Declaration on eHealth
1st Revision[1][2]

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The Croatian Academy of Medical Sciences (CAMS) has published this "Declaration on eHealth" to warn all stakeholders (patients, health professionals, institutions, government agencies, suppliers) to use the huge potential of information and communication technologies (ICT) and solutions to improve health care in Croatia. The Declaration draws attention to areas of infrastructure such as: education, regulation and standardization, medical and health informatics (MHI) as a profession, the obligation of institutions, government bodies and suppliers.

In addition to answering the question "what?", the Declaration addresses the most important question "how?". Instead of the existing "atomization" and disconnection of projects and solutions, the Declaration proposes the realization of a common concept of computerization in health and for health by establishing a central body at the state level (agency, office, institute, etc.) in which expertise, decision-making and financing of health informatics projects at the national level will be concentrated. The central body should function on the principles of professionalism, independence and transparency. The purpose of the proposal offered by the Declaration is to improve the management of health system computerization, which would avoid containment within institutions, enable obtaining and purposeful use of available financial resources and experts, and achieve the necessary cooperation, which would bring the results in ICT support to the health system.

Key words: eHealth; medical informatics; declaration

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[1] The last section of the Declaration has been revised in line with the changes regarding ProRec Center Croatia
[2] Croatian version is available at: http://www.amzh.hr/nakladnistvo/deklaracije/

Preamble

Modern ICT enter all spheres of human life and existence. Accordingly, medicine and health must be included. This technology facilitates access to information, enabling dissemination of knowledge and supporting responsible decision-making.

Examples of misuse and even abuse of the technology point to the need for the introduction of rules in its use. To avoid mistakes and misuse of ICT in medicine and health care, it is necessary to assess the possibilities of such technologies, set up a framework, adopt standards for information infrastructure, quality and safety and define an appropriate education.

Medicine and healthcare are very sensitive areas in terms of human life and work, and any inappropriate use or misuse of medical information can lead to undesirable outcomes.

The fact is that Croatia is working on the computerization of the healthcare system. Computerization of primary health care mainly refers to the storage of patient data in digital format and data exchange with the Croatian Health Insurance Institute (CHII).

Components that will enable primary care physicians to continuously learn through information infrastructure and information system, routinely consult (telemedicine) with colleagues and specialists, to review and complete national databases, to communicate directly with the patient through ICT, do not even exist in the plans yet, so a big, organized job is ahead. Hospitals, as well as polyclinics, have their own ideas and are constantly working on developing their own information systems that would meet their information needs.

Public health institutes (but also other participants) are developing subsystems based on data coming from health institutions. Much of this data is stored in the medical records of their patients. However, sending this data to other institutions requires additional work of health care staff (work reports, data from medical records), which often results in delays and sometimes incomplete data. Therefore, health statistics reports are late. Furthermore, health records are generally fragmented (some patient data is in primary care, some in hospitals, and much of the medical data is kept by patients at home). All this complicates access to patient data, which creates problems in direct medical work of health care providers.

The process of computerization of the health system itself is not going smoothly. As a rule, health professionals (as users of the health information system) are not involved (enough) in its development, and they are not satisfied with the results (with software products they receive). It is often unclear how they could influence the improvement of the system, to whom to suggest and how, or, how to replace painlessly a software product that does not satisfy them.

Therefore, the Committee for eHealth of the Croatian Academy of Medical Sciences proposes the Declaration defining the framework for the application of modern technologies, educational frameworks for health professionals and general informatics professionals, as well as frameworks that will raise the quality of eHealth, and thus the quality of the health system.

Framework

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1. eHealth

eHealth is a common name for the development, implementation and evaluation of ICT in the health system for the needs of health professionals (routine / professional work; continuing education or lifelong learning; evaluation of professional work; research) and for the needs of all citizens (care for their own health; information on the health system; reliability of health information on the Internet).

> *There are different terms talking about the application of ICT in health and medicine (biomedical, medical and health informatics, health portals, medical advice on the Internet, information for patients, computerization of health care, internetization of health system, telemedicine, telehealth etc.). It is useful to create an umbrella term, like eHealth, that includes all the above.*

2. Health information is an issue of public interest

Health information collected in health institutions daily serve to make decisions related to efficiency and management of the healthcare system. Good and valid healthcare system is an issue of public interest for both the state and the society.

> *The amount of information in the healthcare system needs the modern ICT. The decision-making needs facts, i.e. available, accurate, up-to-date, timely, secure and unchangeable information. In the same time, the public interest requires the principle of data protection (in terms of general human rights and international and national legal acts on health data protection in the health system), as well as ethical principles in the handling of medical and health data.*

> *Public money may only finance clearly designed health computerization projects with the ultimate meaning, and concrete practical goals (aimed at the direct, immediate benefit of citizens that they can perceive, feel and use). Improving the system (or any process) without practical benefit to citizens, must not be a sufficient reason to use the public money. Such projects need redesign.*

> *The private health institutions should also a part of their data (of public interest) make available and involve them in production of public information of interest for the state and the society in general.*

3. Ensuring and improving the quality of health care

Investing in eHealth will ensure and enhance the quality of healthcare.

> *The ICT in the healthcare system is a means to further improvement the quality of health care based on solidarity, accessibility, comprehensiveness, efficiency and equity. A sustainable and high quality health care we cannot achieve without investing in ICT in health care. Investments must be appropriate (with an amount based on the experience of developed countries) and in line with the results that these investments should yield.*

4. Defining the medical and health informatics as an activity in healthcare system

The law should define the activities of medical and health informatics (MHI) in healthcare facilities as well as standard of MHI professional team (MHIP team).

Different types of experts are necessary for the planning, development and management of ICT in health care facilities. The structure and size of the team depends on the level of health care (primary, secondary, etc.) and the degree of computerization at that level. Following the example of other medical professions, it is necessary to develop a legal framework that would define the activities of MHIP.

The ICT development plans in the health system must also contain clearly defined needs for ICT staff. It is necessary to identify the good practice of balanced development and management of certain functionalities of the system by their ICT employees and involvement of external experts. Addressing the status of ICT professionals, i.e. MHIP in the healthcare system contributes to positive staff selection.

5. Establishment of an umbrella institution for medical and health Informatics

Strategies, construction and supervision of health information system should be entrusted to a body, as an umbrella institution (institute, agency, office) which operates on a national level.

Nothing (highlighted in this Declaration) can happen only spontaneously, i.e. through the cooperation of existing entities in health care or outside it. A body in charge of building and supervising the national health information system needs to be established. Such an institution must be an umbrella, i.e. that no one can do anything with public money independently of this body. Such a body must be independent. It must have a significant budget for the needs of central development of health informatics (in accordance with the standards in developed countries).

6. Involvement of medical professionals in professional teams of medical informatics

Inclusion of medical professionals of different profiles into MHIP teams will improve and facilitate the development and management of ICT in the healthcare system.

Understanding the needs of the healthcare system, medical technology and the possibilities of ICT is essential for the successful development and management of the information systems in medicine and healthcare. Establishing a system of sub-specialization of MHIPs and the definition of professional status will encourage the entry of medical professionals in this field.

7. Legal regulation of computerization of healthcare system

The harmonized legislation should fully support the entire area of eHealth.

Some of the existing regulations/laws related to healthcare are not completely consistent. Therefore, they should be adjusted or upgraded. Legislation should regulate the content of medical documentation, including electronic health records, policy and information security as well as the position of the central institution described in Section 5.

8. Change management

The introduction of ICT in the healthcare system requires changes in the way of working of both individuals and organization. Therefore, change management is essential.

At the top of the pyramid of any computerization project there must be an appropriate change management project (work organization, education). Tasks for all other projects / activities also arise from the change management project.

Education

9. eHealth issues in the education of health professionals

The educational curriculum of every health profession must include topics on eHealth.

> *For the effective use of modern ICT in medicine or the health profession (doctor, nurse, medical technician, etc.) it is necessary to know the principles, possibilities and limitations of ICT and acquire skills for its use. Avoiding formal, factual, and superficial teaching, and insisting on understanding and putting technology in the context of everyday activities in the health system, is necessary. It is important to encourage health professionals to active assess the strengths and weaknesses of the application of specific technologies and procedures.*

10. Health / medical topics in the educational curriculum of ICT professionals

It is necessary to establish a new educational profile, i.e. profession of medical / health IT professional (MHI specialist). It means to introduce health/medical topics in the educational curriculum of ICT professionals who want to work professionally in eHealth area.

> *The fact is that the collaboration of health professionals and ICT specialists will be more effective if both parties have knowledge in common. This implies that healthcare professional should achieve certain skills and knowledge in the field of MHI, and ICT specialist specific knowledge and skills related to medical and health issues.*

11. Education for change management

Users of ICT based system (existing or in future) must be involved in the design of that system from the mere beginning. More than that, involvement of users in testing, continuous monitoring and evaluation of the system must be condition sine qua non. Users' education must have the highest priority in the process. All stakeholders must be informed timely and appropriately about everything that is important for the system (purpose of the system, system development, results of testing, monitoring, evaluation, etc.).

> *The postulates of change management imply that the users of the future system should be involved in the computerization project from the very beginning (and, continuously, in all phases of project development). It must not happen, that system users get to know the system just after its completion. Therefore, strategists, planners, computer scientists, and health professionals need to understand the basics of change management, so that they can participate, plan, and implement the project successfully. In addition, change management must be regulated organizationally - to establish the way of communication between users and system manufacturers.*

Communication

12. Communication between health care institutions, and health care institutions with health care users

Citizens must be able to communicate (in a way that is tailored and useful to them) with any part of the health system. Healthcare professionals and healthcare institutions are also obliged to communicate with each other.

All participants in the health system (healthcare users, healthcare providers) should be enabled to use methods of e-communication. The Ministry of Health, clinical hospitals, the Croatian Health Insurance Institute (CHII) and other health insurances, the Croatian Institute of Public Health (CIPH) and other institutes should be leaders by example. Therefore, the healthcare institutions should have their own up to date web. There should be information useful to the health care users (e.g. about diagnostic unit or practice, working hours, about health professionals, contact, etc.). Information on health could be useful for healthcare users too (e.g. health education, how to achieve health information or maintain it - the reliability of such information should be confirmed by HONcode certification). Healthcare institutions should proactively apply technologies that enable data exchange between institutions as well as two-way communication (institutions with healthcare users) which could increase the quality, speed / ease of service providing, and reduce costs and errors.

Quality of eHealth

13. Integration of health information

Health Information System (HIS) must integrate all the data/information circulating in the health system and, with a high degree of security and protection, ensure availability of data to authorized entities.

Every healthcare user should have their own unique electronic health record (EHR) with data coming from various health care facilities (family medicine office, other medical specialty, hospital, laboratory, diagnostic unit and elsewhere). The EHR does not necessarily have to be physically on the same place. However, any part of the EHR must be linked to others whenever is necessary, meaning, when is required by an authorized person (health professional with patient at the point of care), and with the patient's consent. Every health care user must be able to find out who used his/her data, when and what data, as well as what rights (law) or authorizations allowing to do that.

14. Health statistics as an issue of public interest

Data on health status of citizens and health services provided in health care institutions are the basis for making periodic statistical reports (used by the CIPH, network of county institutes of public health, and other institutes and agencies). The purpose of health statistics is to diagnose health status of the population, surveillance on the health system, and basis for public health interventions in the population as well as in the organization / reorganization of the health system itself.

Extracting of data from the patients' EHR (information on treatment, prevention, medical procedures, etc.) enables the health statistics reports to be current and immediate (without delay). Using the data in any part of the health system and cooperation of the institutions and agencies in health sector will help to improve the quality of work. Indicators of the quality of work are instruments measuring such activities. Retrieval and use of data should be anonymously (identity of health care user should not been known). Part of health statistical information should be available to users outside the health system too.

15. Health registries

Any health registry should be a result of extracting data that already exists in the EHR. Information on deaths obtained from the Registry of Deaths should also enter in the EHR. In this way, they become usable for the purposes of the health registry too.

> *Extraction of data from the patient's EHR, will enable updated and completed health registry.*

16. Standards and standardization

Standardization is a prerequisite for the proper functioning of any system. This refers to standardization in the education system (at all levels of education), in science and research (appropriate definition of scientific areas, fields and branches) and in everyday practice (eg in daily medical/health practice, in development and use of health information systems, etc.).

> *"Standard is a document adopted by consensus, approved by the competent authority, which for common and repeated use, provides rules, guidelines or characteristics for activities or their results, and ensures the best level of organization in the given circumstances" (Act on Standardization). Also, standards are medical guidelines (e.g. Guidelines for the treatment of hypertension, etc. issued by international professional bodies) as well as recommendations of other international bodies and organizations (e.g. Recommendations on Education in Biomedical and Health Informatics, or the Code of Ethics for Medical Informatics given by the International Medical Informatics Association (IMIA)). Regarding standardization of health information system, it is necessary to follow the European (CEN, CENELEC, etc.) and international standards (ISO, HL7, etc.) and standards adopted by Croatia (Croatian Standards Institute, CSI).*

17. Certification of software and other products

Any product (before its use) must pass the certification process: verification of functionality, security of data and information system itself, as well as interoperability. For this purpose, it is necessary to set the primary criteria that a product must meet, establish a body that will implement the certification process, define the period for which the certificate will be valid as well as the conditions for a potential recertification of products.

> *When it comes to the HIS, EHR, etc., the body that conducts certification must include a variety of professions: (1) users / health professionals, (2) Medical Informatics and ICT professionals, (3) lawyers, and (4) a variety of professions and individuals potentially interested for considered problems.*

18. Obligations of producers and vendors about software product for healthcare system

All software applications intended for the same user group (eg family medicine) must be compliant. This means that each new software product must ensure direct interoperability with other software products in a given area (eg family medicine) developed according to the given criteria. In other words, it must be possible to export data in a standard format that any software product intended for the same field of application can accept.

> *Establishing the criteria that a software product must meet, respecting standards and certification criteria will increase responsibility of producers and vendors, as well as freedom of end users (health professionals) in choosing or replacing software products.*

19. Obligation to comply with European initiatives in eHealth

Development of EHR systems must be compatible with European initiatives in eHealth.

The European Institute for Health Records (EuroRec) in 2009 launched a project to harmonize the quality of the EHR system in the European Union. On the Croatian side, the Croatian Society for Medical Informatics (CSMI) participated in the project. The establishment of the ProRec Center in the Republic of Croatia in 2013 enables a direct connection with European activities in the field of e-health and involvement in European and Euro-Atlantic projects of the European Commission coordinated by EuroRec.

19. Obligation to comply with European initiatives in eHealth

Abbreviations

CEN	European Committee for Standardization - European Organization for Standardization (http://www.cen.eu/cen/NTS/What/Pages/default.aspx)
CSMI	Croatian Society for Medical Informatics (http://www.hdmi.hr)
EuroRec	European Institute for Health Records - an independent nonprofit organization in Europe to promote the use of high quality EHR (http://www.eurorec.org)
EHR	Electronic Health Record
HIS	Health information system
HL7	Health Level Seven International - an international organization of production and exchange of communication standards in healthcare, also a group of such norms (http://www.hl7.org)
HONcode	Code of Conduct devoted to medical and health Web sites - a certificate on the reliability of health information on the Internet (http://www.hon.ch)
CAMS	Croatian Academy of Medical Sciences (http://www.amzh.hr)
CIPH	Croatian Institute of Public Health (http://www.hzjz.hr)
CSI	Croatian Standards Institute (http://www.hzn.hr)
CHII	Croatian Health Insurance Institute (http://www.hzzo-net.hr/)
ICT	Information and Communication Technology
IMIA	International Medical Informatics Association (https://imia-medinfo.org/wp/welcome-to-imia-the-international-medical-informatics-association/)
ISO	International Organization for Standardization (http://www.iso.org/iso/home.html)
MHI	Medical and Health Informatics
MHIP	MHI profession
ProRec	https://www.hzzo.hr/en/osnovana-hrvatska-udruga-za-elektronicki-zdravstveni-zapis-prorec-hr/