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PROPOSTA DE APLICABILIDADE DA PRESERVAÇÃO DIGITAL AO PRONTUÁRIO ELETRÔNICO DO PACIENTE

APLICABILITY PROPOSAL FOR DIGITAL PRESERVATION OF PATIENTS' ELECTRONIC RECORDS

PROPUESTA DE APLICABILIDAD DE LA PRESERVACIÓN DIGITAL A LA HISTORIA CLINICA ELECTRONICA DEL PACIENTE

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RESUMO: Apresentam-se os resultados preliminares de uma pesquisa sobre a preservação e a curadoria digital, bem como a possibilidade de aplicabilidade ao contexto da documentação sanitária, enquanto memória da saúde. A pesquisa teve por base a seguinte questão: Como o padrão *Open Archival Information System* (OAIS) pode ser aplicado aos prontuários eletrônicos do paciente, na perspectiva da preservação de conteúdos digitais, visando a assegurar a confidencialidade, confiabilidade, autenticidade e acesso, a quem de direito, à informação registrada nesses documentos? O objetivo básico é estudar a literatura referente à preservação e à curadoria digital, com ênfase no padrão OAIS, considerando a possibilidade de sua aplicação para o desenvolvimento de um Repositório Digital de Prontuários Eletrônicos de Paciente, observando-se o ordenamento jurídico concernente a esse tipo de documento. Pesquisa exploratória pautada no levantamento do estado da arte sobre o tema em lide. O corpus do estudo foi constituído de 01 (um) prontuário (cinco volumes) da especialidade da nefrologia, com recorte no ano de 1970. O estudo empírico foi no Serviço de Arquivo Médico e Estatística, do Hospital Universitário Walter Cantídio da Universidade Federal do Ceará. Os achados evidenciam que, embora já existam várias iniciativas sobre a preservação digital da documentação cientifica tecnológica e cultural, não encontramos experiências sobre prontuários. Ademais, o modelo OAIS pode ser aplicado ao contexto do prontuário eletrônico do paciente desde que observadas às características particulares de legalidade de acesso a esses documentos, bem como os requisitos e/ou diretrizes para implementação de um Repositório Digital para Prontuário Eletrônico de Paciente.

PALAVRAS-CHAVE: Preservação digital. Prontuário eletrônico do paciente. Curadoria digital.

ABSTRACT: We present the preliminary results of a research on digital preservation and curation, as well as the possibility of applicability to the context of health documentation, as a memory of health. The research was based on the following question: How can the Open Archival Information System (OAIS) standard be applied to patients' electronic records, with a view to preserving digital contents, to ensure confidentiality, reliability, authenticity and access to who rightly owns the information recorded in these documents? The basic objective is to study the literature regarding preservation and digital curation, with emphasis on the OAIS standard, considering the possibility of its application for the development of a Digital Repository of Electronic Patient Records, observing the legal order concerning this type of document. Exploratory research based on the state of the art survey on the topic under discussion. The corpus of the study consisted of 01 (one) medical record (five volumes) of the specialty of nephrology, focusing on the year of 1970. The empirical study was in the Medical and Statistical Archive Service, Walter Cantídio University Hospital of the Federal University of Ceará. The findings show that, although there are already several initiatives on the digital preservation of scientific technological and cultural documentation, we did not find experiences on medical records. Furthermore, the OAIS model can be applied to the context of the patient's electronic medical records, provided the particular characteristics of legality of access to these documents are observed, as well as the requirements and/or guidelines for implementing a Digital Repository for Electronic Patient Records.

KEYWORDS: Digital preservation. Electronic patient records. Digital curation.

RESUMEN: Se presentan los resultados preliminares de una investigación sobre la preservación y la curaduría digital, bien como la posibilidad de aplicabilidad al contexto de la documentación sanitaria, mientras que memoria de la salud. El problema de la investigación es: ¿Cómo se puede aplicar el estándar Sistema de Información de Archivo Abierto (OAIS) a las historias clínicas electrónicos del paciente, en la perspectiva de la preservación del contenido digital, con el propósito de asegurar la confidencialidad, la confiabilidad, la autenticidad y el acceso, a quién tiene el derecho, a la información registrada en estos documentos? El objetivo básico es estudiar la literatura concerniente a la preservación y la curaduría digital, con énfasis en el estándar OAIS, teniendo en cuenta la posibilidad de su uso para el desarrollo de un Repositorio digital de las historias clínicas electrónicas del paciente, observándose el ordenamiento jurídico de este tipo de documento. Es una investigación exploratoria basada en el análisis del estado del arte sobre el tema. El corpus del estudio fue constituido de 01 (una) historia clínica electrónica del paciente (cinco volúmenes) de la especialidad del nefrología, concerniente el año de 1970. El estudio empírico ha sido hecho en el servicio del archivo médico y estadística, del hospital Walter Cantídio de la Universidad Federal del Caerá. Los resultados evidencian que, sin embargo algunas iniciativas ya existen la preservación digital de la documentación científica tecnológica y cultural, pero no han sido encontradas experiencias en las historias clínicas electrónicas del paciente. Además, el estándar OAIS se puede aplicar al contexto de esto documentación desde que se observen las características particulares de su legalidad del acceso, así como los requisitos y/o las directrices para sé colocar en práctica un repositorio Digital para las historias clínicas electrónicas del paciente.

PALABRAS CLAVE: Preservación Digital. Historias clínicas electrónicas del paciente. Curaduria digital.

1 INTRODUCTION

The striking speech of the philosopher Jacques Derrida draws attention to the unique need to preserve documentation for future generations. In the Health field, this practice becomes fundamental, not only in relation to the results of scientific research, but also, of Electronic Patient Records (PEP), due to the frequent appearance of new diseases as well as the resurgence of others, almost always with innovative features and often much more powerful. Preservation of the PEP - a major representative of the so-called sanitary documentation - would guarantee research and comparative studies based on these sources to investigate the emergence of these diseases or whether they are 'innovated' as well as the therapeutic measures implemented in view of their Cure, or even the prescribed guidelines for living with them. Therefore, the decision on a policy of preservation of these documents is sine qua non both for evidence-based medicine and for research, teaching and legal evidence, when dealing with issues of treatment, ethical conduct or another factor.

Considering the history of information preservation, it is well known that it follows the history of humanity from the most remote records of knowledge of the time, such as those made on the walls of caves, papyrus and parchments. However, in the ambit of Library and Information Science, the catalog of the Library of Alexandria prepared by Calimachus and the publication of the Bibliotheca universalis in 1545 by Conrad Gesner have been preserved. In the formal education of these areas, the work entitled Cours de bibliographie by Louise-Noelle Malclès, published in 1954, stands out. However, the progress made in documentation preservation took place through the establishment of policies developed by the United Nations Educational Scientific and Cultural Organizations (UNESCO) and the International Federation of Library Associations (IFLA), published in 1970.

These policies establish the goal of collecting and making available bibliographic records of all countries in an international information network, considering the possibility of knowing the existence of the document, its location and access. These actions have been prescribed in the proposals and traditional methods of Universal Bibliographic Control through the institutionalization of the 'legal deposit' still in force in the national libraries of the different countries of the world.

However, given the great production of knowledge records in digital media provided by the latest electronic and digital information and communication technologies, this certainty of security is already beginning to be questioned. According to Térmens (2013), digital support is fragile and there is still no security confirmation of its long-term preservation due to the degradation of the raw material used in its manufacturing and the obsolescence of the technological media of storage recording and and the costs involved. In addition to these characteristics, it is also important to mention the skills of librarians, archivists and museologists to work in this new niche of work.

In the face of this problem, the United Nations Educational, Scientific and Cultural Organization (UNESCO) took up these issues and launched in 2003 the 'Letter on Digital Preservation' and the 'Free Software for Repository and Preservation System 'In 2007. According to the UNESCO Guide (2003, p. 28-30), digital preservation is defined as the set of activities or processes responsible for ensuring long-term access to information and cultural heritage existing in digital formats. In the perception of Arellano (2008, p.23), such preservation is not confined only to bitstream sequences. On the contrary, it is associated with the "[...] set of decisions that defined the basic formation of the informational object as a single object" and involves the "[...] determination of digital metadata of the contents of the documents in the stored information and in the way they were stored." In other words, it is at the core of the theoretical and pragmatic actions of the disciplines that make up the Information Science area, mainly associated to both the descriptive and thematic representation of information as well as to mediation and management.

There are already several metadata preservation models, among them the Open Archival Information System (OAIS) standard, which proposes to describe a conceptual framework for a complete and universal system of permanent digital document storage and specifies how digital documents should be preserved since its insertion in the digital repository until its availability for access by the end user (FLORES, HEDLUND, 2014). However, when it comes to patient records, we did not find literature directly addressing this issue.

This is one of the motivations to investigate this object of study, based on the following question: How can the OAIS standard be applied to the patient's electronic records, in view to preserving digital contents, in order to ensure confidentiality, reliability , authenticity and access, to those who rightly own the information recorded in these documents? In the search for answers to this research problem, we defined as a goal to study the literature regarding preservation and digital curation, with emphasis on the OAIS standard, in order to consider the possibility of its application for the development of a Digital Repository of Electronic Records of patients, considering the confidentiality, reliability, authenticity and access to information retrieval, observing the legal order concerning this document.

The methodology adopted in this research shows it is an exploratory qualitative study, with the functionalist method as support for our analysis, since, according to Kruppa (1994, p. 55), this method understands society as a "[...] Living organism, an integrated whole, where each part performs a function necessary to balance the whole." When this concept is applied to the Electronic Patient Record, it can be inferred that it is configured as an organism whose structure is constituted by a set of documents with the necessary records so that the illnesses the patients are confront are known, as well as the actions to be or that have already been implemented in favor of curing the diseases and restoring the patient to the normal state.

For the study of the medical records, we are based on the analysis of the contents registered in these documents, in order to be able to structure some categories that will allow the applicability of the OAIS standard. The corpus of the study consisted of one (01) medical record (five volumes) of nephrology, with the cut-off/delimitation of the year 1970. The locus of the empirical study is the Medical and Statistical Archive Service (SAME) of Walter Cantídio University Hospital of the Federal University of Ceará.

2 BIBLIOGRAPHIC EXCHANGE ON DIGITAL PRESERVATION

For the purposes of this article, we consider it important to state our understanding of preservation. Such concept refers us to the idea of safeguarding things and objects of the world as well as to the relations of affectivity between the subjects. It is set up as a kind of care, defense support, in the broad sense of the term. However, in the scientific environment, Silva (1998, p. 2) presents as preservation concept "... any action that is intended to safeguard or recover the physical conditions [of documents]."

Concerning digital preservation, it emerges with the predominance of the electronic medium and its 'transversality' in daily practices and in all dimensions of life (TAVARES, 2012). It is not a fad, but a new culture that needs to be encouraged, so that the cultural, scientific and technical documentary heritage is not lost. Hedstrom (1996, p.189) states that digital preservation refers to "[...] planning, resource allocation and application of methods and technologies to ensure that digital information of continuous value remains accessible and usable [...]."

On their turn, Waters e Garrett (1996) present the concept of digital preservation associated to the intellectual aspects of the document, its integrity and accessibility of long-term information. They further argue "[...] preservation of integrity and accessibility is not only limited to protecting digital information against unauthorized access...", but also "...against misuse resulting from misinterpretation or misrepresentation of information by computer systems [...]", to which we also add human intervention. The United Nations Organization for Science and Culture (UNESCO, 2003, p. 18) extends this concept by clarifying that digital preservation "[...] is used to describe the processes involved in maintaining information and other types of existing digital assets."

Based on the concept formulated by UNESCO, Arellano (2008, p. 30), in his reflections, argues that an effective digital preservation demands the adoption of basic conditions, methods and technologies that allow integrating the levels of preservation "physical, Logical and intellectual nature of digital objects ". According to the author, physical preservation focuses on "[...] contents stored on magnetic media (audio and cassettes, VHS and DAT tapes) and optical discs (CD-ROM, WORM and rewritable optical discs)." In relation to logical preservation, it seeks "in technology, updated formats for insertion of data (electronic mail, audio and audiovisual material and network material), new software and hardware that keep its

bits current, in order to preserve its reading capacity ", while in the context of intellectual preservation the "[...] focus are the mechanisms that ensure the integrity and authenticity of information in electronic documents." In this line, the National Archive Council (CONARQ, 2009, 15) argues that [...]" The challenge of preserving digital archival documents is to guarantee continuous access to their contents and functionality, through technological resources available to the time of its use." This challenge applies to other categories of documents.

We believe that in this type of preservation, Intellectual Property issues must also be observed, since the vulnerability of these documents can generate damages for its authors and users. Therefore, Intellectual Propriety Rights (IPR) (apud ARELLANO, 2008) directs that in this case, consideration should be given not only to the content but also to any action related to the software (copies, encapsulation of content, software emulation, migration of content) that may infringe the authorizations of specific use to which it was accredited. Regarding the electronic patient record, all the requirements are relevant, since the records of the health conditions of a citizen demand a greater accuracy in the treatment of these sources, both from the point of view of the integrity of their content as well as aspects of confidentiality and reliability in their access.

2.1 Requirements, strategies and standards of digital preservation

Digital preservation requires adherence to certain requirements so that results are not compromised. The requirements may be of a functional or non-functional nature. Bullock (1999); Thomaz and Soares (2004), Formenton, Gracioso and Castro (2015), supported by the concepts of the OAIS model, identify nine minimum requirements for digital preservation, namely:

a) To set the boundaries of the object to be preserved by clearly defining which elements will be effectively maintained.

b) To preserve the physical presence consisting of protecting the physical files, that is, the primitive layer of support of the information to be represented (computer files, series of bits).

c) To preserve the content by ensuring the access ability at its lowest level, for example, ASCII text, regardless of changes, modifications and other variations of fonts and layout features.

d) To preserve the visual presentation through the application of fonts of different formats and sizes, presence of white space, columns, margins, headers, footers, pagination, and so on.

e) To preserve the functionality of the original, for example, verbal texts, graphics, audio and video embedded, hypertext format.

f) To preserve the authenticity by ensuring that the accessed object is exactly the sought one, having been preserved in its original form.

g) To accompany the digital object over time, being necessary to locate it in the correct edition or version.

h) To preserve the provenance by identifying the origin of the object and detailing its history in order to confirm its authenticity and integrity.

i) To preserve the context, maintaining its dependence on hardware and software, its modes of distribution and its relationships with other digital objects.

In addition to these requirements, it is necessary to observe the documents prepared by the Technical Chamber of Electronic Documents (CTDE) of the National Council of Archives (CONARQ), which deal with the requirements for computerized archival records management systems - e-ARQ Brazil. As well as the Guidelines for Implementation of Reliable Digital Repositories of Archival Documents and Technical Guidance in the 3 - Scenarios for the use of RDC-Arq in conjunction with the SIGAD. Such documents indicate parameters for reliable digital repositories and/or archival systems so that authenticity, identity, integrity, confidentiality, availability, access and preservation can be guaranteed, given the perspective of the need to maintain documentary collections for long periods Of time or, even, permanently (CONARQ, 2015). It is worth mentioning that, although these normative documents mention the patient record in its scope as a documentary type, they do not contemplate the digital preservation requirements for this type of document with particular characteristics, governed even by specific regulations, such as the Federal Council of Medicine (CREMEC) and the Federal Nursing Council (COFEN).

Regarding digital preservation strategies, Bullock (1999) reviewed the literature and organized it into two groups: preservation strategies, which include migration, emulation, printing and preservation of technology. And also those that "take control of the situation," that is, they require the adoption of standards, the development of guides, the documentation of the sources and the investment in infrastructure - hardware, software and personnel - and/or partnerships. In addition to these strategies, preservation and digital curation necessarily require the determination of digital metadata. It is therefore directly inserted in the area of thematic or indexal and descriptive representation of the information. According to Bentes Pinto (2001), the thematic representation is understood as the set of activities that seek to identify, in verbal or nonverbal texts, the clues that can be considered as better indicators of its content aiming at the recovery of the document itself or the knowledge recorded in them.

Regarding the metadata, the Working Group on Preservation Metadata (WGPM) of the Online Computer Library Center (OCLC) classifies them according to functional categories or reasons for their adoption in:

a) Descriptive – to facilitate the identifying and discovery of sources.

b) Administrative – to support the management of sources within a series.

c) Structural – to connect or gather the componentes of a complex informational object (WGPM, 2001, p. 3).

UNESCO (2003, p.94) goes further to define that the objectives of the adoption of digital preservation metadata are:

a) Identifying the material for which the preservation program is responsable.
b) Informing what is necessary to maintain and protect the data.
c) Informing the user, when applicable, what is necessary to resubmit the intended object, or its defined essential elements, regardless of changes in storage and access technologies.
d) Recording the history and effects of the facts related to the object.
e) Documenting the identity and integrity of objects to ensure their authenticity.
f) Allowing the user and the preservation program to understand the context of the object.

Innarelli (2007, p. 71) adds that digital preservation "[…] is not restricted to the study of media, backup techniques, migration techniques, authentication techniques, etc." Goes on to add that "this subject must be studied in an interdisciplinary and institutional way, and it is up to the information professionals to guarantee the preservation and maintenance of the digital document in a complete and authentic way."

These reflections show studies and research involving the issue of digital preservation regarding electronic patient records, since it is a unique document for the preservation of the memory of health in the world.

2.2 Some standards of digital preservation and curation

In what concerns the models and patterns of digital preservation, we found several, among them: Open Archival Information System (OAIS), Trusted Digital Repository Model (TDR), Preservation Metadata: Implementation Strategies (PREMIS). In this article, we will focus only on the OAIS Model.

The Open Archival Information System (OAIS) is a conceptual reference model, still considered as an open system for archiving information that disciplines the preservation and maintenance of access to information in the long term. It was commissioned by the International Organization for Standardization (ISO), developed and coordinated by the Consultative Committee for Space Data Systems (CCSDS) in the NASA environment. In 2003, it became an international standard, called ISO 14721:2003, with the goal of establishing an information archiving system through an organizational diagram composed of people who accept responsibility for preserving information and making it available to a community (SOUZA, et al., 2012).

The OAIS is made up of four entities: Producers, Consumers, Administration and the Archive itself. Producers provide the information to be preserved. Consumers use the preserved information. A special class of consumers is the target community (set of consumers capable

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of understanding the preserved information). Administration is the entity responsible for setting the most general file policies, but it is not involved with the file routine (this activity is performed by a function within the file itself). Image1 below illustrates this environment.

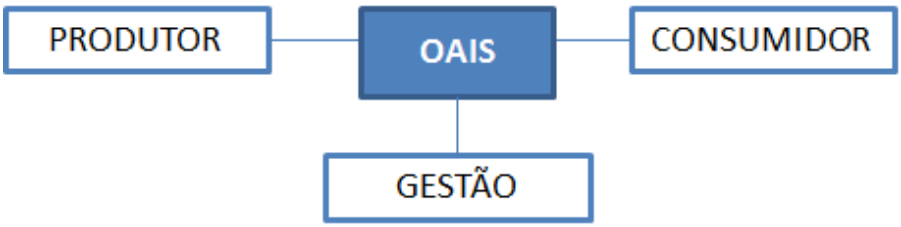

Image 1. The contexto of na OAIS model
Source: NASA/CCSDS, 2012.

The OAIS functional model is broader and consists of six large blocks of processes within a digital preservation file: ingestion, storage, data management, administration, preservation and access planning (Image 2).

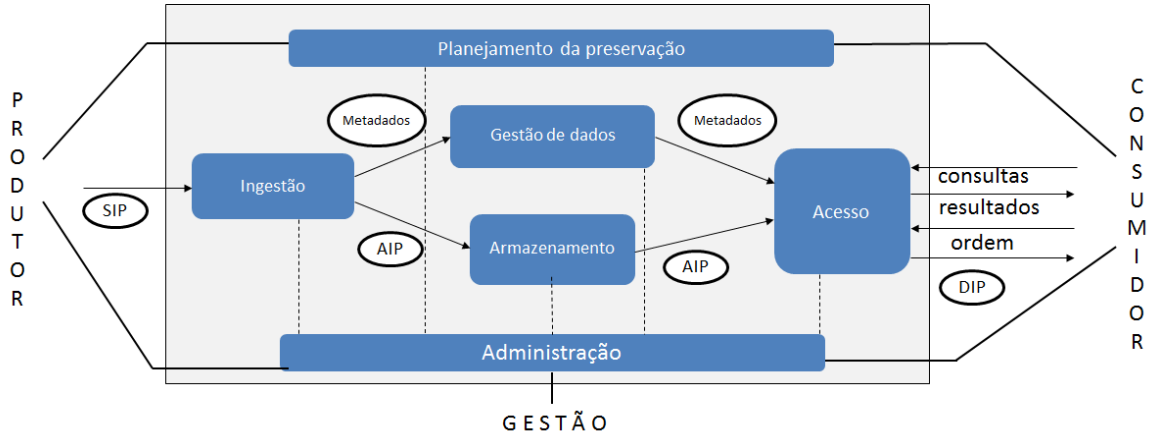

Image 2. OAIS model's functional scheme Esquema funcional do modelo OAIS
Source: NASA/CCSDS, 2012.

The functional entities manage the information flow between the entities that form the OAIS environment and identify the functional components of the files related to the preservation of digital objects (ARELLANO, 2008, p.20).

It is also important to understand the information model for insertion of long-term digital information preservation metadata that the OAIS scheme included. This pattern takes into account that creating and deploying preservation metadata tend to be a key component of most digital preservation strategies.

3 EMPIRIC STUDY

As we have already mentioned in this article, the experiences of digital preservation have been put into practice in the context of cultural, scientific and technological memory. Therefore, we deem necessary the application of this technology in health organizations, particularly in the documentary collection related to the care actions of a sick person.

The corpus of the study consisted of 01 (one) Electronic Patient Record (five volumes), specialized in nephrology, with a delimitation of the year 1970 for the study, to contemplate Brazilian legislation on the custody of these documents, which has "[...] a minimum period of 20 (twenty) years, from the last record, for the preservation of medical records..." (BRAZIL, 2002, p.2). Because the medical record is registered analogically (paper) and organized in five volumes, with approximately 500 (five hundred) pages, we asked SAME for permission to digitize it in order to facilitate the handling and study of this documentation for the construction of an initial digital preservation proposal specific to this type of document.

The locus of the empirical study is the Medical and Statistical Archive Service (SAME) of the Walter Cantídio University Hospital (HUWC) of the Federal University of Ceará (UFC), which is financed by the Unified Health System (SUS) and a reference in kidney transplantation, reason that motivated the choice of medical records of this specialty.

3.1 Research Corpus: electronic patient's records

The patient record is a document drafted by the health multidisciplinary team in their actions to care for the sick person. This documentation includes the records of data, information and clinical and non-clinical knowledge that becomes the so-called Sanitary Documentation. As prescribed by Resolution No. 1,638 / 2002, of August 9, 2002, of the Federal Council of Medicine (CFM), it is considered a record a

> [...] a single document consisting of a set of registered information, generated from facts, events and situations on the patient's health and the legal, confidential and scientific assistance provided to him or her, which enables communication between the multiprofessional team members and the continuity of care provided to the individual.

Although the patient's medical record has the function of clinical documentation, it is also included in the range of documents for use by health organizations in their care, management, didactic, research actions, as well as a financial and legal document. According to the final report of the Grupo de Expertos en Información y Documentación Clínica da Espanha (GEIDCESP, 2001, online),

> Clinical information [which is recorded in clinical documentation] is also part of the process of active participation of patients or users in clinical decision making. In this sense, the first thing to note is that information is a process of relationship and is, therefore, a dialogical, spoken process, in which there is a continuous interaction and exchange of information between the health organization and the patient.

Therefore, according to Professor Casabona et al. (2006), are included in the clinical documentation, in addition to the verbal texts, those considered non-verbal, such as: imaging tests, reference values for chemical and laboratory tests. The functions of clinical documentation are, among others, to facilitate and improve patient care, to facilitate and fasten communication between the multiprofessional team, as well as their interaction with the patients, as well as being a source of information for research and clinical and epidemiological studies that may be used in the education, management and inspection processes of health auditing agencies. The medical record is also a source that expresses health indicators.

Regarding non-clinical documentation, even if it is fundamental in the care process, it is not related to health data. Examples of this type of documentation are those related to administrative, nutritional, pharmacy, maintenance, protocols, diets, etc. In the understanding of Casabona et al. (2006, p. 142), all data, information and knowledge generated within health organizations are classified as sanitary data, although not always clinical. This documentation is related to patients and the management of services. The first case - related to patients - includes the prescriptions, requests for exams, referrals to specialists, discharge report, data related to health plans etc. Now in the second case, we find material requests, contracts, call scales, holiday requests, protocols, contracts, controlled vocabularies or thesaurus, etc. Corroborating this idea, Bentes Pinto (2014, p.5), understands the sanitary documentation as being a

> [...] very particular type that escapes the characteristics of other types of gray literature, starting with the protection of access guaranteed by general and specific legislation. The understanding of this documentation is necessary in order for it to be represented and organized in order to meet the needs of those who seek it, respecting the legal system of each country and also international, such as the Constitution, Access to Information Law, Universal Declaration of Human Rights and the Universal Declaration of the Human Genome.

In turn, the legal aspects related to the medical record involves authorship, ownership of medical records, authorization of access, confidentiality, reliability, security and preservation, described below:

a) Authorship – We can consider that the authorship of the record is collective, since the multiprofessional health team (physicians, nurses, nursing technicians, physiotherapists, psychologists and social workers) writes in these documents. Some make raw data annotations; Others interpret patients' narratives and add their knowledge in decoding the messages emitted by them, or even information from their professional knowledge. Thus, the writing of the medical record is, in a way, collective.

b) Access – Although the medical records belong to the patient, their access demands special care and is ensured by legislation related to health ethics, such as the Federal Council of Medicine (CFM) and the Federal Nursing Council (CFEN). In addition to these, in the Brazilian case, access to this documentation is ensured by item X of article 5 of the Federal Constitution of 1988 which states: "intimacy, privacy, honor and image of persons are inviolable, guaranteed the right to compensation for the material or moral damage resulting from its violation" (BRAZIL, 1988, p. 2). It is therefore understood that that right is of

undoubted relevance. There are several other laws that provide for the inviolability of privacy and intimacy, such as the Penal Code, Civil Code, Criminal Offenses Act, Codes of Ethics, Universal Declaration of Human Rights, among others.

c) Confidentiality – It can be said that it refers to the distinction between public and private. It is the assurance that the doctor and other staff members should assure the patient that their data will not be disclosed without their consent.

d) Reliability – Is based on the trust that patients place in the records made by physicians and other professionals of the multiprofessional patient care team.

e) Security – Guarantee that the data recorded in the medical records or in the documents that compose it are protected. One of the options that is already being used for data security generated in PEPs is encryption.

f) Digital preservation – Attentive to the care needed to maintain the integrity of what was recorded in the patient's electronic records and those who are in the analog support.

4 PRELIMINARY RESULTS

From the literature studies on the OAIS model, we realized that, regardless of the type of documentation, the planning of a digital preservation project is complex, since it involves a huge amount of variables throughout its development and long-term follow-up.

Regarding the possibility of applicability to the Patient's Electronic Record (PER), which records the information and knowledge of all care actions undertaken for the health of a sick person and that may serve as a research source, including for the Big Data in health, this preservation is even more complex. In this sense, we consider, among others, the following variables: multiterminological, thematic metadata, descriptive, access and retrieval of information, financial and legal, political, strategic, educational and research, management, interoperability, security, authenticity, privacy, reliability, confidentiality of patient data and professional secrecy. Therefore, in the digital preservation of the PER, in addition to all these variables, it is still necessary to observe the particular characteristics related to legal issues of access to these documents

Thus, following this pattern, we find that, in the case of medical records, the preservation proposal takes into account the same structure, but, of course, adapted to the reality of these documents, as follows:

a) P**roducer** – We consider the multiprofessional health team, since it produces and records data, information and knowledge in the patient's chart.

b) C**onsumers** – We understand they are the actual and potential users: multiprofessional team of health, Ministry of Health, Patient, Researchers (duly authorized) and Health field students, in general.

c) **Management** – In the proposal of this research, this refers to SAME because it is the Health Documentation Unit that manages and defines preservation policies in health

organizations, obviously following the legal framework of the Federal Medical Council, the Constitution, the Civil Code, the Universal Declaration of Human Rights, the Access to Information law and national preservation policies. For better understanding, we elaborated the functional scheme for the digital preservation of these documents, according to Image 3.

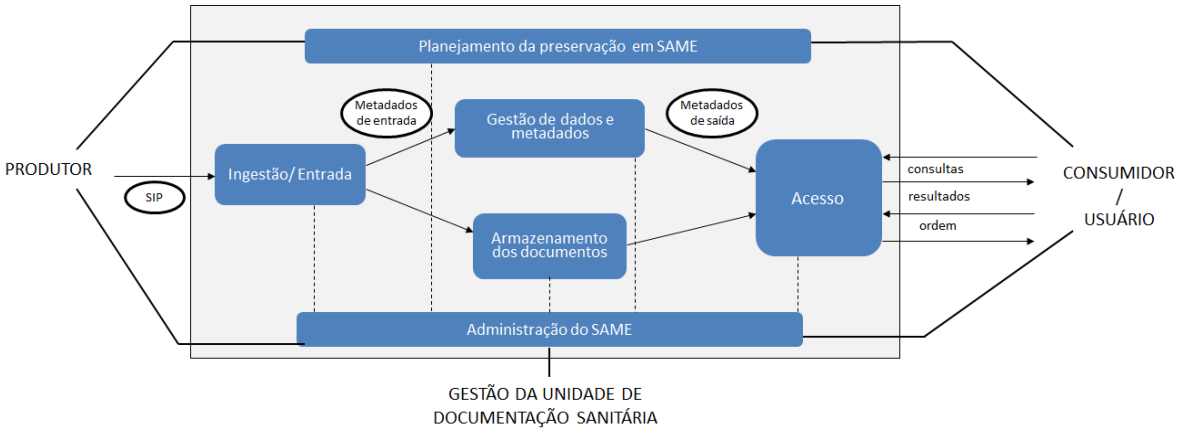

Image 3. Aplicability of the OAIS model for SAME

Source: Adapted from the OAIS model

Regarding the internal components of the OAIS model's applicability, we adapted the six blocks of such model in intake, document storage, data and metadata management, access and preservation planning in SAME, as follows:

a) Intake: Is the first module of the preservation system, considered in this research the entry of medical records. Due to the fact that this documentation is governed by legal regulations, this entry is only made after the approval of the Records Commission of each health institution, in order to guarantee the origin and integrity of the document as well as the revision and validation of the writing of the medical records. Such action will be configured in the so-called Submission Information Package (SIP). This evaluation is necessary, because, as prescribed by the Federal Medical Council in its Resolution no. 1.931/2009, Art. 87, "It is forbidden for the physician... To cease preparing a legible medical record for each patient" (BRAZIL CFM, 2009).

Likewise, Resolution COFEN No. 311/09, in its Section II ─ Article 72, mentions that nursing professionals must "record the information that is inherent and indispensable to the care process in a clear, objective and complete way" (BRAZIL. CFEN, 2007). Other considerable attention is related to the control of possible viruses that could damage the information recorded. After this control, the extraction of metadata related to patient identification, diagnosis, evolutions, discharge report etc. is done. In this step, it is necessary to guarantee the authenticity of the document, adopting a digital signature or checksum, to ensure its integrity. Only after this rigorous analysis can the medical record be sent to storage.

a) Document storage: At this stage, like the previous one, one must have all the attention so that authenticity, security, integrity and confidentiality/privacy are guaranteed, to also take care of the duplicity of copies.

b) Data and Metadata management: In this module, the descriptive and thematic metadata defined in the intake are managed in order to guarantee, in a standardized way, all the contents registered in the document, in order to facilitate the preservation and curation of this documentation in SAME.

c) Access: Due to the records being of restricted access, attention must be paid to the need for an interface that indicates the access by means of a password that certifies and legally guarantees the authenticity, security, integrity, confidentiality/privacy of documents and allocated metadata.

d) SAME Preservation planning: Responsible for the monitoring the technologies (hardware and software) aiming at updating the system of preservation of medical records. To this end, elaborates and decides the policies to be adopted in the health organization that must be in line with the health policies of the Nation-State.

All these modules should be in symbiosis so that the flow of information and communication of the patient's medical records preservation system is carried out with the lowest possible noise and ensures the legal aspects of authenticity, security, integrity, confidentiality/privacy of the documents and metadata assigned. In addition, ratify the interoperability between each of these modules.

5 FINAL THOUGHTS

Preservation and digital curation are subjects that, in general, are still open in the field of Information Science. In applying this concept to the field of Health, particularly to the sphere of the Electronic Patient Record, this gap is even greater because it is a very particular documentation and governed by specific legislation that involves the multiprofessional health team as producer of the patients' medical records and responsible for the information recorded in them; Health organizations as responsible for the custody of these documents; Patients and actual and potential consumers who will be able to access such documents, provided they follow specific legislation.

According to the results of our study, we verified that the OAIS reference model, although it has been proposed for the preservation of scientific memory and culture, can be perfectly applied to the SAME space, especially in sanitary documentation, as is the case of patient records. However, aspects related to ensuring the preservation of medical records and taking into account their legal aspects, as well as their authenticity, reliability, integrity,

confidentiality/privacy, auditing, electronic signature and proper custody should be observed.

This study is the 'kickoff' of studies that consider the importance and means to be used for the digital preservation of Electronic Patient Records through the development of an Electronic Records Management System or Repository in conformity to the OAIS standard. It is, therefore, a still incipient study on this subject. Therefore, it is urgent that studies and research evolving this theme be increasingly encouraged in post-graduate programs in Information Science, in interdisciplinarity with the Health Sciences, Computing, Law, Archivology, among others.

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