Ethics and the electronic health record: description of an integrating system of electronic health records in Argentina and a proposal to shift towards a patient-centered conception

Julián Verona[1,2,3]

[1] *Central Laboratory, Hospital Dr. Felipe A. Fossati, Balcarce, Argentina*
[2] *Confederación Unificada Bioquímica de la República Argentina, CUBRA*
[3] *On behalf of the IFCC Task Force on Ethics (TF-E)*

ARTICLE INFO

Corresponding author:
Julián Verona
Av. Favaloro 706, Balcarce (7620)
Buenos Aires
Argentina
Phone: +542266662757
E-mail: julianverona@hotmail.com

ABSTRACT

The Electronic Health Record (EHR) constitutes a complete information system useful for patient care, epidemiological studies and public health policies development.

We describe the Integrating System of EHRs of the Autonomous City of Buenos Aires (CABA), established by Law 5669, of 2016.

Although we consider the Integrating System of EHRs implemented by CABA very appropriate, we propose, first, that health services no longer store comprehensive EHRs. Instead, complete information would reside in one or several servers sheltered by civil society. Second, information would become integrated only when patients require it and grant access.

The patient would now be in a position of strength (complete autonomy). Instead of asking for his data he would be asked for them. In this sense, the patient will have to exercise the emerging responsibility of

reciprocity to the benefit of his own care and the care of others.

❖❖❖❖❖

INTRODUCTION

The neoteric SARS-CoV-2 pandemic exposed like never before the need to disclosure personal information to allow health system to better identify potential COVID-19 infections and track the spread over time. However, current digital solutions for monitoring have implications for privacy and data protection (1). The development of a versatile and innovative system to handle health information in a useful way for the requirement of the society and respecting the rights of people becomes increasingly necessary.

The health record is the obligatory, foliated, systematic and comprehensive documentation of a single patient medical history across time within one particular health provider's jurisdiction. It contains the day it started, patient's identification data and composition of his family nucleus including a list of the health status of immediate family members as well as their causes of death, family common diseases distributed by gender. This information may give clues about genetic, physiological and pathological backgrounds. There may also contain a family genealogical chart. For children and teenagers health record will include growth charts and developmental history to compare with age-matched mates. Children's behavior such as timing of talking, walking, etc. is also significant. Social history is helpful to know what sort of community support the patient may expect during a major illness. It would also disclose possible causes of illnesses. Habits are important too, especially those related tobacco use, alcohol intake, exercise, diet, and sexual behavior or orientation. There are also incorporated records of the acts carried out by physicians and assistants such as:

prescription and supply of medications, studies and practices conducted, treatments established, dietary prescriptions, interventions carried out by specialists and surgical protocols. Surgical history includes surgeries performed to the patient with a narrative detailing what the surgeon did. Obstetric history lists prior pregnancies and their outcomes including any complication. Internments include medical admissions and discharges, diagnoses, prognoses and evolution. In addition, allergies, vaccination certificates, the patient's willingness to donate their organs and the condition of voluntary blood donor, as well as informed consents that have been issued will be enclosed. In general, it is necessary and obligatory to incorporate in the health record any data that reflects the real information on patient's health status (*veracity*) (2). Based on subjective/objective assessment plan (SOAP) notes, problem-oriented health record (POHR) is a method of recording data about the health status of a patient in a problem-solving system and in an easily accessible way that encourage ongoing assessment and revision of the health care plan, by every actor in the health care team. The POHR consists of four components: the database containing all the information about the patient, a complete problem list (complaints), initial plans for each problem and daily progress notes, organized by problem and written in the SOAP format (3).

According to the International Standards Organization (ISO), the Electronic Health Record (EHR) is the repository of information regarding the health status of an individual in computer processable format, stored and transmitted securely and accessibly by multiple authorized users, having a standardized format that is independent of the EHR system used and aimed at the support of continuing, efficient and quality integrated health care (4).

In parallel, the Pan American Health Organization defines EHRs as records of the health information

of each patient in electronic format which can help health professionals in decision-making and treatment. In any case, the EHR is a document contained in a database, administered through computer programs, in which records of each health care event are endorsed with the provider's electronic or digital signature. It is compiled and maintained by health care agents from institutions or services. The concept of EHR goes beyond the mere digitalization. It constitutes a complete information system useful for patient care, epidemiological studies and public health policies development. The EHR offers a wide list of benefits: it guarantees accurate identification of patients, their safety and confidentiality, accelerates medical consultation appointments and scheduling, helps professionals to save time in administrative tasks, enables to share clinical information, improves legal certainty of professionals, increases the quality of health care, avoids the waste of unnecessary drugs and diagnostic studies, improves decision-making processes, reduces mistakes derived from illegibility of drug prescriptions, reduces paper expenses and helps to preserve the environment, and facilitates epidemiological surveillance, among others. There are also risks associated with its implementation: to be short-sighted and not understand the significance of implementing it for the benefit of the health system as a whole, confidentiality issues (also identified as a benefit), violation of privacy rights, problems arising when trying to computerize inefficient processes, interferences during medical consultation caused by the need to dedicate increase attention to the electronic system, among others (5).

A systematic review conducted by Kruse *et al*. (6) identified 39 barriers to EHR adoption within the literature selected (n = 27). The most frequently mentioned were initial cost (67%), technical support (33%), resistance to changing work habits (30%), maintenance/ongoing costs (30%), training (26%), privacy concerns (19%),

insufficient time (19%) and workflow challenges (19%). In addition, Katurura *et al*. (7) performed a systematic literature review concerning e-health technology in South African organizations and found that social, technical and environmental factors influenced the success or failure of the implementation.

It is necessary to emphasize that data cannot be used for purposes other than those that motivated its collection and that public or private health facilities and professionals can collect and process personal data related to physical and mental health of patients, provided they respect professional secrecy, according to Argentine Law 25036 (8).

The health record is of patient's property. At their simple request, a copy of it, authenticated by competent authority of the health care institution, must be provided within 48 hours. Faced with the refusal, there is a legal remedy called action to protect personal data or *habeas data* in order to ensure access and collection. The Ombudsman may intervene in this process in a cooperative manner.

Health care facilities and professionals, owners of private offices, are in charge of health record's care, custody and administration, and must implement the necessary means and resources to prevent access to the information contained therein by unauthorized persons.

In Argentina, the EHR must be conceived in a way that allows effective compliance with National Law 26529 (9), *"Patient's rights, medical history and informed consent"*, approved in 2009. These rights include assistance by health care professionals, without impairment or distinction due to their ideas, religious beliefs, socio-economic status, race, sex, sexual orientation, etc.; receive dignified and respectful treatment by health care agents, preserve privacy and confidentiality, and accept or reject certain medical or biological therapies or procedures, with or without

expression of cause, as well as later to revoke the manifestation of will. Argentine National Law 26061 (10), *"Law for the integral protection of the rights of girls, boys and adolescents"*, of the year 2005; establishes their right to intervene in decision-making regarding their health. Patients who present irreversible, incurable diseases or who are in a terminal stage have the right to express their will regarding the rejection of surgical procedures, artificial resuscitation or the withdrawal of life support measures, when they were disproportionate in relation to the perspectives of improvement. In these cases, measures and actions that lead to adequate control and relief of the patient's suffering must be maintained. The patient has the right to receive health information related to their health and to carry out medical consultations to obtain second opinions on the diagnosis, prognosis and/or treatments of their diseases.

The Law also refers to the informed consent understood as the declaration of the patient's will regarding the actions carried out on his body for his health. The consent will be issued by the patient after receiving clear, pertinent and opportune information about his health status, the proposed procedure, the expected benefits, the warning about the risks and adverse effects, the mention of the existence of alternative procedures and the foreseeable consequences for not performing the medical practice. Informed consent must be documented in the EHR.

The implementation of the EHR should lead to better compliance with bioethical principles of *autonomy*, *justice*, *beneficence* and *non maleficence*. The former implies the right to decide with which professionals personal health information will be shared. It also implies prior consent of the patient before undergoing medical practices. The second refers to the State should guarantees equitable health care and adequate accessibility to all its citizens. And the latter two, indicate professional acts always have as their end the benefit on patient's health, avoiding or minimizing harm.

CASE HISTORY

The Integrating System of EHRs of the Autonomous City of Buenos Aires (CABA), established by Law 5669 – *"Electronic Medical Record Law"* (11) of 2016, is a good example to be considered, since it has many characteristics to guarantee the rights of patients and bioethical principles.

In the area of CABA, 35 hospitals, 74 primary care centers, 1 ambulatory reference medical facility, 2 children's dental centers and 2 mental health centers are in function. It is structured into 12 geographical areas to organize health care delivery. The health system has a total of 41,000 employees (12).

The implementation of EHR requires registration in the EHR Registry and compliance with the requirements for its certification. The Integrating System of EHR is under the orbit of the Ministry of Health of the CABA, which offers the necessary software and hardware to allow the interconnection of the various databases of public, private and social security health care facilities, constituting a repository of health information contained on them. In order to harmonize the information generated in different health services, technical standards are set for the data and the information contained in the EHRs.

The Integrating System of EHRs stores minimum people identification data and basic sanitary information. The patients are incorporated through a registration process that allows their identity to be verified and accredited in order to assign an EHR. The EHR identifier assigned at each health facility must be associated with patient's unique identifier in the Integrating System of EHRs.

The Integrating System of EHRs accounts for the information contained in each EHR, the accesses

to the database and the modifications. It ensures that the information was available to the patient and authorized users. It offers the possibility of managing appointments and preparing recipes through remote access. In addition, it permits the continuity of health care by allowing attention in different facilities, through health information exchange (*interoperability*). As an added value, it provides demographic information that can be used for public health policies design.

The CABA Ministry of Health is the certifying authority for the digital signature that will identify each of the users registered in the EHR Registry. This registry provides advice, training and technical support to health care institutions to implement EHRs and achieve its *certification*.

Professionals and patients can access the system through an authentication process using username and password. There are three levels of *access*: consultation, update and modification. Since the information contained in the EHR is confidential, access requires the authorization of the patient. In cases in which he/she was disabled to authorize it, the intervening health professional may do so compulsively, leaving record of it and respecting the principle of *confidentiality*.

Beyond the updates and modifications made by authorized persons, the EHR has the quality of remain unchanged (*integrity*) over time (*durability*). Every time one of these actions is carried out, it should be kept a record of it, even if it was intended to correct an error. Once validated, no data can be removed and, if a correction is necessary, the new data is added with the date, time and validation of the person responsible for the correction, without deleting the corrected. The system allows associating the actions carried out on the information unequivocally to an individual or entity, leaving trace of the respective access (*traceability*).

The testimony of the health care event must be simultaneous or immediately after the provision of the service (*opportunity*) and, since the patient has access, he can verify the effective performance of this act in a timely manner. That is, he can track access to his / her clinical information. The patient has the right to know the data entered in their EHR (*privacy*) and to request a copy (*portability*). In case of incapacity or inability to understand the information due to his physical or mental state, it must be provided to his legal representative or beneficiary.

The system guarantees the *security* of the information avoiding the illegal or illegitimate use that could harm the interests or the rights of the EHR owner.

DISCUSSION AND PROPOSAL

Currently, the EHR constitutes a significant part of patient-centered care, defined as care provision consistent with the values, needs and desires of patients and achieved when health care professionals involve patients in health care discussion and decisions (13). Patient-centered care includes effective communication, partnership and health promotion. In other words, it means exploration of the patient's diseases and illnesses to develop an understanding of patient's health care experiences, finding common ground upon which a health care plan can be developed mutually and tailoring health care plans based on reflections on the patient's past health history and current health context (14).

The Integrating System of EHRs described above represents a fairly good example of what we can do with new technology. The Federal District (CABA) took the initial step and, surely, replication by the other districts (the provinces) will follow. Over time, the system may become universal and would cover the whole country. However, as stated by Hägglund and Scandurra, introducing a national patient accessible EHRs service is a complex socio-technical challenge (15).

The Integrating System of EHRs has essential characteristics directly implicated with patient's rights and bioethical principles: *veracity, interoperability, certification, access, confidentiality, integrity, durability, traceability, opportunity, privacy, portability* and *security*.

We endorse the extensive use of the EHR and consider the Integrating System of EHRs implemented by CABA very appropriate. However, we pretend to go far beyond and propose a shift in three main aspects: data ownership, storage and administration.

Since the patient has a recognized right over the information contained in his/her health record, he/she is actually in a position of weakness given the information resides in and is administered by an institution. Then, he/she is in the need to ask for something that actually belongs to him/her.

From our point of view, institutions should no longer safeguard EHRs. Instead, they should be sheltered by the civil society, constituting a true social value. They should be free from political interference or economic interests. Physically, the information could be contained in one or several servers or it could even reside at the individual level, on demand (Figure 1).This does not mean health services will no longer keep records of the actions they carry out or the information they generate. Instead, we propose they should have disaggregated information while the integrated should be in patient's hands in the form of patient-centered EHR.

Health institutions would get the integrated personal information only under express permission granted by the patient (Figure 2). In other words, the EHR would be administered by patients. A system of this nature would guarantee patient's rights in a real way, avoiding any type of unauthorized review by the health care system and restricting the use of the information only for the purposes authorized by patients.

| Figure 1	Health information storage
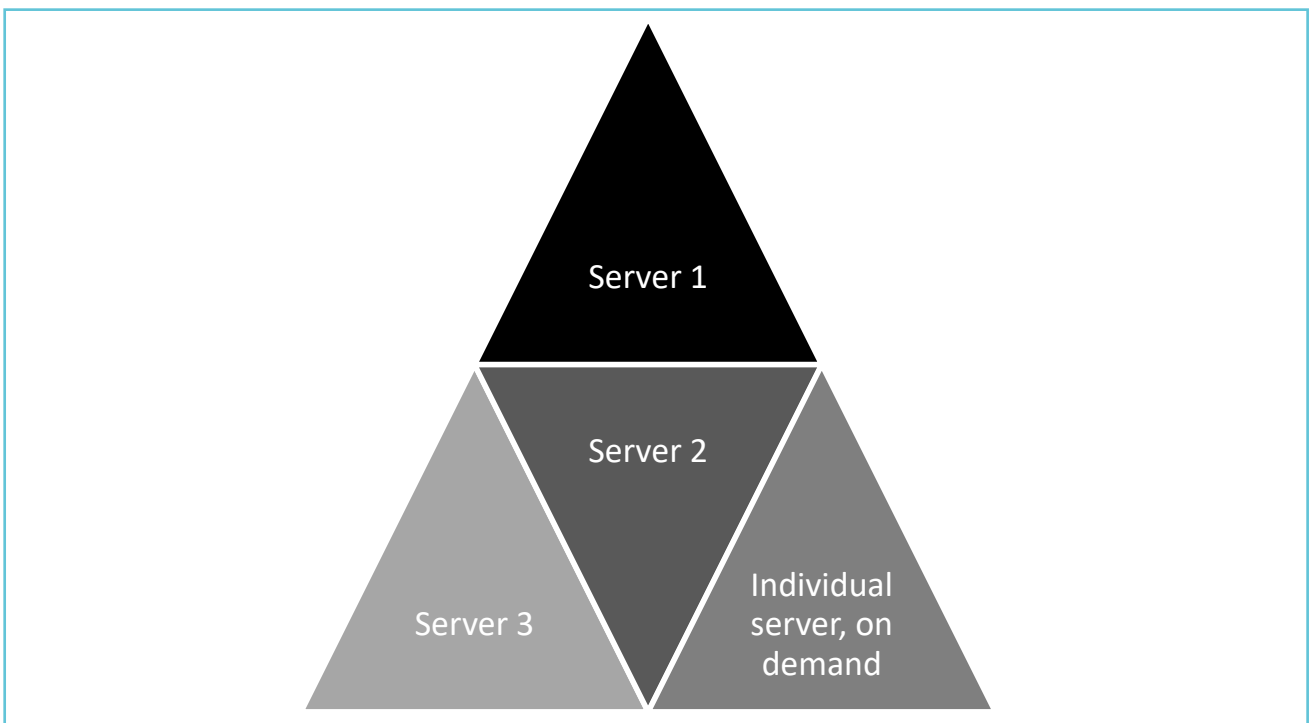
Health information contained in several servers, including individual on demand.

To pose an example, suppose a patient attends to a laboratory service and, then, undergoes an imaging study. Laboratory will generate, store and upload data to the patient-centered EHR. Image service will do so with images. Laboratory and image services individually could look for the studies they have done, but each piece of information will remain disaggregated until the patient attends to consultation and grants access. At this moment, the physician will be able to see both studies in an integrated EHR automatically generated in real time (Figure 2). Now suppose the patient went to two different health care services and, in the second visit, it is necessary to seek into his/her entire health record. In the same way, information coming from the two health centers and stored in external servers would become integrated as a whole under patient permission.

This kind of administration would give patients complete autonomy with respect to who views their integral health information. Actually, this restriction could affect the principle of *justice* since ignorance of information recorded in the health record could generate the need to carry out studies and tests already done. Clearly, this situation would generate a misuse of resources. It could also be affected the right of health care professionals to have access to the information contained in the health record; the principles of *beneficence* and *non maleficence* could then be compromised (*primum non nocere*, not to harm) (16). In fact, professionals would have the right to ask patients for access to their respective EHRs, to perform with professionalism. At this point, a new responsibility for the patients emerges: that of *reciprocity*. It implies that patients would allow their EHR data to be use to the

| Figure 2 | Real time generation of patient-centered electronic health record |
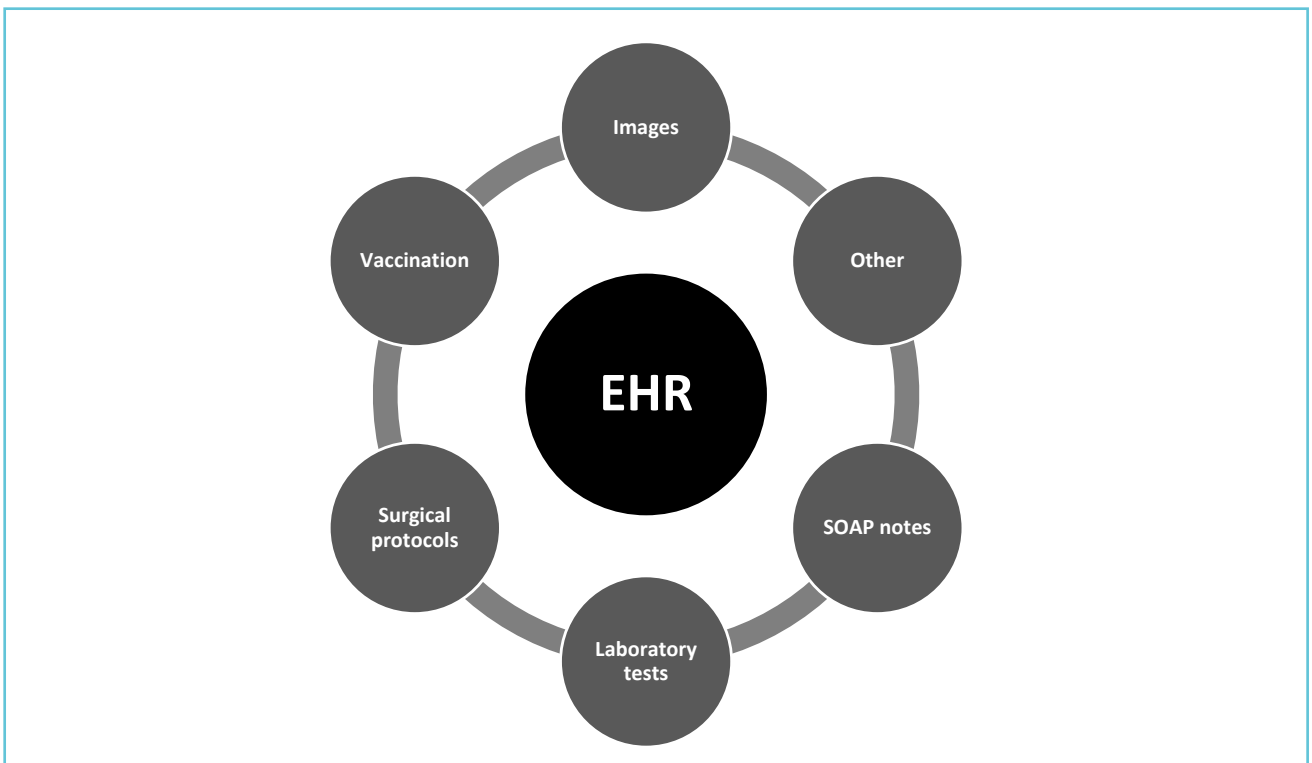
Health care institutions having disaggregated information while the electronic health record is generated at the patient's request.

benefit of their own care and the care of others (Figure 3) and this should include the release of the information for population studies and epidemiological research (observational and case-control studies). For these purposes, data quality is a subject of mayor concern and patient's reviews are highly important. Data must be accurate and reliable to avoid potential hazards that could range from individual harm to erroneous conclusions caused by bias at population level (17).

Although, the patient is the owner of his health record, there are issues that should be open access to health care providers: blood type, allergy to certain drugs, pathologies of epidemiological relevance or any meaningful information for health care in an emergency or serious context. The above could be expressed in a general way, with pre-established formulas, without going

into details that could affect *dignity*, *integrity*, *vulnerability*, *professional secrecy*, among other issues.

From an operational point of view, an application designed in this way should be easy to use. Verbal expression or a simple exchange of text messages should be sufficient to have the necessary access code and be able to view the health record for a certain period of time. This would give full participation to the patient and allow professionals to consult and upload health events. Institutions or individual professionals would initiate a session to access the application and thus the responsibility of each professional act would be established. Personal preferences and predetermined informed consent would be incorporated into the application in digital format, which would constitute valid consent for

| Figure 3 | Relational equation of bioethical principles including reciprocity and professionalism |
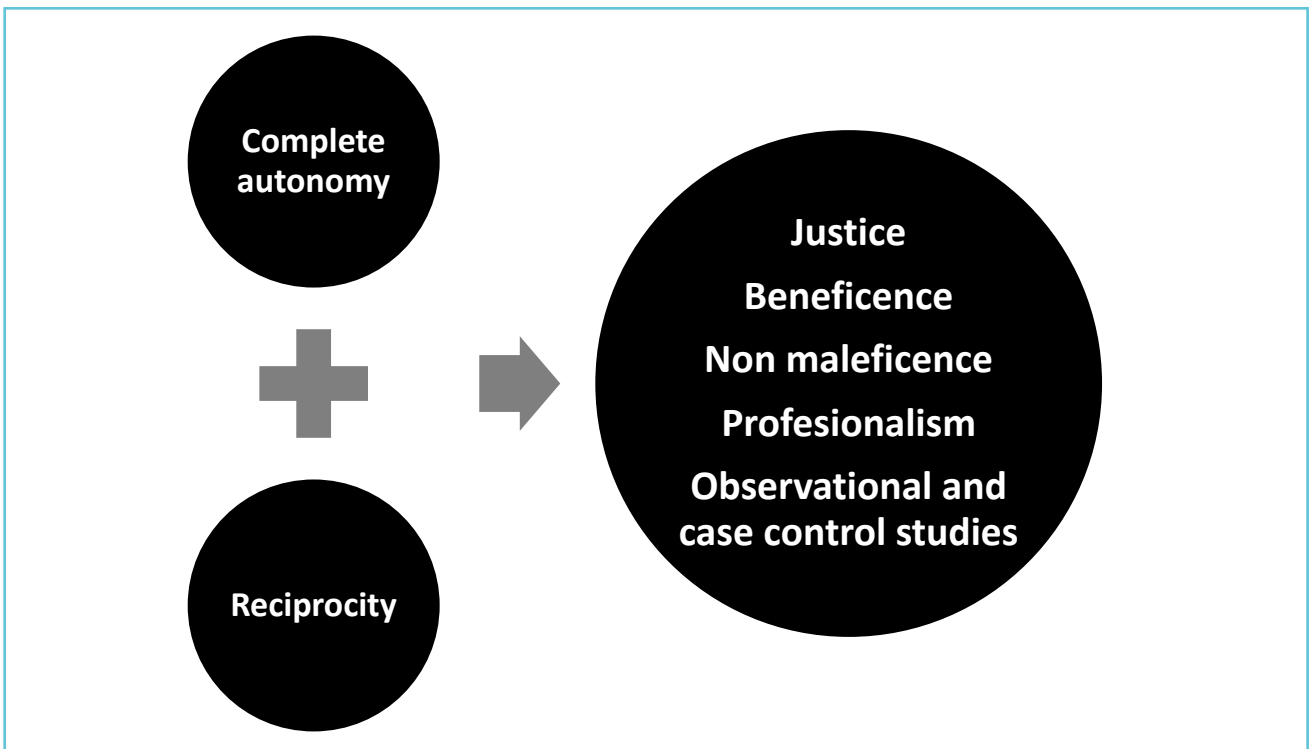
Patient exertion of complete autonomy plus the emerging responsibility of reciprocity warrant bioethical principles of justice, beneficence and non maleficence, ensure that health care providers perform with professionalism and permit to conduct epidemiological research (observational and case control studies).

situations where the patient's circumstances made it impossible to obtain. The application would support different types of data formats: text, portable document format (pdf), audio, image, video, etc. The system would also include vaccination programs and the recommended frequency of carrying out medical practices in order to ensure adequate prevention and would issue the corresponding alerts. In special circumstances (accidents, loss of consciousness, etc.), compulsory access by institutions or health care professionals would be possible, but the system would register the entry. This could be done through fingerprints or facial recognition. The application would also have the ability to manage geographically referenced epidemiological information through the use of global positioning capabilities (GPS) of smart phones and would allow public health centers to extract real time global data. For these centers, interfaces specifically designed for data acquisition and analysis would be developed in accordance with international regulations. Then, the reflection made in the first paragraph of the introduction refers to a well conceived EHR.

Finally, a SWOT (strengths, weaknesses, opportunities, threats) analysis must be carried out on the system adopted by the CABA, trying to find out its ability to coordinate with equivalent systems from other jurisdictions that may constitute their own integrated EHRs systems in the future (18). A strategic plan proposal should be considered to formulate an alternative for the growth, development and articulation of integrated EHRs systems, based on introducing proactive changes: that of the repository and that the administration of individual EHRs were in patient's hands, as the unique owner of his health data.

CONCLUSIONS

After reviewing the Argentine legislation on the matter and the auspicious initiative conducted by the CABA, here we propose a radical change in the conception of EHRs. It would happen to belong by right and now also in fact to the patient. It would reside in one or several servers protected by the civil society or even in individual repositories, on demand. Institutions would only have disaggregated information. The EHR would be administered by patients. In this way, greater guarantees regarding their rights would be given to the patient, and bioethical principles would be observed. The patient would now be in a position of strength (complete *autonomy*). Instead of asking for his data he would be asked for them. In this sense, the patient will have to exercise the emerging responsibility of *reciprocity* both for his/her own wellness and for the wellness of the others. However, the implementation of such a system will take a long time and will require the design of an appropriate information network and the change of mind of many actors including patients. Clearly, patient-centered EHR as described above constitutes a tangible expression of bioethical principles and a paradigm shift in health information ownership, storage and administration.

REFERENCES

1. Organisation for Economic Co-operation and Development (OECD). 23rd report "Tracking and tracing COVID: protecting privacy and data while using apps and biometrics". April 2020.

2. Guillum RF. From papyrus to the electronic tablet: a brief history of the clinical medical record with lessons to the digital age. Am J Med 2013;126(10):853-857.

3. Wright A, Sittig DF, McGowan J, Ash JS, Weed LL. Bringing science to medicine: an interview with Larry Weed, inventor of the problem-oriented medical record. J Am Med Inform Assoc. 2014;21(6):964-8.

4. International Organization for Standardization (ISO). Health informatics — Electronic health record — Definition, scope and context. ISO/TR 20514:2005(en). https://www.iso.org/obp/ui/#iso:std:iso:tr:20514:ed-1:v1:en. Accessed, May 2020.

5. Pan American Health Organization. Electronic Medical Records in Latin America and the Caribbean: An Analysis

of the current situation and recommendations for the Region. Washington, DC: PAHO, 2016.

26riers to Electronic Health Record Adoption: a Systematic Literature Review. J Med Syst. 2016;40(12):252.

7. Katurura MC, Cilliers L. Electronic health record system in the public health care sector of South Africa: A systematic literature review. Afr J Prim Health Care Fam Med. 2018;10(1):e1-e8

8. Ley Nacional 25036, "Ley de Protección de Datos Personales", Argentina, 2000.

9. Ley Nacional 26529, "Derechos del paciente, historia clínica y consentimiento informado" Argentina, 2009.

10. Ley Nacional 26061. "Ley de protección integral de los derechos de las niñas, niños y adolescentes", Argentina, 2005.

11. Ley 5669, "Ley de Historia Clínica Electrónica", Ciudad Autónoma de Buenos Aires, 2016.

12. Faretta F, Levi D, Marques L, Ferrante D, GiussiBordoni MV, Baum A, de Quirós FGB. Developing an Electronic Record Tool Representative of Primary Health Care in the Public Health Care System of Buenos Aires City. Stud Health Technol Inform. 2019;264:516-520.

13. Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. Soc Sci Med. 2000;14:1087–1110.

14. Little P, Everitt H, Williamson I, Warner G, Moore M, Gould C, Ferrier K, Payne S. Preferences of patients for patient centered approach to consultation in primary care: observational study. BMJ. 2001;322(7284):468-72.

15. Hägglund M, Scandurra I. A Socio-Technical Analysis of Patient Accessible Electronic Health Records. Stud Health Technol Inform. 2017;244:3-7.

16. Meslin EM, Schwartz PH. How bioethics principles can aid design of electronic health records to accommodate patient granular control. J Gen Intern Med. 2015;30 Suppl 1:S3-6.

17. Lee LM. Ethics and subsequent use of electronic health record data. J Biomed Inform. 2017;71:143-146.

18. Shahmoradi L, Darrudi A, Arji G, FarzanehNejad A. Electronic Health Record Implementation: A SWOT Analysis. Acta Med Iran. 2017;55(10):642-649.