The ICT use in the implementation of Directive 2011/24/EU

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Abstract. This article has as main objective to evaluate the role of information and communication technologies (ICTs), in particular the eHealth (electronic health), in the implementation of the directive 2011/24/EU, of the European Parliament and of the Council of March 9th, on the exercise of patients' rights in cross-border healthcare within Member States of European Union. Being currently underway the deadline for transposition of the Directive, it is important to analyze the probable results for national health systems. Innovatively, the Directive specifically proposes the implementation of a European network of eHealth in the provision of cross-border healthcare. Within ICT, we focus on telemedicine as a key tool for the implementation, on a context of public budgets constrains. In this context, it is assumed that the EU will support and promote cooperation and the exchange of scientific information between member states within the framework of a voluntary network composed by the national authorities responsible for health (or eHealth). We apply the S.W.O.T. (strengths and weaknesses, opportunities and threats) analysis to forecast the main points that should be focused on deeper research. We discuss the technological, economic and social aspects of the use of ICT on the implementation of the directive. It is thus important to evaluate the context of ICT by S.W.O.T. tool to define strategies to sensitize policy-makers, health managers, and citizens, in order to be able to turn threats into opportunities and mitigating the weaknesses in the implementation of the Directive and to promote a better healthcare access for citizens, ensuring safe, effective healthcare and with different quality.

Keywords: health systems, ICT, European Union.

JEL Codes: I10, O30, O52.

1. Introduction

This article has as main objective to evaluate the role of information and communication technologies (ICTs) to health, in particular the eHealth (electronic health), in the implementation of the directive 2011/24/EU of the European Parliament and of the Council of March 9, 2011, on the exercise of patients' rights in cross-border healthcare.

Being currently under way the deadline for transposition of the Directive, it is important to analyze the opportunities and threats that the same result for national health systems, in particular in ICT.

It is important, here, to show that the directive covers the topic eHealth, eHealth to date becomes original throughout Community law published in the form of regulations and directives. In this context, it is assumed that the EU will support and promote cooperation and the exchange of scientific information between

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Member States (MS) within the framework of a voluntary network composed by the national authorities responsible for health (or eHealth) designated by the MS.

Moreover, each national health service presents its specifics that can be evaluated as strengths or weaknesses that may motivate or reveal barriers to the implementation of the Directive.

It is thus important to evaluate the context of ICT by S.W.O.T. tool to define strategies to sensitize policy-makers, health managers, and citizens, in order to be able to turn threats into opportunities and mitigating the weaknesses in the implementation of the policy and to promote a better healthcare access for citizens, ensuring safe, effective healthcare quality in different MS.

Thus, in Chapter 2, it is a short presentation of 2011/24/EU Directive; in Chapter 3, we examine ICT and the use of information in health. Chapter 4 applies the S.W.O.T. tool to cross-border healthcare and the use of ICT, and finally, Chapter 5 presents the main conclusions and future research.

1.1. Short presentation of Directive 2011/24/EU

The process of European integration, which started in the fifties of the last century, had not essentially any public health concern. Such a process was evolving and its essence was adapting and following the evolution of people, having now assumed health a top priority inside of the European Union (EU).

What we observe before the publication of Directive 2011/24/EU of the European Parliament and of the Council of March 9 (Directive) was, for example, the Regulation (EC) No 883/2004 of the European Parliament of April 29, which aimed to promote the movement of citizens in the EU, enhancing the mechanisms of coordination of national social security systems of the MS. The provisions of that Regulation only include the classic branches of social security and apply to the situation of citizens which stay in another EU country, other than the country where they reside, namely a temporary displacement within MS that can benefit from necessary medical services. It is for the legislation of the State where it is made to stay, the determination of the financial terms for the exercise of these services. However, costs are reimbursed by the social security agency of the country of origin. This right is created by the European health insurance card, which may be requested by each EU citizen.

It should be noted that the regulation mentioned above and in particular the EHIC presented some limitations from the perspective of access to cross-border healthcare, which the Directive 2011/24/EU of the European Parliament and of the Council of March 9 undertakes to complement. Moreover, the process of European integration, the issue of public health protection was almost forgotten until the signature of the Treaty on the Functioning of the European Union (Campos and Simões, 2011) [1]. More specifically, the EU health strategy “Together for health: a strategic approach for the EU 2008-2013” reflected in the white paper, came at a crucial time, i.e. shortly after the enlargement of the EU from 15 to 27 countries, and aims to obtain concrete improvements in health in Europe.

According to the study carried out by the Portuguese Health Regulation Authority (ERS), in 2012 [2], the Directive proposes to establish rules to facilitate access to cross-border healthcare insurance and quality in the EU, so as to ensure the mobility of patients and promote cooperation on healthcare between different in covering situations where the patient receiving healthcare in a Member State other than the Member State of affiliation as well as the situations of prescribing, dispensing and supply of medicinal products and medical devices, if these are provided as part of a health service.
Despite the promotion of cross-border healthcare, the Directive transposition into national laws and their application must not constitute an incentive for patients to treatments outside the respective Member State of affiliation.

It is important, here, to show that the Directive covers the topic eHealth (electronic health) assuming that the EU must support and promote cooperation and the exchange of scientific information between them in a part of a voluntary network composed by the national authorities responsible for health (or eHealth) designated by MS. Are still defined the goals of eHealth as well as the respective guidelines, and the European Commission to adopt the measures required for the creation, management and transparent operation of the network.

In the context of the goals of eHealth defined, the need to achieve a high level of trust and safety of the patient's clinical data stands out, the need to draw up guidelines on a non-exhaustive list of data to be included in the summaries on patients, which can be shared among health professionals, in order to allow continuity of care and promote patient safety across borders, and effective methods that allow to use the medical information for public health purposes and research; and in providing support to develop common measures on identification and authentication to facilitate the portability of data in the context of cross-border healthcare.

Thus, ICT in the line of health, in particular the eHealth, assumes a key role for the implementation of the Directives. ICT for health not only takes place in eHealth, it also includes health information systems and media and communication in health, so that such concepts will be discussed in the next section, however, giving special importance to that most influence the implementation of the Directive.

1.2. ICT and the use of information in health

For decades, the medical records on paper were the most common. Usually, the data were inserted by a doctor into a form. The access and mobility of information on paper were very limited. The paper was also the most used for the flow of information between the various players in the healthcare process: requirements of medicines and complementary diagnostic examinations, certificates and medical reports, communication of appointments or surgeries.

This paradigm changed and new forms of recording and using information gained space in the health sector. The change was made possible thanks to the development of ICT. Today, affordable technology exists to create and maintain complex information systems.

The registration of information about each patient is one of the bases of health information flows. The information stored about a patient may be used to detect patterns and build a story to a better understanding of the patient. The medical record can also be used as a memory aid and health professionals as a means of data transmission in health (between institutions or in monitoring the patient for several doctors, in collaboration). An electronic medical records system in full operation (with total elimination of paper-based records and access by multiple healthcare professionals) reduces medical errors and improves the efficiency and performance of the Organization. The potential from the use of ICT on health is mainly visible when treating patients with complex diagnoses that need cross-specialty care and substantial clinical information [3].

In addition to the improvement of the practice, the electronic medical record presents a unique opportunity to improve scientific research in health. The electronic medical record enables you to identify patients suitable for certain clinical trials and allows you to add information about the application of different
therapies (such as apply, in which patients, with what results). The difficulty is to reconcile the privacy of patients and the availability of data for scientific use.

As a first step, the electronic medical records were closed systems within each institution. The next step was to computerize communication between the health institution and third parties, as for example: between the institution of health and pharmacy or between the institution of health and laboratories and diagnostic examinations. That is, the computerized prescribing, medical report, communication between the doctor and the patient.

In fact, there has been a gradual replacement of the manual for a prescription electronic procedure, through which the doctor sends medical orders directly to a computerized system. The electronic prescription is a prescription perfectly legible and complete. Shamliyan, Duval, Du & Kane (2008) [4] found that the use of electronic prescription of medicines, in the United States, is associated with a decrease of 66 percent of the total number of errors in prescriptions for adults. The health benefits are indisputable. The savings achieved can help fund the implementation of electronic prescribing systems.

When the electronic prescription is integrated into more complex information systems (for example, is inserted in the hospital system or on a network of different healthcare providers), you can speed up the implementation of doctor's order, directing the order directly to the recipient. The use of electronic prescription for other services besides medication has the same advantages of speed and correction of the request.

Despite the advantages, the introduction of electronic prescription is slow and more problematic than expected (Aarts and Koppel, 2009) [5]. The most common difficulties are: little interoperability between systems; the adoption of different systems for different suppliers, which discusses the adaptation of health professionals; difficult to use and systems without enough support from their departments.

The electronic medical record is complemented with new forms of communication between doctor and patient that allow new types of spatial organization of health services, by allowing the patient/patient contact without that they are in the same physical space.

Electronic medical records, electronic prescription and new forms of communication between health professionals and patients are already implemented hospital wide and inter-hospital, namely electronic medical records, electronic prescribing, telemedicine. The next step will be the implementation of these tools at transnational level, i.e. between different national health systems.

Telemedicine is pointed out as a solution for overcoming the distance issues between health actors. Telemedicine is understood as "the distribution of health services in which the distance is a critical factor and that health professionals use ICT for the exchange of information, for the diagnosis, treatment and prevention of disease or injury, research and evaluation, as well as in continuing education in public health; all this in the interest of the development of the health of the individual and their community "(WHO, 1998) [6]. An essential tool for telemedicine is the video conferencing that enables consultation, even if the patient and the doctor are not in the same physical space and allows you to assemble teams of health professionals from a distance. Telemedicine can be complemented with the use of robots, by means of the remote control. That is, a doctor may perform an intervention or examination with a device that controls remotely.

Literature shows that the specialties that use telemedicine the most are: pathology, surgery, emergency and trauma and radiology. Also it shows that the majority of telemedicine projects link health professionals, and only a few link professionals straight to patients (Salibaa et al., 2012) [7].

The new information and communication tools have great potential for integration of health services, but certain conditions of implementation and operation have to be safeguarded, in particular the level of
information security. The two fundamental aspects of data security in electronic health systems are: confidentiality and integrity (Cheng and Hung, 2006) [8].

Preserving the confidentiality involves the prevention of unauthorized or incorrect disclosure of patient data. The patient's concerns are essentially the embarrassing health information disclosure and unauthorized access by insurance companies, employers or creditors. It is important to avoid that the patient data be used illegally to discriminate for reasons of health.

Data integrity involves preventing unauthorized modification of data. It is as important for patients as for doctors. For patients, it is important that the data in their health records are not changed without a reason, by varying the medical decision and the success of therapy. For doctors, it is important that no one can change records without authorization, so that they can be a proof to verify the medical responsibility in clinical results. Confidentiality and integrity often go against a third aspect of health: availability data, which implies the accessibility of data and information when and where needed. This shock is due to the need for balanced information security with the need for access in a coherent way to ensure proper care, and this is not always an easy task, given the variety and quantity of personnel and entities included under the care of a patient.

We note the existence of a set of tools that are already being used by health systems and that can be adjusted to contribute to an effective implementation of 2011/24/EU Policy. The level of cross-border care, information and communication tools can contribute to greater integration of health systems in and for the prevention, diagnosis, treatment, monitoring and better management of public health.

Some experiences are already going on as presented by Doering et al. (2013) [9]. The project involved hospitals in the Netherlands, Germany and Switzerland. Authors identified a set of variables that contribute to the success of the project, namely: the motivation for the project, the recognition of existing benefits and the carefully implementation of the project.

The European Space Agency (ESA), the International Telecommunications Union (ITU) and the WHO developed the Telemedicine Alliance project. The project produced several recommendations for achieving interoperability between national health ICT systems [10].

In the EU, we have some examples of aspects of the health sector which are increasingly integrated. The most relevant is the sector of drugs. With the creation of the EMEA (European Medicines Agency), in 1995, the Union moved into a system of centralization and homogenization of the drug market. In addition to the centralized procedure for marketing authorization for medicinal products, EMEA works in conjunction with the national agencies in sharing information about medicine. At this point, it is possible for any European citizen information online about any medicinal product authorized by the centralized process.

2. S.W.O.T. analysis on the use of ICT for cross-border healthcare

The S.W.O.T. analysis is usually a tool of strategic audit of an organization and its environment. It must be one of the first steps of planning, focusing on the key issues. S.W.O.T. stands for the 4 dimensions of analysis: Strengths and Weaknesses (internal factors), Opportunities and Threats (external factors). Despite being initially designed to be used in strategic business planning, it was adapted and used in addition to the business context (Andrews, 1980 [11]; Hill and Westbrook, 1997 [12]). In this section, we adapt the S.W.O.T. analysis to the analysis of the use of ICT, for an effective implementation of the directive EU/24/2011. Our main goal is to systematize a set of parameters that may influence our outcome, in order to provide an improved path for studying the subject and to support on policy making.
As shown earlier, the directive explicitly refers to the online health resource, including eHealth, revealing a possible force to the implementation in healthcare. A wide path has already been traveled by MS at national level in the implementation of ICT in healthcare. And the trend towards the use of ICT in healthcare is growing. Take advantage of this "installed capacity" and this technological movement in support of ICT, are forces to the use of ICT in policy implementation. However, for this to be possible electronic tools compatible for transfer of information between countries must have available. It should be noted that such a situation might reveal a weakness in the implementation of the policy, if in possession of disparate and incompatible electronic media in the transfer of information related to users.

In addition to the compatibility and standardization of computer systems for the sharing of information, proves to be necessary to make available, by electronic means reliable, secure and quality, relevant clinical information and standardized, as well as the personal health records of citizens/patients. A recommendation report of PwC for the European Commission (PwC, 2012) [13] exposed that the majority of websites of the National Contact Points do not present the information types that are included in the Directive. This is an obligation of the MS that is not accomplished yet. The accessibility of information is crucial for both professionals and patients.

However, we should recall that the EU countries find themselves in a context of economic recession which may delay/prevent investment in new ICT solutions in health. This may not happen if it is demonstrated the efficiency gain in the use of information technologies. It is thus a priority for the implementation of the policy of investments in ICT in order to create synergies and economies of scale. Let us remember that internationally, the potential of information technologies for the provision of more effective healthcare is recognized (Espanha, 2010) [14]. A relevant factor is the distinct working methods undertaken by health professionals who may be a barrier to the use of ICTs in health. One way to overcome this obstacle is that ICT will need to demonstrate efficiency gains, and they have to be more users friendly and promote quality healthcare and effective so that healthcare professionals are encouraged to use them. Another issue is the aptitude to adopt and accept a new technology that is not equal in the EU countries. The “Special Eurobarometer 382 - Public Attitudes towards Robots” [15] showed that, on the average, 22% of the European citizens are favorable to the use of robots in healthcare, but 27% are against it. However, the differences between countries are considerable (from 8% to 38%, for favorable and from 14% to 53%, for unfavorable).

The various health systems were outlined, in general terms, in the light of two models: (i) the Bismarck's model and (ii) the Beveridge model, originating in Germany and United Kingdom, respectively. In essence, both advocate the principle that healthcare should not depend on the ability to pay, and therefore the associated income contribution. In addition to the common essence, in fact, all have their own characteristics that could put barriers to policy implementation, so you will need to create concrete implementation rules the same for national health systems do not overlap the right of movement of patients in cross-border healthcare. In 2012, the “Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services” was released [16] that discusses several legal issues that are still unsolved and that are important for the implementation of the Directive.

And, finally, with regard to cultural and linguistic issues in the EU, you may remember that mainly multilingualism has been part of politics, Community legislation and practice since the time of the Treaty of Rome. As a number of policies were evolving, multilingualism is also emerging as an element of the EU's external policies, as highlighted by the Euro-Mediterranean Summit of the Ministers of culture. It is evidenced that the two general objectives of multilingualism policy includes, on the one hand, enabling citizens to be fluent in two languages in addition to their mother tongue (a goal called “mother tongue plus
two languages”), and on the other hand, to sensitize the citizens to the linguistic diversity of European society and make it an asset for intercultural dialogue and competitiveness. Therefore, the possible weakness that could be put as a barrier to the implementation of the Directive is already a generic strategic policy within the European integrator block. In fact, European integration has not evolved towards the adoption of a common language. Such contingency imposes the use of translation services, which in health can be even more demanding due to the technicality of the language employed. If, at the level of communication among professionals such a problem may not be very relevant (given that the scientific dissemination is done in English, running this as a *lingua franca* for this area of knowledge), the problem is most relevant in developing information systems that put in contact professionals and patients from various countries.

Finally, the health conditions of populations of different countries, namely the prevalence of diseases and general health state, are distinct due to geographical differences, cultural, food and lifestyles. Such differences can be a real obstacle to a full implementation of the directive. In this field, the potential for information sharing of eHealth is essential to enable health professionals to deal with less common health problems in their countries of origin.

### Strengths
- The Directive 24/2011/EU explicitly mentions the use of *eHealth*.
- Instruments used in healthcare in MS.
- The growing trend in international trade, in the use and promotion of ICT in health.

### Weaknesses
- Disparate electronic tools and sometimes incompatible for transferring information between the MS.
- Diversity in health systems in MS.
- Distinct working methods undertaken by health professionals.
- The directive does not resolve the question of linguistic or cultural differences.

### Opportunities
- New model of the relationship between the citizen and the health professionals, based on information sharing.
- Standardization of tools in use in MS.
- Standardization of patient information.
- The implementation of the directive can press the use of ICT as demonstrated the efficiency gain.
- The need arises to create computer tools more *user friendly*.

### Threats
- Possibility not to make available, by electronic means, of quality and secure trusted, relevant scientific information, as well as the personal health records of citizens.
- Possibility of delay of complete and up-to-date reporting to users and health professionals.
- Context of economic recession which may delay/prevent investment in new ICT solutions.
- Investments in ICT that do not create synergies and economies of scale.
- Differences in the prevalence of diseases and general health state, in MS.

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A detailed analysis of the elements of the table should now establish S.W.O.T. strategies to leverage the strengths and minimize the weaknesses, seize opportunities and overcome the threats. In this way, it is hoped to contribute to an effective implementation of the directive, maximizing the contribution of ICT in the process.
The implementation process will have to deal with the diversity of health systems, health states, working methods and use of ICT, in MS. For such diversity to be exceeded, the directive implementation strategy should be based on standardization and unification of systems and tools. ICT can play a key role, because the standardization can happen in back office, without which you feel unsafe or threatened before major changes of their workout routines.

The implementation process should involve health professionals, on two levels: on the delineation of common tools at EU level and in the mutual knowledge of the systems and tools used in each of the MS.

A phased implementation is strategically preferable so as to create a virtuous cycle of accession to eHealth, facilitating the implementation of this Policy. In fact, if every step is demonstrated the potential for synergies and economies of scale of the use of ICT, it will be easier to get the commitment of and pressing the use of ICT in health, boosting the results at national and EU levels. It is important that investments, especially in a context of economic austerity, should be socially profitable for such economies may be ready by stakeholders and policy-makers.

3. Conclusions

With this article, it was intended to consider strategically how ICT for health, in particular the eHealth and telemedicine, could contribute to an effective implementation of Directive 2011/24/EU of the European Parliament and of the Council of March 9th, on the exercise of patients' rights in cross-border healthcare.

An institutional policy framework, with particular focus on the treatment of eHealth in the document, is presented to better understand this issue. Then, the paper points out the ICT solutions in health, in particular telemedicine, and how ICT may play a crucial role on the implementation of the directive.

Finally, we devise a S.W.O.T. analysis and settle the main policy implementation strategies, using ICT. We should notice that the implementation of the Directive does not depend solely on ICT. However, it demonstrates that ICTs can have a fundamental role in the provision of cross-border healthcare, if the investments in technological infrastructure can achieve economies of scale that demonstrate their social profitability. The diversity of realities may hinder the implementation of the policy, and should the effort be channeled for the standardization of systems and involvement of professionals.

The integration of the ICT tools may result on a real cross-border eHealth system. Any eHealth relies on internet usage, so that the European system cannot be different. Such a system would have to ensure the safe and rapid information sharing between professionals, between professionals and patients. But, to ensure maximum effectiveness and efficiency, it would have to go beyond the flow of information and be a platform for delivery of health services with value for patients and for the MS.

The future research should focus on the analysis of the different systems of each country, in order to allow a diagnosis of differences to alleviate and vicinity to enhance.

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