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The Borderline Issue of Ethics in the Future Medicine: Privacy Solutions for the Communication Systems in Telemedicine

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ABSTRACT: Telemedicine solutions are transforming our education, medical practice, and the relation between patient and medical professionals. The telehealth industry is no exception to this trend and the great development in this new field of home-based telemedicine represent great evidence that this system is the one of the future medicine. Since the economic and technologic development is not identical with the ethical appropriateness and justification, this is a serious problem that has to be taken into account. Hence, the use of telemedicine solutions and the mediums of data transmission, invite to a debate about their socio-ethical implications for the traditional goals and moral ideals of the healthcare practice.

The purpose of this article is to document a well-based socio-ethical system that we used in our e-health study, and which respected the socio-ethical standards regarding the relationship between health care professionals and patients, healthcare privacy and confidentiality, and informed consent.

KEYWORDS: Telemedicine, communication systems, electronic devices, socio-ethics intelemedicine,borderline issue.

I. INTRODUCTION

In the beginning of the 2013, the Department of Cardiology from the Emergency Hospital "Bagdasar-Arseni" within the University of Medicine and Pharmacy Carol-Davila, Bucharest, accepted the challenge of participating into a European project which proposed the testing of telemedical solutions and became part of the "Future and Technological Alignment Research (FI-STAR)" FP7 project.

Not only for Romania, but also for the whole Europe, the testing of the telemedical solution in different fields of medicine, and especially in cardiology, represents a new area that is still at the beginning. During the whole 2014s, our team involved in this project developed a mobile application – CARDIOSTAR – that is used by the cardiovascular patients with the purpose of guidance and monitoring of the process of rehabilitation after the discharge from the hospital [1].

II. BACKGROUND

As technology, informatics and communication systems record a spectacular progress from day to day, the new developments in these domains are also included in many other branches of science. An important contribution of these innovations is noticed in the medical science where we assist to a new field with exceptional perspectives telemedicine [2]. The prognosis in this domain is the transition from the classic medicine at the bed of the patient, as well as that one metbehind the scenes (all that include the following up of the evolution of the patient in a classic way, of the biological parameters and their interpretation) where the main element is the human one, to a new era of medicine were the human element becomes only the supervisor of the processes that are recorded and interpreted by

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the electronic devices [3-5]. If until a few years ago the doctor-patient contact and the follow-up of the patients evolution was realized only by scheduled appointments in "face-to-face" meetings, theactual technology makes possible the follow-up of the patient and his medical parameters from distance (when the patient is at home, at work, in holiday and so on), through medical monitoring devices, with the means of wireless data transmission, and through themeetings that can be in real time, but not absolutely. This scientific progress is obviously an excellent medium beneficial both for the medical stuff, and for the patient, offering flexibility, decrease of the afferent costs of the medical services and the possibility of approaching in proper time the new occurred medical problems [6-8].Even if this new trend in medicine is at a first sight only a beneficial one, we confront today with a very important problem regarding the socio-ethical aspects,[9-11] do the telemedical systems offer protection and safety for the private data's of the patients?

III. SUMMARY OF THE SOLUTION

The Cardiac Rehabilitation Program has been designed to use mobile solution for cardiac patients, in order to guide them through their Rehabilitation Process after an Acute Cardiac Event.With its interactive graphical interface which automatically collects vital parameters from Bluetooth capable devices, it becomes an enjoyable tool that allows real time monitoring and rapid interaction with the health care professionals.
In this way the patient has fully access from his home to the entire Cardiac Rehabilitation plan: nutritional guidance, medical therapy, monitored physical activity sessions and educational material regarding healthy lifestyle implementation.Thanks to the fact that it offers more security with the help of the monitoring devices and with knowing that someone will be available in case of abnormalities, it increases the quality of life after a cardiac event.

In comparison with the rest of the rehabilitation methods it offers freedom in planning the daily rehabilitation activities, sothe chances for long life implementation of regular physical activity and other healthy habits increase.

At the beginning of the 2015s, we started the implementation of this program to our patients that correspond with the inclusion criteria of this study.
The program is structured classically in 3 phases:

- Phase I the hospital phase (3-7 days).
- Phase II the early post discharge phase (4 weeks) also closely monitored by health care personnel.
- Phase III the long term maintenance program.

At discharge, depending on the Rehabilitation plan the patient receives an Android Smartphone, with the preinstalled Cardiac Rehabilitation Solution or the solution is installed on its personal mobile phone.

On the mobile application, the caregiver introduces the patient's personal thresholds, for the medical parameters that are monitored during the entire rehabilitation process. Additionally, a nutritional guide and his personal medical treatment plansare uploaded into the solution.
For his home rehabilitation phase he also receives a set of monitoring devices, capable of transmitting automatically data throw Bluetooth: a blood pressure measurer, pulse oximeter for Oxygen saturation, a cardiac watch for the permanent heart rate monitoring and chest strap for electrocardiogram monitoring.
The rehabilitation process lasts around 4 weeks, depending on the cardiac disease and patient's evolution. During this period the patient has to perform some daily/weekly activities:

- Measure the blood pressure, Oxygen saturation in the morning and in the evening and before and at the end of the exercise session.
- Wear the chest strap during physical activity for monitoring the ECG.
- Permanent use of the cardiac watch for constant monitoring of the heart rate.
- Perform regular aerobic physical activity (walking, jogging, cycling) 3-5 time per week.

At the end of the rehabilitation process, he performs another ECG treadmill test that objectively quantifies the overall improvement of the cardiac fitness during the rehabilitation process. Depending on its evolution the patient is guided to Phase III of the rehabilitation process.

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IV. THE SOCIO-ETHICALISSUE

In terms of the socio-ethical issue we faced the following problems:

The informed Consent,the Romanian mentality is still skeptically regarding the signing of any paper, even of an informed consent that contains the protocol of the study. Even if our study does not involve any major risk for the patient because there are not given any drugs to be afraid of the adverse reactions, there are not performed invasive investigations, all the procedures are open and detailed presented and the patients agree with the procedures, there still exists the fear that behind the free offeris hiding a high risk that will condemn them to pay an important sum of money sometime in the future, or a high risk ofirradiation or even of death, while they accept to measure some vitalparameters and to change their lifestyle.This problem was a major impediment in the selection of the patients. Even if our study was especially addressed to the population with a medium to high level of education, even between these, the problem of assumed risk by signing the informed consent was one with an important impact.This situation is not found in other countries with a higher level of culture, where the people are used to sign every medical document [12,13]. While confronting this problem in our study, we found necessary a careful selection of the patients.We accepted only those patients that have no dubiety and that totally agreed with the terms of the informed consent, and the rest of them could not be enrolled in the study.

- The security of the mobile application. It is very important and absolutely necessary that every application that contains medical information to be secured. From the very beginning, our application was created with an interface for logging through user and password that are required every time when the patients wants to enter into the application. Even if the medical information recorded in the application have a limited numbers of parameters, all this data are confidential and we considered absolutely necessary their protection.
- The protection of the data transmitted through the electronic devices. The transmission of data from the electronic devices to the central station in our department was realized via internet network. The collected data can be accessed only by the doctors from our team that supervise this activity and this access is realized only using a user and a password, that are introduced into the program from the central station allocated only for this study.
- The protection of the recorded data on the mobile application by the previous patient towards the next patient that has to receive the mobile device. Every time when the devices are taken from one patient at the end of on stage of the study for a certain patient, all data recorded in the application are deleted, and also the application is deleted and reinstalled to offer the maximum comfort and safeties for both patients.
- A reliable feedback from patients regarding the socio-ethical aspects and security aspects. This feedback regarding the comfort and the safety of the devices and of the whole study was obtained via some questionnaires that were addressed both for professional team (doctors, engineers, nurses, programmers, and the coordinator stuff) and for the patients. They all can express their opinion regarding the respecting of the socio-ethical standards in this study.

V. MATERIAL AND METHODS

We realized a transverse sub-study at the end of phase beta of our research (after the patients used the devices at least for one month, we mention that the inclusion in the study started in January 2015). Until now we have 50 patients included and we realized in this sub-study an analysis of the patient's and of the professional stuff opinion regarding the respecting of the socio-ethical standards. In the same time these questionnaires were analyzed pointing out some conclusions. The questionnaires for the stuff people were divided from the beginning into two groups, 25 questionnaires completed by the professionals with a high level of education (doctors, programmers, engineers, boarding stuff) and 25 questionnaires for the stuff with a medium level of education (nurses, assistants of medical/informatics laboratories, technicians). The results that are presented in this article are those from an evaluation at the middle point of the study, the final results will be published at the end of 2015s. The questionnaires are anonymous and they respected the Europeanstandardsregarding the observed parameters and the scales that were used. They were composed by the European Coordinator Committee of the whole FI-STAR project.
The analysis was performed using Fisher-test Two-Sample for Variances, t-Test: Paired Two-Sample Assuming equal Variances, t-Test: Two-Sample Assuming equal Variances, Chi-Square test. A p-value < 0.05 was considered

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statistically significant.

VI. RESULTS

Demographics

The median age in the patient`s group was 31, range 28-63, in the professional's group was 42range 29-49, and in the group with medium level of studies was 65, range 46-77. In all the three groups the majority were females (72%, 84%, respectively 58%). A detailed view of these descriptive parameters is presented in the table below (Table 1).

Characteristics in the patient's group	**Statistics**
Age, Yrs. (median, range)	31(27-63)
Male, n (%)	7/25 (28%)
Female, n (%)	18/25 (72%)
Characteristics in the professionals group (high level of studies)	**Statistics**
Age, Yrs. (median, range)	42 (29-49)
Male, n (%)	4/25 (16%)
Female, n (%)	21/25 (84%)
Characteristics in the group with medium level of studies	**Statistics**
Age, Yrs. (median, range)	65 (46-77)
Male, n (%)	21/50 (42%)
Female, n (%)	29/50 (58%)

Table 1: Demographics

Questionnaires results

The score value is standardized as the following description: optimum score value(satisfactory score) for the patients and the professional's group 5 – 15, and for the group with medium level of studies, as well as for the whole lot is 4 – 12.Unsatisfactory score for the first two groups is 16 – 25 and for the last group, as well as for the whole lot is 13 – 16. In all groups was remarked that the satisfactory score prevailed with a significant p-value (<0.05) as follows: in the patient's group $p=1.05*10^{-9}$, in the professional's group $p=1.55*10^{-8}$, in the group with medium level of studies $p=1.79*10^{-9}$, and for all the lot $p=4.25*10^{-21}$. The detailed data's and statistics are presented below (Table 2).

Characteristics in the patients` group	**Statistics**	**p-value**
Score (median, range)	10 (5-17)	$1,05*10^{-9}$
Satisfactory Score (standard 5-15)	22/25 (88%)	
Unsatisfactory Score (standard 16-25)	3/25 (12%)	
Characteristics in the professional's group (high level of studies)	**Statistics**	**p-value**
Score (median, range)	9 (5-19)	$1,55*10^{-8}$
Satisfactory Score (standard 5-15)	21/25 (84%)	
Unsatisfactory Score (standard 16-25)	4/25 (16%)	
Characteristics in the group with medium level of studies	**Statistics**	**p-value**
Score (median, range)	7 (4-16)	$1,79*10^{-9}$
Satisfactory Score (standard 4-12)	46/50 (92%)	
Unsatisfactory Score (standard 13 -16)	4/50 (8%)	
Comparison between Scores in the lot (all people that filled the questionnaire)	**Statistics**	**p-value**
Score (median, range)	8 (4-19)	$4,25*10^{-21}$
Satisfactory Score (standard 4-12)	88/100 (88%)	
Unsatisfactory Score (standard 13-16)	12/100 (12%)	

Table 2: Comparison of the parameters

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VII. DISCUSSION

It is obviously that our study was well rated and appreciated from the socio-ethical point of view. The analysis will be presented with the final results of the whole study at the end of this research. At that moments we will present also a detailed analysis of the factor that were unsatisfactory rated. But at this moment this cannot be done because we still have only few persons that rated with unsatisfactory score. Until the end of the study we intend to double the number of the patients included in this study that will enable an overview analysis upon these indicators of quality. At this moment both the patients and the stuff are generally satisfied by the quality of the devices and the private security, the protection of the data, and the respecting of the socio-ethical standards.

VIII. CONCLUSION

Telemedicine is a wide area for the future, and the socio-ethical field is in a great and quickly development, its standards being at the border between the standards of two great domains: ethics in medicine and ethics in informatics and engineering. Ethics in telemedicine is a borderline issue, an interesting and new approach, because the telemedicine area is itself a new area. Our study brings an important contribution even in this aspect of socio-ethical issues in telemedicine, by developing a great internal telemedical network in our department of Cardiology that is able to ensure the comfort and the safety of the medical private data of our patients.

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