

Declaration on eHealth - 10 years later

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Abstract. Declaration on eHealth (Declaration), the project of the eHealth Committee of the Croatian Academy of Medical Sciences (CAMS), was published in 2011 on the website of CAMS. With minor changes, the text of the Declaration in Croatian is available on the website of the CAMS and, in English, in the Bulletin of the Croatian Society for Medical Informatics (CroSMI) and on the social network ResearchGate.net. To find out what happened to the Declaration after 10 years, an evaluation was carried out according to the OECD's input-output-outcome-impact model, (a) through direct consequences, i.e., official documents quoting some of Declaration's statements, and b) through facts being in line with the Declaration, occurred after the Declaration was published. The paper describes input, output, outcome, and impact as the steps in evaluation. The main outcomes are listed in the table, then titles of documents, as well as quotations confirming compliance with statements in the Declaration. Considering the effect, five statements in the Declaration have achieved a noticeable effect in the Croatian eHealth. Although not yet fully implemented (like, some hospitals have not yet implemented the system compatible with the central health information system; there is the health portal for communication with citizens, but it is unknown how many citizens use them for now; criteria and protocols for the certification process have been defined, but certification is not entirely in accordance with EuroRec criteria; medical / health informatics issue (MHI) for future healthcare professionals exists, but differently in different teaching programs, even for the same type and level of educational institutions). There are several outcomes in accordance with Declaration and international trends, which could be considered as the effect of the Declaration. Finally, there is no complete and satisfactory solution for eHealth even internationally. Thus, it takes more time and effort to fully achieve the digitalized health system at the national and international level.

Keywords: Declaration on eHealth; impact

About the Declaration

The Declaration on eHealth (Declaration), a project of the eHealth Committee of the Croatian Academy of Medical Sciences (CAMS), was published in 2011 on the website of CAMS. With minor changes, the text of the Declaration is available (in Croatian) on the website of the CAMS (1) and, in English, in the Bulletin of the Croatian Society for Medical Informatics (CroSMI) and on the social network ResearchGate.net (2) as well.

The “minor change” in the revised text of the Declaration on eHealth refers to statement 19 (Obligation to comply with European eHealth initiatives) which mentions the Prorec National Center which did not exist at the time the Declaration was published. Association, Prorec Croatia was founded in 2013 (3). Therefore, the text “Given the fact that Croatia does not have its own national ProRec center included in the EuroRec network, the Croatian Society for Medical Informatics (CroSMI) is participating in the project as a partner. The establishment of the ProRec Center in the Republic of Croatia would enable a direct connection with European activities in the field of eHealth and involvement in European and Euro-Atlantic projects of the European Commission coordinated by EuroRec” replaced by “On the Croatian side, the Croatian Society for Medical Informatics (CroSMI) 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 eHealth and involvement in European and Euro-Atlantic projects of the European Commission coordinated by EuroRec”

According to the Portal of Croatian scientific and professional journals (Hrcak) on the readability of the Declaration in the period from 15 February 2021 to 28 February 2022, the Declaration was visited by 187 people and 75 of them downloaded the text of the article. In parallel, the Declaration (in English) is also available through the social network ResearchGate (2) through which it has gained 45 accesses.

There is no information on the reading of the Declaration on eHealth published on the website of the CAMS from 2011 until today.

Evaluation, or, what happened after the Declaration on eHealth has been published?

Project success or failure is not an absolute category. Both, success and failure of a project depends primarily on the criteria according to which the project is evaluated, but it also depends on who carries out the evaluation (4). The basic criterion for the evaluation of the Declaration will be the acceptance of its statements by the system to which the Declaration refers. The second criterion is time, the period elapsed from the day when the Declaration saw the light of the day to the moment when the evaluation is carried out. In this case, the period is ten years (from 14 March 2011 to the end of February 2022).

The eHealth Declaration will be evaluated directly and indirectly:

- (a) through direct consequences, i.e., official documents quoting some of Declaration’s statements, and
- (b) through facts being in line with the Declaration, occurred after the Declaration was published.

The latter, of course, cannot be treated as a consequence of the Declaration, but the consistency of the facts with the statements in the Declaration is talking about a certain harmonization of the Declaration and what digital transformation in health implies.

Methods

According to OECD (5) „evaluation of an individual development intervention designed to achieve specific objectives within specified resources and implementation schedules, often within the framework of a broader program”. The *Declaration on eHealth* can be considered here as an *individual development intervention* within the *framework of the broader program*, here, the *digital transformation of healthcare system*. The categories that are mentioned are: input, activities, output, outcome, and impact. In practice, activities are often attached to the input. So, the evaluation can be reduced to four categories, i.e., input-output-outcome-impact scheme (Figure 1).

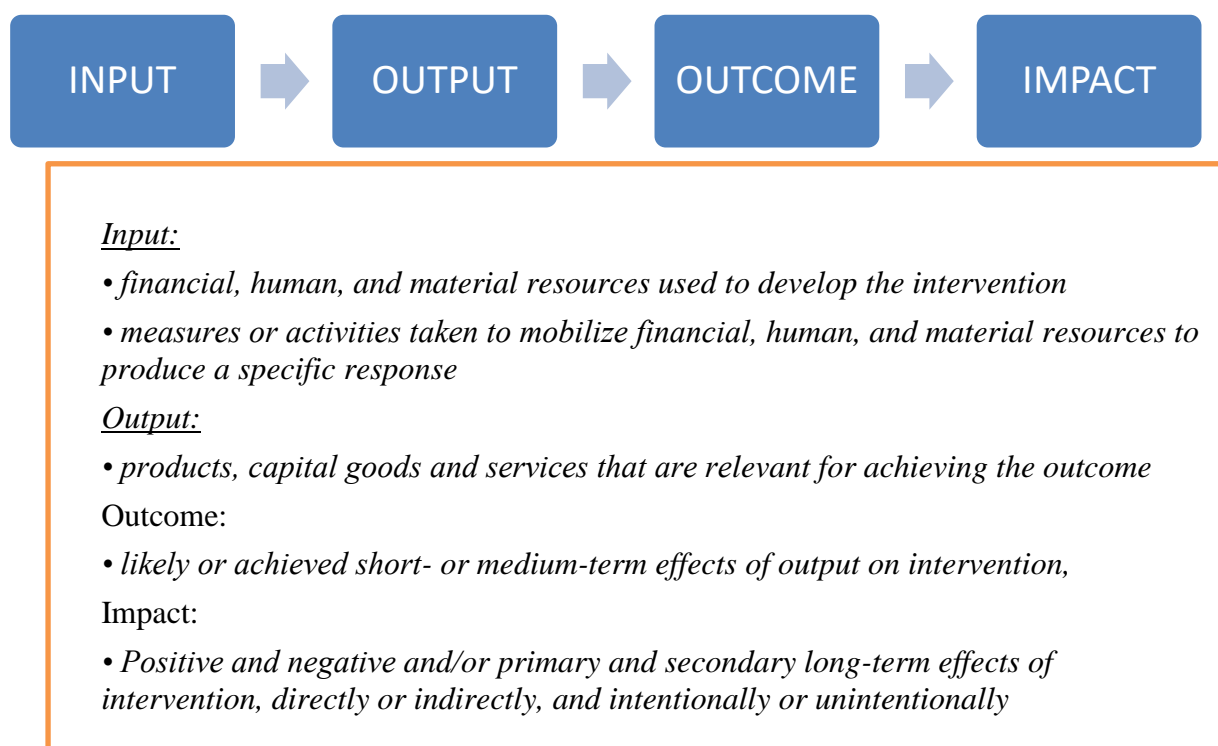


Figure 1. Model of a project evaluation

Results

Input

The basis of input is human and minimal material potentials within CAMS and CroSMI:

1. Establishment of the eHealth Committee in CAMS; involvement of health professionals and information and communication technology (ICT) professionals; initiating cooperation with CroSMI

From the Minutes: At the meeting of the Telemedicine Committee held on May 28, 2009, it was decided to rename the Telemedicine Committee as the *eHealth Committee*. Josipa Kern was elected Chair of the Committee. The work of the Committee includes members from the former Telemedicine Committee, who expressed readiness to continue working in the new Committee, and several new members (Marijan Erceg, Đuro Deželić, Inge Heim, Silvije Vuletić, Biserka Bergman Marković, Predrag Pale, Miroslav Mađarić, Anamarija Margan, Luka Kovačić, Branko Richter, Božica Trnka, Vesna Ilakovac, Zdravko Huber, and Ivan Pejakić).

In addition to proposing topics to be addressed by the eHealth Committee:

(ICT for the needs of the healthcare system and healthcare users; education in medical informatics for health and technical staff; establishing the medical informatics profession; standards - cooperation with the Croatian Standards Institute and the Technical Committee (HZN / TO215); certification of ICT applications - compliance, functionality, security, interoperability, legal matter, ethical aspect and code for medical informaticians; systematization of procedures for improving the health information system through continuous participation of doctors, nurses, etc., improving electronic health records, advertising health facilities online with HONcode for reliable health information)

it was decided that the result of the Committee's work will be the the document *Declaration on eHealth* in Croatia. The CAMS will present the views of the Committee. The Declaration should be published as the official document of the CAMS, and media need to inform the public about these views of the CAMS.

2. Written materials, papers on ICT in healthcare system, i.e. references in the past five years: a review by Haux (6) on health information systems "past, present, future", then a special issue of journal Acta Medica Croatica published in 2005 dedicated to the informatization of healthcare system in Croatia (7-11), one of the first papers on systematic approach to informatization in Croatia (12) and the international conference EFMI STC 2007 with a series of papers published in international journals (13-16).

3. Working on the text of the Declaration - proposals, agreements, discussions and amendments.

Output

1. Final text of the Declaration on eHealth - permission of the CAMS leadership to present it to the public, i.e., stakeholders in the healthcare system and health policy

2. Presentation of the Declaration

a. Tribune (March 14, 2011) at the Croatian Medical Association, Šubićeva 9, Zagreb

b. MI2011 (Varaždin) - invited lecture at the Symposium of the CroSMI

- c. Publication on the CAMS website
- d. Declaration on eHealth. News on PLIVAMED.net 2011 (17)
- e. Declaration on eHealth. News on the website of the Association of Teachers of General and Family Medicine (18)
- f. Declaration on eHealth. News in Croatian Journal of Public Health (19)

Outcome

Outcomes, "*likely or achieved short-term or medium-term effects*" are presented in the field of policy (Croatian or European laws, regulations, guidelines), and the profession (professional associations such as the Croatian Society for Medical Informatics, eHealth Committee of the Croatian Academy of Medical Sciences, faculties and health institutions such as the Croatian Institute for Health Insurance (CIHI), the Croatian Institute for Public Health (CIPH) etc.).

Outcomes are documented by original documents, and by quoting parts of these documents that confirm the compliance of the document with the statement in the Declaration (Table 1)

1. Direct outcomes of the eHealth Declaration:

Official documents *The Strategic Plan for the Development of eHealth in the Republic of Croatia* and the *National Strategy for the Development of Health* (20.21) quote certain statements of the Declaration on eHealth, represent the direct outcome of the Declaration.

2. Indirect outcomes of the Declaration:

- a. Various official documents, which are in accordance with the statements of the Declaration on e-health.

These are the *National Development Strategy of the Republic of Croatia until 2030* and the *National Health Development Plan 2021-2027*. (22, 23), *National Recovery and Resilience Plan 2021-2026*. (24), regulations and laws (25-29), the *National Public Health System* (30), the establishment of the Directorate for eHealth (31), a series of operational activities and protocols (32-35).

- b. Activities in accordance with the Declaration

Establishment of working groups within the professional association CroSMI (36-38), initiatives for education relevant for process of digital transformation of the healthcare system (39, 40)

- c. European sources and documents in accordance with the Declaration

The inclusion of Croatian eHealth in European trends and the European Commission's support for Croatia's efforts to digitize health care system (41-43) are in line with the statement of the Declaration on the necessity of international cooperation.

Impact

The impact of the project / intervention, in this case the Declaration, assumes that the results of the project / intervention have become an integral part of the system. The impact of the Declaration, "positive / negative, primary / secondary long-term effects of intervention, direct / indirect, intentional / unintentional" is as follows:

1. Compliance with Statement 9 of the Declaration

- a. By the decision of the Ministry of Science, Education and Sports, health informatics issues was introduced into the curriculum of nursing school in 2019 (40).

2. Compliance with statements 12 and 13 of the Declaration

- a. eReferral, eFindings, eDischarge letter, electronic data exchange - communication of health institutions with each other in the country and internationally (32, 41-43)
- b. Health Portal for healthcare users (35).

3. Compliance with statements 17 and 18 of the Declaration

- a. Certification protocols with list of technical and functional requirements (33,34)

Conclusion

The Declaration on eHealth reflects the requirements for digital transformations of the healthcare system. Digital transformation is a process of adapting the existing system, processes, human resources, education, etc. for continuous improvement in the light of ICT. Technologies are also changing more and more. New technological solutions and improvements require insistence on education. In its conclusions of the report on the digital transformation of the healthcare system and health (44), the European economic and social committee, as well as the Declaration on eHealth, emphasizes the need for appropriate education in modern ICT for all stakeholders. Special emphasis is placed on healthcare staff and users of healthcare system services.

Such efforts in Croatia have been underway for decades. For example, HMI issues have been incorporated in the curriculum of medical faculties, polytechnics in the field of health, and from 2020 in secondary nursing schools. Empowering the health professionals in the process of digital transformation of healthcare is leading to their increasingly important role in improving existing applications and developing new ones (evaluation of existing applications by health professionals), in raising awareness of the value of health data, and their importance for secondary use (45-51).

Another important direction of digital transformation is colored by technology itself, problems of legal and ethical nature, standardization and interoperability, international harmonization, and cooperation (52-57). It should be noted that Croatia's efforts have been supported in Europe (58), and with key documents (Croatian eHealth Strategic Development Plan 2020-2027 and Action Plan 2021-2022).

As for the impact of the Declaration, it can be said that there are only (or even) five statements that have achieved an impact in the health system. However, all of the above has not yet been fully implemented (e.g. there are hospitals without information system compatible with the central health information system; health portal for communication with citizens exists, but an open question is how many citizens are using it; certification protocols exist, but have been not completely harmonized with EuroRec criteria; MHI education exists, but has not been uniform at all medical / health educational institutions - neither in content nor in position in the curriculum). However, there are several outcomes that are in line with the Declaration and international trend but have not yet shown satisfactory impact. Certainly, it should be considered that there is no final, even satisfactory solution internationally yet, and more time and effort is needed to realize not only the digitalized healthcare system in the national framework, but also internationally.

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Table 1. Outcomes of Declaration on eHealth

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>1. eHealth</p> <p>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).</p>	<p>(1) Accepted term "eHealth"</p> <p>(2) The umbrella national strategic document until 2030, among the policy priorities in the field of health and health care, states faster digitization and data protection.</p> <p>(3) Strategic goal in NRRP: C5.1. Strengthening the resilience of the health system. Reform measure: C5.1. R5 eHealth.</p> <p>(4) In the introduction to the national health development plan, e-health is addressed.</p>	<p>(1) Ministarstvo zdravlja, HZZO: Strateški plan razvoja eZdravlja u Republici Hrvatskoj – SPeZ. Sažetak. Zagreb, 2014. (str.3), Dostupno na: https://zdravlje.gov.hr/UserDocImages/dokumenti/Programi,%20projekti%20i%20strategije/Strate%C5%A1ki-plan_razvoja_eZdravlja.pdf</p> <p>(2) National Development Strategy of the Republic of Croatia until 2030, Dostupno na: https://hrvatska2030.hr/dokumenti/</p> <p>(3) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p> <p>(4) National health development plan 2021.-2027. Available at: https://zdravlje.gov.hr/UserDocImages/2022%20Objave/Nacionalni%20plan%20razvoja%20zdravstva%202021.-2027..pdf</p>	<p>(1) "The National Health Development Strategy in the period 2012-2020 has recognized information and communication technology as a means of achieving its goals and has emphasized informatization and eHealth as a priority No 1. This priority is achieved through the introduction of the eHealth system."</p> <p>(2) "Faster digitalization of health systems and health services" priority of policy in the field of health and health care: (p. 79)</p> <p>(3) "... the contribution of eHealth to the development of healthcare will be incorporated into the National Health Development Plan 2021-2027." (p. 989)</p> <p>"The aim of the Croatian eHealth is to improve control capacity by more effective use of data and to encourage innovative healthcare solutions to the goal of the better management of the healthcare system." (p. 1004)</p> <p>(4) "eHealth will be an integral component of reform processes, with the aim of ensuring the improvement of quality and efficiency of health care for the entire population. In the Republic of Croatia... Information systems are still not fully complete and integrated to enable integrated health care providing the patients In the center, neither sufficient expert human resources for the development and management of these systems were developed...." (p. 3)</p>	<p>In this document, terms of eHealthcare, eHealth, digitalization of the health system are considered as synonymous</p>

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>2. Health information is an issue of public interest</p> <p>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</p>	<p>(1) Awareness of the importance of health data / information; inclusion of all health institutions in eHealth;</p> <p>(2) The umbrella national strategic document until 2030, among the policy priorities in the field of health and health care, states the establishment of a national information management system.</p> <p>(3) In the NRRFP as the goal of the reform measure C5.1. R5 states the following: "The goal of Croatian eHealth is to improve management capacity through more efficient use of data and encourage innovative solutions in health care in order to better manage the healthcare system." (p. 1004)</p>	<p>(1.1) Ministarstvo zdravlja, HZZO: Strateški plan razvoja eZdravlja u Republici Hrvatskoj – SPeZ. (Sažetak) Zagreb, 2014. (str.3); Dostupno na: https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi.%20projekti%20i%20strategije/Strate%C5%A1ki-plan_razvoja_eZdravlja.pdf</p> <p>(1.2) Health Data and Information Act (NN 14/19). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2019_02_14_26_9.html</p> <p>(1.3) osnutak radne grupe za sekundarnu uporabu zdravstvenih podataka (Gvozdanović K. Radna grupa za sekundarnu upotrebu biomedicinskih i zdravstvenih podataka (SEKA). Bilten Hrvatskog društva za medicinsku informatiku (Online) [Internet]. 2020 [pristupljeno 29.01.2022.]; 26(2):39-43. Dostupno na: https://hrcak.srce.hr/244848</p> <p>(2) National Development Strategy of the Republic of Croatia until 2030, dostupno na: https://hrvatska2030.hr/dokumenti/</p> <p>(3) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p>	<p>(1.1) "Public health and health system managers will have a timely direct insight into complete and quality data"; "Use of health statistics to support the decision -making and establishing a reporting and warning system";</p> <p>(1.2) "This Act determines the rights, obligations and responsibilities of the legal and natural persons of the health system of the Republic of Croatia in the field of data management and information in healthcare, defines terms and basic principles of collecting, use and processing of health data and information, competent authorities, quality and health data processing, their protection and inspection and professional supervision, for comprehensive and effective use of health data and information in health care to improve and preserve the health of the population in the Republic of Croatia. "</p> <p>(1.3) "The use of data created and collected in the procedure of providing health care and direct care of the patient to improve safety and treatment outcomes, measurement and control of quality of care, business management and resource optimization, population health, decisions at all levels of health system, and research and development "</p> <p>(2) "Improving the management capacity by establishing a national information management system, more effective by collecting and using data in the management of the health care system" (p. 79)</p> <p>(3) "The national healthcare management system will be established; regularly apply reporting tools on the health of the population as a substrate for targeted activities of the prevention and care of the disease; build national capacities for data analytics;" (p. 1005)</p>	

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>3. Ensuring and improving the quality of health care</p> <p>Investing in eHealth will ensure and enhance the quality of healthcare.</p>	<p>(1) The umbrella national strategic document until 2030 highlights the use of telemedicine and digital technologies in increasing the availability of medical services.</p> <p>(2) Strategic goal in NRFP: C5.1. Strengthening the resilience of the health system. Reform measure: C5.1. R5 e-Health. Telemedicine and mHealth stand out in the implementation.</p>	<p>(1) National Development Strategy of the Republic of Croatia until 2030. Available at: https://hrvatska2030.hr/dokumenti/</p> <p>(2) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p>	<p>(1) "Special attention will be paid to the availability of medical services on the islands and in rural areas, but also for citizens who have specific needs in the use of health care, using the capabilities of telemedicine or digital technologies." (p. 77)</p> <p>(2) "With the use of telemedicine and mHealth, it should be allowed to provide available and continuous cardiovascular health services to patients in remote and rural areas, significantly increasing the availability of specialist health services in local daily hospitals, improves specialist and patients' efficiency, and are greatly reduced waiting lists and costs to provide these health services." (p. 1005)</p>	
<p>4. Defining the medical and health informatics as an activity in healthcare system</p> <p>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).</p>	<p>(1) Establishment of the ELVIS Working Group at the Croatian Society for Medical Informatics (CroSMI)</p> <p>(2) The qualification standard of the university specialist in medical informatics and the related study program</p>	<p>(1) Fišter K. Radna grupa za evaluaciju i razvoj obrazovanja iz biomedicinske i zdravstvene informatike te mogućnosti zapošljavanja ciljanih stručnjaka u hrvatskome zdravstvenom sustavu (ELVIS). Bilten Hrvatskog društva za medicinsku informatiku (Online) [Internet]. 2020 [pristupljeno 04.02.2022.];26(2):39-43. Dostupno na: https://hrcak.srce.hr/clanak/355764</p> <p>(2) Šimić D.ur. Medicinska informatika. Kvalifikacije i zanimanja. Varazdin: FOI 2015. ISBN: 978-953-6071-46-3</p>	<p>(1) "The ELVIS Working Group mission is to evaluate and develop education and employment opportunities in biomedical and health informatics in Croatia."</p> <p>(2) "... that the standards of profession described here shall contribute to defining the activities of medical and health informaticians, and the standards of the professional team of medical informatics ..."</p>	
<p>5. Establishment of an umbrella institution for medical and health Informatics</p> <p>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.</p>	<p>Following the idea of the Declaration on the Establishment of the Central Body for eHealth, the Directorate for eHealth was established in the Ministry of Health.</p>	<p>Ministarstvo zdravstva. Uprava za e-zdravstvo. Dostupno na: https://zdravlje.gov.hr/o-ministarstvu/ustrojstvo/uprava-za-e-zdravstvo/4779</p>	<p>Established sectors:</p> <p>(1) for the support and supervision of information systems and</p> <p>(2) for implementation and improvement of information systems</p>	

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>6. Involvement of medical professionals in professional teams of medical informatics</p> <p>Inclusion of medical professionals of different profiles into MHIP teams will improve and facilitate the development and management of ICT in the healthcare system.</p>	<p>(1) The umbrella national strategic document until 2030 highlights the use of technologies in strengthening human resources in health care, and the "mix of competencies".</p> <p>(2) Establishment of the ELVIS working group at the Croatian Society for Medical Informatics (CroSMI)</p>	<p>(1) National Development Strategy of the Republic of Croatia until 2030. Available at: https://hrvatska2030.hr/dokumenti/</p> <p>(2) Fišter K. Radna grupa za evaluaciju i razvoj obrazovanja iz biomedicinske i zdravstvene informatike te mogućnosti zapošljavanja ciljanih stručnjaka u hrvatskome zdravstvenom sustavu (ELVIS). Bilten Hrvatskog društva za medicinsku informatiku (Online) [Internet]. 2020 [pristupljeno 04.02.2022.];26(2):39-43. Dostupno na: https://hrcak.srce.hr/clanak/355764</p>	<p>(1) "In accordance with principles of education policy, a comprehensive national plan for strengthening human resources in healthcare will be developed in order to adapt and harmonize educational programs and needs of medical institutions, with special emphasis on lifelong development of professional competencies. The adoption of new approaches will be intensified, such as changes in the "mix of competencies" of the workforce (for example between nurses and doctors) through competence transfer, redesign of medical training and use of technologies to mitigate the effects of labor shortages." (P. 77).</p> <p>(2) "... appropriate education of health professionals of all profiles, including doctors and nurses / technicians, as well as education and employment of biomedical and health informatics experts at all levels of the health system are needed. "</p>	
<p>7. Legal regulation of computerization of healthcare system</p> <p>The harmonized legislation should fully support the entire area of eHealth.</p>	<p>New laws on the regulation of health data and information, as well as on cyber security and the establishment of a working group on information and cyber security (ICS) were adopted.</p>	<p>(1) Health Data and Information Act (NN 14/2019). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2019_02_14_269.html</p> <p>(2) Act on Cybersecurity of Key Service Operators and Digital Service Providers (NN 64/2018). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2018_07_64_1305.html</p> <p>(3) Regulation on Cybersecurity of Key Service Operators and Digital Service Providers (NN 68/2018). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2018_07_68_1399.html</p> <p>(4) Draft of the Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 (Act on Information and Communications Technology Cybersecurity Certification) (EU). Available at: https://vlada.gov.hr/UserDocsImages/2016/Sjednice/2021/Prosinac/87%20sjednica%20VRH/87%20-%2017.docx</p> <p>(5) Belani H. Radna skupina za informacijsku i kibernetičku sigurnost (IKS). Bilten Hrvatskog društva za medicinsku informatiku (Online) [Internet]. 2021 [pristupljeno 07.02.2022.];27(2):38-41. Dostupno na: https://hrcak.srce.hr/260279</p>	<p>(1)-(4) By using terms such as electronic health records, and addressing many of the topics that the Declaration lists as necessary to be regulated, one can see: statistics, documentation, standards, quality, etc.</p> <p>(5) "The mission of the ICS Working Group is to raise the readiness of Croatian healthcare institutions and other stakeholders for information and cyber security, by strengthening the competencies of health staff, transferring knowledge and experience, and raising awareness among decision makers about the importance of information and cyber security."</p>	

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>8. Change management</p> <p>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.</p>	Establishment of Directorate for eHealth: Decree on the internal organization of the Ministry of Health (NN 97/2020)	Vlada Republike Hrvatske. Uredba o unutarnjem ustrojstvu Ministarstva zdravstva. Dostupno na: https://narodne-novine.nn.hr/clanci/sluzbeni/2020_08_97_1827.html	".. provides ongoing support, training, and technical and advisory assistance to all users of national health information systems in the use of interfaces and applications"	
<p>9. eHealth issues in the education of health professionals</p> <p>The educational curriculum of every health profession must include topics on eHealth.</p>	Incorporating medical informatics issues into the education of nurses	Matić I, Kern J, Matić N. Načela administracije. Zagreb: Školska knjiga 2019. Udžbenik za četvrti razred medicinske škole za zanimanje medicinska sestra opće njege/medicinski tehničar opće njege. MZO odobrilo za uporabu 2019. godine. Dostupno na: https://www.medicinskaskolapula.hr/wp-content/uploads/2021/07/POPIS-UDZBENIKA-ZA-2021.-2022.-SKOLSKU-GODINU.pdf	It is an integral part of the educational curriculum, and includes topics on health data and information, health information systems, as well as data / health system protection.	
<p>10. Health / medical topics in the educational curriculum of ICT professionals</p> <p>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.</p>	Qualification standard of a university specialist in medical informatics and a related study program	Šimić D (urednica). Medicinska informatika. Kvalifikacije i zanimanja. Varazdin: FOI 2015. ISBN: 978-953-6071-46-3	"... that the occupational and qualification standards described here will contribute to the definition of medical / health informatics activities and the standards of the professional medical informatics team, and result in the launch of an interdisciplinary postgraduate specialist study program in Medical Informatics"	
<p>11. Education for change management</p> <p>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.).</p>	No information			

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>12. Communication between health care institutions, and health care institutions with health care users</p> <p>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.</p>	<p>(1) Communication between PHC and hospital or specialist-consultative health care, as well as rehabilitation institutions (Connecting electronic medical record (EMR) to electronic health record (EHR); Connecting electronic personal health record (ePHR) and EMR, connecting health institutions with each other).</p> <p>(2) Strategic goal in NFRP: C5.1. Strengthening the resilience of the health system. Reform measure: C5.1. R5 eHealth. The implementation highlights tools for feedback and interaction and putting the patient at the center of care.</p> <p>(3) The sixth measure in a row in the NPRZ 2021-2027. refers to the establishment of digital solutions in the Health Information Infrastructure of the Republic of Croatia for the promotion of disease prevention and a healthy lifestyle. Measure 3 states the establishment of digital eHealth and mHealth platforms.</p> <p>(4) Communication with health care users</p>	<p>(1) HZZO. Obavijest o uvođenju eUputnice, eNalaza, eOtpusnog pisma. Dostupno na: https://hzzo.hr/novosti/e-uputnice-zamijenile-papirnatu-uputnicu (2020)</p> <p>(2) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p> <p>(3) National health development plan 2021.-2027. Available at: https://zdravlje.gov.hr/UserDocsImages/2022%20Objave/Nacionalni%20plan%20razvoja%20zdravstva%202021.-2027..pdf</p> <p>(4) Health Portal. Available at: https://portal.zdravlje.hr/portalzdravlja/login.html</p>	<p>(1) "... within the CEZIH system... eReferral, eFinding, eRelease letter enabling primary care physicians to send a request through eReferral for services in specialist-consultative health care". "The eFinding will be submitted to the primary care physician, but it will also be available to the patient via the Health portal on the eCitizens platform."</p> <p>(2) "In order to empower citizens with digital tools to get feedback and establish patient-centered care, it is necessary to systematically encourage the use of digital tools to empower people to care for their own health, encourage prevention, and enable feedback and interaction between the user and the healthcare provider." (p. 1005)</p> <p>(3) "Establishment of digital solutions in the Health Information Infrastructure of the Republic of Croatia for the promotion of disease prevention and a healthy lifestyle. Systematic encouragement of use of digital tools for empowering citizens in the care of their own health and enabling interaction between users and health care providers will improve health promotion and disease prevention. The eHealth applications should be able to stimulate prevention, support monitoring of patients' health routines, self-care plans and events in the care process (examinations, measurements, medication, weight goals...), provide motivational or educational feedback, as well as interaction between users and providers of health services." (p. 24) "The establishment of digital eHealth and mHealth platforms for communication with patients will enable better information and easier orientation in patient care." (p. 33)</p> <p>(4) The portal is part of the CEZIH system and is intended for reviewing health information by patients.</p>	<p>The eReferral function properly in hospitals today. The problem of subsequent findings on the eReferral (e.g., X-rays and labs made on the basis of an internal referral) has also been resolved. It was also resolved that e-ordering can be ordered on A5 referral.</p> <p>What remains as problem is that specialist-consultative healthcare findings that were made in emergency rooms, i.e. not related to eReferral, still do not go to CEZIH and PHC cannot reach them.</p>

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>13. Integration of health information</p> <p>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.</p>	<p>(1) Linking different EMRs into a single EHR.</p> <p>(2) Strategic goal in NRP: C5.1. Strengthening the resilience of the health system. Reform measure: C5.1. R5 eHealth. The implementation of the interoperability of Emergency Medical Service (HMS) - unified emergency hospital admission (OHBP) and remote monitoring of HMS is emphasized in the implementation.</p> <p>(3) For goal 2, the measure under no. 12, which refers to the IT connection of all health care providers.</p>	<p>(1) Health Data and Information Act (NN 14/2019). Available at na: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2019_02_14_269.html</p> <p>(2) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p> <p>(3) National health development plan 2021.-2027. Available at: https://zdravlje.gov.hr/UserDocsImages/2022%20Objave/Nacionalni%20plan%20razvoja%20zdravstva%202021.-2027..pdf</p>	<p>(1) "Medical documentation is a set of medical records and documents created in the process of providing health care by authorized health care providers, which contain data on the health status and course of treatment of patients."</p> <p>(2) "The Croatian Institute of Emergency Medicine is implementing the project 'Expanding and Improving the Use of Telemedicine Services '. The project includes creation of preconditions for the establishment of a functional national telemedicine framework for the service of transferring vital parameters of patients from HMS to OHBP and remote monitoring of outpatient HMS. The outcomes of the project include 1. Situation analysis, 2. National framework for the establishment of remote monitoring of HMS and 3. Action plan for the introduction of supervision and a framework for monitoring implementation. "(P. 1006)</p> <p>(3) "IT connectivity of all health care providers. IT connectivity of health care providers at all levels of health care will enable better coordination and integration of care, minimize the redundancy of collected data, and secondary use of health data and information in the Croatian health system. Healthcare is segmentally computerized, and applications are developed according to the principle of project approach. An online catalog of eHealth / mHealth applications, with accompanying descriptions and application examples and a defined metadata standard, can contribute to compliance, interoperability, and better control of the interdependence of projects and their products. This measure includes improving and establishing the interoperability of information systems for rapid response in crisis situations such as epidemics and pandemics of communicable diseases and other natural disasters. "(P. 32)</p>	<p>The existing eKarton is not equivalent to EHR in the sense that EHR should consolidate all data from all health care institutions where the health care user receives the service, while eKarton contains only part of such information. EMR works separately, ePHR is not functional (except in cases where the patient has an automatic data logger, eg CPAP). The EHR has not been resolved in its entirety. The connection between the PHC laboratory and the pharmacy (ePrescription) is fully operational.</p>

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>14. Health statistics as an issue of public interest</p> <p>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..</p>	<p>(1) The Health Data and Information Act determines the rights, obligations and responsibilities of institutions and persons in the healthcare system of the Republic of Croatia in the field of health data and information management, defines the concepts and basic principles of collecting, using and processing health data and information. competent bodies, quality and processing of health data, their protection and inspection and professional supervision, for the purpose of comprehensive and effective use of health data and information in health care to improve and preserve the health of the population in the Republic of Croatia.</p> <p>(2) Strategic goal in NRRP: C5.1. Strengthening the resilience of the health system. Reform measure: C5.1. R5 e-Health. The implementation emphasizes the need for a legal basis and ethical guidelines for the secondary use of health data.</p> <p>(3) The National Public Health Information System is an organized system of information services of the Croatian Institute of Public Health, shared with cooperating institutions. The system enables the management of public health information and processes for recording, receiving, using and archiving health data.</p>	<p>(1) Health Data and Information Act (NN 14/2019). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2019_02_14_269.html</p> <p>(2) National Recovery and Resilience Plan 2021-2026. Available at: https://planoporavka.gov.hr/dokumenti-113/113</p> <p>(3) HZJZ. National Public Health Information System (NAJS). Available at: https://www.hziz.hr/nacionalni-javnozdravstveni-informacijski-sustav-najs/</p>	<p>(1) "The Croatian Institute of Public Health (hereinafter: CIPH) is responsible for: - submission of statistical data - collecting data on public health, and health and safety at work, - transfer of confidential microdata or aggregated data, - submission of reports on the quality of transmitted data every five years to the European Commission or Eurostat (Article 15)</p> <p>"1. To ensure a uniform system of statistical surveys, uniform methodological principles and statistical standards shall be applied on data in the field of health. 2. The completeness of data in medical documentation and dana in the field of health care is supervised and controlled by the organizationally superior person responsible for the documentation and / or records of health care providers and other legal and natural persons in health care. 3. The competent healthcare professional and other employee who entered this information and the respondent (patient or person providing the personal data) are responsible for the completeness and authenticity of the original health data entered in the medical documentation." (Article 23)</p> <p>(2) "It is therefore necessary to establish a legal basis and ethical guidelines for the secondary use of health data. This would enable the use of existing and future data that will be collected and generated in the Croatian health care system. In this way, their potential for health would be realized, which would make Croatia an equal and active member of the European Commission's initiative to establish a European Health Data Area." (P. 1006)</p> <p>(3) "The National Public Health Information System is an organized system of information services of the Croatian Institute of Public Health, shared with cooperating institutions of the Institute. The system enables the management of public health information and processes for recording, receiving, using and archiving health data. "</p>	<p>„The National Public Health Information System is a set of information services and processes that are shared in agreement with collaborating institutions</p> <p>It is located on the state information infrastructure of the Center for Shared Services of the Republic of Croatia, with backup data storage at a remote location within the state borders and with additional replication at the location of the Institute.</p> <p>Users access the system from their own or public networks - Hitronet, CARNet or the Internet. The connection of the central system to external networks is achieved through an infrastructure consisting of network equipment and devices implemented through the distribution and protection layer. "</p>

Table 1. Continued

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<p>15. Health registries</p> <p>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.</p>	Health registers exist, but they are only partially filled with data from electronic medical records of health institutions	<p>Ministarstvo zdravlja, HZZO: Strateški plan razvoja eZdravlja u Republici Hrvatskoj – SPeZ. Zagreb, 2014. (str.4). Dostupno na: https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi,%20projekti%20i%20strategije/Strate%C5%A1ki-plan_razvoja_eZdravlja.pdf</p>	"The eHealth system should ensure the automatic filling of health and other registers of interest to public health (eg the current epidemiological situation), and research in the field of medicine and health care"	Not realized in practice
<p>16. Standards and standardization</p> <p>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 (e.g., in daily medical/health practice, in development and use of health information systems, etc.).</p>	Establishment of the Directorate for eHealth	<p>Uredba o unutarnjem ustrojstvu Ministarstva zdravstva NN 97/2020. Dostupno na: https://narodne-novine.nn.hr/clanci/sluzbeni/2020_08_97_1827.html</p>	"... introduces and takes measures, and supervises the application of semantic, procedural, technical, and organizational standards for professional and business areas within the regular activities of state health institutes, the Croatian Health Insurance Institute, and state health agencies and guidelines, recommendations and instructions in health system as the minimum requirements that health information systems must meet "	There is no rulebook yet. Cooperation with the Croatian Standards Institute is not visible from the cited document.
<p>17. Certification of software and other products</p> <p>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.</p>	<p>(1) Certification - criteria and procedure: Definition of criteria, bodies conducting certification.</p> <p>(2) The regulation regulates the competence for certification (CIHI on behalf of the Ministry of Health)</p>	<p>(1) Protokol za provođenje certifikacije; Popis poslovnih procesa za koje se obavlja certifikacija s popisom tehničkih i funkcionalnih zahtjeva. Objavljuje se na CEZIH-u po grupama proizvođača (kao Zapisnici za certifikaciju). Dostupno na: http://www.cezih.hr/aplikacije.html (Objavio HZZO 2016);</p> <p>(2) Health Data and Information Act (NN 14/2019). Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2019_02_14_269.html</p>	<p>(1) "... must have functionalities related to the operation of CIHI or the system for which CIHI is the operator ..."; Article 16 of the Law on Data and Information in Health Care</p> <p>(2) CIHI is responsible for "- conducting the procedure of checking the readiness to connect IT solutions to the central part of CEZIH; - providing certification services in terms of issuing digital certificates for users, subsystems and applications of CEZIH" (Article 16)</p> <p>The Ministry of Health is responsible for "- conducting verification of software applications used in the health information infrastructure of the Republic of Croatia in terms of control of compliance with prescribed standards and specifications based on set benchmarks" (Article 28).</p>	

Table 1. Continued

Statements and explanations	Outcome	Documents about outcome	Quote/comment based on document	Comment to "statement-outcome"
<p>18. Obligations of producers and vendors about software product for healthcare system</p> <p>All software applications intended for the same user group (e.g., family medicine) must be compliant. This means that each new software product must ensure direct interoperability with other software products in a given area (e.g., 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.</p>	<p>Agreements on business cooperation of software solution manufacturers (so-called Gx) for primary health care and specialist-consultative health care with CIHI.</p>			<p>There are informal arrangements of leading software application manufacturers to achieve compliance of all these applications.</p>
<p>19. Obligation to comply with European initiatives in eHealth</p> <p>Development of EHR systems must be compatible with European initiatives in eHealth.</p>	<p>Since joining the EU in 2013, Croatia has been actively participating in the eHealth Network with the right to vote and participate in working bodies and expert groups. Since 2019, the Croatian health system has been connected to the eHealth Digital Service Infrastructure (eHDSI): https://ec.europa.eu/health/e-health-digital-health-and-care/electronic-cross-border-health-services_en</p>	<p>(1) EHealth Network Guideline on ePrescriptions and eDispensations. Available at: https://ec.europa.eu/health/document/download/b744f30b-a05e-4b9c-9630-ad96ebd0b2f0_hr</p> <p>(2) EHealth Network Guideline on Patient Summary. Available at: https://ec.europa.eu/health/document/download/e020f311-c35b-45ae-ba3d-03212b57fa65_hr</p> <p>(3) National Contact Point (NCP) - NCPeH Croatia. Available at: https://hzzo.hr/en/national-contact-point-ncp</p>	<p>(1) Electronic cross-border healthcare ePrescription and dispensing of medicines allow EU citizens to pick up medicines in pharmacies in other EU Member States, thanks to the electronic transfer of prescriptions from their country of residence to the country of travel.</p> <p>(2) Electronic cross-border health service, patient summary, which contains important information about the patient's health, e.g., about allergies, medications he takes, previous illnesses, surgeries, etc., is part of the electronic health record. A digital summary of medical patient data allows a doctor to obtain, in his or her own language, relevant information about a patient who comes from another EU member state and may speak another language.</p>	<p>(1) With the help of ePrescription, Croatian citizens can pick up medicines in pharmacies in Finland, Estonia and Portugal. Pharmacists in Croatia accept ePrescription of citizens from the same countries. By 2025, both services will be gradually introduced in the following EU member states: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, France, Greece, Croatia, Ireland, Italy, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Germany, Poland, Slovakia, Slovenia, Spain and Sweden.</p> <p>(2) Doctors from Malta, Portugal, the Czech Republic, Luxembourg and France can access the health data of Croatian citizens in the form of patient summary. Croatian doctors can access health data of citizens from: Czech Republic, Malta, Portugal. Over time, medical images, laboratory results and discharge letters will be exchanged throughout the EU, and later also complete health records. All Member States can be involved in the exchange of ePrescriptions and medical patient summaries.</p>