected since each one is representative of a specific "area" inside the hospital; furthermore, each of these departments can be said to represent the overall area due to its scale in terms of beds, patients and number of staffs.

Table 8.2 The study sample

Area within the hospital	Ward
Specialist Medicine Area	Gastroenterology Ward
Medical Area	General Medicine Ward
Maternal and Infant Area	Maternity Ward
Emergency Area	A&E Ward

Two of the departments selected have specific characteristics leading to their inclusion in the study sample: A&E was the first ward to complete the EMR adoption and the maternity ward was the last (in order of time).

The Head Clinician, Head Nurse and Junior Clinicians from each of the selected wards were interviewed. Compared to the Italian case study, other specific staff profiles were included in the sample: clinical advisors for the project and receptionists. These roles will be explained in greater detail below.

The following table (table 8.3) identifies the actors included in the sample, who were selected based on their role within the organization.

Table 8.3 The interview sample

Participant role	Key	Number
Member of RIE's Strategy Board	STB	1
eHealth Director	HD	1
Member of financial office	FO	1
Clinical Advisors	CA	4
Head of Nurses	HN	4
Head of Clinicians	HC	4
Receptionists	R	4

8.4. The interview results

8.4.1 The Antecedents of the EMR project - origins of this EMR project

The different actors interviewed suggested various reasons for the adoption of the system. The main reasons were:

1. To support clinical staff and admissions procedures;

2. To support the implementation of a Patient Archive Communication System (PACS) and enable the communication of laboratory results, digital and radiology images across the hospital;

3. To support staff for the delivery of patient care to large volumes of patients using electronic ordering and reporting of laboratory and radiology tests and integrating key clinical information.

The need to manage casualties and reduce clinical risks was mentioned less frequently. Only two interviewees said that a main reason was to improve efficiency in terms of saving time and cutting costs. Following the transcription of the interviews, the reasons were categorised according to two types of drivers for adoption: *clinical and organizational drivers.*

The eHealth Director, a key actor in the overall adoption and implementation process, maintained that:

If it wasn't for the clinical staff, we would not have the system. The medical Chief Executive here at the time heard their voice, he really listened to them...people need it and then he made it happen." (HD/1)

The eHealth Director also described the "Antecedents" of the EMR Project in a really clear way:

"Up to 2004 the situation at RIE was marked by inefficient processes; clinical decision making was based on a minimal information service that was not patient friendly and bore an unacceptable level of risk.

To give you an idea, 5 years ago we had 3 A&E systems, 4 Radiology systems and 3 separate Patient administration systems. I think we had a total of 17 systems doing almost the same things and patient details were registered in different systems and it was impossible to get the full picture."(HD/1)

When asked to identify the main reasons for adoption, he listed several points that he defined *"drivers" for the adoption*.

He mentioned the subsequent reasons in order of importance:

1) *support for the clinical staff;*

2) *being able to support integration of the Picture Archive Communication System (PACS);*

3) *supporting the work done by laboratories.*

He explained that

"this hospital was designed so that the laboratory service has a single central booking area with few staff...so it was looking for help to manage this and electronic ordering provides a way of doing this ...It was the possibility to get all the information and demographic data so they do not have to enter this data and look for it in others papers."(HD/1)

The last quote is interesting because it highlights the relevance of the systems in terms of *advantages for professionals and staff.*

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According to a Member of the Strategy Board interviewed:

> *The overall project is the reflection of the commitment and dedication of both the NHS Lothian and TrakHealth teams, working together to make this happen. As part of the move from Lothian's current systems, over a million patient records were transferred to the new TrakCare system from both the previous Patient Administration and A&E systems. Previously these systems were operated independently from each other and led to unnecessary repetition of data entry during the patient care process. The new system will allow all or part of the patient records to be available to clinicians at a time and place when it is needed, supporting high-quality patient care through faster access to patient information."(STB/1)*

As mentioned above, the interviewees identified other reasons for adoption when emphasizing the **relevance** of the system. In particular, a clinical advisor working for the eHealth Department and in charge of supporting and supervising the Maternity unit said:

> *"From an organizational point of view, clinical staff wanted to have more information about their patients, let's say about mums, such as more strategic info coming out from Trak, they could do more work with planning activities also for long period" (CA/3).*

Another interviewee offered another interesting explanation, mentioning the need for *patient information in real time throughout the entire hospital*, enabling enhanced patient safety in this way, as one of the main reasons for adoption:

> *…The main problem was that paper records were not reliable. We didn't have any choice; we just needed a better system. At the time, we had a huge storage problem with storing these records. We can't store them on site, they have to be somewhere else, and then we've got to wait until somebody finds them and we periodically lose them. So having an electronic system means that we'll get easy access to the patient's record, when the patient is there. Instead of having no records and information about patient because they're in a storage facility. (CA/4)*

As emphasised by two people in our sample (the Member of the Strategy Board and the Member of the Financial Office), the system offered the opportunity for *adequate administrative information for care and operational managers*, since it helps to streamline the collection and the processing of administrative data with minimal workload for health care professionals.

> *"Trak lets you collect and store huge amounts of data. It supports administrative processes related to patients' data, assuring information is broadly available, timely, reliable and always correct, or as we used to say: 'correct first time' (STB/1)*

> *The initial purpose leading to system adoption was not related to financial motives, namely the billing process. However correctly carrying out administrative recording activities for patients can help to prevent many corrective operations associated with the billing and invoicing phase, or financial and accounting activities in more general terms. (FO/1)*

Even if the EMR system is still not fully integrated with the financial system, the interviews illustrate a very positive attitude to the completion of this process from both the clinical and financial/ administrative side, as we will see later.

As mentioned above, two main types of factors led to the adoption of the system: clinical reasons and the administrative reasons. According to Bergen and Berg (2004), the clinical factors refer to the desire to improve and develop all activities related to the *segments of care* and *care facilitation*. The former includes all the tasks done by primary care providers and functions of the information system designed to support this work, such as electronic order entry and results systems. *Care facilitation* consists of the processes involved with diagnostic and therapeutic activities carried out by separate units to facilitate primary care: radiology, laboratories, pharmacy.

According to the data analysed, the reasons leading to the adoption of the system, which can be considered clinical factors in this case study, are:

- Improvement of patient logistics, increasing the number of cases handled each year;

- To support the implementation of PACS, enabling data sharing across the hospital;

- To support staff for the delivery of patient care to a large volume of patients, using electronic ordering and reporting of laboratory and radiology investigations and integrating key clinical information.

As was noted in the interviews we conducted, administrative ambitions, including IT support for patient administrative processes , are lower than ambitions for the segment of care and care facilitation. This generally implies opting for information systems with more limited and modest functions to cover the most prevalent patient administrative activities (Berg and Bergen, 2004). Although only a minority spoke about the importance of the EMR system for supporting the patient administration process, it has to be taken into consideration that it can make a crucial contribution to improving efficiency within the hospital.

After analysing the reasons leading to the initial decision to adopt an EMR system within the Royal Infirmary of Edinburgh , we investigated how the selection of the system happened.

We questioned several of the people in our sample, but the project manager offered the most instructive answer.

> *"Before choosing the system we adopted, we had the opportunity to look at several options (HD/1)*

One option was Intersystems Trak S.n.c. and another was a company that supplied a number of core systems at the time. He did not mention the name of the other potential supplier for reasons of privacy and ethical considerations. A major problem at the time was that the NHS was undergoing many changes and the Lothian Health Board was reorganized 6 years ago in Scotland. Prior to this, there was a series of separate hospitals; consequently clinicians were obliged to work exclusively on paper, as they would have had no information otherwise. This meant that information collected at one site was not available at other sites, as they had totally different IT systems to carry out the same activities. The other major supplier supplied huge administrative systems and laboratory systems, so the final choice was between Intersystem and the second supplier.

In order to select the system, the hospital proceeded in a clear way:

> *"We undertook the usual evaluation: supplier presentation, discussion, cost - benefits analysis.*
>
> *We had to produce a case study for submission to the Scottish Government.*
>
> *The preferred option was chosen halfway through a workshop we organized and I think we had about 60 people at that workshop. The majority were clinicians and all the clinical staff put their hand up for Intersystems." (HD/1)*

Both options were presented and the details of the analysis conducted by the Information System team were also presented.

> *"…all of the analysis we did was presented and we told them what we saw, what we didn't see; we told them about the costs. And we gave them an overall view of the system." (HD/1)*

The clinicians **unanimously** decided to adopt Intersystem Trakcare.

The system was simpler to use and to engage for its interface. They realised that

TRAK would be a much better solution in terms of integration compared to what

the other supplier was offering. The eHealth Director added:

> *"I think they felt Intersystem as a supplier was more able to list what the organization needed, while the other supplier was very rigid and said what they should do and what they should not, so they had very clear reasons for choosing TRAK." (HD/1)*

The 60 people who took part in the workshop were invited because they were

involved in the process in various ways and this was the final part of that process.

All of the people interviewed, especially the members of the Strategy Board and

the advisors involved in the project, when asked to identify the person who was

most influential in encouraging EMR adoption, and they mentioned the same

person: the eHealth Programme Manager, who was EMR project manager at the

time of adoption. All of the interviewees, including clinical and nursing staff who

did not know him personally, mentioned him as the leading actor within the

project and said he encouraged EMR adoption, playing a major role in making it

happen.

8.4.2 Implementation Process

Some very interesting data concerning the implementation process emerged from

the interviews with several actors included in our sample. According to the

information collected, new roles were identified within the hospital to manage the

implementation of the Trakcare system. The implementation started at the RIE

site in December 2005 (first go live) and the Trakcare system was implemented

throughout the hospital by June 2008. One clinical advisor said:

"In that period we had an agreed implementation plan that said what we are implementing, when we are implementing it and how.

For example, in December 2005, we were implementing hospital-wide functions at RIE". (CA/2)

The implementation was to be "hospital based" so that all the units in the hospital went live at the same time. The eHealth Director clarified:

"For the main implementation, we all went live together, we "piloted" subsequent implementations, such as immediate discharge letters …so we chose a couple of medical wards to see if it was good enough to roll out and to learn what we needed to learn, what we needed to change before going live in all units."(HD/1)

The implementation of the system was structured: it started by implementing the most relevant functions across the entire hospital, and then continued by piloting additional functions in single wards in order to test them and to get feedback from staff working on the selected wards. This helped make any adjustments based on results and progress made in using the system. Furthermore, by selecting wards for the pilot test of the new functions, they could analyse how the system worked in different scenarios: inpatients, outpatients, emergency ward. The clinical advisor on the General Medicine Ward said:

"An area we are currently starting to pilot is the online review of results.…Currently almost all results return electronically to TRAK from the laboratory What we are looking at is how we can read these results and we are going to test how we think this can work for us.

We are piloting this function in an inpatient ward, an outpatient ward and the Emergency department. We would like to understand how well it works in the different scenarios: inpatient, outpatient, emergency.

Accident and Emergency is a ward where the system is put to good clinical use."(CA/1)

The system implementation was managed by the "Information System implementation team" and was overseen by a "Programme Board", namely a group that initially met once a month and still meet on a monthly basis to oversee the implementation, formulate advice, verify if any help is needed and provide it in this case.

The Chairman of the group is the Divisional Clinical Medical Director; the group itself consists of a number of senior clinicians, including the Director of eHealth Department and the Senior Operations Director for the Divisions. Other people are also involved but they are less relevant according to the eHealth Director.

Other key roles were identified during the implementation process and people were appointed to these new positions. Clinical advisors were identified for the implementation of the system in a specific ward. They worked for a specific ward but held different positions at the time of the adoption. For example, we interviewed the clinical advisor for the maternity department, explained how this change took place:

> "Well when…when I came into the project, they were implementing electronic medical records in the Maternity Unit. And I was employed at the time as a qualified midwife on the Maternity unit, ward 209.
>
> Then in July 2008 a job was advertised for a clinical advisor to come and join the project". (CA/3).

This means a position was posted to support the implementation of the system within the unit. No external people were taken on by the hospital to support the implementation process; instead, people were selected who already knew the services provided by the hospital and by these particular wards and were moved to cover the new positions.

At this point, we should give further details about the actors included in our purposive sample. As mentioned above, several new roles were taken into consideration compared to the previous case study.

The clinical advisor is a new role created during the implementation phase after the EMR system was adopted. He or she is closely related to the ehealth office.

Clinical Advisors perform specific activities:

- They accurately represent and apply the best practices and methods of clinical and technical expertise and clinical and technical leadership of the project by conceptualizing, developing and administering training and service delivery to improve strategies, projects and tools;
- They evaluate interventions by developing, enhancing or reinforcing the use of new systems to build the capacity of staff, consultants in technical content areas and provide training and service delivery;
- They supply technical input on strategic program and system planning, design, implementation and evaluation.

Furthermore, "Implementation staff" were defined to carry out Trak implementation. This support team was initially quite informal. Subsequently, according to the Clinical Advisor in charge of coordinating the Implementation Staff, the role of the new team, consisting of 3 people, grew and is now:

> *"Picking up on the mistakes that people were making….In fact, looking at the EMR system implemented, we realized we needed to go back and support staff, we had to show them what they were doing wrong and correct it. So that's how we came about.*
>
> *I have been appointed to this new position since January 2007, before that I was worked as a Nurse in the Surgical Unit. My contract was due to expire in 2009 but then they asked me to continue and help get staff on the wards using Trak properly".(CA/2)*

The members of implementation staff are employees working in the eHealth Department who do operational management activities. They work full time and report both functionally and hierarchically to the eHealth Director.

Furthermore, a "Key users group" was identified at each hospital site: about 200 people (both medical and nursing staff), particularly interested in Trak and its strategic development were involved in several meetings.

> *"We were looking for people who were interested in Trak, and wanted to ask questions and find out new things about it; every second month, they have meetings, they come along, and we tell them new things that are happening, and they bring issues they have got, to get it right and we find out how to solve the problems they encountered." (CA/2)*

The Implementation Staff and the Key users group initially met once a monthly but now meetings are scheduled every second month. Although there are about 200 Key users in total, probably about 20 people took part at each meeting, since different people came to different meetings.

Key users are employees who were decentralized across the hospital and continue to work as they did before the adoption of the system. Their expertise resides in their particular sphere of work. They are trained in information systems and information management skills by the eHealth Office staff and the Implementation staff in particular.

The impact of their work is essential above all for the wards where they work. As mentioned by the interviewee, the number of key users is significant, and their role is extremely relevant for obtaining information about what happens on the wards in terms of the use and acceptance of the system and any problems encountered during the implementation process.

The Implementation staff do not only use this type of meeting to keep in touch with clinical staff.

> *"We went round, we asked what the regular routine was, and we identified some issues to debate for each site....Then we went around the departments to find out people's feeling, and help with Trak. And so we did that, until they got to know it..."*
> *(CA/4)*

The implementation staff continued this approach throughout the implementation process and after the roll out of the essential functions across the different departments in order to share their knowhow of the system.

The role of *"Super user"* was also defined: people able to train other people were identified in each ward. These people work on the ward and are very motivated so they act as "local facilitators" for each department, supporting staff and training new staff; they are a communication tool, firstly by putting out any information to the Support Staff and then doing the same back, giving out information about functions updates and answering any questions.

The Implementation group set up a skill-based system in collaboration with the Ehealth Department, to train the super users on training techniques. The Implementation Staff also checked their knowledge of the Trak system and issued a Super User certificate so they can operate in a specific ward.

> *"We have it all down on paper, with check boxes, until it's electronic and then they've got jobs they can do with their staff and their departments, to make sure they're competent."*
> *(CA/2)*

The identification of super users will facilitate any new Trak developments, because there will be a network of people to exploit. Additionally it will be useful

for staff working in the department with a problem, as they will have somebody local who is able to help solve the problem and answer any questions without having to wait for a member of the ehealth group to show up.

Super Users are very interested in Trak; they are often already conversant in ICT so their experience is a sort of "knowledge tool", meaning they have developed good Trak skills in the past by attending training programmes held by the Implementation Staff. They offer themselves as volunteer "Super users" for their ward.

It sometimes happens that the unit managers identify who can be a Super User, however according to the Chief of the "Implementation Staff:

> *"Ideally, we'd like people to volunteer to do it..." (CA/2)*

Being a volunteer not only means they offer themselves spontaneously, it also means they will not get any financial reward. It is a way to certify their skills in using an EMR system and could be helpful for them to add this information on their Curriculum Vitae when applying for another job.

Therefore, volunteers have to be motivated; they have to like Trak and be competent in using it.

According to these factors, the Implementation staff set up a "skill based system" where they teach super users training techniques. After completing specific courses, their system skills are checked using specific assessment sheets with tick boxes. This is a way to certify they have the required skills to train staff in their wards: they will be able to train new staff on how to use Trak after the training programme and the assessment and also help people already working in the ward

to solve day to day problems and make use of new functions. This implies that people within the department are no longer required to attend training courses outside the ward. As a result, they do not have to leave their place of work and can get all the help and training where and when they need it. We should remember that people opted to become super users but they do not get any extra money for doing this work.

However this can be recognised as a key strategic role supporting the implementation phase. Previous studies (such as Bygholm, 2001) have also found that knowledge about a specific HIT system is best communicated by persons who are familiar with clinical applications and functions and who are able to integrate the ways of performing tasks with the daily working praxis.

This training focuses on learning how to use the system based on existing work practices within each ward. The introduction of such systems produces effects on existing work conditions and users need to learn how to integrate electronic and interpersonal communication of information.

Users need to feel that the value gained from the adoption of the new system will be higher than the challenges and the effort spent learning how to use it and for changing the previous way things were done. (Keshavjee et al. 2001).

In this specific phase of the implementation process, the role of super users within the departments is extremely precious but also challenging. All of the nurses we interviewed defined the training activities done by Super Users on the wards to be very helpful and acknowledged that they had more problems and wasted time trying to figure out how to manage some of the system functions before this role was introduced.

Furthermore, the head nurse, who is a Super User for one of the wards in the analysis, stated:

> "I started using Trak five years ago and I found it very simple and intuitive to use…I had some experience in using a PC and maybe this helped me. Then, before the system roll out within our Department we attended some training courses; let's say 3 full days training.
>
> Then we started using the system and last autumn the clinical advisor delegated to our wards from the ehealth office asked for people interested in attending a course for training other people in using Trak. I usually help my colleagues and so I offered as volunteer and my colleagues also suggested my name. I think Trak is a very useful tool and I think it has changed not only how they manage patient records but also how they communicate with each other, the way we provide patient care services, and perform job responsibilities. For these reasons, I decided to also take part in the skills assessment test, since I think Trak can effectively change the way we work and help our patients"(HN/4).

However, not all the people reacted in such an enthusiastic way as Super users.

According to ehealth Department advisors and based on what staff said themselves during the interviews, many people were sceptical because they were asked to do something that they didn't do before.

> "It's like any change, people automatically say, oh… They've got a fear of change. For the majority of them, when they realized all they had to do was a few clicks on a screen, then, most of them thought well, is that it? Okay, we can do that. Another set of people was more unsympathetic to using the system and it took us a long time to convince some of them what they were doing, the way they were working with paper records was actually taking longer. And if they would just don't do that they have just to click on the screen, that's a lot quicker!! For example if the nursing staff have to do blood exams on patients, the doctors would write the forms out. So they have to wait for the forms, and then they would go and take the blood. Now they do it all online, and there's no forms, no paper involved. A little label prints out, with the patient's details, they stick it on the blood sample, and away it goes, that's it. If you enter the ward and say to them, right, we're gonna take all that away, and you're going back to the old system, and you're gonna do it on paper forms, oh no, no; no, no, don't do it; don't do it. They thank me afterwards. So

although they complain that it was time consuming initially, they don't want to take it away either." (CA/2)

Furthermore, the way people reacted to the adoption and implementation of the system depended on the age and a person's attitude to ICT in general.

When the implementation started many people did not use IT. Younger staff knew how to use a PC but older doctors and nurses were a bit more reluctant. After some time, they started to recognize that it can help to cut their workload since a lot of information is stored on TRAK: clinical letters for nurses, patient discharge letters for doctors, test results..

Doubts were initially raised on the wards about safeguarding patient privacy when using the EMR system.

In some departments, staff felt that the initial training was poor:

> *"We were greatly criticized for training, they felt training was,*
>
> *was very poor." (HP/1)*

But the eHealth Department and the Strategy Board understood these needs and came up with solutions, such as Implementation Staff and the role of Super Users on the wards.

Focusing on the current level of integration, information is stored on Trak concerning:

- All patient administration functions;

- All in-patient systems;

- All in-patient attendances;

- All planned operations;

- All emergency operations.

RIE receives referral letters sent by General Practitioners (GPs) for consultations, which are sent electronically with attachments and notes.

Trak produces full discharge letters both for inpatients and outpatients. They are stored on Trak, printed out and sent to GPs. However, a pilot project was launched in the A&E Department in October 2010 to send discharge letters to GPs electronically.

8.4.3 The evaluation process

As mentioned in the methodology chapter, this section aims to offer an in-depth understanding of the role of the system within the organization and to explore how it affects people's conditions at work.

We identified 4 macro-categories of impacts based on the literature reviewed concerning the impacts of EMR (Bates et al., 2000; Protti et al, 1998; Pagliari et al, 2008):

a. Impacts on the health care delivery process;

b. Impacts on people working within the organization;

c. Impacts on patients

d. Impacts on relationships with other stakeholders - institutional or not

As mentioned above, in addition to the documents analysed for this case study, we also had the opportunity to scrutinize an evaluation report produced at the end of 2010 for the Programme Board. We will describe people's perceptions first and then discuss the results contained in the report.

Based on the interviews carried out, staff working on the wards (clinicians, nurses, receptionists) had the most informed position for answering the questions related to the evaluation.

The eHealth Director added some interesting information on the evaluation process and how it was defined and scheduled.

"We do not have complex software that works as an evaluation tool, but we have defined a set of indicators for monitoring a system's result. We have to provide some details on the project approved by the programme Board each year, like the quantitative benefits we are looking to deliver...so they can assess if we have delivered these results...This is a way for monitoring the system, how is it working, how the implementation is running and to make adjustments and changes, if and when required.

The first thing is to listen to what people who use the system 24 hours a day said." (HD/1)

He also listed some results from an administrative and clinical point of view.

"We have a number of things that follow from the drivers.

The integration with PACS has really been one of the major successes, we really had good results and clinicians were very happy about it ...since we started to provide laboratory results, final reports and images all together...

...they were saying that they need to...they need to have information at their finger tips.

From the administrative point of view, we have electronic referral receipts from the GPs...Before that, to find a referral, the administrative staff had to go to the referral system, print off the referral from TRAK, type the name, enter the details into Trak to make them available. So it was a very time consuming process. (HD/1)

The paragraph below discusses users' opinions on the impacts delivered by the EMR system, divided into 4 types of impacts.

a. Impacts on the health care delivery process;

One of most highly acknowledged benefits resulting from the adoption of the EMR system within the hospital is related to the perception of EMR's speed which helps to save time. The majority of clinicians we interviewed sustain that the adoption of EMR reduces *waiting time* for laboratory test results and enables diagnostic images to be viewed in real time, saving time in the execution of daily activities. The respondents also confirmed that the adoption of EMRs produces relevant results in terms of *accuracy, completeness, ease of understanding and reliability of information*. As mentioned in the methodology chapter, all the respondents were selected due to certain characteristics, such as working in the hospital at least since the adoption of EMR system.

At the time of data collection, they have some experience using the system and started to recognise some adjustments compared to the starting phase.

> *"Compared to the initial phase, Trak is now used with more functions, such as for example blood tests, X-rays, and so on.*
>
> *At the start, it was only used for a few types of information and later they started to use it for more functions.*
>
> *It was helpful for some activities and it also helped to save time…it is much easier working on the ward." (HC/2)*

According to the majority of clinicians interviewed Trak helped:

- Check results;

- Alert information about allergies;

- Identify where patients are located in the ward;

- Send letters to GPs.

In particular, a clinician said:

> *"It helped in ordering investigations, and in knowing which patient is in the department, where he is and who he has been referred to.*
>
> *I think it "improved the patient flow", in terms of how the process happens when a patient comes to the front door and it is much smoother and easier to manage with the Trak system. After visiting a patient, I simply type into Trak what I have written on a sheet for the GP and if I have to prescribe something, I just prescribe it." (HC/1)*

Another clinician on the maternity General Medicine Department emphasized the possibility to *get results in real time*:

> *"The biggest impact now is that we can get information in real time, and that was not something we ever had before. There are a lot of improvement programmes that have been going on since the initial adoption. Trak has allowed us to be able to look at the patient pathways and measure them all the way along… and measure the time people are waiting. And then the other big opportunity offered by Trak is the information sharing and integration of data among the different hospital sites…we have so many hospitals within Lothian". (HC/3)*

However, one clinician in the General Medicine ward did not agree that saving time enhanced decision-making processes (especially at diagnosis level).

> *"I don't think I saved time in visiting patients since I think it depends on each case and it cannot be standardized. The system can help in getting exams from laboratories and tests available in real time and to have a clear and accessible picture of previous patient attendance". (HC/2)*

Others even think that using the system is time consuming, since they have to learn how to use a new system and have to work differently to how they have always done.

A receptionist from the A&E ward, one of busiest in the hospital, also said:

> *In this ward we admit more than 100 persons a day and...I've been working here for 8 years ... I don't think the most relevant effect produced by the system is time saving...I think the main benefit is the accuracy of information.(R/4)*

However, after discussing this result with the eHealth Group clinical advisor for this ward, it emerged that this perception may be due to the fact that the main users had to dedicate more time during the initial phase of adoption, but they would learn how to use the system over the years and then use the system more quickly and more fluently, so it would then help them to save time.

The interviews with the nurses in the study sample pointed out that the adoption of the system helped by producing *more legible notes* that are easy to understand without the need to deduce or decode clinicians' handwriting.

Interestingly enough, we found that respondents acknowledged significant improvements in their activities in terms of enhanced ability *to plan admissions, more accurate diagnosis and treatment and the reduction of errors in prescribing tests and compiling reports*.

Results in terms of the impacts on *risk management are mainly linked to the presence of alerts*, whereas the interviewees refer to the reduction of errors associated with the integration of information between different wards and throughout the hospital at all phases of patient workflow. Comprehensive medical information not only provides the healthcare provider with alerts, but also with information for reducing different types of errors and avoiding unnecessary, or redundant, invasive clinical tests.

Furthermore, many interviewees were open about the importance of the system for producing positive effects in terms of the improvement of *treatment and service-*

related activities. This has led to organizational changes that currently allow for better planning of admissions, more accurate treatment and fewer errors in prescribing tests and compiling reports.

On the other hand, the interviewees found that the adoption of the system has not affected or scarcely affected the definition of diagnosis. One of the clinicians in the A&E ward was particularly clear about the use of the system for the formulation of clinical diagnosis:

> *"The system isn't very helpful for diagnosis, since I have to identify the problem and the way to solve it. However, the system is very helpful for ordering investigations and other types of exam....it helps a lot.*
>
> *In some senses, we can say that it helps the diagnosis process "indirectly", since it lets us have easy access to a patient's history. In fact it also helps the sharing of info with GPs: we type notes for GPs and we receive referrals from them."* *(HC/4)*

This last comment is very interesting because it shows that clinicians are more confident with the information they receive before they decide on a clinical diagnosis: they have safer and more reliable information thanks to Trak.

b. Impacts on people working within the organization

The interviewees in the different wards agree that the most relevant effects on people working within the organization are at *"communication level"*, expressed as improvements in the interaction between clinicians and nurses on the same ward and between different units and hospital sites.

The eHealth Director offered a very clear answer to this question:

> *"Of course, the adoption of the system affected people working within the hospital and their daily activities. When we started the project, many people did not use IT. A doctor does not use IT for his job...there is no reason to use a PC.*
>
> *For junior staff, they know how to use a PC but older staff, like doctors and nurses, were a bit more reluctant and we continue to have that, even if we reduced their workload since a lot of information is stored on TRAK...."(HD/1)*

Furthermore, both nurses and clinicians recognise that the adoption of the EMR system helped provide all of the patient's information on previous admissions and this helped interactions and communication between members of staff, as is discussed below.

> *"It has definitely improved relationships between clinicians and nurses.... in the sense that we can all access the same information without going around and asking for details, or results and information in general terms." (HN/3)*
>
> *"We can also check and get all the information about previous attendances, and about particular problems we need to be aware of, such as if children are on the protection registry or if they suffer chronic problems, such as diabetes or if they have any allergies." (HN/2)*

There was general consensus that the adoption of the system did not enhance the commitment of clinicians and nurses.

> *"The system did not affect clinicians' and nurses' commitment as this is not related to the use of the system."(HC/2)*

Staff's involvement and level of commitment seems to be independent from the EMR system adoption. It may exist or it may not within an organization, but it is not related to the EMR adoption and use.

c. Impacts on Patients

When asked about the impacts the system produced on patients, there was general agreement that patients are not aware of the use of the system. However, in one ward alone, both clinicians and nurses agreed that patients know the system is in use and it led to them feeling safer and under control. This was the Maternity ward and the staff interviewed sustained that patients staying in their ward are quite a bit younger than most people admitted to hospital.

> *"In Maternity, we are dealing with a generation, because obviously it's young reproductive women that are having babies, so you know, when I started midwifery, over 20 years ago, the people I was looking after were the same age as me...Whereas now, the people that are coming in to have babies are 20 years younger than me. And they're a generation who have been brought up with computers. They use computers at school, they work with computers in their job, they might be IT people, they are involved with computers. So they seem to expect care to be computerized. They don't expect you to be sitting writing lots of sheets of paper. So I think their acceptance of an electronic system is probably much better than in the past.*
>
> *So from that point of view, I think they are accepting it, and it doesn't matter." (HC/3)*

However many clinicians and nurses interviewed were concerned about the possibility that patients' confidential data can be revealed to someone who can use it in uncorrected way for different reasons. In particular one clinician within the Gastroenterology ward declared that he is especially worried about the fact that it is possible to access patients' data also from outside the hospital, when one works at home. This can help to better schedule clinicians' time but can lead to privacy problems: a laptop can be stolen and external people can force the access to confidential data.

Due to the relevance of this theme, privacy issues related to EMR adoption will be further discussed below.

d. Impacts on relationships with other stakeholders

When asked about this dimension of impacts, 6 interviewees said that relationships with other stakeholders may be hugely affected by the system, even if this can only be seen in the long term. According to all interviewees, this may be strongly influenced by the new situation in Scotland.

In February 2010, in fact,NHS Scotland signed a framework contract with Intersystem S.n.c for the supply of InterSystem's TrakCare healthcare information system as the new national patient management system for Scotland. The press release said "the contract is a national framework in line with Scotland's eHealth Strategy that will enable any Health Board access to the system and associated modules over the next four years".

The new system will help to speed up and improve the effectiveness of patient care in Scotland by ensuring patient information will only need to be entered once for it to be immediately accessible by authorised staff in other care settings. The TrakCare patient management system includes hospital and mental health patient administration, order communications, results reporting and clinical support tools. A number of optional modules are available for accident and emergency, hospital electronic prescribing and medicines administration, pharmacy management, maternity, neonatal and Theatre. Five NHS Boards decided to purchase the system at the start (Ayrshire & Arran, Borders, Grampian, Greater Glasgow & Clyde, and Lanarkshire) and take advantage of the national framework agreement. Together with NHS Lothian, these five Boards care for 70% of the Scottish

population. The total value of the initial contract will be in excess of £44M. Additional Health Boards are already in discussion about how this framework may benefit them.

The eHealth Director at RIE emphasized this concept and said:

> *"In Scotland, in a number of years, when the system will be implemented at all other sites, the system will help to share the same view as a few go live...I think that in terms of full EMR we have to wait few years after the hospitals go together, but I think that it can happen. Clinicians and patients will both be winners from a system which will track patient journeys from referral to discharge. It means clinicians will have easier and quicker access to medical records and patients will benefit from having more time with healthcare professionals." (HD/1)*

As mentioned above, we had the opportunity to access and analyze some documents issued by the organization such as an evaluation report containing data related to the results delivered by the systems, produced at the end of 2010 for the Program Board.

The eHealth Director pointed out some of the results produced:

> *"We did some examinations and we had a conservative estimate of how much time it saves in the departments by having details electronically and we found that they saved hundreds of Mondays a year. We estimate that by stopping printing all clinical discharge letters for GPs, we will be printing 1 million less piece of papers a year. And then you have to put each one of them in an envelope and send them to GPs. This mean that there is potential for savings from an administrative perspective and it can help make us more efficient." (HD/1)*

According to the report, the adoption of the system improved the delivery of care, allowing clinicians access to results in real time. Furthermore, based on the data contained in the report, the system removed the need for repeated tests due to lost reports.

The use of the system improved the management of requests to laboratories and also improved the compliance of requests. 5 years after the adoption of the system, it was also acknowledged as supporting the clinical information provided electronically to laboratories. An interesting fact is the percentage of electronic ordering of blood tests in July 2010: 99% of the total amount of blood tests performed within the A&E ward. 97% of blood tests were ordered electronically by in-patients wards and 89% are ordered the same way by outpatient wards. The same results were true in Radiology for the ordering of X-rays. The possibility to send electronic GP referrals helped save more than 300 hours per month. Communications with clinical wards occur 1 day earlier compared to before the adoption. Electronic discharge letters also helped save time for communications with GPs, since letters are now received 3 days earlier than before EMR adoption. This is a selection of the information contained within the evaluation report, offering an idea of the indicators used for monitoring system performance and the results achieved in the past years.

8.5 Observations

We started by observing routine activities and one of the most relevant event is represented by patients' reception and admission. We had the opportunity to observe this peculiar event in two departments: the Gastroenterology and the A&E Department.

As we know the A&E Dept is one of the busiest department within an hospital, and the observations we carried out demonstrated that it has more than 100 hundred admissions. Patient reception and admission is organized in a very structured way: the patient presents himself at the reception and there the receptionist ask to the patient or to a person who is coming with him/her if this is

the first admission. In the case the patient has been already admitted all the information already stored in the EMR, otherwise they have to ask some basic information.

The nurses carry out triage, which includes all the activity to estimate the patient's condition at the moment of his arrival to the A&E Department and the nurse, has to identify the problem and give them a triage category. All this information is typed on Trak and through the system it is possible also book a bed in the department and check all the relevant information.

Furthermore, during the day we spent in the Department some people were visited and then they were discharged. In this case the receptionist accessed the patient's EMR file and send the discharge letter electronically to the GP. In another case the patients were addressed to a different department after the visit and through Trak was possible to book a bed in the department. Spending some time within the department in particular in the reception area, offered the opportunity to get an unique point of view. The researcher feel fully plunged within the context and as a much within the context and as a member of the staff itself (since this represent an hot point within the department).

Furthermore we noticed that many objects took part in the process: the Emr system, clinical records, diaries, sheets of paper, post-it notes but the most relevant appear to be the computer and the EMR system.

These objects contribute in some ways to the reception and admission process.

These objects contribute to the admission process and they "comprise ordered" relations that materialize in the patient/nurse interaction" (as adfirmed by Bruni, 2003).

All these objects are closely connected and then all the information are integrated in the EMR system that represents the most relevant object. However these non-human objects require human intervention, even if they guide the human interaction and they involve other objects.

8.6 Conclusion

The results in this chapter are generally consistent with the behaviour and perspectives discussed in the chapter on the conceptual framework. In this case study, the main driver for adoption came from the clinical staff and not from the business staff, and the preferred system was chosen from two potential systems during a workshop with clinical staff.

According to Ash et al (2003), the adoption process must be marked by "consensus" about the need for the adoption of the system and about the system selected. As generally illustrated by interviewees, the selection and adoption process was participatory. This process is important for the generation of commitment about the adoption process as Øvretveit et al. (2006) also found: extensive software testing the vendor's claims for baseline functionality and the system's adaptability to local needs is important before implementation. In fact, user frustration with software problems can quickly mount and result in resistance to implementation.

In previous studies (Zukerman et al., 1998; Glouberman and Mintzberg, 2001, Lium et al. 2008), introduction of EMRs has often been attributed to the administrative part of hospital organization. However, one of the greatest challenges to date is to try involving both administrative and clinical parties so the managerial part is preoccupied with budget, economy and accounting (Glouberman and Mintzberg, 2001) and clinical staff are focused more on medical

excellence. This is exactly what happened in this case study: both parties were involved and played a great role in the decision to adopt the system; clinical staff (clinicians and nurses) were also involved in the selection phase.

It emerged very clearly that the implementation process was managed by the Implementation group and overseen by a "Programme Board". All the interviewees agreed that the project leader, the eHealth Director, was very competent and considered the project was well planned and organized. In this case, a well-functioning, IT-department in the hospital facilitated the implementation process and this was also similar to other studies (Øvretveit et al., 2007, Berg, 2003), which argued that the decision about the system should be participatory, but once made, implementation should be directed and driven.

As broadly discussed in this chapter, implementation took place in an incremental manner and all the stakeholders were involved in the implementation process. This led to the definition of specific roles during this phase and the allocation of responsibilities. A crucial step was the identification of "Key user groups" consisting of about 200 people based across the hospital, who were particularly interested in Trak and its strategic development. Another crucial step for the implementation process was the definition of "Super users" in each ward. These are people (clinicians and nurses) capable of training other people. They work on the ward and are very motivated; they attend special training courses and are assessed themselves. This is consistent with the theory proposed by Berg and Bergen (2004) that identified user-involvement as a being important to foster the ownership of the systems that will actually match work processes. It is not enough to include a few potential users in the project group and have them negotiate the system specifications, discuss implementation plans and the achievement of organization change in a meeting.

Social-technical approaches favour a central role of the users throughout the development process, even if defining how to involve the users is not easy (Faber, 2003 Hartswood et al, 2003). In fact, it often happens that users are only consulted a few times in meetings whose setup mitigates any real involvement of users or any real openness of the designers (Markussen, 1994).

The interviewees in this case study clearly emphasized that implementation process happened in an incremental way; all the stakeholders involved in the process were able to learn from previous steps and the overall process was marked by continuous adjustments (Berg, 1998).

Finally, focusing on the evaluation process, it emerged very clearly in this case study that a set of indicators was defined for monitoring impacts in terms of efficiency and savings and that the adoption of the system produced real and measurable benefits and impacts on hospital performance.

Furthermore, the use of qualitative interviews also helped shed light on the impacts on the people working at the organization, on patients and on relationships with other stakeholders (Kaplan, 2001).

Based on the social interactionist approach to evaluating medical informatics applications, this study considers users to be active participants in what occurs because they may modify information systems during their design, implementation and use.

The adoption of the system produced visible goals defined at the initial phase and over the past 5 years and this helps to show the efficiency of the system and its effectiveness for staff. Furthermore, continuous adjustments by the eHealth Department were based on the results of routine reviews and meetings with key users from the departments. In conclusion, the case study found that strong

commitment and appreciable results in the long term to be the main characteristics.

These results are due to the strong commitment of all the users involved in the adoption, implementation and evaluation process, who were invited to take part in the introduction of the system from the initial phase and were required to understand why change was necessary, so that the concept of envisioning an immediate gain as argued by Berg (1998) then becomes important.

As we were told during the interviews, clinicians generally accepted changes once they saw that the change facilitated their workload and/or improved the quality of their work. This point also illustrates the importance of not focusing solely on the ability of the EMR system to support individual users conducting single tasks, but of emphasizing the potential effects of the EMR system on clinical workflow.

The next chapter will discuss some ethical and privacy issues related to EMR adoption recurring at both study sites.

CHAPTER 9

CASE STUDY IMPLICATIONS:

A discussion of EMR systems and ethical issues

In the case study analyses, a major concern, which was expressed at both study sites, was the issue of the potential ethical challenges in the routine use of EMR systems. This chapter addresses this issue as a discussion of the implications of key research findings, which in itself, may be a major obstacles in the implementation of EMR systems.

The purpose of this chapter is to identify and critically explain the ethical issues that may arise from the adoption of information and communication technology systems in health care organizations. The chapter will discuss the ethical issues arising from the adoption of EMR, underlining several constraints concerning ethics in terms of autonomy, privacy, and confidentiality. Finally, the chapter analyses some possible solutions to deal with this kind of problem in order to reduce the negative effects of EMR use on ethics sphere.

9.1 Introduction

For some time years the role of ethics in public health matters has been broadly investigated and discussions around these themes have been increased after the adoption of ICT in health care sector. However, the issue about protection of patient privacy isn't a matter of modern times, in fact physicians dating back

centuries "have abided the oath of Hippocrates that oblige them to keep the silence thereon, counting such things to be as sacred as secrets" (Bulger, 1987). Furthermore, during the years, revolutionary changes in health care organizations have driven the concept of privacy from the mere relationship between medical professionals and their patients to a wider organizational and inter organizational context, as a result of a health care service provision process that involves several different systems.

To analyze the ethical issues related to the adoption of EMR it is necessary to evaluate the innovation process that has evolved the health care sector. In particular, the need to improve quality, efficiency and effectiveness in the delivery of health services has driven many organizations to invest in ICT adoption, even if this sector is developing to ICT much more slowly than other sectors, for example the financial sector (Borgonovi, 2001).

9.2 Electronic Medical Records and ethical issues: insights from the two case study analyzed

As discussed above, the adoption of ICTs in the health care sector and, in particular, the adoption of integrated clinical systems, such as EMR, are said to produce several benefits both concerning the organization adopting them that the final users of health care services, such us patients. However all the e-health benefits "have to be traded off with the privacy consequences" (Rindfeisch,1997), for example EMR by facilitating the access to patient information reduces clinicians time in defining the diagnosis and reduces also the waiting time for patients, but this may imply a reduction of their privacy and the risk of disclosure of personal information.

In particular, according to Kluge (2001), EMR can be considered, as a "patient analogue" since it does not represent just a technical instrument for collecting, storing and managing clinical information, but it is characterized by an "ontological status that renders it independent and such as a reification of the patient" . For this reason the same author argues that EMR should be "guided by the same ethical principles as the treatment of patients themselves"(Kluge, 2001). Furthermore, it must also be noted that "patients are becoming increasingly anxious about the privacy of their medical records"(Harris-Equifax, 1996), since they are scared about the possibility that their confidential and personal data could be "shared with insurance companies, governments, researchers, pharmaceutical companies" (Mandl, Szolovits and Kohane, 2001) and that current laws do not forbidden these data exchanges

For these reasons, some authors argue that the personal electronic medical record has to be controlled by the patients themselves (Mandl et al, 2001) even if this meant that medical professionals could not access relevant information to fulfil their claimed responsibilities. So, we can argue that the ethical approach to EMR has to be based on *"deontological ethics"*, which stresses the autonomy of patient and the respect of their wishes, but also on an "*utilitarianism approach*" that aims at achieving the "maximum profit for the greatest number" (Bentham, 1996), for example through the exchange of information and data among different organizations, by adopting common standards, guidelines and other methods to secure information exchange.

Indeed, the use of EMR to collect, store and manage patients' information has increased the possibility of a more complete picture of patients' problems and to aggregate data from different databases. However this if has increased the

problems concerning potential hackers attack of electronic databases and its impact on the patients' privacy.

According to the National Research Council (1997) the concerns about the use of EMR in health services and how it can threated privacy of patients' are based on 2 concepts:

1) each person *has the right to control* his own data and all the processes concerning its diffusion and use;

2) information concerning patient confidential data can be revealed to someone who can use it in incorrect way for different reasons, such as for economic and social interests.

In fact the use of EMR in heath care practices could affect patient rights in several ways. According to Anderson et al. (2007) it could affect or alter in someway patient *privacy*, meaning the right that each patient has to protect its own data, *confidentiality,* referring to the duty that each professional has to his clients, in this case the health professionals toward the patient, and also *security*, concerning the mechanisms that protect information exchanges within and between organizations.

In particular*, confidentiality* represents a duty for doctors who have to respect patients' privacy. In fact "patients have a right to expect that information about them will be held in confidence by their doctors" (General Medical Council, 2003) and this means that health professionals are responsible for the confidentiality and security of their patients' information. Indeed this could become very difficult and challenging when EMR is used to collect and deliver

information about patients since branches could sometimes occur due to different causes, such as human error or lack of security in computer systems.

Based on the analysis carried out in two case study settings included in this thesis, it is possible to classify the matters about privacy highlighted by users in working with EMR systems into 3 macro-categories: i) Apprehension about *inappropriate delivery of information,* that can be due to unauthorized users who access data and uses them with purposes that conflict with organizational policy or from external people who force the access to the databases; ii) *Concerns about the information exchange between health care organizations and other institutions,* such primary care organizations, governamental organizations pharmaceutical industries; iii) Concerns about the possibilities of losing confidentiality data.

Indeed, *both* clinicians and nurses interviewed were concerned about the possibility that patients' confidential data can be revealed to someone who can use it in uncorrected way for different reasons and about the fact that it is possible to access patients' data also from outside the hospital, when one works at home. Some attempts to solve these concerns about privacy, confidentiality and security issues related to EMR use within healthcare organizations, have been put in place both in Italy and in Scotland.

In Italy, it has not yet defined a specific regulation about EMR and the rules of the Code of Privacy (Law 196/2003), which governs the management and organization of medical records in general, without distinguishing a discipline specific for electronic ones, are applied to date. However one article in particular, the article 92 of the Code, can be applied to manage EMRs system privacy issue. This provides general principles for which also the electronic medical record, although not explicitly mentioned, must ensure comprehensiveness of the data and

ensure separation of data relating to individual patients from other data. In addition, the access to EMR data is permitted to specified people only under certain conditions. Furthermore, according to the Code, a system of electronic authentication and authorization for the identification of persons authorized to access the data contained in the PCs have to be adopted. Secondly, to protect personal data against the risk of intrusion and computer viruses, it is mandatory to install firewall, antivirus, and to update regularly such security tools. Thirdly, it must be adopted procedures for keeping copies of data security and the restoration of the same. However, these are only some "minimum safety requirements" which must be considered in using the computers containg the patient's medical record, but not enough to assure privacy, confidentiality and security of patient data.

In Scotland, all NHS health records are considered as public records under the Public Records (Scotland) Act, and they must comply with legal and professional obligations such as the Data Protection Act 1998 and the NHS Scotland Confidentiality Code of Practice, which provides guidance to NHS employees on the necessary safeguards to maintain patient confidentiality. Furthermore in Scotland the eHealth programme supports healthcare delivery process by promoting the safe, effective and appropriate use of information in NHS Scotland by ensuring that the information governance safeguards are built into electronic solutions from the beginning.

However as stated above, based on the case study analyzed and also on debates at national and international level, *confidentiality and privacy* still remain one of the most relevant concerns related to the use of EMR systems.

9.3 Access to record in Healthcare: ways to improve privacy protection.

According to the President of the Internet Healthcare Coalition, John Mack, to ensure that Internet use will improve the effectiveness of Health care it is "imperative that access and quality to health Information on the Internet" (Mack, 2002) proceed together. This concept can be explained through the equation "Access+ Quality= Equity" (Mack, 2002)In order to apply this equation, several efforts are required to develop codes and principles to improve ethical approach in using information systems to manage health information and to improve the quality of services delivered.

As emerged from the case studies carried out and also based on researches conducted by other scholars and also research centres involved in studies about the relationship between the use of information systems to support clinical information data, in particular EMR systems, ethical issues represent one of most relevant dilemma related to the use of ICT within health care sector.

Indeed many studies have also have tried to suggest some solutions and initiatives that, through the coordination among them, can improve, safely, the overall quality of services provided to patients. Some of these suggestions include: (i)Regulations; (ii)Standard and guidelines; (iii) Code of Conducts; (iv) Codes of Ethics; (v)Technical solutions.

First of all, *regulations* "should enforceable and have the force of government behind them" (Layman, 2003). An example is represented by the "*Health Insurance Portability and Accountability Act* of 1996 that proposes a set of standards to regulate, the electronic interchange of health information and to protect the confidentiality and security of electronic health information that are

not specific to particular technology" (Wimalasiri, Ray and Wilson, 2005). However, the main weakness of regulations is represented by their limitation to some specific geographic area and to specific jurisdictions (Kluge, 2001), while information systems in health care are enlarging application to broadest areas. For this reason the "limited jurisdiction of regulation makes it impractical to oversee a global phenomenon" (Layman, 2003).

A second type of solution is represented by the adoption of "*Standards and Guidelines*". Standards are defined by authorities with specific responsibilities or, sometimes, are established by consensus, while guidelines are recommendations for doing or not something. Both are considered as "voluntary efforts to provide consistent and responsible services" (Layman, 2003). However, according to some scholars and practitioners, standards must be considered as a general approach to confidentiality and patient security, and today several types of standards that organizations could adopt. These include the standards established by the International Electrotechnical Commission, the so called "IEC 61508" or the "Directive 95/46/EC on the Protection of Individuals with regards to processing of Personal Data and on the Free Movement of such Data"(Wilson, 1999) exist. Another example of standards is Health Level 7 (HL7) that is a "voluntary consensus standard for electronic data exchange in health care environment" (www.HL7.org) that allows information sharing among different systems, such as between EMR and laboratory systems. These guidelines can be considered similar to standards, but their effectiveness depend crucially by people adopting them and how they use them.

For these reasons many practitioners and experts sustain that more comprehensive and wider applicable solution than regulation, standards and guidelines are

needed. Many organizations for example, started to introduce "*honour code*" also called "code of conducts" based on some principles such us the obligation to put information about the author, the date of the last modification of clinical documents, and to identify the specific source of data. The Health on the Net Foundation's Code of Conduct (HONcode) (Boyer et al., 1998) and "Towards European Accreditation and Certification of Telematics in Health"(Rigby, 2001) are two examples of honour codes. However this third solution cannot be considered as the best one to *solve* privacy and confidentiality concerns about the use of EMR in health care since these codes are limited to single organizations and cannot be considered applicable to all the other organizations.

Another type of solution that has been developed is represented by the "*Codes of Ethics*", which are "principles designed for developing ethical health information and resources on the Internet"(Mack, 2002). Some examples of codes of ethics are represented by the "*eHealth Code of Ethics*," prepared by The Internet Healthcare Cohalition, and "The Ethical Principles for offering Internet Health Services to Consumers" by Hi ethics organization. The internet Healthcare Coalition promoted the development of "The eHealth Code of Ethics" in 2000. This code of ethics aims at improving security in using ICT in health care and to protect patient privacy assuring the benefits that derives from the use of EMR system in clinical practices. According to the vision statement of the code of Ethics, *"The goal …is to ensure that people worldwide can confidently and with full understanding of known risks realise the potential of the internet in managing their own health and the health of those in their care"*(Internet Health care Coalition , 2000). In particular the eHealth Code of Ethics established an ethical framework based on 8 principles.

Table 9.1 The eHealth Code of Ethics: principles

Candour	The information about products and services concerning health care must be disclosed on the Internet by the organizations providing these services;
Honesty	The services and the information provided through the use of ICT and Internet must be truthful;
Quality	The information provided by ICT must be always accurate, precise, up-to date and in a high level layout;
Informed Consent	Each patient has the right to define who can have access to his own personal, confidential and sensitive data;
Privacy	The information systems in health care sector must respect the privacy of patient whose data has been collected, stored and managed through ICT ;
Professionalism in online health care	The health professionals must respect ethical obligations to patients and that research and data diffusion must be conducted according to rigorous rules;
Responsible partnering	The health care organizations in selecting their partners must be accurate and must use responsibility;
Accountability	The information systems used for health care purposes must offer the possibility to final users to give feedback.

The e-Health code of Ethics, can be considered as one of the most relevant initiatives concerning ethical issues arising from the adoption of information systems, and in particular EMR, to support health care, for several reasons: firstly it is based on rules that come from ethical considerations and doesn't adopt just a legal perspective. Secondly it developed a broadest approach that can include all the type of stakeholders involved in the health care processes, both providers and users. Thirdly, it has been promoted and implemented by one of the most influential non-profit coalition, the Internet Healthcare Coalition, ensuring a great international extension. Lastly, the definition of the code has been based on an

open participation process, and the feedbacks of different stakeholders have been included in the final version.

Furthermore, one must notice that to reduce security and privacy concerns *technical solutions* must also be adopted, such as the implementation of the same systems used by banking industry which allow access to personal accounts without security problems. The real challenge lies in persuading the providers in investing funds and times in securing these systems. A great help can come from the adoption of institutional policies such as regulations standards and code of ethics.

However, even if several interventions have been developed, applied singularly it has been founded not effective. For these reasons more comprehensive solutions are needed to address the ethical issues concerning "ICT adoption in health care systems and in particular in clinical area, since the use and the role of information systems is rapidly extending" (Kluge, 2007). It could be defined an ethical approach that takes into consideration all the different solutions/interventions discussed above in order to develop a model that could be applied to different context at national and international level. This model will:

- take into consideration the regulations and laws specific of each jurisdiction;

- adopt the relevant standard and guidelines defined by several institutions concerning ethical issues arising from ICT adoption and use;

- apply the main principles stated by honor codes and code of ethics;

- persuade the providers to develop common technical solutions applicable at global level.

9.4 Conclusion

This chapter presented the main ethical issues arising from the adoption of information system in the health care sector, offering some insights coming from the two case studies carried out. In particular, the chapter discussed the ethical concerns related to the adoption of electronic medical records, which are clinical integrated systems, that can be considered as "patient analogue" and for this reason should be "guided by the same ethical principle as the treatment of patients themselves" (Kluge 2001), focusing on different level of threats to patient privacy. It appears clear that there is awareness about the relevance of privacy and confidentiality issues related to the adoption and use of EMR systems, both based on the findings arising from the case studies and also from debates at national and international level. For these reasons, even if this is not the focus of the thesis, we decided to present and discuss in this chapter this topic. Some possible solutions that have been adopted to deal with these problems, have been illustrated above. However this big issue is not yet resolved, and enduring solutions that take into consideration all of the previous issues, to develop a more effective approach to ethical issues for all the situations are needed.

The final chapter will elaborate upon the main findings of this thesis, highlighting the main contributions of the thesis but also the limitations of the study and how they have been addressed.

CHAPTER 10

DISCUSSION AND CONCLUSION

This Ph.D project started with a broad analysis to investigate the key issues in the development of Information and Communication Technology (ICT) in the health care sector, with the intention of making an in depth study of the effects of the adoption of EMRs on the organizations adopting them. The thesis studied the enactment of ICT policy at two study settings that have adopted the same EMR system produced by the same supplier. This chapter begins by drawing together the findings from this research, stating how they relate to the aims of the research and what they have contributed to the purpose of the study as identified in chapter 5. Then it considers the ensuing policy and managerial implications concerning promotion of ehealth, especially related to the adoption, implementation and evaluation of EMR systems. In this way, the thesis makes a theoretical and methodological contribution by way of comparative international research into the development of e-health and the use of ICT in the health care sector. By focusing on EMR systems, it offers practitioners and policy makers a better basis for the analysis of ICT usage and its impacts on health care service delivery.

10.1 Introduction

Information and Communication Technology (ICT) has made a considerable contribution to the modernization of public administration at all levels. However,

the effective adoption of IT has changed over the years as technology has evolved and its incidence among organizations has grown. Over the years, the diffusion and prevalence of IT has grown in order to adjust to technological developments, the evolving needs of organizations and the managerial tools implemented.

Information and Communication Technology (ICT) have improved efficiency and quality in many sectors of the economy (Hendrick 1994; Heeks,1999). However, there is a distinct need for ICT and information system enhancement in the delivery of health care. Healthcare organizations have found that they do not have adequate systems to deliver strategic change (Westbrook, 2009). To remain competitive, public health care organizations are looking to information technology for help: building an electronic health information infrastructure will channel an immense amount of effort and resources. Government intervention has been called on in order to speed up the Health Information Technology (HIT) adoption process, based on the widespread belief that its adoption, or diffusion, is too slow for the benefit of society. In practice, although some administrative information systems are already in place in the healthcare sector, such as those for billing, scheduling, and inventory management, there is scant adoption of extensive clinical information systems. However many countries recognize the need to make advances in healthcare ICT.

"Modern healthcare is in transformation with the introduction of new medical technologies, evidence-based medicine…and new financial models", (Vikkelsø, 2007) and healthcare systems are becoming increasingly dependent on IT. In particular the EMR "is predicted to change and improve health care" (Kazley and Ozcan, 2007). Many studies have demonstrated that there are several potential benefits deriving from EMR adoption (Caccia 2008; Hillestad et al. 2005) concerning *efficiency gains*, *improved patient safety*, *clinical governance* and

patient empowerment. These effects are especially important in a "unified Europe", since EMR systems should promote integration and data sharing among different health care organizations in different EU countries.

The term eHealth only came into use in the year 2000, but has since become widely prevalent (Pagliari et al. 2005). Oh et al. noted that the term eHealth "encompasses a set of disparate concepts, including health, technology, and commerce". They went on to observe that "eHealth, as used in these definitions, usually referred explicitly to health care as a process, rather than to health as an outcome" (Oh, et al. 2005). It is important to note that there is no consensus on the meaning of eHealth among academics, policy-makers, providers and consumers. "The majority (..definitions) emphasize the communicative functions of eHealth and specify the use of networked digital technologies, primarily the Internet, thus differentiating eHealth from the field of medical informatics" (Pagliari et al. 2005).

This study is framed within the e-Health stream of research and has focused on Electronic Medical Record (EMR) systems in particular. The definition of e-health embraced in this project is: "*e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology*"(Pagliari et al, 2005).

In this context, Electronic Medical Records are information systems that manage both the "distribution and processing of information" (Lærum and Faxvaag 2004) that are necessary for the patient care delivery process.

This comparative study have analysed how EMR systems are adopted by different healthcare organizations and their impacts, focusing on:

- Antecedents of the EMR project;

- Implementation processes used;

- Impacts produced.

Diffusion theory with the lens of the social-technical approach provided the theoretical framework for the analysis. The two case study hospitals selected for analysis are Aosta Regional Hospital run by Aosta Local Health Authority, Italy, and the Royal Infirmary of Edinburgh in Scotland.

After a having provided an overview of the key issues arising over e-health policy development through a comparative analysis of the UK and Italy, the thesis provides an insight into how EMR systems are adopted, implemented and evaluated within acute care organizations. the study A multi-method approach to data collection in the two case study sites was employed. Several strategies were used for data collection: documentary analysis (such as "hospital acts", reports and documents related to the adoption and implementation phase) in order to identify the reasons for the adoption of the EMR system and its role, interviews and observations. The interview process aimed to answer the research question by exploring the subjective accounts of people working at the hospitals (including clinicians, nurses, General Directorate, Medical Directorate and the CIO). Observations of interactions were also carried out in the field sites.

After providing an overview of the key issues in ehealth policy development by means of a comparative analysis between UK and Italy (chapter 6), this work provides an insight into how EMR systems are adopted, implemented and evaluated at acute care hospitals (chapters 7 and 8). In this way, the thesis offers an improved basis for the analysis of ICT usage and its impacts on health care service delivery for practitioners and policy makers involved in the health care sector. It does, so, by means of systematic, comparative international research into the development of ehealth and the use of ICT in the health care sector, making a theoretical and methodological contribution, and focusing on EMR systems in particular.

These findings have already been discussed in depth in chapters 6-9, but this chapter draws them together in a concise form and discusses how they relate to the study's research objectives and aims, as identified in chapter 5.

10.2 The research objectives and research findings: an overview (a synthesis)

The main purposes of the study were:

1. *to identify* the key issues in the development and implementation of ehealth;
2. *to evaluate* how the adoption of EMRs influences health care service provision in hospitals, analysing how these systems affect the organization and the operations of its main users and stakeholders.

This purpose is led by two types of motives: *academic* and *social*.

- the primary reason is to fill a gap in literature in terms of systematic comparative international research into the evaluation of the impacts of IT,

and EMRs in particular, by making a theoretical and methodological contribution;

- the study also aims to contribute to the development of advice for public decision makers by offering a better basis for the analysis of IT usage and its impacts on service delivery for practitioners and policy makers involved in the health care sector.

Accordingly, the project seeks to address the following research questions:

- o *RQ1: What are the key issues in the implementation of e-health?*
- o *RQ2: How are EMR systems adopted by different health care organizations and what are their main impacts?*

1. What are the key issues in the implementation of e-health?

Healthcare systems in the EU are expected to face substantial challenges in the future. New methods developed for early diagnosis and treatments add to the surge in spending, but some medical progress may well cut costs in the long term. Investment in technologies for prevention and health care is a tool to help the population stay healthier for longer. The effective management of technology is therefore a major determinant of future spending.

As discussed in chapter 6, the European eHealth industry is currently estimated to be worth €20 billion. The market for ICT designed to support better healthcare delivery is still at an early stages and the availability of relevant ICT solutions is still relatively poor. The reasons include:

- low awareness of user needs and insufficient sharing of experiences;
- lack of standards and interoperability;
- high development costs for solutions;

- challenges in performing the evaluation of EMRs.

ICT can play an important role in dealing with the challenge of curbing expected increase in public expenditure, and improving the cost-effectiveness of patient care via the introduction of eHealth, for example.

The significance of the ICT phenomena can be seen from the multiplicity of documents and reports emerging within the EU. The 2004 eHealth action plan was the first document adopted by the EU relating to eHealth. This document covers several topics, from electronic prescriptions and electronic health records, to the use of new systems and services to reduce waiting lists and reduce medical errors. The EU adopted i2010 the following year: a strategic framework that aims to coordinate the actions of Member States to facilitate digital convergence and meet the challenges of the information society and so also eHealth. In 2008, the European Union focused on defining the basic concepts of eHealth, such as electronic health records and interoperability, and set out the guidelines for the development and deployment of interoperable electronic health records to safeguard the basic rights of patient privacy and data protection. The "digital agenda", which deals with the development of ICT in Europe, was introduced in 2010 to continue the i2010 initiative. As this concerns eHealth in particular, it plans to carry out pilot projects to provide *secure* online access to personal health records by 2015 to European citizens, and proposes recommendations to define a common minimum set of patient data to ensure the interoperability of medical records accessed or exchanged electronically between Member States by 2012.

It is important to look at the policies implemented by the European Union so far because they shed light on the EU guidelines for the development of eHealth. It would seem that the current priorities of the European Union are interoperability

and the security of the clinical data of European citizens. To achieve this, the first step is to achieve interoperability among the different countries and understand which eHealth programmes and strategies have been adopted by them.

Based on our analysis of policy documents marking the development of health programmes in the different contexts considered in this study (see chapter 6), we drafted different approaches to eHealth policy development by considering the different bodies in charge of editing and publishing the policy acts, plans and strategies, the stakeholders involved in the definition and development process (policy makers, clinical professionals, external consultants). Of the several eHealth policies examined, the Scottish experience suggests that *collaboration and cooperation* between policy makers and practitioners leads to better results in the development and implementation of eHealth plans.

Furthermore, the Scottish Executive Health Department recognized early in the process that "***people, not the technologies, are the key issue for implementation***." This is also in line with the results found in the Scottish case study: the extensive involvement of users in the selection of the system enhanced their *commitment* to its implementation and also boosted a positive attitude towards the day to day use of the system, increasing their trust in its potential as system users. Conversely, in the Italian case study, the lack of user involvement due to the "top down approach" and administrative and managerial priorities that overtook the professional voices in the hospital, led to the widespread perception among staff that the system had been *imposed* upon them.

The success of the Scottish implementation of EMR suggest that clinical and nursing staff should be actively engaged at all stages, both at national level for the definition of eHealth policies and programmes and at organizational level, namely

the need for user involvement during the selection and adoption of HIT at healthcare organizations.

The table below summarizes the approaches identified in the different contexts analyzed. This analysis shows that Government sometimes plays a key role in defining policies (see paragraph 6.6) and sometimes has a more pragmatic approach (see 6.7) led by strong communication between clinical professionals and policy makers.

Table 10.1 Approaches to eHealth policy development

EUROPEAN UNION *Integrated and collaborative approach*	
UK *Transformational Approach*	**ITALY** *Multilevel Approach*
SCOTLAND *Pragmatic Approach*	**VALLE D'AOSTA** *Functional Approach*

Apart from the above different approaches, this study identified several key characteristics concerning the eHealth policy development process that are evident in all the settings analyzed. Three characteristics in particular emerged as being of particular importance:

- the eHealth policy process is strictly related to the context in which it is defined and developed;

- there are different levels for the definition of eHealth policies: local level, national level and global level;

- all governments have different starting points, resources and goals at different levels;

Based on these common characteristics and on the different approaches identified and largely discussed in chapter 6, this study also uncovered some interesting evidence that can be considered "lessons learned" that are useful for developing further ehealth policies.

The policy development process has to put several elements together with a multifaceted approach. It should

1) *Ensure cooperation between professionals and policy makers*. This is consistent with other studies, for instance Pagliari (2005) who found that failure to engage end-users in the process of developing new systems is a classic mistake in design projects. Involving potential users in the design of systems can help programmers to better address stakeholder needs, test systems for their usability and functionality so as to avoid potentially expensive post-roll-out operations, and engender a sense of ownership which can facilitate implementation (Preece et al. 2002.).

2) *Clearly define goals and priorities at local/regional, national and supranational level*. In this study, delivering better care through the adoption of Information Technology, and EMR systems in particular, was revealed to be a priority in four out of the five settings analyzed. (See chapter 6).

3) *Ensure communication and integration between related programmes, avoiding fault replication*. "The policy development and implementation at a national level is often done with little or no reference to best practice or lessons learned in other countries, despite the many overlapping issues inherent in the development of national eHealth strategies". (McConnell 2004, 36, p.33).

4) *Ensure continuous interaction with contingent circumstances*, making up the situation in which the policy must be developed in terms of previous policy and actions delivered and in terms of citizens' needs.

5) *Open up the policy process to feedback from objective observers*, to obtain valuable comments and suggestions by qualified people.

2. How are EMR systems adopted by different health care organizations and what are their main impacts?

Electronic medical records (EMRs) have the potential to transform healthcare delivery by increasing efficiency and productivity, enhancing the quality of service and enabling patients to engage more in their care (Mahmood et al. 1993). In many sectors of the economy, the effects of technological innovation on the performance of an organization have been proven (Hitt et al. 1996), whereas there is still the need for extensive evidence of the actual impacts of such innovation, including the implementation of EMR systems, in the healthcare sector.

In literature, the studies that have focused on this either present results from isolated projects or discuss single types of impacts. In practice, health care providers are urging for proof with regard to the effects of EMRs in order to commit to such innovations. Furthermore, they need adequate tools to monitor and assess the nature and direction of their impacts on performance, not only for use once EMRs are a routine part of hospital processes, but throughout the implementation phases in order to assess potential gaps and achieve optimum implementation.

However, as previous chapters have shown, in a complex and specific context in the healthcare sector: the selection, adoption, implementation and evaluation process cannot be conducted in a separate way, as many studies did by focusing on the last phase (Ammenwerth et al. 2003; Himelstein et al 2005). Consequently, it was necessary to go beyond a list of the impacts on efficiency and effectiveness that technological innovations may produce and identify those most applicable to the healthcare industry in order to assess how EMR systems contribute to healthcare performance.

It was necessary to analyze the overall process of EMR introduction within the organization by analyzing the key stages: selection, adoption, implementation and evaluation (adapted from Rogers, 1995). In this study, the social-technical approach has been used as a lens to investigate the overall process of introducing and propagating EMR systems, taking into consideration that the way a technology is adopted, implemented and evaluated is affected by the users' objectives, preferences and communication patterns (Kaplan, 1997). According to this approach, the systems adopted, the main users and followers and the organizations in which the innovations are adopted, interact with one another and each of these elements process should be regarded as dynamic rather than static variables during the innovation.

In relation to the evaluation process, many authors (Mahmood et al, 1993 Hitt et al. 1996; Devaray et al. 2002; Dameri et al. 2005) have shown that a purely economic evaluation is not appropriate in an environment like healthcare, since it fails to take more "social" effects into account.

Furthermore, impacts on different healthcare organizations should be compared as well as how EMRs generally affect the performance of an organization in terms of speed and extent, whilst recognizing that different contexts and individual

organizational strategies could mitigate or enhance some of the expected impacts.

a) The selection and adoption Phase.

The two hospitals involved in this study had a different approach to the introduction of the EMR system, but both went from the co-existence of several clinical and administrative systems to a single EMR system, even if RIE had more expertise in this field. In particular, Valle d'Aosta Hospital is a regional hospital, the only one in the regional area whereas the Royal Infirmary of Edinburgh is an acute care teaching hospital.

The first set of implications regard the <u>origins of the EMR project</u>, and the related process of selection and adoption of the system. At Aosta Regional Hospital, *the decision was been taken by the General Director* of the Hospital who was in charge at the time of adoption; according to clinicians, nurses and other members of staff, the decision process was not participative at this stage. Moreover clinicians and nurses were only notified about the decision *after the selection process* when a steering group was defined that included four departments. These departments were selected by the General Directorate, even if several Head Clinicians indicated their availability to be used as pilot department.

At RIE, the second hospital analyzed, the *main driver for adoption came from the clinical staff*, not the business staff, and the preferred system was chosen from two potential systems during a workshop attended by clinical staff. The second case is consistent with some studies (including Ash et al. 2003) that argued that the adoption process must be characterized by "consensus" on the need for the introduction of the system and on the system selected.

The selection and adoption process in Valle D'Aosta was characterized by a "*top down approach*", without promoting personnel participation in the process from the selection phase (Øvretveit et al 2007).

In contrast, RIE adopted a "*bottom up approach*" during the selection and adoption phase, listing the needs of end users, involving them early on, thoroughly and systematically (Suchman, 1978; Lipscombe, 1989). A *participatory process* in selecting the EMR system represents a distinctive way to generate and improve commitment to the project within the organization.

Conversely, if this process is imposed it can generate user frustration and can impact on the implementation process and on the overall use of the system. At Aosta Hospital, people started to use the system without any idea of why it was being adopted and this produced a lack of commitment to the project. Only people involved in the steering group and selected by the strategic board were informed, while all the other users or their main representatives were unaware of the adoption of the system and its selection.

Based on evidence relating to ehealth policy development in the two Regions where the hospitals are located, we drafted some tentative conclusions: *the systems are related to the general ehealth policy and to the approaches put in place for the definition of ehealth programmes.*

In Valle D'Aosta, the policy development process was marked by the lack of involvement of professionals for the definition of ehealth plans, compared to Scotland, whereas external consultants with technical skills played an important role. The overall policy development process seemed to be led by a functional approach to the introduction and development of the ehealth strategy: the policies aimed essentially to guide the purchase and technical development of the IT system. The documents analyzed, in fact, concern health care and social issues in

general and the adoption of technologies is mentioned as a technical and support tool, but not in a strategic or comprehensive way. In Scotland, on the other hand, the development of the e-health policy over the last ten years was marked by determined collaboration between policy makers and practitioners leading to the goals identified and enhancing their commitment to these.

b)The implementation process.

As mentioned above, the selection, adoption, implementation and evaluation process must be regarded as different phases of the same process (the introduction of an innovation) and not as many distinct and unrelated processes. They are actually interrelated and represent stages of an iterative process in which the previous step influences the results achieved in others (Øvretveit, 2007)

A consequence of the way in which the adoption process was conducted in the Italian case study was a sort of initial resistance among users towards system implementation. Previous studies have shown that the lack of user commitment and involvement at the initial stage represents one of most frequent causes of project failure (Berg, 1999)

Another key element that marked the implementation process was "training". Again, the two hospitals acted in different ways despite introducing the same EMR system.

At Aosta Regional Hospital, the IT Office provided some technical training courses for clinicians only. However, it does seem clear that they offered only operational support since interviewees clearly mentioned that there were no courses on the strategic importance of adopting an integrated information system. On the other hand, nurses maintained that few events were held to introduce the

new system and no technical courses were organized to support the implementation phase.

At the Royal Infirmary of Edinburgh, after extensive training courses arranged at the initial phase to guide the introduction of the new system, support staff managed the training delivered by *Super users* on the wards. Furthermore, as discussed in chapter 8, the implementation at RIE happened in an incremental way and all the stakeholders were involved in the implementation process, leading to the definition of specific roles during this phase and to the allocation of responsibilities. In particular, a "Key users group" was identified, namely about 200 people from across the hospital who were particularly interested in the EMR system and its strategic development, and "Super users" were appointed on each ward. These are clinicians or nurses who are capable of training other people; they work on the ward and are very motivated so they act as "local facilitators" in each department, supporting staff and training new staff. In order to do this, they attended special training courses and subsequently took an assessment test, which was certified.

This is consistent with the theory proposed by Berg et al.(2004) that identified user-involvement as an important element to foster ownership of the systems: "it is not enough to include a few potential users in the project group to have them negotiate the system specifications and discuss implementation plans and the achievement of change in a meeting" (Berg and Bergen, 2004).

Social-technical approaches favour a central role for users throughout the development process, even if deciding how to involve users is not easy (Faber, 2003 Hartswood et al, 2003). It often happens that users are only consulted a few

times, in meetings whose setup mitigates any real user involvement or any real openness of the designers (Markussen, 1994).

"Monitoring actions" represents another recurring theme relating to the implementation phase. According to the nurses, clinicians and other members of staff interviewed at Aosta Regional Hospital, there were no monitoring actions defined before adoption, before the project went live or during the implementation process in terms of plans or tools to monitor project progress, its impacts, and costs and so on. At the Royal Infirmary of Edinburgh, routine controls and monitoring were scheduled to focus on project progress and all the stakeholders involved in the process were able to learn from previous steps. This implied that the overall implementation process was marked by continuous adjustments and happened in an *incremental way* (Berg, 1998). The second case study is also consistent with the results found in many other studies on the implementation of HIT within health care organizations: a successful implementation needs strong monitoring and rigorous evaluation before the adoption, *in itinere* and *ex post*, using indicators of safety, quality, accessibility and impact on workflow (Car, Pagliari et al., 2008; Lium et al. 2008; Laerum et al. 2004).

c) The Evaluation Phase.

To analyze the impacts produced by the system, we tried to get an in depth understanding of the role of the system within the organization and how it affects people's conditions at work. We consequently identified four macro-categories of impacts based on the literature reviewed concerning the impacts of EMR (Bates et al., 1999; Protti et al, 1998; Car, Pagliari et al., 2008):

    a.   Impacts on the health care delivery process

b. Impacts on people working within the organization;

c. Impacts on patients;

d. Impacts on relationships with other stakeholders - institutional or not.

Based on the analysis at Aosta Hospital, our data clearly points to benefits produced by the EMR system in terms of better health care delivery processes.

As discussed in chapter 7, the medical and nursing personnel interviewed found that the advantages derive from the speed and ease with which medical data is now shared. EMR also increases the quality of information with respect to its completeness and accuracy.

In terms of cutting costs, clinicians emphasized the effectiveness of EMRs thanks to the *dematerialization* of the old paper files and better information sharing, making the diagnostic process leaner and more effective. However if the Medical Director and the CFO maintained that there were no tools for monitoring this type of cost savings at the moment. It should be noted that all of the impacts identified in this case study are actually "*perceptions" of clinical staffs and administrative people,* since the analysis highlighted the lack of systematic assessment and tools to monitor EMR impacts at Aosta Hospital.

On the other hand, as discussed in chapter 8, RIE found r*eal and measurable benefits and impacts*: indicators (for example time saved in sending paper letters to GPs) for monitoring different types of impacts were defined prior to the adoption of the system and adjusted during the implementation phase according to needs and the evolving situation.

Other parameters were considered in the study (such as organizational efficacy and impacts on patients) but at Aosta Hospital they do not seem to currently

benefit as much from the introduction of electronic records, apart from the reduction in risks for patients, since the system helped by minimizing the issues of incorrect and conflicting drug prescriptions, enabling automatic alerting (for allergies) and reducing the duplication of invasive medical examinations. At RIE, the EMR system produced great benefits at *"communication level"* in terms of improved interaction between clinicians and nurses on the same ward and across different departments and hospital sites. The adoption of the system at this Hospital also resulted in the definition of *new roles and responsibilities* on the wards and affected the traditional way of 'handling' the care process: technology affects the distribution and content of work tasks, it alters the flow of information and affects the visibility of the work tasks and information flow (Westbrook et al, 2009, Berg, 2005, Kaplan, 2001). It will also change relationships between health care professionals and other staff because of this (Berg, 2001). However, users at Aosta Regional Hospital noted no findings in this dimension; this can be explained by the fact that this hospital is still at the implementation phase, but doctors and nurses were optimistic about improvements in this area.

Concerning the impacts on relationships with other stakeholders, the EMR system at the Italian Hospital enabled better information sharing between Acute Care Providers and Primary Care Providers (this is still in the initial phase), as GPs also have the opportunity to access a patient's full medical history. It also enhanced the relationship between the hospital and the Regional Government (which financed 50% of the total amount of the initial investment) and improved communications between departments, which are located in different sites at Aosta Regional Hospital due to territorial constraints, producing an unexpected result in this way (according to the Medical Director).

Similar results in terms of relationships with other stakeholders are expected at the Royal Infirmary of Edinburgh and in the national context, since a contract was signed in 2010 for the definition of a national framework in line with Scotland's eHealth Strategy so that any Health Board will be able to access the Trak system and associated modules over the next four years, promoting the creation of a national patient management system in Scotland.

Furthermore in these case study analyses, a major concern, which was expressed at both study sites, was the issue of the potential ethical challenges in the routine use of EMR systems. Based on the findings arising from the case studies but also according to the recent national and international debates, it appears clear that there is awareness about the relevance of privacy and confidentiality issues related to the adoption and use of EMR systems. Some attempts to solve this issue were achieved: we have presented in chapter 9 some of the most relevant solutions proposed. It seems as a "plethora" of efforts is offered: regulations, standard and guidelines, code of conducts, codes of ethics and technical solutions. However this big issue is not yet resolved, since the pragmatic way to try to solve these problems does not address the agency/humans dimension and does not propose practical tools for preventing data from external attack. For these reasons enduring solutions that take into consideration all of the previous issues, to develop a more effective approach to ethical issues for all the situations are needed.

10.3 Similarities and differences between the two case study sites.

Before drafting conclusions and identifying the main contributions in this study for addressing the research aims identified in chapter 5, we will discuss the findings we have summarized in the previous paragraphs and try to review them based on the similarities and differences at the two study sites included in our

research. The table below shows the main characteristics that typify the two hospitals.

Table 10.2 Main characteristics that typify the two hospitals

Aosta Regional Hospital	Royal Infirmary of Edinburgh
Acute care Regional Hospital	Acute Care and teaching Hospital
The only Hospital in the region run by the Local Health Unit (LHU)	One of the four main acute hospitals – the Royal Infirmary of Edinburgh, the Western General Hospital, the Royal Hospital for Sick Children, and St. John's Hospital – operating within Lothian NHS Board
Has three main separate locations across the Region	The RIE is on a single new site opened in 2003 and built through PPP contract
50% of the EMR project was funded by the Regional Government	100% of the EMR project was funded by RIE
Lack of a structured plan focused on ehealth (in general policy documents and acts on health and social care)	Structured and continuous policy planning concerning ehealth for better care delivery
Lack of communication between policy makers and practitioners for definition of the ehealth programme	Strong communication between policy makers and practitioners for definition of the ehealth programme
IT consultants with technical skills supported the IT office on the EMR project	The ehealth Programme Manager and the eHealth Department played a central part in the EMR Project
Technical training by IT staff	Training (both technical and for clinical purposes) managed by the Implementation staff, delivered by Super users and supported by clinical advisors in the eHealth department
Average age of clinicians and nurses: 44 years old	Average age of clinicians and nurses: 32

Based on this format, differences can be identified between the two Hospitals both in the "outer" and "inner" contexts (Greenhalgh et al. 2005), as mentioned in chapter 2.

The term "outer context" means all the factors that can affect and influence, in a positive or negative way, the adoption and implementation of innovations within a health care organization and are related to a "wider environmental context"

(Wejnert, 2002; Baldridge et al. 1975; Di Maggio and Powell, 1983). The term "inner context" means the hospital context and includes both the hospital's structure, culture and the way of working within a service organization (Fitzegerald et al. 2002).

In this study, two main elements from the outer context were seen to be particularly important for influencing the innovation process within the hospitals analyzed:

1. **Institutional arrangements**: the ehealth policies in Scotland at regional level appear to benefit from a close relationship between clinical professionals and policy makers, while Valle d'Aosta suffers from the lack of involvement of professionals in the development of policies and programmes. This has led to different approaches in the definition of ehealth guidelines at regional level and consequently to different adoption and implementation mechanisms at organizational level. This study defined the Scottish method as a *Pragmatic approach* toward ehealth policy development (6.7) and the method of driving the adoption and implementation of IT used in Valle d'Aosta as a functional approach, (6.6).

2. **Level of resourcing**: at the Royal Infirmary of Edinburgh the project was entirely funded by the hospital while the EMR Project in Valle d'Aosta was co-funded by the Regional Government (7.4). The presence of regional funding can be interpreted as "external pressure" on the introduction and implementation of the project at the hospital coming from an outer context.

Exploring "inner context" factors affecting innovation were found to be particularly important in this study:

1. **Level of existing expertise within the heath care organization**: the Royal Infirmary of Edinburgh can count on a competent IT project leader and a team with professional knowledge of the organization's characteristics. At Aosta Regional Hospital, on the other hand, external IT consultant groups played a key role; they had the benefit of technical knowledge but were less aware of the inner context. This led to the focus on user needs at organizational level at the first Hospital and to more technical and formal attention on IT introduction in the second case.

2. **Management style and managerial attitude towards change**: namely the extent of user involvement in the innovation project and the degree of favour to change. As discussed in previous chapters, the Royal Infirmary of Edinburgh created huge user involvement both during the selection and implementation phases, while the system at Aosta was selected by the General Director and there was a lack of communication and user involvement during the adoption phase resulting in a degree of scepticism and resistance among users during the implementation phase.

10.4 Comparison with findings from other studies

As discussed in chapter 4, the theoretical framework of the analysis was based on the diffusion theory through the lens of a social-technical approach. The last part of this thesis compares the results of our research with Rogers' diffusion theory and with social-technical aspects found in studies that applied the latter

perspective. We focus on the factors that previous studies found to be important for successful implementation. Previous empirical studies have attempted a similar method, including the comparison by Øvretveit et al. (2007) of a large Swedish teaching hospital, shortly after the merger of two hospital sites, with the results of other studies and the verification of the presence of features predicting successful implementation of innovation (Rogers, 1995).

Øvretveit and colleagues (2002) also identified a lack of empirical studies focusing on this topic and for this reason claimed the need for further research combining Rogers' theory with other frameworks. This study attempts to combine elements from Rogers' theory with elements related to social-technical aspects (Berg, 1999) The table below (table 10.4) summarizes features of innovations that empirical studies have shown to influence the adoption and implementation of ICT within service organizations. This type of comparison highlights some interesting results that will be discussed in the following paragraphs.

According to Rogers (1995), all of the attributes identified in table 10.4 are positively related to the level of IT adoption except for complexity, since the more complex an innovation is perceived, the slower the rate of adoption will be. Focusing on our two case studies, we found some differences but also some similarities. In both case studies, the adoption of the EMR system was perceived as being better than the previously existing situation. According to Rogers (1995), the *relative advantage*, as perceived by members of the organizations, is positively related to its rate of adoption. More recent empirical research into innovations in health care (Greenhalgh et al. 2004; 2005) has argued that innovation processes marked by clear advantages in terms of efficiency and effectiveness are adopted and implemented in a simpler way.

Table 10.4 Features of innovations that empirical studies have shown to influence the adoption and implementation of ICT within organizations

		AOSTA REGIONAL HOSPITAL	ROYAL INFIRMARY OF EDINBURGH
Rogers' features	*Relative advantage* the degree to which an innovation is perceived as being better than the idea it supersedes.	YES	YES
	Compatibility the degree to which an innovation is perceived as being consistent with existing values, past experiences and needs of the potential adopter	YES	YES
	Complexity The degree to which an innovation is perceived as relatively difficult to understand and use.	YES	NO
	Trialability The degree to which an innovation may be experimented on a limited basis - possibility of experimentation)	YES (Piloted in 4 departments)	No (Hospital based adoption)
	Observability The degree to which the results of an innovation are visible to others	NO	YES
Social-technical features	User involvement in selection and implementation	Limited	Yes
	Implementation as a process of organizational change	Limited	Yes
	Iterative change process based on the previous step	No	Yes
	Definition of indicators for evaluation purposes	No	Yes

Concerning *compatibility*, the EMR system appeared to be compatible with values and with previous ideas at both Hospitals. This implies that "the more compatible an innovation with norms and values, the less change in behaviour it represents"

(Rogers, 1995 page 245). According to Rogers, compatibility can also refer to the needs of potential users and their social systems and can be considered a determinant of successful assimilation (Denis et al. 2002; Ferlie et al. 2001).

Valle D'Aosta Regional Hospital appeared to suffer from a limited level of compatibility due to the lack of involvement of professionals in the policy development process. At organizational level, it also suffered from a lack of user participation in the selection and adoption phase. On the other hand, RIE had a high level of involvement and commitment both at macro level (policy processes) and micro level (organizational context).

Considering the *complexity* variable, according to Rogers and subsequent studies (Denis et al., 2002; Marshall, 1990), innovation is more extensively adopted if it is perceived as being easy to use by key players. Based on the data collected, it appears that users at Aosta Regional Hospital, especially nurses, perceived the system as being difficult to use, while it was considered as being easy to understand at RIE and that using it simplified operations. This may be due to the "training process" and how it was organized (provided by IT people at Aosta Regional Hospital and by Super Users and members of implementation staff at RIE).

Concerning the *trialability*, or the possibility of experimentation, Aosta Regional Hospital decided to start the implementation process in certain pilot departments and then extend it to others, while RIE managed the implementation on a hospital-wide basis. The decision to proceed without piloting the implementation could be due to the perception that the system was easy to use and the fact that other systems already existed in radiology and test laboratories at RIE before the adoption of Trak. However, according to Rogers (1995) and other studies (Plsek, 2003), trialability is closely connected to complexity and guaranteeing a

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"trialability space" is relevant for the adoption of ICT, such as EMR, (Øvretveit, 2002)

The last attribute that Rogers identified (1995) as predicting successful implementation is *observability*, meaning the degree to which the results of an innovation are visible to others, which is positively related to the rate of adoption (Denis et al. 2002, Øvretveit et al.2002). At Aosta Regional Hospital, the absence of indicators and tools for the systematic assessment and monitoring of EMR impacts reduced the degree of observability of results, which were achieved through the use of systems based exclusively on user perception. At RIE, the definition of visible goals before the adoption and the continuous evaluation process helped to make results visible and demonstrate the system's efficiency and effectiveness to staff.

As far as the other attributes derived from the social-technical approach are concerned, we included features mentioned in several studies, especially Berg (1999, 2003), Kaplan (2001, 2003) Ash and Kaplan (2001) and Øvretveit (2002). We found limited evidence of the first two items identified (user involvement and organizational change) at Valle d'Aosta Regional Hospital while they constitute a significant element of the overall innovation process at RIE. The process at RIE was characterized by *iterative and incremental changes* based on previous steps and on learning what has been already done; clear indicators for evaluation were defined before the adoption phase, to monitor the project results ex ante, in itinere and ex post.

These attributes were not found in the innovation process at Aosta Regional Hospital, which suffered from the absence of indicators and other evaluation tools.

The results found in this study can be considered relevant for several reasons:

- Firstly, the research compared different acute care organizations that have adopted the same EMR system;

- Secondly, the study made a comparison with attributes from cases framed within the diffusion theory stream of research and from research adopting a social-technical approach to the innovation process in order to verify the presence of features considered as "predicting" successful adoption, as argued by Rogers, or as a way to "develop patient care information system that not only not fail but that actually help to restructure our traditional ways of doing the care processes" (Berg, 2003 page 300).

We can now draw some conclusions on the subject of why adoption and implementation happened in two different ways and how this may have influenced the results produced by the same EMR system at two acute care organizations.The elements from the inner- and outer contexts and the attributes from diffusion studies and social-technical research, discussed above, also support our conclusions.

As discussed in chapters 6 and 7, the EMR system produced results at both Hospitals, even if some differences were evident.

At Aosta Regional Hospital, the system has been in place since 2009 and has produced some short term results, above all in terms of improved quality and sharing of information among different departments and Hospital sites, as indicated by the perceptions of the clinical and administrative staff. However, at the time of the analysis and data collection, Aosta Regional Hospital was in the early stages of adoption, whereas RIE had benefited from longer exposure to the system and the process enjoyed high levels of commitment at the Scottish

Hospital, producing valuable results in the long term.

Based on our analysis, we can advance some tentative conclusions about the future development of the EMR project at Aosta Regional Hospital, taking into consideration the specific elements of the inner- and outer contexts and the attributes that can be considered as predicting successful and sustainable implementation in the long term based on previous studies. The EMR project at Aosta Regional Hospital appears to suffer from a lack of a shared vision between the strategy Board and members of staff at the hospital and the lack of a strong project management role defined within the hospital Nevertheless, the system has been in place since 2009 and some results have been produced in the short term, especially in terms of information quality and data sharing.

It has been observed "authoritative decision may increase the chance of initial adoption within an organization but may also reduce the chance that innovation is successfully implemented and routinized" (Greenhalgh et al, 2004).

This comment applies to the Aosta case study: the overall project can be defined as a *technology-centred project*, with *top-down driven adoption*, based on a *technical approach during its implementation*. In the Italian case, it seems that the project was led by the conviction that IT can transform the business of the organization. Technology was put at the heart of the change process. However, as previous studies have pointed out, it should be remembered that a technology-centred project may not be sustainable or replicable, even if it initially appears to succeed to deliver the project objectives, as happened at Aosta, since such projects often depend on the technology itself, they may not be incorporated properly within the organization and have not resulted in any organizational change.

At the Royal Infirmary of Edinburgh, a different style of management is in place marked by a strong project management role. An eHealth department was set up at the Hospital with people who are computer-literate but are not only technicians and include staff who used to work on the wards. They recognise *information as a key organizational resource* that is central to all organizational functions. However, IT is relegated to a "secondary role": it is seen as a valuable means to achieve certain goals, but not as an end to itself. The introduction and implementation of IT is fully integrated into *the process of organizational change* and is driven by project objectives. This is consistent with Heeks' theory about the approaches towards IT adoption within public organizations (Heeks, 2001).

10.5 A multi-dimensional approach towards the innovation process within health care organizations.

The adoption of particularly innovative and complex information systems requires adequate planning of their implementation, which must involve the definition of an impact measuring method to assess the effects of decisions made by an organization and to direct future ones.

Consensus is also growing with regard to the role of ICT in the health care sector, due to the evidence of its efficiency and effectiveness found during recent years. Furthermore, we can presume that e-health will have the capability to change the clinical relationship with patients. As discussed above, EMRs have the potential to empower patients through greater access to personal data, health information, and communications tools, which may aid self care, shared decision-making and clinical outcomes. However, there are many challenges, including lack of user involvement as well as the evaluation process, that must be overcome in the near future.

Implementing change that affects an organization's structure and culture, work processes, behaviour and communication channels can be considered as one of the most difficult and challenging tasks to overcome when conducting an innovation project at a healthcare organization. Measures and guidelines to promote active "change management" at all system levels, both in the inner- and outer contexts, may facilitate better implementation of HIT and EMRs in particular.

Eight main steps can be identified in this management approach to guide the introduction of innovation within an organization

1) *Identification of clear and specific goals* to be achieved with the adoption of the system;

2) *Acceptance of the need for the innovation and change process* by key stakeholders;

3) *Definition of a project group* including, but not limited to, the IT department;

4) *Identification and communication of a clear plan* and schedule for the innovation project;

5) *Identification and selection of the new system* by means of detailed analysis (cost-benefit analysis and SWOT analysis)

6) *Identification of new roles* within the organization based on the new needs of the organization;

7) *Definition of a clear training programme*, delivered by people familiar with the clinical tasks and issues;

8) *Definition of indicators for monitoring* the organization's performance before the adoption, *in itinere* and *ex post*

These are important considerations for providing a tangible response to the

corporate need to identify the best way to adopt, implement and assess the overall organizational, cultural, technological and economic investment and for providing objective guidelines with regard to the nature and direction in the medium and long term, which could depend on the type of organization, as this study found with regard to acute care settings.

10.6 Conclusion

As largely discussed in previous chapters, this study is framed within the e-health stream of research and investigates the specific medical system called Electronic Medical Records, in particular.

The study also examined two study settings that adopted the same EMR system made by the same provider. This comparative study aims to analyse how EMR systems are adopted by different health care organizations by focusing on the antecedents of the EMR project, on the implementation processes used and on the impacts produced.

This work provides an overview of the key issues associated with e-health policy development by means of a comparative analysis of the UK and Italy and provides an insight into how EMR systems are adopted, implemented and evaluated within acute care organizations.

10.6.1 Thesis contributions.

This study makes a contribution in a number of ways; these are outlined in the paragraph below and include:

- a contribution to literature on e-health;
- a theoretical and methodological contribution
- a practical contribution.

a) Contribution to literature on e-health

The thesis *contributes to existing literature on e-health* with regard to the research context and the specific focus of the adoption, implementation and evaluation of EMRs. In terms of *the research context*, although there is a considerable amount of research on the role of ICT in the modernization of the healthcare sector, there is still a lack of comparative studies concerning this topic (Greenhalgh et al. 2005).In particular, there are few comprehensive studies about hospital EMR value; to get a complete picture, one must identify, compare and combine the results of numerous focused and country-based studies. Furthermore, many EMR studies lack a common basis for comparison, since they use different sources of data, research methods and metrics.

Another contribution relates to how *EMR systems influence the delivery of health care services* and how these systems affect the organization and the operations of its main users and stakeholders.

Previous studies (Protti,2002; Bates et. al 2003) tried to make a quantitative evaluation, whereas this study offers an insight into the role of people within hospitals, highlighting how people and systems interact. Furthermore, existing studies are based on single discussions of impacts (Øvretveit et al. 2007). A particularly interesting insight is offered by the case study at Royal Infirmary of Edinburgh , which highlighted the significant value that people can have in the adoption and implementation of these types of systems.

b) Theoretical and methodological contribution

The thesis has made a *theoretical contribution* in relation to the use of the social-technical approach to the investigation of the diffusion of innovation through the different stages of adoption, implementation and evaluation by studying how two

different organizations went about introducing the same EMR system. The study helped identify the nature of the process (in terms of adoption, implementation and evaluation) leading to long term routinization of innovation in health care organizations and the key elements that can predict successful adoption.

We tried to offer a detailed description and interpretation of how innovation happens, starting from the adoption, implementation and evaluation of EMR systems within the health care organization. We used the in-depth case study approach to do this and explore and describe how EMRs were integrated in order to understand how the adoption and implementation of such complex adaptive socio-technical systems happens.

Furthermore, the *research perspective* that marks this research project from a methodological point of view, draws on Actor Network theory, while the dominant perspective of information and communication technology studies has generally been marked by the positivist tradition (Kauber, 1986), which stresses the adoption of previously defined model -controlling variables and testing hypothesis. In fact, most of these earlier studies were based on "methods that neglect aspects of cultural environment, social interactions and negotiation (Lyytinen, 1987).

We decided to use the ANT based on the fact that previous studies demonstrated that the approaches to ICT implementation used in other industries had limited success in the health care sector (Westbrook, 2009) and we decided to consider documents, acts and ICT tools as key players within this innovation process. As a result, we considered the ANT as an analytical technique where the researcher follows actors and tries to understand what they do. It represents a valuable method for understanding and recognizing the value of complex realities which may be neglected by more positivistic and cause-effective approaches (Cresswell

and colleagues (2009), Tantall and Gilding, 1999).

A further contribution of this thesis concerns the adoption of observation methods of enquiry. As discussed in chapter 5, the data collection method used in this study included documentary analysis, interviews and observations. The adoption of the latter method of data collection helped us obtain some very interesting insights for this study. The interview material contributed by confirming much of the evidence from earlier studies concerning the adoption, implementation and evaluation process but did not provide an in-depth insight into the nature of social-technical elements.

c) Practical Contribution

This research also contributed to the development of advice for public decision makers since it helped identify which processes are most valuable for the implementation of innovation within health care organizations and how the processes may be enhanced.

10.6.2 Thesis limitations

As with all research, there are certain limitations to the application of these research findings. The chapter on methodology has already discussed the limitation in terms of the data collection methods adopted, therefore this section considers the *empirical* and *temporal limitations* of this study and how they have been addressed.

There are certain empirical concerns related to the issue of generalization. Some *generalization constraints* arise from this research project, since it is difficult to define how the findings from the two selected contexts can be generalised to apply to other settings. However, it is "the cogency of the theoretical reasoning"

(Mitchell, 1983) and not the statistical criteria that should be taken into consideration. The project aims to make a theoretical and methodological contribution to the evaluation of EMR impacts on the organization and to produce advice for public decision making processes.

There was also *a "temporal" limitation* related to the institutional context of both of the National Health Systems of the two countries analyzed. The e-health policies were subject to ongoing change during the course of this study and we had to define a cut-off time for the inclusion of documents in our analysis in order to take into account how they influenced the innovation processes in the two organizations selected. We included all documents and policy acts issued before the end of 2010, the period when the documentary analysis was scheduled and carried out.

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