



NÁRODNÍ STRATEGIE ELEKTRONICKÉHO ZDRAVOTNICTVÍ

ČESKÉ REPUBLIKY 2016 – 2020

The National eHealth Strategy of the Czech Republic



MINISTERSTVO ZDRAVOTNICTVÍ
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Contents

The National	- 1 -
eHealth Strategy	- 1 -
of the Czech Republic	- 1 -
Abbreviations.....	- 7 -
1 Introduction.....	- 11 -
1.1 Basic information about the strategy	- 11 -
1.2 Summarizing information for the entire document	- 13 -
1.3 Background of the establishment and existence of the strategy.....	- 17 -
1.4 Purpose of the strategy	- 18 -
1.5 Users of the eHealth	- 19 -
1.6 Basic concepts.....	- 22 -
1.7 Relevant strategic documents	- 22 -
1.7.1 Health 2020.....	- 22 -
1.7.2 Interdepartmental strategy	- 23 -
1.7.2.1 The Strategic framework of the public administration development in the Czech Republic for the period 2014–2020	- 23 -
1.7.2.2 The action plan for the digital market development	- 23 -
1.7.2.3 Development Strategy of ICT public administration services and measures to streamline ICT services	- 24 -
1.7.3 International Strategy.....	- 24 -
1.7.3.1 EU Action plans.....	- 24 -
1.7.3.2 Guidelines on the application of patients' rights in cross-border healthcare.....	- 25 -
1.7.3.3 Green book on mobile healthcare (mHealth)	- 25 -
2 Definition and analysis of the problem discussed	- 26 -
2.1 Definition of the problem discussed.....	- 26 -
2.2 The environment, the Czech Republic in an international comparison and expected future development.....	- 26 -
Examples of solutions of electronic sharing and communication of health data in the Czech Republic.....	- 26 -
Examples of foreign solutions.....	- 30 -
The Czech Republic in an international comparison	- 32 -
Prognosis of future development.....	- 36 -
2.3 Examination of existing development	- 37 -
2.4 Development when so called. zero option	- 37 -
2.5 Summary of key results of the analyses	- 38 -
2.5.1 Formulating a preliminary entry vision.....	- 38 -
2.5.2 Analysis of the eHealth participants' expectations	- 38 -
2.5.3 Assessment of the implementability of selected areas of the Strategy	- 38 -
2.5.4 Enterprise Architecture of MoH department	- 39 -
3 Vision and basic strategic aiming	- 40 -
3.1 Intervention logic, hierarchy of the strategy objectives.....	- 40 -
3.2 Vision and global objective of the strategy	- 40 -
3.3 Strategic objectives of electronic healthcare	- 41 -
4 Description of objectives	- 43 -
4.1 Strategic Objective 1 Increase citizen involvement in the care of their own health.....	- 43 -
Measure 1.1.1 A complete overview of healthcare providers, including the quality parameters	- 49 -
Measure 1.1.2 Electronic ordering of a medical service	- 51 -
Measure 1.1.3 Distance electronic consultation of health condition	- 52 -
4.1.2 Specific Objective 1.2 Providing accurate information on health status and treatment plans.	- 54 -
Measure 1.2.1 Easy access to personal health record	- 54 -
Measure 1.2.2 Enabling access to the records of the close persons (in case of a consent)	- 56 -

Measure 1.2.3 Open access to the personal account of payment of healthcare services.....	57 -
4.1.3 Specific Objective 1.3 Development of information support for care for their own health and improving health literacy.....	59 -
Measure 1.3.1 Open and transparent access to information on health promotion and preventative programs	59 -
Measure 1.3.2 Improvement of health literacy with the help of qualified information.....	60 -
Measure 1.3.3 Comprehensive communication and information support for care for the chronically ill	62 -
4.2 Strategic Objective 2 Increasing the efficiency of the healthcare system.....	64 -
4.2.1 Specific Objective 2.1 Data sharing and communication between providers.....	70 -
Measure 2.1.1. Enabling secure sharing of information on healthcare	71 -
Measure 2.1.2. Electronic and effective prescription	75 -
Measure 2.1.3. Requested care among providers (request form).....	80 -
4.2.2 Specific Objective 2.2 Effectiveness of the System and Provided Care.....	83 -
Measure 2.2.1 National and International Comparison of the Efficiency and Quality of Treatment ...	84 -
Measure 2.2.2. Creating Systems and Tools for Tracking Healthcare Costs	85 -
Measure 2.2.3. The Creation of a Dynamic Tool for Evaluating the Effectiveness of the Healthcare System Functioning (BI).....	87 -
Measure 2.2.4. The Elimination of Administrative Burdens and Barriers.....	89 -
4.2.3 Specific objective 2.3 Information and knowledge support of healthcare workers and users of electronic healthcare	91 -
Measure 2.3.1 Comprehensive and Clearly Structured Knowledge and Educational Tools to Ensure Professional Growth.....	93 -
Measure 2.3.2. Information and Popularization Program of Electronic Healthcare Users.....	95 -
4.3 Strategic Objective 3 Increasing the quality and accessibility of healthcare services.....	96 -
4.3.1 Specific objective 3.1 Telemedicine and mHealth	101 -
Measure 3.1.1 Definition of the technical and organizational framework for telemedicine and mHealth	102 -
Measure 3.1.2 Safe and efficient applications in telemedicine and mHealth	104 -
Measure 3.1.3 Creating a framework for data security and portability in telemedicine.....	105 -
Measure 3.1.4 Electronic support of treatment of a patient in the home environment.....	107 -
4.3.2 Specific Objective 3.2 Availability of care	108 -
Measure 3.1.3. Optimisation and management of waiting times for planned surgeries	109 -
Measure 3.2.2. Programs removing inequalities in access to healthcare (e.g. for the digitally excluded, weaker and vulnerable groups)	110 -
Measure 3.2.3. Methodology and evaluation system of the healthcare access.....	112 -
4.3.3 Specific Objective 3.3 Quality improvement and safe service provision.....	114 -
Measure 3.3.1 Assessing the quality of health care provided with analytical and methodological tools.....	115 -
Measure 3.3.2 Support for standardisation of medical documentation and therapeutic procedures	116 -
Measure 3.3.3 Support of treatment and decision making, team communication between the providers of healthcare and social services	118 -
Measure 3.3.4 Crisis and security support on national / regional level.....	119 -
Measure 3.3.5 Life cycle of a medicinal product and medical device.....	121 -
4.4 Strategic Objective 4 Electronic healthcare infrastructure and management	123 -
4.4.1 Specific Objective 4.1 Development of infrastructure for sharing and provision of health services-	128 -
Measure 4.1.1 Optimisation and creation of authoritative registries – authoritative data sources	129 -

Measure 4.1.2 Establishment of (safe) infrastructure for health information exchange at regional and national level	- 130 -
Measure 4.1.3 The implementation of the provision of services management system according to the pattern of eGovernment agendas.....	- 133 -
Measure 4.1.4 Authorisation, authentication and management of providers' authorisations ...	- 136 -
Measure 4.1.5 Management of approvals and accesses	- 138 -
Measure 4.1.6 Easy and accurate patient identification and retrieval of patient data	- 139 -
4.4.2 Specific Objective 4.2 Standards and Interoperability.....	- 142 -
Measure 4.2.1 Clinical terminology and classification	- 144 -
Measure 4.2.2 Interoperability and data structures	- 146 -
Measure 4.2.3 Data and EHR/EMR/PHR access	- 147 -
4.4.3 Specific Objective 4.3 Electronic healthcare management	- 149 -
Measure 4.3.1 Management, policies and strategies of electronic healthcare.....	- 150 -
Measure 4.3.2 Legislative and regulatory framework	- 152 -
Measure 4.3.3 Privacy, quality policy and safety protection	- 155 -
Measure 4.3.4 Collaboration of stakeholders at the national and EU level	- 156 -
Measure 4.3.5 Promoting the adoption and use of standards	- 158 -
5 Strategy implementation.....	- 160 -
5.1 Implementation structure and the strategy implementation control system	- 160 -
5.2 Method of implementation	- 162 -
5.3 Time schedule and priorities	- 163 -
5.4 Budget and funding sources	- 166 -
5.5 System of monitoring and evaluation.....	- 168 -
5.6 Risk management system	- 169 -
6 Conclusion	- 170 -
7 References	- 172 -

Abbreviations

Abbreviation	English term	Czech term
ATC	Anatomical Therapeutic Chemical Classification System	
BI	Business Intelligence	
CEF	Connecting Europe Facility (EU fund)	
CM PH	crisis management of public health	
COPD	chronic obstructive pulmonary disease	
CP&R	crisis preparedness and response	
CzMA	Czech Medical Association of J. E. Purkyně	
CSSA	Czech Social Security Administration	
DASTA	Data Standard of the Ministry of Health of the Czech Republic	
DRG	Diagnosis-related group of clinical cases in medicine	
DS	Data box	
EA	enterprise architecture	
EAHP	European Association of Hospital Pharmacists	
EBM	evidence-based medicine	
ED	hospital emergencies	
eGOV	eGovernment	
EHCI	comparison of health systems in the EU based on qualifying periods, outcomes and richness of the system	
EHN	eHealth Network	
EHR	Electronic health record of the patient (see monolingual dictionary)	
eID	electronic identity	
eIDAS	EU regulation No. 910/2014 on electronic identification and trust services for electronic transactions in the European internal market	
EC	European Commission	
EMR	Electronic medical record of the medicinal operations (see monolingual dictionary)	
EMS	emergency medical service	
EMSS	System of urgent services	
EP	ePrescription – System for electronic prescribing and dispensing drugs	
EPMA Journal	The official journal of European Association for Predictive, Preventive and Personalised Medicine	
ESIF	European Structural and Investment Funds	
EU	European Union	
EPR	long-term electronic pharmacy record	

Abbreviation	English term	Czech term
HL7	Health Level Seven (data standard, organisation)	
HTA	health technology assessment	
HW	Hardware	
ICD-10	see MKN	
ICT	Information and telecommunication technology	
IEEE	Institute of Electrical and Electronics Engineering	
ICT	Information and Communication Technologies	
IS	Information system	
CIMS	Crisis information management software	
IAPHR	Internet Access to Patient Health Records (Project)	
CCHSIS	Coordination Centre for Health Sector Information Systems	
ICD-O	International Classification of Diseases for Oncology	
MoLSA	Ministry of Labour and Social Affairs of the Czech Republic	
Mol	Ministry of the Interior of the Czech Republic	
MoH	Ministry of Health of the Czech Republic	
NAP Czech Republic	National architectural plan for the Czech Republic	
NSA	National Security Authority	
NCEHS	National Centre for Electronic Healthcare	
NIA	National Identity Authority	
NCMDE	National Centre of Medical Documents Exchange (project of the Vysočina Region)	
NML	National Medical Library	
NRHCP	National Register of Healthcare Providers	
NRHP	National Register of Health Professionals	
NSEH	National eHealth Strategy of the Czech Republic	
NHIS	National Health Information System	
OECD	Organisation for Economic Co-operation and Development	
PD	narcotic and psychotropic substances	
OTP	one-time password	
PACS	A computer system that provides acquisition, archiving and distribution of the image across the whole network. The system also deals with the acquisition of the information for the purpose of diagnosis and transmission of information between doctors at remote workplaces.	

Abbreviation	English term	Czech term
PCEHR	Personally controlled electronic health record	
PHR	Personal Health Record (see monolingual dictionary)	
PL	General practitioner	
Paediatrician	Paediatrician	
PPI	Producer price index (of healthcare providers)	
CDP CR	Chamber of Deputies of the Parliament of the Czech Republic	
HP	Healthcare provider	
RFID	radio frequency identification	
GCIS	Government Council for Information Society	
SO X, SO X.X	Strategic objective X, specific objective X.X	
SMS	short message service	
SIDC	State Institute for Drug Control	
TNM	TNM Classification of Malignant Tumours	
ÚNMZ	Czech Office for Standards, Metrology and Testing	
OPDP	The Office for Personal Data Protection	
IHS	Institute of Health Information and Statistics of the Czech Republic	
VPN	A virtual private network is used for virtual connection of physically more remote computers so that they work as if they were directly connected by one network	
PA	Public Administration	
DMD	Working group Electronic medical documentation	
GMIC	General Medical Insurance Company	
WHO	The World Health Organization	
MD	Medical documentation	
AoP	Act No. 378/2007 Coll., on Pharmaceuticals	
AoPPD	Act No. 101/2000 Coll., on the Protection of Personal Data	
AoHS	Act No. 372/2011 Coll., on Health Services and the Terms and Conditions for the Providing of Such Services	
HIC	A health insurance company	



1 Introduction

1.1 Basic information about the strategy

BASIC INFORMATION ABOUT THE STRATEGY	
Name of developed strategy	National eHealth Strategy of the Czech Republic
Category of the strategy	National strategy
Owner of the strategy	Ministry of Health of the Czech Republic
Administrator of the strategy creation	Mgr. Lenka Ptáčková Melicharová, MBA, Deputy of Minister for Strategy
Coordinator of the strategy creation	Ing. Jiří Borej, chief architect of eHealth
Year of strategy processing	2014 – 2016
Approver of the strategy	MUDr. Svatopluk Němeček, MBA, Health Minister
Date of approval	11/10/2016
Form of approval	Approval by the Health Minister of the Czech Republic
Last update	11/10/2016
Related legislation	Government Decree No. 23/2014 (Health 2020) The strategic framework for the development of public administration of the Czech Republic 2014 – 2020 Action plan for the digital internal market development Development strategy of ICT public administration services and measures to streamline ICT services Digital agenda for Europe (European Commission, 2010)
The period of the strategy implementation	2016–2020
Responsibility for implementation	Ministry of Health of the Czech Republic
Implementation	It follows Health 2020 – National Strategy for the protection and promotion of health and prevention of diseases and follows the Strategic framework for the development of public administration in the Czech

	Republic for the period 2014–2020
Background of the strategy establishment	<p>Needs arising from the national strategic document Health 2020. Needs identified by stakeholders in 2012¹:</p> <ol style="list-style-type: none"> 1. the need for development of information and procedural standards 2. the need for institutional anchoring of computerisation of healthcare, budgeting and clearly defined responsibilities for projects in this area 3. the need to establish strategic concept / action plan for the development of eHealth 4. the need for systematic training in eHealth focused on its users and architects of electronic applications (with observing the specifics of the target groups) 5. the need to establish basic criteria for evaluation of eHealth applications in terms of information and communication technologies, economics and the application environment, including legislation, 6. the need to enable regulated, project-based linking records from various sources and the use of data linked this way (after the irreversible anonymisation) for the evaluation of healthcare 7. the need for standardization and interoperability of electronic health records and the general need for implementation of structured and parametrized electronic patient records 8. the need to prioritize scientific research and development in biomedical and health informatics and the transfer of relevant outputs of Czech and European projects in eHealth environment in the Czech Republic
Objective of the strategy creation	<ol style="list-style-type: none"> A. Ensure the support to the program Health 2020, a tool of eHealth B. Provide an essential tool to the state (MoH): <ul style="list-style-type: none"> – for national system of electronic healthcare administration – for the realization of the basic components of a national system of eHealth C. Create a national interoperability framework
Website	http://www.nsez.cz

¹ The seminar "Sharing tools of eHealth from the view of users" organized by the MoH on October 3, 2012

1.2 Summarizing information for the entire document

The document presents an umbrella development strategy for computerisation of electronic healthcare of the Czech Republic in the medium term of at least five years. In certain areas, the document is very specific, on the contrary, it only sets out the basic rules, principles and vision of the future state in other areas. This is a very complex issue and the environment in which many influences operate and the state has just limited resources to enforce even the useful measures.

The presented strategy had to deal with the absence of any general documents of a longer horizon, covering the area in the Czech Republic (e.g. policy or concept). It includes accepted Set of objectives and measures which structurally sets targets for the overall direction of the area in the long-term and determines the basic principles and character of the objectives set. This Set of objectives and measures is partly elaborated into outputs and indicators for the period until 2020, without pretensions to implementation of the entire set within a limited time.

Priorities are set sequentially and are influenced by a number of factors which cannot be effectively detected in the scope of a single strategy document. An important and fundamental task of a strategy is to find such a concept for further development that would provide a common denominator, common shared services and cooperating (interoperable) environment to all the concerned areas. An environment that would allow individual participants to share information in a defined manner and would effectively boost the development of the health system in the context of computerisation of public services.

Strategy does not delegate the burden of building the informatics services and the creation of a central system to the state, which should be compulsorily used by health workers and ultimately by citizens. This solution, although it is sometimes applied in countries with different healthcare system and the organisation, is not acceptable in the context of the Czech healthcare system. The area where the strategy considers an irreplaceable role of the state lies in creating preconditions and fundamental building blocks on which the developed computerisation can rely. Parallels to these basic building blocks are the Basic registers of the Czech Republic which present a prerequisite for unambiguous identification of citizens and organisations and allow or facilitate the effective sharing of information across the public administration.

The state will not create any megalomaniac centralist project, but will provide the basic building blocks of computerisation which allow the gradual establishment and implementation of purposeful subprojects coordinated with strategic objectives and the principles set out in this strategy.

The Ministry of Health will deal exclusively with the preparation of projects that are a priority for the health sector where the role of the state is irreplaceable and which present a necessary prerequisite for meaningful development of computerisation of healthcare. Therefore, the National Strategy for eHealth opens up the ample scope to all researchers of existing and future projects of electronic healthcare to ensure that their solutions could be mutual purposefully aligned to support both the vision and goals of the strategy and support to serve the healthcare of citizens. Only such projects can apply for state aid. Examples of key projects are National register of health professionals and providers, ePrescription, etc. (these projects resulted from the preparatory work on the Strategy and from the conclusions of the working groups, some arose from events such as a legislative change).

Therefore, any subject may apply for the public support if it agrees to the demands of strategies of defined goals, objectives, rules and standards and meets the architectural requirements contained in the publicly published principles of Enterprise architecture computerisation of healthcare. All projects' implementors will have to meet well-defined requirements for data security and transfer at least on the level required by the system of public administration (eGovernment).

The preference aim of the strategy is the maximum use of existing information systems, provided that they meet quality, safety and other requirements for interoperable electronic healthcare systems, namely the requirements for input/output data format and modularity, i.e. the individual information systems can be developed independently, but they will be able to mutually transmit the data, as their structure will be defined. Achieving mutual interoperability of existing electronic healthcare solutions is the investment protection as well and it is the use of the current potential operating applications.

Selected key projects shall always be focused on meeting the goals and indicators set out in this strategy. Proposers of individual projects will follow the guidelines and principles defined by Enterprise architecture computerisation of the health sector in accordance with the overarching principles of building eGovernment. Enterprise architecture of the solutions will be processed for each project based on the methodology prepared for the computerisation of electronic healthcare by the Ministry of Health and therefore, its interconnection with other projects will be ensured. Interoperability with new solutions, including the use of existing services sector and ICT eGovernment services will be also guaranteed. Implementation plans for each upcoming projects will be established in stages. The first stage specifies the plans of priority projects and will be completed by the end of 2016. In this first stage, the deadlines for processing other implementation projects will be determined as well.

The role of the state in defining the concept and priorities of electronic healthcare, particularly in the coordination of its development, is indispensable. The state did not fulfil this role in the long term, besides other reasons due to lack of the necessary experts and expertise of professionals in the field of ICT and the inability of the government in attracting them. The consequence of failed projects of computerisation is great mistrust in the computerisation of medical workers and its benefits, which are accompanied by mistrust in the ability of government to improve the dismal state. National strategy for eHealth had been created for two years in working groups and workshops with experts in a wide representation. The Czech MoH approached representatives of organisations working in healthcare and those from other areas with a request to nominate their representatives to the team for strategy creation and support working groups and delegated representatives then participated in making strategies. The common outputs of the team and working groups were presented and opposed. It was based on the international recommendations for the creation of national electronic healthcare strategies and on foreign experience. To avoid tendentious solution without the participation of public health, the following procedure was respected:

One of the main principles of the National Strategy for eHealth creation is openness and involvement of the widest possible professional and non-professional public among users of electronic healthcare. MoH hereby declares the clear intention to gradually reconcile mutually uncoordinated activities of the state, of the self-government, the commercial sector, health insurance companies and healthcare providers towards fulfilling the vision of the National Strategy for eHealth interoperability and create a familiar environment for all implementors of electronic healthcare services.

However, the National Strategy for eHealth , based on Czech and foreign experience, and using the principles promoted by the Czech Medical Association of J. E. Purkyně gives precedence to the six principles:

- 1) The primary objective of the development of electronic healthcare must be beneficial to patients and to the quality of healthcare.
- 2) Patient's right to ensure the welfare, protection of personal dignity and privacy must not be weakened by means of introducing electronic healthcare, but rather strengthened.
- 3) Doctors and other professionals in the healthcare sector must be involved in projects already in the process of preparing plans, during the planning and during solutions drafting. The opinions of the experts must be actively sought within the framework of projects and adequately taken into account.
- 4) Before the introduction of new tools and services of electronic healthcare into practice, their usefulness, quality, stability and performance must always be adequately verified and evaluated.
- 5) Electronic healthcare introducing based on broadly defined responsibilities is fundamentally not acceptable. When introducing new services and electronic healthcare tools, it is necessary to use positive motivation in particular and to introduce new technologies gradually and prudently so that the continuity and safety of the operation is not jeopardized, the patient is not endangered nor the working conditions of health professionals are deteriorated.
- 6) It is necessary to utilize wherever possible and appropriate for creating new solutions all available scientific knowledge and proven technologies, including standards for the exchange and display of medical information.

An examples of fundamentally incorrect procedure when introducing electronic healthcare was a course of the project of the electronic prescription implemented in isolation as a partial service, entrusted to an institution whose mission is not computerisation of medical services for citizens. Legislation does not allow even in its current form for implement electronic prescribing the most desirable benefits, especially for citizens, doctors and pharmacists – the main users of this system. The project lacked a responsible guarantor of the whole process of computerisation of prescription medications, so called electronic prescriptions, and could not rely on the concept and architecture of computerisation department, nor on the necessary infrastructure of computerisation of healthcare.

The Cabinet Office of the Czech Republic evaluated the state of the digital development of the Czech Republic in a prepared updated Action plan for the development of the digital market (July 2016) as highly unsatisfactory and states: "Digital technologies are fundamentally and at a rapid pace changing the economy and form of companies around the world. Changes, that the digital revolution brings, will inevitably affect the life of each of us.

Even healthcare cannot fall behind in computerisation any more because information and communication technologies can contribute substantially to improving the accessibility and quality of healthcare throughout the company, contribute to greater involvement of the citizen in his own health and help to reorient health systems towards the citizen.

Document structure

This document is divided into several coherent parts. ***The first chapter*** presents basic information about the formation of the strategy and refers to the most valid strategic or conceptual materials the requirements of which are superior to the computerisation of healthcare.

The second chapter presents the outcomes of the key analyses used in developing the strategy and it presents the comparison of the CR with foreign practice.

In the third chapter a vision of computerisation of the Czech healthcare and the structure of the objectives of the national strategy are presented.

According to this structure named ***"The objectives and measures of the National Strategy for eHealth "*** the largest part of the strategy contained in ***the fourth chapter*** is divided and describes, among others a method of fulfilling these goals. The chapter lays out the Set of goals and measures and is divided into four subchapters according to individual strategic objectives:

- | | |
|-------------|---|
| Chapter 4.1 | Increase in citizen involvement in the care of their own health, prevention |
| Chapter 4.2 | Increase in the efficiency of the healthcare system |
| Chapter 4.3 | Increase in the quality and accessibility of healthcare services |

Chapter 4.4 Creation and development of information infrastructure and electronic healthcare management

In each chapter of the strategic objective, the possible actions and requirements for fulfilment of the strategic objective, expected impacts of the realization of this objective, indicators of achievement and the main obstacles and risks of implementation are listed. For each of the strategic objectives, there is a summary table of all subordinate specific objectives and measures with brief outputs and identifiers of achieving the objectives / measures.

The system of objectives is of three-levels. Strategic objectives stand on top. The second level is formed by the specific objectives under each strategic objective. Third level contains a number of measures under each specific objective. Measures are described in separate chapters that help to fulfil the superior objectives. Individual measures describe achievable outputs and indicators of achievement in detail and define the steps leading to the fulfilment of measures in the known cases.

In the above structure, a series of measures of cross-cutting nature is formulated not only in terms of ensuring the infrastructure, information infrastructure and management of electronic healthcare in the fourth chapter, but also in terms of e.g. the requirement on the administrative burden decrease on healthcare professionals and other users of electronic healthcare services and the elimination of inequalities in access to care for the so-called digitally excluded.

The entire document is designed in view of the fact that the introduction of elements of electronic healthcare shall be carried out in compliance with legal and technical conditions and needs of all stakeholders in the system, especially on the part of patients and healthcare providers. Computerisation of selected processes of the healthcare system will be systematically supported in order to motivate patients and providers to implement and use new processes, systems and applications. Electronic healthcare system will be very critically evaluated in terms of potential leakage or misuse of sensitive personal data, especially of patients' data, but also data of physicians and other participants in the system. Therefore, the issues of cybersecurity and privacy shall be carefully considered and tested repeatedly throughout the life cycle of implementation of measures since their design, implementation to operation and change management.

Patients' roles in decisions about their own privacy must be not only respected by the system, but shall be strengthened at the maximum possible extent.

The fifth chapter presents the procedure of implementation and the system of implementation management. During the processing of the strategy, the related project areas were not specified in detail nor the individual projects or their schedule. Detailed timetable of individual measures, projects and activities implementation will be developed during the creation of implementation plans that will be developed after the approval of the strategy based on the priorities of electronic healthcare.

Chapter 5.3 includes a timetable that reflects **priorities defined by the Ministry of Health for the upcoming period**. These priorities are:

- **Creating / adjusting the authoritative registries NRHP, NRHCP**, which will be similar to the basic registers of eGovernment and will be the authoritative source of information to identify subjects and medical workers.
- **Building of basic departmental infrastructure for electronic identity solutions** in the healthcare sector and the associated data interfaces for sharing information. This infrastructure will ensure and strengthen legal and organisational certainty of medical workers and introduces the possibility of continuity when working with electronic correspondence and medical documentation. This project is in compliance with eID solutions implemented by MV will also solve authorization, authentication and access and approvals management.
- Ensuring a **united approach to electronic healthcare services** in accordance with the principles of eGovernment. Cross-section priority, which aims to adapt the processes in healthcare, particularly

- of an administrative nature to maximise the use of eGovernment services and procedures which the citizen understands and has learned to use them in solving life situations.
- **ePrescription** – to prepare the gradual onset of a full-fledged electronic prescription including patient records accessible to authorized physicians, pharmacists and patients with options to check interactions and duplications. This task will require legislative amendments.
 - **To establish / develop National Centre for Electronic Healthcare Systems** which will have the task of coordinating and promoting the development of digitalisation, maintain and develop the concept of national health systems systematically and efficiently.

The sixth chapter is the Conclusion and the last, seventh chapter, is the Bibliography.

1.3 Background of the establishment and existence of the strategy

In the Czech healthcare spontaneous computerisation is reviving, as well as in all other areas of society. Repeated attempts to create a long-term concept of its development and support, which would integrate the various activities and navigate, were not successful and did not lead to a permanent and binding accepted results. Not anchoring of individual upcoming and completed projects in the binding long-term strategy for the development of electronic healthcare is reflected in their usefulness and quality. Therefore, the Czech MoH decided to develop the National Strategy for eHealth (hereinafter also referred to as "NSEH" or the "Strategy") in 2013 in accordance with the Methodology of preparation of public policies applied pursuant to Government Resolution No. 318 of May 2, 2013.

NSEH is a medium-term strategic document that on the basis of the knowledge of the Czech healthcare, social conditions and trends at EU level and the Czech Republic formulates a minimum period of five years strategic objectives and a program for their support and is based on the National Strategy on health promotion and disease prevention "HEALTH 2020". Representatives of all stakeholders in the healthcare sector participated and are involved in preparation and cultivation of NSEH. NSEH defines a set of objectives and measures to which individual implemented projects will be attached.

The following figure shows an illustrative set of the main actors in the context of electronic healthcare strategy objectives.

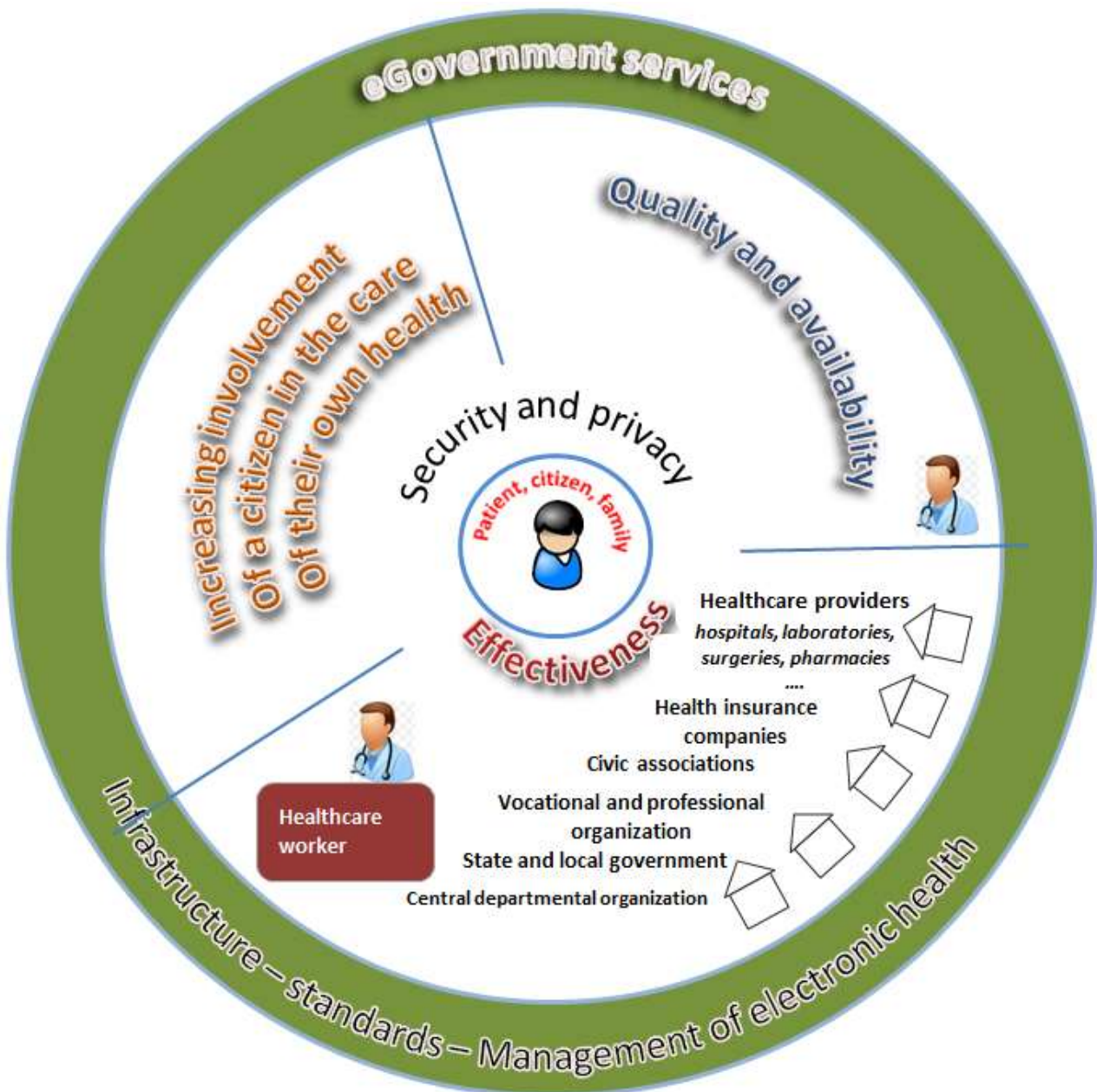


FIGURE 1 Illustrative representation of setting the main actors in the context of electronic healthcare strategy objectives

1.4 Purpose of the strategy

A significant specialization of electronic healthcare is also the introduction of instruments enhancing the overall effectiveness, efficiency and sustainability of the health system in particular which is now threatened by demographic prospects.

Tools of electronic healthcare help to ensure the availability of medical information that can lead to life-saving at the right time in the right place. These also deal with the specific area of the availability of information on cross-border movement of citizens and patients, e.g. the interoperability of health

information systems (i.e. the fact that the information acquired in a healthcare facility are understandable for healthcare workers of another healthcare facilities).

Benefits of health computerisation are obvious and indisputable in countries where it has already been enforced. It brings significant financial savings in the consumption of drugs, reduces duplication of tests, helps to shorten the length of patients stay in hospitals and reduces the frequency of visits to outpatient clinics. It improves access to health services for all groups of citizens.

The strategy defines a set of objectives and measures proposed by the professional and non-professional public and shows which direction the computerisation development should follow. The strategy is systematically linked to the construction and development of public administration computerisation and is related to government programs. Because in the past, no actions to create conditions for the systematic development of computerisation of health by the state were done; the strategy pragmatically defines the priorities in the area of creation of the basic building blocks of computerisation.

Electronic healthcare can substantially contribute to improving the accessibility and quality of healthcare throughout the society. It supports and develops greater citizen involvement in the care of their own health and reorients healthcare systems towards the citizen.

1.5 Users of the eHealth

The main user of electronic healthcare is a citizen whose strengthening of the position is the strategy's task. Around the citizen, in the role of the patient, all the other key participants of the healthcare system led by physicians, pharmacists and other health professionals and healthcare workers are concentrated. Electronic healthcare enables, with the use of the tools of information and communication technologies, a meaningful integration of knowledge and information to accompany the citizen in preventing and solving his/her health problems, and to effectively strengthen the capabilities and capacities of medical workers with these situations.

Manufacturers, suppliers and distributors of medicines, medical devices and technologies, professional, professional and lay organisations, providers and payers of health services, medical equipment owners, academia, state and local government institutions and other entities also belong to those users of electronic healthcare. Electronic healthcare is therefore a multi-branch interdepartmental issue which is briefly connected to several fields of human activity. The classification of the major users of electronic healthcare and its strategies are described in the table below where also benefits for participants and active users of the system are provided.

Target group	Benefit
A patient, an insured, a citizen	<p>Improvement of care quality, better awareness, increased patient safety. Raising awareness and knowledge of their health status and thus the ability to prevent and an active approach to their health and disease. Reducing the frequency of visits to health facilities. Minimising the burden by reducing duplicated tests. Electronic (easy) communication with healthcare providers. Knowledge of their own medical history thanks to the information available and secure access to them.</p>
Family member / caregiver	<p>Access to health records and plans of care for a family member, respectively for a child. Electronic (easy) communication with healthcare providers. Support for mobile devices. Access to and cooperation with relevant medical professionals, respectively with social services workers (doctor, day care).</p>
Medical worker	<p>Increasing the quality of care and reducing the risk of medical errors thanks to a continuum of information. Decision support and support of procedures of evidence-based medicine. Improvement of efficiency and reducing administrative burdens. Improvement of cooperation within the medical teams.</p>
Healthcare provider (healthcare facility)	<p>Reducing the cost of repeated examinations, reducing the likelihood of repeated hospitalizations due to better quality and coordination of care between providers. Immediate access to trustworthy information about the patient to support clinical decision making and diagnosis, including access to images, lab results and medical treatment, including a complete history, including information from other medical devices, e.g. from a hospital of a lower rank. Improvement of efficiency by reducing the time needed for searching for and processing information (the latest laboratory, medication).</p>
A provider of pharmaceutical care (medical facility – pharmacy)	<p>Possibility to provide effective consultation and advisory services through medical and drug history. Reducing the number of fake prescriptions. Access to information on medicaments.</p>
Medical laboratory	<p>Ability to communicate orders and lab results electronically, support of early notice in case of emergency.</p>
State Institute for Drug Control	<p>Highly up-to-date overview of prescribing, batch numbers and lots drug groups; online communication with doctors and pharmacists in an emergency.</p>

Institute of Health Information and Statistics	Access to current anonymous information about the patient, the treatment and medication. The possibility of providing information, overviews and comparisons of treatment and performance of treatment segments to physicians and managers in healthcare. Improvements in options of diagnosis-related group DRG set-up.
Target group	Benefit
Coordination Centre for Health Sector Information Systems	Increased ability to provide informatics and ICT services, to create infrastructure of the health sector on the basis of a thoughtful concept of development and to serve the purpose of implementation of the strategy.
Ministry of Health and other subordinate organisations (NIPH, RHS, embassies,...)	Possibility to fundamentally improve the system of providing healthcare in the Czech Republic, to improve all measurable parameters while maintaining the long-term sustainability of healthcare.
Ministry of Labour and Social Affairs and the Czech Social Security Administration	Cooperation of the social security and healthcare providers (pursuant to § 16 of the Act No. 582/1991 Coll., on Organization and Implementation of Social Security). Electronic communication between LPS and healthcare providers has, among other things, a substantial contribution to improvement in efficiency and to shortening the proceedings concerning insurance benefits and insurance systems, for which it is necessary to assess the health status of the party. Electronic sick certificate brings benefits to citizens, healthcare professionals, employers and the state. There is a synergistic effect of Ministry of Health and Ministry of Labour and Social Affairs.
A Health Insurance Company	The possibility of a better adaptation of the active role of insurance companies to different groups of patients. Creating an environment and means for targeted work with selected groups of patients, especially with patients with chronic diagnoses. Increasing the quality of life of the insured and the parameters of their health while avoiding unnecessary costs. Prevention strengthening.

Table 1 Main users of electronic healthcare strategy (Compiled independently by Ernst & Young: Economical and functional healthcare, 2012, p. 52–53)

One of the main principles of creation of the National Strategy for eHealth is openness and involvement of the widest possible professional and non-professional public among users of electronic healthcare. Therefore, the broader team for creating the strategy in a transparent and open access was created.

MoH appealed to the representatives of organisations involved in healthcare with applications for nomination of their representatives to the team for strategy creation. The following organisations were contacted and these then nominated their representatives. A number of contacted organisations present umbrella organisations or platforms, thus a greater efficiency of public participation in the preparation strategy was achieved.

The list of addressed organisations:

Association of Regions of the Czech Republic, the Platform for electronic healthcare in the Czech Republic, Czech Medical Association of J. E. Purkyně, Czech Association of Nurses, General Medical Insurance Company, Association of Health Insurance Companies of the Czech Republic, Czech Pharmaceutical

Chamber, WHO (CR), IHIS, CCHSIS, SIDC, the OECD, the Ministry of the Interior, the Ministry of Labour and Social Affairs, Coalition for Health, Association of Hospitals of the Czech Republic, the Association of Czech and Moravian Hospitals, the Association of Outpatient Specialists of the Czech Republic, Czech Medical Chamber, Association of General Practitioners of the Czech Republic, Association of Paediatricians of the Czech Republic, the Committee on Health CDP CR, the Association of Pharmacy Owners, AmCham, the Association of Manufacturers and Suppliers of Medical Devices.

Members of the broad team for the creation of the strategy provide external examinations to the created materials and are the source of expert advice. They form the core of working groups which elaborate individual key topics of the strategy. With representatives of various institutions is dealt by team members delegated by them. Educational institutions, professional companies and associations in healthcare are stakeholders in the development of the strategy. These organisations may be and are addressed through their experts with requests for production of sub-themes of the strategy and to provide the missing competencies. Experts representing key creators of information systems for healthcare, who were invited into working groups, also participated in preparing the strategy.

1.6 Basic concepts

Key concepts used in the strategy will be clearly explained, respectively defined in the glossary, which will be published and maintained in its current form on the website of NSEH in a way based on the ordinary meaning of these terms in the context of the National Strategy for eHealth CR.

1.7 Relevant strategic documents

1.7.1 Health 2020

"Health 2020 – the National Strategy on health promotion and disease prevention" (hereinafter also referred to as the "the National Strategy for Health 2020") is a general set of measures for the development of public health in the country. It is also a tool for the implementation of the World Health Organization (WHO) programme "Health 2020", which was approved at the 62nd Session of the Regional Committee of the World Health Organization for Europe in September 2012.

The main objective of the program "Health 2020" is to improve state of health of the population and to reduce the incidence of illnesses and premature death. Another objective is the stabilization of disease prevention, starting up effective cooperation mechanisms between the various departments which will work in the long-term.

As a general summary of the measures, the National Strategy for Health 2020 is further elaborated in various implementation documents (action plans) established in accordance with sixteen set themes of protecting and promoting public health and disease prevention, state of health of the population of the Czech Republic and other topics of public health and health care organisations. One of the themes and at the same time a separate action plan is the Action Plan 11 Computerisation of Health which formulates four strategic objectives:

- 1) Increasing citizen involvement in the care of their own health, prevention.
- 2) Increasing the efficiency of the healthcare system.
- 3) Increasing the quality and accessibility of health services.
- 4) Creation and development of information infrastructure and electronic healthcare management .

Electronic healthcare Action Plan forms the first stage of the National Strategy for Electronic Healthcare.

1.7.2 Interdepartmental strategy

1.7.2.1 The Strategic framework of the public administration development in the Czech Republic for the period 2014–2020

The Strategic framework for the public administration development in the Czech Republic for the period 2014–2020 (hereinafter also referred to as a "the Strategic framework") is a conceptual document, which sets the direction for the development of public administration for the next period (after the end of the implementation of the Strategy for Smart Administration in 2015).

The overall objective of the Strategic framework is to improve the quality, effectiveness and transparency of public administration by targeted interventions focusing on selected weaknesses of public administration.

The strategic objective No. 3 of this framework is to increase the accessibility and transparency of public administration through tools of eGovernment. Moreover, project sector of computerisation of healthcare falls within this objective.

1.7.2.2 The action plan for the digital market development

The Action plan for the digital internal market development was based on the task of the Council of Economic and Social Agreement of 16 March 2015, which obliged the Secretary of State for European Affairs to elaborate themes and actions of the digital agenda, which are not adequately reflected in national policy for the National Policy on Electronic Communications – "Digital Czech at 2.0, Journey to the digital economy" (Digital Czech 2) or have not yet been met. Within Chapter 4 Development of electronic public administration of the action plan, a subchapter Electronic healthcare has been prepared, where in the form of the measures, Ministry of Health is in charge of:

- 1) Finishing the National Strategy for eHealth .
- 2) Creating the architecture of the current and future status of key projects for the development of computerisation.
- 3) Creating a coordination centre for development of computerisation management.
- 4) Implementing key projects / building elements of computerisation.
- 5) Preparing measures to eliminate barriers to the implementation.

1.7.2.3 Development Strategy of ICT public administration services and measures to streamline ICT services

Development Strategy of ICT public administration services and measures to streamline ICT services adopted by the government resolution on November 2, 2015 summarizes the problems of eGovernment, respectively public administration electronic services in the Czech Republic and provides a critical analysis of the current level of eGovernment.

Apart from the fact the document elaborates the key principles valid for both eGovernment and specific area of electronic healthcare, it also includes a separate measure No. 16. titled "Continue with electronic healthcare project, including e-prescribing."

Other relevant strategic documents are **the National Reform Programme of the Czech Republic and the International Competitiveness Strategy of the Czech Republic 2012–2020.**

1.7.3 International Strategy

1.7.3.1 EU Action plans

At this point, out of the previous EU documents, these documents shall be mentioned: the European Commission report on **Accelerating the Development of the Electronic Healthcare Market in Europe** in December 2007 (European Commission, 2007) related to the original Action Plan on electronic healthcare (European Commission, 2004) and dealing mainly with problems emerging with the need for exchange of information on the care process in connection with the free movement of citizens within the European Union.

The current electronic healthcare **Action plan for the years 2012–2020** (European Commission, 2012) follows the Plan of 2004 and responds to the evaluation of the implementation of the previous plan and development in the EU. The entire electronic healthcare strategy must be consistent with the documents of so called Information Society, many of which formulate strategy and vision for 2020.

Action plans of the European Union are conceptual documents that identify obstacles to the implementation of electronic healthcare and are based on extensive studies of the Europe-wide scale. Obstacles identified in Action plans resonate with experience from previous projects in the Czech Republic.

The document "**Digital Agenda for Europe**" is worth noting in particular, published by the European Commission (European Commission, 2010) on 19 May 2010.

Digital agenda includes five tasks related to healthcare:

- to enable secure online access to medical information to the citizens of EU member states by 2015,
- to achieve a broad expansion of telemedicine services by 2020,
- to prepare recommendations by 2012 defining the scope of the minimum common content of patient health information that will be electronically accessible among individual countries,
- to promote European standards for interoperability, testing and certification of health information systems by 2015,
- to support independent and active life for older and disabled people in society through the Ambient Assisted Living project. "

The Czech Republic is preparing with the support of the Connecting Europe Facility (CEF) programme the creation of the National Focal Point of the electronic healthcare (electronic healthcare NCP), which will implement a patient's summary

in the structure defined according to **Guidelines on minimum / non-exhaustive patient summary dataset for electronic exchange in accordance with the Cross-border Directive 2011/24/EU.**

1.7.3.2 Guidelines on the application of patients' rights in cross-border healthcare

A major impact on the computerisation of healthcare and on ensuring the interoperability of health records has **Directive of the** European Parliament and Council Directive 2011/24/EU of 9 March 2011 **on the application of patients' rights in cross border healthcare** in terms of legislation of the European Union, which requires member states to provide for exchange of medical documentation within the EU from 2013 and literally requires "...that patients who use or want to use cross-border healthcare, to have remote access to their medical documentation or at least to its copy..." while the data in the medical documentation "...must be readily available and if necessary will be made electronically available..." (the European Union, 2011). It is the very first binding EU document which focuses on the topic of electronic healthcare (Article 14 of the Directive).

1.7.3.3 Green book on mobile healthcare (mHealth)

In the electronic healthcare Action plan for the period 2012–2020, the benefits of current and future applications of mobile healthcare were recognized by the European Commission, the possible risks involved were highlighted and a **Green book on the topic of mobile health was announced**. On 10 April 2014, the European Commission adopted the Green Book and submitted it for public consultation.

The Green book deals with the possibilities of mobile healthcare and with its technological aspects and represents a problematic area for which it is necessary to obtain the views of stakeholders. It also analyses the potential of mobile healthcare for maintaining and improving the health and condition of the patients and to reinforce their role in the healthcare system.

2 Definition and analysis of the problem discussed

2.1 Definition of the problem discussed

Electronic healthcare is a dynamically developing field on the border of health informatics, public administration and public healthcare and fields created by the business community which are related to health services. Computerisation extends to virtually all the events in the health system; information and communication technologies are widely used by citizens and healthcare professionals in their professional and private lives.

In addition to the mutual interaction between patients and healthcare providers, electronic healthcare engages is mutual communication of healthcare professionals, healthcare providers and the patients themselves. Specialized information systems, computerisation of health records and healthcare, telemedicine, personal, portable and mobile communications systems for monitoring and supporting patients also fall within the competence of electronic healthcare.

The National Strategy for eHealth considers ICT to be supporting tools which allow to solve problems of health systems and healthcare system as a whole.

The proof of this attitude is the structure of the system of strategic objectives clearly declaring binding on the superior strategy, particularly on the strategy Health 2020.

2.2 The environment, the Czech Republic in an international comparison and expected future development

At least four conceptual documents seeking to the conceptual encouragement of computerisation of healthcare at the national level were created since 2009. Some of these documents were not adequately adopted and, above all, none of them was implemented. At the same time, the principles of strategic management were not followed. The consequences of this long-term vacuum of conceptual approach of the state are felt the most when seeking for ways to enforce already implemented partial government projects in the field of computerisation into practice. An example of a non-system solution is a register of healthcare professionals which has already been created, but cannot be applied in practice. Another example of a non-system solution is historical development of ePrescription in the Czech Republic since 2004 until today, or a failed project of so-called eSickNote or condition of the IAPHR project, which cost taxpayers a lot of money.

Even the electronic healthcare projects in the Czech Republic, which are considered successful (e-g. EPACS) cannot be described as examples that can be seamlessly integrated into a system of electronic healthcare services and which are fully consistent with the principles of eGovernment and the National Strategy for eHealth. Although the objective of the strategy is to use preferably the most out of functioning services, the individual solutions, together with the holders of individual projects, will be assessed thoroughly with a view of their most efficient gradual integration into the system of electronic healthcare.

Examples of solutions of electronic sharing and communication of health data in the Czech Republic

To illustrate several practical solutions in the field of electronic healthcare, which were really used in the Czech Republic, here are some selected examples of solutions of electronic communication and sharing of health data in the Czech Republic, taken from a study the Viability of Selected Areas of the National Strategy for eHealth Assessment prepared in 2016 for Ministry of Health. The study documented dozens of

other examples of successful and less successful solutions in the field of telemedicine, electronic prescriptions, electronic-based medical documentation, electronic requisitions, telemedicine solutions, decision support systems, infrastructure solutions of electronic healthcare and others. In relation to the scale, all these examples cannot be included in the basic document of the Strategy and therefore will be published on the website of NSEH.

An important role in the field of computerisation of healthcare is presented by projects of health insurance companies. The intention of the strategy is not to replace or displace the projects of health insurance companies, but rather to guarantee to the citizens that the existing strategies and concepts in the areas of healthcare (primarily Health 2020) and eGovernment (especially the Strategic framework for the development of public administration) will be supported even in the area of harnessing the potential of ICT technologies. For example: 8 principles (strategic objectives) of eGovernment on "Development Strategy for ICT Public Administration Services and its Measures to Streamline ICT Services," on which even the National Strategy for eHealth is based, that leads us "From the uncoordinated management of ICT state to coordinated management and built on a unified architecture and uniform rules." The objective of the strategy is to provide conditions and to implement only the minimum necessary projects so that new projects may be created and the existing services may be modernized for the benefit of citizens and their health. The Strategy does not explicitly aim to promote a competitive environment for health insurance companies nor to limit it.

E-communication of health insurance companies

Health insurance companies communicate with doctors and patients electronically through their own portals, respectively by using B2B services..

Programs Akord and Akord 2 (GMIC)

Quality of care program called AKORD was started on January 1, 2009, first as a pilot project for general practitioners in South Bohemia Region, Plzeňský Region, Moravian-Silesian Region and Ústecký Region, paediatricians throughout the country could have engaged from 1 July 2009. A doctor who volunteers for the program Akord awards a bonus for the use of specific electronic services provided by GMIC, for unavailability, for meeting regulatory criteria for requested care and for medicines and medical devices.

IAPHR

IAPHR project as a project of Electronic Health Book (EZK) was founded in 2001. In 2002 it switched into test operation and in 2004 into routine operation. In 2012 it was stopped by the Minister of Health for not working and useless. In that time, about 2.5 million patients were registered in the project and over 20,000 of healthcare professionals and more than eight thousand healthcare facilities. Throughout its existence, the costs were roughly CZK 1.8 billion, which were invested by its majority owner, the insurance company GMIC. At the time of its emergence, it was a unique project at least on a European scale, however, inconsistencies with legislative developments and binding to a single health insurance company clients avoided its adequate and effective expansion. IZIP project was closed on 31 December 2015 as a result of termination of cooperation with GHIC. According to the available data, the company ZDRAVEL (formerly IAPHR) prepares recovery of the EZK system.

Life Card (Mol Health Insurance Company, ČPZP)

The project is being implemented by Mol Health Insurance Company. It is a safe electronic deposit of an insured's basic health data on servers of Mol Health Insurance Company. The data may be accessed in an emergency to a rescue worker or to a patient. The data from the life cards can also be used when travelling abroad (life card has an automatically generated English version that can be printed) in situations of deterioration or injury.

VitaCard (OZP)

Vita Card is a set of premium online services offered by Occupational Health Insurance Company (OHIC).

Card of My Heart (Škoda Health Insurance Company)

The project Card of my heart is a system of e-services intended for clients of Škoda Health Insurance Company.

Data exchange in the Czech Republic

A key aspect of the concept of electronic healthcare is the exchange of data between information systems. Trend² (2) is a transition from systems whose core is the provider of health services to systems whose core is a patient (Patient-centric systems); however, this trend requires the implementation of interoperability between different systems.

² GOEDECKE J. eHealth Infrastructure and Medical Data Exchange for Health Professionals. In Med@Tel Luxembourg, 2010.

A number of Czech and Moravian hospitals are connected to the gigabyte backbone network CESNET2, allowing among others video-conference and multimedia data transfer in high resolution and quality around the world.

Workflow System (Capitol Development)

WORKFLOW is an information management system for the provision of healthcare and is being developed since 1998. It is designed primarily for doctors' network or health facilities' network and it offers sophisticated tools for increasing the efficiency of collaboration and data sharing between sites. The above-standard features include searching for suitable dates, reporting and modelling of processes in healthcare facilities. The system is based on Internet technologies and can be run in an internal company communication infrastructure or accessed via the Internet.

eMeDocS (the Vysočina Region)

The Vysočina Region is the only region in the Czech Republic which has been advancing for more than 10 years in the field of computerisation in a conceptual way. Devices mainly in the Vysočina Region are involved in the project eMeDocS; a complete list is on the website of the project.

NCMDE system

A proposal to establish the National Centre of Medical Documents Exchange (NCMDE) is based on similar principles to those of eMeDocS and it is therefore a continuation of eMeDocS project. The building of structures with potential support from EU funds is counted for.

MEDICAL.NET (CGM)

System MEDICAL.NET executed by CompuGroup company consists of two layers. Of a client part (an email client) installed for registered users of the network, and of a communication server. A client enables secure message sending to any registered user of the network. A message transmission itself is provided by the network server MEDICAL NET. The system is a secure communication system for the transmission of patient data (e.g. medical reports, requisitions and finds). Currently, 700 communicating workplaces have been involved in the MEDICAL NET system in the Czech Republic.

MISSION (STAPRO)

MISSION (Medical Internetworking Server) of STAPRO company is based on the transmission of encrypted messages based on standard protocols for communication between the client and server parts of the application. To ensure confidentiality of the message content, the system uses powerful cryptographic algorithms; the identity of the sender and integrity of messages are guaranteed by electronic signature. It is a strongly centralized structure of communication system with the transmitted data being stored in the locus in an encrypted form.

IKIS (Agel Health Insurance Company)

The principal product the Medical Systems company, a member of the AGEL group, is IKIS® hospital information system, which is a strategic tool of the AGEL group to manage the provision of healthcare and its reporting. Its essential feature is that it connects information from all hospitals to one information unit and therefore it allows to share and use data among healthcare workplaces involved.

The project eZpráva "Medical email"

The project "Medical mail" of eZprava.net Ltd. company specifies a secure distributed solution for the exchange of messages over the Internet, uses open standards to guarantee the identity of the sender / recipient, message integrity and readability of the report only to the final recipient. The project was

inspired by the US national system for health information exchange "DirectTrust". The type and content of the transmitted messages is not a part of the specification and therefore is not limited. The system was released for the whole country on 1 January 2015, there are 495 active accounts of medical facilities in the system by 27 April 2016.

EmergencyCard for EMS of the Plzeň Region

The system of EmergencyCard of the Plzeň Region ensures access to EMS physicians to life patient data stored in the established health facilities inpatient care of the region.

EPACS

EPACS project is one of the most successful projects of electronic healthcare which operates on a national level. This is a project that creates, maintains and expands the communication infrastructure for secure and trusted exchange of visual data among healthcare providers within the health system in the Czech Republic. The organiser and guarantor of the project is the General University Hospital on behalf of MoH of the Czech Republic. There are currently (January 2016) 290 healthcare providers involved across the country.

ReDiMed

A parallel to the previous project is ReDiMed system which is administered by the Institute of Computer Science of Masaryk University. ReDiMed system is designed to transmit visual records of patients among healthcare providers. It is also possible to additionally attach any other files (e.g. documents, presentations) to these recordings. Currently, 349 healthcare providers and educational institutions were involved. Investigators also provide other services of PACS, including data storage

The ReDiMed project has the Czech and Slovak national connection; many health departments are involved simultaneously in ePACS and in ReDiMed, however, these systems are not compatible [Horák 2013].

Examples of foreign solutions

The European Commission documented in an effort to promote computerisation of medical documentation on its website (<https://ec.europa.eu/digital-single-market/en/ehealth-studies-overview>) studies concerning the introduction of electronic healthcare. Moreover, it also supported the creation of a database of sample solutions of healthcare computerisation in 2006–2008. The project was designed in collaboration of Deloitte & Empirica and the final database is now available at <http://www.good-ehealth.org>, respectively at http://www.ehealth-impact.org/case_tool/main.php is a search tool allowing searching for previous studies not only according to the state but according to the current subject (EHR / ePrescription / screening / etc.).

Visibility policy, defence of usefulness and financial sustainability of electronic healthcare was abandoned by European Commission in 2013, when the mandate resulting from the European Parliament and Council Directive 2011/24/EU (Patients' rights to cross-border care) went to support the implementation of cross-border electronic healthcare services.

For understanding and evaluation of specific projects of computerisation of healthcare abroad, it is necessary to emphasize socio-technical aspect of computerisation expressed in WHO recommendations from 2012 the following rules:

- Technical systems have social consequences.
- Social systems have technical consequences.
- We do not design the technology, but the socio-technical systems.
- We need to understand how humans and technology interact.

Individual nation states retain their own culture, have different historical experiences, are peculiar in access to new technologies and changes in general and have healthcare and social systems on the incommensurate state to each other. Due to this variability, an international comparison of the impact of computerisation of healthcare as a socio-technical effect and its extrapolation to the Czech healthcare system is very difficult.

The WHO recommendations for the strategy in the Czech Republic list the following three projects among the successful international projects of computerisation of healthcare:

Danish national public health Sundhed.dk portal serves as a central coordinating mechanism and inspiration for new services. The portal clearly exceeded the critical mass of patients and professionals, who not only take in, but also help to create content of the portal. Key features for a citizen: directories of names and addresses, e-services (booking, renewal provisions, consultations), calendar of visits, price comparisons, quality and accessibility of services comparison, information on prevention, medical information, laws and regulations, information on hospital waiting lists. The portal also offers a dialogue with other patient, access to personal health data, patient profile calculation, overview of personal history, expression of intention regarding artificial keeping alive to the patients and also offers an overview of medical workers who have access to personal data for feeling of privacy .

The portal also offers editing information on the presentation workplace for healthcare professionals and then searching for diagnoses by ICPC, the entire interdisciplinary list of health and prevention programs, encyclopaedia (Cochrane etc.), patient data (records from hospitals online, personal health profile, access to laboratory data , feedback) and regional data (contacts, regional health news, information about the visits in hospitals).

Norwegian national portal MinHelse.no provides advanced information and services resources that are available through the health funds operating hospitals. Meetings with healthcare providers can be ordered online and the portal provides some qualitative parameters of services provided including waiting times for examinations and treatments. An obvious part is the map with a locator of the nearest healthcare provider. The portal is also connected to the application for choosing a family doctor. However, efforts to create a national portal similar to Sundhed.dk did not result in a Norwegian context of the spectacular success as well as in Denmark.

Norwegian registries play a vital role in maintaining the credibility and transparency in healthcare. Their sufficient amount, completeness and quality guaranteed allow to rely on these data and to use them even further. Key to quality and trust in healthcare is the Norwegian Registration Authority for medical staff which weekly updates the register of healthcare professionals who are authorized or allowed to work in Norway. Here, healthcare organisations verify whether a person has a professional license and a license required for a given workload. Access privileges into hospital information systems are derived from the registry.

The Czech Republic in an international comparison

The study "Overview of the National Laws on Electronic Health Records in the EU Member States and Their Interaction with the Provision of Cross-border Electronic Healthcare Services" (Milieu Ltd - time.lex, July 2014)³, which included 29 countries indicate that only the Czech Republic, Germany, Ireland and Slovenia do not have a functional system for **sharing electronic medical records** introduced at least in pilot scale. Such systems are of the countries surveyed fully in service in Bulgaria, Denmark, Estonia, Finland, Hungary, Malta, the Netherlands, the United Kingdom and in Sweden. Belgium, Estonia, Finland, France, Croatia, Luxembourg, Lithuania, Norway, Portugal, Poland, Austria, Slovakia, Spain and Sweden of the countries surveyed have specific legislation on electronic medical records; in other countries, such legislation is either prepared or electronic health records follow the legislation on medical records in general.

European Commission recommendation on cross-border interoperability of health records (Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (C (2008) 3282)⁴) defines an electronic patient record as a summary report (or its equivalent) on the patient's condition; in 15 of the countries surveyed such a definition is supported by national legislation. In Germany, the definition of an electronic record of the patient is explicitly put into the context of sharing the record between healthcare providers who are involved in providing healthcare. A patient's consent to the sharing of medical records between healthcare providers is required in 9 countries; in some of them, the consent is considered implied if the healthcare providers are involved in the care of a particular patient.

The publication "Electronic Prescriptions Are Slowly Spreading in the European Union" (**2014**) provides an overview of **ePrescription** system introduction in 2009 - in everyday use in Belgium, Denmark, the Netherlands, Spain and Sweden, the existing pilot or at least plan can be found in the Czech Republic, Estonia, Finland, Germany, Italy, Portugal, Slovenia and in England, no plan was found in Austria, Bulgaria, France, Ireland, Lithuania, Romania. "

Electronic prescription was the subject of several international research projects funded by the EU: epSOS, EXPAND, OpenMed; current development is focused on cross-border interoperability and the use of databases of European Medical Agency.

Local or regional systems to support the provision of health services through information and communication technologies (**telemedicine**) are developed in many European regions, including the Czech Republic; however, nationwide expansion of these systems remains limited to the Nordic countries (see papers European Countries on Their Journey Towards National eHealth Infrastructures, EK 2011). However, the success of the British Whole System Demonstrator Programme is undisputed (Whole System Demonstrator program: Headline findings: December 2011, the UK Department of Health): reduction of mortality, reducing the number of hospitalizations, cut in hospitalization time and time of intensive care. Specific issues to be addressed in the context of telemedicine in the Czech Republic:

- requirement of providing healthcare in direct contact with a patient;
- accreditation for telemedicine care;
- responsibility of the individual participants of the value chain.

ITU Publications Filling the Gap: Legal and Regulatory Challenges of Mobile Health (mHealth) in Europe consider the inadequacy of the legislative system as one of the causes of the current situation, which is

³ http://ec.europa.eu/health/ehealth/docs/laws_report_recommendations_en.pdf

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008H0594:EN:NOT>

according to ITU analysis of mHealth in the EU only in the experimental phase. The situation in the Czech Republic in the field of mHealth is identical.

The study Overview of the National Laws on Electronic Health Records in the EU Member States and Their Interaction with the Provision of Cross-border eHealth Services (Milieu Ltd - time.lex) also looked at the specific rules for the **explicit consent of a patient** with storing and processing the data within electronic health records. In Germany, France, Croatia and Italy the principle of opt-in is applied; while in Austria, Luxembourg, Sweden and England it is possible to withdraw agreement with the leadership of EHR appeal process (the opt-out principle). The Czech Republic is among the countries where a patient must explicitly agree with the management and processing of data apart from healthcare providers, the National Strategy for eHealth asserts the principle of opt-out.

In 14 countries an ID card is used **identify patients** for electronic healthcare; in 13 countries the number of health insurance company serves for identification. No specific identification code for electronic healthcare is implemented in any country.

The **right of the patient to inspect / copy the data** from the shared electronic health record is enshrined in 13 countries; there are implemented mechanisms of audited approach in 11 countries which allow to a patient to find out details on access to the records. In five countries, a patient is given the opportunity to modify / delete data from his/her medical record, which was inserted by another entity.

Reliable infrastructure is one of the key prerequisites for the development of electronic healthcare. The report of Stroetman et al. 2011 (European Countries on Their Journey Towards National eHealth Infrastructures, January 2011) considers policies and management processes (governance), the existence of centres of excellence, unique identifiers of patients, health professionals and healthcare providers to ensure the security and confidentiality of data, technical and semantic standardization and matters relating to the reimbursement of care to be elements of infrastructure. ***The report on the basis of European experience states that where there are no strong national or regional institutions, individual healthcare providers do not have the motivation to create such an infrastructure, and intervention from the government is required.*** The study Overview of the National Laws on Electronic Health Records in the EU Member States and Their Interaction with the Provision of Cross-border eHealth Services (Milieu Ltd - time.lex) of 2014 monitors indirectly the existence of the registry of health professionals from the listed infrastructure elements: the rules for identification and authentication (electronic signature card, or other means). There is always a form of register of medical professionals for electronic healthcare applications in the 15 countries where medical personnel are identified with an electronic signature or electronic card (smart card). ***The Czech Republic is listed among the countries where the rules of the identification / authentication and access control of medical personnel do not exist.***

Outputs of the questionnaire:

The Expert group on Quality Indicators (HCQI) OECD authorized by Ministerial Council mandate conducted in March **2016 the second survey on the use of data from a patient's lifetime health record** (EHR) for purposes other than the original purpose of data acquisition (secondary data use). Monitoring population health, monitoring the quality of care, searching candidates for clinical studies and the general solution of scientific research tasks falls within the other purposes of using data. In July 2016, a preliminary evaluation document (DRAFT) titled "Readiness of Electronic Health Record Systems to Contribute to National Health Information and Research is available: Findings of the 2016 OECD HCQI Study of Electronic Health Record System Development and Data Use - Draft OECD Health Division Working Paper," out of which we derive the position of the Czech Republic.

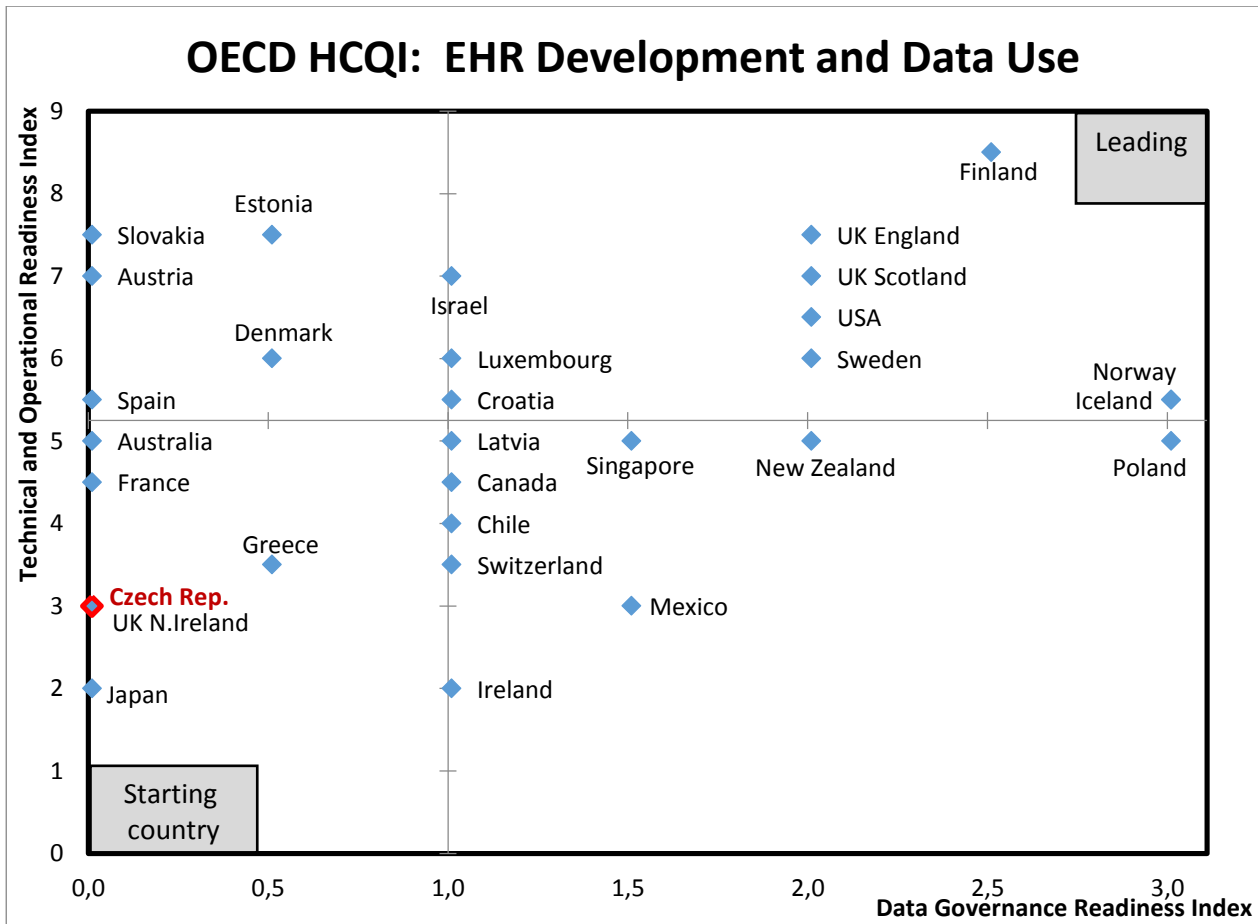
While 18 countries participated in the survey in 2012, in this year's survey (2016) 28 countries voluntarily participated: Australia, Austria, Canada, Chile, Croatia, the Czech Republic, Estonia, Finland, France, Greece, Iceland, Israel, Japan, Latvia, Luxembourg, Mexico, New Zealand, Norway, Poland, Singapore, Slovakia, Spain, Sweden, Switzerland, Britain and the United States. ***The two main directions of the research were***

- 1. technical and operational readiness of national systems supporting the further use of data from the EHR and***
- 2. level of data quality management (e.g. minimum data set, standards and terminology, good practice of data acquisition).***

Graph 1 depicts the position of each country, a central cross characterizes median. The countries located in the upper right corner (first quadrant) represent completely developed use of data from EHR for other purposes, supported by both infrastructure systems and quality control of data in EHR. The second quadrant represents the countries on the way to meaningful use of EHR - with prepared infrastructure systems, but with lower levels of data quality management. ***The countries in the third quadrant, along with the Czech Republic at the beginning of building a nationwide use of data from EHR for other purposes, or those which do not have EHR at all.***

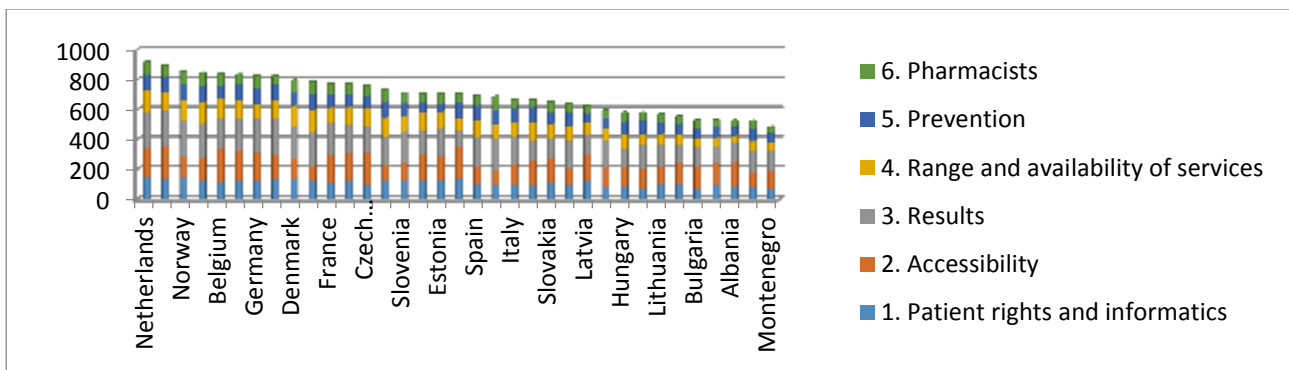
A position of a specific country in each of the surveyed lines is the result of scoring and besides a factual evaluation of government activity, it can be influenced by national cultural and historical experience (e.g. strong emphasis on individual privacy, or vice versa inclination to the congregation) that supports the idea collection and use of data of EHR, or on the contrary brakes those.

Note: The information comes from an upcoming OECD report, which was released for consultation procedure and will be published in September 2016. As for the indicative comparison of the position of the Czech Republic in the issue being solved.



Graph 1 Comparison of countries in real use data from EHR with the marked position of the Czech Republic.

According to the Euro Health Consumer Index for 2015, processed by the Health Consumer Powerhouse, the health system in the Czech Republic won the lowest rating in the area of patient rights and information among the six areas evaluated the performance of the health system. Electronic prescribing, access to electronic medical records, online health service ordering, register of healthcare providers with the evaluation of quality and the like were evaluated. The comparison is shown in the graph No. 2.



Graph 2 Scoring of health system according to EHCI by 2015 (based on sources of Health Consumer Powerhouse, 2016)

Prognosis of future development

We can expect to see more links between the data resources of the Czech Republic and greater use of shared public administration services, including the health sector. The effort to fulfil the principles of development of public administration under the Strategic Framework for the development of public administration in the Czech Republic for the period 2014 - 2020 is obvious; it will bring a number of changes to the health sector, such as the introduction of electronic identity for healthcare professionals and patients (citizens) of the Czech Republic, and later of EU, then deployment of authoritative sources of data and thus simplification of the exercise of agendas in healthcare.

Massive development of computerisation of healthcare can be expected as soon as the basic building blocks of electronic healthcare are finished and the primary framework for interoperability is set. The development will largely depend on the activity of the state in the management implementation and development of computerisation and the establishment of appropriate organisational structures necessary for the development of computerisation.

MoH of the Czech Republic declares a clear intention to gradually align mutually uncoordinated activities of the state government, the commercial sector, health insurance companies and health providers towards fulfilling the vision of the National Strategy for Electronic Healthcare by broad involvement of professional and general public and other participants of the users of electronic healthcare in preparing the strategy and the creation of interoperable trusted environment for all implementers of electronic healthcare services.

2.3 Examination of existing development

A ten-year period of efforts to establish and promote a national plan / strategy for electronic healthcare in the Czech Republic at the national level took a lot of effort and led many experts to handle various analyses and proposals. The trials are considered a valuable source of information and instruction for the National Strategy for eHealth and were used as the default input for strategy processing.

MoH accepted "Intention of eHealth projects" and "Objectives eHealth projects in the Czech Republic" in 2008; the planned implementing projects, however, were not launched. The Czech National Forum for electronic healthcare created "Theses of eHealth Development in the Czech Republic" in 2007 and subsequently in 2010, together with the ICT Union adopted a document "National Plan of eHealth Development"; these materials have become primarily a basis for subsequent dialogue between professionals and public and the state. In 2012, MoH launched the project "Economical and Functional Electronic Healthcare"; the draft "Concept of the National eHealth 2013 to Support Upcoming Projects" emerged from the outputs of realized „Competition on the Design of Computerisation of Healthcare”, which was not accepted by MoH.

At the end of 2013, MoH decided to prepare eHealth strategy according to "Methods of Preparation of Public Strategies" applied pursuant to Government resolution No. 318 of May 2, 2013. On 13 May 2014, the Minister of Health appointed an administrator and a coordinator of preparing "National Strategy for eHealth ", by which the preparation of the National Strategy for eHealth started .

2.4 Development when so called. zero option

Zero option introduces major impacts on the development of the addressed area when the strategy will not be implemented, or rather if the set measures will not be implemented by the strategy. If the state abandons the fulfilment of the objectives of this strategy and will not take any steps, therefore no individual strategic objectives of computerisation of healthcare will be supported.

Firstly, so needed significant strengthening of the role of the citizens in the care of their health cannot be expected, which is one of the essential preconditions for sustainable financing of the health system of the Czech Republic.

Increase of the quality of health services runs into barriers of mutual interoperability and communication between healthcare providers, which will preserve the *status quo*, where the patient is dragged by system of uncoordinated departments with paper documentation and with limited possibilities of electronic communication. Administrative burden on medical staff will continue to grow.

The effectiveness of the health system which is directly dependent on information technology, awareness and coordination of processes will remain undetectable and alternative solutions for computerisation will be searched for, which always run into the non-existent concept of development. Other non-conceptual solutions such IAPHR or eSickNote will appear or other solutions similar to the original eReceipt that cannot be well developed due to legislative obstacles and lack of coordination role in the field of computerisation at the national level. This will bring significant risks in the form of ineffectively spent money and a further decline in confidence in the Czech healthcare computerisation.

The government will keep on enforcing fulfilment of its overriding strategic goals and will push the health sector to fulfilling the commitments, which will generate *ad hoc* activities and projects that would not be linked with each other nor with the concept of development of the resort.

The Czech Republic will be subjected to pressure from the EU for failure to comply with EC regulations in the areas of interoperability, recognition of the rules of cross-border cooperation, etc.

On the one hand, medicine belongs to the more conservative areas, where new techniques are always subject to scrutiny before they are adopted into clinical practice, on the other hand, the doctors and nurses are considered of the most educated people in population among the promoters of the introduction of new

technologies, drugs and procedures in order to improve services provided. The existing technological solutions in the form of various mutually incompatible systems may persist on the market of information systems.

2.5 Summary of key results of the analyses

2.5.1 Formulating a preliminary entry vision

Formulating a preliminary vision of electronic healthcare in the Czech Republic was carried out in collaboration with CzMA and other involved parties in December 2013.

In October 2014, a recapitulation and a comparison of all the previous material of a strategic nature in the Czech Republic relating to electronic healthcare was performed. Among others, there were – for the purpose of formulating the strategic objectives of the system at the national level – simply stated the objectives of the European Union in this area:

- health of citizens – electronic healthcare tools enable sharing the information needed to care for people's health and to save their lives,
- improving the quality of healthcare and access to it – electronic healthcare becomes an integral part of healthcare policy and EU countries will co-ordinate their political, financial and technical strategies,
- improvement of electronic healthcare tools and improvement of their user comfort and usage – medical staff and patients will be involved in the planning, development and implementation.

2.5.2 Analysis of the eHealth participants' expectations

During the initial phase of the project in 2014, the initial assembly of needs and expectations of the various stakeholders in the health sector was performed, which were also an entrance to the strategy processing. An initial analysis was carried out using a questionnaire, which was sent to representatives of the various stakeholders. At the same time, the published outputs of Slovak electronic healthcare strategy were adequately exploited, adapted and translated into the Czech language. The outcomes were used as a basis for the initial design of a set of objectives and measures of the strategy and for processing Enterprise architecture of electronic healthcare.

2.5.3 Assessment of the implementability of selected areas of the Strategy

The outcome of the project "Assessment of the Implementability of Selected Areas of the National Strategy for eHealth " is a detailed description of possible solutions and particularly an analysis of the impacts of the implementation of individual measures on the legislation. Assessment includes analysis of existing practice in the Czech Republic, assessment of foreign solutions, awards of variants etc. The analysis of legislative impacts will be used as soon as the actual projects are formed. The main conclusion of the study is the requirement to prepare a comprehensive law in the area of electronic healthcare.

2.5.4 Enterprise Architecture of MoH department

National Strategy for eHealth will be implemented by concrete projects based on the strategic concept of Enterprise Architecture (hereinafter referred to as "EA") of MoH department.

The goal of EA is the harmonization and coordination of current and future activities leading to the implementation of electronic healthcare with maximum use of existing components and in accordance with the principles of eGovernment.

BASIC PRINCIPLES of development of computerisation according to the concept of EA

- To form a comprehensive and integrated system of electronic healthcare by such projects which are in line with national and departmental architecture and will be able to share data and effectively utilize existing data sources and IT services of the department and of eGovernment.
- Distribution of the complex environment of electronic healthcare in three key areas that logically follow: **Strategy, Architecture, Projects.**
- Linking these three areas through a common model. It must be clear how the strategic objectives are reflected across all layers of the architecture. And it must be clear what transformation projects realize these goals and what is the correct order.
- To form architectures, so that they are based on relevant national frameworks, both methodological and substantive. Especially from the National architectural plan of ICT of the Czech Republic (the Department of Chief Architect of MoI).

Development projects of computerisation must be processed including Enterprise architecture, which is also one of the conditions for absorption of ESIF funds.

The outputs of individual projects of Enterprise architecture (including the initiation projects implemented by MoH in working groups) and related detailed architectural analysis will be published on a special website of MoH. The outputs are used in the processing of the strategy and include an analysis and description of the current state of the department, assessment of the current status of ICT processes and ICT architecture in the department in relation to shared IT services provided by the public administration (source: Ministry of the Interior). Furthermore, the architectures of the future status of selected and priority areas of computerisation are processed and the impacts of contemplated changes to the legislation will be complemented .

MoH will formulate the principles by which computerisation will develop in the field of a particular area under which meaningful, feasible and well-defined projects will be created.

3 Vision and basic strategic aiming

3.1 Intervention logic, hierarchy of the strategy objectives

The basic footholds of the National Strategy for eHealth (NSEH) are The Vision of Electronic Healthcare and The System of goals and measures of NSEH. Interrelated strategic, and specific objectives and actions are described in detail in order to create a basis for processing of feasibility studies, defining and setting identifiers and metrics, assessment of user scenarios. In some cases, the feasibility studies were processed, the identifiers and metrics were defined and set and user scenarios were assessed. In other cases, on the basis of continuous assessment of strategy process and prioritization of topics, they will be further expanded. The system of objectives and measures was the basis for the development of Enterprise architecture of electronic healthcare and mapping the implementation of projects on specific objectives and measures based on this architecture. Within the implementation strategy other implementation projects implementing various measures will be defined according to the priorities determined by main actors of strategy, especially by MoH, respectively its authorized institution.

3.2 Vision and global objective of the strategy

Formulating a vision of electronic healthcare in the Czech Republic was one of the first steps in the creation of the National Strategy for eHealth . The preliminary vision was revised during the project of strategy creation. Creating a set of objectives and actions of National Strategy for eHealth was preceded by accepting the vision.

The overall objective of the strategy is to develop support in the provision of healthcare services using information technology, which brings growth in the availability, quality, safety and efficiency into the Czech healthcare.

Electronic healthcare provides **patients and citizens** with:

- easy and equal access to necessary health services,
- accurate health information, prevention, treatment plans and methods,
- sufficient information necessary to make good decisions about lifestyle, health protection and promotion, disease prevention and healthcare utilisation.

Electronic healthcare provides **doctors, general nurses and other health professionals**:

- accessible, accurate and timely patient information,
- available and verified information on health protection and promotion, disease prevention and lifestyle,
- complete and structured overviews of health status and treatment of patients,
- the possibility of easy team communication and cooperation with other healthcare providers,
- strong information support when making a decision
- comprehensive and clearly structured collections of knowledge and educational tools to ensure professional growth.

Technical and administrative staff of medical devices, health insurance companies, authorized local government bodies and the government will be enabled by electronic healthcare:

- receiving overviews on the parameters and performance of the relevant parts of the health system,
- ensuring the necessary conditions for further development of managed entities or processes,
- effectively planning and distributing resources according to the needs and expectations of patients and health professionals.

**National Strategy for Electronic Healthcare in agreement with the Action Plan 11
Computerisation of Healthcare Health 2020 formulates four strategic objectives:**

- 1. Increase citizen involvement in the care of their own health, prevention**
- 2. Increase the efficiency of the health system**
- 3. Increase the quality and accessibility of healthcare services**
- 4. Creation and development of information infrastructure and electronic healthcare management**

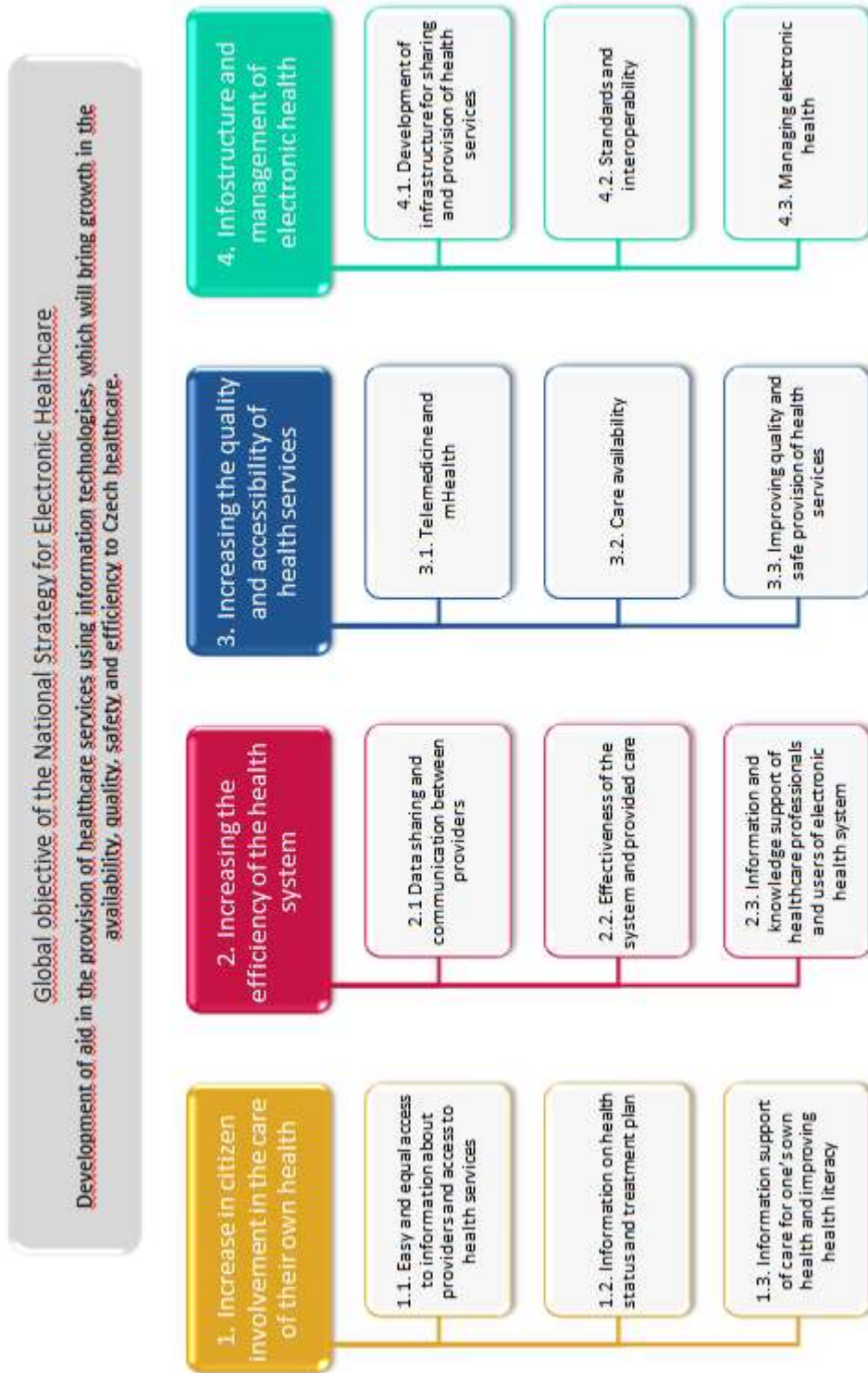
3.3 Strategic objectives of electronic healthcare

Although the vision of electronic healthcare is in all its parts so complex that it affects the entire system of targets and measures, it is possible to discern the specific perspective of the individual strategic objectives.

The first three strategic objectives are focused on the main target users of the strategy.

The first target addresses mainly a citizen, respectively a citizen in the role of a patient, a family of a patient and the like. The second objective is elaborated into specific objectives and actions which shall offer increasing the efficiency of the healthcare system, saving time, increasing competence in decision-making and generally providing healthcare to healthcare professionals, payers and other users of electronic healthcare. Between the second and the third goal there is no sharp interface. The quality and availability of health services are supported by a set of measures in the field of standardization, measurement, ensuring quality objectification, deployment of mobile electronic healthcare tools and the like.

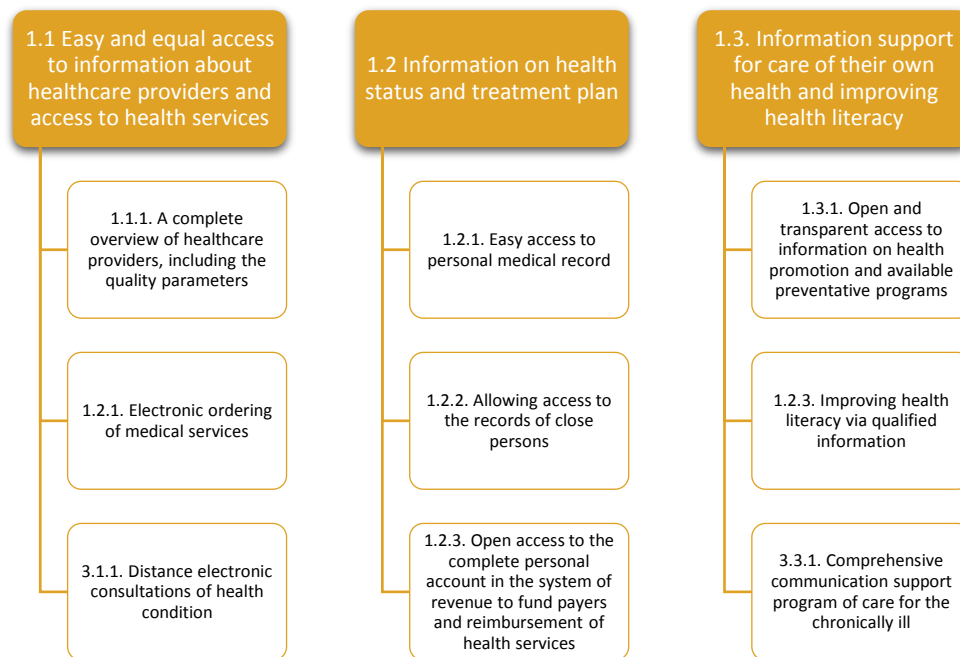
The fourth target covers two areas necessary for the development of the entire electronic healthcare, for achieving the overall objectives of the strategy as well as all previous strategic objectives. The first area is the creation and development of information infrastructure and infrastructure of electronic healthcare, such as e.g. health registers, electronic identity, consent and mandates management, ensuring the necessary standards and interoperability. The second area is the management of electronic healthcare system, i.e. leadership, policy and strategy of electronic healthcare with measures in legislation, privacy, interoperability national and international, market development and motivational environment, promotion of standards into practice with funding models and monitoring and evaluating the strategy. Securing this area should be entrusted to the National Centre for Electronic Healthcare.



Graph 3 A set of objectives of the National Strategy for eHealth

4 Description of objectives

4.1 Strategic Objective 1 Increase citizen involvement in the care of their own health



Graph 4 Structure of Strategic Objective 1

Improving citizens awareness of the healthcare system and encouraging activities for citizens to care for their own health, for the application of healthy lifestyle to reduce risk behaviour, to develop personal responsibility and efficient access to the resources of the health system are factors that positively affect coping with the increasing incidence of chronic diseases in ageing population. Strengthening the position of a citizen in the healthcare system is fully in line with the recommendations of the European Commission Health 2020, it is a way to develop a simple and efficient communication between citizens, healthcare professionals⁵ and responsible public administration authorities.

⁵ Medical staff and other healthcare workers

A. Background and requirements to meet the strategic objective

Services using the tools of information and communication technologies to support the activities of citizens are usually only a part of other specific systems. There is a comprehensive and purposely built a system that would support active participation of citizens in the prevention and care of their own health and

It is necessary to create a system that would provide public services in which a number of entities (e.g. health insurance companies, professional associations, health service providers,...) will participate and which would become such a trustworthy source of information for citizens, while appropriately completing the systems of health insurance companies motivating their insured.

integrated range of existing and newly developed electronic information resources and services.

Such a system will be simply called the **National Health Information Portal** that will be the main source of information on health and health services for a citizen and an important source of information for professional and managerial staff in healthcare. It should provide or convey comprehensive information in the field of healthcare, prevention and health promotion for both the general and professional public, for example:

- information on interactive prevention programmes aimed at improving health literacy,
- a navigator for advisory, consulting and intervention activities in the field of prevention of risk factors of lifestyle, taking advantage of links to trustworthy sources of information,
- epidemiological prevalence studies,
- mathematical modelling of prognoses of diseases, the effectiveness of prevention programmes;
- factually relevant analysis and legislation,
- appropriate tools of social marketing,
- a navigator of community programs using a geographic information system.

B. National Health Information Portal (hereinafter also referred to as "Portal") creates a protected channel of communication between patients and healthcare providers and creates a user-friendly environment for the utilisation of health services (ordering, consultation, extracts from documents, etc.). The impacts of fulfilling the individual specific objectives in the context of the strategic goals

National Health Information Portal uses (refers to) data from other data sources / sites and puts them in context and thus creates a comprehensive, transparent and credible public information source. Mediated information are either guaranteed or the source who is responsible for their accuracy is cited.

To ensure the operation of the portal it is necessary to create respectively to connect the entire ecosystem of subventors and editors and to determine their rights, duties and responsibilities. Here, as in the whole strategy, the objective is to enable the use on a voluntary basis, to provide information with an established fixed rate of expertise and by means of a single approach to electronic healthcare from different providers. It will be a guaranteed supplement to existing services in many cases, not their replacement.

Strategic objective consists of three specific objectives, namely:

- 1) **Ensuring easy and equal access to information about healthcare providers, ensuring availability of services with simple tools of electronic communication**, which is implemented through three measures:
 - **a complete overview of healthcare providers, including quality parameters.** Its output will be provision of a comprehensive and constantly updated information on all healthcare providers. This service enables a citizen to choose healthcare providers according to their needs and preferences,
 - **electronic ordering of medical services.** Its output will be mediation citizens' access to individual ordering systems of healthcare providers and those who do not have them available will have a chance of using the central application for this purpose. This service will simplify citizens' access to health services depending on their needs and possibilities,
 - **distance electronic consultation of health.** Its output will be a protected channel of communication between a patient and his/her physician. This service will enable to solve the needs of a patient for which his/her physical presence in the office is not required.
- 2) **Providing accurate information on state of health and treatment plans** is realized within three measures:
 - **easy access to personal medical record.** Its output is a protected access of citizens to information about their state of health, medications prescribed, the recommended treatment regime, on the dates and the type of check-ups arising from their individual health plans. This service will enable better control over citizens care about their own health,
 - enabling **access to the records of close persons** (at the discretion of a patient or his/her duly authorized representative). For this purpose, a consents management and access of authorized persons system to inspect a patient record, respectively his/her medical records will be established. This service will enable authorized persons to access health information of a citizen and to improve the quality especially of informal care,
 - **open access to a personal account in the reimbursement system for health services.** Its output is to enable / mediate authorized access of a citizen to his/her personal account held by a health insurance company.
- 3) **Development of information support to care for their own health and improving health literacy:**
 - **open and transparent access to information on health promotion and preventative programs.** Its output is an information channel to navigate a citizen towards trustworthy sources of information about healthcare and a healthy lifestyle. This service enables citizens to access the information needed for maintaining health and disease in time for its better handling,
 - **improving health literacy through qualified information.** Its output is an information channel that will lead a citizen towards trustworthy education portals and will offer him/her assistance in dealing with various life situations. This service enables citizens to deepen their knowledge in the care of their health and makes their decision in dealing with life situations in the health and social areas more accurate,
 - **Comprehensive communication and information support for care for the chronically ill.** Its output is making the information about the best treatments for specific chronic diseases accessible and also the authorized citizens' access to their individual treatment plans. This service enables citizens to understand their disease better and to strengthen compliance with medical instructions and quality of self-care.

C. Outputs of the fulfilment of specific objectives

The portal as a tool for the professional information support of citizens, but also health workers and other healthcare workers will become an important tool for supporting and promoting their own health, citizens' awareness of the availability and quality of medical services and will have an impact on improving the quality of healthcare, patient safety and ultimately to increase the efficiency of the health system.

Creating a comprehensive, transparent and credible public source of information will contribute to the growth of health literacy, to limitation of the increase in health risks due to incorrect application of the recommendations in the management of their own lifestyle, to promotion of effective procedures for the care of the chronically ill.

National Health Portal will be operated and managed by MoH of the Czech Republic (or by the designated organisations, such as the National Centre for Electronic Healthcare). The main source of financing will be resources of ESI Funds and of the state budget. In some cases, the use of resources for health insurers companies and private entities, that will have to finance their own economic interests, will be effective. Involving citizens in care for their own health, care for the chronically ill, the use of means of telemedicine, etc. are factors that will be more often motivators for achieving higher efficiency of the healthcare system and therefore involvement of health insurance companies, whose services have portal duplicate, but in an appropriate manner complement and reinforce their positive effect on the health system can be expected. A part of implementation of the strategic objectives will be defining links to electronic services of health insurance companies, HP and many other subjects, for example regions, cities and municipalities, NPOs, etc., and defining the role of various actors in achieving strategic goals.

D. Indicators of achieving the strategic objective

The basic indicator of achieving this strategic objective "Increasing Citizen Involvement in the Care For Their Own Health" will be an increasing number of registered and unregistered users of the National Health Information Portal and the level of satisfaction of its users. The indicators which will be measured by greater involvement of citizens to care for their own health shall be chosen and set.

E. Major barriers and risks of implementation (impact of the zero version of the strategic objective)

A risk when achieving this strategic objective is primarily a complex organisation of subventors and editors and their willingness and involvement to provide valid information to the portal. If the insufficient level of support for the active role of the citizen would persist, the deepening of inequalities in access to health services can be expected as well as the reduction of impact of an otherwise well-designed prevention programmes. Voluntary participation of individual entities must be balanced with high motivation. But it is in many cases based on "public pressure and widespread service." In many cases, the initial motivation for the "first participants" and subsequently for other potential participants, who must expend some effort to enter the portal, is missing. For the successful implementation of the portal, it will be necessary to set up appropriate incentive factors for each target group and to set up their target states in the minimum values / numbers. While the area of identification of medical professionals will be dealt with in detail by the department of health, the identification of citizens is the responsibility of Ministry of the Interior and therefore solutions for citizens in the roles of the patients must be prepared in close cooperation with Ministry of the Interior. Any use of identity resources to meet the needs of electronic healthcare will have to be solved together so that an acceptable way to bridge the gap before the National Identity Area provides sufficient resources for all patients.

Specific objective	Major measures	Title of output	Indicator	Responsible party	Cooperating entities	Relation to other objectives/measures
1.1 Easy and equal access to information about healthcare providers and access to health services	1.1.1.1. A complete overview of healthcare providers, including the quality parameters	The Portal application providing comprehensive and constantly updated information on healthcare providers	Number of visitors to the Portal application	MoH	Healthcare providers, health insurance companies	
	1.2.1.1. Electronic ordering of medical services	The service "Signpost for Ordering Systems" and the service "Central Ordering System of Healthcare Providers"	The number of healthcare providers who enabled ordering through the Portal and the increase the Number of patients who made an appointment	MoH	Healthcare providers, health insurers, CCHSIS	SO 2.2, 3.2
	1.1.3. Distance electronic consultations of health condition	The centrally provided service "Distant Electronic Consultation of State of Health" using the user interface (a protected communication channel between a patient	The number of healthcare providers who enables patients to communicate via a secure communication channel and its growth; the number of patients	MoH	Healthcare providers, health insurance companies	SO 1.3, 2.1, 2.3, 3.1, 3.2
1.2 Information on the state of health and treatment plan	1.2.1.1. Easy access to personal medical record	Channels of communication Service "Providing information on Health and Treatment Plans," and Service "Providing an Excerpt from Medical Documentation"	The number of accesses to information on state of health and treatment plans. The number of accesses to electronic medical documentation via a central	MoH	Health service providers, CCHSIS	SO 1.1, 1.3, 2.1, SO 3
	1.2.2. Allowing access to the records of close persons	Service "Consents for Access to the Health Records Management"	The number of consents made on access to electronic medical documentation or to shared part of the electronic health record (EHR / PHR) for	MoH	Health service providers, CCHSIS	Measure 4.1.5
	1.2.3. Open access to a personal account of payment for health services	The Portal application "Access to Personal Account"	The number of health insurance companies which are involved in this Portal. Attendance and use of services in relation to health insurance	MoH	Healthcare providers, health insurance companies, CCHSIS	SO 2.2
1.3. Information support to care for his/her own health and improving health literacy	1.3.1. Open and transparent access to information on health promotion and available preventative	An ecosystem consisting of redactions, professional companies and technical resources	The number of visitors of the Portal. Satisfaction survey.	MoH	Institute for health literacy, NML, CzMA, NIPH, UZIS, SIDC and other	Measures 2.3.1, 3.3.2, 3.3.3, SO 4.2
	1.2.3. Improving health literacy via qualified information	Creating an ecosystem consisting of experts capable of creating instructions for solving life situations and consequently ensuring appropriate information sources. Expert System providing information services.	The number of visitors of the Portal. Satisfaction survey.	MoH	Institute for health literacy, NML, CzMA, NIPH, UZIS, SIDC and other	Measures 2.3.1, 3.3.2, 3.3.3, SO 4.2
	3.3.1. Compact communication and information support of programmes of care for the	Setting cooperation with health insurance companies – information about their programmes and services, defining plans for chronic diseases within the gestion	The number of health insurance companies that engaged in the support of the chronically ill; the number of healthcare providers	MoH	Health insurance companies, UZIS, healthcare providers, regions	SO 1.2, 2.1, 2.2

Specific objective	Main measures	Title of output	Indicator	Responsible party	Cooperating entities	Relation to other objectives/measures
		health insurance companies. Creating a central component to ensure communications between health insurance companies, doctors and patients.	to support the chronically ill; the number of chronically ill patients who participated in the programme of support for the chronically ill.			

Table 2 – Summary of information for Strategic Objective 1

4.1.1 Specific Objective 1.1 Ensuring easy and equal access to information about healthcare providers, ensuring the availability of services with simple tools of electronic communication

A uniform, generally accessible, complete and comfortable service will provide citizens with a



Easy and equal access to information about providers and access to health services

1. *A complete overview of healthcare providers, including the quality parameters*
2. *Electronic ordering of medical services*
3. *Distance electronic consultation of health condition*

comprehensive view of the network of healthcare providers with the structure of the services provided. It will enable them a simple, safe and secure electronic communication with the medical staff and an orientation within the system. Citizens will get to choose the place of provision of healthcare and social services, consultation or ordering tests. A unified view of the healthcare and related social services would bring significant advantages to the whole system and especially to the citizens.

Measure 1.1.1 A complete overview of healthcare providers, including the quality parameters

A. Background and requirements for the measure implementation

Currently an easily accessible and comprehensive overview of network of healthcare providers supplemented by additional information which would help the citizens with their orientation and supports them in decision-making is not available. The continued absence of those services could lead to deepening of inequalities in access to healthcare services.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The measures will be ensured by the service **"A complete overview of the healthcare providers"**, which will provide easier orientation in the network of the providers, guaranteed and accurate information about availability of healthcare services and it will also provide citizens with a clear overview of providers of the services. The overview will offer, in particular:

- information about the structure of care provided (expertise, staffing, equipment)
- contact information,
- operating and office hours, method of making an appointment and communication,
- geographic information,
- qualitative parameters (position in the comparative methodology)
- existing contractual relationships of health insurance companies,
- an overview of the capacity available for new clients⁶.

A prerequisite for successful implementation is ensuring of necessary information and communication infrastructure, including resolving the identification and the authorization of the providers in the National Register of Healthcare Providers, authentication of the providers of healthcare services, then ensuring the

⁶ Primarily, it concerns a spare capacity of providers of outpatient care for patients.

necessary data resources from the health insurance companies (e.g. the information from the so-called Annex no. 2 to the contract between HIC and HP), or getting the information about the non-contractual healthcare providers from the regional registry.

An important factor of success is motivation of healthcare providers to share information. The opportunities for providers may include using the add-on services of the Portal, particularly ensuring a uniform and secure input channel with a guidepost for other functions, such as the possibility of making an appointment, querying, etc.

The service does not require authorized access of the users – citizens. The service will require authorized access to manage information specific to individual providers.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation is a creation of portal applications, which in a clear and intuitive form offers the possibility to search and view data about the providers of healthcare services, especially based on their name, expertise and focus, geographic scope and applicable contractual relationships of health insurance companies.

Indicators of the successful implementation of measures will be appointed based mainly on the use of services and on the annual growth.

User satisfaction surveys will be carried out.

D. Description of the steps leading to the fulfilment of the measure

First, it is necessary to create an information management system specific for individual providers (operating and office hours, methods of making an appointment and communication, an overview of available capacity for new clients) and to set a model for cooperation concerning sharing the information and mutual awareness.

Furthermore, it is necessary to connect the portal to a source of guaranteed and accurate information, especially to the National Register of Providers of Healthcare Services and to the information about the contractual relationships and about the structure of care provided by health insurance companies.

The next step is to create additional options, such as displaying the provider on the map outputs based on their geographic information, a production of an interface for providing OpenData about health care providers.

It will have to be determined who should bear what costs (what the provider pays for, as a manager of the portal, etc.) and the measures to minimise the administrative burden and costs will have to be implemented to increase incentives for providers.

E. Major barriers and risks

The creation of this service is conditional on credible data sources mainly from the National Register of Healthcare Providers. Unless this data is included, the implementation is threatened. A disclosure of information about healthcare providers beyond the current legislation is subject to the consent of the provider and the provider has the right to refuse the disclosure of such information or certain parts of it.

The risk may be insufficient legislative support for obtaining the information on contractual relations and on the structure of care provided by health insurance companies, beyond the current practice of publishing information on contractual relations under Act No. 48/1997 Coll. on the websites of health insurance companies.

Another risk emerges from the nature of obtaining information necessary for the sufficient knowledgeableness, for example a guaranteed source of accurate geographic information, the source of qualitative parameters when there is not a consensus on quality indicators, the reluctance of providers to provide information beyond the law and publish it on the Portal.

The need for appropriate cost allocation also represents a potential risk (what the provider pays for, as a manager of the portal, etc.), as well as the allocation of the accompanying administrative burdens in order to achieve sufficient incentives for providers.

Measure 1.1.2 Electronic ordering of a medical service

A. Background and requirements for the measure implementation

Some healthcare providers already operate booking and reservation systems. For citizens it would be beneficial if the state created the conditions to allow citizens to order healthcare services by using electronic instruments, wherever it is appropriate.

Analogously, the solution of the service of complaints of records is also required. Citizens would also welcome the possibility of online payment of direct-paid services.

This measure should bring improvements into access to care, reduction of health risks and adverse economic impacts from delays and unnecessary waiting times. At the same time, it should be accompanied by the measures to prevent the negative impact on the population groups with limited access to this service.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

One possible solution is to create a signpost of ordering systems of individual providers on the National Health Information Portal and to provide the service “Signpost of ordering systems” and the service “Central ordering system of healthcare providers.”

The service “**Signpost of ordering systems**” provides a single point which facilitates orientation and navigation for users when accessing ordering systems of providers and other organizations, such as health insurance companies (if they offer a specific service).

The service “**Central ordering system of healthcare providers**” will give providers whose ordering system is not accessible via the web interface the option to enable their patients to make appointments by using the service portal. A provider may communicate in central ordering system either through non-visual interface directly from their local system or they may work with a central ordering system directly through the Portal.

Analogously, the administration service of complaints of agenda can be dealt with at the regional level, by HIC and by the Ministry of Health, according to the nature of the complaint. The service will enable the client to make a complaint about the access to healthcare services or about the quality of healthcare services provided under Act No. 372/2011 Coll., on Health Services. Based on their type, the complaints are sent to the data box of a competent body which is responsible for such a type of complaint.

To ensure the knowledgeable of the users, they will be informed about the changes in making an appointment via messages notification.

The prerequisite for the implementation is an adoption of technical and organizational measures including resolving the identification of providers in the National Register of Healthcare Providers, authentication of citizens and ensuring motivation for healthcare providers to take part in the use of this service.

The benefit of implementation is an improvement in the orientation of citizens and an increase in the availability of care. Another significant benefit is saving time on the part of the citizen/patient and in case of solving the complaints of records, the benefit is its simplification.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation is an introduction of the two above-mentioned services for the citizens and the corresponding supporting applications and creation of a system for cooperation between providers and operators of a central portal and other portals.

Indicators of successful implementation of the measures are the number of providers who enabled making appointments through the Portal and its increase in the upcoming years.

Another indicator is the number of patients who make appointments through the Portal and its growth in the upcoming years.

D. Description of the steps leading to the fulfilment of the measure

First and foremost, the healthcare providers using ordering systems and their solutions will be mapped. Subsequently, the solution will be prepared for the Portal and in collaboration with the suppliers of

information systems for service providers, the implementation of a local ordering systems and their integration to the services of the Portal will be conducted.

E. Major barriers and risks

On the part of healthcare providers who already operate ordering systems, little interest in the services offered can be expected in the first phase. That will change with the development of computerisation and pressure from citizens concerning the quality and availability of the required services. To avoid unnecessary self-indication of examination by a patient which can be provided by for example HPs in primary care, it will be necessary to establish criteria for making an appointment at HP with regard to the need of use of a particular specialization.

Measure 1.1.3 Distance electronic consultation of health condition

A. Background and requirements for the measure implementation

There is currently no single system that guarantees safe electronic communication between a patient and their doctor or pharmacist. Electronic communication is either not carried out at all or is conducted based on conventional communication channels, such as an email, which are unsafe and not suitable for disclosing the confidential information. You need to create an interface for a guaranteed and safe electronic communication between a patient and their physician or pharmacist.

Required interface should enable providers of healthcare services to receive written information from authenticated citizens (query, notification, message) and to send a reply including a confirmation of application. It will be a system concerning a voluntary dialogue of eligible participants, healthcare professionals and patients. This system can be further developed towards interactive services, such as teleconsultation, remote monitoring, interactive assistance systems and similar.

In case of adequate implementation of similar services by multiple entities, e.g. by health insurance companies, information about these services and their properties will be provided.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Fulfilment of the objectives of the measures will be ensured by the service "**Distance electronic consultation of the state of health**", which will provide an electronic communication channel for secure and guaranteed communication between a patient and a physician. Communication can contain file attachments.

Usage of the service is voluntary, it requires authorized access of both sides and thus it prevents misuse of sending messages. The service can be advantageously integrated into the information systems of healthcare providers.

Precondition of the implementation of this service is a creation of an authentication service of patients and medical staff and a creation of a secure communication channel.

It can be expected that this measure will further develop a method of communication between a patient and a physician or a pharmacist, but also communication among healthcare professionals. Moreover, the communication can become part of the patient's medical documentation and it can increase the involvement of formal and informal carers in the whole process.

Legal liability for a damage to the patient will be clearly specified in case of errors in patient's care in this way (e.g. wrong consultation among doctors).

The service will be based on the unique identification of the two communicating parties and because of that, it requires authorised access of its users. The service can be integrated into the information systems of healthcare providers

This measure will bring complexity and directness of information about therapy, reduction of unnecessary visits, balance in the opportunities for access to care, a reduction of health risks to the citizens. The benefit is also an increase in the security and confidentiality of electronic communication between a patient and a physician or a pharmacist. It will be necessary to determine the maximum response time for a consultation so that there is no risk of a danger to a patient if the patient expects an immediate response from a doctor. The service will be set in a way that it is clear that the acute issues cannot be solved in this way, especially if they are endangering life or health.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation will be a centrally provided service “Distance electronic consultation of the state of health” using a user interface and a secure communication channel.

An indicator of a successful implementation of the measure is the number of providers who enabled patients to communicate over a secure communication channel and their growth in the upcoming years. Another identifier is the number of patients who have used this service.

D. Description of the steps leading to the fulfilment of the measure

A creation of a user interface for a secure communication channel. Possible start date of an implementation will depend on the readiness of infrastructure and on the interest of the providers.

E. Major barriers and risks

From the healthcare providers, little interest in the services offered can be expected in the first phase. That will change with the development of computerisation and pressure from citizens concerning the quality and availability of the required services.

The major barrier is economic conditions for distance consultations, i.e. payment for services and also the cost of the necessary equipment and its operation.

Risks also concern the fear of the providers from legal consequences of the content of electronic forms of communication. Another risk is that ICT technology for the time being cannot arrange an adequate contact for health assessment. Distance consultation is suitable only for specific cases and in a certain stage of their development and for certain patients. It also depends on the range, respectively on the number of the media used. Quality of healthcare is during the current method of computerisation often disrupted by a stronger communication of medical staff with electronic devices which is preferable to personal contact with a patient which should be a key indicator of quality of care, the computerisation must take the burden from the health professionals and it must provide them with more room for personal contact with a patient. This risk also applies to other areas of computerisation described by this strategy.

4.1.2 Specific Objective 1.2 Providing accurate information on health status and treatment plans



Information support of care for own health and improving health literacy.

1. *Easy access to personal health record*
2. *Allowing access to a close person's record*
3. *Open access to the complete personal account in the income system to the fund payers and reimbursement of health services*

Insufficient transfer of health information and treatment plans is a major obstacle to a satisfactory two-way communication between a doctor and a patient. Doctors often do not have the possibility to give patients the information about their health status in form of a transparent statement. In the case of health complications or when searching for medical services, patients do not have access to accurate information on their health status and treatment plans that are currently applied on them. Similar services in a restricted form and without the necessary interoperability are offered by some health insurance companies but these are not easily available. The continued absence of those services leads to an increased burden on healthcare providers, to ineffective indication of medical procedures, to the excessive burden on patients and to the potential threat against quality of care, with impacts on the health status of patients.

Implementation of this goal will enable a patient to obtain much broader access to their own medical documents and personal account of health insurance and thanks to that, a patient can be better informed about their health status, provided care and they could also make a better use of the possibility to change providers or obtain an alternative view on care for their health.

eHealth tools must enable a patient to get, keep and at their discretion to provide their medical records for other entities (but not to modify it). Besides this, there will be a continuous record of the shared feature of the patient summary which a patient can agree / disagree to give or not to give or a patient may have the record deleted, while medical records (managed by a medical facility) cannot be deleted by the patient's decision. At the same time, electronic healthcare will enable citizens to complement information (not to interfere in the medical documentation) which they are interested in transmitting to providers and other authorized persons. The system will strictly respect the rules of personal data protection. Involvement of a citizen in the transfer system and in sharing health information is voluntary and subject to their previous informed consent; a citizen may request any time that certain information or their complete record will be deleted from the sharing system, the National Strategy for eHealth promotes the introduction of the opt-out principle.

Measure 1.2.1 Easy access to personal health record

A. Background and requirements for the measure implementation

To get complete information about their state of health, about communicated recommendations, about imposed medical treatments, about drugs prescribed, a citizen gets a preview of their own medical records, which will be available in the structure they choose (based on the purpose of preview) (see Specific Objective 2.1).

This measure will encourage a patient to the adoption of medical treatments and recommendations, it will lead to the reduction of repeated examinations and reduction of the health burden, it will increase awareness and personal security of a citizen, it will also improve coordination of care.

It will reduce the adverse drug interactions thanks to the interconnection of information from the electronic prescription with structured medical documentation of the patient and with the application of the rules.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The measure will be ensured by the service *"Providing health information and treatment plans,"* and *"Providing excerpt from medical documentation"*.

The service **"Providing health information and treatment plans"** will provide citizens and legal guardians with a secure communication channel to gain access to their own electronic medical records. The scope of the medical records via a central interface (Portal) will depend on the extent of the shared electronic medical documentation. Respectively on electronic health record (see Specific Objective 2.1 Data sharing and communication between the Provider). We expect at least a provision of an index of electronic medical documentation (link to the information about executed medical services), this part can be implemented separately because it does not contain information about a state of health (not including clinical data) or about a treatment plan.

The service will enable access to information on health status and treatment plans even of a different citizen if they gave authorized user access to their medical records or electronic medical record.

The service **"Providing excerpt from medical records"** will provide citizens with a secure communication channel for obtaining an excerpt from medical records on request. The service enables a patient to send a request for a statement from their medical documentation to a competent doctor or to a provider of healthcare services. In the same communication channel a doctor sends an extract from the patient's medical records, in response to the request of the patient. The service requires access of the authorized users – citizens.

The precondition of the implementation is:

legislative change in the provision of electronic medical documentation to citizens through centralized solutions,

- launch of the services of an authentication of a citizen and a doctor
- creation of an index of medical records,
- security of the sources of electronic medical documentation and an issuance of appropriate standards which enable this exchange,
- establishing a system of administration of approvals.

The benefit of implementing these services is an increase in the availability of medical documentation and an increase in the patient's awareness about their health condition. Undoubtedly, also the time savings of a patient and a doctor.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Introduction of the service **"Providing information on state of health and treatment plans,"** which builds on the solution of the following components:

- a creation of a secure communication channel for the flow of sensitive information from the source to the user – citizen,
- a creation of a portal application which will in a clear and intuitive way provide the possibility to search and view data from electronic medical records,
- interconnection of a portal to the index of medical documentation and of source of the electronic medical records
- a creation of an interface for providing data of electronic medical records.

An introduction of the service **"Providing excerpt from medical records"** builds on the solution of the following components:

- a creation of a secure communication channel for the flow of sensitive information from the source to the user – citizen,
- a creation of a portal application which will in a clear and intuitive way provide the possibility to demand an excerpt from medical records and to get a delivery and a provision of a statement,
- a connection to the interface for the doctor's communication (portal application and nonvisual interface for the communication with the information system of a specialist).

The indicator of a successful implementation is the number of entries to the information on a state of health and treatment plans. Another indicator is the number of entries to electronic patient records through a central service.

D. Description of the steps leading to the fulfilment of the measure

The first step will be the processing of the concept of the solution and its architecture linked to a number of other shared services and legislative restrictions. A creation of the services will be preceded by steps in the order specified in the output of the measures, it will be necessary to prepare a legislation adjustment concerning the provision of electronic medical documentation. Special attention will be devoted to explaining the concept and details of the entire solution and its implications in medical practice for doctors, other health professionals and citizens.

E. Major barriers and risks

The main risk is the intricacy and complexity of the problem where a series of new services must be created and it will be needed to overcome fears of doctors from the disruption of their rights and the way they work. It will be necessary to eliminate the related time-demands and an administrative and financial burden on physicians. It will be needed to educate citizens and motivate them to use these services.

Measure 1.2.2 Enabling access to the records of the close persons (in case of a consent)

A. Background and requirements for the measure implementation

A citizen gets a chance to enable other people who they trust to have access to selected parts of the information about their own health and to a personal account. In the case of family members, the benefit of this service will be strengthening family ties and an improvement in the the quality of care of informal carers. More chap. 4.1.5 Management of consents and access.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Fulfilment of the measures will be ensured by the service **"Management of approvals for access to medical records"** which provides a citizen with a visual interface for entering new approvals, change and cancellation of assigned consents for physicians, healthcare providers and other individuals (e.g. a family member - father, mother,...). The service enables citizens to pull themselves out from the system.

The service enables citizens:

- a choice whether their electronic medical record (or electronic health record) as a whole or just parts (e.g. an index of medical records, electronic health record, a drug record, etc.) will be shared beyond the law or not,
- to decide about the access of doctors, pharmacists, medical facilities, or for which categories of health workers their electronic health records will be accessible in different life situations (attending doctor, save of live, pharmacist, consultant, etc.)
- an option beyond the rules above to extend access to their record and personal account at any time, e.g. for a chosen doctor, pharmacist or another person (e.g. a family member). Access can be permanent, one-time or time-limited. Access can be revoked by the patient again.

The intention is to provide a patient with full access (or their legal representative) to all the details contained in their own medical records. To increase protection of personal data and to strengthen the protection of privacy, a patient (or their legal representative) will have access to audit information about the access of the other entities (in this case not from a medical facility where it originated), to their electronic patient record and to shared parts of the electronic health record (EHR/PHR).

The precondition of the implementation is a legislative amendment concerning the provision of electronic medical documentation to citizens with the help of centralized or shared solutions, as well as launching services of authentication of a citizen and a doctor, and guaranteed and accurate source of information on the legal representatives, as well as the issuance of appropriate standards to enable the provision of information and ultimately system of management of approvals.

Services of consent management are shared services and will be used in many other cases.

The benefits of this measure consist in particular in the protection of privacy of a citizen and strengthening of confidence in eHealth services.

C. Outputs of the measure implementation, indicators of the successful measure implementation

An introduction of the service “Management of consent to access the health records” builds on the solution of the following components:

- a creation of portal applications which will in a clear and intuitive way offer management of permits for access to the medical records, cancellation or confirmation of keeping an index of medical records, shared electronic record as a whole or just its parts, and it will also ensure the possibility to view access to medical records,
- a creation of an interface for verifying consent to access the medical records.

Indicators of successful implementation of the measure are the number of consent made for access to electronic patient records and to a shared part of the electronic health record (EHR/PHR), for keeping an index of medical documentation (in case the principle of opt-out is not used) or adequate indicators signalling an active setting of consent by a citizen.

D. Description of the steps leading to the fulfilment of the measure

The first step will be the processing of the concept of the solution and its architecture linked to a number of other shared services and legislative restrictions. Creation of the services will be preceded by steps in the order specified in the output measures, it will be necessary to prepare a legislation adjustment concerning the provision of electronic medical documentation and electronic health record (EHR/PHR).

E. Major barriers and risks

The main risk is the complexity of the matter and its interconnection to related IT services. It will be needed to overcome people's fears of sharing their medical records and health records through the portal and fears of violation of security and privacy.

Measure 1.2.3 Open access to the personal account of payment of healthcare services

A. Background and requirements for the measure implementation

To be able to control received care, a citizen (i.e. the insured party) will have a possibility to access their personal account maintained by health insurance company, including an overview of paid premiums for public health insurance. Currently there is no unified system for access to such information. Health insurance companies provide listing of this information upon request or operate their own system for providing this information.

The task of the measure is to create conditions to ensure that every citizen or their legal representative can easily look at their personal account and in case of irregularities complain about the discrepancy between the reported and provided care. Information should serve for a citizen's better overview, for a feedback control and ultimately for a positive economic impact on the system of reimbursement of medical services.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Fulfilment of the objectives of the measures can be provided by health insurance companies by themselves. To ensure a uniform environment and protected access to a citizen's personal account, the central service **"Access to a personal account"** will be created.

This service will make the information on the reported healthcare covered by public health insurance accessible, including the list of contributions paid into the public health insurance scheme, it will also enable complaints about discrepancies between the provided and recognized care by HIC and ultimately it will provide additional information available from the individual health insurance companies (one of the variants is a link to the HIC website).

The benefit of this is in particular the use of a single authentication process of a citizen against the state and health department when using this service and other eHealth services. Additional benefits of the use of access to a personal account are known but people on a broader scale still do not use it or they are not sufficiently motivated for using it. It especially concerns the possibility of the patient's control of the correct reporting of healthcare payments and the possibility of claims about the care which was reported but not received by a citizen.

C. Outputs of the measure implementation, indicators of the successful measure implementation

An outcome of the implementation will be centrally provided service of a portal application such as a guidepost to the information systems of health insurance companies.

An indicator for a successful implementation of the measure is the number of health insurance companies which are involved in the portal. Subsequently an indicator of the traffic and usage of services in relation to health insurance companies will be monitored.

D. Description of the steps leading to the fulfilment of the measure

The first step is to deal with health insurance companies about the form of a solution, about the protection of their data and setting of the rules of cooperation with the operator of the central solution. Further steps are of implementation (creation of a signpost and an interface for citizens for information systems of individual HICs).

E. Major barriers and risks

Unfounded fears of distortions of competition for health insurance companies.

It will be a service only for the persons insured by health insurance companies in the public health insurance system in the Czech Republic. Where the CR is ancillary within the EU/EEC, there can be prospectively thought about the possibility of making such services available also to these patients (whether they already have commercial insurance or something else).

4.1.3 Specific Objective 1.3 Development of information support for care for their own health and improving health literacy



Information support of care for own health and improving literacy

1. *Open and transparent access to information on health promotion and preventative programs*
2. *Improving health literacy via qualified information*
3. *Comprehensive communication support program of care for the chronically ill*

Activation of the patients taking care of their own health and of their relatives is one of the most effective ways to improve the disease prevention and the effectiveness of healthcare. A knowledgeable cooperating patient with the role of an object of the healthcare becomes a real healthcare manager of their own health and contributes significantly not only to an improvement of cost efficiency, but mainly to an improvement of their own lifestyle and in case of illness also to quality of life. It is not about moving the responsibility for health solely on the shoulders of the patient, but it is about providing sufficient, valid and targeted information about the healthcare system itself, reducing the asymmetry of information between patients and medical staff and providing targeted information in case of illness, especially for the chronically ill. A systematic, transparent information support of patients, centred into a single access point is nowadays in the Czech health service sorely missing.

A positive activity is a portal managed by the National Library of Medicine which publishes information on the protection and promotion of health, prevention and treatment of diseases. Furthermore, there are portals such as the National Health Institute which publishes health education materials, CzMA publishes a range of information for patients coming from various professional societies, on various portals. Finally, it is important not to forget portals IHIS and SIDC and portals providing information about medicines. The important thing is that behind these portals there are teams of experts and editors managing their content.

Measure 1.3.1 Open and transparent access to information on health promotion and preventative programs

A. Background and requirements for the measure implementation

A creation and operation of an information portal and navigation system as a guidepost, including examples of good practice, health promotion and primary prevention, would significantly contribute to the growth of the effectiveness of primary prevention and health promotion, and it would simplify access to information for professionals and the general public, including reducing inequalities in health and support of persons who are disadvantaged and at risk of social exclusion.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The aim of this measure is to create an ecosystem consisting of existing editors, professional societies and technical resources, providing information on the protection and promotion of health, prevention and treatment of diseases through their portals.

The measure aims to develop and operate an information portal and a navigation system with a signpost to existing portals with added value of being focused on the life situations of a citizen in search of credible information about healthy lifestyle, health promotion and prevention programs.

Due to the large amount of information, it is needed to methodically prepare and evaluate what information is understandable and useful for the general public and it is also necessary to process a comprehensive promotional and informational concept.

The aim of the measure is also to provide data in a machine-readable form in form of open data (Open Data) for processing in both commercial and non-commercial environment. In this case, a positive impact on the improvement of health of the population is important.

An introduction of the service requires massive promotion and marketing support. The service does not require authorized access of the users – citizens.

The importance of this measure for the health system is significant. Among the benefits of the implementation of this measure there is included (or what the implementation of this measure can help):

- an improvement in awareness of a citizen and inclination to take care of their own health,
- early diagnosis,
- reduction of risk behaviour,
- effective utilization (based on defined indicators) and a reduction in the volume of care – (reduction of cost),
- an increase in the effectiveness of primary prevention and health promotion,
- simplification of access to information for professionals and the general public (the aim of the portal is not to “mirror” the information provided at the portals of the other institutions in the health sector, but to direct a citizen correctly where to find the needed information)
- expansion of educational opportunities for professionals in the field of healthcare and provision of expert information needed for effective diagnosis and treatment,
- reducing inequalities in health,
- increase in calmness of a citizen and their comfort, improvement of a mental state.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation is to create an ecosystem consisting of the existing editors, professional societies and technical resources which will provide information on the protection and promotion of health, prevention and treatment of diseases through their portals. And further:

- ensuring experts (professional societies) who will become subventors (authors) and who will provide objective and reliable information based on current scientific knowledge in the field of medicine and health,
- setting and implementation of editorial process,
- a creation of technical resources of Portal for simple and intuitive use and the use of mobile technologies,
- a creation of open data services.

The indicators of successful implementation of the measure are the number of entries to the portal and their growth.

D. Description of the steps leading to the fulfilment of the measure

The creation of the ultimate solution will be preceded by steps in the order specified in the output of the measures, including the creation of content management system and informational Portal.

E. Major barriers and risks

The main barrier is a limited ability of the state to put such a program into practice with available experts. The risk is a lack of state support to the program whose results will be displayed in the longer term. An inappropriate appointment of trustee(s) and other roles in the proposed system is among the risks that could critically jeopardize the implementation and sustainability of the system.

Measure 1.3.2 Improvement of health literacy with the help of qualified information

A. Background and requirements for the measure implementation

Czech citizens currently have low health literacy and consequently low motivation to take care of their own health and to adapt a healthy lifestyle. Therefore, it is necessary to introduce measures that will increase

the level of knowledge about the risks of lifestyle, skills, attitudes and motivation for a healthy lifestyle and for a change of behaviour in favour of a healthy lifestyle.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

A citizen will have a separate section in the National Health Information Portal. It will include certified existing educational programs (sites) and the newly formed, constantly maintained and professionally guaranteed sources of information.

A reasonable method of ensuring or recognizing (certification) of the information provided will be proposed, adopted and properly stipulated.

This measure is specifically aimed at solving life situations in the health sector where citizens can obtain information about the treatment options and information expanding their literacy when addressing the health situation of their own or of the people who they are taking care of.

The service "**Questionnaire system for dealing with life situations**" will provide a decision tree that will ensure a citizen a navigation to the instructions for the solution of their situation, namely in the area of health problems or their family members or the people they are taking care of. Solving of the life situations will be conducted in the context of the current environment, of the ability of the parties to solve the problem and it is clear that in the future, it will have to be linked to social services which in some cases intertwine with the solution of family situations.

The precondition of this service is setting of a stable cooperation with a representative group of experts who will participate in the selection and in an ongoing assessment of the educational programs, which are made available, and of other sources of information. Massive publicity and marketing support is a prerequisite for success.

The service does not require authorized access of the users – citizens. After logging in, a citizen can use the services specifically aimed at them and at the same time a structure of the menu based on pre-set models will be gradually personalized based on the interaction with the user.

The benefit of this measure is an improvement in awareness in addressing health problems and unexpected situations and in finding available medical services in the right time and place. The implemented measure can reduce risk behaviour, it reduces the volume of the received care – it also reduces costs and increases the effectiveness of primary prevention and health promotion. It simplifies access to information for professionals and the general public.

Educational work of medical professionals will be complemented by other instruments which will serve both citizens directly or the physicians can refer to them or use them by themselves when communicating with patients. An easier orientation of a citizen in life situations related to healthcare can reduce an unnecessary burden of healthcare workers in situations where patients address them in matters not directly related to the healthcare service, for example in case of insufficient orientation in the healthcare and social system.

Another significant benefit is a support of persons who are disadvantaged and at risk of social exclusion and a reduction of inequalities in health. Among other things, they can get the information indirectly, through family, community, or by a targeted influence of various organizations, social services, etc., and on the basis of support for dealing with life situations related to these groups of people.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation is a creation of an ecosystem consisting of experts capable of creating instructions for solving life situations and consequently ensuring appropriate information sources. A suitable classification system used for ensuring the reliability of information sources will be created and it will ensure a professional guarantee provided by the sources of information. The outcome will be also an expert system providing IT services.

An indicator of the successful implementation of the measure is the number of visitors to the Portal.

D. Description of the steps leading to the fulfilment of the measure

The creation of the ultimate solution will be preceded by steps in the order specified in the output of the measures.

E. Major barriers and risks

The main barrier is a limited ability of the state to put such a program into practice with available experts. Without ensuring the long-term financial rewards for these experts, the implementation of the measure is not conceivable. The risk is a lack of state support to the program whose results will be displayed in the longer term.

Measure 1.3.3 Comprehensive communication and information support for care for the chronically ill

A. Background and requirements for the measure implementation

Care for chronically ill patients and chronic disease prevention have not received yet the level of attention in the Czech Republic which is usual in the similarly organized systems of providing health services and payments. Programs of care for chronically ill patients are not used across the expedient scope, they lack an effective and convenient communication support. Continued lack of support programs of care for the chronically ill leads to an inefficient cost growth for a growing group of citizens suffering from non-communicable (i.e. civilisation) diseases. Availability of health services will be limited and the sustainability of the reimbursement system will be threatened.

An introduction of disease management programs for chronic diseases which will serve like a tool which reflects the patient load and which balances the increased costs of insurance companies with above-average frequency of chronically ill patients, will require enhanced information support.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The implementation of the objectives of this measure will be ensured by the service "**Support for the chronically ill**" which ensures access to care plans for patients with various chronic conditions which will be developed in cooperation of professional societies with health insurance companies and it will also declassify an individual treatment plan of an individual patient created by their attending physician. The service should enable feedback control of effectiveness of the treatment plan by health insurance companies.

The precondition of the implementation of this service is defining and setting specific indicators of success of individual treatment plans. These indicators must be established on the basis of consensus of health insurance companies and medical societies.

Another prerequisite is authorized access to medical plans conducted by physicians and authorized access of authorized personnel of health insurance companies to the figures of the indicators. The concept of the solution will be specified by binding outcomes of the working group which consists of representatives of health insurance companies and medical societies.

The preconditions of implementation:

- targeted marketing and communication campaign,
- a service requires authorized access of citizens to their individual treating plans kept by their physicians,
- an implementation of an interface for communication with the information systems of health insurance companies,
- an implementation of an interface for communication with information systems of physicians.

If the implementation of the measure takes place, citizens, health professionals and payers also receive a tool for a measurable improvement of care for the chronically ill.

The benefits of this measure are aimed at citizens, healthcare workers, agency workers who receive structured reports on an applied plan of care, on the default health parameters, on the progress of the plan and its results.

The indicated benefits of such measures are:

- effective course of treatment,
- optimal cost and expected outcomes of the treatment plan,
- increase in the effectiveness of primary prevention and health promotion,
- early diagnosis.

They have a positive impact on the patient because they increase patient's interest in their own health and they increase their awareness in order to avoid risky behaviour. Indirectly it increases the patient's sense of calm and comfort and it improves their mental state.

It will be appropriate to discuss how to enhance the effects of this measure by an appropriate coordination with the proposal of organizational measures for the integration of care for chronically ill at all levels in the health sector (esp. a general practitioner, specialist, hospital) with the help of ICT.

C. Outputs of the measure implementation, indicators of the successful measure implementation

An output of the implementation is setting cooperation with health insurance companies – information about their programs and services, defining plans for chronic diseases within the competence of health insurance companies. Furthermore, a creation of a central component to ensure that the communication between health insurance companies, doctors and patients.

The indicator of a successful implementation of the measure is the number of health insurance companies which engaged in the support of the chronically ill; then the number of providers who were involved in supporting the chronically ill, and finally the number of chronic patients who participated in the program of support for the chronically ill.

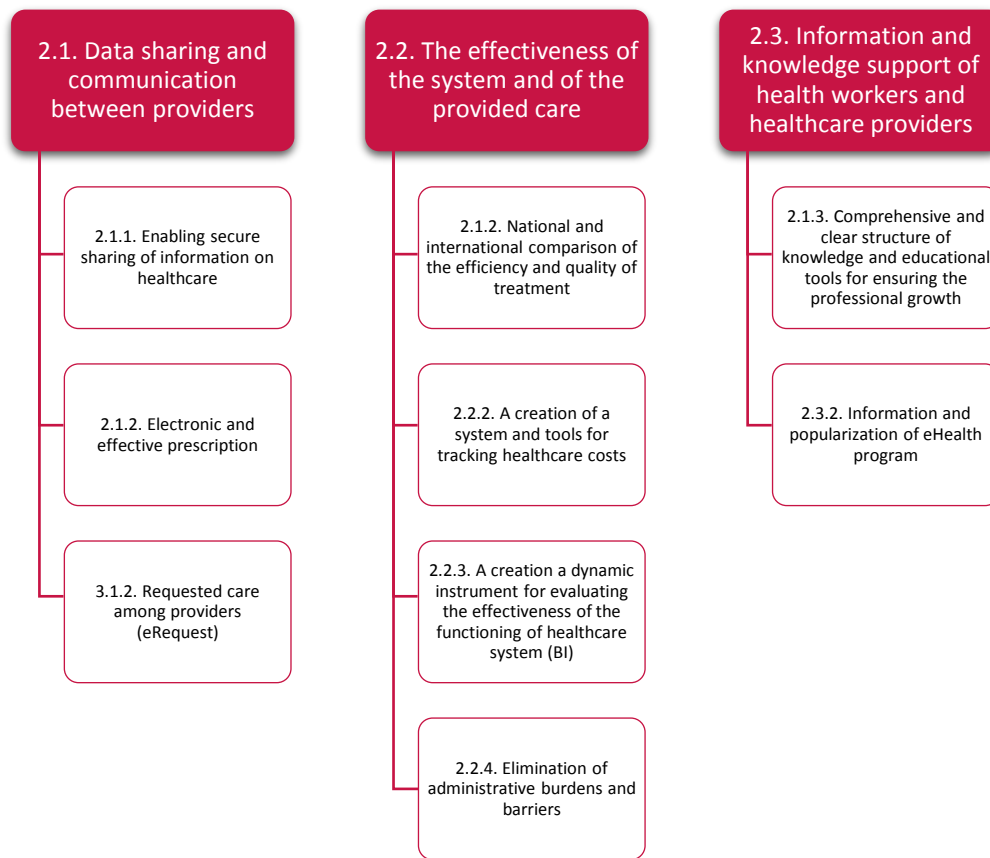
D. Description of the steps leading to the fulfilment of the measure

An implementation of the measure will be preceded by the steps listed in the output of the measure. A legislative amendment for providing support to chronically ill patients will be also needed, including support through the Portal and also a creation of an application for support for chronic patients.

E. Major barriers and risks

We can expect a slow process of creating individual treatment plans for chronic diseases. The risk is unwillingness of HPs to build and make individual treatment plans to authorized persons and a lack of motivation of health insurance companies to cooperate with the Portal which is providing this service. At the same time, these programs could be a tool for competition of insurance companies (in that case, a citizen would then be only informed by the central portal about the programs of individual insurance companies). The measure requires extensive legislative changes, whether it be on the remuneration of doctors, free choice of a provider or patient motivation. A risk is an ineffective or even a lack of marketing and communication support.

4.2 Strategic Objective 2 Increasing the efficiency of the healthcare system



Graph 5 Structure of Strategic Objective 2

A. Background and requirements to meet the strategic objective

The Czech health system has undergone over the last 20 years a major development towards modern electronic information systems. Healthcare facilities are equipped with a number of information solutions and with the necessary communication and information technologies and in spite of that there is an insufficient share of information about the patient's condition and the course of their treatment. Sharing information among providers is only limited and in many cases does not take place at all or in a totally insufficient scope. Therefore, the issue of management and sharing of medical records is a major theme of the whole strategy. In the follow-up health and social care, the tools for sharing information have not been constructed at all, respectively an involvement of providers into existing communication network is at its

Inadequate communication between providers will not only lower the efficiency of medical services performed but it mainly contributes to a higher burden for the patient (e.g. by a repeated testing) and in some cases even to the threats of the security of treatment.

minimum.

For the systems used, the question of authentication of documents, archiving and destruction in accordance with legislation is not satisfactorily solved. A national definition of so-called "emergency data set", which information systems of providers would extract from the latest medical records and which they would be able to electronically share, is also missing. In the absence of a definition of legally possible and functionally contrived, various proprietary solutions are created but they are inadequate for the providers

of health services in the 21st century. In addition to poor and unsatisfactory markets with products, a lack of investment in information systems by providers is also a simultaneously occurring problem.

The reasons for this can be seen particularly in the vague legislative framework and the absence of infrastructure which would allow secure transmission of health information between providers and then in the absence of guaranteed and mutually compatible systems allowing sharing medical records among authorized providers of health services, mutual portability and access of patients and their representatives. Existing systems for health records which are built by some health insurance companies lack these qualities. Furthermore, a lack of standardization of medical records, which significantly limits the ability of health workers to properly interpret medical records created in another clinic. This can in extreme cases lead to tragic consequences. The above mentioned causes significantly reduce the validity and threaten the ability of an unequivocal interpretation of shared and transmitted data.

Even though on the market, there are several proprietary solutions for an exchange of healthcare information systems and regional data exchange but the possibility of interconnection of these systems is limited, as well as state-guaranteed alternative ensuring affordable, secure and guaranteed environment for the exchange of medical information.

B. The impacts of the fulfilment of individual specific objectives within the context of the strategic objective

The strategic objective consists of three specific objectives and corresponding actions:

- 1) Data sharing and communication between providers:
 - enabling secure sharing of information on healthcare,
 - electronic and effective prescription,
 - requested care among providers (requisition)
- 2) The effectiveness of the system and of the care provided:
 - national and international comparison of the efficiency and quality of treatment,
 - creation of a system and tools for tracking healthcare costs,
 - creation of a dynamic tool of evaluating the effectiveness of the healthcare system functioning (BI),
 - elimination of administrative burdens and barriers.
- 3) Information and knowledge support of health workers and users of eHealth
 - comprehensive and clear structure of knowledge and educational tools for ensuring the professional growth,
 - Information and popularizing program of eHealth users.

Strengthening of **information sharing and communication among providers**, expansion of electronic ordering of health and social care, a creation of a personal health record that enables with the patient's consent to share especially the so-called emergent data (if an opt-out is possible), drug records and other clinical data and basic health and social needs of citizens. It will be allowed to the patients to have access to information about their own healthcare, access of health professionals to key information whenever needed and thus it will improve the efficiency, quality and safety of health service provision. By connecting this system to the European network of eHealth, the commitments of the Czech Republic to support the mobility of EU citizens will be fulfilled. All of these systems will be integrated with information systems of healthcare providers via standard interfaces and made available to citizens through the Portal.

It is also necessary to create an effective motivational tool for ensuring that the data in an electronic health record are current, complete and reliable and also a system of approvals which will by its granularity and setting support these requirements. The strategic goal is a cooperation of all entities which are responsible for the effectiveness of health and social services during the creation of such an instrument.

Another area that will **increase the efficiency and quality of the system** is an area of standardization of health services and health and social services. The aim of standardization is to promote a creation of so-called clinical procedures or protocols for individual workplaces. Clinical protocols and similar instruments will ensure that the selected processes of healthcare will be carried out in the same manner, will be normally documented, including possible variations.

The efficiency of healthcare is related besides standardization to **promotion of education** of health workers, to knowledge support and to the development of tools to support clinical decisions.

Electronic documentation and data sharing will contribute to the development and implementation of tools supporting automated evaluation of healthcare. They will enable e.g. an automatic detection of adverse drug interactions, warnings concerning the allergies of patients, recommendations for prescription, warnings concerning an inefficient method of treatment and similar. All these measures reduce inefficiencies and improve the quality of care provided.

To verify the effectiveness of selected targets and measures, it is essential to verify and evaluate the effectiveness of healthcare services. That's why the measures in this area are also a part of the strategy of eHealth.

C. Outputs of the fulfilment of specific objectives

An outcome of specific objectives is an improvement in the efficiency of health and social-health services. New, now non-existent solutions will be created for planar information sharing among providers of health services, the cooperation will improve on the interface of health and social care and the position of patients will significantly improve in the healthcare system. State (or responsible managers at all levels) will be able to measure the effectiveness of the system, to decide on the required investment, proposal and implementation of measures on the basis of valid data on the offer and demand of individual types of services. The state implements its commitments with respect to the cross-border exchange of health data.

D. Indicators of achieving the strategic objective

The measure of achieving the strategic objective will be a change of the position of a patient in the health and social-health services and a change of collaboration processes within health and social-health system. Without these changes, it is not possible to increase the efficiency of services and other benefits of eHealth. The number of these targeted benefits is difficult to measure directly so because of that, we suggest following proxy indicators:

- existence of legislation and mandatory standards that allow for a shared personal health record built on the principles set out in this strategy,
- the number of authorized administrators of a personal health record (EHR/PHR) in the Czech Republic whose services are used by healthcare professionals and citizens,
- national focal point of eHealth
- an existence of a fully-fledged electronic prescription constructed in accordance with this strategy,
- an existence of a fully-fledged electronic requisition constructed in accordance with this strategy,
- the state's ability to measure the benefits of computerisation of health service and impacts of computerisation on the efficiency and quality of health services,
- an existence of approved communication strategy of eHealth.

E. Main barriers and risks of implementation (impact of the zero option of a strategic objective)

The implementation of the measures proposed for the implementation of this strategic objective assumes complex changes in legislation, building the key elements of information infrastructure and particularly complex change of processes starting from a creation of medical records via its sharing and access to patients. It is a very large task that cannot work without high investments, long-term communication campaigns and finding a suitable motivation of participants to be involved in such a radical change of the processes. The complexity of processes, investment and legislative demands are the main risks of implementation which we see. It may be needed to legally treat a new categorization of health, social health, and social services. Typology on border of health and social care is not effectively defined nowadays. Support of system efficiency and provided long-term care cannot workout without a creation of a system and information tools for the implementation of managed care for selected groups of chronic patients.

But the benefits can greatly surpass the cost if the implementation is conducted thoughtfully, purposefully and in a long-term cooperation with the users of the system while respecting the maximum of their needs.

Specific objective	Main measures	Name of an output	Indicator	Responsible party	Cooperating entities	Reference to other objectives/action
2.1. Data sharing and communication between providers	2.1.1. Enabling secure sharing of information on healthcare	Verified and working components of national infrastructure for the exchange of medical records; a developed and practically verified service of management of a personal health record. Routinely operated by the National Focal Point of eHealth	<ul style="list-style-type: none"> - The number of solutions of exchange of HD incorporated into national infrastructure for the exchange of medical records - The number of types of legislatively correct, primarily electronic-based HD in national infrastructure - The proportion of HPs incorporated into national infrastructure for the exchange of HD - The number of authorized administrators of a personal health record whose services are used by healthcare professionals and citizens - The volume of exchange of electronic-based MD in national infrastructure - Patient summary, legislatively defined and introduced into practice 	MoH		Measure 1.2.1, 1.2.2 Measure 3.3.2, SO 4.1., SO 4.2
	2.1.2. Electronic and effective prescription	Computerisation of all key processes associated with the issuance of prescription for all types of drugs; computerisation of all types of prescriptions. Computerisation of vouchers for medical devices.	<ul style="list-style-type: none"> - Share of electronically issued prescriptions from all issued prescriptions (85%) - Share of electronically issued drugs from all drugs issued on prescription (95%) 	MoH, SIDC		Measure 3.3.2, 3.3.3, 3.3.5, SO 4.1., 4.2
	3.1.2. Requested care among providers (requisition form)	Converting paper forms into electronic forms and electronic document circulation. Subsequently fully data-structured form.	<ul style="list-style-type: none"> - Share of computerisation of various types of vouchers from the total number of types of coupons (75 %) - Share of electronically issued vouchers from all the electronic vouchers issued (85%) 	MoH		SO 1.2, SO 4.1, 4.2
2.2. The effectiveness of the system and of the care provided	2.2.1. National and international comparison of the efficiency and quality of treatment	The existence of a set of well-defined and by professional public accepted quality indicators. The existence of a system of collecting data and evaluating the quality of healthcare. Availability of a comparison of health outcome.	Functional system for transmitting requisitions; Share of health service providers included in the infrastructure for the exchange of medical records	MoH	IHIS, health insurance companies, Health insurance office	Measure 1.1.1, 1.3.1, 3.3.1

Specific objective	Main measures	Name of an output	Indicator	Responsible	Cooperating entities	Reference to other
2.3. Information and knowledge support of health workers and users of eHealth	2.2.2. A creation of a system and tools for tracking healthcare costs	The ability of effective planning and efficient provision of health services; information on the development costs of individual homogeneous tribes of the persons insured by regions.	Same as the outputs	MoH	IHS, health insurance companies, Health insurance office	Measure 3.3.1
	2.2.3. A creation of a dynamic instrument for evaluating the effectiveness of the functioning of healthcare system (BI)	Selected data and outputs of BI tools available to the public under the state program of open data; a set of analytical tools will be available to academic and research institutes	The number of new available data files; the number of new online presentation and analytical tools built over data sources and the number of user access to them.	MoH	IHS, health insurance companies, Health insurance office	Measure 3.3.1
	2.2.4. Elimination of administrative burdens and barriers	Development of primarily electronically maintained medical documentation; digitalization of administrative processes.	The number and an increase of the number of health facilities with fully digitized medical records, The number of medical facilities using electronic sick note.	MoH		SO 4.1, 4.3
	2.3.1. Comprehensive and clear structure of knowledge and educational tools for ensuring the professional growth	Verified and reliable sources of information in an appropriate structure. Competence of medical librarians will include the knowledge of methods of acquiring, searching and sharing information.	comprehensive system of teaching and education to promote knowledge and skills as specific information literacy of health workers and other healthcare workers in health system; - Implementation of a comprehensive system of teaching and education to promote knowledge and skills as specific information literacy of health workers and other healthcare workers - Implementation of a comprehensive system of teaching and education to promote knowledge and skills as specific information literacy of users	MoH	NPC Institute for Health literacy, CzMA	SO 1.3, Measure 3.3.2, 3.3.3, 4.2
	Information and popularizing program of eHealth users	A creation of a draft of a communication program of eHealth; Long-term update of the program.	A creation of a draft of communication program of eHealth	MoH		SO 4.3

Table 3 Summary of information for Strategic Objective 2

4.2.1 Specific Objective 2.1 Data sharing and communication between providers



Data sharing and communication between providers

1. *Enabling secure sharing of information on healthcare*
2. *Electronic and effective prescription*
3. *Requested care among providers (requisition)*

A. Background and requirements for implementation of the specific objective

A key aspect of computerisation of healthcare is an exchange of data between information systems and sharing information wherever they are needed to ensure safe, effective and quality healthcare. The trend is to move from a system centred on the medical facility to systems centred on the patient (patient-centric); this trend, however, requires the implementation of interoperability between different systems and building new, yet non-existent solutions that will enable information to be effectively communicated, shared and searched. At the same time, these solutions must contribute to raising awareness of a patient, strengthening their position in the system of health and social-health services.

Inadequate communication between providers does not result only in lower efficiency and higher costs of health services, but also in a greater burden on a patient (e.g. by repeat testing) and in some cases even in a threat to the safety of treatment due to the lack of information available to health and social workers who are providing the health and social services (e.g. prescriptions, allergies of a patient to certain drugs, prescribed diet, the dangers of a fall or other risks). This situation affects mainly children, elderly patients, patients with mental illnesses or with other forms of disadvantage.

At the same time in connection with the mobility of citizens of the European Union, there are imposed new requirements to ensure citizens' rights in cross-border healthcare, including requirements to promote international interoperability of electronic health records.

In the case of non-implementation of the proposed measures, the Czech Republic will lag behind even more in the area of computerisation and with a high degree of probability, it will not be possible to increase the efficiency of health services and strengthen the role of a citizen in the system. Czech Republic would not in this case be able to meet its obligations towards the EU in the area of cross-border healthcare.

The causes of this situation are given in part A of this strategic objective.

B. The impacts of the implementation of the individual measures on a specific goal

A specific objective includes the following measures:

- enabling secure sharing of information on healthcare – the secure sharing of electronic data enables an increase in the efficiency of treatment, reduction of risks during the treatment for the patient and shift from the healthcare system centred on a provider to a system centred on a patient. Information therefore travels primarily toward the patient and not vice versa,
- electronic and effective prescription – this measure aims like the previous one at strengthening the role of a patient, at increasing of the efficiency of the system and safety of health service provision. An electronic prescription is the first step to build a system of a shared health record or a personal health record of a patient,
- required care among providers (eRequest) – this measure will not only promote the exchange of medical records but also the standardization of the content of its selected parts and detailed information on the demand and offer of selected health services.

C. Indicators of achieving the specific goal

The objective will be achieved when the main obstacles will be removed which prevent an efficient electronic exchange and sharing of health data and if the key projects of eHealth are implemented in a full-fledged form: the electronic prescription, a health data exchange system and electronic requisition forms. To achieve this goal, it is necessary to implement a number of steps in the legislative, technical and standardization areas. A necessary precondition is a creation of an appropriate management system of eHealth, thus finding a holder of the projects who is responsible for the systematic construction and for a long-term conceptual development of constructed systems and services. In this regard, the attainability of the objective is dependent on the results of the strategic objective no. 4.

Indicators:

- existing infrastructure for global exchange of medical records
- existence of legislation and mandatory standards that allow for a shared personal health record built on the principles set out in this strategy,
- an existence of authorized providers of a personal health record (EHR/PHR) in the Czech Republic whose services are used by healthcare professionals and citizens,
- national focal point of eHealth
- an existence of a fully-fledged electronic prescription constructed in accordance with this strategy,
- an existence of a fully-fledged electronic requisition built in line with this strategy.

D. Main barriers and risks of fulfilment (impact of the zero-option of a specific objective)

Effective implementation of the proposed measures is dependent on building the necessary infrastructure of eHealth, particularly infrastructure for secure and guaranteed data exchange, a creation of binding standards ensuring interoperability of transmitted data and a guaranteed content of a shared personal health record and all components of the identity space. The main risk is therefore a possible failure of measures built in the strategic objective no. 4.

Measure 2.1.1. Enabling secure sharing of information on healthcare

A. Background and requirements for the measure implementation

Currently, there is no uniform national system for the transmission of messages between communicating parties. Issues of a transfer, the ensuring the credibility, non-repudiation of sending and receiving of messages are secured by every information system on its own or rather by using one of the existing proprietary solutions. In these systems, however, the possibility of interconnectivity is limited and it still lacks a state-guaranteed alternative providing affordable, secure and guaranteed environment for the exchange of medical information.

Besides the requirement for standardized data transmission within the national health system, saturated nowadays especially by DASTA standard, there arises also a need to ensure a previously neglected aspect of international standardization of health data transmission and above all building of a uniform system for the secure transmission of medical data.

An attempt to link existing communication systems is yet an unrealized project of Vysocina region - National Centre for exchange of medical records (NIX HD).

DASTA Standard (indeed not even the international standards with the same focus) **systematically does not address issues of physical data transfer or their security.** Another level of exchange of medical information and the opportunity for the development of telemedicine applications or continued access to patient health information are represented by guaranteed personal health records. Existing solutions of several insurance companies are certainly a good foundation, but they lack a unified structure of minimum data and for technical and probably for competitive reasons, they do not offer the option of portability.

Along with the need for transition to electronic medical documentation, a comprehensive solution and an appropriate setting of the rules and conditions are required which are related to the time of deposit of electronically-led medical documentation, authorized by the conversion of paper documents, the administration of shredding characters, liquidation of no longer required medical documentation – all with respect to the effective management of resources necessary for storing data at the providers even on the national level, output for archiving selected documents, the rules applicable for the handling and security of sensitive data on patients and health professionals.

Sharing and information exchange must be set so as to avoid situations where while going through medical records, a patient finds out that they have a major illness before their attending physician does or that they think so without it being the truth.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The aim of this measure is to build the necessary infrastructure for the exchange of medical records, and further to specify the legislative, technical, security and content standards for the implementation of the shared health record (EHR PCEHR) and its reference implementation. The state will be a default administrator of the electronic record and a guarantor of system for sharing medical data. Other entities can, however, become administrators of electronic health records on the basis of a free choice of a patient (e.g. health insurance companies, health service providers and private operators) if they implement their electronic repositories in accordance with established standards and if they meet all the given requirements concerning their administration and operation. Patients will have a possibility to choose a manager of their medical record and the ability to move between different managers without a loss of a guaranteed part of the health record.

A precondition for the exchange and sharing of information is a creation of conditions for a transition to electronic-based medical documentation, including a complex solution and the appropriate setting of rules and conditions related to the time of storing of electronically maintained medical documentation, authorized by the conversion of paper documents, the administration of shredding characters, liquidation of no longer needed medical documentation while respecting the effective use of resources. The role of the state is also indispensable in creating the national contact points (or locations) of eHealth, as stated in Article 14, Directive of the European Parliament and Council 2011/24/EU on the application of patients' rights in cross-border healthcare and from the approved work plan of grouping European eHealth Network for years 2015-2018.

Infrastructure of sharing of healthcare information will include all the necessary components ensuring communication (both for end-users and for the connection of information systems), the necessary safety features to prevent misuse of sensitive information and to protect the privacy of patients and it will be connected to a single system of identity management and authentication of health professionals and others healthcare workers and patients. All systems will be supported by the processes of user access control their operational monitoring will be ensured - logging of access and events.

System of transmission of health information will provide a guaranteed and secure transfer of information between medical service providers including the possibility of connecting other used communication systems through standardized interfaces.

The part of the solution will also be a support of national and international exchange of health information. The system will ensure the mutual translation of reports created in different versions of the supported standard data interfaces and it will provide basic terminological services (mapping of selected terminological and classification systems and their translation) and it will offer services of a national contact point (or locations) of eHealth.

Given that the Czech Republic is building a National focal point of eHealth (NCP of eHealth) with support from the CEF, it will be required to implement a patient summary in a structure defined according to Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross-border Directive 2011/24/EU. Consequently, from that there arises a demand for an introduction of the patient summary into the infrastructure of exchange of health information.

Part of the infrastructure will be:

1) System of the transfer of health information

The aim of the extension of the system will be the engagement of outpatient and general practitioners and other providers of health services and the connection with providers of health and social services. The system will be complemented by the possibility of translation of supported message formats or the content of the transmitted information will be unified and standardized to ensure semantic interoperability. The system will be connected to the national focal point of eHealth enabling cross-border cooperation between EU member states in health service.

2) Index of medical records

Index of medical records can be used by persons authorized by a patient or by a patient themselves to obtain medical information, including video and other multimedia documents stored by health providers.

Index of medical records - an overview of the existing available medical documentation stored with health service providers and an overview of the locations of the shared electronic health record of a patient. Index of medical records can be used by persons authorized by a patient by a patient themselves or to obtain medical information including video and other multimedia documents stored by health providers. Any such request and provision of documentation will be noted in the system with the reasons for its consulting. This record will be available to a patient and to control authorities.

3) Personal health record (EHR/PHR)

Personal electronic health record (EHR/PHR) will include selected medical data, drug records and the results of the selected examination. Records will be via the index immediately available to authorized providers of health services and to a patient. The minimum range of shared health information (electronic health record), obligations of providers of health services and rules of access, rights and duties of administrators will be established by legislation.

Personal health record will allow permanently to store the selected medical data, drug records and the results of the selected examinations. Records will be via an index of medical records instantly available to authorized providers of health services and to a patient and also to other persons (doctors of medical assessment services working in the Ministry of Labour and Social Affairs, pharmacists, physicians or

inspection physicians of health insurance companies). Records will be available both in a web interface and for direct access to the information systems of healthcare providers (if providers implement this access into their systems). The minimum range of shared health information (electronic health record), obligations of providers of health services and rules of access, rights and duties of administrators will be based on the applicable legislation and they will be implemented in accordance with the national eHealth strategy. The system will also allow entries of information by a patient in the specified part of the list.

Enough time in advance, it is appropriate to respond to the need to share selected information for social services, which is, among other things, the future in a form of integration of services. Integrated health and social services cannot be effectively introduced in a large-scale without shared PHR (or EHR) with social services. The future sharing must have a legislative support.

4) Administration of a patient's consent

Management of patient consents is described in detail in Measure 4.1.5.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Verified and working components of national infrastructure for the exchange of medical records:

- current solutions used for the exchange of health information in the Czech Republic will be gradually incorporated into the national infrastructure,
- legislatively properly kept, primarily electronic medical documentation will be involved in the exchange of medical records in the Czech Republic in the measurable range.

Developed and practically verified services of management of personal health records which are in accordance with the National Strategy for eHealth:

- at least one service of management of personal health records (EHR / PHR) in the Czech Republic will be operated in accordance with the National Strategy for eHealth and will be used by healthcare professionals and citizens.

Routinely operated by the National Focal Point of eHealth:

- patient summary will be introduced into national practice,
- functional national infrastructure for the exchange of medical records is linked to the National Focal Point of eHealth.

Indicators:

- the number of solutions of exchange of medical records included in the national infrastructure for the exchange of medical records
- the number of types of documents (discharge report, surgical protocol, etc.) legislatively correct, primarily electronically-based medical documentation in the national infrastructure,
- a share of health providers incorporated into national infrastructure for the exchange of medical records
- the volume of exchanges of electronically-based medical documentation in the national infrastructure,
- patient summary, legislatively defined and implemented in practice.

D. Description of the steps leading to the fulfilment of the measure

- 1) Analysis of the legislative and regulatory framework (2016).
- 2) Implementation of legislative changes (2016-2020).
- 3) Preparation and adoption of a separate law for eHealth (2016-2019).

The steps below are dependent on the implementation of the legislative, organizational and technical measures and are dependent on the outcomes of the Strategic Objective 4 which is aimed at building the necessary infrastructure.

- 1) the initiation of the project National Focal Point of eHealth (2017).
- 2) launching the National Focal Point of eHealth (2018).

E. Major barriers and risks

Implementation of this measure is dependent on the implementation of a number of legislative amendments without which only partial steps will be possible and the benefits of the entire measure will be considerably reduced.

The risk is dependence on the creation of the necessary infrastructure (indexes, endorsements, identity space etc.) linked to the eGovernment and to the financing of this infrastructure - the subject of the measure in the Strategic Goal 4.

Given the long time needed to prepare and adopt a separate law for electronic healthcare, there is a threat that many new unsystematic solutions will be created and it will narrow the space for the conceptual computerisation of health system at the national level, therefore, the basic outline of the Act should be adopted quickly.

An exchange and sharing of information need to be implemented in a way that there is no rapid sharing of electronic medical records without any intention, i.e. aimless sharing information to prevent information overload. There must be no unsolicited exchange of health information. An attending physician will have to be enabled to adjust what they should be sent, as well as an appropriate categorization of medical documentation or medical records will have to be chosen in order to achieve clarity of work with information on the user side. At the same time the system must be introduced in a way that remote access of a patient to data contained in the medical records does not make a barrier for physicians, which would lead to an undesirable restriction of information recorded in medical records.

Measure 2.1.2. Electronic and effective prescription

A. Background and requirements for the measure implementation

ePrescription in the Czech Republic is a long-discussed topic. In the past, a number of attempts to implement electronic prescription emerged: a module within IZIP, a project of electronic prescription under the VZP Akord and the like. Local solutions of electronic prescriptions (within a medical facility or a group of healthcare facilities) are a normal part of hospital information systems.

Although all the target groups (government, doctors, pharmacists) are aware of the benefits of electronic prescription and of the fact that the electronic prescription is a current trend promoted within the EU, an adequate national system has not been managed to introduce in the Czech Republic since 2007.

Mandatory use of electronic prescription is enshrined in existing legislation (see Description and analysis of the current legal framework below) with the effective date of 1 January 2018. In the current solution of electronic prescription we are lacking some functional units without which it cannot be achieved declared systemic benefits or active support of the project by doctors or patients. These are mainly:

- 1) Information about the drug history of a patient including information about all prescribed and in reality issued medications, fully conditional on the consent of the patient.
- 2) Follow-up option of interaction treatment control and the connection of other additional functions.
- 3) Full-fledged active feedback to the issuance of prescribed medicines in pharmacies by prescribers.
- 4) "Mobile" prescription – an issuance of prescription to a patient without the necessity for acceptance of a paper dispatch and in some cases even without visiting the office.
- 5) Mobile prescription – a possibility to prescribe from a mobile device or from the web interface of a system.
- 6) Possibility of using anonymous data about the prescription for factual and economic analysis and for prediction of drug consumption.
- 7) Connecting of a drug record and electronic health records, with access of physicians and pharmacists on the basis of the patient's decision.

The current system of **central repository of ePrescriptions** and legislation governing its implementation and operation are from the perspective of the potential benefits a project which is currently not able to fulfil the full potential of computerisation of prescription. In the current legislative situation, the project cannot implement a significant portion of the potential benefits of the system and meet the expectations of the society. That is the main reason for unfulfilled expectations of doctors, pharmacists and the public. It is necessary to complete a variety of functional features and upgrades, some of which were part of the

original concept, but subsequently unrealized mainly due to insufficient legal training (the relevant act was among other things presented but not discussed).

Description and analysis of the current legal framework for electronic prescription

Legislation containing the adjustment of electronic prescription includes in Section 80 et seq. Act no. 378/2007 Coll., on Pharmaceuticals ("AoP"). This law sets that physicians may after a consultation with a patient issue a prescription in a paper or an electronic form. Exclusively in electronic form, a prescription for medicine shall be issued with limitation according to Section 39 (4), subsection c) of AoP and a prescription which prescribes a medicine containing cannabis for medical use.

Electronic prescriptions must be according to AoP sent by a doctor to the central repository of electronic prescriptions⁷. The central repository of electronic prescriptions is a central data repository for the collection and processing of electronically prescribed medicines⁸ which is established and operated by the State Institute for Drug Control as a part of its organization.

Mandatory use of electronic prescription and the exclusion of paper forms is enshrined in Art. I, paragraphs 54, 157, 230 and 263 of Act No. 70/2013 Coll., amending Act No. 378/2007 Coll., on Pharmaceuticals and amending certain related acts (the Pharmaceuticals Act), as amended, **with effect from 1 January 2018**.

An adjustment concerning the issuance of medicinal products is also included in Act No. 167/1998 Coll. on addictive substances, which in Section 13 sets that a medicinal product containing an addictive substance in category 1 may be issued exclusively on the electronic prescription, if it is set out so by the Act on Pharmaceuticals.

Compared to the legal regulations mentioned above, Act No. 268/2014 Coll. on Medical Devices in Section 47 sets that a prescription, i.e. a voucher, can **only** be issued **in a paper form**.

Current legislation concerning an electronic prescription is relatively isolated and addresses only the issue of prescribing and issuing medicines. E.g. the issue of drug record of a patient as a comprehensive record of the previously used or long-term use of drugs is not adjusted. The ambition to solve this deficit was related to the AoP amendment submitted to the Chamber of Deputies as print copy 1056/0⁹, this proposal was not discussed by the Parliament and was criticised by the professional public due to the deficits in privacy of a patient¹⁰.

The current legislation of electronic prescription also does not address the connection of emerging records to the patient's medical records modified by AoHS, although this link is significant for a comprehensive and effective functioning of the system of data sharing and communication between healthcare providers. Link of data in a central repository of electronic prescriptions to the registers of health insurance companies¹¹ and basic registers¹² is not regulated, either.

In the context of the above analysis, it can be stated that there is no sufficient legal basis for the fulfilment of the partial measure Electronic and effective prescribing. Although e.g. a functional unit "Information about drug history of a patient, including data on in actually issued drugs" could from the perspective of AoPPD be put in place on condition of a patient's consent, most of the functions could not be implemented because the appropriate state authorities do not have sufficient authorisation for them. All authority in terms of management and operation of the central repository of electronic prescriptions, except for the power to enact implementing legislation specifying the method of communication with this repository, is entrusted to the State Institute for Drug Control, without the obligation to integrate with other systems of eHealth or an obligation to respect architecture of eHealth system, if the Ministry of Health has set such an architecture. Other functional units outside of an electronic repository of prescriptions, however, are not regulated by law and entrusted to any authority.

¹⁰ See PROKEŠ, J. The Amendment to the Act on Pharmaceuticals. *Legal views*. Vol. 2010, No. 6 p. II.

¹¹ See Section 24 of Act no. 551/1991 Coll. on the General Health Insurance Company of the Czech Republic, as amended, and Section 21 of Act no. 280/1992 Coll. on Departmental, Professional, Company, and Other Health Insurance Companies.

¹² Act No. 111/2009 Coll., on Basic Registers, as amended.

Resolution of the Czech Government dated November 2, 2015 No. 889 sets the Development Strategy of ICT services of public administration and its measures to streamline ICT services, which the State Institute for Drug Control, as a manager and operator of the central repository of electronic prescriptions is obliged to fully respect.

B. A description of the implemented measure and the benefits and the impacts of the implementation of the measure

Full-featured electronic prescription system will contain all of the parts enabling the implementation of missing functional units and an achievement of the anticipated benefits of the solution. These functional units will be gradually built on the basis of an identified catalogue of needs of all users of an effective system of electronic prescription and in accordance with the relevant EU legislation (e.g. European Parliament and Council Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, Directive of Commission 2012/52/EU of 20 December 2012 which sets measures to facilitate the recognition of prescriptions issued in another member state).

To hear the legitimate objections of doctors, pharmacists and patients and to fulfil the intentions of the strategy of computerisation of health, we propose to make such changes in legislation that will allow implementation of a number of missing additional functions, especially the implementation of a long-term record of electronic prescriptions, making it available to patients, authorized physicians and pharmacists and to other entities having access on the basis of statutory authorization (e.g. health insurance companies) or based on the patient's decision.

The way in which these functional units are realized is also important. The system of electronic prescription will be implemented to fully respect the needs and interests of patients and to bring to prescribers and pharmacists not only a duty but also the indisputable benefits.

This procedure ensures that the system is compulsory only from the moment when its functional and technical characteristics are at such a level to satisfy not only the interest of the state and needs of central departmental organizations but to also help the other users of the system. Benefits of the solution must balance the demands and requirements on doctors and pharmacists. At the same above procedure declares a clear commitment from the state to build such a system.

Minimum conditions, whose fulfilment is a prerequisite for the mandatory use of electronic prescribing:

- 1) A single identity area of resort will be ensured (unique identification of medical staff, of healthcare providers, of a patient/the insured within the Ministry of Health or rather within health and social-health electronic agendas). The system of electronic prescription will use the service of this identity space. There will be implemented a simple, inexpensive, reliable user-friendly identification of doctors and pharmacists protecting privacy with a high degree of availability – users of electronic prescription system will be identified in the simplest, yet in the safest and the most secure manner and in accordance with the principles of electronic civil service.
- 2) The doctor will be able to prescribe the medicine and the pharmacy will allow its issuance whenever an urgent interest of the patient will required it, even if the functional means of electronic prescribing are not available.
- 3) The obligation will be accompanied by a motivational program for the use of eHealth tools (incl. system of electronic prescription) for pharmacies and doctors.¹³
- 4) Availability of technical infrastructure (networks) – the state shall take the necessary measures to ensure technical infrastructure in offices where there is no way how to objectively commercially reach it. Demonstrable unavailability of technical infrastructure (especially high-speed internet with defined

¹³ It is an essential condition formulated by the key users of the system of electronic prescription, by physicians and pharmacists.

parameters of availability in the hours of service of a provider) will be one of the exceptions from the requirement to prescribe electronically.

- 5) Adequate verification by a pilot operation – the system will become mandatory only after a sufficiently long planar verification (e.g. in a specific region) for all major types of medical facilities.¹³
- 6) The system will allow a preview for patients, physicians and pharmacists to the EPR (electronic record of a prescription), including available history of prescriptions, on the basis of legal authorization or by the patient's decision.

Computerisation of processes associated with prescribing and issuing of drugs is one of the areas that promise the highest benefits in terms of all the major players in the health system, therefore, providers, payers, regulators and especially the patients themselves. Potential of savings is in more rational prescribing of medicines, adequate diagnostics and number of medical procedures. Among the clear potential benefits of electronic prescribing in the full range of functions, there can be included:

- for patients: The option of issuing a prescription without visiting a doctor, therefore a comfort, flexibility and a save of time for patients and their relatives, even if only for a small proportion of cases. Possibility to order medicines at the pharmacy. Possibility of increasing patient's safety (in case of including check of drug interactions).
- for doctors and pharmacists: Information about the drug history of a patient, increase in the safety of treatment – a possibility to use the control of undesirable interactions of drugs prescribed and issued with help of the data from all health facilities. Possibility to take care of some of the issuances remotely without the need to invite a patient – the save of time and convenience both for a client and a doctor. More accurate data on the actual issuance of medicines to patients and their payment, and thus a better basis for fulfilling the refunding limits
- for a pharmacy: Automatic loading of all the data on the prescription prior to its issuance – faster processing of a prescription. Significant restrictions on the possibilities of falsifying prescriptions. Minimisation of the possibility of erroneous transcription of data from the prescription. Faultless accounting of the pharmacies and subsequent payment by an insurance company will reduce paperwork and direct loss of refusals of prescriptions,
- for the state and insurance companies: An electronic prescription cannot be faked, it also brings the possibility of easier control of the prescriptions and of the real drug dispensing. Data collected through electronic prescriptions can be used in anonymised form for scientific, research or statistical purposes and to support strategic decision-making.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The basic objective of this measure is global and mandatory adequate computerisation of all the key processes associated with the issuance of a prescription to all types of drugs (including medicines containing narcotic drugs and psychotropic substances and medicinal cannabis), the issuance of drugs and an administration of history of prescribed and issued drugs. Another objective will be computerisation of all types of prescriptions (i.e. prescriptions and requisitions for prescription of medicines and vouchers for prescribing medical devices). In terms of fulfilment of these goals, the following indicators will be monitored :

- a share of electronically issued prescriptions from all issued prescriptions (85%),
- a share of electronically issued drugs from all drugs issued on prescription (95%);
- a share of computerisation of various types of vouchers from the total number of types of coupons (75%),
- a share of electronically issued vouchers from all the electronic vouchers issued (85%).

D. Description of the steps leading to the fulfilment of the measure

Final system of electronic prescription will be built on the foundations of the existing system and will be a fully integrated part of eHealth. It follows a number of limitations and dependencies on the other projects of computerisation of health system which its implementation must respect. An indispensable condition for the achievement of the system of electronic prescription is a change of the number of existing regulations or rather laws. For this reason, the implementation of the measures will be gradual and long-term.

The existing system of electronic prescription is after the failure of relations with the original contractor operated in an alternative manner. Its operator, the State Institute for Drug Control (SIDC), must according to the existing legislation ensure its full operational readiness from 1 January 2018. So the start of the development and implementation cannot be postponed until the moment when the legislation allows the construction of a fully-fledged system (in terms of the above functions and principles). For this reason, the implementation of the system is divided into several phases.

The first phase of implementation of the system will be prepared in accordance with current legislation, but with maximum regard to the future desired functions of the system. There will also be the work on drafting the outline of the law and the enforcement of the legislative changes preventing the construction of a fully-fledged system, including the possibility of computerisation of medical certificates. Discussion and adoption of the relevant legal regulations should be undertaken in such a way that they shall be in force by 1 January 2018 at the latest. Before this date, the preparation of the second phase of the implementation of the system will begin so that a fully-fledged system of electronic prescription, after proper pilot testing and the transition period, becomes compulsory as soon as possible. The second phase will already implement a fully-fledged system of electronic prescription enabling the implementation of all kinds of prescriptions, exchanges of prescriptions across borders, the existence of long-time records of electronic prescriptions of a patient (integrated into the electronic record of a patient accessible to the patient).

Estimated further development will include the computerisation of medical vouchers and other functional modules resulting from the analysis of future needs and requirements. Electronic system of prescription will be continuously developed and upgraded in line with future requirements and principles of sustainability.

Framework schedule is given in the table:

Description of a step / stage	Opening	Completion
Stage I – the implementation of the computerisation system of prescription as required by existing legislation	01/04/2016	31/12/2017
Preparation of legislative changes	01/05/2016	31/08/2016
Discussion and adoption of legislative changes with effect from January 1, 2018		01/01/2018
Preparation for the second phase of implementation	01/08/2017	31/12/2017
Implementation of the second phase of the system	01/01/2018	31/12/2018
Pilot operation	01/01/2019	30/06/2019
Transitional period / start of system into the production environment	01/07/2019	31/12/2019
Mandatory global use of the computerisation system of prescription	01/01/2020	01/01/2020
Preparation and implementation of the next stage of implementation of the computerisation system of prescription	30/06/2018

Table 4 Framework timetable of steps leading to the fulfilment of measures

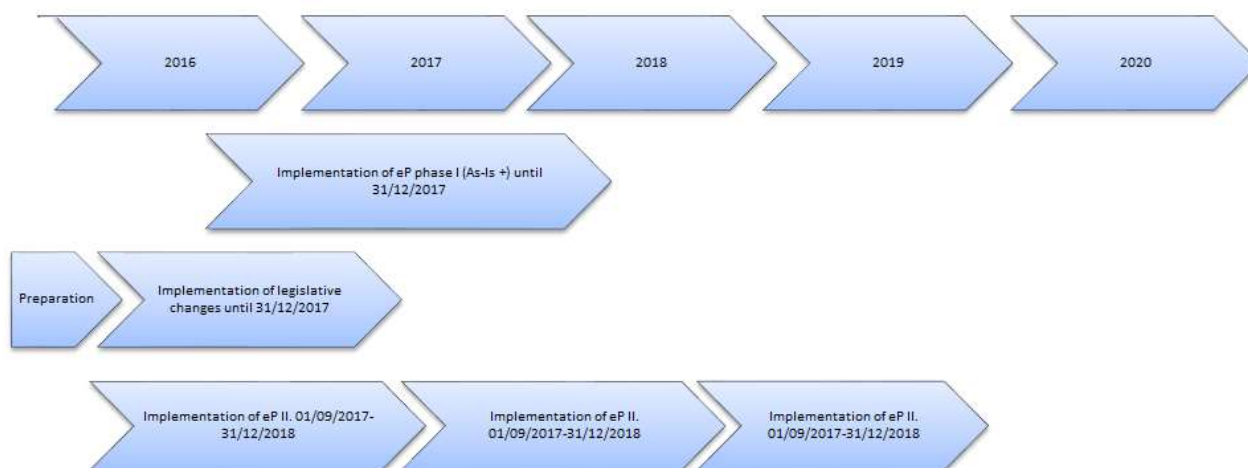


Diagram 1 Schedule of Basic Steps

E. Major barriers and risks

Among the key barriers and risks, there are mainly the length and uncertainty of the legislative process. Another risk is that the necessary infrastructure of eHealth will not be managed to be built – especially NRHP and NRHCP registers as authoritative sources of data and another parts of so called identity system and a system for the management and administration of patient's consent.

And finally, the most important risk is the risk of rejection of doctors and pharmacists if it is not constructed in accordance with their needs and expectations. Even small details can have an impact, e.g. if an electronic prescription is not properly prescribed by a doctor in the current system, the wrong header of prescription cannot be corrected at a pharmacy. The solution can be either validation, i.e. the verification of the accuracy of all the entered data already during prescribing of electronic prescription by a physician or allowing the intervention and corrections by a pharmacist when issuing the drug. For successful implementation of electronic prescription it is necessary to prevent changes in the conditions of reimbursement of pharmaceuticals and medical devices and changes in restrictions of prescription according to expertise, if the text of classifications is not available.

Measure 2.1.3. Requested care among providers (request form)

A. Background and requirements for the measure implementation

Electronic requisition forms, in literature labelled by the abbreviation CPOE (Computerised Physician Order Entry), are an essential tool for reduction of the administrative burden on medical staff. The literature indicates that an introduction of the electronic requisition form in the range greater than 60% decreases an average length of hospital treatment¹⁴. Incorrectly implemented requisition forms may lead to increased administrative burden and consequently to inaccuracies and errors. In the context of eHealth strategy, "extra-mural requisition forms" are primarily dealt with where it is necessary to achieve semantic and process interoperability between the systems.

The aim of eRequest is to create a work flow completely ensuring the ordering process of health services between two providers, including communicating the results of the orderer, the transfer of advanced data specifying the clinical context of the request, storing the results in a shared medical documentation, sharing status information of orders and results, informing a patient on follow-up activities (visit of the workplace,

¹⁴ <http://www.healthcareitnews.com/news/how-cpoe-can-reduce-length-stay>

preparation for the collection and so on.) in a safe and guaranteed way completely replacing the circulation of paper documents (a paper requisition form and communication of results).

Inside of the medical facilities, an exchange of electronic requisition forms between workplaces and between different information systems of the same medical facility is in national practice a widespread phenomenon. Quite often, in the case of communication between different information systems the standard DASTA, exceptionally HL7, are used for this purpose. The possibilities of monitoring of status information of requisition forms for healthcare workers are different in different implementations. A certain element, operating based on standardization, is the data interface and a set of specific formats of requisition forms used in the public health insurance system.

When communicating with laboratories, sometimes the methods of Good Laboratory Practice and National Code of laboratory items are used. Further standardization, for instance of so called profiles of laboratory tests, is not sufficiently widespread. In the majority of cases, the requisition forms are printed in parallel with the electronic form (not meeting the requirements of primarily electronically maintained medical documentation) and they are used in a paper form or filled in the forms of health insurance companies. Information about the copy of the requisition form is then added to the paper requisition form or printed and sent to the applicant's workplace in paper form separately, in parallel with the electronic form. Information systems of an orderer and a contractor generally provide the possibility of cumulative views, or rather further processing of the results of the same patient. Patient access to electronic requisition form is usually not possible.

Solutions should create conditions for purely electronic management of work flow of requisition forms with the use of guaranteed electronic service of requisition forms to which a patient has access. The service would provide basic standardized functions of eRequest. The service would be possible to be accessed from the information systems of an applicant and a contractor, from the EHR/PHR citizen and through the portal. It would be decided based on the decision of a citizen and healthcare providers whether and to what extent this service would be used in a specific situation and whether it would complement or replace other solutions of an electronic requisition form used by healthcare providers or operators of EHR/PHR. In cases where it is justified, the access to the work flow of an electronic requisition form will be enabled to the authorized persons of health insurance companies.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Paper requests nowadays serve as a voucher for a patient for additional treatment or examination. This option remains maintained for a patient, although a transfer of a requisition form into an electronic format removes illegibility of handwritten requisition forms, which will increase safety of a patient and reduce errors in the system. Structured record of a requisition form allows the implementation of the systems for decision support (duplication of tests, frequency limit, the possibility of pre-approval of requirements for insurance payment, allocation of a suitable provider, a recommendation for a patient, notification on an appointment).

An automatic transfer of eRequest from an applicant to a provider will eliminate a significant volume of paper circulating on the part of an applicant and a provider. An electronic requisition form can ensure verification of the originator, which reduces the possibility of fraud with the requisition forms. The customer can see how their requisition form is treated (information on the status of request processing).

On the side of a provider (recipient), a requisition form will be automatically assigned to a correct patient, which saves time when copying patient data and it will reduce errors again. Sufficiently structured clinical part of a requisition form can in cooperation with the system for decision support estimate the time needed for the surgery before the patient arrives, it can facilitate device configuration, and participate in the process in any other way.

eRequest will be stored in a separate repository and will be accessible from the electronic health record of patients, since they are the bearers of the requisition form. There would not be a system of exchange of peer-to-peer, but the principle of Store & Forward.

Electronic transmission of results will save costs during the circulation of the paper version, it will accelerate information transfer and reduce errors. At the same time, it will enable another qualified

practitioner (e.g. a general practitioner, internist) or a patient to see the results of examinations or the status of processing requests from the environment of the electronic patient record.

Situations also must be avoided when during the consultation of medical records a patient learns that they have a major illness before their attending physician does or that they will think so without it being the truth.

The preconditions for the fulfilment of the objective:

- 1) a prerequisite is a functional system for the transfer of requisition forms,
- 2) institutional roofing of following activities:
 - mapping of different scenarios using requisition forms and follow-up data support (advice results, etc.)
 - gradual definition of a data structure of each type of eRequest (the most common/most problematic). With varying degrees of structuralisation of the data (in the long run a complete structuralisation of all types of request forms).

C. Outputs of the measure implementation, indicators of the successful measure implementation

The aim of eRequest is first to convert an existing paper form to an electronic form (automatically filled with information about a patient + free texts + digital image) and to implement electronic circulation of a document. Subsequently, a switch to a fully data-structured form (free text replaced with clinical terminology, a sketch describing the clinical terminology including the notes that a voucher is valid for 7 days or containing specific information on the validity of a requisition form). List of goals and outputs at the same time is as follows:

- functional system for the transfer of requisition forms created in line with NSEH,
- fulfilment of the system by specific types of requisition forms,
- a connection of the system to the solution of EHR
- a connection of the system to health insurance companies,
- a connection of the system to the information systems of orderers and contractors.
- Indicators are as follows:
 - functional system for the transfer requisition forms created in line with NSEH,
 - a share of health providers incorporated into national infrastructure for the exchange of medical records.

D. Description of the steps leading to the fulfilment of the measure

In compliance with Measure 2.1.1, the next steps are dependent on the implementation of the legislative, organizational and technical measures which will be the outputs of the Strategic Objective 4 for building the necessary infrastructure. The individual steps are as follows:

- a creation of the concept of eRequest,
- implementation of the system for the transmission of requisition forms in accordance with NSEH,
- connection to the HP, EHR and HIC,
- pilot testing, launch to routine operation and evaluation.

E. Major barriers and risks

Implementation of this measure is dependent on the implementation of Measure 2.1.1., which means it requires legislative adjustments.

The risk is insufficient cooperation with the existing operators of systems of electronic requisition forms. An appropriate choice of the system administrator will have a great impact on the acceptance of the solution.

4.2.2 Specific Objective 2.2 Effectiveness of the System and Provided Care



The Effectiveness of the System and Provided Care

1. *National and international comparison of the efficiency and quality of treatment*
2. *Creating a system and tools for tracking healthcare costs*
3. *Creating a dynamic tool of evaluating the effectiveness of the healthcare system functioning (BI)*
4. *Elimination of administrative burdens and barriers*

A. Background and requirements for implementation of the specific objective

If healthcare computerisation is to be successful and its cost acceptable, it is necessary to build services that are beneficial to patients, health professionals and others involved in the process of providing healthcare. The key principle of the National Strategy for eHealth is primarily practical value for its users. That, among other things, outweighs any higher demands on the quality of medical documentation as well as costs associated with the implementation of electronic healthcare. One of the important areas that are undoubtedly useful is to measure the efficiency and quality of healthcare. Data collected within the scope of digitisation of healthcare will be made available in the form of information about the effectiveness and quality of the healthcare system as a whole and about provided care across multiple providers and types of care, including the possibility of comparing providers in the Czech Republic and selected data from abroad. The last of the proposed measures is a key principle of building electronic healthcare and it is a purpose to which the measure is to be subordinated.

B. The impacts of the implementation of individual measures on the specific objective

The specific objective includes the following measures:

- national and international comparison of the efficiency and quality of treatment,
- creation of a system and tools for tracking healthcare costs,
- creation of a dynamic tool of evaluating the effectiveness of the healthcare system functioning (BI),
- elimination of administrative burdens and barriers.

The specific objective will be achieved if most of the proposed measures will be implemented. In particular, the ability of regulators to systematically evaluate the quality and efficiency of healthcare and to influence it purposefully will be achieved. The last of the proposed measures helps to increase the efficiency of the system by means of computerisation constructed in full compliance with the tools of the computerisation of the state, elimination or rather minimisation of additional administrative burden is a prerequisite for building all systems. This is related primarily to a need to make such legislative changes that will allow fully digital administration of medical documentation and sharing it whenever a patient's interest or wish requires it.

Without the ability to measure the effectiveness and quality of healthcare, it is not possible to properly allocate resources to this system and therefore it is not possible to manage this system. The government would in this case completely resign from its role and the healthcare system would continue its development in a cost-deformed environment under the influence of lobbyists of individual interest groups. Equitable development of healthcare services shall be only an illusion in that case.

C. Indicators of achieving the specific objective

Indicators of achieving the specific objective will be:

- the existence of a legislative environment that enables an efficient administration of purely digital medical documentation, including a solution to transform existing paper and electronic medical documentation,
- a gradually developed set of techniques and benchmarks for measuring the benefits of healthcare computerisation and its impact on the efficiency and quality of healthcare.

D. Main barriers and risks of fulfilment (the impact of zero-option of the specific objective)

The main risks are in the area of costs to implement measurability of the effectiveness and quality of healthcare, and the unwillingness of interest groups to accept a more transparent system of evaluation and remuneration of health services. It is one of the main risks of the entire strategy of healthcare computerisation. They can be eliminated particularly by educational programs combined with purpose-built campaigns.

Measure 2.2.1 National and International Comparison of the Efficiency and Quality of Treatment

A. Background and requirements for the measure implementation

The question of an evaluation of the quality of healthcare stands at the forefront of the interest of professionals and amateurs mainly for two reasons; one is the need to monitor the benefits of medical technologies and thus the legitimacy of their use, the second is the gradual change in the status of the patient (client) in the healthcare system that gradually changes from an "object" of care to a "subject" of care and the issue of quality of care becomes his personal interest. According to the WHO, the definition of quality in healthcare includes six basic dimensions:

- efficacy – healthcare must be effective and its effectiveness must be supported by facts (evidence based)
- effectiveness – healthcare must be provided in a manner ensuring maximum utilisation of resources and preventing waste,
- availability – adequately accessible in terms of time and geographical location and equipped in terms of the extent of necessary means and human resources,
- acceptability / patient orientation – healthcare must take into account the preferences and aspirations of individual service users and cultural practices of their communities,
- justice – healthcare may not differentiate between personal characteristics of the recipient, such as gender, race, ethnicity, or socioeconomic status,
- safety – risk of damage to the users of services must be minimal.

The quality of healthcare has a variety of other aspects such as a methodology of measuring, the perceived quality versus an objectively measurable quality, etc. Although many institutions are trying to measure the quality, there, in the Czech Republic, has not been built a universally accepted system nor a methodology for measuring the quality or, more precisely, its individual dimensions.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

National and international comparability of efficiency and quality of healthcare will be achieved by creating a database of indicators and a database of reference data for individual types of healthcare providers, or rather healthcare areas. An essential part of the solution will be a methodology of creating indicators that are ensuring the long-term development of indicators, and a mechanism for inclusion of new groups of diseases according to the state of public health both in the Czech Republic and abroad. The base of indicators will be based on international methodologies and recommendations and will be developed within individual professional societies and working groups of CzMA and in cooperation with academic departments. When creating a system of indicators to compare the efficiency and quality, experience previously acquired in the Czech Republic (MoH, IHIS and health insurance companies) will be used. The

method of comparison will be harmonized in a way so that it will be possible to compare parameters with foreign healthcare systems and with individual providers, especially those from the EU countries. The comparison will then be easily accessible to care providers at all levels in order to compare the efficiency of their own department with anonymised data from other providers in the Czech Republic and abroad. The anonymisation will allow a protection of sensitive information but will also enable relevant views on the effectiveness of treatment according to geographic, population, diagnostic and other distribution to be able to compare comparable data and parameters with subsequent effects for improving efficiency and quality of the provided care. Summary results of comparisons of selected indicators suitable for public presentation will be available to the general public. The comparison system, or rather its data, will also be possible to integrate into existing health information systems in hospitals and primary care clinics, so that users may work in an already established and familiar information systems and the information made available would become as close to the daily work of providers as possible.

C. Outputs of the measure implementation, indicators of the successful measure implementation

An indicator of a successful measure implementation will be the existence of a set of well-defined quality indicators that are accepted by professional public. The existence of a system of data collection and evaluation of quality in selected areas of healthcare – ideally respecting all six dimensions of quality according to WHO. The availability of results comparisons of healthcare in the Czech Republic with results of quality in other countries measuring quality.

D. Description of the steps leading to the fulfilment of the measure

The measures will be fulfilled by following these steps:

- establishing an expert panel of healthcare quality,
- determining the fundamental areas of healthcare quality measurement in the Czech Republic,
- specifying a set of indicators and necessary data sources for their measurement,
- implementing a voluntary participation of healthcare providers to collect data and assess the quality of healthcare, on a voluntary basis with clear motivational rules.

E. Major barriers and risks

The main risks include a difficult setting of metrics of quality achieving for various types of providers so they would objectively and fairly reflect the quality of services. Furthermore, the need to introduce a collection of selected clinical data or at least reporting results of quality measured locally at the level of individual health facilities. However, this barrier can be overcome, for example in cooperation with health insurance companies and positive incentives to healthcare providers to improve the quality of healthcare. The measurement of quality mustn't primarily serve the purpose of sanctions for poor quality, but to identify the quality and its systematic favouritism.

Measure 2.2.2. Creating Systems and Tools for Tracking Healthcare Costs

A. Background and requirements for the measure implementation

Tracking healthcare costs is the primary task of individual providers and managers of healthcare facilities that are responsible for net profit. However, it is also essential for the objective determination of an adequate compensation and equitable distribution of resources from the public health insurance among providers. It is in the interest of the government and health insurance companies to develop quality healthcare and ensure high availability of care for all residents. This task must be performed as efficiently as possible. The question of efficiency is closely related to costs, performance and quality of healthcare. To be determined objectively, there must be available data on all key types of medical care, or rather providers, and for the widest possible range of services.

The Czech Republic has available only a very limited set of data on the costs of healthcare facilities, especially inpatient healthcare facilities providing acute medical care, other costs of various types of services were calculated under the terms of the so called point valuation of medical procedures in the so called calculation sheets. For a long period, the list of medical procedures has been criticised in terms of its

structure and in terms of the validity of point valuation of individual procedures. When creating calculation sheets, a uniform methodology had not been complied with; it is possible to observe differences in the valuation and in the granularity of procedures between different specialisations, as well as in valuation of technology costs. It can be stated that despite several attempts at updating, point valuation procedures are not an objective basis for evaluating production, and certainly not for the evaluation of the real costs of healthcare facilities.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

To monitor the effectiveness of treatment, but also to set motivating and fair payment for healthcare, it is necessary to know the costs of healthcare providers and define their products. Therefore a sufficient amount of comparable data of costs and procedures from all, or at least a sufficient amount of selected providers from a network of so called reference providers, is expected to be available.

In the department of acute inpatient care with regard to the refinement of the DRG system, a network of reference hospitals, whose cost and performance data of costs and procedures are collected in IHIS, was gradually developed and is being extended. But the data are not yet available in sufficient quality and are not accessible to other providers, research institutions, or analytic teams of founders, and thus may not be used for comparing or processing economic analyses.

The aim of this measure is to create methodologies for reporting cost data, support the creation of an adequate network of reference healthcare facilities and make the results of the cost survey in defined types of healthcare facilities, or rather healthcare department, available to professional public. Within these methodologies, a process of entering information for reference data providers will be developed and acceptable conditions for cooperation will be created for them.

A data storage with defined services will be created and the process of collecting data to that storage will be ensured by clearly defined processes from all authorized sources. The storage will contain data from reference hospitals, but also from other facilities that will wish to voluntarily participate in the comparison. Data storage of healthcare costs will provide services of extraction of information for lay and professional public, science and research.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Target situation for the government, regions and other relevant entities: the ability of effective planning and efficient control over spending resources.

Requirements for achieving the objective: knowledge of the development of costs on the input side in each segment of healthcare (PPI – Producers Price Index) (hospitals, specialist clinics, ambulance of GPs and pediatricians, sanatoriums, except for individual specialisms).

Conditions of implementation: Knowledge of real input prices of medical materials and medical technologies, personnel costs and other cost elements (including costs of acquisition and operation), forming relevant classifications.

Target situation for healthcare providers: available new tools enhancing the ability to efficiently provide healthcare services, possibility of self comparison both within the Czech Republic and internationally.

Prerequisite of implementation: creation of a methodology for monitoring the costs of each case, its implementation in hospitals, refinement, development and control of compliance with valid rules. Benchmarking of healthcare providers so that healthcare providers classified by individual parameters could be compared with healthcare providers of similar classification parameters, both within the Czech Republic and internationally.

Target situation for health insurance companies: information on the expense-to-revenue ratio of homogeneous groups of the insured by regions across the system.

Prerequisite of implementation: establishment of a methodology for tracking homogeneous groups of the insured. Determination of payment mechanisms which clearly value the care for insured individuals, not a category of provided care (falling value of a point, maximum payment, ...).

Target situation for lay and professional public, science and research: clearer and more accurate information about the expense-to-revenue ratio of the system as a whole, categorised by specialisms, individual diagnostic groups or diagnoses. Data for science and research (university departments, professional associations) for the creation and refinement of classifications.

Prerequisite of implementation (lay and professional public): a gradually increasing ability of individual providers to show public more clearly and more comprehensibly how much the individual care for a patient cost (excluding long-term burdens of individual healthcare providers).

Prerequisite of implementation (science and research): an access to aggregate data from individual providers.

D. Description of the steps leading to the fulfilment of the measure

Basic steps leading to the fulfilment of this measure will include:

- a solution to the motivation of healthcare providers to participate in the cost survey,
- creation of a methodology for monitoring the costs of each case, its implementation in hospitals, refinement, development, and control of compliance with valid rules,
- creation of similar methodologies for cost tracking of other types of providers,
- development of a methodology for monitoring homogeneous groups of the insured,
- creation of a network of reference data providers. Creation of a system of collecting cost data and obtaining reference data on the basis of making contracts,
- creation of a system allowing benchmarking of providers,
- creation of a system providing information about the expense-to-revenue ratio of the system as a whole, categorised by specialisms, individual diagnostic groups or diagnoses. Data for science and research (university departments, professional associations) for the creation and refinement of classifications,
- ensuring access to aggregate data from individual providers for the needs of science and research.

E. Major barriers and risks

The main risk is the possible reluctance of healthcare facilities to disclose cost data as well as the difficulty of setting an acceptable and broadly feasible methodology of cost allocation.

Measure 2.2.3. The Creation of a Dynamic Tool for Evaluating the Effectiveness of the Healthcare System Functioning (BI)

A. Background and requirements for the measure implementation

Healthcare system generates potentially very interesting data useful both to support evidence-based medicine and clinical research, management decisions or protection of public health. The problem is that data are stored in several separate storages – storages of health insurance companies, NHIS registries, clinical information systems of providers and it is very difficult to make them available for the purposes mentioned above. Modern systems for processing large data sets (big data) allow processing large, heterogeneous data sets without having to build a centralized data warehouse. The advantage of these systems is the ability to work with unstructured data and with data available in various formats (text, audio, video) and repositories (databases, files, web pages, social networks).

The European Commission is preparing a draft of recommendations for policy on processing large data sets in healthcare; relevant recommendations have yet to be released in 2016. The importance of the question of the so-called big data emphasises the fact that the draft of recommendations (as amended on June 1, 2016) covers a wide spectrum of issues – from legislation through requirements for data sharing, protection of personal data, standardization, communication strategy towards clinical centres to finance.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The aim of this measure is to build a tool, or rather a set of tools, for evaluating the effectiveness and quality of healthcare system functioning, enabling the creation of managerial and analytical outputs of

existing and emerging bases of medical data, including the ability to process unstructured information (especially clinical information written in free-form text in medical records, who and under what conditions will have access to this information must be determined in the process). Because of the connection with the setting of accesses and use of sensitive personal data, the level of accessibility of these kinds of information to individual facilities and those accountable for the outputs will have to be determined.

Medical BI system will find use in many areas of priority interest of the Czech healthcare system, e.g. for monitoring and evaluating the effectiveness of treatment of chronic patients (diabetes, COPD, cardiovascular diseases, etc.), for searching new knowledge from available clinical and administrative data (data mining), with the possibility of working with unstructured information, but especially for data enrichment and their evaluation in terms of geographic, demographic, industrial, personal, behavioural, hygienic, and other profiles with the aim of creating effective preventive measures, incentive programs as well as monitoring the effectiveness of medical procedures, patterns of care of individual healthcare providers, etc.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Selected data and outputs of the BI tool will be available to professional and lay public in sufficiently aggregated and anonymised form as part of a government open data program and a set of analytical tools will be available to the academic and research institutes under a license for access and use. The success of the implementation of the measures can be gauged by the number of new available data files, the number of new online presentation and analytical tools built for the data sources and the number of user accesses to them (traffic).

D. Description of the steps leading to the fulfilment of the measure

The primary step will be to create a motivation of individual data storage administrators to release the data they manage for further use, which involves the removal of any legislative restrictions and preparation of a sample methodology and tools for preprocessing and adequate anonymisation of data to ensure privacy.

Consequently, it is necessary to design and implement the chosen BI tools by means of grant calls, primarily for academic and research institutions but also for other institutions. In collaboration with the target users, it will be necessary to create analytical resources and outputs according to their interest.

For the purposes of preparation of analytical outputs, an analytical group, which will be capable of defining analytical, statistical and exploitative models and effectively use the built BI tools while meeting the tasks of target system users, will be created.

A dynamic tool will be built gradually, in accordance with other steps of computerisation of healthcare, especially in connection with the completion of other tools – e.g. the registry of covered healthcare, electronic personal health record, and after making other electronic information resources available in the healthcare sector.

E. Major barriers and risks

The success of this measure supposes to use the BI tool with detailed data of electronic healthcare and therefore cooperation of individual administrators of data storages, finding a suitable anonymising process, and use of a meaningless identifier (identifiers) of subjects and patients, and an acceptance of security rules allowing working with large heterogeneous files of medical records in accordance with legislation and guaranteeing data protection and privacy of patients. Selected data and outputs of the BI tool will be available to professional and lay public in sufficiently aggregated and anonymised form as part of a government open data program and a set of analytical tools will be available to the academic and research institutes under a license for access and use.

Legislative restrictions can be considered the most significant barriers and risks of this measure. Another risk could be the use of existing data beyond the originally defined framework. A consent of individual entities must be ensured when e.g. health insurance companies are competitors to each other.

In order to effectively use the high investments in such technologies, a large amount of data, that is individual documents of "message" type in a shared storage, should be available. With regard to the protection of personal data, it cannot be predicted to what extent this measure will be legislatively possible in advance.

Measure 2.2.4. The Elimination of Administrative Burdens and Barriers

A. Background and requirements for the measure implementation

The European Commission strategy "Digital Single Market", approved on May 6, 2015, projected e.g. into a government document "Action Plan for the development of the digital market in the Czech Republic", enshrines the principle of "digital by default" for fully electronic submission and "Once-Only" for linking data resources in the government and public administration using basic registers, when a citizen reports basic changes only once and the rest of the public administration will know about the change and may not require it repeatedly. It is expected that full electronic submission available not only to Czech citizens, but also to other EU countries, will be guaranteed by extension, linking and consolidation of data resources of public administration and its effective and safe use by individual administrations. The same is expected in the healthcare computerisation and other fields.

The mentioned government document states that: *"The Czech Republic is also aware of the importance of the development of electronic public administration (eGovernment), which is a necessary prerequisite for reducing administrative burdens and successful development of national and European digital market. The Czech government approved a Strategic Framework for the Development of Public Administration in 2014–2020 and implementation plans for its fulfilment."*

This strategy meets the categorical requirement that the healthcare computerisation will not increase, but will reduce the administrative burdens for all participants in the healthcare system, namely the citizens/patients on one hand and doctors, pharmacists, and other healthcare professionals on the other.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Inserting healthcare data into information systems should be the primary way to capture these data and their possible transfer to paper (printing) should be a secondary requirement. That's why healthcare computerisation methods that will reduce or completely suppress duplicate data entry will be supported.

All participants should benefit from the introduction of healthcare computerisation. However, it is likely that some participants will have to accede to the controlled transfer of financial costs and benefits. For example filling out additional forms or a purchase of specific software or hardware in order to transfer data to central systems in the doctor's office can save resources on the side of health insurance companies or central institutions of the healthcare sector, but may increase the costs and deprive doctors of their time. These costs and time loss should be not only minimized, but also balanced out by suitable benefits for doctors.

An example of reducing administrative burdens is dealing with medical notes electronically, which will, in case a majority of employers gets involved in the system, enable to significantly simplify the process and save considerable number of employees in public administration.

If problems are wrongly handled, the implementation of the strategy can potentially increase the administration on the side of healthcare providers significantly (e.g. in the management of access rights to services of electronic healthcare). Therefore, the topic of reducing administrative burdens and barriers must be seen as transversal principal topic and each project of electronic healthcare must be assessed from this perspective.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Implementation of this measure will contribute to the development of digital medical documentation and digitalization of administrative processes.

Indicators of successful implementation will be:

- the number and percentage increase in the number of healthcare facilities with fully digitalized medical records,
- the number of healthcare facilities using an electronic medical note.

The measure is an auxiliary measure to increase the overall efficiency of the healthcare system, both at the level of individual providers and the system as a whole.

D. Description of the steps leading to the fulfilment of the measure

- simplification and clarification of the legislative framework for the management of digital medical documentation and its sharing,
- an introduction of electronic medical note in cooperation with the MoLSA and CSSA,
- preparation of a call from operational programs for the development of digital documentation and digital support of medical processes.

Digitalization of medical documentation and digital support of processes in healthcare is closely associated with securing the basic infrastructure of electronic healthcare, or rather eGovernment, especially in the area of identification of entities and information security (cyber security).

E. Major barriers and risks

The main barriers and risks can be:

- the length and complexity of the legislative process,
- the dependence and interdependence on building an infrastructure of electronic healthcare.

4.2.3 Specific objective 2.3 Information and knowledge support of healthcare workers and users of electronic healthcare



Information and Knowledge Support of Healthcare Workers and Users of Electronic healthcare

1. *Comprehensive and clearly structured knowledge and educational tools to ensure professional growth*
2. *Information and popularization program of users of electronic healthcare*

A. Background and requirements for implementation of the specific objective

Healthcare computerisation is an opportunity not only to increase the efficiency of the healthcare system and bring it closer to citizens, but also to challenge its future users who will acquire new knowledge and skills necessary to make full use of electronic tools. Questions of security of personal data and privacy of patients, rights and responsibilities of individual participants, procedures in life situations will be dealt with. These questions will need to be answered and the answers presented in the necessary extent and form of a reasonable level of knowledge and expectations of different groups of participants, mainly healthcare workers and other workers in the healthcare sector and citizens in different age and educational groups. Electronic healthcare will also allow broad sharing of best practices, knowledge bases and evidence based information resources between healthcare workers. Their acquisition, introduction to clinical practice, and efficient use in providing healthcare is another example of the challenges of computerisation that must be adequately addressed.

B. The impacts of the implementation of the individual measures on the specific objective

The purpose of individual measures is to prepare healthcare workers and other workers in the healthcare sector on the environment of electronic healthcare, equip them with the essential skills and knowledge necessary for efficient use of the systems. On the other hand, the point is to communicate in a clear, understandable and appropriate manner the benefits and risks of the system to the general public. For this purpose it is necessary to choose the right tools and use these tools on a long-term basis.

C. Indicators of achieving the specific objective

In the short term, the indicator of achieving the specific objective is especially the existence of the communication strategy of electronic healthcare.

In the longer term, it will be important to monitor the ability of healthcare workers to work effectively with information and tools of electronic healthcare. Indicators:

- the elaboration and implementation of sustainably complex system of schooling and education to promote knowledge and skills as specific information literacy of healthcare workers and other workers in the healthcare sector and users of electronic healthcare
- the existence and application of approved communication strategy of electronic healthcare
- the allocation of resources to ensure the communication strategy

D. Main barriers and risks of fulfilment (the impact of zero-option of the specific objective)

The risk is a long-term resistance of healthcare workers and citizens to computerisation caused by the general distrust against storing and sharing medical records in information systems that are not under the control of providers. Previous negative experiences of users of electronic healthcare in the Czech Republic are of importance as well. High average age of doctors in the outpatient care and lower availability of high speed internet in the Czech Republic are also important. In case of using EBM resources, a language barrier has an impact. A clear motivation is often lacked for the acquisition of new skills.

The full effect of the measures will not be achieved unless individual surgeries/offices will be equipped with computer technologies, software, high speed internet access, mobile applications and unless the education of doctors in the operation of computer technology and medical software will be ensured.

Measure 2.3.1 Comprehensive and Clearly Structured Knowledge and Educational Tools to Ensure Professional Growth

A. Background and requirements for the measure implementation

Medical and health informatics is still largely a side issue of training future healthcare workers. This leads to the fact that graduates coming into practice often recognize the problems of medical informatics and retrieval of information sources in the course of practice. It is often the young doctors who are entrusted with the responsibility for administrative activities related to the execution of medical profession and from whom it is expected to engage in medical research. For this activity, however, they do not come properly equipped from the medical faculties and learn the good practice after "being thrown in at the deep end."

B. Description of the implemented measure and the benefits and impacts of the measure implementation

This measure pursues two main objectives.

- 1) The first objective is a broad support for the use of ICT in healthcare, namely for the development of specific computer (or rather information) literacy of participants of electronic healthcare system, and in particular the promotion of specific knowledge and skills that enable an effective use of electronic healthcare system and its services and support of knowledge of rights and duties of its users. Citizens and healthcare workers must, among other things, get an initial idea of the opportunities and benefits of tools that they will be able to use. It will be necessary to mitigate the barriers for users, originating in the transition to new technologies and systems.
- 2) The second objective is a broad support for the use of evidence-based practices in healthcare. It will be supported by the implementation of a comprehensive system of teaching and education to support knowledge and skills as specific information literacy of healthcare workers and other workers in the healthcare sector who provide healthcare services, engage in teaching and science and research in the healthcare field with a specific focus on evidence-based practices and disclosure of relevant knowledge bases, information resources and techniques.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Healthcare professionals will be able to use verified and reliable sources of information in an appropriate structure, providing opportunities for individual and institutional training in areas related to healthcare computerisation, but also evidence-based medicine, knowledge tools to support clinical decision making, and quality assessment of information resources. Competence of medical librarians will include methods of acquiring knowledge, retrieval and dissemination of information, as well as the ability to convey the appropriate search strategies and facilitate the healthcare professional or layman searching for relevant information in this field. Healthcare computerisation is also related to new challenges arising from globalization of medical information. It brings new topics such as semantic interoperability and tools for its implementation, classification systems, or clinical nomenclatures and terminology.

Teaching of electronic information tools and other tools of electronic healthcare will be a part of the teaching programs of healthcare workers and medical librarians.

The indicator for the successful implementation of the measure:

- elaboration of sustainably comprehensive system of teaching and education to promote knowledge and skills as a specific information literacy of healthcare workers and other workers in the healthcare sector, present and future, who provide preventive healthcare or services in the protection and promotion of public health, engage in teaching and science and research in the the healthcare sector with a specific focus on evidence-based practices and relevant information resources and techniques.
- development of a sustainably comprehensive system of teaching and education to support knowledge and skills as specific information literacy of users of electronic healthcare, with the inclusion of undergraduate and postgraduate levels of education,
- implementation of a comprehensive system of teaching and education to promote knowledge and skills as a specific information literacy of healthcare workers and other workers in the healthcare sector, present and future, who provide preventive healthcare or services in the protection and

- promotion of public health, engage in teaching and science and research in the the healthcare sector with a specific focus on evidence-based practices and relevant information resources and techniques,
- implementation of a comprehensive system of teaching and education to promote knowledge and skills as a specific information literacy of electronic healthcare users.

D. Description of the steps leading to the fulfilment of the measure

In the area of evaluation of information resources quality, it will be required to execute a series of sequential steps leading to a draft Methodology of Evaluation of Trusted Sources of Health Information and application of this methodology in practice. A gradual solution in a team of information professionals (National Medical Library) and representatives of the medical and paramedical professions is expected. The gradual phase solution includes:

- mapping issues through research,
- assessing the applicability of existing international methodologies in Czech online environment,
- statistical evaluation of the results of the methodology proposals (monitoring of selected indicators in the online environment), the definition of constraints and limits of its own methodology,
- a draft of its own methodology.

In the field of education it will be necessary:

- to create an information and educational materials on electronic healthcare tools for professional and lay public,
- to create online teaching materials for different target groups and push them into the teaching practice,
- to prepare new accredited training programs in the fields of information management in healthcare, searching and evaluating information in the era of widespread use of information and communication technologies in healthcare.

E. Major barriers and risks

The introduction of new educational programs reflecting electronic healthcare services that are being built must, to a certain extent, become a part of the entire strategy as well as the individual projects. The main risks can be seen in the length of the implementation of the educational programs to practice and in the length of the educational processes themselves. In other words, suitable methods of introduction of new knowledge into practice will have to be found, and these efforts must be allocated with adequate resources. From the point of view of tools of information support of healthcare workers decisions, the question of access to commercial knowledge bases will have to be addressed.

Measure 2.3.2. Information and Popularization Program of Electronic Healthcare Users

A. Background and requirements for the measure implementation

Electronic healthcare is a new element in the healthcare system and the experience of neighbouring countries shows that a successful implementation of the system must always be preceded by a wide information and educational campaign about its benefits, benefits for the society and various specific population groups (chronically ill, children, poor or otherwise marginalized groups of citizens, foreigners, etc.), but also about the risks that the use of electronic healthcare services is potentially linked to.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The introduction of electronic healthcare services will be accompanied by a necessary campaign; the ability to use the services of the system will become a part of basic digital literacy of the population. This measure will promote the development of information, popularizing, and educational tools and materials (information commercials and videos, information brochures and electronic manuals) for the general public – users of the electronic healthcare, including language variants for foreigners.

C. Outputs of the measure implementation, indicators of the successful measure implementation

To implement this measure, it will be crucial to analyse target groups (citizens, foreigners, patients, chronic patients, patients suffering from different types of diseases, family members of patients, healthcare workers and other workers in the healthcare sector, taxpayers, regulators, politicians, etc.). Different social and educational groups must be distinguished, their information needs identified, and effective methods of an information and communication campaign, that ensures full public awareness of the benefits and risks of healthcare computerisation and individual electronic services and of the risk management and long term government plan in this field, must be found.

The information campaign must be comprehensive, inventive, long term, and must include a broad spectrum of tools from information brochures, media, and internet resources to social networks. Marketing experts as well as representatives of key target groups, i.e. patients, citizens and healthcare workers, must be involved in its preparation. Without these steps, the acceptability of the systems and the entire electronic healthcare strategy is being compromised by the public (professional and lay). The outcome of this measure will be:

- 1) creation of a communication strategy for electronic healthcare,
 - an analysis of key groups and their information needs,
 - design of information tools,
- 2) long-term update of the strategy, completion of new sections that cover new components and services of electronic healthcare, and a long term implementation of the communication strategy.

D. Description of the steps leading to the fulfilment of the measure

First and foremost, a draft of a communication program must be prepared. Individual steps will be specified in the phase of an implementation plan.

E. Major barriers and risks

The main risk is the underestimation of this communication campaign.

4.3 Strategic Objective 3 Increasing the quality and accessibility of healthcare services

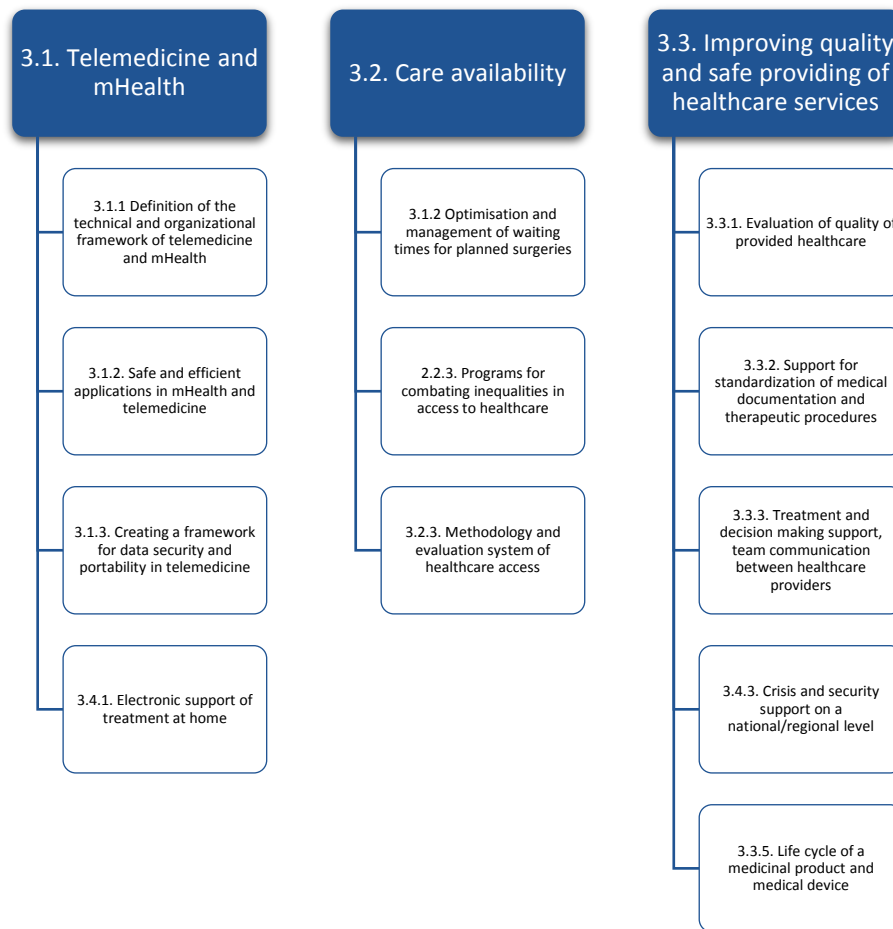


Chart 6 Structure of Strategic Objective 3

A. Background and requirements to meet the strategic objective

Contemporary medicine is a complex, multidisciplinary and team discipline requiring narrow specialization of individual medical teams as well as their close cooperation. Ensuring information sharing and support of team cooperation and coordination is still only a partially fulfilled challenge for the modern digital healthcare. The most noticeable benefits of computerisation can be expected in this area.

An extension of the current range of healthcare services for telemedicine solutions that fundamentally develops the communication between a healthcare worker and a patient is a way to improve the quality of care, specify information about the development of a patient, and increase the efficiency of services, e.g. reduce the number of necessary outpatient visits

With a set of new electronic services, which will provide citizens with clear orientation in the offer of healthcare services and will enable a selection of services according to individual preferences (time, place, quality), an orientation of patients in the healthcare system and an increase in the availability of healthcare services will be improved.

The implementation of national and international comparison of results, quality and safety of healthcare provided in various specialisms contribute to an increasing erudition of healthcare workers to better manage the healthcare system.

B. The impacts of the fulfilment of individual specific objectives within the context of the strategic objective

The strategic objective consists of three specific objectives, namely:

- 1) **Telemedicine and mHealth**, which is implemented through four measures:
 - **definition of the technical and organisational framework for telemedicine and mHealth.** Its output will be reimbursement mechanisms, other organizational instructions, and descriptions of the recommended technical solutions,
 - **safe and effective applications in telemedicine and mHealth.** Its output will be practices of classification and evaluation of telemedicine and mHealth solutions,
 - **creating a framework for data security and portability in telemedicine.** Its output will be guidelines for data and communication standards for telemedicine solutions,
 - **electronic support of treatment in the patient's home environment.** Its output will be with workplaces of qualified supervision with technical equipment and professional competencies.
- 2) **Care availability**, which is implemented through three measures:
 - **optimisation and management of waiting times for planned surgeries.** Its output will be a system for identifying the demand for services and management of waiting times.
 - **programs for combating inequalities in access to healthcare (e.g. or digitally excluded and weaker or vulnerable groups).** Its output will be an established methodology of services assessment from the viewpoint of equal access to healthcare.
 - **methodology and evaluation system of healthcare access.** Its output will be an established methodology for assessing the availability of services in relation to a current demand.
- 3) **Improving quality and safe providing of services**, which is implemented through five measures:
 - **evaluating the quality of provided healthcare by analytical and methodological tools.** Its output will be a systematic process of continuous refinement and improvement of quality monitoring procedures with an emphasis on the implementation of the internationally-proven methodologies and nomenclatures of quality of care,
 - **standardisation support of medical documentation and therapeutic procedures.** Its output will be a methodological and tool framework to standardize and formalize therapeutic procedures and introduce the internationally recognized clinical terminology (SNOMED-CT) into selected areas of medicine,
 - **support of treatment and decision making, team communication between the providers of healthcare and social services.** Its output will be a plan of gradual information connection to providers of social care and a platform for sharing knowledge and skills,
 - **crisis and security support on a national/regional level.** Its output will be linking systems in the pre-hospital urgent phase, the hospital phase (emergency departments of hospitals and specialized centres), and systems for emergency management within the crisis management of public health,
 - **life cycle of a medicinal product and medical device.** Its output will be a higher efficiency and safety of the process of administration of medicinal products and medical devices, and also a reduction of the transaction costs associated with logistics of the products.

C. Outputs of the fulfilment of specific objectives

Through meaningfully implemented information and communication technologies the availability of services and the care quality will be improved, more patients will be treated in the same time frame, some routine tasks requiring personal participation of medical personnel will be limited, and some of the risks arising from a lack of information and participation of a human during transmission and processing without the support of information and communication technologies will be reduced. The level of safety for healthcare providers and patients will increase and ultimately bring savings in the public health insurance system. Information on the availability and quality of care will be made available as much as possible and will be simplified to make them comprehensible to the widest possible audience of providers and patients.

D. Indicators of achieving the strategic objective

The basic indicators of achieving this strategic objective "Improving the quality and accessibility of health services" are:

- measurable increase in the use of telemedicine services in the common practice of Czech healthcare,
- creating a transparent tool for monitoring and managing waiting times for selected types of health services for citizens and provide quantified view of the demand for health services for the payer,
- systematically removing inequalities in access to care for vulnerable groups,
- the introduction of instruments for measuring and assessing the availability of health services,
- a tool is introduced for monitoring the effectiveness of health services increase in the use of telemedicine, enhancing the role of the patient in the treatment process and also for his/her evaluation of the services provided,
- a tool is introduced for evaluating the quality of health services, standardization of therapeutic procedures and the structure and content of medical documentation.

It will be necessary to select and adjust the indicators by which to measure the effect of improving the accessibility and quality of healthcare.

E. Main barriers and risks of implementation (impact of the zero option strategic objective)

The risk to achieve this strategic objective is the complex and extensive methodological base for the implementation of partial measures, the need for legislative changes, organisational measures, and the willingness and motivation of providers to measure the quality of their services, the publication of the results and the difficulty of implementation mechanisms for quality improvement. In the Czech Republic it is possible to legally provide only one quality of care, being the quality care *lege artis*. We are thus ensuring the quality and safety of healthcare services, which is a substantial difference in meaning, also involving other parts of the strategy.

The main barrier for the deployment of telemedicine services applications into practice at present is to ensure the sustainability of their economic cooperation, including medical staff. Effective integration of telemedicine processes in healthcare is a complex set of tasks that cannot be reduced to mere acquisitions of technical solution and its commissioning. In contrast, the use of modern information and communication technologies in healthcare is one way to cope with increased interest in services, especially on the part of the chronically ill and at the same time improving the quality, speed and precision in processes of care

Specific objective	Main measures	Output name	Indicator	Responsible party	Cooperating entities	to other objectives/ measures
3.1. Telemedicine and mHealth	3.1.1 Definition of the technical and organisational framework for the telemedicine and mHealth	It will be specified in the implementation plan.	It will be specified in the implementation plan.	MoH		Measure 1.1.3, SO 4.2, SO 4.3
	3.1.2. Safe and effective applications in the telemedicine and mHealth	The classification system for evaluating telemedicine solutions.	Guidance document "Classification system for evaluating telemedicine solutions."	MoH		SO 1.3
	3.1.3. Creating a framework for data security and portability in the telemedicine	It will be specified in the implementation plan.	Creating the guidelines containing data and communication standards.	MoH		SO 4.2, Measure 4.3.5
3.2. Care availability	3.4.1. Electronic support of the treatment in the patient's home environment	Organisational, legal and institutional framework for the functioning of workplaces using the telemedicine. Defining the technical and qualification requirements of the workplace.	It will be specified in the implementation plan.	MoH		SO 1, Measure 4.2.3
	3.2.1. Optimisation and management of waiting times for planned surgeries	A system for identifying the demand for selected health services; the management system of waiting times.	A system for identifying the demand for selected health services; the management system of waiting times.	MoH	Health insurance companies	SO 1.1:
	3.2.2. Programs combating inequalities in access to healthcare (e.g. for the digitally excluded and weaker or vulnerable groups)	Introducing a system for evaluating, measuring and improving equal access to the healthcare.	Introducing a system for evaluating, measuring and improving equal access to the healthcare.	MoH		SO 1.1, 1.3
	3.2.3. Methodology and evaluation system of the healthcare access	Introducing a system for evaluating, measuring, and improving access to the healthcare.	It will be specified in the implementation plan.	MoH	Regions, CZMA, health insurance companies	SO 1.1, 1.3, SO 2.2.

Specific objective	Main measures	Output name	Indicator	Responsible party	Cooperating entities	Reference to other objectives/measures
3.3. Improving quality and safe provision of health services	3.3.1. Evaluating the quality of provided healthcare with analytical and methodological tools	Adoption and implementation of a system validated, long-term measured and internationally comparable indicators of quality.	It will be specified in the implementation plan.	MoH	IHS, health insurance companies	SO 2.2
	3.3.2. Support for standardisation of medical documentation and therapeutic procedures	Methodological and instrumental framework for formalising of recommended practices. The introduction of internationally recognized clinical terminology (SNOMED-CT) in selected areas of medicine	It will be specified in the implementation plan.	MoH	IHS, CzMA	SO 4.2 Measure 1.3.1 Measure 2.1.1, 2.3.1
	3.3.3. Treatment support and decision-making, team communication between the providers of health and social services	Creating a plan for the gradual linking information with providers of social care. Providing a platform and infrastructure support tools for sharing knowledge and skills	EBM processes measurable increase in medical practice	MoH	CzMA, MoLSA, CSSA	SO 2.1 SO 2.2, Measure 2.3.1
	3.4.3. Crisis and security support on the national/regional level	It will be specified in the implementation plan.	It will be specified in the implementation plan.	MoH	MoI, regions	SO 4
	3.3.5. Life cycle of a medicinal product and medical device	Increase efficiency and security of the process of administration of medicinal products and medical devices. Reducing transaction costs associated with logistics of preparations.	It will be specified in the implementation plan.	MoH	SIDC, CzMA	Measure 2.1.2, SO 4.1

Table 5 Summary of information for Strategic Objective 3

4.3.1 Specific objective 3.1 Telemedicine and mHealth



Telemedicine and mHealth

1. *Definition of the technical and organizational framework for telemedicine and mHealth*
2. *Safe and effective applications in telemedicine and mHealth*
3. *Creating a framework for data security and portability in telemedicine*
4. *Electronic support of the treatment in the patient's home environment*

A. Background and requirements for the implementation of the specific objective

The dynamic development of devices for scanning physiological functions created a category of devices that have the relevant accuracy and reliability, delivering ease of use and patient comfort of use in a small size and at very reasonable prices. Both in terms of reliability, comfort, size and financial requirements of developing and data communications. Together they created the basis for the **so-called telemedicine solutions**, which dramatically extend the possibilities of communication between healthcare professionals and patients.

Increase in incidence of chronic diseases in the general population, along with an increase in higher ages exert pressure on the availability of health services. While maintaining the current concept and scope of the network of healthcare providers, along with the usual indicating rules and procedures for the organisation of the relationship patient – health worker, we can expect further growth in both the number of outpatient visits and hospitalizations in the acute and follow-up inpatient care segment.

Along with that, the interest of some social groups of the population grows in the active attitude to their own lifestyle. They are intently devoted to assessment of their own health, looking for specific information on the development of health indicators. For this purpose, a variety of wellness programs are created, often with sophisticated technological support. This attractive software solutions develop interest and self-care in the consumer product category of mobileHealth (mHealth).

B. The impacts of the implementation of individual measures on the specific objective

Ensuring the conditions for the application of telemedicine solutions

The government's task is to establish a legislative framework for the safe use of telemedicine technology. It must also create conditions for the safe use of telemedicine solutions and set rules for verification and approval of the technical and safety parameters.

Benefits from the application of telemedicine solutions

Extension of the current range of health services for telemedicine solutions will be a way to reduce the number of necessary outpatient visits and hospitalizations of chronically ill patients. Positive impact on the decrease in mortality, morbidity and cost of healthcare is known from extensive studies carried out in the European Union member countries. At the same time, thanks to the use of telemedicine systems, patient adherence to treatment is increased (i.e. compliance with therapy, therapeutic regimen measures, etc.) as well as interest in their own health.

Systematic and proven monitoring indicators of the health status of patients through a secure and accurate remote transmission of clinical data will increase the efficiency of health service provision. It will be the way to developing a system that in the current situation has neither the personnel nor the financial resources for the extensive growth and sustainability.

Growth of expectations of patients and the impact on network capacity of health services, resulting from demographic contingent burden of an ageing population, **manifested by increasing the number of**

chronically ill patients, can be eliminated by the introduction of advanced practice of care organization, allowing facilitating access to health services through the use of modern technology telemedicine solutions. This way you can ensure sustainable development of the whole system.

C. Outputs of implementation, indicators of achievement

Indicators of this specific objective will be specified when creating implementation plans. In principle they will be focused on outcomes resulting from the measures implemented, particularly the creation of

For effective application of telemedicine solutions into practice it is necessary to define areas for application of telemedicine performance, specify indication groups of patients and diseases, technical conditions of delivery, verify their effectiveness and to determine the amount and method of payment of costs.

mechanisms for refunding application procedures of telemedicine; continue to create applications to verify the principles of HTA in telemedicine solutions, and finally evaluation of the growth of telemedicine solutions being implemented in practice and the number of their users.

D. Main barriers and risks of fulfilment

The main barriers to telemedicine can be seen in ensuring the economic sustainability of services and telemedicine applications under current refunding conditions and resistance to related organisational changes in the care, sometimes referring to the uncertainty of the legitimacy of the use of funds in terms of their legality.

The risk is that the administrative authorities and taxpayers will not create conditions that will motivate healthcare providers to engage patients and telemedicine solutions in their active use. As a result, there will be pressure on the availability and equal access to health services providers, network expansion, resulting in rising costs. Other consequences are reflected in the lack of personnel and unsatisfactory performance of the education system, limiting the adaptability of the workforce will be another risk.

Failure to deal with the question of transparent conditions for telemedicine can create a "grey area" of healthcare, in which, due to findings from developed countries and pressure of modern technologies penetrating into everyday professional and personal lives, some medical facilities with telemedicine will experiment in changing economic conditions (e.g. typically only for the period of the awarded grant) and other departments (as well as entire geographic areas) due to the aforementioned uncertainty shall rather not get experience with the benefits of telemedicine in the long term.

Measure 3.1.1 Definition of the technical and organizational framework for telemedicine and mHealth

A. Background and requirements for the measure implementation

The application of telemedicine approaches in the Czech Republic is still mainly in the context of studies and pilot projects. Their focus is usually quite narrow and specific, reflecting the intentions of the contracting authority without targeting towards a broad application. Support from payers (health insurance companies) is very limited and unsystematic. However, it is safety and quality solution at a solid level, researchers are not directed purposefully towards implementing or enforcing standards. Telemedicine solutions do not receive enough training and educational support that would lead to their active acceptance by providers, payers and patients.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The development of telemedicine procedures will be supported by the following solutions:

- solutions enabling diagnosis, treatment and monitoring the development of the patients (or implanted devices) remotely (also includes telemonitoring for diagnostic and therapeutic purposes), including the assistance of qualified supervision,
- online education, coaching, physiotherapy and complementary solutions for monitoring the development of physiological parameters of patients remotely (also includes video +

- teleconsultation with a doctor and telemonitoring to obtain more and better data about the patient and his behaviour remotely),
- solutions to support decision making, documentation of interventions and operations of healthcare workers (i.e. without the direct participation of patients in the solution; also includes transmission and evaluation of video images and other data acquired by another expert)
 - mHealth solutions to promote prevention, awareness and health maintenance condition with loose relationship to a particular treatment process (voluntary, or an application only recommended to a patient, typically in smartphone software, and/or measurement of selected physiological parameters).

Examples of possible payment mechanisms in telemedicine:

- 1) In principle, it covers all (device, interventions, , transfer fees, service, assistance of a qualified supervision).
- 2) Monitoring quality parameters of care. Payment in the context of the volume of paid interventions to the specific healthcare provider.
- 3) Payment only for interventions. Investments to be left on a healthcare provider or grants. In the case of the introduction of supply of services (currently only exceptions in the Czech Republic) – the introduction of a specific code for services (first, analyses and thorough preparation need to be processed).

Securing grants, private investments of healthcare providers can be a financing alternative.

Standardisation is an important aspect of the telemedicine development. Possible approaches to standardisation:

- use proprietary protocols for each device. This approach has risks, because each manufacturer applies different procedures, in addition, especially foreign manufacturers are concerned. It is necessary to unify these practices,
- sensitive conditioning of paid interventions only at standardised solutions, e.g. according to IEEE. It is appropriate to propose standards e.g. for video conferencing (incl. HW, resolution, connectivity). It is also necessary to consider the risk that the standard becomes the main barrier to development, from the perspective of the life of a telemedicine solution,
- the use of recommended standards needs to be accentuated.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The indicators will focus on expanding telemedicine applications in practice, i.e. the number of pilot projects by the individual categories of solutions, further, meeting the refunding mechanisms (e.g. the number of calculation sheets of interventions), and finally achieving standardisation in the field of telemedicine.

D. Description of the steps leading to the fulfilment of the measure

Individual steps leading to the fulfilment of the measure will be described in the implementation plan.

E. Major barriers and risks

An active and effective participation of telemedicine solution would be jeopardized by two facts on the part of providers. The first is the lack of economic incentive (especially of reimbursement from health insurance), and the second is the need for organizational changes to ensure efficient routine operation of telemedicine solutions and sometimes demands for new activities resulting from the need to support patients and communicating remotely and relevant administration.

Measure 3.1.2 Safe and efficient applications in telemedicine and mHealth

A. Background and requirements for the measure implementation

In the current state, telemedicine solutions and studies of their use in clinical practice are usually formed on the basis on the requirements of the provider to solve specific problems or a group of problems linked to a specific group of patients. The studies are usually clinically focused, and in particular their impact on healthcare of the patient is considered.

Besides the benefits for treatment, for each solution of the provision of health services also economic, social and ethical effects needs to be considered. Only fully examined and classified solutions should be given space to enter into a controlled environment of the provision of healthcare services.

If no procedures to evaluate telemedicine solution occur, payers would most likely be very reserved to open the way for their inclusion in regulatory mechanisms. Furthermore, there would be an risk of expanding qualitatively unacceptable solutions with possible negative impacts on security, privacy, or threatening social acceptance of telemedicine as a whole.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

It is necessary to create a classification system to evaluate telemedicine solutions.

A draft structure of aspects of the classification system:

- 1) Area of indications and the description of the solution.
- 2) Technology security evaluation.
- 3) Evaluation of clinical efficacy.
- 4) Evaluation of benefits for the patient.
- 5) Evaluation of economic efficiency.
- 6) Evaluation of organisational aspects of solution applications in the system.
- 7) Evaluation of ethical and socio-cultural impacts of a telemedicine solutions applications.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome is the creation of a classification system for evaluating telemedicine solutions. This classification system will be used for the creation of evaluation reports. Only such a solution will be permitted in practice which in all aspects of evaluation reached the level classifying quality admissibility.

For evaluation of mHealth applications that do not fall within the regulation of medical devices, principles based on the document prepared by the European Commission, "EU Guidelines on the Assessment of the Reliability of Mobile Health Applications" will be used.

For the evaluation of telemedicine solutions in the framework of European research projects, a sophisticated assessment model called MAST (Model for Assessment of Telemedicine) was designed, which was put in practice in and also outside EU countries. This model is based on HTA and is multidisciplinary (includes 7 domains in which results of specific solutions are evaluated).

Indicator of achievement is the creation of the guidance document "Classification System for Evaluating Telemedicine Solutions."

D. Description of the steps leading to the fulfilment of the measure

Individual steps leading to the fulfilment of the measure will be described in the implementation plan.

E. Major barriers and risks

The risk is lengthy creation of the organisational institutional framework needed for the implementation of the classification system.

Measure 3.1.3 Creating a framework for data security and portability in telemedicine

A. Background and requirements for the measure implementation

Telemedicine solution must necessarily integrate technological elements functionally linked to patient data and tied to his medical records, optimally to the electronic medical record (EMR, EHR). Such a composed line combines data transmission, transformation and preservation. The use of the standard data transmissions or the use of standards of sharing documents in the Czech Republic is not yet regulated or settled among users.

For successful integration of telemedicine solutions into existing health information systems, it will be necessary to design and implement data and communications standards to ensure the safe transfer, simple takeover, exact and efficient data archiving of telemedicine systems. The aim of this measure is to choose the appropriate national and international standards and recommendations, on the basis of a national framework specifying data security and interoperability of telemedicine as part of a national framework of healthcare standards. In other words, to ensure that, for example, there is no danger to the patient, his/her health and his/her privacy.

B. A description of the implemented measure and the benefits and impacts of the implementation of the measure

Overview of requirements for the integration of telemedicine solutions by categories:

- 1) If the telemedicine solution has an interface, it should be integrated with the EMR, at least with the clinical information system of the provider. Data archiving should be performed consistently.
- 2) Collected data should be stored in the EMR. The choice of solutions should always be conditioned by the existence of the data collection concept. In the case of communications services (tele, video), store

Involving patients, family members and providers of home healthcare providers and telemedicine services must be accompanied by the emergence of new processes and information solutions to support an integrated socio-medical care at home.

the only records of the sessions can be stored, but under certain conditions and to a proper storage. In case of partial payments, the selected data should be stored into the EMR.

- 3) Records of operation should be archived (stored in the EMR, at least in the provider's clinical information system).

Options, conditions and elections for data transmission:

- internet access for patients from anywhere,
- providing special secured area of the network in mobile and fixed networks,
- to be solved interdepartmentally in relation to the national strategy,
- define the operating conditions other than in the operation of conventional systems due to the following reasons:
 - a. personal data protection,
 - b. data security,
 - c. regulated costs,
 - d. operation regulation, limiting abuse.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Indicator of achievement is the **creation of guidelines containing data and communications standards** for telemedicine solutions.

D. Description of the steps leading to the fulfilment of the measure

Individual steps leading to the fulfilment of the measure will be described in the implementation plan.

E. Major barriers and risks

The risk is that the administration shall not formulate in time recommended and mandatory standards, thus creating space for the development of proprietary and mutually incompatible solutions. Sharing information will then depend on the approach of the individual suppliers of the telemedicine solutions, data portability shall not be guaranteed. This limits flexibility in the use of telemedicine solutions and prevent their operative entry into the existing information exchange systems or into complete systems of sharing medical documentation. It will be necessary to prevent that the EHR (PHR, EMR) records are not unreasonably glutted with data of telemedicine measurements.

Measure 3.1.4 Electronic support of treatment of a patient in the home environment

A. Background and requirements for the measure implementation

The possibility of implementing healthcare in the home environment of a patient is included only to a limited extent in the complex provision of health services. Most of the tasks related to examination and treatment are directed to the provider environments. This brings greater operational, technical, and organisational costs for providers and patients in comparison with home care in indicated cases. Particularly, in the case of chronically ill patients, it is also a significant interference with the comfort and quality of their lives and the lives of their family members.

For the successful adoption of telemedicine solutions, which provide care for chronically ill patients in their home environment (i.e. the natural environment of the patient outside the medical facility) during hospitalisation and after hospitalisation, it will be necessary at the required quality and security levels, in addition to general (technical, safety, legislative and reimbursement) assumptions stated above to ensure the integration of new processes of care into the existing health system, especially the unequivocal identification of responsibility for the organisation of healthcare outside medical facilities, e.g. in the home environment.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Securing the services of assistance of qualified supervision when using telemedicine solutions

Pursuing effective enforcement procedures both in the practice of providers and in the environment of patients will require the assistance of trained and technically sufficiently equipped workplaces. Their role will be to manage technological equipment, distribution, safety checks and quality control of measured values, efficient and effective interventions, communication with indicating physicians, patient education. Focused and professional support to increase safety and efficiency in the application of telemedicine solutions.

Application of telemedicine solutions at home without the support of assistance of qualified supervisors within the pilot project would bring significant organisational burden to healthcare professionals and did not bring positive effect to improve the availability and safety in service provision.

Information campaign

Long-term information campaign aimed at presenting benefits to patients and healthcare professionals will help remove doubts about the safety and potential mistrust of new ICT technologies and therapeutic approaches for users of these services in clinical practice and in the home environment of patients. Properly structured information campaign shall generate positive expectations and induce in patients and medical staff willingness to accept changes in the organisation of care.

Weak or no awareness of the benefits of telemedicine solutions for application in the home environment would mean a reduction in the success of their implementation.

C. Outputs of the measure implementation, indicators of the successful measure implementation

- 1) Creating organisational, legal and institutional framework for the functioning of workplaces using telemedicine (including qualified supervision). Defining the technical and qualification requirements of the workplace.
- 2) The creation of centres using telemedicine (including qualified supervision) with technical equipment and professional competence to carry out this activity.

D. Description of the steps leading to the fulfilment of the measure

Individual steps leading to the fulfilment of the measure will be described in the implementation plan.

E. Major barriers and risks

The risk is tedious creation of institutional organisational provision of assistance services of qualified supervision. A campaign aimed at presenting benefits to patients must be guided appropriately and responsibly, so that it does not arouse unjustifiable feeling of excessive expectations in patients.

4.3.2 Specific Objective 3.2 Availability of care



Care availability

1. *Optimisation and management of waiting times for planned surgeries*
2. *Programs combating inequalities in access to healthcare (e.g. for the digitally excluded and weaker and vulnerable groups)*
3. *Methodology and evaluation system of the healthcare access*

A. Background and requirements for the implementation of the specific objective

Access to healthcare is among the key factors in determining health inequalities. Access to healthcare and its quality significantly increase the likelihood of overcoming disease, reduce the risk of complications and premature mortality. Health systems suffer from the lack of resources (both financial and human) and their uneven geographical and social distribution. These factors have an impact on access to care.

B. The impacts of the implementation of individual measures on the specific objective

A set of new electronic services that will allow patients clear orientation in the offer of health services and enabling selection of services according to their individual preferences (time, place, quality) will be achieved by improving the orientation of citizens in the healthcare system and increase the availability of health services. These services will be through a web user interface or mobile accessible anonymously, some functions however, will be unlocked after the verification of user's identity.

In the area of primary care, as stated in Measure 1.1.2 Electronic ordering of medical services, free network capacity will be published for the possibility of registering (in the field of general practical medicine, in the field of general practical medicine for children and adolescents, in dentistry or in the field of gynaecology and obstetrics). In the field of outpatient care (including primary), a patient will be able to make a reservation either directly or through the attending physician. A dynamic calendar when making a request for reservation will ensure effective use of the surgery. Availability of planned interventions, including special planned care, will be transparent due to the register of waiting patients (or the insured). The register will also include information on selected patients, where the nature of the disease allows. In cases where the patient is indicated for an intervention, but decides not to undergo the intervention yet, it will be possible to get an idea about the future capacities required on the part of providers and resources on the part of insurers.

C. Outputs and indicators of achieving the specific objective

A detailed set of indicators will be specified in the implementation plan.

D. Main barriers and risks of fulfilment (the impact of zero-option of the specific objective)

Some measures, or steps for their implementation will be time-consuming and will require good coordination of participants (particularly care providers and payers), especially in the absence of common interest.

Although we only assume implementation in the public health insurance system, we can expect the need of legislative changes to facilitate the implementation of the proposed measures, and it will also be necessary to find and agree on effective motivational factors for all participants of the process in the implementation of individual measures. The implementation of this measure will require financial resources. Failure to meet these requirements is also a risk for the implementation of this specific objective.

Measure 3.1.3. Optimisation and management of waiting times for planned surgeries

A. Background and requirements for the measure implementation

Currently in the Czech Republic, Decree No. 307/2012 Coll., on Local and Time Availability of Health Services, is in force. Individual healthcare facilities publish, not always on a regular basis, the information about waiting times for certain planned health services covered by the insurance. Monitoring the local and time availability is the responsibility of insurance companies, which, through network management, setting reimbursements and volume of care must ensure acceptable waiting times. This information is generally published on its website of each medical facility. With services available on-line, patients may hence get information about monitored waiting times on the website of a large part of healthcare facilities. Comparing waiting times, however, is time consuming and each person must perform it himself/herself. The actual waiting lists, however, do not guarantee the order of candidates and lack transparency, the estimation of actual waiting times for surgeries at different providers is thus very difficult.

A prerequisite for the improvement of information about waiting times is tracking or management of waiting times across healthcare providers. It will be necessary to monitor and evaluate waiting times for planned interventions and compliance with the rules so that they are not in violation of the principles of equal access for all population groups. If necessary, it will be necessary to implement measures and correction rules to optimise waiting times.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

In the first phase, a system for identifying the demand for **selected health services** (especially planned expensive surgeries) will be created. The current lack of information on demand, for example, adversely affects the allocation of resources and efforts for management and contractual services. Demand will be identified for the selected scheduled surgeries or special care. The fact that a patient was identified to perform a specific procedure will mean that he/she fulfilled indication criteria and that it will be necessary to ensure of appropriate care for him/her in the foreseeable future.

In the second phase, the patient will be placed on a waiting list being allocated a date of the intervention (i.e. initiation of treatment), and the ultimate date of intervention (i.e. initiation of treatment) to which the patient is entitled. The date of intervention may be indicative with ongoing specification or fixed. In any event, the system should be able to select the date at the patient's wish **in spare capacity**. The central register shall allow inspection requirements for the assignment of the patient to a particular treatment, and will continue to ensure transparency while including the patient in the queue respecting the protection of their personal data. Providers of health services will be able to parametrise the waiting lists with regard to demand contracted by health insurance companies.

The system will also address situations where there is an interruption of waiting times and situations when there is a change in the contracted provider of the planned intervention. These situations and their solutions will be described and known.

C. Outputs of the measure implementation, indicators of the successful measure implementation

- a system for identifying the demand for **selected health services**, collects most of all requests to implement planned interventions,
- Information contained in the system and the system itself are available according to established rules to all participants in the process according to their roles (e.g. the patient, physician/specialist, healthcare provider, payer).

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable for the implementation of the measures will be specified in the implementation plan in order to:

- make the necessary legislative changes,
- process rules/methods for indications, calculate waiting times, waiting list management, etc.,
- create a system for identifying the demand,
- establish a system for the management of waiting lists.

E. Major barriers and risks

It is likely that both systems will require legislative changes because they work with sensitive data of patients. Management of waiting times will allow reallocation of funds from the payer of care and capacity to meet the needs of required services on the part of healthcare providers.

An objective risk is that, despite the evident need, the reallocation needs not be performed.

The introduction of benchmarking in this area may go against the intentions of the insurers. The extent and form of disclosed information needs to be set up responsibly in connection with a link between the patient's free choice and contracted capacities and reimbursement of insurers.

Measure 3.2.2. Programs removing inequalities in access to healthcare (e.g. for the digitally excluded, weaker and vulnerable groups)

A. Background and requirements for the measure implementation

Article 35 of the Charter of Fundamental Rights of the EU guarantees everyone the right of access to preventive healthcare and to receive medical treatment under the conditions established by national laws and practices. Act No. 198/2009 Coll., Antidiscrimination Act, determines the right to equal treatment and non-discrimination, *inter alia* to access to healthcare and its provision. Government Regulation No. 307/2012 Coll., on Location and Time Availability of Health Services, is another legislative tool for resolving, if possible, equal access of to citizens to healthcare. This measure is to guarantee citizens of the Czech Republic timely access to healthcare of a specific type.

Within the National Strategy for eHealth , it is not possible to address the issue of equal access to healthcare in its entirety. However, it is possible to identify areas and issues of equality of access to healthcare that can be solved or improved within computerisation or within the computerisation of healthcare. Problems of obtaining information about healthcare and its accessibility for all population groups in the context of the "digital world" is not currently perceived by the majority population as a significant problem. This may be one of the reasons for the lack of addressing this issue mainly with respect to the handicapped, the socially disadvantaged and/or excluded, foreign-language minorities and other groups. which can be summarized under the term "digitally excluded". Therefore, in the context of computerisation of the health system it is necessary to implement programs and actions to improve equality of access to healthcare for these groups.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Implementation of measures will significantly enhance the possibility of the patient to orientate oneself in the offer health services, which will undoubtedly be reflected in improved access to them. Telemedicine resources will help to ensure oversight of health of the patient in the home environment, thus contributing not only to the higher efficiency of the provision of health services, but also to reduce barriers to access of vulnerable groups to healthcare (minimising transport and other costs on the part of the patient).

It is necessary to prepare a methodology for evaluating equal access to healthcare. Prepare a set of key indicators for assessing equal access, bearing in mind what the easiest and fastest data collection for calculating the indicators so that results can be quickly evaluated, updated and subsequently as necessary take adequate measures to establish equal access to healthcare for all groups of population.

For all existing and newly introduced health services provided, factors of their availability to all population groups, especially to the groups with the largest risk of unequal access to them must be assessed (physically handicapped, elderly, underprivileged and/or excluded, immigrants, foreign-language minorities, groups without internet access). Each provider and payer of health care must ensure that access to health services provided as well as information about those services is equal for all population groups. They should meet at least the following:

- services and information available about them via the Internet must be accessible to the visually impaired and in foreign languages reflecting the percentage of foreign-language minorities,
- services and information about them available on the Internet must also be available on telephone hotline service founded by providers and care payers.

Programs for increasing computer literacy of the population, especially those that are focused on "digitally excluded" population groups, will be supplemented by modules focused on the delivery of health services and obtaining information about them. Similarly, programs increasing computer literacy of health workers will include sections focused on the possibility of providing health services and information about them via the Internet and the improvement of communication with patients via information technologies.

These steps will improve the awareness of all groups of the population of health care provision and enable to increase its availability and improve the equality in the care provision.

C. Outputs of the measure implementation, indicators of the successful measure implementation

For outputs and indicators of successful implementation of measures, the following applies:

- methodology for evaluation of equal access to health care will be processed, preferably in cooperation with the EU and neighbouring states in order to make comparisons,
- newly introduced services will always pass the assessment according to the methodology for evaluation of equal access to health care,
- there will be a regular evaluation of equal access to health care, according to compiled methodologies followed by recommendations for improvement or correction of deficiencies,
- when evaluated in two consecutive assessments, the condition of the later evaluation must be better than the previous.

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable for the implementation of the measures will be specified in the implementation plan in order to:

- develop a methodology for evaluation of equal access to health care. Subsequently, regular collection of information and data for the evaluation of equal access to health care will be ensured,
- as well as regular evaluation of the implementation of equal access to health care in accordance with the compiled methodologies,
- as well as implementation of these programs for improving equal access to health care:
 - a. information and access to health care available on the Internet will be made available for the visually impaired and the minority language groups,
 - b. call centres (passive and active) will be created / hot lines and contact information institutes by the care providers and payers to increase the awareness of the availability of health care for the digitally excluded (socially disadvantaged groups, groups of people without the access to the Internet),
 - c. programs increasing digital literacy of health workers will be created,
 - d. the programs increasing digital literacy will include a module aimed at obtaining information and access to health care,
 - e. a proposal to use the involvement of Czech POINT mediation services to citizens especially in small villages will be processed.

E. Major barriers and risks

The risk is the increase of costs of providers and health care payers associated with an increase in the number of channels providing health care and information about health care as well as the long time necessary to implement some measures into practice.

Finding the relevant key indicators for assessing equal approach will also be difficult.

Measure 3.2.3. Methodology and evaluation system of the healthcare access

A. Background and requirements for the measure implementation

Requirements for care accessibility are described in Government Regulation No. 307/2012 Coll., on location and time availability of health services. Within the meaning of that provision, the availability is described by two attributes:

- local availability, described by the time (minutes) necessary to get to the providers of relevant health services (type of service, expertise),
- time availability, described in weeks notice to perform examination/treatment.

In the legislative rules or methodological standards, the attributes of availability of modifiable computerisation of health services are not taken into account (second opinion, telemedicine, diagnostic assessment on the basis of home diagnostics, etc.).

It is needed more than ever to identify the demand for health services and to evaluate its overhang. At the same time it is necessary to allow for a better allocation of resources and management of health services for the benefit of the optimal utilisation of the contracted capacities to ensure local and temporal availability of health services.

Legislative amendments in connection with the determination of the criteria for access to care and provision of appropriate tools for the reallocation of resources and funding will probably be necessary, especially depending on the detailed specification of the resulting accessibility criteria.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Specific methodologies and models for various areas of health care (e.g. ambulance service, general practitioners, dentists, specialists, etc.) will be developed and applied to help objectify the demand for health services e.g. with respect to geographic specifics of citizens' settlements. **Methodologies for evaluating the availability of care** will be prepared and further refined and specified by the current state of demand and availability of health services. Underpinning of the methodological problems of assessing development in demand will be substantial not only according to the short-term statistics but from the long term point of view as well. The reason, among other things, is avoidance of unjustified fluctuations in the financing of health services on the basis of short-term deviations from long-term trends in demand. Based on the evaluation of the availability of health care services, care payers will be better able to perform the re-allocation of funds for the incentive/disincentive of care providers so as to set the availability of health care services in relation to current demand.

C. Outputs of the measure implementation, indicators of the successful measure implementation

For outputs of the implementation of the measures and indicators of successful implementation the following applies:

- methodologies for the assessment of the availability of health services, preferably in cooperation with the EU and neighbouring states in order to make comparisons,
- regular evaluation of the availability of health services with regard to demand,
- establishment of criteria for adequate access to healthcare services in relation to demand by region (geographic distribution)
- creating the necessary infrastructure for the implementation of this measure.

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable for the implementation of the measures will be specified in the implementation plan in order to:

- create methodologies and models to assess the availability of health services,
- create the architecture of a future solution and implementation plan,
- regular performance evaluation of the availability of health services processed according to the methodologies and models,
- providing tools for the payer of care, which enable to perform synchronised reallocation of funds to motivate health care providers to optimize accessibility in line with current demand.

E. Major barriers and risks

The implementation of the measures will probably be conditioned on the achievement of necessary legislative changes. The risk is difficult coordination of payers and providers in making changes in the reallocation of resources and funding.

4.3.3 Specific Objective 3.3 Quality improvement and safe service provision



Improving quality and safe provision of health services

1. *Evaluating the quality of provided healthcare with analytical and methodological tools*
2. *Support of standardisation of medical documentation and therapeutic procedures*
3. *Support of treatment and decision making, team communication between the providers of health and social services*
4. *Crisis and security support on national / regional level*
5. *Life cycle of a medicinal product and medical device*

A. Background and requirements for the implementation of the specific objective

The quality of care often varies greatly within the health system depending on a variety of conditions and parameters of specific medical facilities and staff who work and provide health service in them. Differences in the quality of services create the effect of inequality in access to care for different population groups. It is desirable that the healthcare system and its components make use of the electronic tools to promote understanding of differences in quality of the care, to assess the quality and to quantify these differences and enable them to develop steps to better standardise quality of care wherever it is possible and necessary. In connection with the quality will be the evaluation of the effectiveness of clinical care, expressed objectively in measurable data and subjectively by the patient.

B. The impacts of the implementation of the individual measures on the specific objective

Improving the quality of health services can be achieved by the following measures, in particular by the standardisation of medical documentation, diagnostic and therapeutic procedures followed by continuous evaluation of quality of health care provided by analytical and methodological tools.

The quality of care provided is closely related to other measures which support the decision-making systems, team communication between providers of health and social services. There will always be an emphasis on safety and protection of patient privacy (an integral part of service quality). Systems of monitoring of the life cycle of medicinal product and medical device also contribute to the quality and safety of services.

To ensure a positive acceptance of new systems by the health workers all its parts must comply with the following requirements:

- information presented must be valid and their currency must be verifiable,
- simple user interface and integration of new information into existing outpatient, hospital and other information systems,
- reliability, minimal time and financial demand placed on individual healthcare providers and measurable benefits of electronic services,
- health care professionals must ultimately be reassured and convinced that shared information is securely transmitted and stored and is not being abused.

C. Outputs and indicators of achieving the specific objective

Indicators are based on completing specific subordinate objectives.

D. Main barriers and risks of fulfilment (the impact of zero-option of the specific objective)

The difficulty of the setting of the quality measuring system is both a risk and an opportunity.

Measure 3.3.1 Assessing the quality of health care provided with analytical and methodological tools

A. Background and requirements for the measure implementation

The electronic health system is missing a set of tools and methodologies that encourage understanding of the differences in the quality of care, qualification and quantification of these differences and allow to implement steps leading to better standardisation of quality of care wherever it is possible and necessary.

These tools enable an objective comparison of the quality of care among providers of health services in the country and abroad. Quality evaluation is required primarily to achieve positive motivation of health providers to continuously improve health services, rather than using penalty or ostracism. It is required that providers are able to compare their process and result indicators and parameters with similar care facilities in domestic and international comparisons and simply and clearly identify where there is room for improvement in quality.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

It will realize its potential of existing data and statistics, and above them will create **a systematic process of continuous refinement and improvement over the method of monitoring the quality** of different types or kinds of care, diagnosis groups, individual providers, geographic units and many other parameters.

It will also put emphasis on the **implementation of internationally tested methodology and nomenclatures of quality of care** in cooperation with regulator, insurance companies, professional groups and other stakeholders. Information will as far as possible be made available and simplified to make them comprehensible to the widest possible audience of providers and patients (citizens), including general beneficiaries of the health sector and individuals outside the sector (education, some public authorities, e.g. regional authorities – the department of health and others).

Creating a comprehensive incentive for healthcare providers for continuous quality improvement of health services (and their long-term monitoring and evaluation) may be due to the sensitivity of the issue rather complicated, especially if the selected results will be provided to the general public. A number of methods for measuring quality is so objective that the discovery and publication of quality should not only be a matter of course, but part of the relationship between providers, patients and payers of care. Choosing the correct procedure and strategy will be the main task of the expert panel that should take patronage over this area.

C. Outputs of the measure implementation, indicators of the successful measure implementation

There will be **a set of validated, long-term measurements and internationally comparable quality indicators**, including quality indicators from the perspective of the citizen. The results of qualitative comparisons will be able to be integrated into hospital and outpatient information systems and will be one of the possible inputs to support doctors' decisions about therapy.

Indicators of successful implementation will be set out in the implementation plan. They will be based on the following attributes:

- the existence of an expert panel which will be in charge of proposals in measuring health care quality,
- budget for design, localisation and validation of quality indicators
- the number of generally used sets of quality indicators
- the number of fields in which there is a routine, global quality measurement
- the percentage of workplaces (depending on the type) involved in quality comparison.

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable for implementing the measures will be announced in the implementation plan.

For the implementation of measures we assume the following basic steps:

- Expert panel will be established (appointed on the basis of professional criteria); the necessary budget for the operation of this panel will be allocated. The task of the panel will be, either alone or in collaboration with a specialist supplier, to ensure the creation of a methodology for measuring quality indicators

- a strategy for measuring and comparing the quality of health care will be developed,
- expert panel (or its supplier) will suggest a set of national quality indicators and will make a proposal on how they will be measured,
- an entity will be elected, or selected on the basis of tenders, which will carry out professional activities related to the retrieval of foreign resources, design and validation of sets of internationally comparable indicators of quality, which are measurable from the available data, it will not be a one-off project, but a gradual and long-term refinement and improvement of processes of evaluation of the quality of the care,
- coordinated by the Ministry of Health, data acquisition system will be built for the measurement of quality (it will be a complement to existing systems for routine data collection or, exceptionally, for creation of new systems)
- a system for presentation of results and comparison between providers will be built and the system will be linkable both with the health portals and with the information systems of providers,
- a system of incentives for healthcare providers to participate in a long-term survey of quality health services will be proposed,
- health care facilities will be involved on the basis of voluntary consent or contractual conditions (e.g. the conditions of accreditation, terms and conditions of HICs,...).

The exact sequence of steps and timetables for implementing the measures will be subject to further analysis.

E. Major barriers and risks

A difficult task which needs to be fulfilled is that it can be complicated to maintain motivation for service providers to continuously improve the quality of health services. Another risk is the difficulty and also the necessity of setting evaluation parameters with respect to various operating conditions of the care, e.g. location, availability of complementary services, socio-economic status of the population, etc.

Measure 3.3.2 Support for standardisation of medical documentation and therapeutic procedures

A. Background and requirements for the measure implementation

Even top-quality healthcare information systems are only as good as the data they work with. In terms of ability to understand the meaning of information in the medical documentation and documentation and to work effectively with the documentation (share, evaluate), it is necessary to gradually unify and standardise the content and structure of various types of medical documentation and to map used specialized terminology (particularly terminology and the use of abbreviations). In this area, there is unfortunately a large degree of freedom and the lack of standardisation significantly reduces the ability of health workers to correctly interpret medical records. This can in extreme cases lead to tragic consequences (incorrect interpretation of laboratory results communicated without stating the measurement units, abbreviations confusion, etc.). Above causes significantly reduce the validity and threaten the ability of an unequivocal interpretation of clinical documentation.

Conversely, standardisation of medical documentation can contribute to the development and implementation of tools supporting automated evaluation of health care, which will enable e.g. automatic detection of adverse drug interactions, warnings for allergy patients, recommendations of prescription, notice of inefficient method of treatment and the like. All these measures reduce inefficiencies and improve quality of care.

To increase the quality and safety of healthcare services we will need to standardize therapeutic procedures, further formalise and continuously update and create software tools to support physicians in the process of following those procedures. Standard therapeutic procedures are created on the ground of professional societies CzMA in cooperation with leading academic and clinical centres. Their formalisation and ongoing updates will be supported.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

To achieve international interoperability and for easier analytical processing of medical documentation it is necessary to initiate a gradual and very long-term implementation of internationally recognized clinical terminology (SNOMED-CT) into selected areas of medicine, to document local terminological customs and to standardize the types of clinical documentation.

Information tools used to support annotation and automatic classification of clinical documentation will allow the introduction of international clinical terminology with minimal requirements on medical staff.

C. Outputs of the measure implementation, indicators of the successful measure implementation

- standardisation of therapeutic procedures,
- creation of methodological and instrumental framework for formalizing of recommended practices,
- creating databases of formalized clinical knowledge in the form of metadata repository, more precisely, of clinical archetypes
- introduction, more precisely, specification of standard content and structure of various types of medical documentation in accordance with international standards,
- information tools supporting the implementation of international terminology.

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable will be processed in the implementation plan.

E. Major barriers and risks

Medical documentation and therapeutic procedures are the exclusive domain of health workers. The risk is that changes in this area will be carried out insensitively (too quickly, on a blanket basis, without respect), which may result in rejection of standardisation as a whole by these workers.

Measure 3.3.3 Support of treatment and decision making, team communication between the providers of healthcare and social services

A. Background and requirements for the measure implementation

Possibility of professional communication and consultation of inter-disciplinary teams within individual providers and between providers themselves, with medical assessor MoLSA and CSSA and the sharing of process and outcomes of treatment for individual patients or groups of patients, is a way to improve the quality and effectiveness of care provided. Promoting cooperation, team communication and knowledge sharing will lead to improvement in the education of health professionals and spread of good practice. The possible introduction of clinical treatments into protocols without compromising the possibility of individual procedures outside these established clinical protocols, will contribute to improving the quality and safety of healthcare services provided.

Clinical information systems which offer on-line searching of drugs used by the patient, the possibility of connection to database of drugs and finding drug interactions, the possibility of immediate evaluation of recommended therapeutic practices is used to support treatment and information to make informed decisions. These systems facilitate the work of health professionals and improve the safety and quality of health services provided.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Created tools will be available to healthcare providers in the form of web services or individual modules integrable into information systems, and **the role of the state will be mainly to provide an authoritative basis of proven clinical and pharmacological knowledge**, e.g. in the form of national licenses and to ensure their long-term administration.

C. Outputs of the measure implementation, indicators of the successful measure implementation

There will be a plan for the gradual linking of information with providers of social welfare, medical officer so that the target state fulfils a complete view of the patient through the health and social care ingredients and allows to coordinate and optimize both types of care based on individual needs of citizens.

The indicator for the successful implementation of the measure is the achievement of a measurable increase in the proportion of reported cases that will be supported and assessed by a formalized and recommended procedure until the time specified in the implementation plan.

D. Description of the steps leading to the fulfilment of the measure

Individual steps will be specified in the implementation plan and will include:

- providing a platform, infrastructure and tools for knowledge sharing,
- audit of the existing standards, the allocation of current and useful standards for the purpose of their progressive development and utilization, along with the new procedures
- creation of infrastructure for the creation and implementation of recommended clinical practices,
- ensuring the implementation of supporting software solutions and knowledge bases (drug interactions, quality benchmarking and treatment results)
- support of the development or acquisition of software tools that allow analyzing unstructured text for the needs of science and research

Overall infrastructure and created database of formalized therapeutic procedures (Measure 3.3.2) must offer positive incentives for software producers and health professionals so that they are used by them.

E. Major barriers and risks

The risk is a complicated legal base of guidelines. Such as technical standards may now be only a recommendation. If the obligation is expressed to be strictly observed, it must be treated legislatively. The failure to create a trusted environment for decision support for physicians is a risk as well.

Measure 3.3.4 Crisis and security support on national / regional level

A. Background and requirements for the measure implementation

With adoption of Constitutional Act No. 110/1998 Coll., On the Czech Republic's security, work began on the creation of national security system, whose vital and integral part of the system is also providing health care, represented by the Ministry of Health and other health systems on the territory of the state, for example, the Ministry of Defence, Interior, Justice, etc. The construction of safety system is fitted with a set of administrative offices and their activities are regulated by the administrative legislation in force, supplemented by other, primarily by Act No. 240/2000 Coll., on Crisis Management. Within the meaning of this Act, the system of crisis management bodies includes sets of security advice and crisis staff.

Construction of the crisis management department respects the organisational structure of the department, management level and scope of the various healthcare providers. It is currently two-level, i.e., it includes ministerial and regional levels.¹⁵

In terms of emergency preparedness of healthcare system, computerisation is a key area for emergency planning and response to crises. In these situations the possibility of linking key data sources into protected information system systems of government must be guaranteed, e.g. integration with the crisis information management software (CIMS), or linked to European information systems.

The issue of sustainability of health systems is closely related to the area of the so-called protection of national and European critical infrastructure, which is coordinated by the Ministry of Interior. This is to protect such facilities and services, which destruction would lead to the collapse of the socio-economic system in Europe or in individual member countries. The health sector is integrated into the program of protection of critical infrastructure, both at national and European level. Within the interministerial panel of EU-27 and the WHO, a single view of system of necessary services has been agreed on to ensure the so-called crisis preparedness and response and emergency response (CP&R= Crisis Preparedness and Response).

The main elements of this system of emergency services (EMSS = Emergency Medical Services System) are in the pre-hospital phase ("out of hospital") Emergency Medical Service (EMS = Emergency Medical Service); in hospital phase ("in hospital"). Those are urgent admittances of hospitals and specialised centres (ED = Emergency Department), ensuring the functionality of EMSS for emergencies and crisis situations is Crisis Management of Public Health (CM PH = Crisis Management of Public Health)¹⁶ and for the protection of public health, PHC = Public Health Care (public health authorities in terms of hygiene stations).

Protection of information and data used by healthcare providers through health information systems also needs to be seen from the point of view of crisis management and ensuring cyber security. In order to ensure data protection against misuse and cyber attacks it is necessary to focus on compliance with standard measures stipulated by the Act No. 181/2014 Coll., on cyber security and on amending related acts (Act on Cyber Security) and on its implementing regulations.

Healthcare operational centres of providers of emergency medical service in accordance with Act No. 240/2000 Coll., on crisis management and amending certain acts (the Crisis Act), as amended, and Government Regulation No. 432/2010 Coll., on criteria to identify critical infrastructure element, as amended Government Regulation No. 315/2014 Coll., the general measure issued by the Ministry of Interior designated critical infrastructure elements and individual providers of emergency medical services counties were designated as operators of critical infrastructure. Providers of emergency medical service are required to carry out all obligations in the area of critical infrastructure protection, which are given to them in above-mentioned legislation. In terms of electronic health, it will mostly consist of securing of

¹⁵ According to NAVRÁTIL.L. et al. : Fundamentals of Disaster Medicine. South Bohemia, Ceske Budejovice, 2008. Available from <http://zsf.sirdik.org>.

¹⁶ The text is based on lectures of D. Hlaváčková at Disaster Medicine conference – Brno, 2009.

information systems used as support for the operational management of providers of emergency medical services.

Providers of inpatient and day-care providers who are obliged to process the trauma plan according to Act No. 372/2011 Coll., on health services and the terms and conditions for the providing of such services (Health Services Act), as amended, in which they will adjust a set of measures applied in mass disasters, in most cases, they do not use any specialised information systems, which would be subject to the obligations of the law on crisis management. Providers who use information systems for this purpose are those providers who in terms of cyber security are required to comply with the conditions stipulated by the law on cyber security.

Besides the possibility of linking key data sources into protected information systems of government, the health sector needs to have its own information system for emergency preparedness and subsequently, for crisis management. This system will be "essential component" to the referenced connection; including the possibility of connecting the necessary information systems used in health care just for preparation and planning within the department and its individual components, forming so-called crisis infrastructure, within which mentioned "critical infrastructure" for both national and European level still lacks.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Effective linking of emergency services system in the pre-hospital phase, in the phase of hospitalisation (emergency receptions of hospitals and specialized centres) and for emergencies and crisis situations within the crisis management of public health will be supported.

It will be supported by the creation and implementation of truly effective convening of competent persons, more precisely, teams, at all necessary levels to tackle emergencies and crisis situations.

When designing specific measures privacy of patients and their medical documentation and protection of personal data of employees of health service providers and others must be respected. Also the two-level arrangement of crisis management department must be respected. Specification of these measures, determination of the outcomes, indicators and defining the risks and other steps will be done in the implementation phase of the strategy and included in its update.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Indicators of successful implementation, based on the achievement of measurable progress of implemented measures, will be set out in the implementation plan.

D. Description of the steps leading to the fulfilment of measure, schedule, follow-ups

Steps and timetable for implementing the measures will be included in the implementation plan.

E. Major barriers and risks

Main barriers and risks of implementation of measure will be identified in the implementation plan.

Measure 3.3.5 Life cycle of a medicinal product and medical device

A. Background and requirements for the measure implementation

The results of the group for International Studies applied to the environment of Czech hospital care through a Czech expert panel¹⁷ raise the following conclusions:

- about 5% of all drugs is poorly administered,
- about 7% of poorly administered medication is causing the patient serious health problems that require subsequent correction of the treatment, new tests, additional medication and extended hospitalisation period,
- prolongation of hospitalisation due to incorrect medication of the patient is on average 2.9 days and more.

According to the European Association of Hospital Pharmacists (EAHP), 39% of errors occur at the time of prescription of a medicine by a physician, 23% in the process of logistics and preparation, i.e. at a pharmacy or in the wards, and the remaining 38% of errors occur when the medication is administered by a nurse. Although the majority of medication errors do not cause patient side effects, some misconducts result in not only the deterioration of the patient's condition, but also in additional costs of the treatment. The costs are not minor. Contrarily, they amount to several dozens of millions annually, depending on the size of the hospital.

The basis of an effective system of safe pharmacotherapy in the hospital is to electronic prescription of medicines. Such system significantly eliminates errors caused by illegible prescription and enables efficient evaluation of medication by a pharmacist using database applications, e.g. to check drug interactions.

Errors in administering of medication and overall inefficiency of the medication process have a much greater extent than is generally known. In Czech medical facilities the process of medications, unlike other processes in the hospital, has not been innovated much in the past few decades.

It is known from practice that e.g. great losses occur while administering and issuing medicinal products to persons staying with social service providers (for example, if three months worth of medicines are issued to a person who dies the next day, the right practice is to simply: take a bag with yet unpacked medicines back to the pharmacy for disposal). There are requirements to enable output directly to the institution determining the conditions for storage of medicines (and their dispensing / administration to client), which would help to reduce these losses.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Electronic health enables to bring new powerful features into the entire process without which it is impossible to deal effectively with the situation described above. This is e.g. The systems of labelling of medicinal products based on RFID, QR codes and their corresponding classifications, single (unit-dose) systems, tableting systems, transportation systems, wireless telecommunication networks etc., and their effective use in the entire logistics chain, from production, distribution, storage (pharmacies, stores, consignment stores, cabin stores) across administration, to taking the medicines.

Due to the high percentage of errors already incurred when prescribing the drug is the creation of a system of electronic record and its links between outpatient, hospital and emergency care, an important element in reducing drug-drug interactions and contraindications with a significant positive impact on the outcome of patient treatment while reducing the cost of medical care.

¹⁷Zeno Veselík, Personalised, Predictive and Preventive medication process in hospitals Rather-still missing: professional opinion survey on medication safety in Czech Hospitals (based on professional opinions of Recognised Czech health care experts), EPMA J. 2014; 5 (1): 7. Published on-line 2014 May 1

This is mainly underpinning of key interactions e.g. between health and logistics staff, patients, following the route of a medicinal product after its admission by particular nurse or doctor for particular patient, or on concrete bed and room and record of the actual use to the settlement of all requested (changes in medication, changes in patient condition) and undesirable (fall, vomiting or other depreciation of medicine) events.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The measure aims to increase the efficiency and safety of the process of administration of medicinal products and medical devices by introducing new technologies and achieve improvements in the following areas:

(1) the right patient is administered (2) the right medicine (3) in the right dose (4) at the right time and (5) correctly. At the same time (6) correct documentation is kept and patient gets (7) the correct information about the drug, including pharmacovigilance.

The secondary objectives are to reduce the transaction costs associated with the logistics of medicinal products throughout their life cycle, from production to consumption and consistent quality throughout the process. Given the risks associated with the use of medicinal products from circulating defective batch / lot / pack throughout the process, special emphasis is put on ensuring traceability of items in the largest (in terms of efficiency), yet effective (in terms of cost and feasibility) granularity (i.e. not to follow everything at any cost).

Implementation of measures should lead to a reduction of errors in medication at least by 30%.

Other indicators of successful implementation will be set out in the implementation plan.

D. Description of the steps leading to the fulfilment of the measure

Steps and timetable for implementing the measures will be announced in the implementation plan.

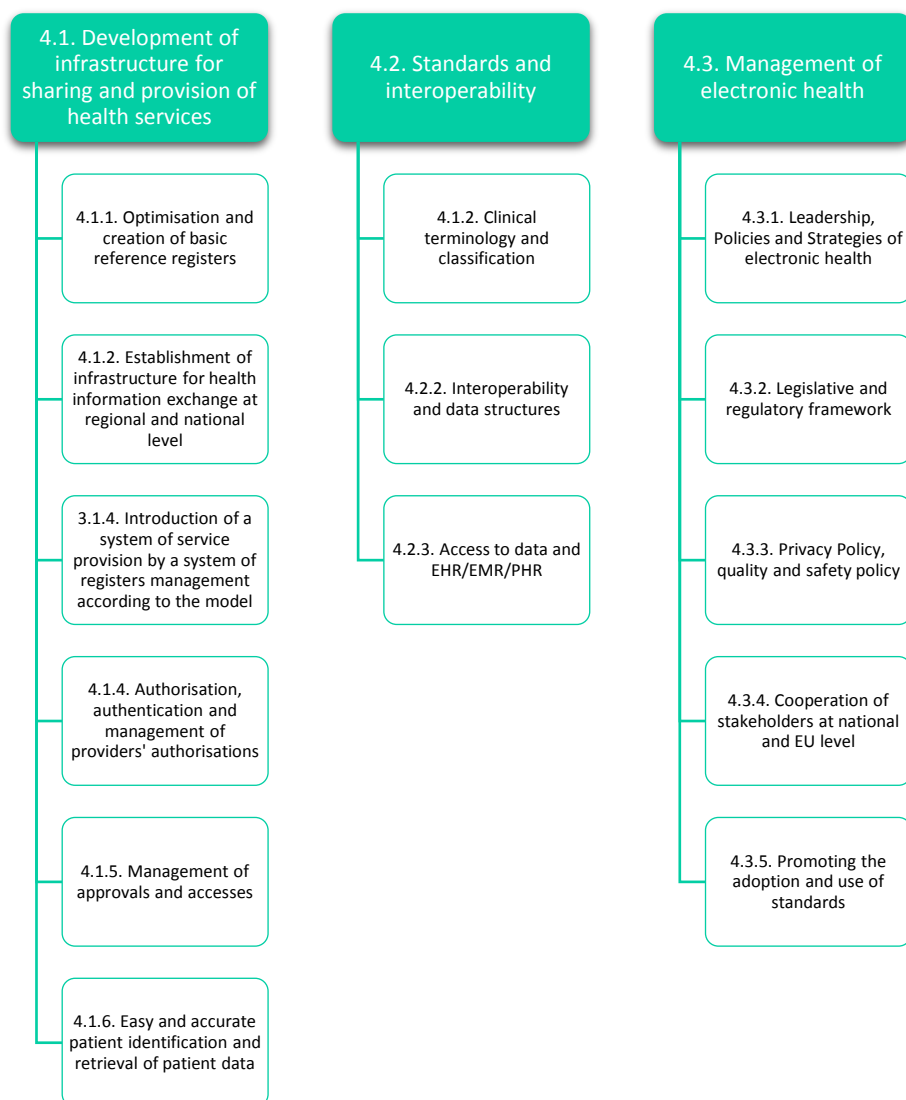
When implementing the measure we expect the use of outputs of implementation of the Directive no. 2011/62 / EU (Anti-counterfeiting Directive), the use of outputs realization Commission Implementing Regulation No. 520/2012 (on the performance of pharmacovigilance activities) and in compliance with the other requirements of this strategy.

E. Major barriers and risks

Risks:

- legislative obstacles to overcoming the barriers in the tracking of the flow of information across the health system,
- a different motivation of individual participants of optimized processes,
- legislative barriers to the introduction of tablet systems into medical practice,
- inadequate logistics infrastructure supporting transport and overall traceability of pharmaceuticals and medical devices in healthcare facilities (pneumatic post, robotic transportation systems, networking for the Internet of things, tablet devices,...)
- costs accompanying implementation of the Anti Counterfeiting Directive,
- unsatisfactory state of implementation of electronic prescription and dispensation in the country.

4.4 Strategic Objective 4 Electronic healthcare infrastructure and management



Graph 7 Structure of Strategic Objective 4

The strategic goal of computerisation of Health is to improve the availability and transparency of health services, increase the efficiency and transparency of public administration and support of the program Health 2020, through the tools of electronic health as a specific part of eGovernment. Introducing elements of electronic health must be carried out in compliance with legal and technical conditions and needs of all partakers in the system, especially on the part of patients and health care providers. Computerisation of selected processes of health system will be systematically promoted in order to motivate patients and providers to implement and use new processes, systems and applications. In addressing electronic health documentation patient should be able to choose a manager for their data without worrying about privacy breaches and data loss. The infrastructure development will create a basic technical and safety framework which defines authentication principles and mutual compatibility and interoperability of different systems and solutions.

An important consideration when building electronic health services and will be technical solution to work ergonomics in electronic health environment. This can be a significant factor in choosing ways to implement electronic health services so that they deliver the expected effects.

A. Background and requirements to meet the strategic objective

Electronic health will be built on the basis of Czech and foreign experience and will be based on the following principles:

- 1) The primary objective of the development of electronic health must be contribution to patients and quality of health care.
- 2) Patient's right to ensure the welfare, protection of personal dignity and privacy must not be weakened by means of introducing electronic health, but rather strengthened.
- 3) Doctors and other professionals in the health sector must be involved in projects already in the process of preparing plans, the planning and drafting solutions. The opinions of the professional public must be within projects actively sought and adequately taken into account.
- 4) Before the introduction of new tools and electronic health services into practice their usefulness, quality, stability and performance must always be adequately verified and evaluated .
- 5) Introduction of electronic health based on generally established responsibility is fundamentally wrong. When introducing new services and electronic health tools we need to use mainly positive motivation and introduce new technologies gradually and prudently so as not to jeopardize the continuity and safety of operation, endanger the patient or deteriorate the working conditions of health professionals.
- 6) Wherever possible and appropriate, it is necessary to utilize all available scientific knowledge and proven technologies during the creation of new solutions, including standards for the exchange and display of medical information.

B. The impacts of the fulfilment of individual specific objectives within the context of the strategic objective

Electronic health management system must ensure an efficient, controlled and coordinated introduction of computerisation in accordance with national interests and priorities expressed in national strategies. To fulfil this task, it is necessary to establish a body fitted with responsibility for the management system of electronic health and equipped with the necessary powers, the professional capacity and adequate financial resources. This entity will be managed and controlled by MoH with the involvement of other key organizations.

C. Outputs of the fulfilment of specific objectives

The strategic objective consists of three specific objectives and corresponding actions:

- 1) Development of infrastructure for sharing and provision of health services:
 - optimisation and creation of authoritative registries - authoritative data sources,
 - rise (of safe) infrastructure for health information exchange at regional and national level,
 - introduction of a system providing services system management agendas according to eGov model,
 - consolidation of health, hygiene and other registers as tools of electronic health,
 - authorisation, authentication and management of providers' authorisations,
 - management of approvals and accesses,
 - easy and accurate patient identification and retrieval of patient data.
- 2) Standards and interoperability:
 - clinical terminology and classification,
 - interoperability and data access,
 - data structures and sets, EHR, EMR, PHR,...
- 3) Management and Infrastructure of electronic health:
 - leadership, policy and strategy for electronic health,
 - legislative and regulatory framework,
 - privacy, policy, quality and safety,
 - cooperation of stakeholders at national and EU level,
 - promoting the adoption and use of standards.

D. Indicators of achieving the strategic objective

The primary identifier of achievement of this objective is the provision of the body responsible for the management of system of electronic health (National Centre for Electronic Healthcare – NCEH). Another two indicators are shown in the relevant specific targets.

E. Main barriers and risks of implementation (impact of the zero option of strategic objective)

The main risk is not finding a political consensus on the creation of the National Centre and its provisions. If it fails to be created, the state will not be able to fulfil the goals of the strategy or the commitments to Action Plan No. 11 Health System Computerisation, National Health Strategy 2020.

Electronic healthcare system will be very critically evaluated in terms of potential leakage or misuse of sensitive personal data, especially of patients' data, but also data of physicians and other participants in the system. Therefore, the issues of cybersecurity and privacy shall be carefully considered and tested repeatedly throughout the life cycle of implementation of measures since their design, implementation to operation and change management. Patients' roles in decisions about their own privacy must be not only respected by the system, but shall be strengthened at the maximum possible extent.

The intention of the strategy is the establishment of the National Centre for Electronic Healthcare (NCEH), which will be responsible for the preparation and development of computerisation of health care, however, the outputs of the centres will depend on the involvement of many experts, mostly IT professionals who actually will establish eHealth and then maintain it. On the Czech market, there is a long-term shortage of IT professionals, the competition with the private sector is high, therefore the issue of attracting and retaining human resources poses a risk and one of the main barriers to the implementation of Strategic Objective 4 Electronic healthcare infrastructure and management.

The basic prerequisite for coordinated and successful development of electronic health is consistent processing of the complete Enterprise Architecture (EA) MoH and the related sub-system architecture (SA) of individual information systems, which have a major impact on the implementation of the objectives of the proposed strategy. Therefore, it is necessary that the architects and the creators of new ICT systems and services respect the existing environment, knowing what new business roles and services they create and who will be the user. At the same time the architecture must clearly specify the requirements for technical solutions to applications and data sharing, capacity and performance characteristics of sub-components and the necessary secure infrastructure.

Specific objective	Main measures	Output Name	Indicator	Responsible party	Cooperating entities	Relation to other specific objectives
4.1. Development of infrastructure for sharing and provision of health services	4.1.1. Optimization and creation of authoritative registries -	Commissioning registers NRHP and NRPZS	Commissioning registers NRHP and NRPZS	IHS	CCHSIS MoH	SO 1,2,3
	4.1.2. Establishment of (safe) infrastructure for health information exchange at regional and national level	National infrastructure for the exchange and sharing of medical records and electronic health records will be created	Processing Enterprise Architecture of Electronic Health; creation of the role and institute of Chief Architect of Electronic Health	MoH	CCHSIS	
	3.1.4. Implementation of service provision by system of agendas management according to the pattern of eGovernment	Processing Enterprise Architecture of Electronic Health; creation of the role and institute of Chief Architect of Electronic Health	Processing Enterprise Architecture of Electronic Health; creation of the role and institute of Chief Architect of Electronic Health	MoH	SIDC, ÚZIS, SIDC and other organizations in the health sector	SO 4
	4.1.4. Authorisation, authentication and management of providers' authorisations	Creation of spaces of identity and authentication services for healthcare professionals and persons authorised healthcare providers	Functioning Authentication services	MoH	ÚZIS, SIDC, health insurance company, MoLSA, Mol, SIDC	SO 1, 2, 3
	4.1.5. Management of approvals and accesses	Management system of approvals and accesses	A functioning management system of approvals and accesses	MoH	ÚZIS, SIDC, health insurance company, Mol, SIDC, CzMA, Regions	SO 1, 2, 3
	4.1.6. Easy and accurate patient identification and retrieval of patient data	Authentication mechanism for client health services	Functioning services of authentication	MoH	ÚZIS, SIDC, health insurance company, Mol, SIDC	SO 1, 2, 3
4.2. Standards and interoperability	4.2.1. Clinical terminology and classification	Creation of national framework for the management and development of medical terminologies and classifications; establishment of centralized terminology services	See Measure 4.2.1.C.	MoH	ÚZIS, CzMA	SO 2 (exchange of medical documents)
	4.2.2. Interoperability and data structures	Institutional support of harmonization, profiling and further development of national and international data protocols; introduction of system of certification of health information systems.	See Measure 4.2.2.C.	MoH	ÚZIS, CzMA	SO 1, 2, 3

Specific objective	Main measures	Output name	Indicator	Responsible party	Cooperating entities	Relation to other specific objectives
4.3. Administration of electronic health	4.2.3. Access to data and EHR / EMIR / PHR	Institutional development of security standards in EHR and data access control; specification of standards	Indicators will be specified when drawing up the implementation plan of the specific objective 4.2	MoH	IHIS, CzMA	SO 1,2, 1,3, 2.1, 2.2, 3.3, 4.1
	4.3.1. Leadership, Policy and Strategy of Electronic Health	Establishment of special team NCEHS which will have overall responsibility for the design and building of electronic health	Provisions NCEHS and fulfilment of SO 4.1 and 4.2.	MoH		SO 1,2,3,4
	4.3.2. Legislative and regulatory framework	The bill on electronic health	The bill on electronic health	MoH		SO 1,2,3,4
	4.3.3. Privacy Policy, quality policy and safety	Creation of policy of quality and safety, and its integration into the system of computerisation management	Creation of policy of quality and safety, and its integration into the system of computerisation management	MoH	OPDP, NSA	SO 1,2,3,4
	4.3.4. Cooperation of partakers at national and EU level	Support of national and international interoperability within eHealth Network	The indicator will be specified in drawing up of the implementation plan.	MoH		SO 3,4
	4.3.5. Promoting the adoption and use of standards	Creation of competency centre for the management and development of standards	Creation of a competency centre for the management and development of standards	MoH	IHIS, OSMT	SO 4.2

Table 6 Summary of information for the strategic objective 4

4.4.1 Specific Objective 4.1 Development of infrastructure for sharing and provision of

services



Development of infrastructure for sharing and provision of health

1. *Optimization and creation of authoritative registries - authoritative data sources*
2. *Establishment of (safe) infrastructure for health information exchange at regional and national level*
3. *Booting service provision system management agendas according to the pattern of eGovernment*
4. *Authorisation, authentication and management of providers' authorisations*
5. *Management of approvals and accesses*
6. *Easy and accurate patient identification and retrieval of patient*

health services

A. Background and requirements for implementation of the specific objective

Czech healthcare lacks a functional infrastructure, electronic health provides shared information services in the health sector, as well as in other sectors. These infrastructure services are necessary for meaningful development of computerisation and it is clear that these services will form **the basic building blocks of computerisation**.

Clear priorities in the development of infrastructure services is creation of authoritative data source - National Register of Medical Professionals (hereinafter also referred to as "NRHP") and the National Register of Healthcare Service Providers (hereinafter also referred to as NRHP '), functioning pursuant to the amended Act 372/2011 Coll. Another priority is to create conditions for credible communication between stakeholders and organizations with unquestionable identity. This objective will be realized in cooperation with the Ministry of the Interior and will use eGovernment services in accordance with Directive eIDAS.

In connection with the computerisation of health care measures must be taken to ensure asset protection of authorities operating in the field of ensuring security, public order or other essential interests of the Czech Republic, which could be threatened when achieving the goals of the National Strategy for eHealth , especially in connection with data linking within the electronic health system. For the purpose of taking appropriate measures private analyses will always be handled, they will be consulted with those bodies, in order to assess the impacts of proposed projects on their activities.

B. The impacts of the implementation of individual actions on specific goal

Outlined measures to this specific objective will be implemented gradually and electronic health will have a major impact; They are a precondition for the start of computerisation.

C. Outputs and indicators of achieving the specific objective

- implementation of NRHP, NRHCP registers,
- implementation of identity spaces and authentication services for the Ministry of Health,
- creation of departmental information and data interfaces (for information sharing, connecting to eGov, etc.)

- creation of infrastructure for the exchange and sharing of medical documentation.

D. Main barriers and risks of fulfilment (the impact of zero-option of specific objective)

The risk is the lack of the necessary capacity on the part of MoH and other directly controlled organizations, which are designed to meet this goal and the constraints imposed by the difficult acquisition of ICT professionals in government. The impacts of these limitations have long been addressed at the Government Council for Information Society (GCIS).

Measure 4.1.1 Optimisation and creation of authoritative registries – authoritative data sources

A. Background and requirements for the implementation of the measure

None of the health systems can not do without reliable identification of subjects, not even without a network of authoritative data describing the medical and medico-social environment (healthcare providers, patients, payers, etc.).

Therefore, it is necessary to create authoritative sources of information. These resources are essential for the development of electronic health. The major authoritative source of information will be the registers NRHP and NRHCP. Combination of information about a particular healthcare professional and healthcare providers (or about place of provision of health care) will also help to define the scope of permissions in electronic health.

Similarly, steps will be taken to build additional authoritative sources of information in the field of pharmaceutical, medical devices, public health, and the like. Possible role of a central register of the insured in electronic health systems should be clarified, and possibly appropriate measures for its wider use will be accepted. To create a layer of authoritative data sector it is necessary, in cooperation with the substantive registry administrators and other information sources, to gradually start to catalogue and semantically and syntactically standardise the data. Authoritative information will be provided through Informational and Data departmental interfaces in different formats (web services, information on the Portal, in the case of public data OpenData).

B. Description of the measure implemented and the benefits and impacts of the implementation of individual measures

In the first phase registers NRHP and NRHCP will be put into operation. For the introduction of other authoritative data methodology for creating and cataloguing authoritative data must be established; then simultaneously, phasing in the catalogue of authoritative data sector can start.

During the implementation, the following architectural principles will apply:

- Principle of four-layer architecture of Public Administration - (services, information systems, technological infrastructure, communications infrastructure) + additional domains of architecture. Source: NAP CR
- from isolated computer systems to shared ICT services – (from isolated operating environment to coordinated network of national and regional data centres interconnected by secure communications infrastructure). Source: Development Strategy of ICT services of public administration and its measure for streamlining of ICT services
- authoritative data hierarchy – In individual registers separation of authoritative part, containing master data, from agenda part, containing data relevant for a specific agenda, will be necessary
- sharing of data on individuals and legal entities - to impose a standard way of publishing and sharing of individual data on natural and legal persons and entities other data from the key agendas of public administration. Source: Development Strategy of ICT services of public administration and its measure for streamlining of ICT services, Act No.111/2009 Coll. on Basic Registers,
- the use of departmental data interface for provision of authoritative data.

Authoritative data of Ministry of Health bring a significant effect in the computerisation of health care and their importance for resort is similar to the importance of creation of basic registers eGovernment.

Authoritative information will serve organizations and beneficiaries in the resort to obtain valid and binding information.

C. Outputs of the measure implementation, indicators of the successful measure implementation

Indicator of achievement of the first phase is the launch of registers NRHP and NRHCP via departmental data interface. In the next phase, it is the commissioning of registers containing authoritative data on the field of drugs, medical devices, and public health.

Communication and information exchange is the basis for any cooperation in health care and ensuring it is an essential need and a prerequisite for its operation in the digital era.

In terms of health information exchange is the requirement of availability of broadband internet throughout the Czech Republic for healthcare providers prerequisite for participation in the system.

D. Description of the steps leading to the fulfilment of the measure

Individual steps will be implemented in this order: commissioning of NRHP and NRHCP, commissioning of Departmental data interface as a single interface for provision of authoritative data on the sector and commissioning of other authoritative data in the field of pharmaceutical, medical devices, and public health.

E. Major barriers and risks

The risk is an urgent need for these registers and therefore little time for their integration into the surrounding systems and setting up all the necessary processes and agendas for individual editors and readers.

Measure 4.1.2 Establishment of (safe) infrastructure for health information exchange at regional and national level

A. Background and requirements for the measure implementation

There is currently no unified system of unambiguous identification system nor for transmission of messages communicating parties on national (healthcare providers, health professionals, citizens and organizations participating in the processes of the Ministry of Health). Any information system that uses communication between these entities, deals with the identification of subjects in a proprietary manner.

Most information systems communicate with the public through portals or websites, occasionally using mobile applications.

Currently, transmission of medical reports is done within health information systems of healthcare providers (e.g. PACS). Existing projects aim to build up and disseminate communication infrastructure for secure and credible exchange of data between healthcare provider, but so far without the necessary coordination and interoperability.

While the Czech Republic currently lacks a national health system of terminology used in the context of electronic communications. The aim of introducing uniform terminology is primarily to ensure semantic interoperability, improve quality of care and patient safety by means of structured information in electronic health record.

The role of the National Contact Point on cross-border payments for provided health services from public health insurance office is carried out by health insurance office. The requirement for the near future is the creation of the National Focal Point of electronic health, ensuring in accordance with binding EU Directive border the exchange of electronic prescriptions and patient summaries, and the introduction of exchange into routine practice.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Description of the measure:

- 1) Promote the construction and development of broadband communications (including mobile) networks so that access to electronic health care is available to all citizens and healthcare providers.
- 2) Build a secure communications infrastructure for health information exchange and use of electronic health services. This infrastructure will provide in particular:
 - unambiguous identification of the communicating parties,
 - access to information services (portals, web services, etc.) via mobile and fixed networks,
 - mobile access (access from mobile devices)
 - safe, synchronous and asynchronous transfer of messages and files, including the secure transmission of visual documentation,
 - security service including the indisputableness of responsibility for sending messages,
 - terminological services and translation services supported by the data and semantic standards.
- 3) Build a National Focal Point of electronic health and ensure the prerequisites of national and international interoperability within the framework of EU projects.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The outcome of the implementation will be national infrastructure for the exchange and sharing of medical documentation and electronic health records services connected to the National Contact Point of eHealth. Its main services are mainly state-guaranteed services for secure, guaranteed and trusted exchange of messages and documents. It will be based on the use of indices of medical documentation and electronic health records and it will enable the expression of agreement / disagreement with sharing of patient's medical documentation, and the management and sharing of electronic health records within an agreed range.

The long-term goal is to blanket the use of national infrastructure in the healthcare process, from both healthcare providers, as well as by citizens.

Measurable indicator of the gradual achievement of long term objectives will be the number of active entities linked to national infrastructure and the number of services provided by the central infrastructure.

D. Description of the steps leading to the fulfilment of the measure

Through projects, among which will be implemented the following activities, the state will build necessary communication infrastructure for the blanket computerisation of eHealth; especially for a system of exchange and sharing of medical documentation and electronic health records. In cooperation with the responsible institutions, coverage of all localities of healthcare providers with broadband will be mapped and subsequently secured. Mandatory broadband internet access as an essential condition of consent for the provision of health services will be put into practice.

To build and put into practice **National System of exchange and sharing of medical documentation and electronic health records** departmental methodology will be issued in advance, including rules for secure and credible communication infrastructure for health information exchange and use of electronic health services.

Project of **construction and implementation of authentication services** that enables unambiguous identification of communicating parties, supporting authentication of citizen using the National Identity Authority (hereinafter also referred to as "NIA") provided by the MoI, and logging of authorised healthcare providers through the services of identity space Ministry of Health will be implemented.

Another project in this area will be project **Information and departmental data interface**, which will make visual and non-visual central services available, namely:

- National Health Information Portal,
- departmental data interface,

- exchange and sharing of medical documentation and electronic health records using indices of medical records and electronic health records,
- government of approvals and mandates,
- electronic prescription,
- providing authoritative information on health professionals, healthcare providers, policy and ministerial dials.

To ensure the above principles, security system of synchronous and asynchronous transfer of messages and files will be built - a national system for the exchange and sharing of medical records and electronic health records, including government approvals and mandates, based on the following principles:

- the principle of free access of citizens to the medical documentation kept on him/her,
- the principle of absolute liability of healthcare providers for medical documentation,
- principle of minimisation in the area of keeping of personal data,
- equivalence principle of paper and electronic forms of medical documentation – rights and obligations are the same for both formats,
- the principle of free choice of the people to decide on the extent of the sharing of electronic medical documentation above the legislative framework,
- the principle of free choice of a citizen to decide on the keeping / not keeping of his shared electronic health record,
- the principle of free choice of a citizen to make their medical documentation and electronic health records accessible to a third party, as a tool to promote patient - family - community relationships,
- the principle of gradual and long-term transition from the current text-based (poorly structured) medical documentation to structured electronic medical documentation,
- principle to guarantee the credibility of shared information for an authorised person,
- the principle of strengthening confidence in the safety of (not being able to be exploited) the system's environment,
- principle of availability of shared information for an authorised person in real time.

Condition for building a system of exchange and sharing of medical documentation and electronic medical records is the processing of architectural visions into technical level, legislative enablement of keeping of patient summary and index of medical documentation, issuing departmental methodology for the exchange and sharing of medical documentation and electronic health records.

In the area of transfer of video documentation a project will be implemented to complete the current system, in terms of the exchange and sharing of medical documentation and electronic health records as a national ministerial system for the exchange of video medical documentation.

A prerequisite for the success of the strategy is to ensure the credibility, inviolability and non-repudiation of responsibility for sending and receiving message. Architectural vision for the system of exchange and sharing of medical documentation and electronic health records in security services will be developed, in particular cryptographic and signing services to the technical level. Security system project for the exchange and sharing of medical documentation and electronic health records will be simultaneously developed and implemented and will be reflected in the methodology for the exchange and sharing of medical documentation and electronic health records.

In the **terminology services** and translation between supported data and semantic standards, it is necessary first of all to issue a legislative regulation on standards for electronic health care and on this basis to add to the system for the exchange and sharing of medical documentation and electronic medical documentation a central translation services between supported data and semantic standards. In addition, a long-term national plan for the gradual introduction of medical terminology SNOMED CT will be launched simultaneously .

The National Focal Point of eHealth for the exchange of electronic health records in the EU will be completed and put into practice.

E. Major barriers and risks

The main barriers and risks in implementing the measure which will need to be eliminated have been identified:

- conservative approach of health professionals to health computerisation,
- Legislative restrictions on privacy
- consensus of critical mass of professional medical public in setting of standards for electronic health
- long-term process of establishing a national system of terminology,
- This risk could be a reluctance to invest relatively large sums on creation of the system.

Measure 4.1.3 The implementation of the provision of services management system according to the pattern of eGovernment agendas

The aim of this measure is to adapt the processes in healthcare, particularly of an administrative nature so as to maximise the use of eGovernment services and procedures which the citizen understands and has learned to use them when solving life situations.

A. Background and requirements for the implementation of the specific objective

Some of eHealth services will acquire the character of "agendas" of public administration, such as registration of health workers" competences, health workers evidence, etc.

Development Strategy of ICT services of public administration and its measures to streamline ICT services (Government Resolution of November 2, 2015, No. 889) defines the relationship between the services of the public administration and the various types of ICT services. This document clearly identifies and describes the main shortcomings of the current state of development of eGovernment and summarizes the main measures for achieving the strategic objective "Increasing the availability and transparency of public administration through tools of eGovernment".

When introducing electronic health, the following principles of eGovernment listed in the "Strategy of development of ICT services of public administration and its measures to streamline ICT services" will be followed:

1. From uncoordinated management of ICT state to a coordinated one, built on a unified architecture and uniform rules.
2. From dependence on suppliers to its own competence to effectively manage the development and operation of ICT in the country.
3. From independent and inconsistent public administration processes to standardized, coherent, high-quality, effective and measurable public administration services.
4. From specialised official counters to digital self-service facilitated by coordinated publication of user-friendly ICT services.
5. From isolated to connected and open of public administration and to qualified decisions leading to higher efficiency of services VS.
6. From isolated computer systems to shared ICT services.
7. From isolated identity systems to uniform systems of identities of users of public administration and public officials.
8. From passive acceptance of legislation and ICT projects in the EU to active participation in the preparation of new legislation and ICT projects in the EU.

The National Strategy for eHealth is not parallel with the eGovernment strategy, but a strategy to address the specifics of the health sector, in a clear linkage to eGovernment strategy.

Organisation of the Ministry of Health is responsible for a variety of administration¹⁸ defined by the relevant legislation. Performance of these agendas and related processes fundamentally affects the efficiency of the whole sector but also burden the citizens when solving life situations related to all participants in the health system (either as a patient or medical staff).

In preparation for the strategy, a series of analytical and architectural work analysing the current informatics services and data sector was done. The outputs of individual projects of Enterprise Architecture of Ministry of Health and the related detailed architectural analysis will be published on the website. Principle and the ultimate goal is to maximize the use of Data Fund of CR and eGovernment services, such as the use of basic registers, identity solutions, etc. The outputs of computerisation and development principles were formulated in collaboration with expert working groups and consulted with the Chief Architect of Ministry of Interior. In accordance with these outcomes and principles, suggested informatics services are outlined in the strategy, for example ePrescription, authoritative source of information about health professionals and healthcare provider and the like. Computerisation of health care that builds on actions and activities of specific objective 3.1 of the Strategic Framework – Completion of a functional framework for eGovernment.

B. Description of the measure implemented and the benefits and impacts of the implementation of individual measures

The realization of this goal is understood as a cross-cutting activity supporting and controlling compliance with the rules set out in MoI documents "Strategic Framework for the development of public administration in the Czech Republic for the period 2014 - 2020" and the Implementation Plan for the strategic objective No. 3 "Increasing the availability and transparency of public administration through tools of eGovernment".

¹⁸ Term agenda, according to the Act on Basic Registers means "summary of activities consisting in the performance of a defined group of interrelated activities within the scope of public authority.

Particularly respecting the following rules of computerisation:

- 1) Conceptual securing of the functioning and implementation of eGovernment ICT projects (including legislation and management of ICT investments).
- 2) Education in the field of ICT and eGovernment, including cyber security.
- 3) Completion of eGovernment.
- 4) Promoting the principle of Open Data.
- 5) Expansion, interconnection and consolidation of data fund of public administration and its efficient and safe use according to individual agendas.
- 6) Completion of infrastructure and storage of information and communication systems of public administration and eGovernment.
- 7) Increase in cyber security of ICT VS.
- 8) Implementation of the system of electronic identification, authentication and authorisation and other confidence building services.
- 9) Computerisation of support processes.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The main output of the implementation of this measure is to interconnect the processes of Ministry of Health with processes imposed in public administration.

Indicators of this measure are:

- The creation of role and Institute of **Chief Architect of eHealth**, which will promote the development of new IT services in accordance with legislation and ensure consistency of the processes and implemented projects
- Processing of **Enterprise Architecture of eHealth** in accordance with the methodology of eGovernment services making and methodology issued by the MoH. This architecture will ensure compliance and consistency of services and processes created with the above principles.

D. Description of the steps leading to the fulfilment of the measure

Fulfilment of the measure will be done in the following steps:

- creation of an institute of Chief Architect and processing of Enterprise Architecture of eHealth
- promotion of the creation of new information systems and, in particular, the creation of development concepts of ICT services in the healthcare sector.

E. Major barriers and risks

The main barrier is the difficulty to enforce coordinated process of computerisation, where the management organization of the sector is not ready to build ICT systems to create architecture and expend sufficient resources to support ICT systems. An example is underfunded hospital information systems, which are mostly technologically obsolete, management of the hospitals often wants to replace them modern solutions that are on not available on the market. Internationally used systems are not offered in localized form, foreign vendors offer comprehensive enterprise solutions, which are significantly more expensive than the national market is ready to accept.

The risk is long-term absence of coordination of computerisation of healthcare in the country. Another risk may be exaggerated and insensitive efforts to implement agenda where it is possible to use simpler and less formal procedures which do not increase administrative complexity.

Measure 4.1.4 Authorisation, authentication and management of providers' authorisations

The complexity of health systems is determined by the need to protect sensitive data and by the need for controlled, fast and secure way of providing them to authorised persons.

A. Background and requirements for the measure implementation

Currently there is no unified authentication service that would allow access to authorised persons of who provide healthcare to the electronic health.

It is therefore necessary to provide clear and reliable identification of all entities and safe and transparent management of access to data and services of electronic health, the so-called authentication and authorisation, and implement the associated system of identity management and permissions.

There are some partial solutions, which currently provide authentication of authorised persons, including health professionals, in particular:

- Authentication Service for access to health, hygienic and other registers,
- authentication service to access the ePrescription service,
- authentication services of health insurance companies.

These systems are mutually incompatible, and none of the existing solutions currently meets the requirements of eGovernment and does not meet the needs of electronic health.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The strategy in the areas of authentication and authorisation of health workers and healthcare providers is based on the following main principles:

Authentication principles:

- **use of existing resources** – if the entity already has a satisfactory means of authentication it should not be forced to use another one,
- **recognition means eGovernment** – it is necessary to accept public means introduced in legislation of eGovernment,
- **sufficient level of assurance and credibility** – a means of authentication, its issuance and administration of the conditions fulfil given conditions , namely the determined level of guarantees,
- **party autonomy in private law** – medical worker has the opportunity to use different convenient means of authentication than a private person.

Principles of authorisation:

- **full access to information** – Systems must not hinder legitimate users' chance to use the services and data that affect the quality of health services, to the extent specified by the law and by wishes of the patient, see description Measure 4.1.5 Management of approvals and accesses .
- **auditability of user activity** – systems record the activity of users with services and information, the records are made available to the owners of the data.

The requirements in the areas of authentication and authorisation can be summed up in two areas:

- ensuring simple, affordable, yet reliable and robust method of user authentication system
- Securing control of access to data and electronic health services.

Strategies in the areas of authentication of health professionals and authorised health providers is to prefer the authentication services of eGovernment, especially through services of **the National Identity Authority** (hereinafter also referred to as "NIA"). It is assumed that under the NIA, the following ways will be used to log in:

- login using EOP CR (electronic identity card) by NIA,
- login authentication data via data boxes through the NIA,
- Login using private provider of identification and authentication services through the NIA,
- login using external means of electronic identification in accordance with eIDAS mediated by NIA.

As alternatives to authentication and identification of medical personnel and authorised persons, healthcare providers will use the services of **Information and Data departmental interface 2.1.3v** within which identity space of MoH will operate.

A healthcare worker can therefore make use of authentication means of eGovernment (eOP Data Box, eIDAS), as an alternative they can use departmental authentication service, which will allow multi-factor authentication (OTP, smart card, SMS, etc.).

Area of authentication of users for accessing electronic health, including support for authorisation will be provided by Information and data departmental interface built by the state.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The main outcome of the implementation of the measure is to **create spaces of identity and authentication services for healthcare professionals and authorised healthcare providers** for access to electronic health services mediated by National Identity Authority. If a medical staff employee is not able to use the services of the National Identity Authority, they will use the authorisation service, which on the departmental level will be provided by Information and data departmental interfaces.

In the area of authorisation for services and data, Infrastructure Information and Data departmental interfaces will be used.

Indicators of fulfilment are:

- creation of an acceptable method of authentication for health workers
- the creation of departmental Information and Data Interface for purposes of authentication of healthcare workers.

D. Description of the steps leading to the fulfilment of the measure

The primary task is to create a departmental Information and Data Interface, which will mediate authentication and authorisation services. To fulfil the objectives of the measures it will be necessary to implement the integration of National Identity Authority in cooperation with the MoI.

E. Major barriers and risks

The main risk for the identification and authentication include implementation delays and legislative amendments for the implementation of the National Identity Authority services. This risk can be eliminated by using alternative ways of authentication through Information and Data departmental interface services.

Another risk is the lack of layers of authoritative data on healthcare workers, which is necessary for the implementation of authorisation services.

Measure 4.1.5 Management of approvals and accesses

A. Background and requirements for the measure implementation

Access for authorised persons to shared electronic medical documentation (index of medical documentation, electronic health record), see the description of Measure 2.1.1, will be determined by the security policy of electronic medical documentation, which guarantees authorised users' access to specific parts of electronic medical documentation based on their roles and based on the patient's decision. The active role of the patient is yet a principled basis on which this policy will be built.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Security policy will allow to:

- Registered general practitioner's access to all parts of electronic medical documentation, unless the access is restricted by law,
- access for all the persons entitled by the law,
- access of other entitled persons to medical documentation (or its parts), based on the patient's decision.

The electronic health system will guarantee the following to every citizen, in particular:

- 1) Choice of whether their electronic medical documentation defined by legislation as a whole or just its parts (e.g. an index of medical documentation, electronic health record, just a drug record, etc.), will be kept or not.
- 2) To decide on the access settings of doctors, pharmacists, medical facilities, alternatively, to which category of health workers will be their electronic health information beyond the information defined by the legislation accessible, in different life situations (doctor, emergent components, issuing pharmacist, consultant, etc.).
- 3) Possibility to extend access to your records and personal account beyond the aforementioned regulations at any time, e.g. to the chosen doctor, pharmacist or another person (e.g. a family member). Access can be permanent, one-time or time-limited. Access can be revoked by the patient again.
- 4) Full access for the patient (or his legal representative) to all the data kept on them in the medical documentation, including the ability to export data in the health system in supported formats for their own use.
- 5) Access for the patient (or his legal representative) to audit information on other entities access to their shared electronic medical documentation.

C. Outputs of the measure implementation, indicators of the successful measure implementation

In implementing the above principles, management system of approvals and accesses will be established. The system will be built on the principle of opt-out. This means that it will implicitly presume consent of the patient with the management of all parts of the shared electronic medical documentation, and with the permission of all authorised healthcare providers (e.g. doctors treating them, paramedics in emergency situations, etc.) to access to their electronic medical documentation. Citizens will be allowed in advance of the introduction of shared services of medical documentation, as well as any time in its course, to cancel their consent, or re-enable it.

We assume that the management system of approvals will be used in the context of health systems for the needs of authorised health information systems.

D. Description of the steps leading to the fulfilment of measure

Steps to fulfil the measure will be discussed during project development "Establishment of (safe) infrastructure for health information exchange."

E. Major barriers and risks

As per Measure 4.1.2.

Measure 4.1.6 Easy and accurate patient identification and retrieval of patient data

One of the basic tasks in the provision of health services is the identification of patients. This operation is carried out by healthcare workers in various stages of health service provision. Primary identification is performed by checking the identification document (identity card, passport, but often only the insurance card, which de facto is not an identification document), presented by the patient; secondary identification e.g. by checking of identification bracelet of hospitalized patients or by checking the information contained in the medical documentation .

In the case of certain medical services that are provided remotely, e.g. telephone consultation or other telemedicine services, is the possibility of direct user authentication limited or impossible.

A. Background and requirements for the measure implementation

Simple, straightforward and trustworthy identification of patients, i.e. citizens, and getting verified data about them is essential for the development of electronic health.

In the Czech Republic, there is currently no central, shared, widespread service guaranteed by the state, by means of which the citizen, the patient, the insured could electronically identify themselves. Currently, there are the following services that allow electronic identification of patients, however, they are not available across the board:

- Authentication of citizen through authentication services of the Public Administration Portal, which uses the identity space of data boxes. This service can only be used by the owners of the data boxes
- Authentication of citizen through portals of health insurance companies, which can only be used by registered clients, and only within the services provided by a particular insurance company.

Another starting point for identification and authentication of patient is Regulation of the European Parliament and Council (EU) No. 910/2014 (eIDAS), the implementation of which is the law on electronic signatures. Regulation pays special attention to facilitating secure electronic identification and authentication, which introduces two basic electronic tools:

- systems of electronic identification and authentication - the registration of persons to on-line services,
- services that create trust - applications based on electronic signature.

The requirements for identification and authentication of the patient can be summarized in the following four points:

- provide clear and credible identification of patients,
- ensure a reliable identification of all citizens, including newborns,
- ensure the identification of persons from other EU Member States in accordance with applicable legislation of the EU and non-EU foreigners,
- ensure the existence of alternative solutions for the identification of patients (e.g. the unconscious patient, amnesia patients or patients who are for some other reason unable to prove their identity)

The area of electronic identification and authentication has a major impact on the strategy for identification of patients, citizens and the insured. eIDAS regulation in the field of electronic identification sets out the obligation to recognize some means of electronic identification for access to on-line services provided by the public sector, which were issued in another EU Member State other than that in which the provider of on-line services is established. Authentication services in the Member States of the EU will be created, and the area of electronic health is obliged to recognize and use the these authentication services since September 18, 2018.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

Strategy in the field of identification and authentication of patients based on the following binding principles:

- use of existing resources – if the entity already has a satisfactory means for authentication should not be forced to use another one,
- Recognition of means eGovernment – it is necessary to accept public means introduced in legislation of eGovernment,
- coping with urgent situations – access to essential information from authorised systems without user authentication,
- user choice of means – health services client can use a convenient means at their discretion,
- sufficient level of assurance and credibility – a means of authentication, the issuance and administration meet the conditions, therefore specified level of guaranties.

The clients of health services, i.e. patients, the insured and citizens will be able to make use of the means of authentication included in the National Identity Authority (NIA), which will be operated by the MoI. The possibilities of utilisation of these resources for logging:

- login using eOP CR through the NIA,
- login using DS authentication data via the NIA,
- login using private provider of identification and authentication services through the NIA,
- login using external means of electronic identification in accordance with eIDAS mediated through the NIA.

As an alternative for patient identification and authentication for access to electronic health, it is appropriate to use authentication services provided by health insurance companies.

Consideration will be given to gradual introduction of abstract numbers of the insured as a departmental ID and appropriate measures will be taken.

The identity of the patient will be in all cases checked against central registry of insured persons or again the Citizen register.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The basic outcome of the implementation and the indicators of the measure is **an authentication mechanism** for a client of health services (patient, insured person, citizen), which can be used to access electronic health.

D. Description of the steps leading to the fulfilment of measure

Basic prerequisite is the implementation of Information and Data departmental interface that provides authentication services for clients of health services. To enable authentication by means of eGovernment it is necessary to implement, in cooperation with the MoI, integration of National Identity Authority. To enable alternative authentication of clients of health services it is necessary to integrate authentication services of health insurance company.

E. Major barriers and risks

Currently, the main barriers are the capacity of the MoH, which is essential to achieve this task, and the absence of the National Centre for Electronic Healthcare System, which would coordinate this activity.

4.4.2 Specific Objective 4.2 Standards and Interoperability



Standards and interoperability

1. *Clinical terminology and classification*
2. *Interoperability and data structures*
3. *Access to data and EHR/EMR/PHR*

A. Background and requirements for the implementation of the specific objective

Electronic health is not only medical, but also societal phenomenon that is able to help not only effective collaboration between care providers, but also contribute significantly to the changing role of the patient in the system and to position them at the centre of the system. In order for this cooperation to function, health workers must be able to work together, and above all, understand one another. In the area of electronic health, interoperable information systems can help with this new way of understanding.

Background

Interoperability of information systems is generally achieved through standardisation of data content, data interfaces, standardisation of processes and scenarios. To ensure precise meaning of the transmitted data into semantically distant surroundings (e.g. from a hospital to another hospital or in cross-border care), it is also necessary to harmonize clinical terminology.

In the Czech Republic data communication in health care is provided mainly through the national data standard (DASTA CZ), developed under the auspices of MoH and under the guarantee of the Czech Society of Medical Informatics and Scientific Information CzMA.¹⁹ It can be stated that most of today's electronic data interchange in health care is implemented using this standard. Current status in the field of global data standards and terminology is not fully harmonized and their national implementation will necessarily require their clarification and harmonization for local needs (the so-called localisation). Among foreign standards, which are penetrating the domestic market, especially with the supply of medical equipment and related information subsystems, are the most widely used DICOM HL7 v2 and in new implementations on group level of providers or regional level selected profiles of IHE are promoted.

Requirements for implementation

Standards ensuring mutual understanding of the clinical content of communication have to be not only suitably chosen, but also maintained and systematically developed in the long term, as the need of users to communicate grows and as the knowledge in medicine deepens. The process of

¹⁹ Standard DASTA in the CR is developed and used by healthcare information systems for more than 20 years.

harmonization of terminology, data interfaces and protocols is therefore never ending process, which must be systematically supported.

The freedom of patient regarding the choice of technical means by which information about their health is kept and possibly shared must be preserved as much as possible. The state's role will mainly consist of determining and enforcing the communicational, technological and safety standards in the area of medical documentation and health records.

National and cross-border interoperability can be achieved only through deliberate and systematic implementation of appropriate standards and therefore **national standardisation framework will be built.**

B. The impacts of the implementation of the individual measures on the specific objective

The main advantage of the national standards in comparison with global standards, is its flexibility and broad support for all critical information systems. On the other hand, problems arise when providing technical cooperation with other systems that deliver or utilize existing health information and that are equipped with interface according to international standards. The number of these devices with the development of instrumentation and information technology grows; historically it showed to a greater extent in the Czech Republic when interconnecting the hospital information system, PACS (Picture Archiving and Communication System). In addition to international commitments in the field of standardisation (i.e. the replacement of national standards, international standards) and promotion of a common EU market and rising demand for cross-border cooperation in health information systems, we lose the possibility to utilize the knowledge and experience contained in the global standards by keeping incompatible national technical regulation .

It is therefore evident that the use of global standards in the long term (5-10 years or more) is more necessary and advantageous than the separate development of national standards. However, when considering the optimal selection of standards, the existing standards can not be ignored, nor the time and financial demands on locating alternative standards.

C. Outputs and indicators of achieving the specific objective

- 1) Building of National Interoperability Framework.
- 2) Implementation of a standardisation framework (institutional and procedural securing and the adoption and development of interoperable standards in health care).
 - a. processing and maintaining a system of standards for various areas of application of information and communication technologies in healthcare,
 - b. development of the concept of transition to international standards,
 - c. maintenance of existing national standards where necessary,
 - d. acceptance or gradual convergence of national and selected European and global standards, while respecting the development of this area in the EU member countries,
 - e. creation of terminological services for management, change management and mutual mapping of used classifications and terminology,
 - f. creation of national metamodels, and of conceptual and information models
 - g. creation of national systems for a formalized knowledge management.
- 3) Identification of appropriate global standards to ensure interoperability across borders (with neighbouring countries).
- 4) Localisation of the chosen standards.
- 5) Implementation of transfer bridges between national and global standards.
- 6) Progressive ending of further development of the national standard.

D. Major barriers and risks

The risk is a generally reduced need to follow the standards and participate in standardisation activities because of the long-term neglected state of standardisation in medical of the Czech Republic, up to the level of university education.

Another risk includes a possible pressure on the adoption of fast, linear and non-system solutions because of the absence of a long-term plan in the national and international standardisation of medical informatics.

The barrier shall be a slow adoption of new standards, processes and interoperability due to a slow recovery of instrumentation and software in the health system.

The risk is also the incorrect understanding and implementation of the functions of the standard which would lead to the rejection of the entire solution by users.

Measure 4.2.1 Clinical terminology and classification

A. Backgrounds and requirements for the implementation of the measure

Semantic interoperability can be defined primarily as the ability of two entities (people or information systems) to communicate in such a way to preserve the original (clinical) meaning of the communication. This can be partially achieved through the harmonisation of clinical language (use of abbreviations, reduction in terminological variability, introduction of rules for the method of writing laboratory results, clinical knowledge formalisation, etc.). But the problem of understanding between linguistically different areas given by the limits of information systems shall still remain unresolved. These are still not able to fully understand the non-formalised clinical text, translate it into other languages and further process it in the automated way (classify, aggregate information and possibly draw conclusions to support decision-making).

Therefore, the national and international **classification and terminology systems** have been developed – some of them (e.g. International Statistical Classification of Diseases and Related Health Problems, National Register of Laboratory Items) have been commonly used in the Czech Republic for already a number of years and are part of the majority of healthcare information systems.

Classification Systems (MKN 10, MKN-O, TNM, ATC, ICD-10-PCS and many others) are intended primarily for statistical or administrative inclusion of monitored characteristics into categories. So-called clinical terminologies and ontological systems are used for a detailed description of a clinical state – the SNOMED CT System²⁰ (Systematised Nomenclature of Medicine – Clinical Terms) is the best known and most widely used.

Therefore, besides the comprehensive clinical terminology, semantic interoperability over the data model may also be ensured by using generally known (shared), classification systems and enumerations. For these classifications, a central terminological service should exist, which publishes classifications, their unequivocal identification, supports mapping between individual classifications,

²⁰ SNOMED CT is a systematically organized, machine processable dictionary of medical terms. The SNOMED CT System terminology contains not only codes for individual terms, but also synonyms and definitions for the use in clinical practice, description of relationships between terms and a number of other attributes. The terms from all major areas of healthcare (diagnoses, symptoms, examinations, interventions, drugs and material terms from the area of organisation of healthcare, public health, etc.) are included. Currently, SNOMED CT is considered as the most complete, clinically validated, multilingual medical terminological system in the world.

controlled (and acceptable in terms of implementation) development (with regard to older data stored in health information systems).

Terminology and classification systems need to have certain quality, in particular, they need to be clear, hierarchically structured and thus suitable for analytical purposes.

The area of **administration and representation of (not only clinical) knowledge (metadata repository)** is the last area required for ensuring electronic healthcare. The ability to understand rests not only in the knowledge of words and phrases (i.e. the used terminology and data sentences), but primarily in the common knowledge of their meaning. This can be created and shared via a variety of means, e.g. using common textbooks, encyclopaedias, dictionaries, educational websites, etc. In all cases, however, it is appropriate to store the knowledge via a system that is general, transferable and in a method that can be used again.

B. Description of the implemented measure and the benefits and impacts of the implementation of the measure

Within the measure, the following shall be implemented:

- 1) Systematic support of science, research and innovations in the field of terminology (creation of mapping algorithms, creation of qualitative methodologies, creating new terminologies, adaptation of knowledge representation, etc.).
- 2) Creation of a national framework for the management and development of medical classifications and terminologies.
- 3) Establishment of a central terminological service providing change management, publishing and mapping terminologies and classifications.
- 4) Selection of an appropriate system for knowledge management
- 5) Establishment of a central service for managing clinical and technical (information) knowledge
- 6) Selection of a set of terminologies and classifications for the use in various domains and sectors (medical care, rehabilitation care, palliative care, aftercare, laboratory medicine, reporting etc.).
- 7) Conduction of localisation/internationalisation and mapping classifications and terminologies in the international SNOMED CT System.

C. Outputs of the implementation of the measure, indicators of a successful implementation of the measure

- all used registers, terminologies, classifications are published in Czech and in substantiated cases (e.g. clinical) at least in English,
- all registers, terminologies and classifications are issued according to the rules of the national framework (the change proceedings is conducted)
- available mapping between issued registers, terminologies and classifications is routinely used in information systems,
- controlled terminology demonstrably facilitates re-usability of stored data (in research, quality management, etc.),
- in this area scientific and research activities are developed.

D. Description of the steps leading to the fulfilment of the measure

The individual steps are described in Part B.

E. Major barriers and risks

The risks are identical to the risks set out in Chapter 4.4.2. Part C.

Measure 4.2.2 Interoperability and data structures

A. Backgrounds and requirements for the implementation of the measure

A data protocol between particular communicating systems needs to be completely defined for the implementation of semantic interoperability. The full definition of the protocol always includes:

- domain description / reasons of communication,
- description of individual actors – application roles and their responsibility,
- Communication scenario, structure of transmitted information,
- data representation and
- syntax.

This definition shall always gradually expand according to the needs of communicating parties.

Like in clinical terminologies and classifications, also in the area of data and data structures, we need to proceed systematically and with consideration. Therefore, also individual measures shall have a similar character and shall aim at creating a systematic framework for the management and development of data standards and knowledge.

B. Description of the implemented measure and the benefits and impacts of measure implementation

Within this measure, we shall implement the following:

- 1) Institutional support of harmonisation, specialisation and further development of national and international data protocols (urgent dataset, e- Prescription, discharge reports, laboratory reports, imaging examination, e-Request form ...) created in order to:
 - create reference information and technological models and meta-models,
 - create metadata repository and publish data therein in the appropriate way,
 - create transfer mechanisms between national and international data sets to support cross-border interoperability,
 - describe methods of using standards for specific cases (so-called implementation guides) and describe communication scenarios, use IHE profiles,
 - specify data interfaces and minimum content and functional requirements for health information systems.
- 2) A system of certification of health information systems introduced.
- 3) Science, research and innovation in the field of development of interoperable solutions (new domains, critical evaluation, comparison, mapping) supported systematically.

C. Outputs of measure implementation, indicators of the successful measure implementation

The outputs and also the indicators of achieving the measure are as follows:

- 1) Common practice in the development of standards shall include at least:
 - analysis of user needs,
 - separate views: Information (technological agnostic), Computing and Technological (the so-called Generic Component Model (2)),
 - complexity management (generalisation/specification): restrictions are applied to the general standard that define the national context. Even that leaves a free hand for the application of additional (stringent criteria) for local implementation,
 - reference model for consistent development, harmonisation and generalisation,
 - universal meta-language for describing the protocol,
 - complex data types (elevate the level of abstraction).
- 2) Most systems in use shall pass certification.
- 3) In that area, scientific and research activities shall be developed.

D. Description of the steps leading to the fulfilment of the measure

The individual steps leading to the fulfilment of the measure are stated in Part B above.

E. Major barriers and risks

The risks are identical to the risks set out in Chapter 4.4.2. Part C.

Measure 4.2.3 Data and EHR/EMR/PHR access

A. Backgrounds and requirements for the measure implementation

When managing medical data, the principle of privacy protection of both the patient and physician needs to be respected (most frequently mentioned concerns about the implementation of eHealth). Therefore, the access to data needs to be not only secured and audited, but both the patient and physician needs to have their data under maximum control.

Therefore, the patient should have a possibility to decide whether the index of his/her medical documentation is kept and whether, by whom, and to which extent, his/her electronic medical record is kept. And also, who shall have access to it and in which situations and whether it shall be possible to provide his/her medical records within cross-border healthcare.²¹

Similarly, the physician needs be able to check whether the information provided by him/her was made available only to authorised persons and in accordance with the security policy of the system of sharing of medical documentation and medical records and he/she also needs to be sure that the provided data cannot be modified without his/her awareness.

To ensure privacy protection and access control, adequate infrastructure needs to exist. The **concept of an independent bank of medical records**²² seems to be appropriate. This concept allows the patient to choose the manager of his/her data. This entity then provides and archives data in accordance with the law and with patient's preferences and is fully responsible for ensuring all the parameters mentioned above.

Minimum functionality of the EHR/PCEHR systems needs to be defined at the process, user level as well as at the semantic and data level. This definition should again be based on the international knowledge (EuroREC, openEHR, HL7 EHR/PHR functional models, data standards) and best practice. State guarantees are required, primarily due to the concerns about ensuring general security in the system.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The measure shall be implemented in the following steps:

- 1) Institutional security of standards development in the area of EHR and data access management (management of policies of sharing electronic medical records) shall be created
- 2) Standards for the method of management and the minimum content of the shared medical record (EHR, PCEHR) shall be specified.
- 3) Other functional, process, technical and security requirements for the system management and administration of the shared medical record (medical records bank) shall be specified.
- 4) Policies of data access management within electronic healthcare and especially a shared medical record shall be specified.
- 5) Science, research and innovation in the development of the concept of EHR or PCEHR and systems of independent medical records banks shall be supported systematically (additional

²¹ see also Measure 2.1.1.

²² see Measure 2.1.1 and also Methods of Information in Medicine 2014, Vol 53:
<http://methods.schattauer.de/en/contents/archivestandard/issue/1849.html>

functionality, data mining method for clinical studies, definition of additional data interfaces, etc.).

In addition, science, research and innovation primarily in the development of the concept of EHR or PCEHR and systems of independent medical records banks shall be supported systematically (additional functionality, data mining method for clinical studies, definition of additional data interfaces, etc.).

C. Outputs of the measure implementation, indicators of the successful measure implementation

Outputs of the achievements are as follows:

- 1) Professional and general public accepted the system of information access management to be credible.
- 2) In this area, scientific and research activities shall be developed.

Indicators shall be specified when drawing up the implementation plan of Specific Objective 2.4.

D. Description of the steps leading to the fulfilment of the measure

The individual steps leading to the fulfilment of the measure are stated in Part B above.

E. Major barriers and risks

The risks are identical to the risks set out in Chapter 4.4.2. Part C.

4.4.3 Specific Objective 4.3 Electronic healthcare management



Electronic healthcare management

1. *Management, policies and strategies of electronic healthcare*
2. *Legislative and regulatory framework*
3. *Privacy, quality policy and safety protection*
4. *Cooperation of involved parties at the national and EU level*

A. Background and requirements for the specific objective implementation

The state's role in defining the strategy and priorities of electronic healthcare, and particularly in coordinating its development, is indispensable. The state is not able to meet this role in the long term, especially due to the absence of necessary professional capacities and professional experience in the field of ICT governance. Proven models of long-term development of the national electronic healthcare are usually based on the existence of a specialized centre with a long-term assignment, which is responsible for the preparation of concepts, solution architecture and material implementation of the strategy adopted by the governing bodies in the form of individual projects. The involvement of wider specialist scientific, academic, professional and industrial capacities, non-profit companies and initiatives is the integral part of the process of concept and architecture creation. Without the fulfilment of this conceptual and coordinating role, the additional development

Currently, in the Czech Republic, there is no expert authority capable to provide a continuous development of the concept of electronic healthcare, creation and management of its architecture, project preparation in accordance with the concept and priorities of the Czech Republic in the area of computerisation of state administration and guarantee of a reliable operation of the Electronic Healthcare System.

of the National Electronic Healthcare System is not possible.

This fact jeopardises the fulfilment in the following areas:

- failure to meet the commitments of Action Plan No. 11 Computerisation of the National Health Strategy 2020 – in the National Health Strategy 2020
- infeasible National Electron Health Strategy and long-term concept of the state in the field of health computerisation,
- discrediting the Ministry of Health as a guarantor of the development of efficient health system through computerisation,
- incompetent (without a possibility to access consequences) approving applications for funding individual ICT projects directly managed by the organizations in the ministry,
- uncontrolled development of computerisation leading to inefficient spending funds on individual ICT projects – individual systems cannot respect the rules of interoperability, if they do not exist,
- achievement of the set strategic objectives of the National Electronic Healthcare Strategy,
- insufficient coordination with the development of eGovernment and the non-use of invested and functional services of public administration.

This shall result, apart others, in continued backwardness of the Czech Republic in the development of computerisation and failure to meet the commitments of interoperability with other EU countries.

B. The impacts of the implementation of individual measures on the specific objective.

In the previous part A, the negative impacts that we need to face are described. In the following specific measures, the specific outputs that shall prevent negative measures are specified.

C. Outputs and indicators of achieving the specific goal

The indicator is consistent with the indicator of the strategic objective.

D. Major barriers and risks

The main barrier is the provision of adequate resources necessary to ensure electronic healthcare management. The risk is primarily a need to create a body or institution of the National Centre for Electronic Healthcare so as to have all necessary competences, sufficient autonomy and authority, clearly defined tasks, budget and wages attractive enough to be able to ensure necessary experts. A person responsible for failure, i.e. a healthcare professional, healthcare provider or any other entities, shall be determined for each electronic health service.

Measure 4.3.1 Management, policies and strategies of electronic healthcare

A. Backgrounds and requirements for the measure implementation

The existing electronic healthcare development confirmed that while the level of individual information systems is well developed, in the areas surpassing information needs of individual entities, a coordinating role of the state is required and you cannot rely only on the power of the market and information systems supplier. This concerns mainly the areas of conceptual securing the national and multinational interoperability (standards) and certain necessary infrastructure components (e.g. basic registers and the secured communication environment). In these areas, the state remains logically irreplaceable and is the one that should determine and guarantee the rules of the game (through legislation and inspection activities, codification of quality standards and methodologies and support of training of health professionals).

The role of the state in defining the concept and priorities of electronic healthcare is also irreplaceable and the state needs to fulfil this role in the long term, including ensuring coordination with other components of the state, local governments and international cooperation at the highest level. Without fulfilling this conceptual and coordinating role, the additional development of the National System for Electronic Healthcare is not possible.

On the other hand, the possibilities of the Ministry of Health of the Czech Republic, moreover acting in the regime of the civil service, are limited. The evidence can be long-term falling behind the development in the neighbouring countries as well as the current situation in computerisation.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

In order to fulfil this general objective, we need to institutionalise, consolidate and gradually build up necessary organisational structures. The key structures shall include the National Centre for Electronic Healthcare, which shall collaborate with other organisations such as professional organisations forming information base, National Centre for Nomenclatures and Classification, accredited testing and certification bodies for electronic healthcare information systems, regional authorities, directly controlled organisations of the MHCR, MoLSA, CSSA, etc.

The key task is to build a long-term sustainable, professionally independent team of **the National Centre for Electronic Healthcare (NCEH)**, which shall assume overall responsibility for the preparation and building of electronic healthcare. The National Centre for Electronic Health shall

have not only professional competence and responsibility, but also the appropriate power to enforce the fundamental principles of computerisation in accordance with the adopted national strategy.

The main tasks of the National Centre for Electronic Healthcare shall be as follows:

- **Managing and updating the NSEH** (National Strategy for eHealth), and continuous management of the Action Plan of healthcare computerisation, respecting legislative changes, external influences, financial possibilities of the sector and technological progress.
- **Development of the architectural concept of computerisation built on the principles of Enterprise Architecture** (hereinafter also “EA”), which is the basis for the controlled development of computerisation in accordance with the individual objectives of the National Strategy for eHealth .
- **Fulfilling the Health 2020 Strategy in the field of computerisation.**
- **Ensuring communication among involved parties and fulfil the role of the coordinator of electronic healthcare development** at the national level, including ensuring cooperation at the international level.
- **Controlled development of computerisation:**
 - Cooperation in healthcare computerisation projects funded or co-funded from public sources (both national and European). Assessment of projects in terms of compliance with the national concept and established principles of development and utilisation of existing shared services.
 - Assessment of the compliance of the prepared projects with the current legislative requirements or initiating legislative changes necessary to put individual projects to life.
 - Preparing and ensuring the feasibility studies of all aspects of healthcare computerisation.
 - Coordination and management of priorities of the implemented computerisation projects so that they could follow each other and, thus, use the outputs of already completed projects.
 - Coordination of electronic healthcare development from the central level so that the constructed systems and implemented investments would be preserved to a maximum extent. The purpose is to strengthen interoperability, implementation of necessary standards and certifications or another model of verifying information systems compatibility.
 - Creation of new services or the procedural regulation of the existing electronic health services so that the key and state-guaranteed electronic healthcare services would be in line with the defined principles of introducing public administration services and could be developed in line with the development of public administration services. Part of this intention is the integration of selected electronic healthcare services in the eGovernment environment, especially those that have the character of the execution of administrative decisions.
- **Evaluating the ongoing fulfilment of individual objectives of the National Strategy,** monitoring of qualitative and quantitative parameters of performance.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The indicator is consistent with the indicator of the strategic objective.

D. Description of the steps leading to the fulfilment of the measure

The first step is to discuss and approve the organisational security of the NCEH ensuring proper functioning of the electronic healthcare system, including competencies and responsibilities and competencies of the superior strategic body, the working title “the eHealth Council” representing key stakeholders in the health sector.

The second step is the implementation of this centre and the organisation of professional capacities.

The third step is to build a system of interdependence and cooperation of the key organisational units and competence centres and all interested stakeholders so that the preparation and

implementation of the electronic healthcare system would be most transparent and efficient, fully in line with the needs of its users.

E. Major barriers and risks

The risk is an insufficient political support and underestimation of the impact of inactivity.

Measure 4.3.2 Legislative and regulatory framework

A. Backgrounds and requirements for the measure implementation

Implementation of individual objectives and measures of the strategy is often conditioned by the existence of an appropriate legislative framework. Requirements for changing or creating specific legislation shall accompany the whole process of the NEHS implementation. Proposals for changes shall be initiated continuously by the guarantors of individual areas of computerisation and shall be subject to coordination by the Ministry of Health of the Czech Republic.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

The Ministry of Health drew up the first legislative impacts on the implementation of the primary measures. These steps shall include a detail elaboration of necessary legal steps to implement individual specific objectives, including identification of necessary legislative changes at the level of specific provisions of individual legal regulations.

During the implementation of individual specific objectives and implementation plans, the Ministry of Health of the Czech Republic also expects the necessity to implement public tenders, preparation, negotiation and conclusion of contracts with suppliers of information and communication technologies and other partners involved in these projects, performing impact assessments on personal data processing (data processing Impact assessment), identification of necessary measures such as ensuring consents of data entities and other expert support in healthcare , IT/ICT and personal data protection. Therefore, among others, for the purposes described above, the Ministry of Health of the Czech Republic shall inquire highly specialized consulting services particularly in healthcare, IT/ICT and personal data protection, especially in relation to the contracting authority's projects in the field of computerisation of health and setting the legislative framework for healthcare computerisation in the Czech Republic in connection with the projects at the level of the European Union.

When creating a legislative framework of the strategy, the following steps shall be taken:

- The legal regulation of the electronic prescription in Act No. 378/2007 Coll., on Pharmaceuticals, as amended, shall be amended so that it would be possible to implement a full-fledged electronic prescription system, including a long-term record of electronic prescriptions and additional functions (see Measure 2.1.2. Electronic and effective prescription). Under this amendment, the condition of mandatory electronic prescription shall be taken into account, which are:
 - building and putting necessary electronic health infrastructure into operation and ensuring a uniform identical space of the sector,
 - simple and secure identification of the users of the electronic prescription system,
 - possibility to prescribe medication, whenever the patient's interest shall require so (e.g. even outside the surgery)
 - creation of an incentive programme for the use of electronic healthcare tools (incl. the electronic prescription system) for pharmacies and physicians,
 - adopting measures to ensure the availability of technical infrastructure and adding exceptions for the situations where the availability of infrastructure is not objectively achievable,

- sufficient verification of the functionality of the system via pilot operation, embedding an electronic record of the prescription and a possibility of making it available on the basis of the patient's consent. (For a detailed and accurate description of the conditions, see Measure 2.1.2. Electronic and effective prescription).
- A guarantor and administrator of the electronic prescription system shall be identified. The competences in the area of management and operation shall be defined for the system administrator, while respecting the principles construction principles of the departmental systems of the Ministry of Health. Legislation shall in a technologically neutral way set system target parameters without the ties to specific technical solutions and shall clearly regulate the rights and obligations of individual participant of the electronic prescription system.
- The **legal regulation of keeping medical records** shall be amended in Act No. 372/2011 Coll., on Health Services and the Terms and Conditions of their Provision (the Health Services Act), as amended, and in Decree No. 98/2012 Coll., on Medical Documentation, as amended, so as to enable effective keeping medical records in the electronic form without concurrent keeping document records. Concurrently, the requirements for the systems of keeping electronic medical documentation shall be amended in detail in order to strengthen the protection of the privacy of affected persons and enhance credibility of electronically generated records.
- A comprehensive **legal regulation of sharing medical documentation** shall be created, including a legal regulation of the index of medical documentation and electronic medical record and its patient part. The rights and obligations associated with the transferring and inspecting the shared medical documentation shall be defined, including safety requirements for the operation of the systems for sharing documentation, indexing documentation and keeping the electronic medical record. Also the entities responsible for sharing and the power of the elected body to determine in a binding manner a minimum radius of the mandatory implemented standards and formats for the exchange of medical records shall be determined. This legislative regulation shall respect the principle of voluntary participation in the system and shall take the patient's maximum freedom of choice and privacy protection into account. At the same time, the relations to the adjustment of the health insurance and health insurance companies shall be modified due to the interconnectedness of the records on provided care with the reimbursement and cost registration system.
- The National System for Electronic Healthcare shall prepare **the opinions clarifying the impact of the legal regulation on the area of telemedicine and mHealth** to increase legal certainty of involved entities in this sector. In particular, the impact of legal regulations of liability for defects and failures of telemedicine and mHealth tools, the impact of legal regulation of medical devices and the impacts of legal regulation of providing healthcare services for the purposes of telemedicine shall be analysed, discussed with the experts and explained.
- **Basic electronic healthcare infrastructure**, including identical space and including administrative and statistical registers shall be governed by legislation in detail. This legal regulation shall replace the existing regulation of the National Healthcare Information System in Section 70 *et seq.* of Act No. 372/2011 Coll., on Health Services, which was criticised by the Office for Personal Data Protection and was accepted only under the condition of its temporariness. New legislation shall be based on the maximum respect for the privacy of persons involved and reflection of their rights under European Parliament and Council Regulation 2016/679, general regulation on the protection of personal data and shall enable processing personal data only to the necessary extent. Electronic healthcare infrastructure shall be legislatively linked with the eGovernment systems, especially with basic registers pursuant to Act No. 111/2009 Coll., on Basic Registers, as amended and shall be built in accordance with the principles of Act No. 365/2000 Coll., on Public Administration Information Systems and the Principles of Enterprise Architecture of the Ministry of Health. In the area of identification of patients, health professionals and other entities, the electronic

identification means shall be used at maximum in accordance with European Parliament and Council Regulation No. 910/2014, on Electronic Identification and Confidence Building Services, while respecting the rights of persons involved to choose the identification means and privacy protection.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The institutional electronic healthcare structure
in the form of legal constitution of

the National Centre for Electronic Healthcare and
determination of its competencies shall be enacted.

With regard to the complexity of the expected legislative changes and the need for the institutional anchoring of the electronic healthcare administration, in addition to the urgently needed partial amendments to Act No. 378/2007 Coll., on Pharmaceuticals and Act No. 372/2011 Coll., on Health Services, a bill on electronic health shall be prepared, which shall regulate the key elements of electronic healthcare of general importance, shall take into account the issue of cybernetic security and personal data protection. The exceptions to these general legal regulations shall be clearly defined and justified and the law shall be built on the principles of optionality and limitedness to the registered consents of the persons involved.

D. Description of the steps leading to the fulfilment of the measure

The individual steps are described in Part B.

E. Major barriers and risks

The risk is insufficiently strong political support, which shall be necessary to consolidate the legislative environment and undergo a complex legislative procedure.

Measure 4.3.3 Privacy, quality policy and safety protection

A. Backgrounds and requirements for the measure implementation

Privacy freely refers to the personal sphere of the human life that cannot be intervened without his/her consent. A sense of privacy extends much farther than the Act on Personal Data Protection stipulates, especially, due to the reason that what is considered private varies according to the nature of the individual, his/her historical experience, cultural belonging and is the result of an immediate and unrepeatable decision. The right for privacy is embodied in the Civil Code as well as in the Charter of Fundamental Rights and Freedoms.

Data general digitisation, data aggregation and administration centralisation in general may interfere the above stated right of individuals or healthcare providers to protect their privacy. All the more it is necessary that the electronic healthcare concept would respect privacy sensitively to the maximum extent and would not jeopardise the adoption of the whole concept both at the level of OPDP and at the level of professional medical and patient public.

Electronic health shall respect to the maximum extent those principles which do not disturb the sense of privacy of the patient:

- sharing information on a voluntary basis,
- support of very fine (but comfortable) data access control,
- choice of the operator and manager of data storage of sensitive data,
- minimising compulsory centralized (non-anonymous) administrations,
- the possibility of voluntary participation in a non-anonymous administrations,
- at least an audit record in the cases when the privacy is broken by law.

At healthcare services providers, this shall include primarily the following principles:

- minimizing compulsory administrations,
- support of very fine (but comfortable) control of data access to documents, including the possibility of allowing access after a phone contact,
- possibility of gradual formation and expansion of the confidence zone (I -> patient -> specialist),
- automation and minimisation of the administrative burden of providers when fulfilling information and statistical obligations,
- possibility of voluntary participation in non-anonymous administrations,
- at least an audit record in all cases of the access to provider's shared data.

From the users' perspective, the predictable behaviour of systems, systems security against unwarranted interferences at both the physical and logical level, is a necessary prerequisite for maintaining a sense of privacy. In general, when designing and managing, you can apply techniques similar to the techniques of other information systems of state administration with regard to the nature of managed (sensitive) data.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

- 1) To build a concept and overall architecture of the Electronic Healthcare System and prepare binding quality and safety system policies so that the principles of maintaining the safety and

security of sensitive data and privacy of all the users of the system would be guaranteed to the maximum possible extent.

- 2) Include the requirements for compatibility of individual systems within electronic healthcare with the adopted policies and principles in the acceptance proceedings of each electronic healthcare component and ensure that they would become part of the certification requirements for information systems.

C. Outputs of the measure implementation, indicators of the successful measure implementation

An indicator of this measure is to create quality and safety policy and its integration into the computerisation control system.

D. Description of the steps leading to the fulfilment of the measure

The individual steps are described in Part B.

E. Major barriers and risks

The risk is an incorrect application of privacy protection stipulated in healthcare legislation.

Measure 4.3.4 Collaboration of stakeholders at the national and EU level

A. Backgrounds and requirements for the measure implementation

Cooperation of all stakeholders at the national level, particularly the involvement of the experts, suppliers, state administration and local governments and public participation is a necessary prerequisite for a transparent method of creating and implementing the National Strategy for eHealth .

Formal cooperation, exchange of information and experience in the field of electronic healthcare at the EU level was enacted by the adoption of Directive No. 2011/24/EU on the Application of Patients' Rights in Cross-border Healthcare. The Czech Republic fully transposed the directive by Act No. 372/2011 Coll., on Health Services and Terms and Conditions of their Provision (the Health Services Act) as of 28/04/2014. The amendment to Act No. 48/1997 Coll., on Public Health Insurance and Amending and Supplementing Some Related Laws, as amended, and certain other laws is another transposing regulation The directive assigns to the Commission to encourage Member States to cooperate when providing cross-border healthcare in the border regions.

The multinational organisations such as the WHO, OECD, ITU or the ECDC are also engaged in health computerisation in a considerable extent, both in formulating principles and recommendations for the development and implementation of electronic healthcare strategies and in accessing the achieved level and, last but not least, electronic healthcare services participate in solving common themes of the member states, e.g. in addressing cross-border threats of infectious diseases.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

There are many potential benefits of cross-border cooperation, particularly, a larger choice for patients, improvement of specialist training for health care providers, greater mobility of both patients and health professionals, reduction of waiting lists, enhancing quality, efficiency or a faster medical emergency in geographically contiguous regions.

On the basis of Article 14 of Directive No. 2011/24/EU, the European eHealth Network (eHealth Network – hereinafter also referred to as “EHN”) was established as a voluntary network connecting national authorities responsible for electronic healthcare.

The implemented measures shall include:

- 1) Active participation of strategic initiatives at the appropriate political and expert level within EHN and other similar initiatives of the EU and supranational organisations.
- 2) Creating necessary prerequisites (budgetary, material, personnel) for the active involvement of Czech experts and institutions into European projects in the field of eHealth, especially in the areas of development of cross-border interoperability and cooperation and coordination of these activities through the National Centre for Electronic Healthcare.
- 3) Identifying and creating conditions for active grasping and managing one or two international strategic initiatives relevant for other EU countries. Enabling shifting a role of a passive participant in a role that influences, helps to create and in some cases also manages electronic healthcare innovations in the EU.

C. Outputs of the measure implementation, indicators of the successful measure implementation

The EHN network represents the main control and coordination mechanism at the high level in eHealth issues within the EU and is composed of competent authorities of the EU member states responsible for eHealth. The Czech Republic participates at the level of the deputy of the minister of health. Within the eHealth Network, mainly **national and international interoperability** shall be supported. The guidelines on the list of patients’ minimum medical records to be shared within cross-border interoperability are the first step towards creating common interoperability frameworks. We may observe that the Commission in cooperation with the member states encourages interoperability because just interoperability shall allow the exchange of electronic medical records, starting with summary data and electronic prescriptions of patients, in accordance with the requirements in the area of mobility of EU citizens and their personal data. This would provide new opportunities for the expansion of digital systems and it would encourage the implementation and adoption of solutions consisting of electronic healthcare on a large scale. The involvement of a wide range of stakeholders, strong participation of end users and open international cooperation are the essential factors of the success.

The indicator shall be specified in drawing up the implementation plan.

D. Description of the steps leading to the fulfilment of the measure

The individual steps are described in section B above and shall be further elaborated during the preparation of the implementation plan.

E. Major barriers and risks

The key barriers and risks are finding an optimal way to institutionalise development of computerisation; implementation of legislative changes, which shall enable creating the necessary information infrastructure of electronic computerisation, implementation of computerisation projects and their continual development in the proposed target range; timely allocation of sufficient funds for implementation of projects defined under the Set of Objectives of the National Strategy for eHealth ; shortage of qualified employees in public administration needed to ensure the implementation of the project; effective redistribution of benefits among electronic health users in order to ensure their sustainability.

Another barrier is a limited access to effective cross-border cooperation caused by many obstacles, such as legal regulatory incompatibility, lack of follow-up treatment and the absence of a legal basis for entities engaged in cross-border healthcare.

Measure 4.3.5 Promoting the adoption and use of standards

A. Backgrounds and requirements for the measure implementation

When ensuring interoperability of information systems within electronic healthcare, different types of standards shall play a key role. Irrespective of whether these are national or international standards, their open and systematic development or localisation and long-term development need to be ensured, according to how the health and information environment and the needs of users of these standards shall change. The choice itself and the development of standards, however, are not a sufficient step, if we do not ensure their consistent application by users and support in information systems.

It is therefore necessary to ensure that both the life cycle of standards and inspecting and enforcing standards into practice shall take place.



Figure 2 Change of the standard



Figure 3 Life cycle of standards and processes of their administration and enforcement

Preference shall be given to open standards, which represent the lowest dependence on specific technology or a supplier and stimulate the competition of the solution, not the standards themselves. An open standard (in the sense of international understanding of openness) needs to meet the following requirements²³ :

- specification of the standard needs to be publicly available either free or just for an administrative fee,
- the standard needs to be owned and managed by an official national or international standardisation institution, consortium or an open group (standard may not to be owned and controlled only by a single entity),

²³ CERRI, D., Fuggetta, A. Open standards, open formats, and open source. In J Systems Softw 2007;80(11):1930-1937.

- management of the standard needs to be transparent and open – anyone must have the right to participate in standardisation. Decisions needs to be made transparently and consensually,
- possibility to implement the standard without a license and other charges. Patents, if they are part of the standard, need to be provided free of charge,
- the standard needs to allow expansion and reuse within other open standards.

B. Description of the implemented measure and the benefits and impacts of the measure implementation

- 1) To ensure the creation of a competence centre for the management and development of standards for electronic healthcare needs with the objective to:
 - ensure systematic selection and development of open national and international standards,
 - ensure the full life cycle of standards.
- 2) Ensure harmonisation of standards between domains.
- 3) Classify standards and determine the obligatory extent of their use.
- 4) Ensure audit and enforcement of using mandatory standards within accreditation activities, certifications of software components via promoting motivational tools and inspecting the method of their use.

C. Outputs of measure implementation, indicators of successful implementation of the measure

Creation of a competent centre for the management and development of standards is an indicator of achievement.

D. Description of the steps leading to the fulfilment of the measure

|The steps leading to the fulfilment of the measure are stated in Part B.

E. Major barriers and risks

The main barrier in enforcing standards can be seen in the complexity and difficulty of implementation of new technical specifications for the producers, the absence of other motivational tools, in conjunction with a low added value for end users.

The risk is the complexity and size of the existing norms and standards in contrast with the lack of experts in the country.

5 Strategy implementation

5.1 Implementation structure and the strategy implementation control system

The implementation of individual computerisation projects is a demanding task, which requires multi-level management.

The Ministry of Health of the Czech Republic retains its control and supervisory role (role of **the coordinator responsible for healthcare computerisation** and NEHS implementation), which shall be applied through **the Steering Committee for Computerisation Development established by the Ministry of Health of the Czech Republic**.

The Steering Committee for Computerisation Development shall be formed with the participation of representatives of state authorities, regions, health insurance companies, patients, providers, professional and academic sphere, etc. Resolutions and other outputs from the activities of the Steering Committee shall be a base document for the coordinator responsible for healthcare computerisation and other executive bodies and departments.

The National Centre for Electronic Healthcare (NCEH) shall be a coordinator and governing body of the implementation of computerisation. Its role is described in Measure 4.3.1. This body shall be accountable to the Steering Committee for Computerisation Development, which shall be responsible for the audit of the implementation of the Strategy and assessment of the compliance with the NCEH's objectives.

The intention of the NCEH regulation was approved by the NCEH Steering Committee on 11/02/2016 and also by the resolution of the Health Committee of the Chamber of Deputies of the Parliament of the Czech Republic No.123/2015.

The department of the chief architect, which shall initially operate at the Ministry of Health of the Czech Republic and then it shall be transferred to the NCEH, shall be authorised by architectonic supervision over computerisation development. This unit shall closely work with the Department of the Chief Architect (DCA) at the Ministry of Health of the Czech Republic.

Also the experts from individual already existing working groups that contributed to the NCEH creation shall cooperate in the preparation of the implementation. These groups are professionally represented by major organisations and key entities, therefore, it is important to cooperate and continue to maintain transparency of individual projects and monitor their added value declared in the NCEH.

The current situation in recruiting ICT professionals in state administration is a major problem resonating in all the ministries and the lack of available experts needs to be solved via changes in the method of remuneration, external forces or outsourcing. When creating implementation structures, we have to take this situation into account.

The procedure of autonomous transformation of current structures in the target state is expressed via a simplified diagram Organisational structure of strategy formation and implementation. After approving the strategy, the Steering Committee for the creation of the strategy shall cease to exist and the Ministry of Health of the Czech Republic shall establish the Steering Committee for Computerisation Development in parallel with the National Centre for Electronic Healthcare.

The Ministry of Health of the Czech Republic shall immediately establish the department of the chief architect, which shall be responsible in particular for the architectural concept of computerisation development, creation of information services of the ministry, methodical management,

communication with other ministries, etc. At the same time working groups shall be transformed according to topics solved by priorities.

When implementing the set objectives, the readiness of organisations involved needs to be analysed, their enterprise architecture needs to be mapped and relevant motivating factors need to be identified. These activities have already been initiated in the creation of AS IS analyses of selected organizations. When implementing information and communication technologies in the healthcare system, the identification of operational risks, including their elimination shall be required instead of mandatory introducing new technologies without sufficient completion of solutions of any atypical and critical situations and the systematic introduction of new solutions into operation shall be required. Only after all risks are identified and eliminated, the mandatory use shall be required, if such a requirement is purposeful and should not be rather replaced with a system of positive motivation.

Such positive motivation for health providers should be especially demonstrable operational and economic benefits, whether benefits in direct cost savings or in the saving of work of qualified healthcare professionals. In the event of the absence of this natural motivation, it is neither good and nor expedient to replace it with a directive approach and threats of sanctions. The solution should be based on the obvious positive effect also for patients.

In justified cases, especially arising from superior legislation (identification of entities, security), the determination of the obligation shall not be avoided.

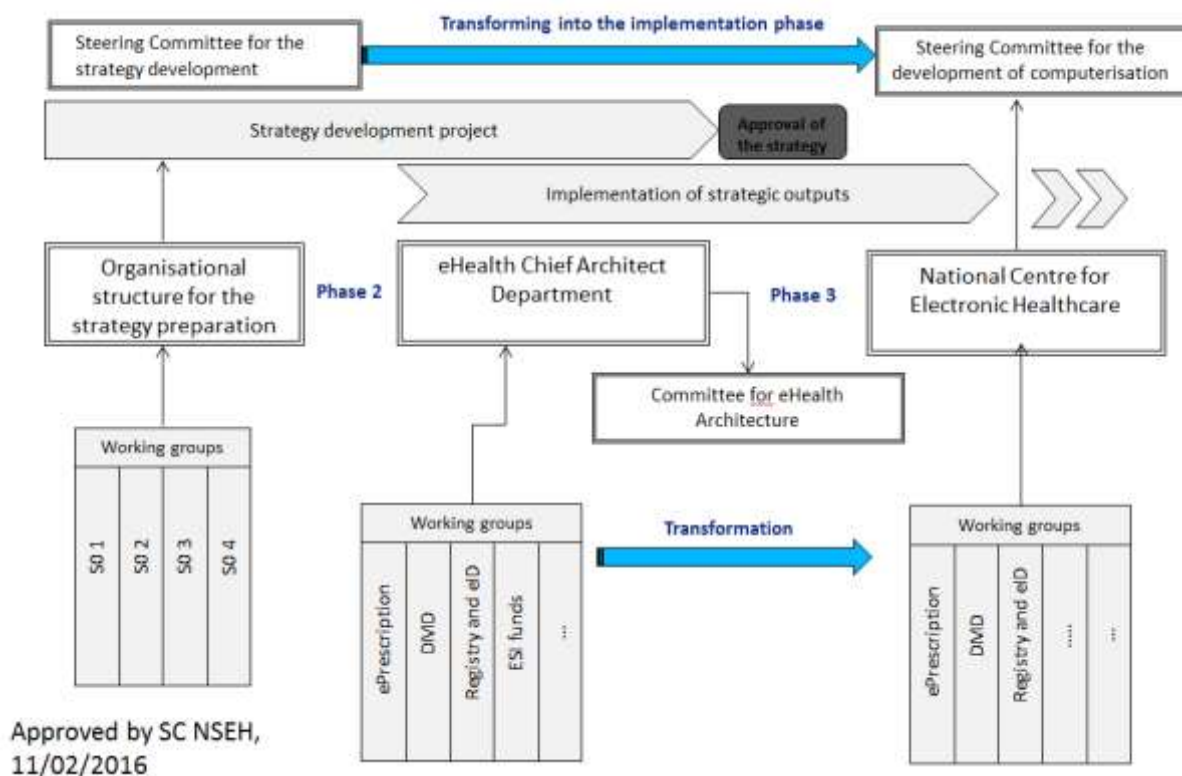


Figure No. 4 - Organizational structure of strategy formation and implementation

5.2 Method of implementation

Since the beginning of 2016, the preparatory works on the mapping of the Enterprise Architecture of the key areas of the health sector in particular in directly controlled organisations have been in progress. Within the audit of the current state of key elements of the architecture, a model of provided services and their links has been created. The principles, rules of infrastructure interoperability and development and design of the development of infrastructure key elements have been created.

The key project goals that focus on infrastructure projects stated in the time schedule have been identified and, concurrently, a negotiation on project financing has been in progress with the governing bodies of the MRD CR and the MLSA CR.

After approving NCEH, the Ministry of Health appoints the Chief Architect of Electronic Health, who shall be responsible for the compliance with the set rules and shall cooperate and, subsequently, from this perspective, approve proposed projects. The promoters of individual projects shall follow the guidelines and principles defined by the Enterprise Architecture of the health sector and in line with the superior principles of building eGovernment. Each project shall have the Enterprise architecture developed according to the methodology prepared by the Department of the Chief Architect of Electronic Health, and thus its interconnection with other projects and objectives of the strategy shall be guaranteed.. The National Centre of Electronic Healthcare shall be built, which shall continue to coordinate the development of computerisation and guarantee interoperability of new solutions, including the use of existing services of the ministry and eGovernment IT services.

The implementation plans of individual upcoming projects shall be determined in several stages. The first stage specifies the priority projects plans and shall be completed by the end of 2016. In this first stage also the deadlines for preparing other implementation projects shall be set.

When processing legislative objectives and modifications, the Guidelines for Regulatory Impact Assessment (Art. 2, Paragraph 2.2. of the General Principles for Regulatory Impact Assessment (RIA) approved by Government Resolution No. 76 dated 03/02/2016) shall be followed reasonably so that it would be obvious among others that the problem cannot be solved otherwise than through legislation. In the implementation plans, the alternative solutions and consequences of failure to adopt proposed solutions and plans for legislative changes shall be assessed.

For the purposes described above, the Ministry of Health of the Czech Republic inquires highly specialised consulting services particularly in healthcare, IT/ICT and personal data protection in relation to the projects of the contracting authority in the field of computerisation of healthcare in the Czech Republic, especially in the preparation and implementation of the strategy of computerisation of healthcare in the Czech Republic and setting up the legislative framework of eHealth in the Czech Republic in relation to the projects at the EU level.

The implementation plans shall include:

- plan of the implementation of activities (activities, etc.) leading to the fulfilment of objectives,
- time schedule for the implementation of individual measures, activities, actions
- specific accountability and responsibility for individual measures, activities and actions,
- budget and specific sources of funding,
- set of indicators derived from NCEH indicators
- risk register.

5.3 Time schedule and priorities

This chapter describes a general schedule of the implementation of NSEH individual objectives and measures, see Figure No. 5. The schedule divides the task into three categories: a priority task, whose implementation has been or shall be initiated immediately; medium-term, in which a measurable progress should be achieved by 2020; and others, setting long-term direction without necessarily prioritizing by 2020. The accuracy of this setting shall be reassessed semi-annually based on the current developments. At the same time it captures the targets and measures categorical in such a way in relation to project areas, respectively, project plans, specified in detail in the chapter dedicated to funding strategy. Last but not least, the present scheme gives a general idea of mutual dependence (interdependence) of priorities, objectives, measures and project areas or intentions in time.

A detailed time schedule of the implementation of individual measures, projects and activities shall be developed within the creation of the implementation plans, as stated in the implementation procedure described in Chapter 5.2 above.

For all individual goals, implementation steps including preparing the necessary legislative changes need to be set explicitly. Following this, also the steps concerning the legislative process of these changes, otherwise the submitted time schedule is not feasible.

A slow progress of necessary legislative steps can lead to a shift in implementing the objectives of the strategy over a longer time period and, therefore, from this point of view the whole strategy needs to be continually reassessed and updated with the emphasis on the current development of priorities of healthcare computerisation.

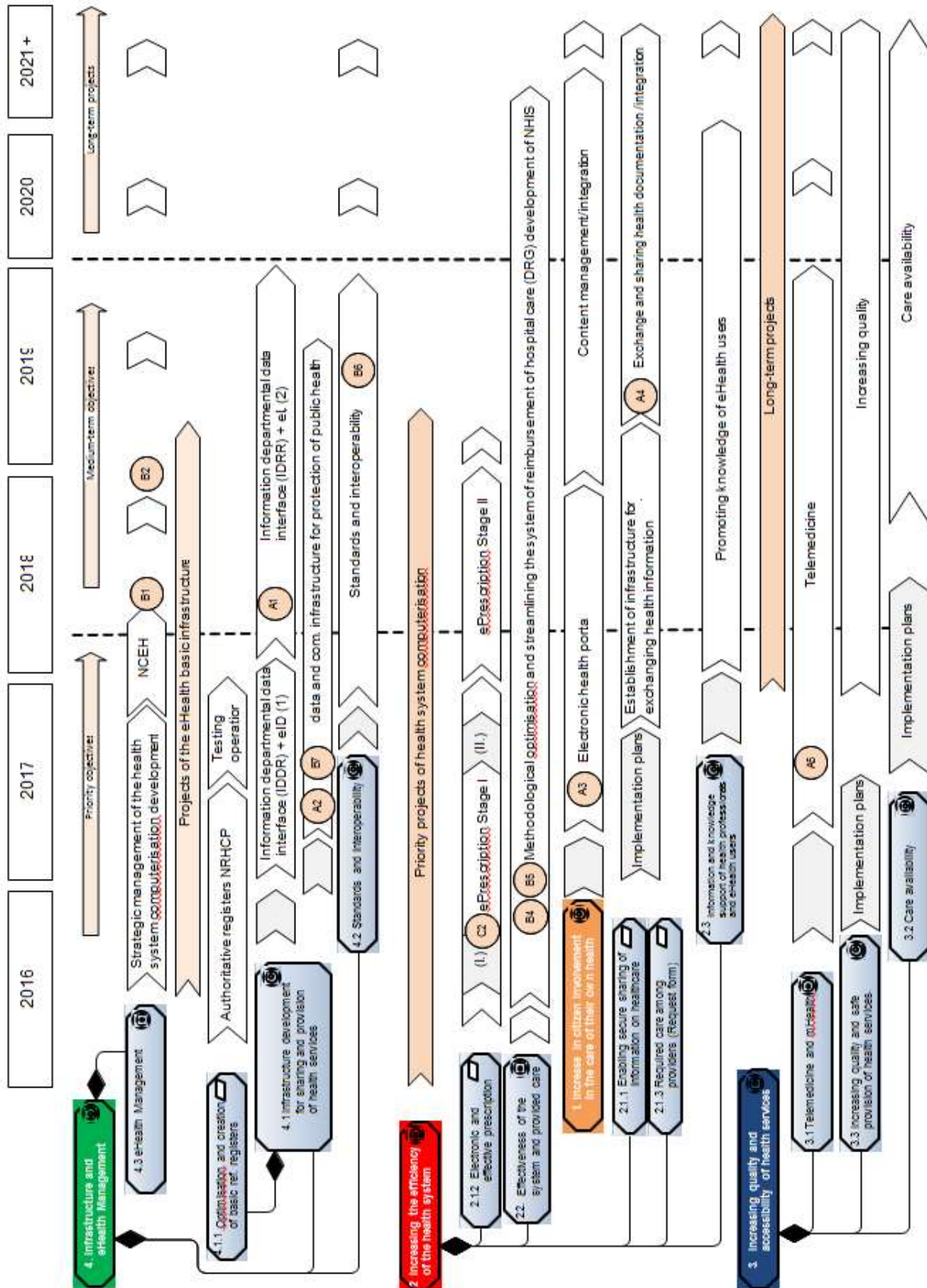


Figure No. 5 Time schedule of the implementation of NCEH priority areas

Caption to Figure No. 5

- Individual strategic objectives are stated in the corresponding colour of the set of NCEH objectives.
- Activities marked in grey show the preparatory stage for the implementation – creation of the implementation plan.
- The ring marks the links to project plans defined in Chapter 5.4 Budget and funding sources. The schedule thus provides a link to the source of funding.
- White arrows without description mark that the activity does not end with implementing the project intention and reaching the set of identifiers, but needs to be maintained, developed and modified according to current requirements.
- SO 3 – The progress and extent of the implementation of individual measures of this strategic objective shall be determined according to the analytical conclusions and studies.
- SO 4.3 – The NCEH successful implementation conditions the implementation of a number of other measures, in particular the need for personnel and specialised expert capacities for the specification of individual intentions.

The schedule shall be updated regularly to reflect the actual development of computerisation and took the development of additional services of the health sector, eGovernment and also technological progress into account.

5.4 Budget and funding sources

The implementation of individual projects, fulfilling visions and the objectives of the National Strategy for eHealth closely relates to finding financial resources and ensuring their optimal allocation, therefore, creating a sustainable funding model.

The primary sources of funding to ensure implementation and support of the implementation projects of the National Strategy for eHealth shall be secured within the budgeted expenditures of the budget chapter of the Ministry of Health and medium-term expenditure limits of this budget chapter or region budgets.

Concurrently, the European structural and investment funds shall be another important source. In this case, the methodological guideline of financial flows of the programmes co-financed from the EU structural funds and investment funds for the programming period 2014 - 2020th is the basic framework of financial management. The obligations of recipients is to ensure co-financing the project – i.e. a share of total eligible costs (co-financing share of national resources) and financing any ineligible expenses if incurred during the project implementation.

Other financial support mechanisms – Norwegian funds, the instrument for connecting Europe CEF, WHO sources (Agreement on Cooperation between the Ministry of Health of the Czech Republic and the WHO Regional Office for Europe) may possibly be another source of funding.

In certain cases, the sources of health insurance companies shall be a substantial motivator initiating positive changes leading to savings.

Securing from public health insurance sources is therefore also important to expect, at least in the scope of services, which are expected to be managed by individual health insurance companies.

For the period 2017 - 2020, the Ministry of Health of the Czech Republic aims at obtaining funds in the amount of 1,581 MCZK for the computerisation of the health sector from the European structural and investment funds IROP. It deals with the governing bodies about subsequent project plans, which are updated continuously during the formation of the strategy and they may be also modified:

- Building a basic eHealth information infrastructure – a departmental data interface for communicating transactional information systems
- Strengthening and securing data and communication infrastructure for the area of public health protection and promotion
- Building and development of the public health and e-health IS ("Portal")
- Sharing medical documentation, implementation support at healthcare services providers
- Support of the development of computerisation of GPs' surgeries and support of the introduction of basic eHealth services in relation to eGOV

The budget of the IROP project plan is stated separately – implementation of measures arising from the requirements of the Cyber Security Act. Here the estimated allocation amounts to 250 MCZK.

These funds shall be used for individual applicants in the health sector, while it is expected that some healthcare services providers (especially hospitals) shall submit other applications to finance their projects.

The Ministry of Health of the Czech Republic also expects a draw-down from the Employment Operational Programme (OPE). The indicative optimistic allocation is 599 MCZK.

The indicative budget for the proposed project plans (IROP and OPE), based on the information as of the date of the NSEH is shown in Table No. 7.

Number	Project objective	Expected recipients	Indicative financial allocation (MCZK)	Stage	Operational programme / other funding sources	Estimated date of commencement of the implementation	Call No.
A1	Building the basic information infrastructure if eHealth – departmental data interface for communicating of transactional information systems	MoH/CCHSIS	297	1	IROP	2016	26
A2	Data and communications infrastructure for protection and promotion	MoH/CCHSIS	160	2	IROP	H1/2017	23
A3	Building and development of IS of public health and eHealth ("Portal")	MoH/CCHSIS	72	2	IROP	H1/2017	26
A4	Sharing medical documentation – implementation support for health providers	MoH/CCHSIS/HP	500	3	IROP	H2/2017	26
A5	Support of the development of computerisation organizations of general practitioners and support of the introduction of basic eHealth services in relation to eGOV	MoH/HP	352	3	IROP	2017	26
A6	Telemedicine	HP/HTU	200	2	ESIF	2017	
	TOTAL		1581				
B1	Strategic management of eHealth in the MoH department	MoH	48	1	OPE	implementation commenced *)	25
B2	National Centre for Electronic Healthcare	MoH	100	1	MoH	2017	
B3	Systematisation, implementation and streamlining of ICT management processes in the Ministry of Health	CCHSIS	15	1	OPE	implementation commenced *)	25
B4	Methodological optimisation and streamlining the system of reimbursements of hospital care in CR	IHIS	242	1	OPE	implementation commenced	19
B5	Centre for Development of Technology Platforms of NHIS Registers	IHIS	74	1	OPE	implementation commenced	19
B6	The National Centre for Medical Nomenclature and Classification	MoH/IHIS	50	3	OPE	2018	25
B7	Streamlining of public administration in the protection and promotion of public health	MoH/CCHSIS/SH I	70	3			
	TOTAL		599				
C1	Cyber safety in the health sector	MoH/CCHSIS	250	2	IROP	H1/2017	10
C2	ePrescription + Infrastructure	SIDC	60	1	SIDC	2016	x

caption:

*) the project is in the approval process

	stage no. 1 – being implemented
	stage no. 2 – to be implemented
	stage no. 3 – reservoir of project objectives

Table No. 7 – Indicative budget for the implementation of the National Strategy for eHealth .

The investments in infrastructure are the key measures of the strategy with which the most extensive material expenditures shall be associated. In the total summary, the overall benefits of both the strategy and key measures themselves fully justify this scope of the investments, which is substantially lower than the current already implemented investments in the projects of the entities other than the Ministry of Health (e.g. IZIP project implementation).

A detailed budget of the NSEH implementation and a description of the specific sources of funding shall arise during the creation of implementation plans for individual strategic objectives (see Chapter 5.2. Implementation procedure).

5.5 System of monitoring and evaluation

Setting monitoring and evaluation is integral part of monitoring the implementation of the National Strategy for eHealth . Setting this system shall be an essential tool in meeting the objectives and measures of the NSEH and implemented projects. It shall also serve to evaluate the results of the implementation of NSEH partial parts.

The proper adjustment of monitoring requires a link to the objectives and measurable indicators and establishing a suitable system for monitoring and continuous recording of monitored data and information. The aim is to set up a system of indicators and the monitoring system that the indicators would express the actual performance of individual targets and thus the success rate of the implemented project could be assessed properly.

The indicators shall be specified during the creation of implementation plans, if not included in this strategy. A set of indicators shall be created, including their target values.

When monitoring, the state and progress of the Strategy implementation, regular information on the state of Strategy implementation shall be continuously ascertained and the implementation team shall compare the obtained information with default values and the anticipated plan. This shall be accomplished through interim reports, respectively, the final report on the Strategy implementation, which shall include the evaluation of the performance indicators, progress in implementing the hierarchical structure of works, schedule, budget, objectives, appropriateness of risk management practices and possibly other aspects of the Strategy implementation.

Evaluation is a complex process, whose aim is to obtain reliable data for strategic management and the management of the Strategy implementation. During the Strategy implementation **the interim evaluation reports**, respectively, **the final report** shall be prepared. The conclusions and recommendations shall be formulated to improve the implementation and a relevant setting to provide feedback. Thus, the evaluation shall contribute to the economy in the use of public funds spent on the Strategy implementation and its individual projects. The requirement is to evaluate the success of individual projects implemented in the framework of the National Strategy for eHealth and its impact on the participants. If needed, external professional capacities can participate in the implementation of evaluation (i.e. in the creation of evaluation reports).

Monitoring shall also include demonstrable **ensuring publicity** of individual measures, activities in accordance with the relevant rules for publicity established by subsidy providers.

The strategy shall be maintained and updated and partial and follow-up strategies shall be prepared through the National Centre for Electronic Healthcare and its governing bodies. We expect that the government shall require regular annual, respectively, biannual reports on the strategy implementation and shall discuss its updates at least once a year.

5.6 Risk management system

Within the implementation of each project, a number of risks shall arise, which the project managers as well as key sponsors need to solve. Therefore, it is necessary to properly set up their monitoring, evaluation and adequate escalation in proper time to eliminate or reduce the impact of risks.

The NSEH implementation programme shall manage risks in line with good practice. According to the principles of project management, each of the follow-up projects shall include "Risk Management Strategy" and "the Risk Register" as the governing documents of projects (according to standard methodologies).

The National Centre for Electronic Healthcare shall be responsible for the risk management system and shall be obliged to identify risks in the risk register, assess them according to the categories determined in advance, suggest a method of handling risks and implement approved measures. The NCEH shall be also responsible for adjusting the system of risks escalation and proper management of the information flow and its proper interpretation and finally for the communication of risks and proposed measures across stakeholders.

In the first quarter of 2017, the implementation plans shall be completed, including the classification of risks and ways to eliminate them for individual objectives.

6 Conclusion

The National Strategy for eHealth, as shown in the system of its objectives and measures, covers many areas of healthcare and the reader may get the impression that it is too ambitious and therefore unrealistic. Beyond all doubt, the implementation of the intentions outlined in the strategy shall be a long-term task exceeding the horizon of ten years. The National Strategy is in its first version also the first step conceptual step of the state towards the countries whose maturity of the healthcare system is accompanied by a conscious use of the potential of information and communication technologies, among which we would like to belong.

We should be aware of the fact that the strategy covers the area of computerisation of processes in the health system and really has no ambition to change the whole healthcare system. The consequences of computerisation shall certainly reflect in a change in some processes and introduction of new roles, whether serving for citizens, patients or healthcare professionals or roles aimed at protecting sensitive information and management of the computerisation system. In many cases, just the promotion of information and communication technologies may be a decisive factor, which shall allow, accelerate or make the desirable changes in the society, in the health system and health care more effective.

In some cases, the strategy presents completely realistic project plans, such as the authoritative registries, solutions of identities, electronic prescriptions. But often the projects and areas are not intentionally specified because they cannot be seriously defined without the intentions being thoroughly assessed, discussed with experts and actually feasible in time and costs. This approach confirms the intention of the contracting authority to enable and promote the conceptual development of computerisation of Czech healthcare completely transparently and gradually, i.e. it does not view the strategy as one mega-project, but as an evolutionary framework and process, which however has its rules, principles and where the roles and responsibilities of the state and other participants are clearly defined.

The strategy is extensive and complicated to a certain extent also because it draws, though in rough outline, future architecture of the whole house, i.e. it captures the current concept of the authors of the strategy, of how the future house should look like, what it should serve for and which important components it should have. So if we create and add individual components, we shall know where they are located in this imaginary house and which ties to other components they have. And that is what all and any similar public concepts and strategies strive for; to prevent uncontrolled development (implementation of unusable projects), useless waste of public resources and in terms of the health sector also of the effort of health professionals, and especially the time and money of our citizens.

In conformity with the contracting authority, the authors of the strategy believe that this difficult way of the support of computerisation shall bring positive results, as the outputs from other states show and that they succeed to adjust the role of the state and its organisations sensitively so as to undertake only that responsibility which is indispensably necessary and the largest possible space would be left for initiatives and market participants in the healthcare system.

Currently, the opportunity to finance the necessary changes via ESI funds from the EU needs to be utilised meaningfully. A reverse side of the coin shall be the pressure on a timely draw-down and thus pushing changes faster, than the conservative medical environment is capable to absorb, than it is advisable from the perspective of interdependence or the state of readiness of eGovernment and, than it is possible in terms of legislative preparation.

As the WHO states in the recommendations for the implementation of electronic healthcare: technical systems have social consequences, social systems have technical consequences and we do not propose technologies, but social technical systems. We need to understand how people and technologies influence each other, when the conservative environment can pose a significant resistance to changes. Therefore, a

sufficient amount of attention needs to be paid to strategy communication, explaining its benefits and changes that it anticipates and understanding technical aspects of healthcare computerisation.

7 References

The list of literature refers to the resources that were available to the team of authors and which they worked with during the preparation of the National Strategy for eHealth .

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