

THE RISKS OF TELEMEDICINE IN URBAN-RURAL AREAS: A SYSTEMATIC APPROACH OF ROMANIAN LEGISLATION

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Abstract

The telemedicine has developed as an alternative of access to medical services for patients from rural areas, but for its benefits the current trend at global level is to expand telemedicine into urban areas. Main reasons for this approach are the small number of articles regarding the risks of telemedicine in Romanian and also the major obstacle to telemedicine adoption represented by the legal considerations. To analyse the effects of the legal regulations on the potential risks was the main objective. For this purpose, a three-step methodology was used to select from a database of 69 normative acts which represent the entire Romanian legislation published between 2000–2019 regarding telemedicine. Using three exclusion criteria, were obtained 18 acts of interest which comprised regulations with implications on potential risks. The results of this study led to the identification of 14 categories of risk from areas like: legal framework, reimbursement, personnel, technological, liability, privacy of data etc. In conclusion, these can affect both patients regardless of the urban or rural residence environment and also the healthcare system. As a final recommendation to reduce the probability of occurrence of risks it is necessary to amend and complete the existent normative acts and issue new regulations only in the telemedicine domain.

Keywords: emergency medicine; regulations; risks, telehealth

1. INTRODUCTION

In the last four years, according to the European Commission (EC), the global telemedicine services market has not experienced any decline, but only a steady increase on average with €2.52 bil. per year, from €16.29 bil. in 2015 at €23.85 bil. in 2018, being estimated to reach €37.08 bil. in 2021 (EC, 2018). The fact is due to the multiple advantages: administrative, financial, medical etc. for all stakeholders involved in the development of telemedicine systems: authorities, physicians, patients etc. If in the developed countries telemedicine has a tradition of over 50 years, in Romania, the process of implementation of telemedicine has only started in the last two decades and not currently completed, being oriented towards rural areas. Almost a decade ago, the World Health Organization (WHO) did not include Romania between the countries who report telemedicine

services, while the neighbouring country Bulgaria, non European Union (EU) countries Albania, Belarus, or others Central-Eastern European countries (Czech Republic, Croatia, Slovenia) were mentioned in an informal, pilot or established stage in the field (WHO, 2010).

Data of the National Institute of Statistics (NIS) from Romania shows that only 19.35% of the medical units were in the rural areas in 2018 (NIS, 2019). The rest of the percentage of 80.65% of medical units (many of them with a high level of competence) were in the urban areas and this shows a pronounced urban character of telemedicine. The population in urban areas is becoming more numerous (56.41% increased with 2.41% from the 2011 census) than in the rural areas (43.59%), which may lead to a reorientation of telemedicine services to cities (NIS, 2016). This is because this kind of rising is accompanied by a growing prevalence of lifestyle diseases (EC, 2018).

The term “telemedicine” consisted of Greek “τήλε” – “at distance” and Latin “medicine” – “disease healing science”, then the prefix “tele” led to a lot of words in modern languages in the domain: “telecare”, “teletriage”, “telenursing” etc. Also in ancient Greeks can be found the origins of the concept of distance medicine, in the messengers who transmitted to the sick people medical advices from the temples dedicated to the gods of health. The historical sources affirm the relation between the various methods of communication (signals with: fire, smoke, lights, sounds etc.) by which deaths, epidemics etc. were announced (Bashshur & Shannon, 2009). But modern telemedicine has developed with the technological advance of the 19th century and there are a lot of evidence about the teleconsultation and transmission of medical information by telegraph, telephone and radio (Zundel, 1996).

From the first interactive video-link between Nebraska Psychiatric Institute in Omaha and Norfolk State Hospital (1964), telemedicine was developed constantly, initially by NASA for astronauts, for rural or hard-to-reach areas in Alaska, Australia, Canada, but also for front-line soldiers. The use of satellites and other advanced Information & Communication Technologies (ICTs) and the emergence of the world wide web (www) have started to expand telemedicine globally since the 90's, and today there is a wide range of applications included in the concepts of tele-ICU, mHealth, u-Health etc.

From over 100 definitions of telemedicine, World Health Organization has adopted this description in extenso: “The delivery of health care services, where distance is a critical factor, by all health care professionals using ICTs for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities” (WHO, 2010).

The expression from definition: “where distance is a critical factor” was the basis for the implementation with priority of telemedicine in rural areas that are not easily accessible, as in cities where is often a quick acces to a hospital. However, this does not mean that teleconsultation or other services are not provided in the urban environment, as long as in cities are on a regular basis: accidents, emergencies, elderly, patients living alone or with several diagnoses (eg. Bove et al., 2013). The rapid expansion of telemedicine is also visible in India, where the Ministry of Health has recognized the importance of this branch, including for suburban areas, where there are only 25% of physicians (Rajendra, 2017). The case of Japan remains like an example of good practice when the risk was seen as an opportunity. The Europe sets the nippon example, where most of the elderly are concentrated in metropolitan areas, and a 2015 law encouraged the rapid development of telemedicine in japanese urban areas (EC, 2018).

In Romania, there are significant differences regarding the development of telemedicine in urban versus rural areas, and the approach of this service from the perspective of the risks involved is near non-existent.

In this context, the article analyses the risks of telemedicine in Romania, based on study of regulations. The article is organized as follows: after introduction are presented some relevant data on telemedicine in European Union with main focus on Romania, followed by a section of literature review. After that are presented the study motivation, objectives and methodology of research. Based on the results of methodology are discussed the regulation and risks of telemedicine in Romania. The study ends with conclusions and recommendations.

2. RELEVANT DATA ON TELEMEDICINE IN EU AND IN ROMANIA

From the approaches of the last 15 years to define and place telemedicine in the domains that use ICTs, sometimes telemedicine being confused with telecare (WHO, 2010), the most studies include telemedicine in the telehealth and the last domain is included in the eHealth field (Dyk in Carrasqueiro et al., 2017). In the Figure 1 it is represented the place of telemedicine between the domains which are using ICTs and a synthesis of the elements which compose the definitions of all terms involved is presented in the Table 1.

TABLE 1 – THE ELEMENTS OF THE DEFINITIONS OF THE TERMS: eHEALTH, TELEHEALTH AND TELECARE

| Terms→ | eHealth | Telehealth | Telecare |
|-----------------|---|--|--|
| Actions | share, store, retrieve | delivery | Uses |
| Content | electronic health data | preventive, promotive and curative services of healthcare services | alerts and sensing ICTs |
| Purpose | prevention, diagnosis, treatment, monitoring, educational and administrative services | research and evaluation, health administration services, education of healthcare providers | continuous, automatic and remote monitoring of care needs, emergencies and lifestyle changes of individuals with disabilities or elderly |
| Specific | at the local site or at distance | only at distance, not always a physician | for supporting patients' self-management, to remain independent in their home environment |

Source: adapted by the authors from Carrasqueiro et al. (2017)

Therefore, telemedicine has in common with telecare the use of the ICTs for connecting users at distance and exchange of information. Telemedicine is different from telecare which is usually used for remote monitoring of social, physical or mental cases already diagnosed, because telemedicine is used mostly for teleconsultation, tediagnosis (Figure 1) and delivery mainly medical curative services. The majority offer of curative services is one of the criteria that is applied in differentiation of the pure medical services compared with other types of health services (profilactic, counselling, support, planning, cosmetical, palliative, sanitary transport etc.) and also a criterion to distinguish between wellness tourism and the medical one (Stoica, Bugheanu & Ciocoiu, 2019).

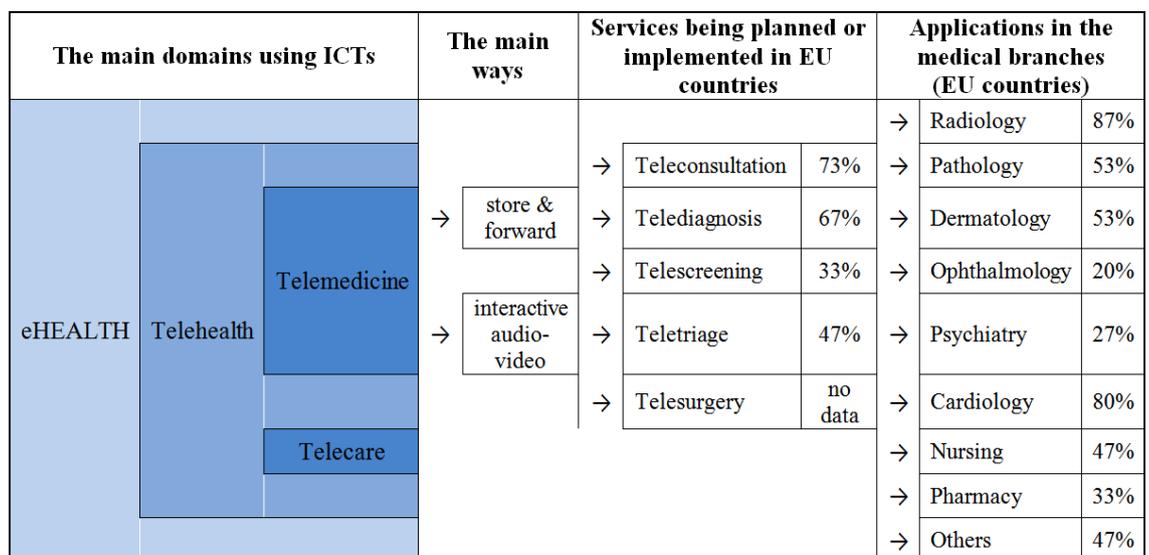
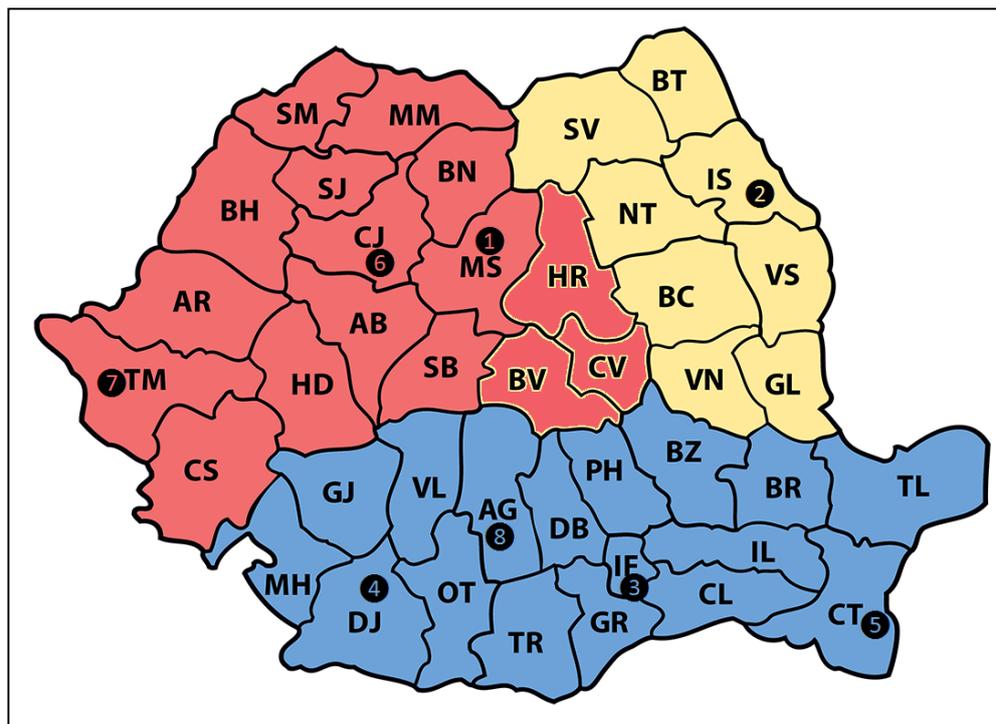


FIGURE 1 – THE TELEMEDICINE: FRAMING, SERVICES AND APPLICATIONS

Source: adapted by the authors from Carrasqueiro et al., 2017

At a EU level, the most required services of the telemedicine are teleconsultation and tediagnosis and the most applications in the medical sector could be found in radiology and cardiology branches. Other data (EC, 2018) shown that Romania occupied in the eHealth European market a final place with a revenue per inhabitant for telemedicine of €1.04, while the EU-24 average is €3.05. Instead, in the same study, Romania is placed on

a good position – the 9th from 30 European countries – for the use of electronic networks for ePrescription (59.8% of general practitioners). But for the patient data exchange with healthcare providers Romania is situated in the last third: 22nd position from 30 countries, with only 15.9% from the general practitioners who are using data exchange. The market demand for telemedicine in Romania is estimated at over 1 mil. inhabitants (EC, 2018). Top 5 specialties going to benefit from the telemedicine services according to the physicians opinion, include: radiology, cardiology, emergency medicine, family medicine and dermatology (Poenaru, Poenaru & Vinereanu, 2014). Also, there are opportunities for a lot of other specialties that can benefit from telerehabilitation: orthopedics, rheumatology, neurology, psychiatry, elderly or persons with disabilities like tetraplegia or depression (Dogaru, Stănescu & Pasca, 2014). In fact, at the national level the most developed system of telemedicine is for emergency medicine and all the important centers and units are in urban areas (Figure 2).



Acronyms: Telemedicine Coordination Center – TCC; Emergency Clinical Hospital – ECIH; Emergency County Hospital – ECtH; Emergency County Clinical Hospital – ECCH; Region of Romania – R.; Hospitals – Hs; Emergency Receiving Unit – ERU; Mobile Emergency Service for Resuscitation and Extrication – MESRE; Data reception and analysis – DRA
 Legend: ① Central TCC in the ECCH Targu Mures coordinates 40 Hs the Central-Western R. [●]; ② North-East TCC in the ECCH Iasi coordinates 26 Hs in the Moldova R. [●]; ③ South TCC in the ECIH Bucharest coordinates 23 Hs in the Southern R. [●]; ERU & MESRE that provide DRA: ④ in the ECCH Craiova ⑤ in the ECCH Constanta; ⑥ in the ECCH Cluj-Napoca; ⑦ in the ECCH Timisoara; ⑧ in the ECtH Pitesti.

FIGURE 2 – THE TELEMEDICINE NETWORK FOR THE EMERGENCY MEDICINE

Source: realised by the authors from the Ministry of Public Health Order No. 2021/2008 and from Olaru, Pandrea & Oprea (2016)

The TCC from Targu Mures was founded in 2009 and the other two TCCs from Iasi and Bucharest in 2011 and in all three centers are reception and data analysis units (Vlădescu et al., 2016), apart from the other five on the map presented above. However, not all units are functional (such as the one in the county hospital from Pitesti), a fact found in discussions with the MESRE paramedics. It is important to note that the volume of transmissions is not to be neglected and is constantly growing, the situation has been presented in the Table 2, for the most important telemedicine center at the end of first seven years after telemedicine system implementation.

TABLE 2 – THE VOLUME OF TRANSMISSIONS, THROUGH THE TELEMEDICINE SYSTEM (2009–2015), IN THE TELEMEDICINE CENTER BUCHAREST

| | |
|--|---------------|
| Data transmissions made by first aid crews to the MESRE dispatcher | 44,422 |
| Data transmissions reported in the ERU-MESRE Bucharest Department by the Bucharest-Ilfov Ambulance Service | 39,115 |
| Subtotal pre-hospital data transmissions | 83,537 |
| Patients remaining in the hospitals that initiated the call following multidisciplinary telemedicine consultations | 254 |
| Patients transferred to a hospital with a higher level of competence, following the call through telemedicine | 841 |
| Subtotal transmissions used inter-clinically | 1,095 |
| Total transmissions counted through the Telemedicine Center Bucharest | 84,632 |

Source: realised by the authors from Olaru, Pandrea & Oprea (2016)

According to the authors above, in the Telemedicine Center Bucharest alone, the number of estimated annual transmissions exceeds 25,000 in the pre-hospital and over 200 inter-clinical ones. Also, for over one thousand patients it was possible – by the telemedicine system – to avoid risks and costs for unnecessary transfers or to avoid the immediately vital risk, because they have been transferred to a hospital with a higher level of competence.

3. LITERATURE REVIEW

From a simple look at the research in the field it can be observed that in countries with a long tradition in the development of telemedicine there have been constant concerns regarding both the risks and the benefits of telemedicine and often only the risks. In countries where the process of implementation and development of telemedicine systems is not complete, there are predominant articles in which telemedicine benefits are listed. The phenomenon is explained by the fact that the benefits most presented by Hjelm (2005) and Carrasqueiro et al. (2017) extend to all the parties involved: authorities (improving decentralization and autonomy); healthcare providers (reducing the personnel deficit and healthcare cost); physicians (quick multidisciplinary consultation, support in establishing diagnoses, reducing home visits); patients (increasing access to medical services, second opinion, continuity of care, avoiding travel costs and contact with hospital infections), professional associations and universities (quick access to medical information and education) etc. Several studies cited by Scott Kruse et al. (2016) shows in concreto how many hundreds of miles, minutes or dollars can save on average a patient using telemedicine instead of going to the physician.

Even though telemedicine has appeared to rapidly support patients in inaccessible places for risk assessment, most researchers do not separately treat risks considering the rural or urban residence environment. Using expert comment, Zhang (2016) draws attention to several risks, specifying their main causes, such as: the risk of malpractice caused by technological malfunctions or the risk related to the security of the patient's medical information, when it is not properly regulated. He pointed out that medical insurances avoids coverage of telemedicine services, which leads to an increased risk of liability. Medicare covers only telemedicine services when the beneficiaries are in a rural site (Lee Bentley & Mehta, 2019), but there are projects to extend the cover for urban areas, where are many patients. Like many other authors, Zhang considers that in the absence of a physical examination, there is a risk of an incorrect diagnosis (eg. the one established on distorted images). But he is one of the few authors who refers to the risk of virtual abuse. This type of abuse is regulated in the case of face-to-face visits between the physician and the patient, but requires clear regulations in the case of telemedicine. Like virtual abuse, virtual frauds, is hard to prove by patients. Frauds can reach up to \$1 bil., the most current example being an indictment in Tennessee (USA) of a telemedicine company that sells pharmaceuticals at high prices (Lee Bentley & Mehta, 2019). The last authors, but also Pratt (2019) propose methods to avoid legal risks (liability, malpractice, reimbursement, data security etc.) by physicians, such as: obtaining licenses, choosing those providers and authorized communication equipment, knowing the legislative differences, call recording, training for the use of systems etc.

Jolly (2019) also agrees with this opinion and proposes to check the insurance policies before using telehealth services to avoid a risk of liability. Another cause that confuses potential beneficiaries of telemedicine services is the difference in licensing by states, as some states offer providers the opportunity to deliver limited services outside the state where they are authorized. Although, Jolly highlighted that it is the practitioners responsibility to know what rules should be applied, Jolly acknowledges that “there is no one consistent place” to consulted all those rules. In order to minimize the risks of incorrect diagnosis and/or treatment, are required open communication and collaboration between physicians-teleprovider-patient/family, regarding the consent and acces to all important personal information of the patient (Jolly, 2019; Becker et al., 2019b).

The main conclusion of Guise, Anderson & Wiig (2014) in a systematic review of telecare was that a better identification and description of the patient's safety risks are needed. One of the causes is the difficult reporting of incidents that depend on the voluntary actions of patients or home health care providers. The authors' solution consisted in greater transparency and standardization in reporting patient safety issues to improve the evidence base. Amongst the most frequent sources that may generate patient safety risks that have been identified in telecare systems are: nature of homecare environment, poor patient compliance, poor system integration, patient anxiety and dependency, lack of guidelines accessibility and technology issues, changes to staff workload, change in the nature of clinical work and lack of patient and/or staff knowledge and understanding (Guise, Anderson & Wiig, 2014). If for most sources it does not matter the urban or rural environment, in the last case it is important to remember that is a big educational gap between rural and urban areas and Kontos et al. (2014) demonstrated that patients with lower levels of education had significantly lower odds to use online tools and mHealth. The lack of evidence, awareness and education holds up widespread adoption of telemedicine (EC, 2018).

For the stage of telemedicine in the EU, one of the most comprehensive survey was developed by the Carrasqueiro et al. (2017) using as a tool the questionnaire which was answered by 18 countries. The respondents provided information on the progress and evaluation of the implementation of their national telehealth systems and also on what is of interest in the present study: the barriers to the adoption of telemedicine. Often in the literature, the topic of risks derives from the study of barriers, drawbacks, obstacles etc., this being not only a semantic problem, as some researches assimilate the risks of the barriers, like in the example from below – Figure 3.

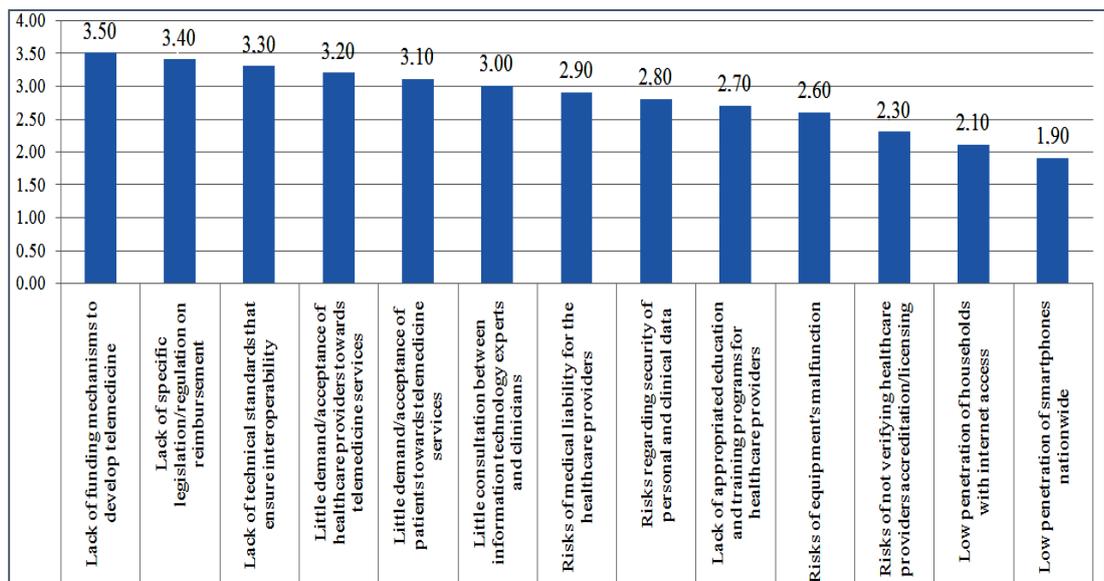


FIGURE 3 – BARRIERS TO TELEMEDICINE ADOPTION IN EU COUNTRIES

Source: selected and adapted by the authors from Carrasqueiro et al., 2017

In a top 5 of the barriers besides those presented in the Figure 3, were more framed: the lack of reimbursement procedures for telemedicine services, the absence of telemedicine services sustainability and the absence of a national strategy towards telemedicine development. Other barriers to telemedicine adoption are related to: evaluate the quality of services, low government support, high cost of equipment, lack of knowledge and skills

of healthcare providers and patients to use equipment and systems, lack of education and training programs (for patients), lack of specific regulation on patient's confidentiality and privacy etc. It can be seen that one of the most important barriers is the lack of specific legislation, regulation and procedures/guidelines on reimbursement of telemedicine services and the harmonization of the legislation in the field occupies a middle place. The risks of supplier liability, data security, equipment's malfunction or license non verification are highlighted by a score that places them in the second half of the ranking. If the low penetration of high-speed internet bandwidth in rural areas does not represent an important barrier, this means that there are opportunities for providing high-level internet – a telemedicine *conditio sine qua non* – in urban areas.

It has been shown that tele-intensive care unit (tele-ICU) implementation has improved clinical and financial outcomes and decreased claims of malpractice by 50% (Becker et al., 2019b). The 24-hour/week functional tele-ICU system mitigated the causes of medical errors that led to incorrect diagnoses (medicolegal risk), by: a second automatic opinion, adequate flow of information (eliminating false alarms), permanent communication between practitioners or between them and patient's family etc. (Becker et al., 2019b). The authors also list the obstacles that stand in the way of extending tele-ICU related to legislation, the reimbursement of licenses or the adoption of a uniform standard of care etc. In a previous study (Becker et al., 2019a), the same authors recognized the unique capacity of telemedicine to improve medical services for millions of patients both in rural and urban areas. The tele-ICU system, at least in the field of intensive therapy, represent a good example of urban telemedicine.

4. MOTIVATION, OBJECTIVES AND METHODOLOGY

The motivation of this study consists in following reasons:

- all important bodies and empirical studies remark that the legal considerations are a major obstacle to telemedicine adoption (WHO, 2010; EC, 2018; Carrasqueiro et al., 2017; Poenaru, Poenaru & Vinereanu, 2014);
- risk management issues may be an important barrier to the telemedicine implementation (Mair et al., 2007);
- all system procedures regarding the risk management include the specific legislation under which the activities are carried out;
- in the online space, the number of articles in Romanian regarding risks in telemedicine is more than over 22 times smaller than articles in English.

Regarding the last aspect, it was assumed that a patient will not use complex filtration and a Google search for articles on the risks of telemedicine was conducted. Of the first 100 articles in Romanian only 4 refer to risks, and the rest to benefits, and for the first 100 articles in English the result was approximately inversely proportional, 91% addressing both benefits and risks or only risks. This denotes a disproportionate risk-benefit approach in Romanian articles (Figure 4).

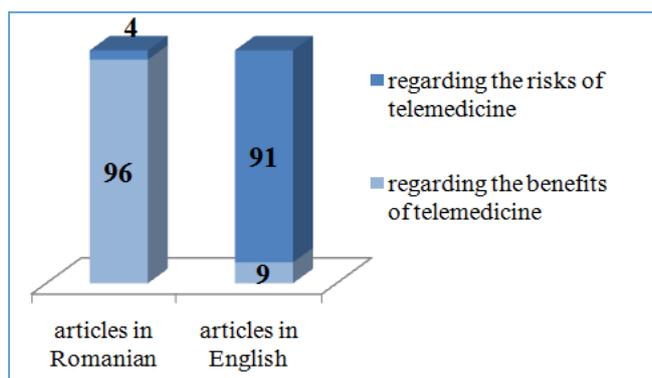


FIGURE 4 – ARTICLES ON THE RISKS AND BENEFITS

Source: selected and adapted by the authors from <https://www.google.ro/search?>

The main objective of research is to analyse the effects of the regulations on the potential risks of telemedicine in Romania, in terms of threats and opportunities.

Starting from the main objective, three sub-objectives were established:

1. Identification of a normative act issued by the legislator expressly for telemedicine and/or for avoiding risks in the field.
2. Establishing the volume and types of normative acts issued to regulate telemedicine in general and the risks in the field, in particular.
3. Analysis of the effects of the legal regulations and provisions on the potential risks of telemedicine.

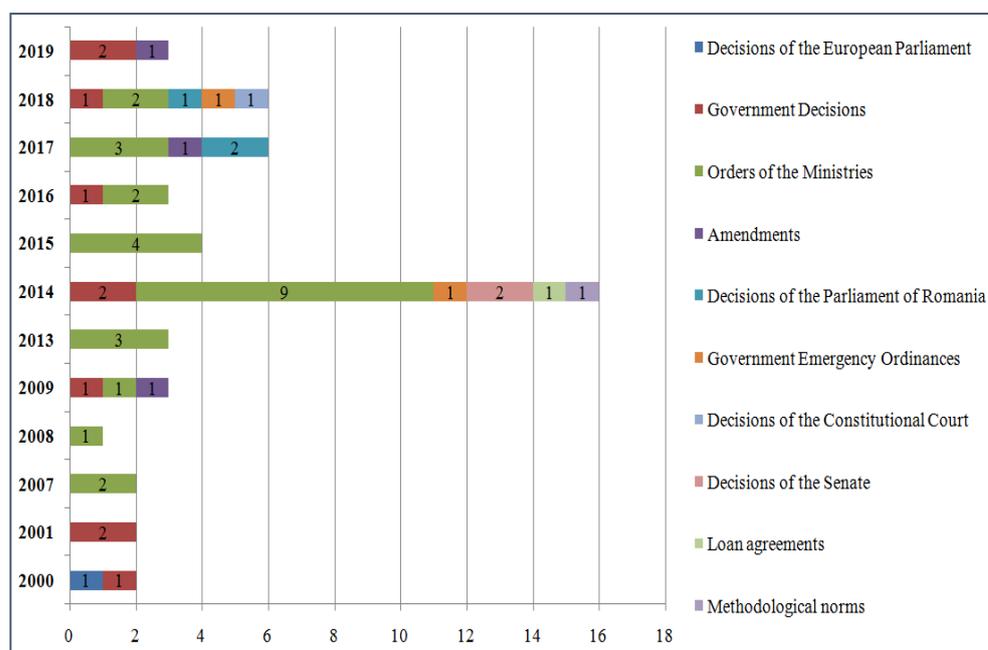


FIGURE 5 – THE NUMBER AND TYPES OF NORMATIVE ACTS WHICH INCLUDE TELEMEDICINE TOPICS, PUBLISHED BETWEEN 2000–2019

Source: realised by the authors after exclusion of duplicate acts from <http://legislatie.just.ro>

The methodology was focus on database and used necessary steps to select the materials like in the other research regarding the risks of telemedicine (Guisse, Anderson & Wiig, 2014; Scott Kruse et al., 2018 etc.), specifying that the methods were applied on databases containing normative acts, completed by the critically commentary. From several legislative databases, depending on the quantity and quality of the acts included, easy access, filtering complexity etc., was chose the legislative portal <http://legislatie.just.ro>. In order to identify the normative acts that include regulations and provisions regarding the risks present in the field of telemedicine, the portal was interrogated in Sep. – Oct. 2019. To confirm the results, in Nov. 2019 another check was made on the page of the Official Gazette of Romania: <http://www.monitoruloficial.ro>. The three steps used to interrogated data base and selected the normative acts were:

- Setting keywords:** except the keywords “telemedicine” and “risk”, the search attempts in the titles and contents of the normative acts of some combinations of keywords (“barriers”, “disadvantages”, “obstacles”, “telehealth”, “telecare”, “mHealth” etc.) returned 0 results or did not return results of interest.
- Exclusion criteria** applied for repealed, duplicate and irrelevant acts. Repealed acts, relevant for comparative studies of the evolutions of the legal norms, are not the subject of the present study. The portal did not allow a valid filtering only according to the legislation in force. Duplicate acts have appeared because the portal extracts the keywords from the annexed acts of the main act (plans, strategies, norms etc.). Irrelevant acts were considered those that update previous normative acts by taking over the same regulations. A lot of part of irrelevant acts were considered those return in which

the word “telemedicine” appears only in the name of structures on organizational charts, forms, services reporting templates etc. (eg. Service of policies, coordination and monitoring of emergency medical care, telemedicine and strategic programs within Ministry of Health).

- iii. **Analysis of the risk regulation** it involved identifying, corroborating and commenting on regulations that may have effects on the occurrence of risks in the development process of the telemedicine system.

The interrogation returned 69 normative acts of 10 types (government decisions, ordinances, orders of the ministries etc.), published between 2000–2019 which include regulations and provisions regarding telemedicine. Most acts (30%) were issued in 2014, in the context of approving the National Health Strategy 2014–2020 and the Action Plan for aferent period or some Loan Agreements between Romania and the International Bank for Reconstruction and Development on improving the quality and efficiency of the healthcare system. For the application of these measures it was necessary that legislator to issue more orders as a secondary legislation (Figure 5).

After data processing and exclusion criteria applied it was obtain a percentage about 26.09% for the target normative acts and 73.91% from acts were excluded (Figure 6).

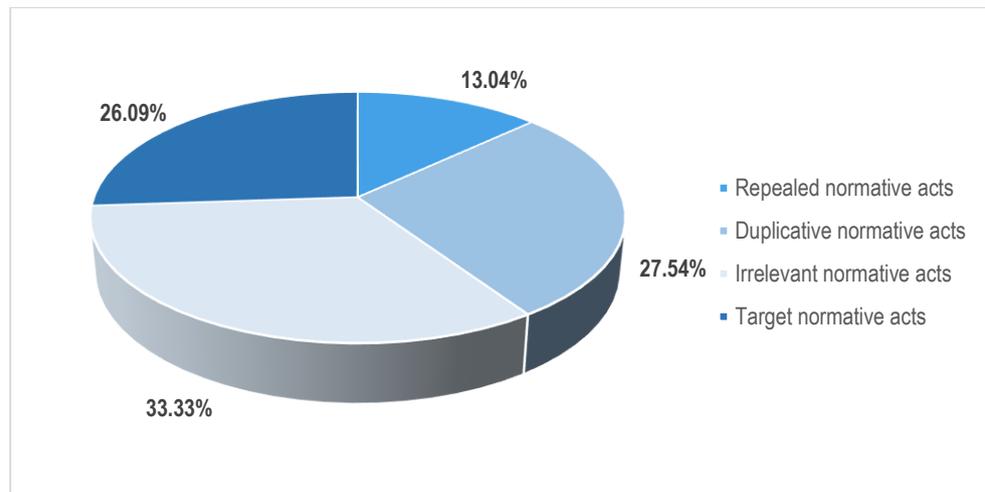


FIGURE 6 – THE PERCENTAGE OF EXCLUDED AND INTEREST ACTS
Source: realised by the authors after data processing from <http://legislatie.just.ro>

5. THE RESULTS OF THE RESEARCH

The flowchart of entire selection process of normative acts until the results are obtained is presented in the Figure 7.

Following the legislation in force and after identifying the regulations and provisions that could have implications on potential risks in telemedicine, the correspondence between normative acts and the respective risks was established (Table 3). The main causes of the risks are the lack of completing, amending, applying, but also failure to comply with procedures or failure to issue new legal acts in the field of telemedicine. 14 categories of potential risks were identified, both for patients and for the health system (authorities, physicians, clinics etc.) and also many of them with the possibility of occurrence both in rural and urban areas. Some risks are closely linked, so when there is a risk of a shortage of qualified personnel, there may be risks of liability, incorrect diagnosis, malpractice etc., known in the literature as legal risks (Becker et al., 2019b; Pratt, 2019). For example, the lack of telemedicine courses in medicine residencies can influence at least 8 types of risk. Also the technological risk influences risks in the area of incorrect diagnoses or the quality and security of services. That is why an overview of the entire regulations and provisions shows higher scores (6-7) for the risks in relation with legal framework, technologies and quality of telemedicine services, representing 38.46% from the total of potential risks.

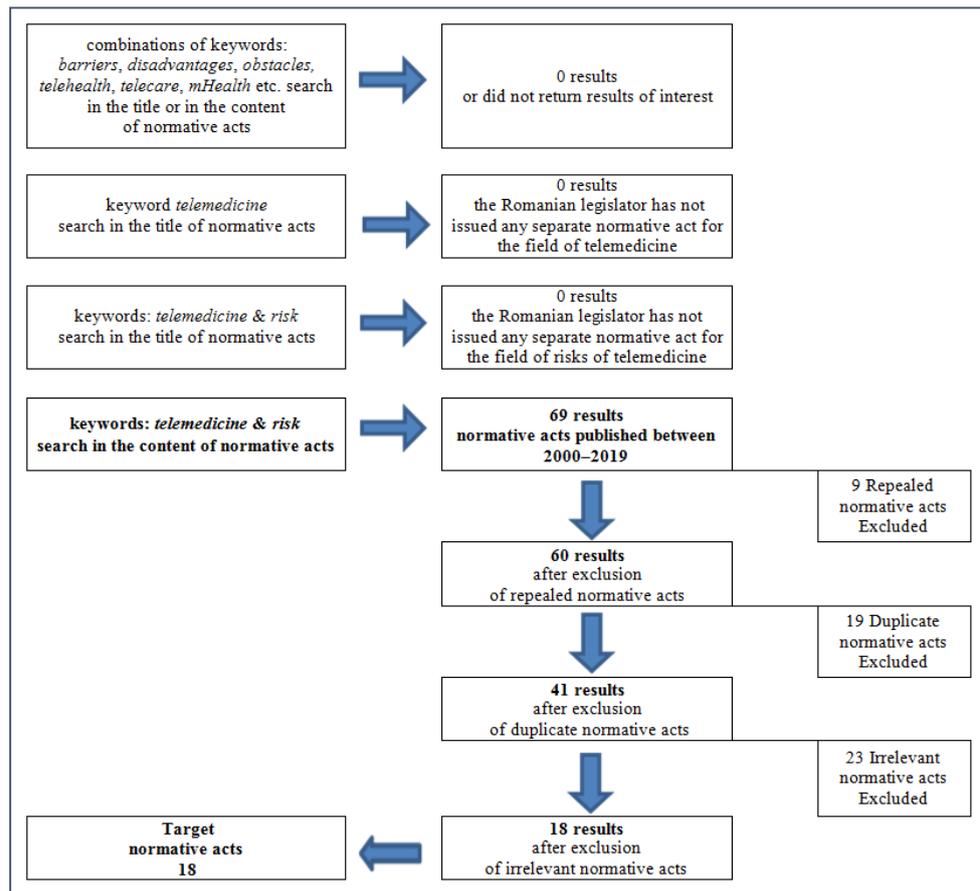


FIGURE 7 – THE FLOWCHART OF SELECTION RESULTS

Source: realised by the authors, after the exclusion stages, from <http://legislatie.just.ro>

7. DISCUSSIONS ON THE REGULATIONS AND RISKS OF TELEMEDICINE

The OMPH no. 1764/2006 mentioned only for 4 specialities in which teleconsultation can be used. Use telemedicine systems by others specialist physicians can lead to risks from at least two categories (h, k). The completion of the order with other specialities used on large scale in EU, like radiology, cardiology etc. (Carrasqueiro et al., 2017) can avoid those risks. In the OMPH no. 2021/2008 is not mentioned the patient's consent, and this fact can have implications on the risks regarding the privacy and confidentiality of personal medical data (a). For the transmission of data and images, patient's consent is mandatory (Olaru, Pandrea & Oprîță, 2016) and is provided in the specific protocols. Discussions with more patients reveal that in practice of emergency cases for the paramedics prevail saving the life, that is why they does not require a verbal consent for transmission data, but aware patient can signe a form. Also, the completion of normative act with "presumptive consent" phrase can avoid risk from first category (a), mostly in the cases of neurological and psychiatric disorders or an unconscious patient.

The GD no. 444/2009 include eHealth and telemedicine broadband development proposals, but more proposals are not fully implemented even after a decade, as it is estimated that only three quarter of households (an increased of cca. 10% since 2009), most of them from the urban areas, has the acces to the internet. This barrier can lead to the technological risk and has a negative influence to the quality of services or to established correct diagnosis (b, e, g).

The OMH no. 1333/2012 metioned telemedicine course in medicine residency only for specialities: nuclear, emergency and family medicine and for generalist assistant. Discussions with several graduate medical specialists (dermatologists, diabetologists, internists etc.) confirm the lack of a telemedicine course in the program and the fact that they did not attend a telemedicine course during the residency. If they will provide consultations and services within a telemedicine system their actions will have implications on most types of

risk (a, b, c, e, f). Also, by completing of this act mentioning other medical specialties, the Ministry of Health will increase the number of physicians who will be able to provide telemedicine services, mitigating the risk of qualified personnel shortages in this segment (j).

TABLE 3 – NORMATIVE ACTS WITH IMPLICATIONS ON POTENTIAL RISKS

| No. | Normative act (no./year) | Regulations and provisions regarding telemedicine | Potential risk areas for the | | | | | | | | | | | | | | Total |
|-----|--------------------------|---|------------------------------|----------|----------|----------|--------------------------------|----------|----------|----------|----------|----------|----------|-------------------|----------|----------|-----------|
| | | | patients | | | | patients and healthcare system | | | | | | | healthcare system | | | |
| | | | a | b | c | d | e | f | g | h | i | j | k | l | m | n | |
| 1 | OMPH no. 1764/2006 | teleconsultation for specialties | | | | | | | 1 | | | 1 | | | | | 2 |
| 2 | OMPH no. 2021/2008 | lack of patient's consent | 1 | | | | | | | | | | | | | | 1 |
| 3 | GD no. 444/2009 | broadband development | | 1 | | | 1 | 1 | | | | | | | | | 3 |
| 4 | OMH no. 1333/2012 | course in medicine residency | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | | | | | | 8 |
| 5 | DS no. 38/2014 | Senate's point of view | 1 | | | | 1 | 1 | 1 | 1 | | 1 | 1 | | 1 | | 8 |
| 6 | GEO no. 2/2014 | jurisdiction of the providers | 1 | | | | | 1 | | 1 | 1 | | 1 | | | | 5 |
| 7 | GD no. 1028/2014 | services for rural areas | | | | 1 | | | | | | | | | | | 1 |
| 8 | OMH no. 761/2016 | organisational structure | | | | | | | | | | | 1 | | | | 1 |
| 9 | OMH no. 1376/2016 | services for rural areas | | | | 1 | | | | | | | | | | | 1 |
| 10 | GD no. 951/2016 | communications in areas without coverage | 1 | | | | | | 1 | | | | | | | | 2 |
| 11 | DP no. 1/2017 | investments in more than 400 units | | | | | | 1 | | | | | 1 | 1 | | 1 | 4 |
| 12 | OMIA no. 65/2017 | Telemedicine Coordination Department | | | | | | | | | | | 1 | | | | 1 |
| 13 | OMH no. 476/2017 | equipment for burned patients | | | | | 1 | 1 | | | | | | | | | 2 |
| 14 | GEO no. 8/2018 | implementing in the military network | 1 | | 1 | | | 1 | | | | | 1 | | | 1 | 5 |
| 15 | DCC no. 355/2018 | amending of regulations | | | | | | | | | | | 1 | | | | 1 |
| 16 | OMH no. 253/2018 | palliative care | | | | 1 | | | 1 | | | 1 | | | | | 3 |
| 17 | GD no. 145/2019 | system for the operating unit | | | | | 1 | 1 | | | | | | | | | 2 |
| 18 | GD no. 324/2019 | equipments for community centers | | | | | 1 | | | | | 1 | | | | | 2 |
| | Total | | 4 | 4 | 1 | 4 | 6 | 4 | 7 | 4 | 2 | 5 | 7 | 1 | 1 | 2 | 52 |

Abbreviations: OMPH – Order of the Ministry of Public Health; GD – Government Decision; OMH – Order of the Ministry of Health; DS – Decision of the Senate; GEO – Government Emergency Ordinance; DP – Decision of the Parliament; OMIA – Order of the Ministry of Internal Affairs; DCC – Decision of the Constitutional Court.

Notes: a. Privacy, confidentiality and security of data; b. Incorrect diagnosis; c. Patient's safety; d. Unequal access; e. Quality of services; f. Reimbursement; g. Technological; h. Liability; i. Malpractice; j. Personnel; k. Legal framework; l. Financial; m. Informational; n. Image.

Source: realised by the authors from target normative acts

By the DS no. 38/2014 includes the Romanian Senate's point of view on the EC's Green Paper on "m-health", the Senate recognise a lot of drawbacks with implications on more risk areas. Thus, it recognizes the risks regarding the protection of personal medical data in the sense of their loss, destruction or alienation, as well as the need to regulate this situation (a). Considers that it is first of all the duty of the providers to continuously evaluate the existing or future risks. Argues that studies and evidence are still needed regarding the economic benefits of eHealth and mHealth implementation and the costs of training medical staff and equipment's acquisition (e, g, j). Information campaigns and training of the target groups are required (m). A complete information of patients by physicians and providers must regarding also the limits of telemedicine: differences from the clinical consultation, privacy, risks, costs etc. In the lack of the Ministry of Health's infrastructure, telemedicine services and their reimbursement are extremely limited, especially in the rural areas (f). An accountability of all parts involve and consolidation of legislation through unitary reformulations at EU level is necessary (h, k). The application of the measures proposed by the Senate to avoid or mitigate the mentioned risks can be done by issuing a secondary legislation.

One of the few regulation regarding jurisdiction is provided by the GEO no. 2/2014. In the case of telemedicine, healthcare services are considered to be provided in Romania or in another EU Member State where the healthcare provider is established. Setting jurisdiction, only after the provider headquarter and without some others provisions in completing, is not enough and has implications on a few potential risks (a, f, h, i, k). Despite the existing EU regulations the risk of reimbursement of healthcare expenses is also present for many other

types of medical services, when a patient benefits of them in other state than the residence one (Stoica, Bugheanu & Ciocoiu, 2019). From the perspective of jurisdiction, there are known a few major obstacles at global level: the absence of an international legal framework to allow health professionals to deliver services in different jurisdictions; the lack of policies that govern patient privacy and confidentiality (data transfer, storage, and sharing between health professionals and jurisdictions) and the risk of medical liability for the health professionals offering telemedicine services (WHO, 2010). The case of dr. Hageseth *versus* Superior Court of California (2007) shows the importance of the jurisdiction extended by the license to deliver telemedicine services. A physician without a license was sentenced to 9 months in prison because he prescribed medication (*via* telemedicine) to a patient who committed suicide (Becker et al., 2019a).

The regulations of several normative acts regarding the implementation of telemedicine especially in rural areas (eg. GD no. 1028/2014 and OMH no. 1376/2016) create the premises of unequal access to telemedicine services of patients in urban area (**d**) as compared to those in rural areas, the first ones being covered only by emergency telemedicine services. An interesting fact is the that EU-level surveys show that a very low percentage of respondents believe that from telemedicine can benefit only the urban community (Carrasqueiro et al., 2017).

The complete non-implementation so far of measures provided for in several normative acts (GD no. 951/2016, OMH no. 761/2016, OMH no. 476/2017, OMH no. 253/2018, GD no. 145/2019 and GD no. 324/2019) especially for the equipment acquisition and training of the personnel needed for the telemedicine system within some sanitary units also have consequences in the sense of the occurrence of risks with especially technological type, but also of another nature (**b, d, e, g, j**).

In the field of eHealth, the DP no. 1/2017 mentioned investments in more than 400 hospital and pre-hospital units that will use telemedicine systems aimed at increasing access to quality health services at cost-effective levels for citizens, especially those in vulnerable groups. Although the final deadline is the year 2023, investments were made at a little over 100 units (Vlădescu et al., 2016; Olaru, Pandrea & Opreț, 2016), maintaining a considerable financial effort for the health system (**l**), whose offer of medical services could have been extended by telemedicine. This proposals taken unmodified in DP no. 53/2017 and DP no. 1/2018 also to give the Government confidence by the Parliament has an invers effect, affecting the image both for the executive and legislative forum (**n**).

The same effect (**n**) has also the GEO no. 8/2018 which stipulates that an operating phase is carried out starting with the 2nd semester of 2018 and consists in the implementation of the telemedicine system under the conditions provided by a GD who was not issued two years after. The Government recognised that an urgently implementing the telemedicine system in the sanitary network of the Ministry of National Defense is given by the NATO commitments. Since 2014, Romania has been involved in a NATO–Russia multinational project that aims to connect three national telemedicine systems from the Russian Federation, Romania and the USA, to improve access to health care services and increase survival rates in emergency situations, including in remote areas (Vlădescu et al., 2016). The Government also recognised that maintaining the current situation would lead to the perpetuation of the identified risks like imprecise diagnosis (**b**) and the lack of legal framework (**k**) prevents the operationalization and implementation of the rural telemedicine system (**d**) and the defense telemedicine information system, respectively the impossibility of its extension (**g**), at national level.

Through analogy with the regulations of the OMIA no. 65/2017, which establishes the attributions of the Telemedicine Coordination Department in emergency medicine, it is necessary to create a similar department (**k**) in order to implement telemedicine in primary care.

By DCC no. 355/2018, was decided that some rules have been eliminated or modified, although they were not the subject of the request for review (eg. reference to art. 16 of Law no. 95/2006, republished in 2015, which regulates the telemedicine information system). The Constitutional Court of Romania accepts the objection of unconstitutionality formulated and finds that the law for amending and supplementing certain normative acts in the field of health is unconstitutional, as a whole. This last example draws attention to the importance of observing all the administrative-legal procedures regarding the modification of some normative acts (**k**) that regulate the field of telemedicine in Romania.

8. CONCLUSIONS AND RECOMMENDATIONS

At EU level, Romania is characterized by a paradox: a middle demand for telemedicine estimated at over 4.51% from population, but by the lowest revenue per inhabitant allocated for those services.

The best implemented telemedicine systems are in the emergency medical assistance and in the military sanitary network with over 100 medical units connected for pre-hospital and inter-clinic data transfer, the most of the units situated in urban or suburban areas.

For its many benefits it is necessary to develop telemedicine for other medical assistance and specialties: primary health care; telerehabilitation; oncology; internal medicine; paediatrics etc. There is also a need for more articles in Romanian language that present balanced benefits and risks of telemedicine.

Not even the Romanian legislator, since 2000 year until today, has not issued any separate normative act for the telemedicine domain or for the risks of telemedicine.

In the current form, the regulations on telemedicine can lead to risks for both the patients from rural and urban areas (unequal access, incorrect diagnoses, privacy, confidentiality and security of data etc.) and for the healthcare system (staff shortage, technological, financial, image etc.).

In order to reduce the probability of occurrence of identified risks it is necessary to amend, complete or apply some normative acts and, of course, to issue some new regulations in the telemedicine domain.

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