

# Ethical aspects in the use of electronic medical records: analyzing who matters the most

## *Aspectos éticos no uso de registros médicos eletrônicos: analisando o que mais importa*

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### ABSTRACT

**Purpose:** To investigate the patients' perspectives regarding the introduction of the electronic medical record into use in an ophthalmologic hospital and its impact on the doctor/patient relationship. **Methods:** The cross-sectional study analyzed the impact of the electronic medical record on the doctor-patient relationship based on the patients' opinions after electronic medical record implementation compared with use of traditional paper records. The same doctor attended all patients and completed questionnaires during patient interviews that analyzed empathy, punctuality, efficiency, information clarity, doctor cordiality, respect, trustworthiness, patient benefits from the technology, confidentiality, and humanized care. The inclusion criteria included age of 18 years or older, adequate cognition, previous treatment in the same institution by the same doctor using paper medical records and later the electronic medical record, and free and informed written patient consent. The exclusion criteria included age below 18 years, inadequate time to answer the questionnaire, first patient visit, doubtful interview responses, and first visit before 6 months after electronic medical record implementation. The data were analyzed descriptively by relative and absolute frequencies. A previous pilot study of 20 patients yielded 95% confidence intervals for the percentages of agreement for the electronic medical record questionnaire responses obtained and found that 160 patients was adequate for performing the study. **Results:** The patients reported that the electronic medical record had a positive impact on the doctor-patient relationship in all areas considered. Over 94% of patients responded affirmatively when questioned about their confidence in the confidentiality of their data, 38.3% noted changes in the doctor's concern for service and 68% agreed that clarity of the information provided by the doctor was greater with the electronic medical record. **Conclusion:** Based on the patients' perceptions, the EMR positively affected the doctor-patient relationship after the implementation of the technology in a private ophthalmologic hospital.

**Keywords:** Electronic health records; Medical records; Physician-patient relations; Information systems; Delivery of health care; Ophthalmology ; Ethics; Bioethics

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## RESUMO

**Objetivo:** Investigar as perspectivas dos pacientes em relação à introdução do prontuário eletrônico em uso em um hospital oftalmológico e seu impacto na relação médico / paciente. **Métodos:** O estudo transversal analisou o impacto do prontuário eletrônico na relação médico-paciente com base na opinião dos pacientes após a implementação do prontuário eletrônico em comparação com o uso de registros tradicionais em papel. O mesmo médico atendeu a todos os pacientes e completou questionários com pacientes que analisaram empatia, pontualidade, eficiência, clareza da informação, cordialidade do médico, respeito, confiabilidade, benefícios para o paciente da tecnologia, confidencialidade e cuidado humanizado. Os critérios de inclusão incluíam idade de 18 anos ou mais, cognição adequada, tratamento prévio na mesma instituição pelo mesmo médico, usando registros médicos em papel e, posteriormente, o prontuário eletrônico e consentimento livre e esclarecido por escrito do paciente. Os critérios de exclusão incluíam, idade abaixo de 18 anos, tempo inadequado para responder ao questionário, primeira consulta do paciente, respostas duvidosas à entrevista e primeira visita antes de 6 meses após a implementação do prontuário eletrônico. Os dados foram analisados descritivamente por frequências relativas e absolutas. Um estudo piloto prévio de 20 pacientes forneceu intervalos de confiança de 95% para as porcentagens de concordância para as respostas do questionário de prontuário eletrônico obtido e constatou que 160 pacientes eram adequados para realizar o estudo. **Resultados:** Os pacientes relataram que o prontuário eletrônico teve impacto positivo na relação médico-paciente em todas as áreas consideradas. Mais de 94% dos pacientes responderam afirmativamente quando questionados sobre sua confiança na confidencialidade de seus dados, 38,3% observaram alterações na preocupação do médico com o serviço e 68% concordaram que a clareza das informações fornecidas pelo médico era maior com o prontuário eletrônico. **Conclusão:** As vantagens do prontuário eletrônico foram o rápido acesso à informação, clareza dos dados, recuperação rápida e organizada da informação e agilidade nos serviços.

**Descritores:** Registros eletrônicos de saúde; Registros médicos; Relações médico-paciente; Sistemas de informação; Assistência à saúde; Oftalmologia; Ética; Bioética

## INTRODUCTION

The phrase medical record originated from the Latin *promptuarium*, meaning “places where things are kept.” Until relatively recently, medical data were recorded and stored on paper; however, with rapid technologic advances in medicine, a more dynamic, practical, and easily accessible system that optimized time and data collection quickly became mandatory.<sup>(1,2)</sup> In 1972, the National Center for Health Services Research and Development and the National Center for Health Statistics of the United States promoted establishment of a minimal structure for ambulatory medical records, and shortly thereafter the first patient electronic medical record (EMR) emerged.<sup>(2)</sup>

In Brazil, interest in EMRs began in the 1990s, and in 2002, the Health Ministry proposed a minimal set of patient information that had to be included in a medical record. The Federal Council of Medicine (CFM), in its 1638 and 1639 resolutions, recognized the EMR as a legitimate instrument of medical attendance.<sup>(3,4)</sup> The CFM determined that the patient’s medical record and the information in it should be discreetly maintained for legal and scientific reasons.<sup>(4)</sup> In July 2007, through resolution 1821,<sup>(5)</sup> the technical standards for the digitalization and use of information systems for storing and handling patients’ records were approved, and the standards authorized elimination of paper records and patient information exchange.<sup>(3-5)</sup>

Health care is one of the most critical arenas in Brazil and the advancement of information technology is essential for disseminating medical knowledge, improving patient care, decreasing the margin of error, and improving the quality of information regarding the clinical history of patients.<sup>(6)</sup> The evolution of systems to store information in a medical record was marked by a study conducted by the Institute of Medicine of the United States; its conclusions visualized a viable process and declared that the EMR was essential for organizing information for teaching, research, and better quality health care.<sup>(2)</sup>

The EMR is becoming more attractive to health institutions that frequently search collections of clinical and administrative information to optimize and quantify care, reduce operating costs, and control improvement and storage of information.<sup>(6)</sup> In practice, the EMR emerged to replace the traditional written records that

for the most part contain inconsistent, subjective, and unreadable annotations and require a large physical storage space.<sup>(2,6)</sup> Data from 2010 indicated that 5% to 9% of Brazilian hospitals had an EMR, and less than 1% had an EMR that was integrated with other areas, e.g., complementary examinations.<sup>(7)</sup>

According to previous reports, the advantages of EMRs include patient satisfaction with the provided services, time of patient care, prevention of medical information loss or adulteration, reduced paper consumption, and reduced physical storage space.<sup>(7)</sup>

The information stored in EMRs is provided confidentially by patients during care or is obtained from examinations or diagnostic and therapeutic procedures. Therefore, the confidentiality of the EMR is a patient right and supported by the Federal Constitution of 1988, in which article 5, item X, guarantees the inviolability of privacy, private life, image, and honor of people.<sup>(8)</sup> These rights also are provided in the Brazilian Penal Code article 159<sup>(9)</sup> and in most codes of professional health ethics. The information in the EMR can be disclosed only with the consent of the patient or his or her caretaker.<sup>(2,4,5)</sup>

Microbioethics is the branch of bioethics that studies the relationships between doctors and patients and institutions and health professionals and analyzes the consequences of the evolution of applied science within the limits of human dignity.

<sup>(1)</sup> Within the evolution of contemporary medicine, the EMR stands out; numerous scientific studies have reported that the technology is a great advance in medicine and facilitates medical work.<sup>(2,6,7)</sup> However, there is no strong evidence regarding the impact of the EMR on the doctor-patient relationship from the perspective of the patient. Studies have reported doctor-patient distancing when using this tool.<sup>(3)</sup> Bibliographic surveys on this subject are scarce and, therefore, it is unknown with certainty if the EMR positively impacts medical care when evaluated from the patients’ perception.

The basic characteristics that must govern bioethics are humility, interdisciplinary and intercultural competence, responsibility, and a sense of humanity.<sup>(1,2)</sup> Humanistic and scientific knowledge must always be considered together; separating them is a danger to the survival of human life and every ecosystem.<sup>(6,7)</sup> Technologic advances must be ethical in that they

must protect ecosystems and the environment in a generic way, which consequently affects every living being.<sup>(10)</sup>

Logging information is a daily task and duty of all healthcare professionals; the resultant medical chart or medical record is of paramount importance and aims to demonstrate the patient's evolution. Paper medical records have been used for a long time but are becoming obsolete, and several difficulties, such as the readability of the handwriting, paper deterioration, physical spaces for storage, loss of files, and others, undermine their continued use.<sup>(11-13)</sup>

With technologic evolution, EMRs have been gaining more and more prominence because they are designed to provide sustainability and support to users through use of complete information that facilitates decision making about optimal treatment for patients.<sup>(2, 10-13)</sup>

The current study evaluated, from the patients' perspective, the impact on the doctor-patient relationship after implementation of the EMR in a private ophthalmologic hospital.

## METHODS

The current cross-sectional study, which included 160 patients treated by the same physician, was conducted in a private hospital specializing in ophthalmologic care. The patient data had been stored previously in a traditional paper medical record and then in an EMR 6 months after integration of the technology into the practice. In the current study, the data were analyzed descriptively by means of absolute and relative frequencies. In addition, the 95% confidence intervals (CIs) for concordance percentages for the EMR questionnaire items also were determined during a previous pilot study that included 20 patients; the pilot study determined that a sample that included 160 patients was adequate for obtaining meaningful data in response to a questionnaire comprised of 10 objective questions. The possible responses to the questionnaire were yes, no, or do not know. The same attending doctor (GMC) administered the questionnaire 6 months after the implantation of the EMR. The total data collection required a period of 6 months and was developed with the application of the questionnaire. The same interviewer previously requested the authorization of the interviewee through the Free and Informed Consent Term (FICT). The Research Ethics Committee approved the study design and followed the tenets of the Declaration of Helsinki for human research and the FICT.

The same interviewer administered the questionnaire, which analyzed the basic criteria of medical ethics: empathy, punctuality, efficiency, clarity of information, cordiality, respect, confidence, benefits of technology to the patient, confidentiality, and humanized care.

The inclusion criteria included patient age older than 18 years, adequate cognition, and previous examination(s) at the same institution by the same doctor with data input into a traditional paper medical record, provision of the FICT to the patient, and the spontaneous willingness of the patient to participate in the study.

The exclusion criteria included inadequate time to respond to the questionnaire, patient interview during first consultation, dubious responses during the interview (ex: when the patient does not understand the context or does not remember about the medical consultation, but answer anyway), and first consultation within 2 months of EMR implantation.

The pilot study that included 20 consecutive patients during 6 months of EMR implementation resulted in a CI of 95% for the estimated global population (n=160), according to the care history of the previous 6 months.

The data obtained through the administration of a questionnaire comprised of 10 objective questions were analyzed descriptively by means of the absolute and relative frequencies. The 95% CIs were presented as the percentages of agreement for the EMR questionnaire items.

The questionnaire present in this study was elaborated based on the literature references, but has not been validated or previously applied to another similar work. That makes the study unpublished, with great scientific relevance.

**Table 1**  
**Distribution of responses to the electronic medical record questionnaire items**

	N	%
1 - In your opinion, has there been any positive change in the doctor's concern about your care?	160	100.0
Yes	59	36.9
No	95	59.4
Do not know	6	3.8
2 - Was the waiting time for the care greater than usual?	160	100.0
Yes	39	24.4
No	117	73.1
Do not know	4	2.5
3 - Was the consultation time longer than usual?	160	100.0
Yes	23	14.4
No	134	83.8
Do not know	3	1.9
4 - Was the clarity (knowledge) of the information provided by the doctor greater with the electronic medical record?	160	100.0
Yes	102	63.8
No	48	30.0
Do not know	10	6.3
5 - Did you feel comfortable in your relationship with the doctor?	160	100.0
Yes	158	98.8
No	2	1.3
6 - Did the doctor show you respect?	160	100.0
Yes	157	98.1
No	3	1.9
7 - Did you feel confident about the treatment offered?	160	100.0
Yes	152	95.0
No	3	1.9
Do not know	5	3.1
8 - Do you think that electronic medical record has advantages over the traditional paper record?	160	100.0
Yes	106	66.3
No	6	3.8
Do not know	48	30.0
9 - Did you feel secure about the confidentiality of your data?	160	100.0
Yes	155	96.9
No	1	0.6
Do not know	4	2.5
10- Did you feel more welcomed, that is, your complaints were valued?	160	100.0
Yes	154	96.3
No	3	1.9
Do not know	3	1.9

**Table 2**  
**Matching percentages of the items**

	N (%)	CI 95%
1 - In your opinion, has there been any positive change in the doctor's concern about your care?	59/154 (38.3)	(30.6-46.5)
2 - Was the waiting time for the care greater than usual?	39/156 (25.0)	(18.4-32.6)
3 - Was the consultation time longer than usual?	23/157 (14.6)	(9.5-21.2)
4 - Was the clarity (knowledge) of the information provided by the doctor greater with the electronic medical record?	102/150 (68.0)	(59.9-75.4)
5 - Did you feel comfortable in your relationship with the doctor?	158/160 (98.8)	(95.6-99.8)
6 - Did the doctor show you respect?	157/160 (98.1)	(94.6-99.6)
7 - Did you feel confident about the treatment offered?	152/155 (98.1)	(94.4-99.6)
8 - Did you feel secure about the confidentiality of your data?	106/112 (94.6)	(88.7-98.0)
9 - Did you feel more welcomed, that is, your complaints were valued?	155/156 (99.4)	(96.5-99.9)
10 - In your opinion, has there been any positive change in the doctor's concern about your care?	154/157 (98.1)	(94.5-99.6)

N: number

## RESULTS

The questionnaire responses were analyzed to determine the patients' perspectives regarding the doctor-patient relationship before and after the EMR implementation.

Because the inclusion and exclusion criteria minimized confusion and the sampling was statistically more reliable, the studied variable was the effect of the EMR on the doctor-patient relationship compared to the traditional medical record based on the patients' perspective. Table 1 shows the responses to the questionnaire items from the 160 patients.

In table 1, except for the item regarding the advantages of the EMR over the traditional paper record, to which 30.0% of patients did not respond, the other questions had 6.3% or less of responses to which the patients responded that they did not know. The percentages of agreement and their 95% CIs are shown in table 2. In this analysis, the "do not know" responses were disregarded.

Table 2 shows that over 94% of patients responded affirmatively when questioned about their confidence in the confidentiality of their data, their comfort level with their relationship with their doctor, the respect shown to them by their doctor, the degree of welcoming they felt and the value given to their complaints, the confidence in their treatment plan, and if they believed the EMR offered advantages over the use of the paper medical record. In addition, 38.3% (95% CI, 30.6-46.5) responded that there was a change in the doctor's concern for service, 25.0% (95% CI, 18.4-32.6) reported that the waiting time for service was longer than usual, 14.6% (95% CI, 9.5-21.2) responded that the consultation time was longer than usual, and 68% (95% CI, 59.9-75.4) agreed that clarity (knowledge) of the information provided by the doctor was greater with the EMR.

## DISCUSSION

The objective of this study was to evaluate the impact of the EMR from the patients' perspective. To our knowledge, this is the first such study to evaluate this subject (search: PUBMED, February 10, 2018).

Table 1 shows that most of the patients' responses were positive regarding the use of the EMR. The confidence in the confidentiality of the medical data felt by the patients (confidentiality principle) was noteworthy, with 96.9% of the patients responding yes. The patients felt confident, respected, and comfortable during consultations. The clarity of information when using the EMR also was noteworthy (question 4), in that 63% of patients perceived greater clarity with the use of the EMR and reported that they have a better understanding of their examinations using the computer than previously on paper.

Some previously reported disadvantages associated with the EMR were that more than 50% of physicians believed that the doctor-patient relationship was affected negatively by EMR implementation, arguing that the computer represented a third person during medical consultations.<sup>(2,10-13)</sup> This observation should be considered, because it suggests a disadvantage associated with use of the EMR in the patients' eyes; this observation was not found in the current study.

Regarding the question about whether the EMR has advantages over the traditional paper record (principle of patient's benefit), 30% of patients responded that they did not know. This raises questions about whether the patients did not feel a difference between use of the EMR and the traditional paper record, were prepared to answer the inquiry, or did not understand the question. Most patients who responded that they did not know were of an advanced age, which may have affected the response. However, there is no way of knowing how the implementation of the EMR has provided advantages for the hospital, patients, physicians, and all hospital health professionals. This is due to failure to establish indicators that could indicate the effectiveness of this technology.<sup>(7)</sup>

The analysis of empathy (question 1) indicated that 59.4% of patients did not discern any difference in the doctor's concern about their care; however, 36.9% of patients responded yes because of the perception that with use of the EMR there was a greater approximation and medical concern during the consultation compared with the traditional paper medical record, which does not agree with some reports.<sup>(2,10-13)</sup>

Regarding punctuality and efficiency (questions 2 and 3), i.e., the lengths of the waiting time for medical treatment and the consultation time, respectively, the answers indicated that there was no difference in the times, 73.1%, and 83.8%, respectively. The answers agreed with a report by the Heart Institute that its experience with EMR implementation showed that the benefits were increased agility in the registry and medical conduct, thus reducing the waiting time for medical care.<sup>(7)</sup>

However, other studies disagreed and considered the EMR to be disadvantageous, with increased time spent on patient care resulting from the learning curve for use of the new technology.<sup>(2,11,13)</sup> It also was noteworthy that regarding cordiality, respect, trust, and humanized care (questions 5, 6, 7, and 10), more than 95% of the patients interviewed answered yes, indicating that the implementation of this tool does not mechanize the medical care or harm the doctor-patient relationship. To the contrary, the patients felt respected, welcomed, and that their complaints were valued. These current results negated statements by some health professionals who expressed annoyance about the EMR be a tool that could mechanize medical care, compromised the humanization of care,

and that patients felt uncomfortable when the doctor divided his attention between the patient and the computer.<sup>(6)</sup>

In the fifth century BC, Hippocrates already encouraged physicians to record their assessments of patients to maintain control over the progression or stability of a disease. In Greek, “ethos” means ethics, i.e., that which belongs to good custom, universal principles, actions that we believe and do not change regardless of where we are.<sup>(2,10)</sup>

In 2007, resolution 1821 of the Brazilian Federal Council of Medicine authorized use of computerized systems to store and record medical information.<sup>(5)</sup> Among the advantages inherent in the EMR are rapid, organized access to information, data clarity, and service agility; however, achieving those advantages requires the solving of ethical, legal, and technical problems.<sup>(2,10-13)</sup>

Among the disadvantages are, more time spent in patient care, the learning curve associated with the new technology, hardware or software defects introducing malicious programs or even viruses to obtain sensitive data could cause loss of all medical files, and also doctor-patient relationship interference. A study on this subject reported that more than half of the professionals interviewed believed that the patient’s medical relationship was affected by implementation of the EMR; they argued that the computer would leave mechanized the medical appointment.<sup>(2,10-13)</sup>

The current study sought the patients’ opinions, following a humanistic philosophy, on the main elements of the doctor-patient relationship, which in most studies of EMRs have not been considered. Therefore, the current objective was to study, through a questionnaire, the patient’s perception of the EMR.<sup>(10-13)</sup> The methodology is classified as exploratory, in which a bibliographic survey was conducted on the subject and interviews were performed with patients who previously received a FICT and who agreed to participate in the interviews.<sup>(10)</sup> As limitations of the study, we can mention the communication bias in obtaining the results, because the same doctor who attended the patient, applied the questionnaire.

The interest in this research arose because in some studies the same statement was observed in which the doctor-patient relationship was impacted negatively due to the use of the EMR. Since the computer is the reason for the distance between the binomial (doctor-patient), several authors have approached this problem in this relationship regarding the informatization of the medical record.<sup>(11,12)</sup> The humanization and dehumanization dilemma that may be caused by the computer is a concern that emerged at the end of the 20th century and should be considered, because no hardware or software can replace the doctor and his or her attention to patients, which supplies them with hope.<sup>(13)</sup>

“Know all the theories, master all the techniques, but as you touch a human soul, be just another human soul” (Carl Gustav Jung).

## CONCLUSION

Based on the patients’ perceptions, the EMR positively affected the doctor-patient relationship after the implementation of the technology in a private ophthalmologic hospital.

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