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THE PATIENTS AND HEALTHCARE STAFF PERCEPTION ON THE PROTECTION OF PATIENTS DATA AND RIGHTS BY PROFESSIONAL SECRECY IN ROMANIA

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Abstract: The core of the doctor-patient relationship is confidentiality and communication. A patient who cannot trust their doctor or nurse will not give the necessary information for good plan care and has a poor prognosis, is not compliant with treatment, and the results will not be good. This study aimed to analyse the perception of healthcare employee and patient's perception of data protection and rights protection by professional secrecy.

Material and methods. This study is a cross-sectional investigation. Data were collected using a questionnaire with three sections from December 2018 to January 2019. The data were analysed statistically.

Results. 2069 respondents completed the survey (1238 healthcare employee – nurses and physicians – and 831 patients). The knowledge about the legislative provision on professional secrecy and data protection seems to be less known in the group of patients in a private hospital (mean score 1.84), but better known in teaching hospitals and public hospital (mean score 2.10 *vs.* 2.01). Then, the knowledge about the legal provision that protects professional secrecy is better known in all three groups of respondents and all three types of hospitals.

Conclusions. Our study revealed a strong correlation between the level of education and the knowledge about data protection and patient's rights protection. Healthcare employee should also be periodically informed about the protection of patients' data and the protection of their rights.

Key words: patient's right, patient's data protection, confidentiality, the patient-doctor relationship.

INTRODUCTION

In recent years, there is more and more talk about security and data protection, whether it be medical or unrelated. Technological evolution has a big impact on the medical field but comes with the risks of data and information security. The use of technology has brought major benefits to patients, has led to more efficient care services, has facilitated communication between physicians and patients, also plays a crucial role in educating the patient and promoting prevention and screening. Moreover, with the help of technology constantly appear innovative medical devices, new drugs and treatment procedures, but also new research possibilities. All of this only makes the medical system more efficient. Diagnosis involves using the information that the patient offers to the doctor, but also the use of the data (eg. RMN, laboratory tests, clinical symptoms and signs). Therefore, we can say that diagnosis is data processing [1]. In the last year, there has been much talk in the public space about data protection and data security. As from 25 May 2018, the processing of personal data shall be carried out following the requirements of Regulation (EU) 2016/679. The main purpose of the GDPR is to adapt and update the principles set out in Directive no. 46/95, in line with the evolution of technology. The GDPR also establishes a uniform set of rules, directly applicable in the Member States of the Union, to effectively protect the privacy of individuals within the European Union [2]. The principles and rules established by GDPR concern a fundamental right of the person – the right to the protection of personal data, guaranteed by art. 8 of the Charter of Fundamental Rights of the EU and Art. 16 of the EU Treaty [3].

The legal provisions on patient rights are found in the Law no.46/2003 [4] and the legal provisions about data protection in the Law no.190/2018 [5].

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Practically, with the help of GDPR, it ensures the control of patient data and the protection of patients' rights.

Respect for the person is the foundation of the patient-patient relationship and imposes two requirements: the right of the individual to make decisions about medical care or participation in studies on human subjects, involving consent, and the need to protect those with reduced autonomy. The principle of autonomy helps patients to obtain and achieve what they want; promotes health; stimulates patients to take responsibility for decisions and control their own lives; but last but not least, it is a factor regulating medicine as a liberal profession. "To help or at least not to hurt" (Hippocrates) bases the benefit principle. In other words, physicians must act in such a way as to promote the well-being of others. Singer considered that "if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it" [6]. In the medical system, the benefit principle is a duty.

Communication in medicine

"The good physician treats the disease; the great physician treats the patient who has the disease" (Colin Robertson & Gareth Clegg. "Storytelling in Medicine") [7].

As researchers agree upon the need for changing the paradigm within the patient-doctor relationship, they emphasize the current predominantly passive role of the patient in his interactions with health practitioners [8]. The authors of Three Functions of the Medical Interview Lazare *et al.* (1995) recommend replacing the commonly used expression of "taking the history" with "interview", derived from the "inter" (between) and "view" (vision, to see), which better serves in the authors' opinion the patient-doctor communication through sharing the opinions. The suggestion of using "interview" is fully justified by the position of the healthcare practitioner, therefore the doctor, who doesn't have to "take" the history of the patient, which gets the passive role in the dynamics, but to communicate in a two-way manner. The doctors' role doesn't have to be limited to receiving the information the patient is willing to offer since the patient has the power and the ability to conceal some of the most important information if he wishes to do so. Therefore, the "interview" dynamics is in the author's opinion a better choice, which statues the active role of both actors, the doctor and the patient [9].

The literature on patient-doctor communication is also covering the distinction between a good doctor and an extraordinary one, as patients usually categorize the healthcare practitioners they interact with [10].

Professor Robert Centor explained in a video interview in 2007 what a patient story is and how to decipher it.

"Each patient represents a story. That story includes their diseases, their new problem, their social situation, and their beliefs. How do we understand the story? We must develop excellent communication skills and gather the history in appropriate depth. We must perform a targeted physical examination based on historical clues. We must order the correct diagnostic tests and interpret them in the context of the history and physical exam. Once we collect the appropriate data, we then should construct that patient's story. The story includes making the correct diagnosis or diagnoses. The story must describe the patient's context. Who is this patient? What are the patient's goals? How might the patient's situation impact our treatment options?" [10].

De Haes and Bensing will take the idea of correct diagnosis based on communication one step forward in 2009, while stating that in the absence of good communication there is no way to establish a diagnosis or a treatment plan. The idea of teaching the communication skills to doctors it became a central pillar of narrative medicine benefits for already established healthcare practitioners but also to medical students or young doctors. De Haes and Bensing claim that young doctors will preponderantly learn by imitation, following the communication style of their teachers and mentors. Studying medicine provides them with less autonomy, therefore there is a set of skills they actually "borrow" from their professors through direct observation [11].

Narrative medicine, which supports the transfer of communication knowledge to medical students and healthcare practitioners and doctors, has become an academic discipline in recent years, starting with narrative medicine school from Columbia University, run by Rita Charon PhD MD. As a doctor and PhD in English literature, with a major in Henry James' studies, Rita Charon will establish a narrative medicine school emphasizing the one specific trait of being a teachable discipline, being able to be transferred as knowledge and skills to younger generations of doctors [12].

"The values and skills of humanistic understanding are as teachable and learnable as any of those we hope and expect to find in physicians and health care workers." [13] (Schleifer, R., & Vannatta, J. B., 2013).

According to de Haes and Bensing, the communication skills applied during patient-doctor dialogue are meant to organize the discourse and to clarify the content of the discourse, with substantial benefits to both the doctor and the patient [11]. The purpose of efficient communication during the medical interview is defined by Rita Charon as the "efficient therapeutic alliance" which provides an equal communication space between the two actors. The alliance participants could be more than two in the case of a family or friends' participation in the above-mentioned dialogue [14]. Modelling the empathy in clinical practice, Jodi Halpern has mentioned in her work "From Detached Concern to Empathy: Humanizing Medical Practice" (2001) that what was once considered an additional layer of education of a doctor – literature and humanities, there is – today is recognized as a central pillar of practising medicine with empathy and reflection [15].

ETHICAL ASPECTS

This study was approved by the University of Medicine and Pharmacy Iasi, Romania Ethics Committee.

Aspects such as confidentiality and anonymity were considered and the respondents were informed about their confidentiality and anonymity in the introduction of the survey. When completing the survey, the respondents were informed about providing their consent concerning the use of the survey results for a study that will be published and the collected data will be used only for research. In the survey, respondents were not asked to provide any contact details. Demographic information from respondents is presented in such a way that no link can be established between the person who reported data and the information provided. Also, we considered the completion of the questionnaire as an agreement to participate in the study.

MATERIAL AND METHODS

This was a cross-sectional study and the information was collected through a questionnaire which was filled out by the respondents online on www.galmedmun.ro. We targeted patients and healthcare employees from North-East of Romania.

The survey focused on the opinion of respondents who volunteered to take the questionnaire.

The questionnaire had three parts as follows: (i) first part – demographic characteristic of the respondents; (ii) second part – patient's rights; (iii) third party – data and patients rights protection. In this article, we assessed only the patient data and rights protection. The questionnaire was completed by 2069 respondents.

The exclusion criteria in this study were:

(a) patients who had been hospitalized more than a year before;

(b) the retired healthcare employee.

The questionnaire was available online for two months (December 2018 – January 2019). The rate of observance of each item was measured on a Likert scale ranging from zero (disagree strongly) to six (agree strongly).

The data was centralized into an SPSS 20 database and processed with the statistical functions at which they are feasible at the 95% CI. Using the specific statistical methods, it was possible to calculate the mean and standard deviation (SD); the quantitative variables were compared using the Student t-test. Also, the ANOVA test was used to evaluate the descriptive statistical indicators: minimum, maximum, mean, median, standard deviation, standard error of the mean, variance, the t-Student test takes into account the variability measurement and the weight of the observations. Test F (ANOVA) used to compare the values with normal distributions in the three groups.

RESULTS

Respondents were 1283 healthcare employee (response rate = 59.84% - 907 (73.25%) physicians and 331 (26.75%) nurses) and 831 patients (response rate = 40.16%).

The age category of respondents varied greatly across the respondents, with the spread of age in the survey goes from age 19 to age 78. The age range for patients group was between 19 to 78 (45.79 ± 15.27 and a median of 45.00). The minimum age for physicians was 27 years and maximum stood at 67 years (46.64 ± 11.67 and a median of 46.00) and respectively the minimum age for nurses 24 years and the maximum stood at 65 years (46.70 ± 11.99 and a median of 48.00) with a significant difference between the mean ages ($p<0.001$).

Concerning the gender of participants in the survey, 434 (52.23%) men completed the survey, while the number of responding women was 397 (47.77%), in the patients' group. In the healthcare employee group, we have the following results: 424 (34.25%) men; 483 (39.01%) women in physicians group and nurses group: 151 (12.20%) men and 180 (14.54%) women.

Table 1. Demographic characteristics of the group

VARIABLES N %	Patients		Physicians		Nurses		p-value
	N	%	N	%			
SEX							
Men	434	52.23%	424	34.25%	151	12.20%	<0.01
Women	397	47.77%	483	39.01%	180	14.54%	
AREA							
Rural	398	47.89%	63	5.09%	16	1.29%	<0.01
Urban	433	52.11%	844	68.17%	315	25.44%	
AGE							
<20	11	1.32%	-	-	-	-	<0.001
20 – 29	153	18.41%	56	6.17%	35	10.57%	
30 – 39	178	21.42%	157	17.31%	139	41.99%	
40 – 49	149	17.93%	220	24.26%	88	26.59%	
50 – 59	144	17.33%	302	33.30%	13	3.93%	
>60	196	23.59%	172	18.96%	56	16.92%	
Mean years	**45.13**		**46.64**		**46.70**		
SD	**4.98**		**11.61**		**11.92**		
LEVEL OF EDUCATION							
Elementary	135	16.25%	-	-	-	-	0.09
High school	157	18.89%	-	-	25	2.02%	
College	317	38.15%	642	34.25%	276	22.29%	
Master	176	21.18%	223	18.01%	25	2.02%	
Phd	46	5.54%	42	3.39%	5	0.40%	
JOB STATUS							
Student	129	15.52%	-	-	-	-	0.39
Public sector	138	16.61%	571	46.12%	204	16.48%	
Private sector	174	20.94%	336	27.14%	127	10.26%	
Unemployed	130	15.64%	-	-	-	-	
Retiring	130	15.64%	-	-	-	-	
Welfare	130	15.64%	-	-	-	-	
WORKING EXPERIENCE IN HEALTH CARE IN YEARS							
<5	-	-	267	29.44%	87	26.28%	0.032
5 – 10	-	-	193	21.28%	141	42.60%	
>10	-	-	447	49.28%	103	31.12%	
Mean	-		15.71		11.07		
SD	-		9.64		8.92		

The majority – 76.95% – of respondents live in an urban area (healthcare employee – 68.77% (844) physicians *vs.* 25.44% (315) nurses *vs.* 52.11% (433) patients).

Cronbach's alpha coefficient overall was 0.87 which proves increased internal reliability. Also, we found that for each section the alpha coefficient was: legislative knowledge 0.74; data protection 0.89; patient rights protection 0.81.

The knowledge about the legislative provision on professional secrecy and data protection seems to be less known in the group of patients in a private hospital (mean score 1.84), but better known in teaching hospitals and public hospital. Then, the knowledge about the legal provision that protects professional secrecy is better known in all three groups of respondents and all three types of hospitals. Also, for the group of patients, the level of education significantly influences the level of information regarding the legislative provision (Kruskal-Wallis χ^2=1,51, p = 0.05). For the group of healthcare employee, the work experience was strongly associated with the level of knowledge of the patients' rights and legislative provisions (p = 0.012).

Regardless of the type of the hospital in which they were treated – private hospital, public hospital, teaching hospital – the patients consider that the healthcare employee must respect the professional secrecy (mean score 4.11 *vs.* 4.14 *vs.* 4.18). They also think that is the responsibility of the healthcare employee to keep and respect the confidentiality of the information and data protection (mean score 3.84 *vs.* 3.75 *vs.* 3.79).

Table 2. Mean score of patients and healthcare employee perception about the protection of patients' rights and data

Data protection & patient rights aspects		Mean ± SD Private hospital	Public hospital	Teaching hospital	*p* value
Knowledge about legislative provisions on professional secrecy & data protection	Patients	1.84±0.82	2.10±0.83	2.01±0.82	**0.03**
	Nurses	1.98±0.84	2.10±0.79	1.87±0.82	0.14
	Physicians	2.03±0.81	1.94±0.82	1.99±0.79	0.06
Knowledge about the legal provisions that protect professional secrecy	Patients	4.18±2.02	4.17±2.03	4.34±2.03	0.54
	Nurses	4.05±1.92	3.90±2.01	4.10±1.98	0.75
	Physicians	3.92±2.06	4.15±1.87	3.92±2.05	0.33
Medical services offered, regardless of the circumstances, must respect professional secrecy	Patients	4.11±1.99	4.14±1.95	4.18±1.88	0.91
	Nurses	4.14±2.00	3.89±1.99	4.25±2.06	0.42
	Physicians	3.84±2.01	3.99±2.05	4.05±2.05	0.44
Awareness of the role and responsibility of medical staff to maintain patient confidentiality and data protection	Patients	3.84±2.00	3.75±1.96	3.79±1.99	0.88
	Nurses	4.14±2.00	4.02±2.03	4.15±2.15	0.88
	Physicians	3.99±1.96	4.31±1.91	4.01±1.96	0.13
Medical staff understood the importance of keeping professional secrecy	Patients	4.25±1.99	4.10±1.96	3.95±2.01	0.22
	Nurses	3.84±1.87	4.08±1.96	3.98±1.98	0.62
	Physicians	4.17±2.01	3.85±1.94	3.89±1.98	0.14
Medical staff understood the importance of personal data protection	Patients	4.09±2.06	3.99±1.97	4.02±1.96	0.58
	Nurses	3.86±1.96	4.02±2.00	3.86±1.96	0.18
	Physicians	4.19±1.89	3.61±2.01	4±2.01	**0.00**
Professional secrecy/confidentiality and patient data protection are at risk due to inadequate resources available to the hospital (lack of access control, inadequate storage facilities, small spaces, few computers, etc.)	Patients	2.04±2.02	1.96±2.04	2.20±1.99	0.37
	Nurses	4.14±2.06	4.01±2.04	4.10±2.06	**0.04**
	Physicians	4.22±1.92	3.91±2.07	4.08±1.89	**0.001**
Patients receive information on their rights and hospitals policy regarding confidentiality and personal data protection	Patients	4.01±2.05	3.72±1.92	3.76±2.12	0.19
	Nurses	2.47±1.07	2.55±1.13	2.49±1.15	0.89
	Physicians	2.59±1.14	2.37±1.11	2.56±1.08	0.08
The rights of patients, as well as the privacy and security of personal data, are seriously dealt with by all hospital employees	Patients	2.62±1.05	2.48±1.04	2.45±1.13	0.16
	Nurses	2.45±1.05	2.55±1.06	2.71±1.15	0.20
	Physicians	2.56±1.14	2.56±1.08	2.52±1.11	0.82
Patients receive information on their rights and hospital policy on confidentiality and personal data protection regardless of their level of training	Patients	2.40±1.08	2.51±1.05	2.39±1.10	**0.02**
	Nurses	2.40±1.16	2.43±1.17	2.61±1.12	**0.05**
	Physicians	2.40±1.15	2.52±1.08	2.56±1.15	0.11
Professional secrecy / confidentiality, but also the protection of patient data are less important than the treatment a patient needs	Patients	3.99±2.03	4.06±2.00	4.09±2.06	0.85
	Nurses	3.97±2.01	3.98±1.97	4.19±1.88	0.66
	Physicians	3.90±2.02	4.23±1.85	4.03±1.97	0.20

The patients considered that the healthcare employee understood the importance of keeping professional secrecy and personal data protection (mean score 4.25 *vs*. 4.10 *vs*. 3.95; and mean score 4.09 *vs*. 3.99 *vs*. 4.02). But at the same questions, for the healthcare employee, we obtain a lower mean score, and only for the group of physicians, we have a positive correlation (p = 0.00).

In order to determine what are the risk for professional secrecy/confidentiality and data protection (lack of access control, inadequate storage facilities, small spaces, few computers etc.) differentiated between type of hospital and healthcare employee, comparisons were made between mean scores as it follows: nurses from private hospital and teaching hospital with higher mean score (4.14 *vs.* 4.10) then nurses from public hospital (mean score 4.01); also, the physician from private hospital and public hospital had higher mean score (4.22 *vs*. 4.08) and physicians from teaching hospital with 3,91 mean score and we have a positive correlation (p=0.04 for nurses group; p=0.001 for physicians group).

The patiens seems to receive information on their rights and hospital policy regarding confidentiality and personal data protection (mean score 4.01 *vs*. 3.72 *vs*. 3.76), but also when they are asked if the receive information regardless of their level of training the mean score was lower (2.40 *vs*. 2.51 *vs*. 2.39; p = 0.02). However, for the healthcare employee the mean score on this item was also lower (physicians mean score 2.59 *vs*. 2.37 *vs*. 2.56; 2.40 vs 2.52 *vs*. 2.56; p = 0.05); (nurses mean score 2.47 *vs*. 2.55 *vs*. 2.49; 2.40 *vs*. 2.43 *vs*. 2.61; p = 0.05).

Respondents considered also that the protection of data are less important than the treatment: patients mean score 3.99 *vs*. 4.06 *vs*. 4.09; nurses mean score 3.97 *vs*. 3.98 *vs*. 4.19; physicians mean score 3.90 vs. 4.23 vs. 4.03 without positive correlation.

Also, we found a significant relationship between awareness scores to right to privacy and confidentiality information and the level of education of the respondents using Pearson's correlation coefficient ($r = 0.05$, $p<0.001$).

DISCUSSION

The healthcare employees – physicians and nurses – have a special mission: they come to the support of patients to manage the symptoms, to increase the degree of information and to respect the treatment plan. A fundamental principle of healthcare practice is to respect the inherent dignity, value, unique attributes and human rights and ensures that the clinical activity is carried out in compliance with ethical, legal and scientific principles [16].

As we can see, patients' rights, but especially the protection of patients' rights and data, are topics that still need to be made known to both medical professionals and patients. Therefore, it seems that healthcare employee needs to be trained regarding the legal provisions, but especially regarding the protection of personal data and rights.

Professional secrecy is an obligation imposed by the medical community to respect the right to privacy of patients. This right is particularly important in the field of healthcare. It is not just an obligation that physicians have towards the patients; is an obligation they have as a profession to society. The obligation to keep professional secrecy is one of the values associated with the profession and is deeply rooted in centuries.

One of the traditional principles of medical ethics is medical confidentiality. Its major concern is to protect the patient's interest in the doctor-patient relationship. According to this principle, the information that doctors learn about their patients during their professional practice should not be disclosed to third parties [17].

The knowledge about legislative provisions on professional secrecy and data protection is very low both among healthcare employee and patients.

Another study carried out by Ceylan and Cetinkaya in 2019, tried to determine the attitude of nurses especially regarding the patient privacy and the results indicated that the level of education is positively correlated with the awareness of legislative provision and are more concerned about confidentiality [18].

Confidentiality is recognized by law as privileged communication between two parties in a professional relationship, such as a patient and a doctor, nurse or other health professionals [19]. Health records contain various types of personal data or otherwise sensitive personal information. Foufi *et al.* presented a rule-based method for de-identification of clinical narrative data. Therefore, the obtained results proved the effectiveness of the system [20]. The method can also be used in further researches, ensuring the protection of patient data and continuing the research activity respecting the ethical principles and GDPR.

Technological evolution has major implications for today's clinical activity. Understanding the optimal use of technology, but taking into account the specific security measures required by the work, as well as the strengths and limitations of these platforms, can ease the day-to-day work of healthcare employee and improve and streamline communication with patients. Another benefit of technology is the ability to store and access data, create databases that are so useful in research. However, patient data can only be used after obtaining informed consent. Smith *et al.* conducted a multi-site survey about patients' views on consent among a diverse group of participants [21]. The results have shown that 15% of parents would give consent for the participation of their children in a hypothetical biobank, but they couldn't detect associations between willingness or attitudes and the consent and data sharing scenario [22].

The way sensitive data such as patient health data is protected is extremely important when it comes to storing and analyzing data. Maintaining these data safely is crucial. For this reason, in many countries, regulations have been adopted that provide some standards in this area. According to a report published in 2017, more than 27 million medical records were stolen in 2016 through 450 procedural violations. The number of security incidents is increasing [23]. Until now, 2016 is considered the year with the most incidents recorded in the medical field. Although there are a growing number of regulations and procedures, it is noted that the loss of medical data is increasing.

In a study, Molnar-Gabor conclude that although the GDPR provides patients better control of the data they provide, it creates legal uncertainty and while it is meant to maintain a high level of protection, it makes the law more difficult to apply. Therefore, uncertainties could outweigh the benefits for several years [24].

Physicians from teaching hospital have more information about data protection and patients' rights protection. The use of patients' medical records is an essential part of medical education. But the use of patient information may conflict with the rules of GDPR, so it is necessary, in this context, for patients to decide whether their cases can be used for educational purposes and written informed consent is required. The teacher physician is responsible for storing and protecting patient data, but also for controlling access to information [25]. Moreover, even students should sign a confidentiality agreement and be informed about GDPR rules.

In general, physicians' perception is that information about legislative changes, procedures and regulations are cumbersome and too little promoted.

Most respondents believe that the level of information on patients' rights, personal data protection is low.

While the protection of patients' rights, the right to privacy and the protection of personal data are closely linked, they should not be treated as identical. In the context of the intensive use of personal data in the medical field and the complexity of the activity in this sector, such a regulation can be considered to bring both general and specific safeguards [26].

In conclusion, due to the changes that take place in the medical system, as well as the technological evolution, the protection of the patient's data as well as the protection of the patient's rights is also in a continuous evolution and adaptation. The study shows the need to periodically inform both healthcare staff and patients about the protection of patient data and the protection of patient rights and revealed a strong correlation between the level of education and the knowledge about data protection and patient's rights protection. Professional secrecy/confidentiality and patient data protection are at risk due to inadequate resources available both in private hospitals and in public hospitals e.g. lack of access control – one computer for 5 – 6 physicians and nurses with one user and one password for all of them; lack of private space for the patient interview and so on. Under the data protection regulations and considering the patients' privacy, the medical staff could benefit of special knowledge in applying Shared Decision Making concepts (SDM) which involves a deep dive into intimate detailing of the therapy approach, which has to be discussed either with the patient, or the patient and his family. Romanian public hospitals do not have, in their majority, designated meeting rooms where the privacy and secrecy of the patients' data can be observed. Although SDM and PCC (Patient Centered Care) are proven to enhance the efficiency of medical care and improve patient-physician communication and overall relationship, as an empirical conclusion, there are no optimal conditions to apply the above-mentioned concepts in Romanian public hospitals with regards to private conversations over medical data. The survey on the patient data protection and patient rights protection is the first study conducted in Romania.

Conflict of interest

The authors declare that they have no conflict of interest.

Study limitation

This study was conducted only in Moldova, North-east of Romania. To gain more data in this regard it is necessary that the questionnaire to be distributed in other areas of the country.

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