Guidelines for the Advancement of Electronic Health Records

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The Guidelines have been proposed for the development of electronic health records (EHR) that must meet the needs of all relevant stakeholders. The system of electronic health records should contribute to the improvement of health services to healthcare users, support the daily work of health professionals and enable continuous improvement of quality at all levels of the health care system. The following concepts are defined: electronic health record, electronic medical record (EMR) and electronic personal health record (EpHR); Any health care user should have one EHR, one EpHR, and multiple EMRs. The parts of the EHR, i.e., the EMR and EpHR, should not be physically kept in the same place, but must be interconnected in case of need (via the health care user unique identification and authentication rules). All EMRs contain data collected by health professionals in health facilities (primary health care, polyclinics, hospitals, public health institutes, etc.). This data can be entered directly or transmitted from medical devices. The EpHR contains data collected and maintained by the health care user. They can be recorded directly or transmitted from a medical device. Data in the EHR may be made available to authorized persons only. Data protection in the EHR should be ensured in three ways: technically, regulatory and through codes of ethics, in line with international initiatives (certification, EU regulations, standards, etc.). The EHR and its components should be used for both primary and secondary purposes. The primary use of the data relates to the individual (diagnosis, therapy, vaccination, etc.). The secondary use relates to population groups (reporting on the health status of the population, the quality of health care, the effects of preventive activities, funding, and research, etc.). The EHR data (structured or not) should be defined by health care professional associations. The ICT experts need to offer optimal technological solutions. The EHR development strategy, as well as supervision (medical, legal, technical, and ethical aspects, as well as standardization) should be entrusted to the institution at the national level, i.e., the Central eHealth Authority. EHR (EMR and EpHR) should be developed in stages, step by step, depending on current knowledge, technology, and material resources.

Key words: electronic health record; electronic medical record; electronic personal health record; primary/secondary use of data

Preamble

Based on Croatian Encyclopedic Dictionary, the *guideline* denotes an established *course of action*. So, guidelines for improvement of electronic health records (EHR) should be understood as the course of action in the life cycle of the EHR system that should:

- Meet the needs of all stakeholders in the health care system
- Support health-professional work
- Enable continuous quality improvement

at all levels and in all parts of health care and thus contribute to preserving and improving the health of all the health care users.

Guidelines are not obligatory.

The EHR concept is not new and in various developed and less developed countries, work is underway to develop guidelines for building and improving EHRs. However, a satisfactory solution has not yet been achieved.

Although medicine is an established discipline, science and profession, each country has certain peculiarities in the organization of the health system which must be considered when applying the information technologies in medical and health-professional work.

Information technologies have already penetrated very well into the health system in Croatia, but still (despite the Declaration on eHealth from 2011 which was incorporated in several official documents on health and health system) there is no single comprehensive solution for EHR. Therefore, the Committee for eHealth of the Croatian Academy of Medical Sciences (CAMS) has started to develop guidelines to determine the optimum way forward.

Abbreviations

CAMS	Croatian Academy of Medical Sciences
CEN	European Committee for Standardization
CEZIH	Centralni zdravstveni informacijski sustav Republike Hrvatske (Central Health Information System of the Republic of Croatia)
EHR	Electronic Health Record
EMR	Electronic Medical Record
EpHR	Electronic personal Health Record
HDMI	Hrvatsko društvo za medicinsku informatiku (Croatian Society of Medical Informatics)
HL7	Health Level 7
HLZ	Hrvatski liječnički zbor (Croatian Medical Association)
HLK	Hrvatske liječnička komora (Croatian Medical Chamber)
HUMS	Hrvatska udruga medicinskih sestara (Croatian Nurses Association)
HZN	Hrvatski zavod za norme (Croatian Standards Institute)
HZN/TO215	Tehnički odbor za normizaciju u medicinskoj informatici pri HZN-u (Technical Committee 215 in HZN)
HZZO	Hrvatski zavod za zdravstveno osiguranje (Croatian Health Insurance Fund)
ICT	Information and Communication Technology
IHCU	Identification of Health Care User (identifikator korisnika zdravstvene zaštite)
ISO	International Organization of Standards (Međunarodna organizacija za norme)
MBO	Matični broj osigurane osobe (Identity Number of Insured Person)
NIAS	National Identification and Authentication System (Nacionalni identifikacijski i autentifikacijski sustav)
PDI	Personal digital identifier (osobni digitalni identifikator)
OIB	Personal Identification (osobni identifikacijski broj)
PIN	Personal Identification Number (tajni osobni broj, lozinka)
PHC	Primary Health Care
PcHC	Polyclinic Health Care
STeZ	Središnje tijelo za eZdravlje (Supervisory Authority for eHealth)
HIS	Health Information System

Introduction

In line with the meaning and logic of integrated health care, the principle of health care providing with the aim of improving patient care and coordination of health care (1), and taking into account the Declaration on e-health (2), it is necessary to integrate the health information:

"Health Information System (HIS) should integrate all the health data available within the system and, by ensuring a high level of security and protection, make the data available to authorized entities ".

Considering the above, the Declaration requires that any health care user has his own unique electronic health record (EHR) filled with data from various parts of health care - primary health care (PHC), polyclinic (PcHC), hospital, laboratory, specific diagnostic or therapeutic unit and elsewhere.

The EHR does not necessarily have to be (physically) stored in one place, but it must be possible to link all its parts on request of authorized person (physician or other health care professional while providing health care to the patient) and with patient consent. Every health care user (i.e. patient) must be able to have complete and simple insight into the information on who used his health information, what information and when, as well as what was the basis for this authorization.

Any approach to solving a problem requires an overview of the area, defining goals and purpose, considering different opinions about the problem and its solutions, and finding or suggesting possible solutions. The development of the EHR is still an incompletely solved problem in the world. Recently, guidelines related to EHR issues have been completed in various countries around the world. Good examples of this are developed countries like the UK and the United States, but some other countries (like India) have followed the same way (3-6).

All the work on the guidelines is generally of more recent date, and guidelines are still under development. Some guidelines are limited in scope - they refer exclusively to one part of the health care system, e.g. the electronic record of patients in a general practice (5).

Each of the guidelines is an attempt to direct the development of EHR in the country towards integrated health care, in line with the organization of the health care system of the specific country.

Although the professional literature and documents of international standardization bodies, mostly use the name electronic health record (EHR), other names appear too - names like "electronic medical record" (EMR), "electronic patient record" (EPR), "personal health record" (PHR), and similar.

Given the fact that Croatia still does not have a complete solution for EHR, and that different names (terms) are used in current documents and communication [e.g. eKarton in the Ordinance on the Method of Keeping of Personal Health Record in the Electronic Form (7)], and that at the same time there are several fragments of a potential solution for EHR, the eHealth Committee of the Croatian Academy of Medical Sciences (CAMS) considers it necessary to clearly define terms and develop Guidelines for improving EHR (hereinafter: the Guidelines) that will help improve the existing incomplete solution.

Purpose and Objectives

The purpose of applying these Guidelines is to develop a new EHR which will be meaningful and useful for both, primary (treatment and prevention at the individual level) and secondary use (improving quality in health, planning and implementing interventions at the population level, improving the health system, education, scientific research, etc.).

The purpose of this paper is to develop such Guidelines.

The objectives of these Guidelines are as follows:

- To define the concepts and terminology to be used in the Guidelines
- To define the relationships between concepts
- To define the functionality of the EHR and its parts at different levels of the health care system
- To consider the necessary infrastructure for the implementation of the EHR
- To establish supervision over the development and functioning of the EHR.

Who will benefit from the Guidelines? And what benefit?

The Guidelines are intended for all stakeholders in the computerization of the health system, i.e. system developers (vendors) as well as users.

Thus, the Guidelines are intended for:

- Those who will develop the EHR
- Those who will use the EHR data for:
    - Their primary needs and activities (oriented to individuals),
    - Secondary needs (oriented to population in care, quality of health care, effects of preventive activities, financing and scientific research)
- The population as a whole.

The benefits of the Guidelines are manifested in giving directions for the development of EHR, in purposeful and meaningful use of EHR data for different purposes, and in better health care for individuals and the population as a whole.

Development of Guidelines

Development of the Guidelines includes the elaboration of individual goals. Concepts which will be used in the Guidelines like electronic health record (EHR), electronic medical record (EMR) and electronic personal health record (EpHR) will be specified, as well as their inter-relationships. Functionality needs will be identified at all the levels of health care - primary health care settings, polyclinics, hospitals, public health, etc.

The Guidelines will discuss the infrastructure elements important for implementation and functioning of electronic records. Primarily, this refers to the protection/security of data stored in EHR, EMR and EpHR, and consequently to the safety of health care users themselves.

Interoperability is an indisputable requirement in complex systems (like the health care system) that require communication of data and cooperation between various settings and health professionals. Therefore, standardization is an unavoidable component in the construction of EHR, EMR and EpHR.

Furthermore, in addition to the code of ethics for health care professionals regarding patient data, information and communication technology (ICT) professionals should also be considered and a code of ethics proposed for them.

Development and functioning of EHR, EMR and EpHR must be legally fully regulated. It is also necessary to consider how to monitor, both the development and the functioning of the EHR.

Electronic health record and related concepts

Due to the variety of names for sets of patient health data used in both literature and everyday health care practice we consider it necessary to introduce basic definitions. The definitions are as follows:

An electronic health record - EHR - is a set of *data and information on the health* of a health care user; data being stored and transmitted electronically, protected and secured, and available to authorized users.

An electronic medical record - EMR - is a set of *medical data* of a health care user, being stored and transmitted electronically, protected and secured, and collected and recorded by health care providers.

An electronic personal health record - EpHR - is a set of data on the health of a health care user; created, electronically recorded, and disposed *by the health care users themselves*.

The authorized users can be health care professionals and the health care user.

Providing the health care to a health care user, the health care professional becomes the authorized user of health care user's data.

Relationship between the defined concepts can be shown by diagram (Fig. 1) which shows who is responsible (input and use) for the data in the EHR, EMR and EpHR.

Therefore,

- Any health care user has only one EHR. The EHR should be created by integrating relevant data from various EMR and EpHR
- The EMR should be created at health care settings (GP surgery, laboratory, hospital wards, diagnostic unit, public health counseling, emergency care, community nursing activity, etc.). In this way, there are several EMRs in which the health professional enters data relevant to his / her scope of activity and according to the regulations on keeping medical records.
- The EpHR should consist of the data relevant to the health status of a health care user and should be entered by the user himself.

All these records can have its own mobile format.

The content and format of the data should be based on the regulation on medical documentation. Detailed elaboration of content and format should be determined by professional societies, i.e. associations (e.g. HLZ, HLK, HUMS, HDMI, etc.).

Linking of data recorded in various EMRs and EpHRs into one EHR (i.e., data from different sources: PHC, hospital, patronage, etc.) is achieved through the identification of health care users (IHCU) and the application of international standards.

The health care user identifier must be an attribute that is unique to each user. However, each user may have multiple identifiers, i.e., multiple digital identities enabling authentication by using any authentication feature (biometrics), person’s knowledge (PIN) or items that the person owns (card, token, chip, etc.).

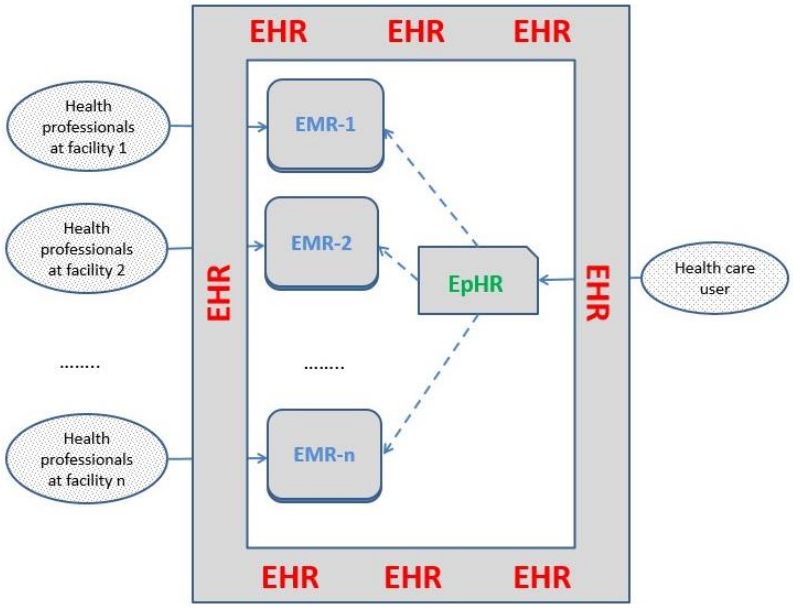

Figure 1. Relationship between EHR, EMR and EpHR

Special attention should be paid to the possibility of unambiguous authentication of health care users in a situation when they need to be provided with health care, and they themselves are not able to provide data that would identify and authenticate them. Therefore, at least one personal digital identifier (PDI) should be an invariant biometric characteristic that undoubtedly ensures the authenticity of health care users. In addition to the simplest one (fingerprint, which is increasingly used in laptops and smartphones), recent literature cites the venous structure of finger (the finger vein) (8) or the venous structure of the palm as one such property (the palm vein). Such technology can check the authenticity of an individual (palm vein recognition technology) with very small errors by contactless scanning of a finger or palm (according to Kumar et al. from 0.996% to 3.112%) (9,10).

In line with the current solutions in Croatia, the identity number of the insured person (Croat. MBO) of the Croatian Health Insurance Fund (Croat. HZZO) serves as the identifier of the health care users. Based on this identifier, the data of health care users in the health system are linked in a single record, in the EHR. At the national level in Croatia, there is a Personal Identification Number (Croat. OIB) which has the same purpose - to connect data belonging to the same person (in different systems).

The fact is that the application of a unique person identifier, especially in various systems, potentially violates the person's privacy. In the world today, there are different solutions that have the same goal and purpose - to connect data about one person, for example, from different health care settings. Finland, for example, has a citizen identification number that is used in all systems, including health care, regardless of where the data is collected and where they are located (11,12). In contrast, in Germany, there is no unique identification number of a person, nor is such a solution being considered (13). Data linkage in Germany is based on special record linkage algorithms, and each system has its own way of identifying a person.

The current European legislation, the General Data Protection Regulation, i.e., GDPR (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, concerns the protection of individuals with regard to the processing of personal data and on the free movement of such data (14). Given that the GDPR refers to the protection of the individual and his data in the health care system, including the EHR, an appropriate technological solution

should be chosen to connect data on health care users in accordance with the GDPR as part of Croatian legislation.

Why one EHR, more EMRs and one EpHR?

Integrated health care implies lifelong monitoring of health care users ("from birth to death"). Data on his/her health and illness recorded at one health care setting, in one EMR, may be needed by health professionals in another setting. Therefore, the connectivity of different EMRs created in different settings is required. Likewise, in some cases of providing health care, it is important for the health professional to gain insight into the data recorded by the health care user himself (e.g., at home or in some special situations) in his personal health record (EpHR). The EHR should link all this data, regardless of where they originated and who recorded them. Private health facilities should also not be exempted.

From all the above, the principle "one person - one EHR" arises.

The development of the EHR system should be carried out gradually (in stages), and the development itself will necessarily depend on:

- Education of participants (health professionals, ICT professionals, health care users)
- Legal basis (regulations)
- Professional support (societies of health professionals)
- Financial opportunities
- Political will (health authorities, etc.) (Fig. 2).

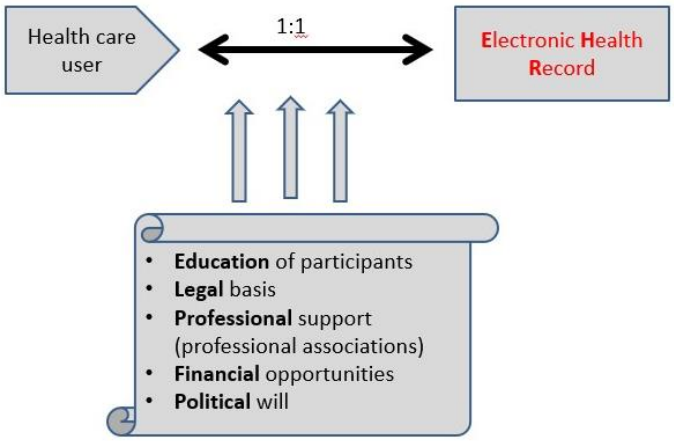

Figure 2. Aim and modulators of the EHR development dynamic

The EpHR refers to the individual. The EpHR is not mandatory for every health care user. It is recommended to health care users for whom monitoring of data derived from outside a health care facility can improve health outcomes.

The EHR functionality and how to achieve it

Both the EHR and EMR are intended for primary and secondary use (Fig. 3).

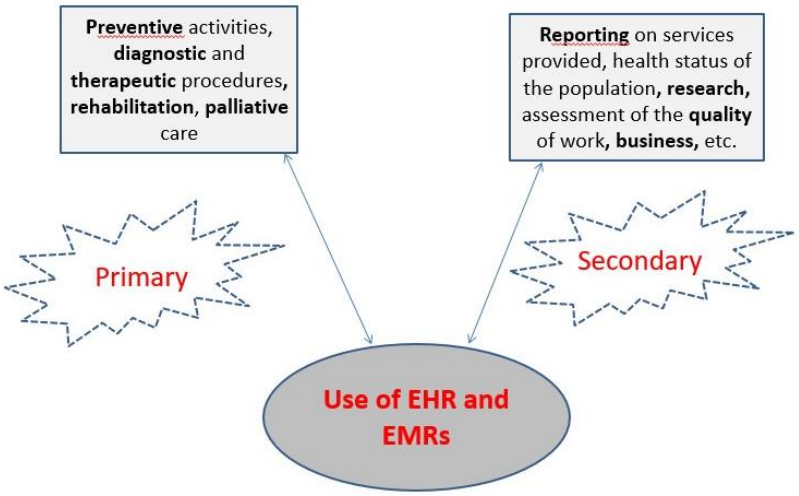

Figure 3. Primary and secondary use of the EHR data

The primary use of EHR and EMR is to aid decision-making in the process of providing health care to the individual (preventive activities, diagnostic and therapeutic procedures, rehabilitation, palliative care).

Data sharing is an integral part of the primary use of EHR. A prerequisite for data sharing between health care professionals is the interoperability of their IT applications. For example, one of the data sharing outcomes can be the active alert to the general practitioner (GP) on the findings of specialists, laboratories, or other diagnostic units and display of this finding in the GP's IT application.

The secondary use of EHR and EMR includes reporting on services provided, health status of the population in care, etc., research (scientific and professional work, the discovery of new knowledge based on data collected in daily work with the patient), assessment of the quality of work, business, etc.

The difference between primary and secondary use of data can be illustrated by the example of panels, recently a part of the EHR in the GP surgery. One of such panels is the Total Cardiovascular Risk Panel developed under the proposed National Cardiovascular Disease Prevention Program: systolic blood pressure, total cholesterol, and HDL-cholesterol will be measured for any man over 40 and a woman over 50 who comes to a GP surgery for any reason (opportunistic screening). Based on these data as well as data on gender, age, and smoking, a 10-year cardiovascular risk will be calculated automatically (SCORE table). The risk for a cardiovascular incident and the LDL-cholesterol value will determine whether hypolipemic treatment is required or not. This is an example of the primary use of the data.

Also, the same panel contains data on early cardiovascular mortality as well as on established cardiovascular disease in the family. The panel is also intended to assess the health status of the population in the care of any GP, specifically in relation to cardiovascular risk factors, which

can be one of indicators of the quality of medical work. This is one example of the secondary use of data.

According to the existing Guidelines for GPs, each GP should cover 20% of their population per year. In this way, after 5 years, the entire population of Croatia will be covered, and relevant data on cardiovascular health of the nation, i.e., total Croatian population, will be obtained. So, it will be possible to carry out scientific research of cardiovascular risk, which is another example of the secondary use of data.

The content and format of data in EHR should be based on the needs of both primary and secondary use. Therefore, it is necessary for professional societies, professional bodies, and representatives of patient associations to develop appropriate criteria by which both primary and secondary use of EHR can be achieved.

Criteria for the functionality or the point of the using EHR can also be developed in stages, depending on the readiness of the health care profession.

The Annex provides examples of information derived from data in the EHR for individual segments of health. It should be kept in mind that both primary and secondary use require the inclusion of data on socio-demographic and psycho-behavioral determinants of health. American colleagues, for example, envisioned for their environment the following set of precisely defined data from the socio-demographic and psycho-behavioral domains to be included in EHR: race/ethnicity (2 questions), education (2 questions), exposure to financial difficulties, stress (1 question), depression (2 questions), physical activity (2 questions), tobacco use and exposure (2 questions), alcohol consumption (3 questions), social cohesion or isolation (4 questions), exposure to violence by an intimate partner (4 questions) and measures of economic development of the neighborhood in which the patient lives (2 measures). The list and forms of the mentioned data were obtained by researching the connection between health and potential socio-demographic and psycho-behavioral determinants (15).

Infrastructure for the implementation of EHR

Infrastructure implies ensuring the general principles of introduction of ICT in certain areas, which are:

- Data security,
- Application of international standards,
- Legal regulations and certifications, and
- Ethics.

Thus, the implementation of an electronic health record system requires the fulfillment of these general conditions. In other words, health care users, i.e. their health data, must be protected from unauthorized use, and any use of this data must be legally and ethically regulated. Continuity of health care requires interoperability of all subsystems, which means that international standards must be applied (Fig 4)..

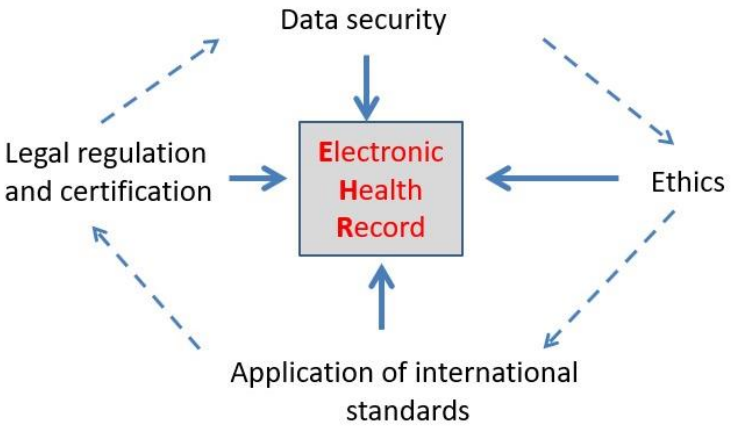

Figure 4. General principles of the EHR implementation

The EHR data security

The safety of health care users also depends on data security in their EHR. Data security implies protection against destruction (accidental or intentional) and against unauthorized use which can result in harm to the health care user by reducing his quality of life.

Data security includes a technical or technological component, as well as legal regulations and codes of ethics.

There are three dimensions of data protection contained in the EHR (EMR):

- Availability - data should be available only to authorized persons
- Confidentiality - authorized persons may disclose information only to authorized persons
- Integrity - only authorized persons can enter or change the entered data.

Traceability of use of the data (who accessed the data, entered the data, and made changes in them), as well as the undeniability and authenticity of the person who did so, must always be able to be established.

When they become an integral part of the EHR, the EpHR data should also be protected according to the same stated principles. In all other situations, the health care user takes care of data security in his/her EpHR.

Once the data become part of the EHR, technologically they must become "eternal." This means that both the original data and the data after the changes must be kept. In this way, it is always possible to reconstruct the data lifecycle regardless of the reason for their change.

Access to data from the EHR, EMR, and EpHR is allowed only to authorized persons. The persons authorized to access the data in EHR and EMR of a certain individual are persons who participate in providing health care to that individual, exclusively at the time when they do so.

Access authorization is proven by credentials.

For now, the health professionals use credentials issued by the HZZO to access the Central Health Information System of the Republic of Croatia (CEZIH). Credentials to access the data in a hospital or other facility not being an integral part of the CEZIH are issued by the manager of the institution’s information system. An individual, a health care user, can access a part of

their health data in CEZIH (so-called eKarton) via credentials of the Central State Portal and the National Identification and Authentication System (NIAS). In the future, in accordance with regulations (including the Patient Rights Protection Act), the health care user should be given access to his EHR.

An authorized person for access to data from the EpHR is the health care user, or the health professional to whom the health care user allows access to his/her data.

Any access to the EHR must be evidenced: who joined the EHR, when and on what basis. If the health care user has allowed access to their EHR, this must be recorded in the EHR access log. Data on any access must be available to the health care user.

Standardization

In limiting the diversity of products, processes, and services, ensuring their compatibility and interoperability as well as in finding the most appropriate solutions, standardization, particularly international standards, have an important role. Together with international standardization bodies (ISO, CEN, HL7, etc.) and related technical committees (e.g., Technical Committee for Standardization in Health Informatics at the Croatian Standards Institute, HZN/TO215) the standardization of EHR / EMR / EpHR requires the participation of professional bodies/associations in the field of medicine, health care and professional bodies/associations in the field of ICT.

Special emphasis should be put on the role of associations of health professionals (medical profession, nursing, etc.) which should define the content and format of data in the EHR / EMR / EpHR. Both primary and secondary use of data should be kept in mind when defining the content and format of data. This means that the cooperation of various health professions is necessary (e.g., when it comes to a diabetic patient, the cooperation of diabetologists, GPs and public health doctors is necessary - treatment, registration, reports, monitoring the quality of work, scientific research, etc.). Useful suggestions can also be expected from other professions such as medical informaticists and other ICT professionals.

It is necessary to consider the application of universal medical language, nomenclatures, and classifications in the development of EHR and EMR. Data protection should also be ensured by applying international standards on the protection of medical and health data related to health care users.

Legal regulations and certifications

Any activity in the field of e-health, including the development and improvement of EHR, should be regulated appropriately. The bases of e-health legislation should be contained in the Act on Health Care. The basic issues that such a law should contain are: (1) clear e-health terminology (EHR, EMR, EpHR), (2) who is in charge and responsible for a particular activity in the development and improvement of EHR and purposeful primary and secondary use of data from EHR (institutes, professional societies), (3) who has an overview and supervision (including the certification process of the EHR system) over the implementation of the EHR.

All EHR management subsystems involved in the Croatian health care system must be certified. The certification of the EHR management system should be performed at the national level and include both technical and functional, as well as semantic, process and business readiness of the system for inclusion in the Croatian health system. The list and detailed content of technical, functional, semantic, process and business (primarily professional) requirements that must be

met by the EHR management system in the certification process should be adopted at the national level and regulated by a bylaw.

Ethics

Ethics include ethical codes of conduct for medical/health professions related to personal and other information about the health care user (e.g., the Code of Medical Ethics and Deontology), but also the Code of Ethics for Health Informatics Professionals developed by the International Medical Informatics Association (IMIA) (16).

Code of ethics should primarily regulate the confidentiality of data on health care users.

The supervisory authority over the development of EHR

The system of supervision over the development or improvement of the EHR should be entrusted to the Supervisory Authority for eHealth (STeZ) as defined in the Declaration on eHealth.

Namely, in accordance with the Declaration:

> *"The strategy, construction and supervision of the health information system must be entrusted to an institution - the umbrella institution (institute, agency, office, etc.) operating at the national level."*

The explanation states:

> *"Everything outlined in this Declaration cannot happen only spontaneously and with the cooperation of the current entities in health care and beyond. It is necessary to establish an institution in charge of building and supervising the national health information system. Such an institution must be an umbrella, i.e. (1) that no one can do anything with public money outside that institution, (2) that it must be independent, and (3) that it must have a significant budget for the needs of central health informatics development (according to relative criteria in developed countries)".*

This approach was confirmed in the Strategic eHealth Development Plan, in February 2015 (17). As the EHR is a fundamental component of the HIS, this supervisory authority should organize the construction and supervise the development or improvement of the EHR.

Useful information related to the application of ICT in healthcare, especially for the construction and use of EHR, can be found in many documents from various countries. We highlight one of the more recent reports contained in a document from England (18).

Conclusion

The implementation of the Guidelines for improving the electronic health record will achieve the meaning and usefulness of the electronic health record in its primary and secondary use.

According to the Guidelines:

- Only one EHR, one EpHR and several EMRs belong to any health care user; parts of the EHR do not need to be physically located in the same place, but they must be linkable via the identification attribute of the healthcare user under certain authentication rules.

- Each EMR contains data collected at health facilities (PHC, polyclinics, hospitals, public health settings, etc.); data are collected by health professionals, by direct entry or transfer from devices producing that data.
- The EpHR data are collected and used by health care user; data are entered directly or transmitted from devices that produce that data.
- The EHR data must be available only to authorized persons; the concept of authorized person should be defined by-laws; the EHR data should be protected on three sides: technically, by regulations and codes of ethics, and in line with international initiatives (certification, EU regulations, standards, etc.)
- The EHR (and its parts) must meet both the primary and secondary use; the primary use is referring to the individual (diagnosis, therapy, vaccination, health care, etc.); the secondary use is referring to groups, i.e., the population in care, improving the quality of work in health care, the effects of preventive activities, as well as financing and scientific research.
- Both the content and format of EHR data should be defined by professional associations of health professionals, and ICT professionals who should find the appropriate technological solution.
- The strategy and development of EHR, as well as supervision from all aspects, should be entrusted to an umbrella institution operating at the national level; according to the Strategic Plan for eHealth Development, it can be the Central Body for eHealth.

The improvement of EHR should take place in stages, in accordance with existing knowledge, technological innovations, and financial possibilities.

The Guidelines for improving the electronic health record are not compulsory. They should be understood as the framework for the development of an EHR system able to meet the needs of all health care stakeholders, support health professional work, and enable continuous improvement of quality at all levels of health care, by contributing to preserving and improving the health of all health care users.

Contribution of the authors

All authors participated in the design of the paper. JK made the concept of the paper, the first text with the titles of the chapters, made schemes for individual chapters and coordinated the work on the manuscript. All authors participated in discussions, writing, and refinement of the paper. BBM, IH, BT, GR, KL, SV made initial texts on the secondary use of data from the electronic health record. PP worked on a text on information security. JK, PP, KL, KF, IH worked on searching the literature on the topic. All authors read the full text and agreed with the final version of the paper.

Annex

The secondary use of EHR data

The secondary use of EHR data of health care users primarily means deriving indicators that reflect:

- quality of work
- an argument for intervention like
    - improving the quality of work
    - work organization
    - additional education of health professionals
- evaluation of the intervention (e.g., patient outcomes based on the intervention carried out by the health care professionals)
- any research leading to new knowledge relevant to medicine and health care system, health professionals and health care users.

The secondary use of EHR data includes the possibility for early warning and response, for example, in case of an onset of acute infectious diseases with epidemic potential.

General practitioner (GP) and EHR

The GPs must be able to evaluate the quality of their own work based on data from the EHR. They must also be able to conduct research in a systematic, independent and documented way. From the data in the EHR, the doctor must be able to find out at any time (for the general population and for the patients registered with their practice):

- The prevalence of certain risk factors for chronic and other diseases and the modes of care
- The prevalence of chronic and other diseases and the modes of care.

1. Risk factors for chronic diseases

Insight into the prevalence of certain risk factors for chronic diseases, the mode of their care, as well as the connection of risk factors with the already established chronic non-communicable diseases:

a. population involvement in risky behavior (smoking, physical activity, diet, use of alcohol and opiates),
b. constitutional risk factors of the population (demographic indicators, anthropometric measurements),
c. other risk factors: hypertension, diabetes, hyperlipoproteinemia,
d. the social environment of the population.

The proportion of patients on whom diagnostic treatment was applied according to accepted guidelines (obliges the profession to define guidelines for the treatment of several major diseases),

The proportion of patients who received preventive measures for chronic diseases (stool for occult bleeding, mammography, breast ultrasound, vaccination against HPV virus, influenza, pneumonia),

Insight into the kind of treatment (pharmacological - number / polypharmacy / and type of drugs, and non-pharmacological treatments), in accordance with the recommendations of the accepted guidelines:

a. the dynamics of change in risk factors in relation to the treatment and the proportion of people with treatment results
b. allergies to certain drugs - anamnestic, clinically or laboratory proven (the origin of the data is important, because data on allergies are often based on the testimony of the patient or doctor, without a proven background, which may ultimately harm the patient),
c. side effects and interactions of individual drugs,
d. insight into use of non-prescription drugs (OTC drugs),
e. insight into other complementary or alternative treatments

2. Identified chronic diseases

Prevalence of identified chronic diseases according to the International Classification of Diseases (ICD), the method of treatment and the connections between lifestyle, risk factors and chronic diseases,

Proportion of patients on whom diagnostic treatment was applied according to accepted guidelines (obliges the profession to define guidelines for processing some major diseases),

Insight into the choice of treatment - pharmacological and non-pharmacological (number and type of drugs /poly-pharmacy, poly-pragmatism /), in accordance with accepted guidelines:

a. dynamics of change of chronic disease by treatment,
b. allergies – anamnestic, clinical or laboratory proven (the origin of data is important because data on allergies are often based on the testimony of the patient or doctor, without a proven background, which may ultimately harm the patient),
c. side effects and interactions of individual drugs,
d. use of OTC drugs,
e. complementary and alternative treatments.

3. Acute conditions

a. insight into acute conditions and diseases according to ICD,
b. correlation with demographic indicators and vaccination,
c. the association of acute condition and chronic disease management.

4. Frequency of antibiotic use

a. relationship between the antibiotic administered and the diagnosis,
b. the type of antibiotic and length of treatment,
c. correlation with demographic indicators,
d. allergic reactions to antibiotics and their side effects,
e. interaction of antibiotics with other drugs.

Today, some elements of the above are addressed through panels - parts of the electronic medical record (EMR) of each patient in primary care.

Specialist-consultative health care (ScHC) and EHR

ScHC includes diagnosis, treatment and rehabilitation of patients. Our goal is to formulate the secondary information arising from EHR that is needed by specialists and other health professionals:

1. Frequency of diagnoses in ScHC (code entered according to ICD) by age, sex, type of occupation, socio-economic status (work organization, procurement of equipment, etc.),
2. Frequency and types of tests with certain diagnoses (cost rationalization in order to avoid unnecessary tests),
3. Relationship between normal and pathological findings resulting from diagnostic procedures in ScHC,
4. Prevalence of risk factors for the development of chronic diseases in patients in SCHC according to demographic characteristics, type of occupation and socioeconomic status,
5. Evaluation of interventions aimed to risk reduction,
6. Types and number (relative/absolute) of prescribed drugs according to diagnoses (whether doctors follow the guidelines, effectiveness of individual drugs),
7. Types and number of diagnostic, therapeutic and rehabilitation procedures - according to demographic characteristics,
8. Relationship between SCHC doctors and GPs in patient care,
9. Correlation of types and frequency of side effects with recommended treatments,
10. Cancellation of outpatient procedures - according to the reason of the cancellation and the type of procedure.

Hospital health care and EHR

Secondary information obtained from the hospital's EHR has the following objectives:

- achieve patient safety
- help doctors and nurses to improve the quality of care
- monitor changes in the health system (*Agency for Healthcare Research and Quality. Advancing Excellence in Health Care*. Available at: http://www.ahrq.gov/index.html).

The following are examples of information derived from EHR data that can contribute to achieving these goals.

All medical activities with inpatients

1. Restraining according to duration, reasons and onset:
    a. the total number of patients restrained
    b. the total number of patients restrained more than once,
    c. the total duration of restraint in hours.

2. Falls:
    a. the total number of documented falls,
    b. falls according to cause - the patient's condition; reaction to treatment, procedure, anesthesia; risky environment; other reasons,
    c. the number of falls that caused the injury,
    d. patients who have fallen twice or more.
3. Bedsore:
    a. the total number of patients with newly developed bedsores,
    b. number of patients admitted with bedsores: total number; stage; the unit of previous residence (other department, house, other institution),
    c. prevalence by the number of localizations,
    d. according to stage (I-IV),
    e. according to localization (sacrum; sciatic bone; trochanter; calcaneus; malleolus; scapula; occiput; other),
    f. incidence of multiple bedsores.
4. Multidrug-resistant organisms:
    a. the overall incidence of MRSA,
    b. incidence of MRSA on surgical wounds,
    c. the overall incidence of Clostridium difficile,
    d. the overall incidence of VRE (Vancomycin-resistant enterococcus).
5. Successful cardiopulmonary resuscitation:
    a. survival 48 hours after resuscitation,
    b. by location (ward, emergency tract, intensive care unit, other).
6. Personnel exposure incidents:
    a. by location (in the ward, in a hospital clinic, in the emergency department),
    b. by type of staff (nurses, doctors, other staff).

Surgical activities

1. Infection of surgical wounds - according to the procedures,
2. Antibiotic prophylaxis - according to time,
3. Peri-operative mortality - according to the procedures,
4. Unplanned re-hospitalization - according to time,
5. Unplanned hospitalization after an outpatient procedure - according to the procedures,
6. Unplanned return to the intensive care unit - according to the procedures and time,
7. Unplanned return to the operating room - according to the procedures,
8. Deep venous thrombosis and pulmonary thromboembolism after surgery - according to the procedures,
9. Pre-operative thrombo-prophylaxis - according to the procedures.

Intensive care or nursing units

1. Use of central venous catheter, ventilator, permanent urinary catheter,
2. Infections related to the use of the central venous catheter; ventilator; permanent urinary catheter,
3. Nosocomial infections (MRSA, etc.):
    a. bacteremia in the central venous catheter,
    b. ventilator-associated pneumonia,
    c. symptomatic urinary tract infection with a permanent catheter.

Units using sedation and analgesia (intensive care units, endoscopy, emergency department, angiography room, radiology).

Complications after sedation and analgesia:

1. according to the unit,
2. according to the type of complication - oxygen de-saturation, aspiration, airway obstruction, sudden drop in systolic blood pressure, etc.

Emergency Medical Service (EMS)

1. Length of treatment according to duration and outcome - hospitalization, admission to the intensive care unit, other,
2. Degree of urgency,
3. Unplanned return to EMS:
    a. according to time, outcome and diagnosis,
    b. the number of patients with two or more returns to EMS within 30 days,
4. Leaving the EMS before the end of treatment - the percentage of patients,
5. Change of approach to the patient due to radiological findings - the percentage of patients whose access to treatment was changed due to radiological findings, method of treatment, degree of urgency, etc.

Psychiatry

1. Self-harm - per 1000 discharges, per 1000 days of hospital stay,
2. Suicide attempt - per 1000 discharges; per 1000 days of hospital stay,
3. Suicide - per 1000 discharges, per 1000 days of hospital stay,
4. Physical assault - per 1000 discharges, per 1000 days of hospital stay,
5. Escape - per 1000 discharges, per 1000 days of hospital stay,
6. Transfer to an acute psychiatric care unit,
7. Re-hospitalization according to the time of occurrence,
8. Measures of physical restraint (tying, clamping):
    a. number of procedures - per 1000 discharges, per 1000 days of hospital stay, per 100 patients,
    b. the number of patients in whom the measure was used two or more times in one stay.

9. Isolations:

   a. number of isolations - per 1000 discharges, per 1000 days of hospital stay,

   b. duration,

   c. number of patients with two or more isolations during the same hospitalization.

Nursing and EHR

The nursing documentation contains information that provides quality control of planned and implemented health care and is an integral part of the patient's medical documentation, i.e., EHR. Patronage healthcare is an example area of nursing in which electronic documentation helps to provide high quality care. Clear, concise, and thorough record-keeping of the patronage health is crucial because nurses are health professionals who sometimes the patient only encounters in their home, so encouraging documentation at the place of care ensures that the data important for treatment are not missed or forgotten.

Whether the documentation relates to an individual, a group, or community, it gives a clear picture of:

- the needs and goals of the individual, group, or community
- undertakings based on assessment need
- results and outcomes of implemented interventions
- knowledge and skills of health care providers, possible shortcomings of health care, and opportunities to improve the quality of health care.

The obligatory part of the nursing documentation contains:

- nursing history
- nursing diagnoses and patient characteristics
- monitoring the patient's condition during hospitalization and continuous monitoring of procedures
- medical-technical and diagnostic procedures
- continuous monitoring of the patient's condition
- health care plan
- list of nursing procedures performed
- discharge letter of health care.

From these data much secondary information can be obtained:

1. Proportion of nursing records containing all required parts, i.e., those that lack some of the parts (e.g., anamnesis, diagnosis, nursing procedures, etc.) - in order to ensure the continuity of care,
2. Proportion of patients by categorization – for better organization of nurses' work, i.e., ensuring enough nurses for quality patient care, and justifying the need for nursing staff,
3. Number of procedures or interventions by type and in relation to the plan,
4. Success of implemented interventions,
5. The outcome of care by the caregiver,
6. Recorded incidents.

It is possible to find out from the constant monitoring of the patient's condition what procedures are administered to the patient and by whom. We can track the duration of a particular procedure and which procedures are commonly most administered to the patient.

Public health needs and EHR

The functions of operational public health are:

- Health monitoring to identify and address community health needs,
- Diagnosing and examining community health problems and health risks,
- Evaluation of effectiveness, availability, and quality of health care for both personal and health organizations and sub-populations of interest for public health,
- Early identification of population health threats and rapid response (EWRS).

The public health administrator and employee should automatically receive this information from EHR:

1. Prevalence and incidence of diseases and conditions according to age, gender, socio-economic status, year of occurrence, geographical location,
2. Vaccination by age, gender, socio-economic status, year of occurrence, geographical location,
3. Disability by age, gender, socio-economic status, year of occurrence, geographical location,
4. Response to national (or regional) preventive programs by age, gender, socio-economic
5. status, year of occurrence, geographical location,
6. Relationship between incidence and response by age, gender, socio-economic status, year of occurrence, geographical location,
7. Frequency of side effects of treatment and vaccination according to age, gender, socio-economic status, year of occurrence, geographical location,
8. Mortality by age, sex, socio-economic, status, year of occurrence, geographical location,
9. place of death,
10. Register needs - entry and exit from the register - re-reason for registration.

Health Insurance and EHR

The insured person needs to obtain the following information from the electronic health record:

1. Health services provided according to:
   a. Institutions and medical discipline
   b. Health care workers in institutions and disciplines,
   c. Recipient's insurance status,
   d. Codes of procedures and disciplines,
   e. Codes in the ICD and disciplines,
   f. Documentation provided by health service,
2. Consumption of ampoules of drugs by discipline,
3. Sick leave.

The description of the necessary information from the EHR depends on the content of the Contract for the provision of health care made between the insured and the health care provider.

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