

Legislative Framework for Telemedicine

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Abstract. *Previous research showed that considerable differences exist in telemedical legislation within different countries. The result points out the existence of major grasp between legislation in the USA, Europe and countries like Croatia. This article deals with analysis of chronological steps of legislation development and enactment. The focus of research is placed on enactment of legislation related to telemedical thematic since 1993 till today. We compared the telemedicine legislation development and the laws in the USA and Europe, and shaped these results as applicable solutions for countries that do not have adequately defined telemedical legislation. Finally we transferred good practices from countries that have developed legislation concerning telemedicine to countries that are yet to face that current issue.*

Keywords. Telemedicine, legislation, framework, legislation development, enactment.

1. Introduction

There are several important components which form every complete and functional system. These components could be software-like, hardware-like, but also infrastructure-like, and all of them are crucial and necessary in a system's lifetime. Although rapidly developed technology and constantly changed software development methodologies enable us to create high performance and fast in reaction systems in almost all segments of our lives, a huge gap is evident toward qualitative and supportive infrastructure that can efficiently deal with all demands.

Such gap can be found in infrastructure that supports telemedicine. Although the telemedicine had become a very important field of research and investment in the past few years, the telemedicine

regarding infrastructure is rather complex and hard to establish. This infrastructure is constituted out of a few completely different fields which include law and jurisdiction, security and confidentiality, patients' and doctors' ethics, standardisation and licensure and so forth. Each of these infrastructure parts is story for itself, as it covers a wide range of aspects that should be included and used in it.

Our previous research [7] conducted in the infrastructure fields of legislation and security, pointed out several different and important facts and problems. First of all, these fields are closely related and intertwined which means that none of them could be developed alone, regardless of the other. In our particular case, security issues are dependent on the standardisation and the legal framework, which could be assumed as prerequisites. Secondly, the process of standardisation and framework creation could take a years and is very expensive, which means that different projects and investments should be planed and performed in order to have touchable results. Finally, telemedicine knows no borders and is *de-facto* international issue, but great differences in different countries exist regarding telemedicine legislation and other infrastructure. Actually, internationalisation emerged as the biggest problem for all countries included in research.

As it can be seen in Table 1, there are big differences in telemedical infrastructure that is established in the USA, Europe and small countries like Croatia (HR). The research showed that Croatia-like countries have only general and base infrastructure components developed but have no specific and concrete results. Those high level and base components are (1) legislation laws defined at high level of abstraction, (2) data confidentiality and privacy perception and (3) defined codex of medical ethics.

On the other hand, good practices in the countries like USA can be used as the examples while their

only concerns are how to perform methodological researches and surveys in order to evaluate the quality of their telemedicine regarding laws, to state full medical licensure procedure for all medical staff (including telemedical), and of course to participate in the creation of international laws and standards which are the only ones that they miss. Even Europe (or the EU countries) could be used as good examples regarding their high level of infrastructure that is developed. In the comparison to USA, EU countries face the lack of quality online information regarding telemedicine laws, and the lack of detail laws that are yet to be created.

Table 1. Comparison results of the telemedicine infrastructure components [7]

Infrastructure component	HR	US	EU
High level abstraction (base) legislation laws defined	+	+	+
Detailed legislation laws defined	-	+	+/-
Telemedicine concerning standards defined	-	+	+
Codex of medical ethics defined	+	+	+
Established and formed telemedicine organizations	-	+	+
Created and maintained web sites and portals	-	+	+
International telemedicine law defined	-	-	-
Aimed financial subventions arranged	-	+	+
Methodical research and surveys performed	-	+	+/-
Data confidentiality and privacy importance perception	+	+	+
Full medicine licensure available	-	+/-	-
Telemedical and telecare programmes running	-	+	+
Legislative bills with concrete information available online	-	+	+/-

Following results showed in Table 1, we expanded our research and tried to find out the steps in the process of telemedical legislation creation (enactment steps), in order to translate them into an applicable framework which should be used in other countries that are trying to create mentioned infrastructure.

Subsequently, in order to create legislative framework for telemedicine, in this paper we present the results of the analysis on telemedicine legislation in the USA and Europe, we point out problems of international telemedicine legislation and clearly state importance of standardisation through the examples and discussion on different telemedicine practices and regarding technical standards like DICOM and HL7.

Finally, the framework is created and given as a set of recommendations which should be followed in countries like Croatia, in order to develop supportive infrastructure which will be able to deal with telemedical systems demands, and to fulfil our expectations as backend of these systems.

2. Analysis of telemedicine legislation in USA

United States are good example for telemedicine analysis because they have both – federal and state laws. In this case we concentrated on federal laws because they are the type of law that is missing in the world. Articles related to telemedicine legislation point out that there is insufficient amount of federal and/or international laws. Reasons for this situation are the lack of technical and telemedical standards and insufficient will and legal power between individual states to communicate the agreement between them [2, 5].

For this reason we created a table (Table 2) concerning only federal laws and bills in the United States, from the first legislation in 1993 till today. We followed the categorization of the bills and laws according to period in which they were proposed and also a category they belong.

According to Table 2 it can be clearly seen that there are some general laws required for further development of the legislation related to telemedicine. Also, if we take in consideration the year in which standards like DICOM (Digital Imaging and Communications in Medicine) and other telemedicine related national and international acts have been created, it is clearly seen that years that follow have greater number of proposed bills and laws. According to this situation, it can be assumed that there is the will for creation of telemedicine legislation, on both federal and state levels, but there must be some firm standards (either technical or concretely related to telemedicine) for which legislative bodies can hold to when they propose bills and laws. In other case it would be too difficult to determinate if there has been any malpractice or leakage of confidential data when there are no standards for which laws can hold to. In that second scenario legislation could only be based on some ethical questions and laws [6, 5, 4].

In Table 2 it can be seen that insurance and other related companies have the will and the interest to participate in telemedicine, and to provide their services to patients in situations where they are greatly needed. But even those businesses that are directly interested to participate in telemedicine cannot and will not participate because there are not any legal frames, or there is no legal framework defined to guarantee them their secure practice. In some cases even the location of insurance payment or the location of insurance office can be taken to

determine where the telemedicine is performing, in country in which the practitioner is located or in that in which the patient is located, or in some third country, and in that way the issue of jurisdiction can be resolved [2].

Table 2. USA Federal laws

Telemedicine regarding law category	Year	1993-1994		1995-1996		1997-1998		1999-2000		2001-2002		2003-2004		2005-2006		2007-2008		
		B	L	B	L	B	L	B	L	B	L	B	L	B	L	B	L	
Administration and regulation	B	2	4	4	1	1	4	2										
	L								1									
Applications and settings	B		1		1	6												1
	L		1			2												
Funding and Appropriation	B	6	6		2	1	1	3										
	L		3	1	3	2	3											
Licensure	B						1											
	L																	
Medical records	B																	
	L																	
Programs and demonstr. projects	B	1	2	3		2	4											1
	L				1		1											
Reimbursement and insurance	B		4	4	9	4	2											2
	L		2	1		1												
Specialties and practice	B				1													
	L																	
Technologies and telecomm.	B	3		1	1	4												1
	L				1													
All categories	B	1	1	1	1	3	2											5
	L	2	7	2	6	4	3											

Legend: B – Bill, L – Law

USA has invested in the past few years a lot of money in the development of telemedicine. That amount of money has risen from a few million US dollars to a few hundred million US dollars per year. Also the number of participants in the project has risen from less than 500 to almost 8000 participants [8]. This shows the rapid development of telemedicine in the USA in the past years, from 1998 until today. Presented data points out the growing awareness and interest in telemedicine and its development. Especially in USA there was a big investment made to develop telemedicine in rural countries where it is the most needed. Related to development of telemedicine in rural parts of countries, in USA that development was based on “Rural Health Care Pilot Program”, there is a risk of companies fighting turf battles. That risk is rising in countries with unsorted legal questions related to telemedicine because such situation is fertile ground for banding of law, especially in cases where there is no law to bend. In turf battles large companies can suppress small ones because they can hire a team of best physicians employed in their centre and offer their services abroad. On the other side, small telemedicine offices

cannot stand that pressure and such low prices because they have smaller (local) market. Some country regulations that are trying to solve that problem are based on the need for physicians to have licenses in countries in which they perform telemedicine procedures. This kind of law has its plus and minus side. The plus side is that in that way country is defending interests of smaller telemedicine offices and preventing bigger ones to run them over. The minus side is higher price of telemedicine procedures and slower development [2, 4].

2.1 Problems of international telemedicine legislation

There are several burning questions that are still present in telemedicine, and which have been put away from the beginnings, but today those questions can no longer be postponed. There is still preset problem of the international and the interstate legislation and standardization. That question can be applied on the issues related to data privacy, licensure of physicians but also on legality of performing telemedicine. Some of these questions are trying to be resolved on international standardization level, but in some cases it is almost impossible to create satisfactory solutions on international level, and such issues are left for states and countries to regulate them on their internal level.

Telemedicine Information Exchange (TIE) is one of the answers to the problem of laws conflicts. TIE is an international project that has been started by collaboration powers of European Union and United States. As the United States are federal states, they have an advantage in defining and conducting legislation related to telemedicine. In European Union member states are not obligated to conduct common laws, and European Union cannot enforce them. Those laws must be approved by every single country, and in some cases, especially where those laws would be most needed, that approval can take very long time.

Questions that arise, and that need urgent legislation attention are related to the problem of defining jurisdiction. It is question whether country that has jurisdiction is the one in which the practitioner or the patient is located, or in some cases there is even third country involved. In that case the best solution would be that all countries involved have agreed on question of jurisdiction and all the issues are already predetermined. But in most situations that is not the case. This question is often not resolved because either states or powerful telemedicine companies have their profit and other goals with which they can benefit from such undefined situations [2, 5, 4].

There are also questions related to the ethics, the confidentiality and the difference in language and culture between states. Most of countries have already determined ethical laws, which can be further fulfilled

with codes of conduct related to telemedicine practice. Those ethical laws can be in most cases easily applied to the telemedicine, but the problem of differences in such laws still remains. There is also a problem in different culture approaches and scopes. So in one country the telemedical procedure performed can be legal, and in other it can be forbidden.

In some cases the money that makes the world turnaround is the reason that some patients will not receive the best treatment possible. In those cases two reasons can be the factor. One of those is the health and social politics of the state that says that telemedicine is in most cases too expensive to be performed on social cases. In most cases that is not directly stated, but the law says that practitioner must be on site where the procedure is performed. Here we can state question, weather the practitioner is "on site" even if he is located in another country during telemedicine procedure. In other cases turf battles can be the reason why patient did not receive the best possible service. In those cases big telemedicine providers can open multiple branch-offices and bush smaller telemedicine provider off the market regardless of quality of their service. Also, big telemedicine providers can hire one, or team of practitioners that will be located in the central office and from there provide their services [1, 4].

"Tachakra et al. (1996) found that patients' concerns about the use of telemedicine in their treatment primarily centred around their fears concerning the privacy of transmitted medical records and other information from which they could be identified [5]." Patients' greatest concerns are related to the problems they meet in everyday life, like in stores, pharmacies and other places where their personal information can be gathered and (mis)used. Related to the telemedicine, patients also concern the question of insurance and responsibility in the cases of malpractice or data misuse/violation.

Most of those questions and issues would be resolved if states would have the appropriate laws and legislations, and also if there would exist more international standards and legislation frames for which the courts could grasp to.

3. Analysis of telemedicine legislation in Europe

Situation in legislation related to telemedicine in Europe is a clear example of situation in telemedicine legislation in the world. There are lots of individual states that have their own laws and customs, and according to them they shape telemedical regulations. European Union does not have the power to enforce standards and mutual laws to every state. And the burning problem is that in some states like Croatia the legislation related to the telemedicine is insufficient.

There is also a problem of different legal grounds, on which states build their legislation [2, 6].

In such confusing and unsorted situations there is burning need for global standards, laws and guidelines. In those scenarios projects like TIE are most welcome. Also workshops like that hosted by the International Space University in Strasbourg where concrete recommendations for actions on national and international level were created are most welcome [6].

Example of state which is trying to well define telemedical legislation is United Kingdom. With well defined general laws that produce firm basis for further legal development, they are also involved in TIE with more than 10 projects. It would be almost impossible to carry out such number of projects without well defined legal basis. In UK patients must sign consent, and before the procedure with its positive and negative aspects is in detail explained to them. Most of data protection and privacy issues can be resolved according to European Data Protection Directive (95/46/EC). This is a good example of directive that has been applied on international level. Also we can see the development of telemedicine by its definition which was also changed over time by European Commission DG XIII. From that it is clearer that new questions and problems will arise while still some old ones are not successfully resolved. In some cases like in the UK, General Medical Council has stated that clinicians, when responsible for confidentiality of electronic information, must protect it from being improperly disclosed while it is transmitted, received or stored [6, 5].

In the UK the "NHS has published guidance for Trusts and Commissioning Authorities on their legal and ethical duty to protect the privacy of patient information in HSG (96)18 'The protection and use of patient information' and HSC 1998:153 'Using electronic patient records in hospitals: legal requirements and good practice'. Moreover, English common law and legislation both provide legal protection for electronic patient information stored in computers [5]." Beside guidance for protection of private data, that protection is based on Data Protection Act and Computer Misuse Act which form a firm ground on which more specific laws can be enacted.

Some researchers state that "legally it is impossible to devolve responsibility for the supervision of medical practice and, prima facie, the issuing of licenses to practice, to one supranational medical authority for Europe that sets universal standards [6]". With that said, it is clear why some telemedicine legislation problems have been put away, and their resolution has been postponed. This is the main reason why some of that problems and questions are left for states to deal with them on internal level. In such cases countries' basic solutions would be general laws which can be applied on

telemedical questions. For example in the UK there is The Common Law Duty of Confidentiality which applies that the information cannot be disclosed without provider's consent. Also there are E-Commerce Regulations which are general and can be applied to any information society service. In that way the legal basis for further development of telemedicine laws are set, if they will be needed [11].

On the European level one such law/directive is Data Protection Directive. In most of stated examples we can see that laws and directives are focused on protection of data and patients privacy.

4. Telemedicine practice and technical standards

In many situations telemedicine legislation is based on technical standards and guidelines. In that way legislation has a basis to build up and to develop. "Weather telemedicine will be successful in the future depends on the creation of a transparent legal framework [1]." This transparency can be achieved through global technical standards to which all manufacturers must apply if they want to be competitive on telemedical market. One of such regulations can be found in EU. "Medical devices, including telemedicine equipment, used and offered for sale anywhere in the European Union must have 'CE' mark, which is an indication that the product carrying it satisfies all the relevant essential requirements relating the safety, quality and performance... [5]"

This is example of global standard, but its appliance can be undermined in countries with unordered and corrupted internal situations. In such countries licenses can be bought and in such situations the certificates cannot guarantee the quality and the level of service for which they are given. In such situations it would be good that there is some sort of state verification before it is approved for that state to use/produce standardized equipment. In one way it would be good that jurisdictional differences do not obstruct telemedicine, but in some cases that "obstruction" is a necessity and is the only way to guarantee the level and quality of service [2]. In stressed situations legal framework should provide security and assurance for both, the patient and the physician in all situations. In telemedical intervention the legislation should assure patients privacy and practitioners responsibility and in situations when something goes wrong legislation should determine who is it to blame and on what grounds. That is almost impossible to achieve without some international standards or at least bilateral agreements between countries involved. In many cases it is hard to determinate who is it to blame; weather it is the ICT equipment or the physician. In such cases legislation based on technical standards can be of the

great help, because the legal entities will already be introduced with some technical standards, and could take them into consideration when determining whose fault it was. In those situations equipment which is certified according to certain standards is easier to examine and determinate if it was hardware malfunction or was it the physician malpractice. In such cases *Bolam standard* must be taken into consideration, which states "...whereby a clinician will not be negligent where they are acting in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art [5]."

Another example is previously mentioned Digital Imaging and Communications in Medicine (DICOM) standard is an application layer network protocol for the transmission of medical images, waveforms, and ancillary information. A single DICOM file contains both a header (which stores information about the patient's name, type of scan, etc), as well as all of the image data. Standard was originally developed by the National Electrical Manufacturers Association (NEMA) and the American College of Radiology for CAT and MRI scan images. It is now controlled by the DICOM Standards Committee, and supports a wide range of medical images across the fields of radiology, cardiology, pathology and dentistry. DICOM uses TCP/IP as the lower-layer transport protocol.

Finally, back in 1987, in the USA was formed "Health Level Seven (HL7)" organisation with the goal of developing an international set of open standards for data format and content that allows different health information systems to easily and effectively communicate with one another. Today, HL7 is an ANSI accredited Standards Developing Organization (SDO) which operates in the healthcare area. "HL7" is also used to refer to some of the specific standards created by mentioned organization (for example HL7 v2.x, v3.0, HL7 RIM et cetera).

5. Telemedical framework

According to previously out pointed information and discussions, we can define basic telemedical legislation framework which include all stated elements. The documents that affect, directly or indirectly, all new telemedicine related regulations can be divided into three main groups:

- ✓ Technical standards
- ✓ Certificates
- ✓ Existing Fundamental Laws

Existing fundamental laws are the legislative base for new regulations and should be respected with no excuse. On the other side, certificates should be included and used as cover to prove the quality and other important data about the organisation or committee that creates regulations or their parts.

Finally, technical standards are the most important ingredient that should be completely respected and according to them, new regulations should be created. Technical standards contain the steps, the protocols and other in detail described information that should be used and implemented in any newly defined telemedicine related regulation.

National and international legislation are the two main groups in which we can divide all regulations. Both of these groups could contain telemedicine-related regulations, specified in form of one of the following documents:

- ✓ Specific laws
- ✓ Code of Conduct
- ✓ Guidelines
- ✓ Regulations
- ✓ Other documents

Putting it all together, we can present this information in a form of directed hierarchical diagram as showed in the Figure 1.

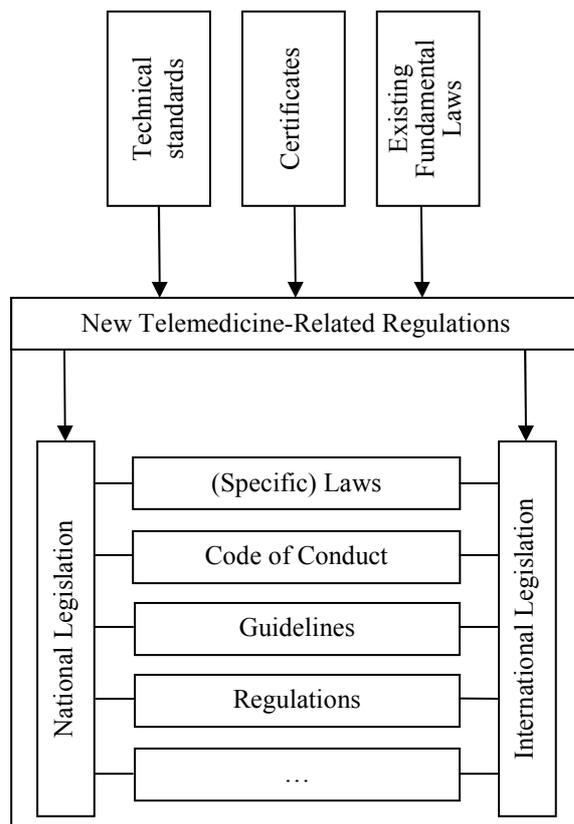


Figure 1. The construction of new telemedicine related regulations

As our research results point out, countries like Croatia should plan and perform their activities of creating legislation following the example of countries that already performed this process.

At the beginnings, countries should emphasize and focus on the first goal - definition of a funding and

appropriation legislative base which will enable the development of all other telemedicine regarding fields. Second main goal for these countries should be to focus on reimbursement and insurance as well as on the programs and demonstration projects, while these are fields which are interested in development of telemedicine and telemedical systems in order to give people a better, reachable and attractive health care.

In the second phase of the telemedicine legislation development process, focus should be put again on the funding and appropriation, and applications and settings in order to create a base for technologies and telecommunication legislation development, which is also important.

Finally, administrative and regulations laws should be included in all phases of legislation development process, but there is no need for them to be emphasized.

6. Conclusion

Taking into consideration today's telemedicine legislative stance, which is situated in the triangle of global laws, local laws and undefined laws, we are facing the question which triangle peak is the most important? Global laws are usually based on international technical standards and the existence of these global laws makes the process of enactment to other countries much easier. Taking this into consideration, we could say that the triangle edge that consists of global international laws and local laws completely depends on both their peaks.

On the other hand, the enactment of telemedicine regarding international laws would improve the overall quality of telemedicine and the security of patient's data as well. But still, there are several questions we are unable to answer write now. For example, will countries be willing to implement or include those international laws and accept them as their own? Are the technical standards the only and adequate legal base? How many of these legislative questions could be solved in codes of conducts, and so on. These are only few of all questions that wait to be answered, but we could conclude that some improvements are certainly made and that there is sufficient level of interest for all of them to be solved.

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