STATE AUDIT OFFICE
OF THE REPUBLIC OF LATVIA

e-veselība

# IS THE PROJECT „E-HEALTH IN LATVIA" A STEP TOWARDS THE RIGHT DIRECTION?

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# Audit report

# Is the project „E-health in Latvia" a step towards the right direction?

## Performance Audit „Information System in Health Care industry"

**Audit performed, based on the Third Audit Department of the State Audit Office Task No.2.4.1-7/2014 of March 31, 2014**

**The photos used for the design of the cover can be found on the website www.sadanduseless.com, www.vmnvd.gov.lv.**

**STATE AUDIT OFFICE**

Third Audit Department

**Dear Reader!**

We have completed a performance audit on information systems in healthcare industry and have prepared an audit report thereon.

Ministry of Health has identified substantial problems in the healthcare industry – an insufficient accessibility of medical records on patients during the process of treatment, an inefficient, paper-based health information summarizing and circulation process, there is no unified approach in public informing process, as well as electronic data exchange process between healthcare institutions and patient and between healthcare institutions and institutions of management is minimal. Moreover, the length of healthy life span of inhabitants of Latvia is one of the lowest in Europe – in year 2013 the medium expectable length of life for women was 79 years, but for men– 69.5 years and this index certifies unsatisfactory overall quality of life in the country, as well as on the overall health condition of inhabitants and the quality of healthcare as a whole.

In order to curtail these problems, the Ministry of Health is convinced on necessity to introduce e-health solutions. Also in the European Union e-health is outlined as one of the key instruments in enhancement of healthcare quality, accessibility and safety.

Since year 2007 e-health is being introduced in Latvia and the institution responsible for introduction of e-health is the National Health Service that is responsible also for implementation of e-health projects co-financed by the European Regional Development Fund with the deadline – year 2015 and the Ministry of Health is supervising the introduction process.

We have carried out this performance audit, taking into account the topicality of introduction of e-health – to ensure the necessary information in the right time and the right place, in order to enhance a better quality of patient care.

We would like to express our gratitude to the Ministry of Health and the National Health Service on cooperation in the framework of the audit, as well as to inhabitants, healthcare professionals, pharmacists and other specialists who provided their opinion in the course of the audit.

**Respectfully,**
**Director of Department**  **Inga Vārava**

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## SUMMARY


***Purpose***

The purpose of the Audit was to verify whether:

- activities of the Ministry of Health and the National Health Service are efficient and productive and purposeful, upon implementation of e-health;
- the funds invested in the project „E-health in Latvia" have been spent purposefully and on an economic basis.

***Motivation***

Audit performance has been performed, taking into account the topicality of implementation of e-health - the term defined in the planning document is the end of year 2015 and during a time period of nine years there have been invested 14.5 mln. of *euro*, but none of the services e-health is available to users, meanwhile since January 1, 2016 the e-health information system shall be upstarted mandatory by all healthcare service providers (in out-patient and in-patient treatment, electronic booking, upon refering to examinations or manipulations, electronic prescriptions and sicknessleave acts).

***The main issue of the audit***

Has the e-health been implemented with an aim to achieve the target – to enhance a more efficient provision of e-health services?

***Audit tasks***

To verify whether the planning documents of the Ministry of Health are substantiated and updated in the sphere of implementation of e-health.

To verify whether e-health is implemented according to the scope, terms and finances defined in the guidelines and the implementation plan.

To verify whether the created e-health information systems provide data safety and high personal (patient) data protection.

To verify whether the superivison of implementation of e-health has been enough efficient.

***Audit methods***

The requirements of external laws and regulations have been analysed and obligatory requirements identified.

Evaluated the policy implemented by the Ministry of Health in the healthcare area and the supervision of implementation, as well as activities of National Health Service, upon implementation of policy.

Evaluated compliance of the information systems of e-health with the requirements of data safety and personal (patient) data protection.

Analyzed results of the performed surveys.

Verified supporting documentation presented by the Ministry of Health and the National Health Service.

Conducted interviews with officials from the Ministry of Health and the National Health Service.

## Key conclusions (a full list of conclusions can be found on page 103)

In order to improve effictiveness of provision of healthcare service, the project implemented by the Ministry of Health - „**E-health in Latvia" is a step towards the right direction,** since it will provide a possibility for patients to ensure a greater control over their health issues, by maintaining healthy habits, lifestyle, increase substantiation of adoption of decisions and speed of service in the healthcare industry, upon ensuring quality and accesible information, patients will receive more quality services and in a shorter period of time upon issuance of prescription drugs.

**Nevertheless the policy prepared by the Ministry of Health in the area of e-health will not be implemented in the planned scope and the planned term, thereby the target-to improve the effectiveness of provision of healthcare services – will be achieved partially.**

As we have previoulsy pointed out to, the direction of the aim of the project „E-health in Latvia" is necessary and important for the society, but already from the very beginning there have been established substantial deficiencies (errors) - the professionals of industry are not involved in the project, a multiple change of institution implementing the project, an ineffective project management and finally - there have not been a sufficient supervision of the project.

Although the Ministry of Health has prepared a planning document for implementation of e-health, during a nine year time period it has not been updated and does not comply with the real situation.

The Ministry of Health has timely prepared the planning documents on development of the e-health, as the use of information and communication technologies rapidly penetrated the health care industry, however the industry professionals were not involved in development of planning documents, no feasibility studies, research and analysis of the health care were performed.

The planning documents prepared - Guidelines „E-health in Latvia" and the implementation plan for years 2008 – 2010 do not reflect the actual current situation, not all of the activities planned in the guidelines are being developed, the financing does not comply with the planned scope or the time frames, priorities for implementation of the e-health have also changed.

Since the Ministry of Health has not updated the implementation plan of the guidelines, the project owner - National Health Service is implementing the project activities in 2015 according to the implementation guidelines for years 2008 – 2010 prepared in 2007.

Although since beginning of the e-health project there have passed nine years (from year 2007) and the Ministry of Health has invested in the project 14.5 mln. of *euro,* nevertheless as of April 1, 2015 the health information system and planned e-services were not accessible to users.

Although the Ministry of Health started implementation of the e-health policy at the same time with several other European countries, including Estonia, the excessively slow pace of implementation of the e-health policy has led Latvia significantly lagging behind the Estonia and in 2013 it was at the last but one position among the European countries. The following factors can be listed as reasons for so low position:

- by year 2015- 45% of the activities planned in the guidelines of e-health have not been started;
- deadlines of the project have for several times been significantly prolonged - from the initial implementation deadlines of the project in 2010 to the 1 December 2015 (for the e-prescriptions information system) and even longer;
- by the 1 April 2015 none of the planned 26 e-services were available to the users, not even in the test environment outside of the National Health Service, as well as risk persists that as of January 1, 2016 not all from 31 e-services will be available to users.

Although the Ministry of Health had funds in its possession for starting using the solutions of stage I of the e-health project (in the sphere of production) in the planned term, i.e., as of year 2013, but practically e-health information system is not available to its users, Ministry is planning to partially start e-health by year 2016, thereby forecasted by the National Health Service financial benefits in amount of 3 mln. of *euro* have not been saved and not directed to provision of other healthcare services.

State Audit Office believes that there is a risk of e-health system not gaining sufficient popularity among the population and the health care service providers, as not all will have access to and understand the e-health system.

Although the completion deadline of the project „E-health in Latvia" is approaching, the activities performed by the Ministry of Health in popularisation of the project, informing and identification of users have been insufficient because:

- up to 17% of health care professionals have no access to internet connected computer at their workplaces;
- computer and internet literacy of up to 41% health care professionals are average or weak;
- only 11% from the health care professionals and pharmacists are duly informed on the project;
- health e-services offered in the portal www.Latvia.lv within framework of the pilot project were used only by 9% of population (e-services were available for the time period from 13 August 2010 to 1 October 2013);

- 47% of the population are generally informed on the project "E-health" and planned e-services, while in average only 11% of population were also informed on planned benefits.

During the course of the project there is established a lack of coordinated planned activities, ineffective management and control, thereby financial resources of the project amounting to more than 760 thousands of *euro* have been spent inefficiently and in an counterproductive manner.

Since the Ministry of Health has not updated the implementation plan of the Guidelines for years 2008 – 2010, then some of the actual costs of implementation of the e-health activities considerably differ from the planned costs, namely, in some positions costs are lower by 81%, while in other by 127% higher than it was planned.

Total actual costs of activities managed by the National Health Service exceed the planned costs by 154 364 *euro* and are with a growth trend of actual costs when approaching the closing of the project.

Impromper drafting of procurement documentation or development of non-quality e-health solutions, as well as due to a slow implementation of e-health, upon perfecting the initially developed e-health solutions, there is a risk that financial resources amounting to at least 483 406 *euro* have been spent unpurposefully.

For the period of implementation of the guidelines financial means amounting to 196 292 *euro* have been inexpediently used, by covering costs of development of concepts and technical specifications for the activities implementation of which is not continued.

A risk persists that the aims of the e-health projects cofinanced by the European Regional Development Fund will not be achieved, thereby the funds used amounting to 11 352 647 *euro* may be found as improperly spent.

Upon implementation of e-health projects cofinanced by the European Regional Development Fund there have not been complied with the requirements of the European Community regulations, nevertheless all projects of the stage I ended in December 2014, the final inspections of the conclusion of project are suspended for multiple times and taking into account that a successful implementation of project of stage II is closely tied to results achieved at stage I, the risk persists that during the closing inspections of projects it will be found that the aims of the projects have not been achieved.

It was established during the audit that the e-health information system as of April 1, 2015 was not ready from the point of view of information data safety and personald data protection, as well as risk persists that on January 1, 2016 it will not be ready for use, at the moment where it will be mandatory to all healthcare providers to use it

Although the data safety within the e-health context was initially identified as having a critical meaning, the National Health Service is still for a long time just at the initial stage of implementation of the safety management of the e-health information system and so far all of the internal legal acts required for safety management of the information systems, including risk management, business contingency testing and standardised users management have not been developed.

National Health Service has not started registration of processing of personal data of the physical persons in the e-health information system – it will be possible only after development of all of the internal legal acts, and there also is a risks that during the registration and pre-registration testing any previously unidentified faults might be discovered, elimination of which will require additional time.

Safety audits of the e-health information system have been undertaken only in the test environment with the system not being fully functioning and without involvement of the safety manager of the information systems, and also the National Health Service has not summarised and assessed at the top label the results of external safety audits and the faults identified by providing the managers of the institutions with recommendations for their elimination with a detailed action plan, deadlines and persons in charge.

National Health Service has not provided the preconditions for high level protection of patients data.

In the e-health information system all patients medical records are freely accessible for all medical professionals without any consideration of their actual daily work requirements and the need to have access to so wide information which is contradictory with the recommendations given by the European advisory institutions, and thus it will initially lead to unsubstantiated cases of data processing, damaging public trust in the system.

Also data processing restrictions by the patients are available only to the restricted amount – a choice must be made between entrusting the medical records to all health care specialists or not to trust these to anybody.

National Health Service currently is unable to independently identify large volumes of all cases of unjustified processing of personal data of physical person and duly act because:

- the audit trail records creation and disclosure functionality is not fully functioning;
- no clear control mechanisms and clear criteria have been introduced for determination of whether an audit trail record shall be automatically identified as unauthorised processing of personal data, no lists of risky data processing cases are formed and their detailed analysis performed.

State Audit Office believes that there is a risk of quality, accuracy and justification of the information available in the e-health information system, as the National Health Service is avoiding the responsibility by delegating it to health care institutions.

Although the National Health Service as a manager and holder of the e-health system shall be responsible for quality of the data actions of the persons performing personal data processing, the Service is planning to delegate a range of areas of responsibility to the health care institutions themselves, thus avoiding responsibility for several critical issues, e.g. assigning, control and cancellation of users rights to the employees of the health care institutions, on accuracy and justification of the patients records stored in the e-health system. Thus the users will have no technological obstacles for accessing all health records of the patients, and moreover – one medical practitioner can delete information entered by another one.

The supervision and control of the implementation of the e-health ensured by the Ministry of Health has not been sufficiently effective

Ministry of Health has not prepared all informative reports required by the legal act of the Cabinet of Ministers on the implementation progress of the e-health policy, and also the inefficient supervision has resulted in too slow implementation of the project, not all of the problems identified have been resolved and the inefficient use of the funding assigned has been permitted.

## Key recommendations for starting using e-health (a full list of recommendations can be foundon page 112)

Grounding upon conclusions of the performance audit, we invite the Ministry to perform amendments in the Cabinet Regulations[1], by amending the wording about the terms of starting mandatory use of information systems, by providing a timeframe for prevention of established deficiencies and conclusion of agreements with the providers of healthcare services, as well as to define a reasonable term-at least 6 months in order to voluntary join e-health information system:

In order to successfully launch operation of the e-health information system, in the point of view of the State Audit Office the Ministry of Health shall ensure execution of the following undertakings:

- Repeatedly perform accepttesting of all developed e-health solutions according to requirements of technical specifications in order to convince about system operation, working capacity together with other systems and semantic compatibility;
- To prevent all deficiencies and imperfections that are related to information data safety and physical entities data protections, for example, to prepare all necessary internal rules and regulations and to acquaint with these all users of the e-health information system, to perform data processing registration in State Data Inspection, to perform a repeated data safety audit after solution accepttesting and prior to initiation of operation in production environment, in order to get convinced about the elimination of previously established errors;
- To develop plan of undertakings with an aim to involve all healthcare service providers that are involved in using of e-health information system, in order to improve effectiveness of healthcare, upon ensuring operatively accesible support for adoption of clinical decisions, grounding upon integrity and trustfulness of e-health data;
- After initiation of operation of e-health information system (in production environment) when healthcare service providers are able to freely join e-health information system, to perform a targeted information campaign to popularize e-health information system.

[1] Cabinet Regulations No.134 of March 11, 2014 „Regulations on Unified Healthcare Industry Electronic Information System"

## Terms and explanations

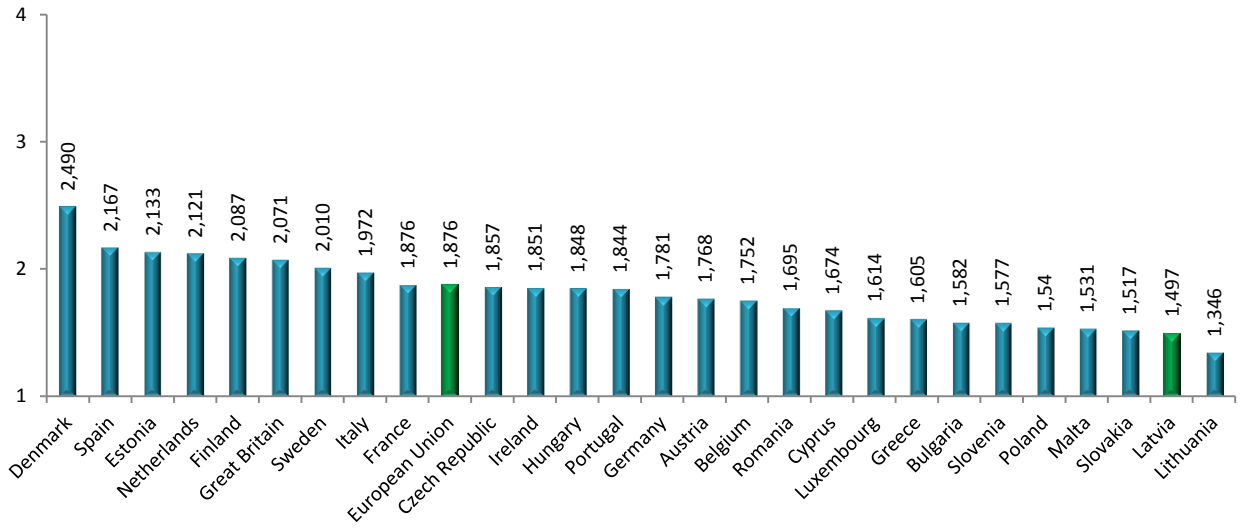
| Abbreviation/ term | Explanation |
|---|---|
| **Audit trail records** | Reflection of activities (accessing, data entering, editing, deletion, printing) performed in the information system in the format of electronic information available for analysis |
| **Authentification** | Process whereby the identity of the user is done in the information system, rights of user to legally access the information system are verified |
| **Health care institution** | Practice of doctors, state and municipal institutions, commercial company registered in the register of the health care institutions compliant with the mandatory requirements set for health care institutions and structural units thereof, and which is providing the healthcare services. Within the meaning of the report the health care institution shall include also a pharmacy. |
| **eEHIC** | Electronic European Health Insurance card |
| **eID** | Electronic personal identity card |
| **EU** | European Union |
| **EEA** | European Economic Area |
| **EHC** | Electronic health card – Personal health record in electronic format accessible to health care service providers and controlling institutions. The electronic health card contains basic information on the person's health required by the doctors concerning the patient. |
| **Expert** | An outsourced expert involved by the State Audit Office - *PricewaterhouseCoopers SIA* |
| **E-referrals and e-booking information system** | Healthcare industry work flow electronic information system, electronic healthcare services booking system and e-health WEB users platform (internet website).<br>E-referrals and e-booking information system ensures electronic booking of visits to physician, circulation of referrals and results of examinations, electronic anamnesis and data transferring to Electronic healthcard information system |
| **E-service** | Electronic service-any type of service that can be provided, upon using internet technologies |
| **Electronic signature** | Electronic service – data assigned with the data block or obtained from its cryptographic transformation and allowing for the data recipient to verify the integrity of the data block and authenticity of the data source, as well as preventing its forgery |
| **E-prescription** | Electronic prescription information system ensures electronic prescription circulation in country, gradually passing from paper to non-paper issuance of prescriptions and processes of clearing, as well assupports work of healthcare professionals and pharmacists, providing information on interaction of medicinal products prescribed to patient |
| **E-health** | E–health means contemporary use of information and communication technologies in all health care areas for purpose of providing quality and efficiency of healthcare services and to make more accessible patient medical records to the same patients and attending physicians, more involve patients in health care process, to urge inhabitants to more actively take care about their health, to improve health of inhabitants.<br>For the audit purposes the e-health shall mean setting up and introduction of the electronic health card, electronic booking or electronic application for the visit, electronic referral or electronic organisation of the health care work flows, electronics prescriptions, public health portal, e-services and integration (cooperation) platforms, as well as the associated systems, information and communication technologies. |
| **E-health portal** | Public health portal – a joint environment created for patients and practitioners, where personal information and electronic services is available. |
| **Ex-post assessment** | Final impact assessment within framework for which the degree of achievement of the set objectives and planned results, as well as justification of funds invested in the achievement of the objective is assessed |
| **Safety of the information** | Ensuring of the accessibility of information (upon user's request he can access information over certain time period), integrity (storage of full and unamended information) and |

| Abbreviation/ term | Explanation |
|---|---|
| **system** | confidentiality (information is received only by duly authorised persons) in the information system. |
| **Information systems user** | A person with access to information stored in the information system or which receives information system services. |
| **Integration platform** | Technological solution that ensures cooperation possibility of individual healthcare industry information systems. |
| **IS** | The information system – system for computerised entering, storage and processing of data providing for access of used to data and information stored in it. |
| **ISO/IEC** | International Standardisation Organisation/ International Electronic Commission. |
| **IT** | Information technologies – a set of knowledge, methods, tools and technical equipment providing for obtaining, storage and distribution of any information by use of computers and communication means. |
| **Expressed agreement** | In the case of expressed approval (in English referred to as the „opt-in" approach) the patient shall express oral or written agreement for use of his data or involvement in the system's operations. Only after expression of such agreement the patient's data is accessible by the indicated persons. |
| **Confidentiality** | Protection of the information against the users attempting to access without a due authorisation. |
| **Feasibility** | Economy (retaining of low costs), efficiency (achievement of set objectives) and productivity (rational use of resources available) of the operations. |
| **Applicability** | To what extent product or internet website may be applicable in order several users could comfortably and effectively achieve their targets according to context of application |
| **Indirect agreement** | In the case of indirect agreement (in English also referred to as the „opt-out" approach) the patient is not expressing oral or written agreement. Instead the patients can request termination of processing of their data. Data of the patient is freely accessible until the patient prohibits access to it. |
| **Patient** | A natural person receiving health care services or seeking those. |
| **Portal** | The network place offering wide range of resources or services, most of which are functioning online, e.g., electronic mail, various forums, browsers, online trade points, etc. |
| **Privacy** | Rights of a physical person or an organisation of control or to define which information can be stored and saved, and who is entitled to use such information. |
| **Telemedicine** | Use of telecommunications for ensuring communication and information exchange between the medical professionals for diagnostics, treatment, consulting and training needs between the health care institutions, other specialists and patients treated by them in various countries of the world. Telemedicine uses telecommunications and data processing technologies to assist patients remotely. |
| **Interoperability** | Two or more functional units together are able to process the data. Exchange of information between the systems, ensuring that the information is understood by all involved applications. |
| **Semantic interoperability** | Exchange of information between the systems, ensuring that the information is understood by all involved applications, which was not originally designed for this purpose. |
| **State Information System** | Structured set of information technologies and data bases, by use of which the receipt, creation, summarising storage, processing, use and destruction of information is ensured as required for performance of the state functions |
| **WEB** | The net – global hypertext system using the internet network as a mean of transportation of the information |
| **WCAG** | Web content Accessibility Guidlines |

# E-HEALTH – WHERE ARE WE?

## Comparison of implementation of e-health in Latvia to experience of other European countries

E-health has a huge potential for ensuring efficient, quality health care therefore the costs of governments in the area of e-health are just ever increasing. The studies[2] refer to financial, legal, social and ethical implementation obstacles, including low awareness level of users concerning e-health benefits, the system in general, as well as insufficient evidence on the cost efficiency and mutual replaceability, as well as increased requirements for patient safety.




Data has been compared by the four equal measuring volumes – electronic health card, health information exchange, tele-supervision, personal health records by expressing these in the indices according to the Factors analysis method[3].

*Figure 1.* **Implementation of the e-health system in the practices of family practitioners in the EU[4].**

E-health accessibility was assessed within the interval from 1 to 4, where index 4 means that all the potential of e-health has been used, nevertheless as we see in the Figure 1 that in European countries the accessibility the index is fluctuating between the numbers 1.3 to 2.4, indicating that the system is accessible, however used just to the restricted level.

If looking at the Baltic countries, Estonia is leading (index 2.133). Estonia stands out by its position in comparison to other countries with similar institutional features. It is well known that the state has in past years made considerable investment to development of not only the e-health, but also the IT programmes.

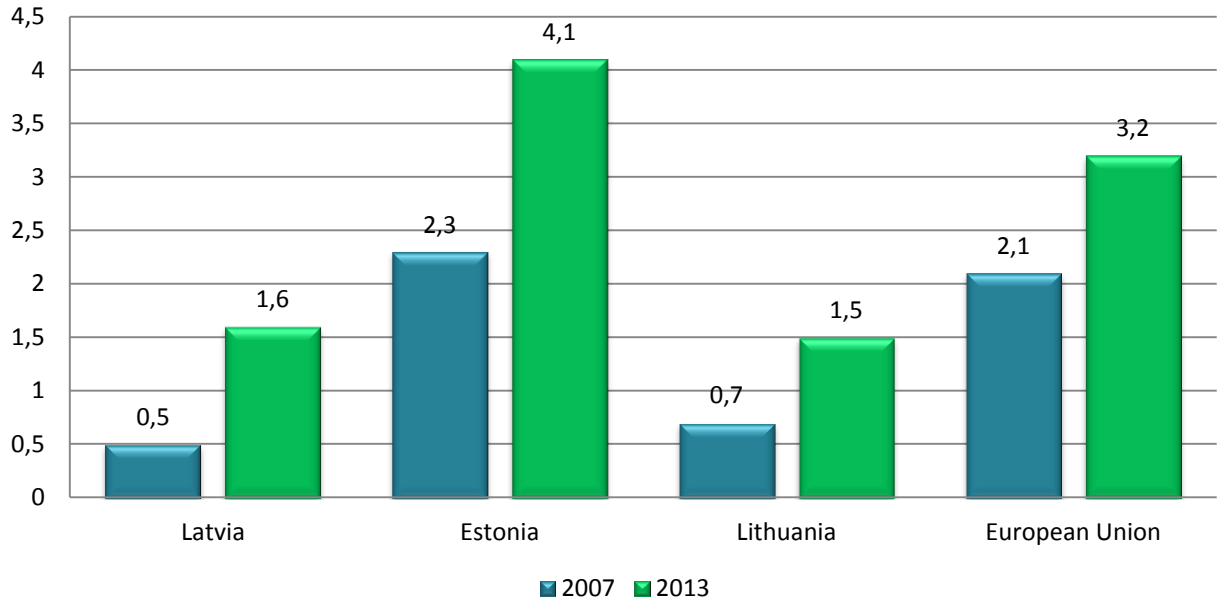
In 2008 in Estonia (development of projects in 2006 – 2008) four various e-health projects have been implemented – electronic health card, electronic booking, electronic image and electronic registration, as well as e-prescription introduced in 2010.

[2] Survey of the health care services „Exploring the challenges of implementing e-health: a protocol for an update of a systematic review of reviews". Available at http://bmjopen.bmj.com/content/5/4/e006773.full, viewed on 27.04.2015.
[3] Study of the European Commission „Benchmarking Deployment of eHealth among General Practitioners (2013)".
[4] Study of the European Commission „Benchmarking Deployment of eHealth among General Practitioners (2013)".

Latvia (index 1,497) and Lithuania (index 1,346) just introducing the e-health system is left in the last place.

Authors of the study invite to learn from the leader of the e-health introduction – Denmark the following aspects:

- the long-term objectives shall be defined at the beginning of the project, however they shall be updated on a regular basis considering the needs of users and technology developments;
- strategy is required to ensure smart use of all resources and careful planning in order to increase delay and failure risks of larger scale projects;
- National IT strategy shall be developed with more stringent guidelines and policy in order to decrease number of mutually contradictory systems used in the health care sector.




(Indexes, where 0 – 0%, 1-20%, 2-40%, 3-60%, 4-80%, 5-100%)[5]

*Figure 2.* **Use of the e-health in practices of family practitioners in 2007-2013.**

As indicated in the Figure 2 the Baltic countries from year 2007 to year 2013 are experiencing increased use of the e-health in the practices of family practitioners over the period from 2007 to 2013. Largest growth is seen in Estonia – by 1.8 points, followed by Latvia with a growth of 1.1 points and Lithuania with 0.8 points. It shall be pointed out that Estonian growth exceeds the EU average growth.

Meanwhile, upon evaluating the total output costs of solutions in various Baltic countries, it can be concluded that they are drastically different, for instance, in Estonia, total costs for the stage I were fluctuating between 2.3 mln. of *euro*, meanwhile in Lithuania, forecasted costs were more than 20 mln. of *euro*.

An approximate conceptual comparison of costs of e-health solutions in Baltic States can be found in Table 1. Table encompasses solely those solutions that are comparable, grouding upon joint targets of use of solutions and similar functionality (i.e. in every country the architecture of solution actually differs, but they are comparable, since the actual targets of their use are equal).

[5] Study of the European Commission „Benchmarking Deployment of eHealth among General Practitioners (2013)".

*Table 1*

**Comparison of costs of e-health solutions in Baltic countries**

| Country / Solution | Latvia (approximate costs, ir EUR) | Estonia (approximate costs, in EUR) | Lithuania (approximate costs in EUR) |
|---|---|---|---|
| E-prescription | 320 000[6] | 230 000 | 1 700 000 |
| Electronic health card | 1 950 000[7] | 1 600 000 | 2 800 000 |

In Latvia the costs of implementation of e-health solutions of stage I in comparison to neighbouring countries (please refer to Table 1), are not substantially higher. Nevertheless it shall be take into account various solution architectures, applied principles, development technologies, time for implementation of projects, etc. and other costs impacting aspects.

## E-health development in Latvia

### *What is e-health?*

Intention and plan to implement e-health in Latvia was initiated in mid 2003. Considering that use of information and communication technologies in health care industry were steadily expanding, the Ministry of Health decided to develop the Information Technologies Council and later in November, 2003 created also a task group with main objective of developing a policy document - guidelines „E-health in Latvia".

The task group of the Ministry of Health prepared a policy document - guidelines „E-health in Latvia", which on 17 August, 2005 was adopted by the Cabinet of Ministers[8].

E-health is a programme for improvement of quality and efficiency of health care by use of information and communication technology tools.

> Ministry of Health considers that a successful and timely implementation of e-health will enhance improvement of public healthcare, by supporting a healthy lifestyle, increasing substantiation of adoption of decision and speed in the healthcare services and will give possibility to patients to ensure a greater control over their health condition, upon providing quality and accessible information.

The meaning of e-health in a wider sense is defined as a health care model is directed to the patient – an ecosystem (see Figure 3), where the involved parties – health care professionals (medical practitioners, pharmacists), patients, health care administration institutions – are interacting by using opportunities provided by the information technologies in order to organise and provide the treatment processes along with the most efficient administration of the health care system.

[6] In order it could be possible to perform comparing with solutions of neighbouring countries, the costs of e-prescription were added also provisional costs of users interface.
[7] In order it could be possible to perform comparing with solutions of neighbouring countries, the costs of e-health card were added also provisional costs of users interface.
[8] The Order of the Cabinet of Ministers of 17 August 2005 No. 560 "On the Guidelines "E-health in Latvia""

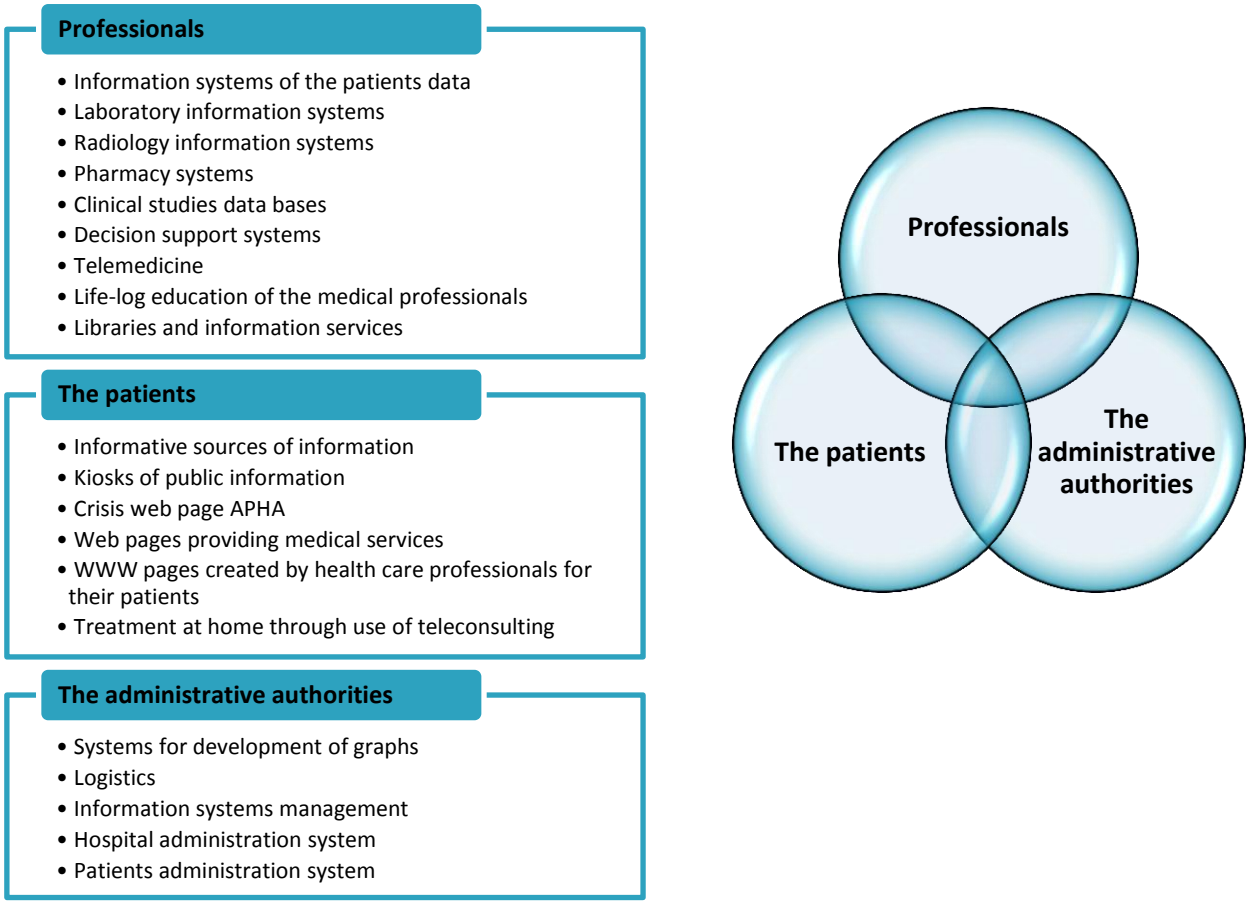



*Figure 3.* **E-health ecosystem.**

The guidelines „E-health in Latvia" set the objectives and benefits to be gained from the introduction of e-health in Latvia – benefits to patients and the public at large, to the health care professionals, managers and health care policy makers and implementers (see Figure 4).

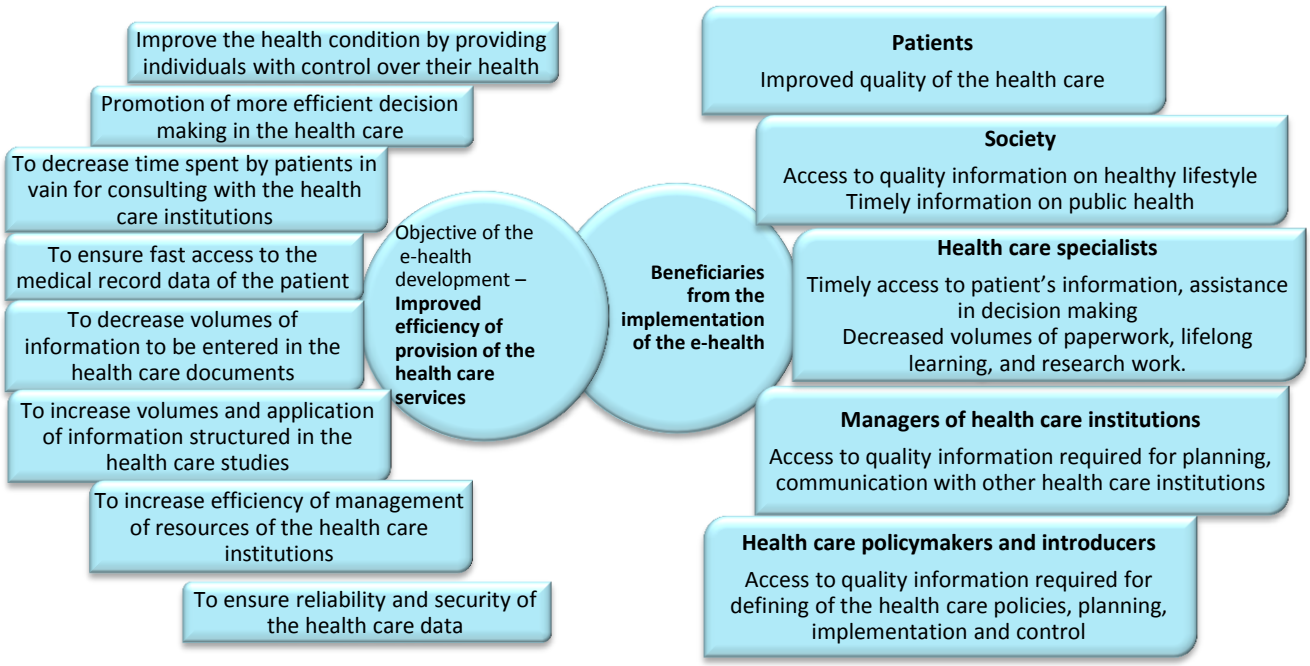



*Figure 4.* **Objectives and benefits from implementation of the guidelines „E-Health in Latvia".**

The key values defined in the guidelines of the project „E-health in Latvia" are the following, see Figure 5:

- public health is the main value of the health care, thus ensuring public health and its constant improvement is the very fundament of the health care system;
- consideration of rights of patients in any situation, respect and care for the patient;
- professionals of the health care are publicly liable for quality and efficiency of services provided;
- in exploring of practical application of options offered by the technologies attention must be paid to how will be initiatives and solutions be adopted by the public and professionals, if they will not be contradicting with public traditions and culture;
- information systems used in the health care shall be safe and accessible according to safety requirements.

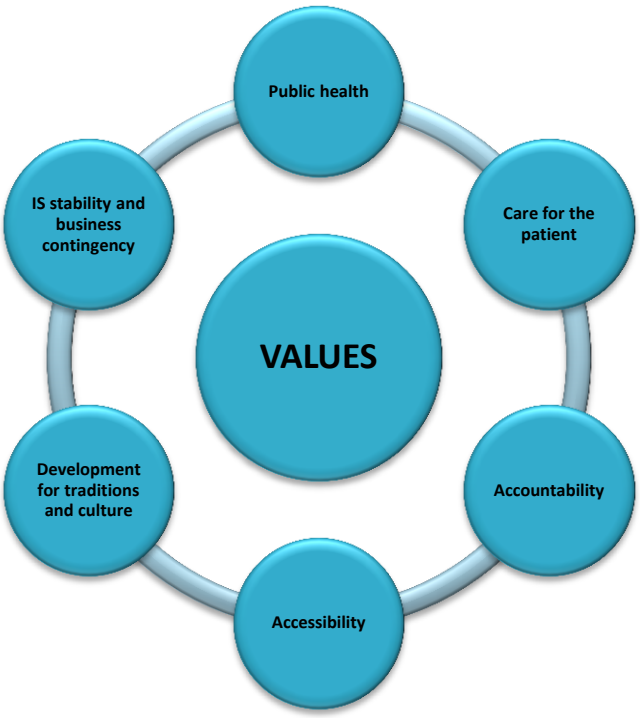



*Figure 5.* **E-health development values.**

The future architecture of the sector, including that of the e-health information system is structuring functional and technical competencies of the existing and required information systems by outlining the limits of the systems, mutual interaction and links, for the scheme of architecture see Annex No.1.

Following the approval of guidelines „E-health in Latvia", within eight months' time the Ministry of Health in August, 2006 set up a task group for development of implementation plan of the guidelines „E-health in Latvia". The Cabinet of Ministers approved the developed plan on 24 October 2007[9].

For purposes of achievement of objectives set in the guidelines and to ensure the planned benefits the implementation plan of guidelines „E-health in Latvia" for 2008 – 2010 contained the list of measures required for introduction of the e-health. In general the measures included

[9] The Order of the Cabinet of Ministers of 24 October 2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010".

were arranged in seven groups of measures to be implemented and the total funding required for implementation of the plan was 42 149 134 *euro*.

Pursuant to provisions of the Section One of the Article 78 of the Medical Treatment Law data of the health care sector is stored in a unified health care electronic information system in order to support organisation of the health care system and to facilitate provision of the health care services, and provisions of the Section Two, which provides that the Cabinet of Ministers is appointing a handler of the health information system, data to be stored and procedure for their processing, as well as procedure for disclosure, the Ministry of Health has prepared the draft regulations „Regulations of the Unified Electronic Information System of the Health Care", which were approved by the Cabinet of Ministers[10] On 11 March 2014.

The above referred Regulations of the Cabinet of Ministers provide the legal framework of the health information system:

- handler of the health information system and obligations thereof;
- services to be provided by the system;
- access ways to the system;
- data to be included in the system;
- procedure for allocation and cancellation of users rights;
- rights to process data in the system by the users groups;
- rights of patients in the system;
- transition procedure and effective dates of the regulations.

The Cabinet of Ministers has provided that the health information system will be handled by the National Health Service.

During the time period from 2003 to 2009 the policy planning and introduction of e-health was led by the Ministry of Health, with various tasks being delegated to subordinate authorities. Considering the expansion of the scope of activities, increasing number and specifics of measures to be introduced, in 2009 a decision was passed to delegate administration and implementation of the project "E-health in Latvia" to the Health Economy Centre[11], but as of 1 November 2011 introduction of the e-health system falls within competency of the National Health Service[12].

***Funding of e-health projects***

For the period from 2007 to 2014 funds were allocated to the implementation of the e-health programme from the state budget and structural funds, for total amount of 20 593 809 *euro*, including.

According to provisions of the e-health implementation plan, stating that funding for implementation of the e-health projects will be assigned from the state grants, for the period starting from 2007 to 2014 for implementation of the guidelines - 2 844 400 *euro* were assigned

[10] Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations of the Unified Electronic Information System of the Health Care Sector".
[11] Regulations of the Cabinet of Ministers of 29.09.2009 No.1119 "Terms of Reference of the Centre for Health Economics" (invalid as of 11.11.2009.).
[12] Regulations of the Cabinet of Ministers of 01.11.2011 No.850 "Terms of Referenc eof the National Health Centre", Sub-Paragraph 3.22.

from the state main budget and used, out of these - 953 544 *euro* for remuneration - 1 406 818 *euro* on goods and services and - 484 038 *euro* on equity capital (see Figure 6).

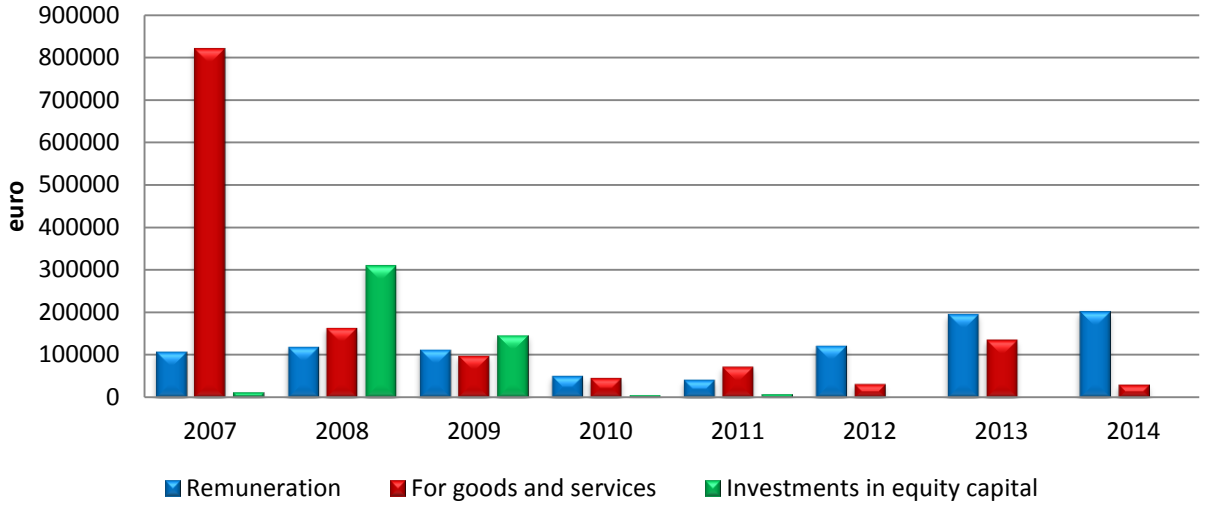



*Figure 6.* **State grant expenditure to introduction of e-health (years 2007 – 2014).**

As of 2009 funding has been attracted for implementation of the e-health from the European Regional Development Fund (planning period 2007 – 2013), which allowed for target oriented and active implementation of the guidelines and planned activities. The amount available until year 2014 was 17 749 409 *euro*, including:

- Project for Development of Unified Control Information System of the Sector by the Health Care Inspection - 325 630 *euro*;
- Project for Setting up of the Control Information System and Dispatcher's Centres of the Emergency Medical Assistance Service and Centre for Catastrophe Medical Aid 5 445 196 *euro*;
- National Health Service is in charge for the existing four projects of e-health implementation for the total value of 11 978 583 *euro*, see Table 2.

*Table 2*

**E-health projects**

| Project | | |
|---|---|---|
| **title** | **time period of implementation** | **total financing** |
| Setting up of electronic visit booking (e-booking) system, electronisation of health care workflows (e-referrals), stage I, creating of public health portal, provision of information security and protection of personal data<br>(project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/015) | from 30.10.2009 to 29.12.2014 | 3 150 846 *euro* |
| Setting up of electronic prescriptions system, stage I<br>(project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/003) | from 08.07.2010 to 07.12.2014 | 581 385 *euro* |
| Setting up of electronic health card and integration platform's information system, stage I<br>(project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/019) | from 11.06.2010 to 10.12.2014 | 3 525 371 *euro* |
| Development of e-health integrated information system, stage II<br>(project ID No.3DP/3.2.2.1.1/13/IPIA/CFLA/008) | from 29.04.2013 to 28.06.2015 extended to 28.11.2015 | 4 720 981 *euro* |

| Project | | |
|---|---|---|
| **title** | **time period of implementation** | **total financing** |
| Development of unified control information system of the health care sector, stage I<br>(project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/006) | from 23.09.2009 to 22.03.2013 | 325 630 *euro* |
| Setting up of the Control Information System and Dispatcher's Centres of the Emergency Medical Assistance Service and Centre for Catastrophe Medical Aid<br>(project ID No.3DP/3.2.5.2.0/09/IPIA/VSMTVA/001) | from 06.04.2009 to 30.06.2015 | 5 445 196 *euro* |

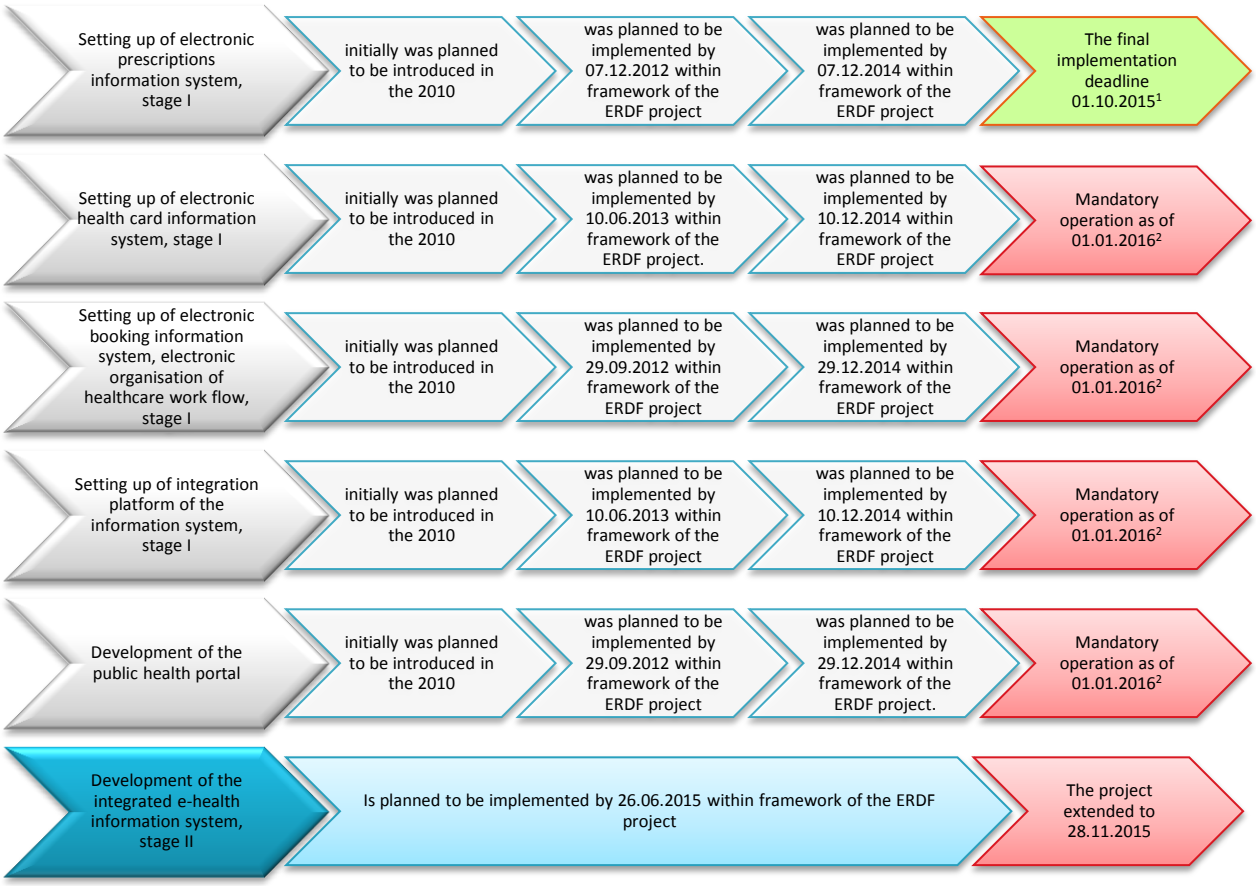
Currently the National Health Service is introducing e-health information system's solutions of the stage I, which are e-prescriptions, electronic health card, electronic visit booking and electronic regulation of work flow, e-health portal and integration platform, as well as integrated information system of the stage II of the - e-health.

According to the Order on Setting up and Active Work of Supervision Committee of Implementation of the e-health Projects of the Ministry of Health of 15 January 2015 certain progress has been noted in the area of implementation of information system of e-prescriptions and electronic sickness leave acts, and detailed deadlines set for implementation of certain activities, e.g., concerning implementation course of e-prescriptions:

- 1 April 2015 – registration of personal data processing in the State Inspection of Data;
- 28 June 2015 – data import from the Management information system in the production environment;
- 1 September 2015 – transfer of e-prescriptions functionality to the production environment;
- 1 September 2015 – signing of contracts on involvement in the e-health and launch of e-prescriptions at the production environment (institutions which were involved in testing of e-health);
- 1 September 2015 – operations of e-health help service are started;
- 1 October 2015 – introduction of e-prescriptions in the production environment for health care institutions and pharmacies;
- 1 January 2016 – mandatory use of e-prescriptions by all health care institutions and pharmacies.

While no more detailed information is available on implementation activities and deadlines of other e-health information systems, just the information that systems were supposed to start running in the production environment already as of 2015 so that any shortcomings in their operations could be identified and eliminated by 1 January 2016, when it is mandatory for all health care institutions and pharmacies to start using the e-health information system.

Currently (i.e. as at 1 April 2015) none of the e-health information systems is running in the production environment and the health care institutions or pharmacies which have signed contracts for testing of the system are unable to test it.




[1] Implementation plan of the E-prescriptions by the National Health Service, dated 16.04.2015.

[2] State Audit Office has not received any detailed plan for implementation of the projects.

*Figure 7.* **Time-frame for implementation of the e-health information systems.**

Within framework of e-health project on 13 August 2010 a pilot project was started offering to public four e-services at the unified public services portal www.Latvia.lv:

- **my family doctor** – within framework of this service a person can obtain information on his/hers own family doctor and that of the minor children;
- **my health care services covered by the state** – within framework of this service a person can obtain information from the "Management Information System" managed by the National Health Service on his/hers or children's visits to doctors, diagnoses and treatment paid from the state budget;
- **my data at the register of sugar diabetes patients** – within framework of this service a person received information on electronically stored information on his diseases at the register of sugar diabetes' patients;
- **Data of my new-borns** – within framework of this service a person receives information stored in the state information system „Register of New-Borns".

The four e-services were available to the public at the portal www.Latvia.lv as of 1 October 2013, i.e. only for 25 months and the number of unique requests of these e-services was 248 808[13] or in average less than 2000 hits per week.

[13] Letter of the National Health Service of 04.07.2014 No.0732/7.2-2/5686.

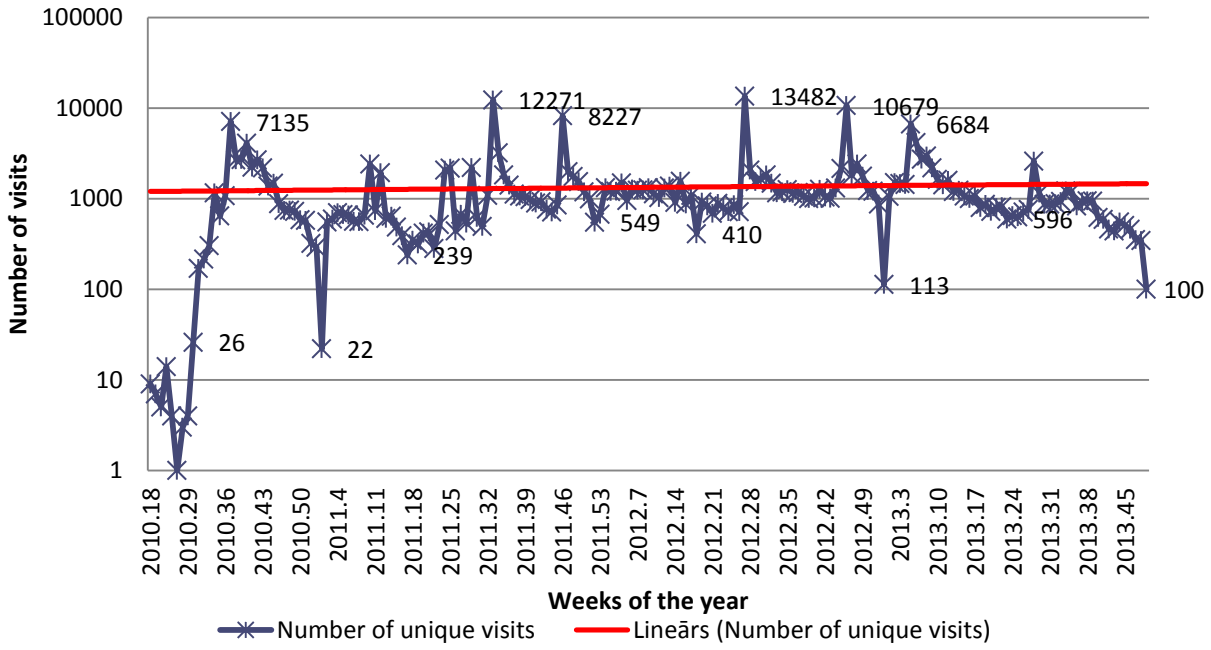



*Figure 8.* **Diagram of visits to the four e-services at the portal *www.Latvia.lv*.**

***Users of the e-health system***

According to the guidelines „E-health in Latvia" the e-health information system will be used to store data on all Latvian residents (according to data provided by the Citizenship and Migration Authority as at the 1 January 2014 the population of Latvia was 2.18 million residents, including people above the age of 16 – 1.85 million) and the e-health information system will be used by at least 25 thousand of health care services providers by entering their patients related data, see Table 3.

*Table 3*

***Health care service providers who shall enter their patient's data in the e-health information system***

| Service provider name | Number |
|---|---|
| Medical professionals – doctors[14] (apart from dentists) | 6967 |
| Dentists[15] | 1476 |
| Medical professionals[16] (with secondary education) | 13 930 |
| Number of in-patient institutions (hospitals)[17] | 65 |
| Number of ambulatory health care institutions[18] | 4718 |
| Number of certified pharmacies[19] | 823 |
| Pharmacists and assistant pharmacists[20] | 2984 |

[14] Statistical yearbook of Latvia, 2014. Available at: http://data.csb.gov.lv, viewed on 29.04.2015.
[15] Statistical yearbook of Latvia, 2014. Available at: http://data.csb.gov.lv, viewed on 29.04.2015.
[16] Statistical yearbook of Latvia, 2014. Available at: http://data.csb.gov.lv, viewed on 29.04.2015.
[17] Statistical yearbook of Latvia, 2014. Available at: http://data.csb.gov.lv, viewed on 29.04.2015.
[18] Statistical yearbook of Latvia, 2014. Available at: http://data.csb.gov.lv, viewed on 29.04.2015.
[19] List of licenced pharmacies. Available at: http://www.zva.gov.lv, viewed on 29.04.2015.
[20] Letter of the Ministry of Health of 13.04.2015 No.01-15/1346.

| Service provider name | Number |
|---|---|
| Number of Blood Service institutions[21], including Blood Cabinets[22] | 60 |
| Number of emergency Medical Aid stations[23] | 190 |
| Number of laboratories[24] | 96 |

### *E-health implementation progress*

According to initial forecasts, at the time of approval by the Cabinet of Ministers of the implementation plan of the „E-health in Latvia" guidelines for years 2008 – 2010, the implementation of the **e-health information system was planned to be completed by the end of 2010,** through development of integration platforms, electronic health card, electronic medical record, electronic prescriptions, electronic booking, electronic work flow information systems, as well as developing portal for development tele-medical treatment and electronic diagnostics and health.

In the middle to 2011 the Director of the Health Economy Centre publically announced that procurements processes for development of the e-health portal, booking/referral, integration platform and electronic health card information system have been completed and their development works will begin. In **2012 pilot projects will be conducted**, involving the health care institutions voluntarily willing to participate. **All projects shall be completed by 2013**, meaning that all the systems shall be operating by then.

When asking for the Cabinet of Ministers to approve the Regulations of the Unified Electronic Information System of the Health Care, in January, 2014 the Ministry of Health informed that as **of 1 April 2014 , that is the deadline of project coming into force, the e-health information system will be available to users at the production environment**, as the health care institutions and pharmacies will be able to sign contracts on use of e-health information system.

In April, 2015 the National Health Service informed that by the 1 December 2015 operation of the e-prescriptions and sickness leave acts information system will be ensured at the production environment and as of **1 January 2016 e-prescriptions functionality will be provided and mandatory to all health care institutions and pharmacies**. However no information is available of other e-health projects and their expected launch dates.

The most relevant overall conclusions on effectiveness of implementation of e-health, including the weak points and strong points, threats and opportunities, are summarized in Appendix No.2.

### *E-health implementation in the future*

Upon continuing development of the e-health information system, Ministry of Health plans to perform the following activities:

- development of the industry statistics;
- setting up of the clinical diagnostics archive;

[21] The blood donors centre and the branches for collection of blood. Available at: http://www.zva.gov.lv, viewed on 29.04.2015.
[22] Blood cainets. Available at: http://www.zva.gov.lv, viewed on 29.04.2015.
[23] Public report of the Emergency Medical Assiatnce Service of 2013. Available at: http://www.nmpd.gov.lv, viewed on 29.04.2015.
[24] Register of health care institutions. Available at: http://vi.gov.lv, viewed on 29.04.2015.

- facilitation of development of radiology information system of the health care institutions;
- setting up of tele-medical consulting centres and e-services;
- electronic data exchange with insurers;
- realisation of information flow of the health care and welfare industries:
  - improvement of services of disability tests by merging systems of the welfare industry (e.g., those of the State Agency for Social Integration, State Employment Agency and State Social Assurance Agency) with the e-health system in order to ensure the required data exchange;
  - information exchange of support information systems with the e-health information system in order to facilitate cooperation between the health care and social care specialists in treatment of patients and to improve quality and efficiency of care;
- improvement of medical coding and classification systems;
- upgrading of tax information services – information on the payments made by a person for the health care services will be transferred from the e-health information system to the information system of the State Revenue Service within course of data exchange process;
- facilitation of interoperability of the existing information systems of the health care institutions and pharmacies is planned;
- introduction of e-EHIC.

# FINDINGS

## 1. Will the e-health be able to solve the problems and achieve objectives?

This section provides assessment of the policy of the Ministry of Health in the area of e-health, its quality and topicality, confidence has been gained whether during the development and implementation of policy stakeholders are involved and verified whether it will be possible to achieve the defined aims, policies and results of activities, as well as assessed accessibility of e-health system to its users.

***Sources of information***

- *The Regulations of the Cabinet of Ministers of 12 March 2009 No. 111 "The Terms of Reference of the Cabinet of Ministers".*
- *The Order of the Cabinet of Ministers of 17 August 2005 No. 560 "On the Guidelines "E-health in Latvia"".*
- *The Order of the Cabinet of Ministers of 24 October 2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010".*
- *Informative report of the Ministry of Health of 23 April 2008 on implementation in 2007 of the Guidelines "E-health in Latvia" and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.*
- *Informative report of the Ministry of Health of 6 November 2014 on implementation of the Guidelines "E-health in Latvia" in years 2008 – 2013 and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.*
- *Assessment of policy influence in the policymaking system. State Chancellery, 2015.*
- *Surveys of stakeholders.*
- *Information from the Ministry of Health and the National Health Service (supportive documents, information, interviews).*

***Audit methods***

- *Compliance of development of policy documents with the legal acts was assessed.*
- *Documents on which the policy development was based were reviewed and analysed.*
- *Involvement of professional organisations in policy development and consideration of interests of stakeholders was verified.*
- *The situation was assessed whether the planning documents required updating.*
- *The results of surveys of stakeholders were analysed.*
- *Interviews with employees of the Ministry of Health.*

***Evaluation criteria***

- *Has the policy been developed for use of information and communication systems in the health care?*
- *Has the policy been prepared on the basis of research, surveys, and situation analyses performed?*
- *Are policy documents updated and reflecting the current situation?*
- *Were professional organisations involved in policy development and were interests of stakeholders taken into consideration.*
- *Has the impact assessment been performed?*
- *Have achievable objectives and measurable resulting indicators been set?*
- *Has the accessibility of the e-health system to potential users been ensured?*

### 1.1. Has objective and high quality information been used in drafting of policy documents?

The policy planning cycle comprises four stages: definition of scope, policy development, decision making and policy implementation stage. The ministries shall be informed on policies which will be having significant fiscal effect or which will be addressing the public in general at least two stages in advance before starting development of current annual budget so that financial and human resources required for development and assessment of the policy could be organised in a timely manner.

At the beginning of e-health policy development an in-depth assessment of the policy effect was required, as use of information and communication technology tools is planned in the project for improvement of quality and efficiency of the health care services.

In-depth economic, social and environmental impact assessment mostly is conducted by involvement of independent experts, but the ministries could be able to handle it themselves or by organising work groups.

The guidelines are a policy document detailing core principles of the government's policy, development objectives and priorities set in a particular sector. Guidelines are usually developed for building of a new policy, as well as in the case when policy governing respective sector has not been set in sufficient detail or is significantly changed[25].

Ministry of Health is a leading state authority in the area of health care, covering such sectors as public health, health care, pharmacy and drugs circulation and developing state policy in the areas of public health and health care, organising and coordinating policy implementation, supervising the health promotion policy realisation at the national and regional level[26].

***Defining of the policy scope***

Considering ever increasing application of information and communication technology tools in the health care sector, in the mid of 2003 the Ministry of Health set up the Information Technologies Council with the main objective being preparation of proposals and coordination of information technologies issues in the health care sector.

Although the Information Technologies Council started its work in 2003, the Ministry of Health was unable to present the auditors with any minutes of its meetings for the years 2003 and 2004. According to the information provided by the Ministry of Health total of six Council meetings were held – four of those in 2005, one in 2006, none in 2007 and 2008 and the last one was held in early 2009.

One of the tasks of the Information Technologies Council was to provide an opinion on compliance of e-health projects with the e-health guidelines[27].

Initially the Information Technologies Council was comprised of representatives from subordinate authorities of the Ministry of Health and just in 2009 representatives were invited also from the professional organisations, e.g., Latvian Pharmacists Union, Latvian Doctor's Association, etc.

A little later, on 3 November 2003 the Ministry of Health set up a work group for development of the guidelines „E-health in Latvia" in order to allow for the policy planning document to

[25] Regulations of the Cabinet of Ministers of 12.03.2002 No.111 „Regulations on the Terms of Reference of the Cabinet of Ministers", Paragraph 15 (effective by 01.03.2009.).
[26] Regulations of the Cabinet of Ministers of 13.04.2004 No.286 „Terms of Reference of the Ministry of Health" Paragraphs 1, 4., 5.1.1, 5.1.7 and 5.2.1.
[27] Letter of the Ministry of Health 09.06.2005. Terms of Reference of the Information Technologies Council.

contain assessment of ways for improvement of efficiency of the health care system considering development of information and communication technologies opening new opportunities for use of technologies in provision of information flow throughout the entire health care cycle, public education and life-long training of medical professionals, at the same time ensuring high profile security of health care information. The Ministry of Health was unable to provide information on the course of meetings of the work group (an agenda items, experts invited, etc.), however a policy document was developed as a result of the group work - guidelines „E-health in Latvia".

The work group set up by the Ministry of Health comprised employees from the Ministry of Health and its subordinate institutions (managers of various levels) and a director of the Radiology Diagnostics Institute of one hospital, which later was involved in implementation of the project[28].

In preparation of the policy document the agenda includes actual public issues requiring solutions.

The work group set up by the Ministry of Health also identified problems the solution of which required implementation of the e-health policy. These problems have been grouped in three blocks (see Figure 9).

**1. Realisation of strategic objectives set by the state for the health care**

- access to health care information has been hindered;
- use of internet for notification of the population is not systematic and coordinated;
- insufficient development of the telemedicine services;
- uneven spread of information technologies between the health care policy makers and owners, providers of the health care services and the recipients;
- uneven spread of information technologies hindering operative exchange of information;
- the state information systems don't have interfaces providing for electronic data exchange with other national registers and information systems engaged in provision of the health care services.

**2. Realisation of the set strategic objectives in the e-government**

**3. Development of e-health in Latvia in all areas is not in line with other initiatives of the public information provision services**

- development of e-health in Latvia in all areas is not in line with other initiatives of the public information provision services and other European countries;
- Latvian participation in the EU networks was started relatively short time ago;
- no electronic medical histories and benefits of storage and information exchange provided by the electronic health cards, prescriptions, potential treatment methods and medications used;
- no support systems of clinical decisions making are used;
- no opportunities provided by the information technologies are used for life-long education;
- patients, when using the internet do not have access to sufficient information concerning the diagnosis, available treatment methods and medications to be used;
- weakly developed care of the patients at home by performing detection of main health condition features remotely;
- cooperation with the insurance companies not well developed;
- policy planning and realisation institutions have no ways of obtaining recent information on the actual situation in respective area of the healthcare.

*Data source: Guidelines „E-health in Latvia"*

*Figure 9.* **Problems for solution of which the implementation of e-health Guidelines is required.**

[28] Order of the Ministry of Health of 03.11.2003 No.302 „On setting up of the task groupo for drafting of the e-health developement strategy".

It was concluded from analysis of problems identified by the Ministry of Health in the Guidelines:

- not a single problem has been identified in the second block containing problems arising from realisation of strategic objectives set by the government in the e-government;
- the areas of actions of the Guideline, activities of the implementation plan and the actual activities of implementation of the e-health information systems project are not addressing many of the identified problems, e.g. no solution has been listed among activities of the implementation of the Guidelines for the problem and the problem is not addressed: *„uneven spread of access to information technologies encumbering operational exchange of information*".

On the basis of the Guidelines the Ministry of Health in April, 2006 set up a work group for development of the plan of the Guidelines „E-health in Latvia"[29]. The work group comprised 15 members, majority of which were employees of the Ministry of Health and its subordinate institutions, representatives of two hospitals and a representative of the Health Care Employers Association.

***The course of policy development***

There is a little information available on the process of development of the policy documents of the Ministry of Health – the Guidelines „E-health in Latvia" and the plan for implementation of the Guidelines in years 2008 – 2010, since according to the information provided by the Ministry documents either do not exist or the persons involved in development of the policy are no longer employed by the Ministry of Health.

Since the Ministry of Health has no information on the course of drafting of the Guidelines „E-health in Latvia" and the information source used, the audit assumed that the documents listed in the paragraph 11 of guidelines are the ones that are used for substantiation of Guidelines.

The documents used in drafting of the Guidelines can be split into four groups:

- national legislative acts;
- EU legislative acts (directives, regulations);
- national policy planning documents in the health care sector, e-government, etc. (strategies, concepts, programmes);
- research, experience, information of the other countries.

The description of current situation in Latvia as presented in the paragraph 2 of Guidelines contains analysis of effective policy documents, legislative acts with problems being identified in the health care sector, e.g., insufficient information and restricted opportunities for performance of impartial situation analysis of the industry, the data accrued is not reliable, no single information source of diseases is available, etc.

While the Ministry of Health has not performed any feasibility studies, research or surveys to identify opinions, interests of the health care specialists, pharmacists, population and other stakeholders, expected results and has not performed situation analysis of the actual health care conditions and use of information technologies, as a result of which SWOT analysis would be made and several scenarios (alternatives) would be developed along with in-depth risk analysis.

[29] Order of the Cabinet of Ministers of 24.10.2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010".

No information has been received from the Ministry of Health on the process of development of the implementation plan of the Guidelines for the years 2008 – 2010 and the work of the work group. The plan has been prepared in exercise of the order of the Cabinet of Ministers No. 560 of the 17 August 2005 „On the Guidelines "E-health in Latvia"".

***Decision making***

The planning documents prepared by the Ministry of Health by their structure and the approval process at the Cabinet of Ministers comply with the terms of reference of the Cabinet of Ministers.

The Ministry of Health prepared and presented at the meeting of the State Secretaries of 25 November 2004 the draft Guidelines „E-health in Latvia", which was supported by the Cabinet of Ministers on 16 August 2005[30] and ordered to develop the plan for implementation of the guidelines and to present it for approval of the Cabinet of Ministers by 1 March 2007.

On the basis of the guidelines the Ministry of Health prepared draft Implementation Plan of the Guidelines „E-health in Latvia" for years 2008 – 2010, and presented it at the meeting of the State Secretaries of 22 February 2007, which later was approved by the Cabinet of Ministers on 23 October2007[31].

### 1.2. Have the policy documents been updated?

The summary of the Guidelines provides that guidelines shall be implemented within the 10 years' time, which is by 31 December 2015, and the implementation plan shall be updated every year considering the funding available and the total planned amount of the investment is about 35.9 mln. e*uro*.

The Implementation Plan of the Guidelines „E-health in Latvia" for years 2008 – 2010 states that required funding is 42.1 mln. *euro*, while the funding required for implementation of all activities listed in the Guidelines for the period from 2007 to 2013 amounts to 71 mln. *euro*.

As one of the priority health care sectors the Guidelines „E-health in Latvia" set the development of the tele-medicine in Latvia by providing telemedicine equipment, users training in all emergency medical aid hospitals, fostering use of video-coordination and development of tele-medical consulting centres by allocating 40% from the entire planned financing assigned to the e-health.

However during drafting of the plan for implementation of the Guidelines the priorities of the Guidelines changed and from the development of telemedicine only the setting up of consulting centre was left, by allocating mere 0.7 mln. *euro* to it, which is less than 2% from the overall planned financing. Moreover by the 1 April 2015 development of telemedicine in Latvia has not yet been started and the Ministry of Health informed[32] that it is planned during the next stages of implementation of the e-health (maybe at the 3rd stage).

Although the Ministry of Health was aware that the funding assigned in 2008 and in the following years does not comply with the implementation plan, but instead it was by 10 times lower than planned, e.g. financing actually allocated for the year 2008 was 0.96 mln. *euro*,

[30] The Order of the Cabinet of Ministers of 17 August 2005 No. 560 "On the Guidelines "E-health in Latvia"".
[31] The Order of the Cabinet of Ministers of 24 October 2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia"" for years 2008 - 2010".
[32] Informative report of the Ministry of Health of 6 November 2014 on implementation of the Guidelines "E-health in Latvia" in years 2008 – 2013 and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.

while the planned amount was 9.2 mln. *euro*, however the Ministry did not consider that any amendments shall be introduced in the implementation plan of the Guidelines.

Also the implementation plan of the Guidelines lists activities which are not covered by the Guidelines, e.g., the implementation plan provides for an activity:

- „*Electronic organisation of health care workflow*" with such-sub activities as e-prescription, electronic booking of visits, electronic organisation of the health care work flow, electronic data exchange with the insurers, while one of the priorities of the Guidelines is „*Informatisation of internal work of the health care*" with the following areas – development of unified health care communications network, increasing share of computers with internet connections and accessibility of the communication networks;
- „*Electronisation of diagnostics and development of telemedicine*" with sub activities – setting up of central visual diagnostics (radiology) archive, setting up of central clinical diagnostics archive, facilitation of development of radiology information system of health care institutions and setting up of the consulting centre of telecommunications, while the Guidelines had planned for development of the telemedicine (acquisition of equipment, training, use of video-coordination, setting up of the consulting centre);
- „*Setting up of unified health care sector's supervision information system*", while the Guidelines do not provide for such action area.

Ministry of Health certifies that some of the tasks included in the guidelines and the implementation plan have lost their topicality over the time. The guidelines and the implementation plan are updated e-health documents as far as the tasks to be performed are concerned[33].

### 1.3. Has impact of the policy documents been assessed?

Ministry of Health has not performed initial assessment of the planning document Guidelines „E-health in Latvia" during the development process of the document, and also has not performed interim assessment for purposes of supervising course of implementation of the planning document and identification of amendments required, but as of year 2008 to 2009 have outsourced and involved consultants that have provided the following opinions:

- on options of measures to be taken and their assessment for efficient application and maintenance of the e-health project results for the 10 (ten) years period;
- on the plan for implementation of the measures of efficient application and maintenance of the e-health project results;
- on the assessment of methodology of the resulting indicators of the measures taken for the Implementation plan of the Guidelines „E-health in Latvia" for years 2008 - 2010.

[33] Letter of the Ministry of Health of 09.07.2014 No.01-15/2433.

### 1.4. Have interests of all stakeholders been considered in implementation of the e-health system?

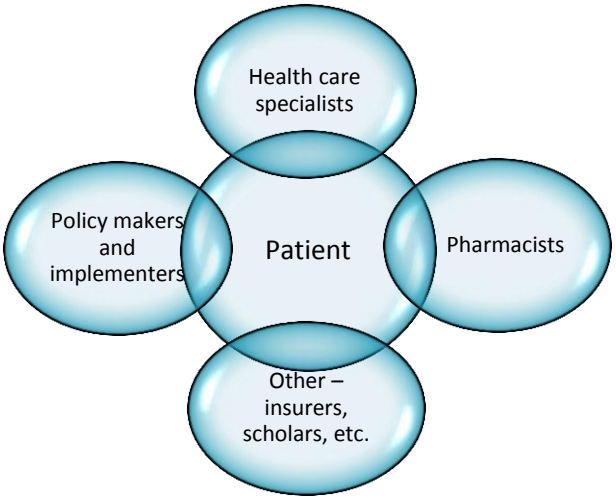



*Figure 10.* **Stakeholders of the implementation of the e-health information system.**

Main stakeholders for implementation of the e-health information system:

- patients (inhabitants) shall be considered as primary beneficiaries who will be benefiting from setting up and use of the e-health information system;
- health care specialists (service providers) are considered as one of the key indicators of the health care information and one of the main users of the system;
- pharmacists are users and creators of the health care system;
- authors and implementators of the health care policy are interested in efficient administration of the health care system and its financial resources, therefore they are one of the most active users of the health care information;
- other concerned parties, e.g., insurers, researchers, scholars are users of the health care information.

According to the information at the disposal of the State Audit Office the work groups for drafting the e-health Guidelines and the implementation plan were mainly attended by one stakeholder – the employees of the Ministry of Health and its subordinate institutions, i.e. health care policy makers, implementers, managers and administrators, but no health care professionals, pharmacists and information and communication technology specialists were invited.

In early April, 2014 survey of the health care institutions – hospitals providing health care services and using information and communication technologies revealed that out of 13 health care institutions:

- seven are using the information system „Ārsta birojs" ("Doctor's Office"), while six are using their own tailor made and maintained information systems;
- nine are entirely or partially satisfied with the current information system, but four are not satisfied with the functionality offered by the information system;

- in response to question related to introduction of the e-health in Latvia, five respondents indicated that they are looking for a centralised solution meaning that hospitals will have to maintain health care services information systems, but six – for a decentralised solution (the health care institution shall maintain its local information systems with option of connecting to state integration platform for data exchange), but two had no opinion;
- in response to a question on whether the e-health system will improve quality of the health care, ensure more efficient use of every *euro* invested in the health care, improve communication options, five of the health care institutions replied that it will improve, while seven ones emphasised problems due to which at least at the beginning the situation will not improve, e.g., because the entire process will be overloaded due to insufficient capacities, costs will increase – acquisition of new hardware, training of employees, hiring of new employees, as documents will still be kept also in a printed format;
- nine health care institutions were not satisfied with communication of the project managers concerning project development by indicating that no sufficient information is provided, five health care institutions had no thorough understanding of the activities to be performed in order to start using the e-health system, while three health care institutions have started working on integration of the systems, six have not started, but the rest had no answer.

In early April, 2015 survey was done of the pharmacies with the widest chain of points of sale involved in provision of the health care services – by trading prescription drugs and using information and communication technologies, establishing that out of six pharmacies:

- four are satisfied with the currently used information system, while two are not fully satisfied with the current information system;
- three would like for the e-health system to be decentralised, but two would like to give up the existing information systems and to operate in high quality e-health system;
- four pharmacies believe that the e-health system will improve quality of the health care and operations of the pharmacies, as the communication will improve between the pharmacies, health care institutions, at the same time decreasing the fraud risk (fraudulent prescriptions, stolen prescriptions), volumes of human resources required, documents circulation will decrease. One pharmacy believes that time required for servicing one client will increase;
- four pharmacies are not satisfied with communication of the project managers concerning project development by indicating that no sufficient information is provided, while three pharmacies had no thorough understanding of the activities to be performed in order to start using the e-health system.

Within framework of the survey performed in cooperation with the Market and Public Opinion Research Centre SKDS the State Audit Office established willingness of residents to use various e-health services. It shall be noted that respondents were of rather positive, not negative opinion about the e-health services – 50% to 54% of the respondents replied that they would be using them, while 33% to 37% would not. E.g., 54% of residents are willing to obtain information on improvement of the health in a single portal, 51% would use the option of electronic communication with health care professionals, and also 51% would like to track financing of health care services received by them, but 50% would use internet to track the course of their health care (diagnoses, treatment process, drugs).

### 1.5. Have criteria been set to measure achievement of resulting indicators and objectives?

The objective is a desired condition that management is willing to achieve through improvement of the respective policy area. It shall be aimed at partial improvement of the situation or complete solution of the problem.

Objectives shall be realistic, by providing an option that funding might be insufficient, as well by planning for action scenarios considering such situation. The objectives are detailed by formulating of the action directions and respective results, which in turn serve as a basis for assessment of the implementation of the policy or the *ex-post* assessment.

In order to address the problems identified the Ministry of Health has defined in the Guidelines „E-health in Latvia" the overall objective and the objectives, as well as provided for policy and operating results.

> The overall political objective of the e-health developement is: improvement of efficiency of provision of the health care services.

Objectives of the e-health development:

- to improve overall health condition by facilitating control of the individual over their own health;
- to decrease wasted time of the patient;
- to improve efficiency of the health care by providing fast access to the required health care data of the patient;
- to decrease amount of data to be entered by the doctor in the system;
- to increase of volume and application of information structured through health care studies;
- to increase efficiency of management resources of the health care institutions;
- to ensure reliability and safety of health care data.

In the e-health Guidelines and the implementation plan:

- theobjectives shall be clear, realistic, however the logistic model of the e-health has not been defined in detail;
- the objectives shall be achievable and measurable, however indicators have not been set for many objectives, but the mentioned indicators are contradictory and formulated with insufficient detail;
- the objectives shall be terminated, but in this case the objectives shall be achieved by the end date of the effective period of the guidelines – 31 December 2015.

In order to assess the achievement of the objectives, the policy and operational results shall be measurable.

The policy results are public changes (in the areas of policy, economy, social, culture, environment, etc.), directly caused by achievement of operational results of one or several institutions affected by the factors of the external environment.

For the foreseen policy results and resulting indicators planned in the guidelines and the implementation plan, see Table 4.

*Table 4*

***Policy results set by the Ministry of Health in the Guidelines***

| Policy results | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|
| Time consumed by the patient in contacting with the health care institutions | will decrease by 5% | | | |
| Time from the moment of patient's application to actual provision of service | will decrease by 10% | | | |
| Time used for filling in of the medical documentation and obtaining of necessary information | will decrease by 10% | | | |
| Time required by the doctor to obtain former information on treatment of the patient (*anamnesis*) | will decrease by 30% | | | |
| Length of administrative procedures of the health care institutions (minutes per visit) | will decrease by 10% | | | |
| Operational notification of health care specialists in the emergency situations (quantity) | will increase by 30% | | | |
| Identification and elimination of inefficient expenses | will increase by 10% | | | |
| Volumes of information on improvement of health available to the public | will increase by 5% | | | |
| Quality of information and opportunities of obtaining it for efficient planning of cost investments | will increase by 10% | | | |
| Public information on organisation of medical treatment | will increase by 15% | | | |
| Complete and timely summarising of the health care information will allow for improvement of the work of health care policy makers and quality of the policies developed. | | | | |

Ministry of Health for achievement of the political objectives defined in the Guidelines has set achievable policy results and the trend of resulting indicators and percentage performance (e.g., will decrease by 5%) for the four years period, but the Ministry has not identified the initial situation in the health care area and has not obtained, summarised data (base data) against which the results (resulting indicators) will be assessed (compared).

Ministry of Health has no methodology and criteria for measuring the resulting indicators after the effective date for implementation of the Guidelines, which is after 1 January 2016.

The operational results are end products of the work of the ministries and institutions, or the services and goods created by using investments (human resources, equipment, etc.) and which are provided to an external client – general population, public organisations, etc.

In order to enable assessment of the results, the resulting indicators reflecting results shall be defined, which will mean numerical representation of achievement of benefits and use of investment.

Resulting indicators expressed just as a percentage without indicating numerical value can be misleading.

For the planned operational results of the Ministry of Health and provisional assessment of the achievement of the operational results made by the State Audit Office as at 1 April 2015 see Table 5.

*Table 5*

**Results of activities set by the Ministry of Health in the Guidelines**

| No | Results of activity | Defined by the Ministry of Health | | | | Actual fulfilment in year 2015 according to Assessments of the State Audit Office |
|---|---|---|---|---|---|---|
| | | 2006 | 2007 | 2008 | 2009 | |
| 1 | Information systems with complete electronic medical history introduced in health care institutions. | 10% | 30% | 60% | 100% | Not fulfilled[1] |
| 2 | Centralised system of electronic health cards has been introduced | - | - | X | - | Not fulfilled |
| 3 | Online services available to patients have been introduced (booking of a visit, registration by the family practitioners, access to own health care data, etc.)<br>*at least once*<br>*on-going* | 0.5% | 3%<br>0.1% | 8%<br>3% | 15%<br>7% | Not set up[2] |
| 4 | Employees of the health care institutions have been trained for working with the IT | | 500 | 700 | 900 | 2340 |
| 5 | New telemedicine centres have been set up | | 2 | 3 | 3 | Not set up |
| 6 | Health care home page has been launched | | X | | | Not launched |
| | **Computers with connection to the internet and health care communication network are available:** | | | | | |
| 7 | In the hospitals: at least one for every three health care specialists | | | | X | 17% of health care professionals have no access to computer technologies at their workplace |
| 8 | At the out-patient health care institutions: one at each doctor's workplace | | | | X | |
| 9 | At the practices of the family practitioners: at least one in each practice | | | | X | |
| 10 | In pharmacies: at least one in each pharmacy | | | | X | 3% of pharmacists have no access to computer technology at their workplace |

Information on performance of the indicators will be summarised by the Ministry of Health at the informative report on fulfilment of the Guidelines „E-health in Latvia", which shall be submitted to the Cabinet of Ministers by 1 May 2016.

According to the State Audit Office the results defined in the Guidelines have not been achieved and might even never be achieved, since, e.g.:

- [1] although it was planned in the Guidelines to introduce the health care information systems with complete electronic medical history, however the Ministry upon assessing of priorities is not currently planning setting up of a unified information system of the health care service providers, but is planning to promote interoperability of the existing information systems of the health care institutions and pharmacies with the existing e-health information system (without attracting financial means);
- [2] although certain progress has been noticed for achievement of the third operational result – as of 13 August 2010 four out of five planned pilot e-services have been developed and made publicly accessible at the unified portal of state and municipal services www.Latvia.lv,

however as of 1 October 2013 these e-services are no longer available to the public. The Ministry of Health has not evaluated achievement level of the indicator for the period while the e-health services were available to public.

Pilot e-services planned by the Ministry of Health and created by the National Health Service – my family practitioner, my state paid health care services, my data in the register of the sugar diabetic patients, data of my new-borns, my vaccines – although initially this service was planned, it was not created and offered to public.

It shall be emphasised that the Ministry of Health had ordered and in 2009 received an assessment of the methodology used for assessment of resulting indicators of the measures taken within implementation plan of the Guidelines „E-health In Latvia" for years 2008-2010[34], which provides for the following drawbacks and proposals:

- the Guidelines shall be updated by detailing objectives of the e-health, policy and operational indicators;
- operational strategy and the indicators shall be updated considering the logical model of the programmes;
- health care statistical reports shall be updated considering additional indicators of the e-health area and information system shall be set up for summarising and reporting of the indicators;
- return on investment of the e-health shall be assessed in monetary terms.

Although drawbacks have been indicated to the Ministry and a proposal has been issued for updating of the policy documents, the Ministry still has not updated and amended the Guidelines „E-health in Latvia" and the Implementation Plan of the Guidelines.

### 1.6. Will the access of users to the e-health be ensured?

Regulations[35] on unified healthcare industry electronic information system provide for that by the 31 December 2015 the health care institutions and the pharmacies sign agreements on use of the health care information systems and as of 1 January 2017 the user of the system will be able to connect to the system (authenticate) in the system only by using a personal ID (eID card). By the 31 December 2016 the user of the e-health information system will be able to connect to the system by using any of the authentication methods offered by the portal www.Latvia.lv.

Although the Ministry of Health when advancing regulations for approval of the Cabinet of Ministers provided that as of 1 April 2014 the health care specialists and pharmacies will be able to sign agreements on the use of the health care information system, however by April, 2015 none of the health care institutions and pharmacies had signed an agreement on use of the e-health information system, since the National Health Service had not provided for such an option.

By the end of 2014 the Authority for Citizenship and Migration Issues has issued 522 000 personal ID cards to residents, which is by 50% less than personal passports, and the e-signature option had been activated only for 1/3 of the cards. So far no solutions have been

[34] The assessment methodology for the resulting indicators of the measures of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 – 2010.
[35] Regulations No.134 of Cabinet of Ministers „Regulations on Unified Healthcare Industry Information System".

found to ensure, e.g., issuing of e-prescription to a patient without activated e-signature of the personal ID cards.

Unless the situation changes only about 9%[36] of population will be able to use the personal ID card as means of authentication for logging into the e-health system. If starting of 2017 logging in the e-health will no longer be possible through authentication means provided by the www.Latvia.lv, majority of the population will have no access to the e-health system.

A public survey procured by the Ministry of the Environmental Protection and Regional Development[37] in December, 2014 concluded that 79% of the respondents don't hold the personal ID cards, e-signature card or a virtual signature. Only 11% are holding personal ID cards and 16% of these have applied also for the electronic signature option. The smart card reader required for use of electronic signature functions is available only to 40% of the personal ID card holders with activated e-signature. Only about 1% of the respondents can use it as a daily authentication tool along with the personal ID card.

According to the public survey organised by the State Audit Office along with the Market and Public Opinion Survey Centre SKDS it was concluded that 5.8% of residents hold a personal ID card with an activated e-signature, while mere 1.4% of the population have a smart card reader required for use of the e-signature.

In order to use the personal ID card with activated e-signature as a connection tool to the system every user needs also an additional smart card reader (price of one smart card reader is about 12 *euro*).

Paragraph 33 of the Regulations[38] provides that patients having no access to the health information system can see information stored in the health information system related to themselves, their authorising person, their minor children and persons in custody at the office of the respective person's family physician or in the presence of any person employed at the practice of the family's physician upon previous agreement.

In order to verify current readiness of health care service providers and information level on introduction of the e-health in Latvia, in February and March of 2015 the State Audit Office conducted survey of 54 health care professionals. It was established from the survey that 17% of the health care professionals do not have access to computers at their work places.

Considering the above there will be considerable part of patients without access to the e-health information system and it will not be possible to access e-health information system at the office of the respective person's family physician.

[36] Assuming that according to the data provided by Latvian Central Statistical Bureau, in October 2014 there were 1,991,800 inhabitants in the Latvia, the 522,000 is about 26% of the Latvian population, where 1/3 of them account for about 9%.

[37] Internet resource: http://varam.gov.lv/lat/publ/petijumi/pet_Eparv/?doc=14321 (resource apviewed on 01.04.2015.).

[38] Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations on the unified electronic information system of the health care sector".

## 2. Have actual activities performed by the National Health Service for introduction of the e-health been appropriate for achievement of the objective?

This section provides summary of information on actual implementation of the e-health system and assessment of the actual compliance of the e-health implementation activities with the planned measures, costs and deadlines. Activities taken for information and education of the potential users of the e-health information system were assessed, opinions summarised from potential users of the e-health information system on their readiness, information level and attitude towards introduction of the e-health system in Latvia.

***Sources of information***

- *The Order of the Cabinet of Ministers of 17 August 2005 No. 560 "On the Guidelines "E-health in Latvia"".*
- *The Order of the Cabinet of Ministers of 24 October 2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010".*
- *Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations of the Unified Electronic Information System of the Health Care Sector".*
- *Informative reports of the Ministry of Health of 23 April 2008 and of 6 November 2014 on implementation of the Guidelines "E-health in Latvia" and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010 in years 2008 – 2013 and 2007.*
- *"PricewaterhouseCoopers" Ltd. Reports "Evaluation of joint health electronic information system development and implementation process", "Evaluation of E-health information system development efficiency".*
- *Information provided by the Ministry of Health and National Health Service on implementation of the e-health system.*

***Audit methods***

- *Assessment of implementation measures of the e-health, assessment of costs and comparison against the planned implementation measures of the e-health and their costs according to the plan for implementation of the guidelines.*
- *Comparison of actual dates of implementation of the e-health against the planned deadlines.*
- *A survey performed to establish awareness of pharmacists and health care professionals on the implementation of the e-health. Time of the survey: 23.02.2015 to 02.04.2015. Respondents - 54 health care professionals and 78 pharmacists.*
- *Analysed information obtained on e-health testing (In March 2015, from 13 pharmacies and health care institutions).*
- *Analysed information obtained on e-health implementation (In April 2015, from 19 pharmacies and health care institutions).*
- *Analysed survey results of Latvian population conducted concerning awareness of and attitude towards implementation of the e-health information system. Time of survey: 13.02.2015 to 26.02.2015. By a stratified random sample method total of 1031 respondents surveyed aged from 16 to 75 years throughout the Latvia. The sample is representative against the general set.*
- *Usability scenario tests in e-health information system test environment.*
- *Interviews with National Health Service officials.*

***Evaluation criteria***

- *Does e-health implementation management ensure achievement of e-health stated goals?*
- *Does implementation of the e-health comply with the planned measures according to the implementation plan of the guidelines?*
- *Is implementation of e-health falling within the set financial budget– 10,102,002 euro?*
- *Is implementation of e-health falling within the set financial budget according to the implementation plan of the guidelines?*
- *Have the e-health services been introduced by the set deadlines (E-prescription - 07.12.2014, electronic health card - 10.12.2014, Electronic booking of visits, electronic organisation of health care workflow and the public health portal - 29.12.2014.)?*
- *Are the health care service providers ready, informed and trained regarding use of the e-health information system (planned activities cover 100% of the involved and concerned persons)?*
- *Has the society been informed on e-health implementation (60% of Latvian population is informed about e-health implementation, 40% is informed about implementation benefits)?*
- *Is information system usable in accordance with its intended purpose without any special user training?*

## 2.1. Do the actions performed in development and introduction of the e-health comply with the plan and the set financial budget?

Grounding upon the assessment[39] prepared by SIA "PricewaterhouseCoopers" on the course of implementation and development of the unified electronic information system of healthcare industry, it was established that the management of projects of the stage I is primarily directed towards the fulfilment of procurement and delivered product acceptance procedures and is not primarily oriented to achievement of e-health targets.

In the management of e-health projects there has not been sufficiently implemented e-health project and program planning - in the beginning of the program there is not developed e-health program plan, where there are together aggregated all e-health project activities. In the projects solely software development plans are maintained , e-health project managers have not maintained integrated project plans that would unify system implementation process and changes in laws and legislations (except for electronic health cards and integration platform in project where was such a plan). Since there is not developed and maintained program activities plan, there is no controlled execution thereby emburdening integration of results of individual projects.

E-health project managers have changed during the course of time and project managers had not enough experience and education in management of similar scope and complexity projects, e-health, information technologies and/or healthcare. For instance, in electronic health card and integration platform information systems development project there have been three project managers (position - project manager) and none of them had education compliant with the scope of project (higher education in management science and higher education or international certification in project management) and experience in management of projects of a similar scope, meanwhile in the e-subscription development project there were only two project managers (position - senior experts), who were not required to have experience working as project managers and only one of them had sufficient experience in project management. Thereby the project managers had not been required to have sufficient skills in order to successfully ensure management of complex projects.

In each of the projects there were organized project board meetings where there was reviewed the status of projects, risks and changes. In the level of the program there is no program manager elected, nevertheless this function at its merits is performed by Department manager of e-health and International Cooperation. Supervisory Council of e-health program has not been acting validly since not all of the institutions - legal successors have taken part at it, thereby program supervision is not ensured from all the stakeholders. Interim Project Advisory Council has not been organized thereby mutual coordination of dependencies, deadlines and changed have not taken part, problems have not been solved in a complex manner in the context of all projects.

As the experts outlined in their report[40] on assessment of effectiveness of development of e-health information systems - generally material limitations and risks for successful implementation of e-helath solution are related neither with technological issues or overall architecture of solutions, but directly with organizational issues. The main errors have been

[39] „Pricewaterhouse Coopers" Ltd. report of 01.01.2015 - report „Assessment of Unified healthcare electronic information system development and implementation course" (agreement concluded with the National Health Service on 14.07.2014).

[40] „Pricewaterhouse Coopers" Ltd. report of 22.05.2015 – report „Evaluation of E-health information system development efficiency".

admitted already in solution planning stage, nevertheless the good practice examples and experience of other countries recommend a gradual implementation of e-health issues and especially accentuates that is not advisable to implement all projects simultaneously, nevertheless in Latvia there were initiated three large scale projects that the final results currently only partially are ensured with compatibility - every project is planned and directed comparatively autonomously, by including various procurements, developers, offered technologies, etc.

In the course of implementation of projects integration management of various projects is not ensured according to the best practice, as well as the overall management of architecture is not implemented according to the recommendations of best practice, that is also characterized by the features that the most essential e-health solutions compatibility problems are related to compatibility of infomation semantics and these are directly related to planning of conceptual architecture of fragmentary solutions - a unified data architecture has not been developed for individual solutions and the architecture management function has not been performed in full.

Experts point out that overall the e-health solutions have both the technical potential and conceptual potential as well, in order they could be further developed and could bring a positive impact to healthcare industry in future.

## 2.2. Are the activities performed in e-health development and implementation compliant with the plan?

***Planned implementation measures of the e-health***

For purposes of achievement of the objectives set in the guidelines and ensuring the planned benefits, the implementation plan of the guidelines defines the necessary implementation activities of the e-health. In general the activities included in the plan can be arranged in seven groups of measures to be taken (see Figure 11) and the overall funding required for implementation of the plan is 42 149 134 *euro*.

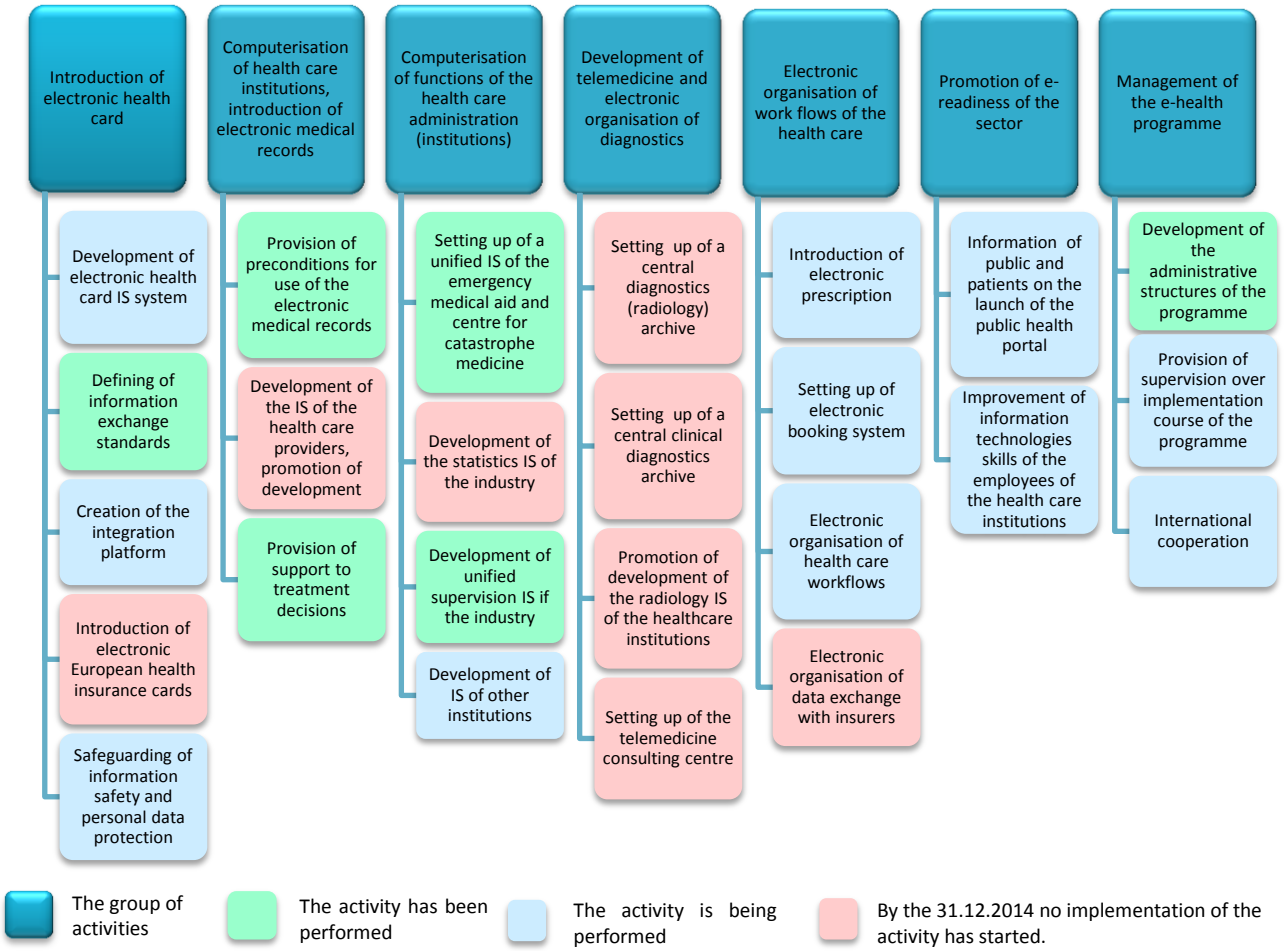



*Figure 11.* **The activities of the Implementation Plan of the Guidelines „E-health in Latvia" for years 2008-2010.**

Analysing the information on compliance of actual implementation activities of the e-health with the implementation plan of the Guidelines „E-health in Latvia" for years 2008 – 2010, the activities for implementation of the e-health can be split in three groups – the activities which have been implemented, the activities being performed and the ones, implementation of which has not started by 31 December 2014 (see Figure 11). In order to provide an overview of share of each group of measures in the overall package of the e-health, the initially planned funding has been given for respective groups of activities according to the implementation plans of the Guidelines (see Table 8 at the page 53).

***Implemented e-health activities***

The following activities of implementation of the e-health have been actually fulfilled (Figure 11):

- the information exchange standards set;
- preconditions for use of the electronic medical records have been ensured;
- support to treatment decisions has been provided;
- a unified information system of the Unified emergency health care and Catastrophe medicine service has been developed;
- stage I of the Unified supervisory information system of industry has been developed;
- e-health program management structure created.

For implementation of these activities in year 2008-2010 the planned financing is 10 634 160 *euro* or 25% from the overall necessary financing.

***Continued undertakings, implementation progress***

National Health Service is continuing implementation measures of the e-health funding of 12 255 551 *euro* or 29% from the total financing and measures are implemented within the framework of the state budget funds assigned and from the co-financing of the projects from the European Regional Development Fund:

- „Setting up of an electronic booking, electronic organisation of the health care work load system, stage I, development of public health portal, provision of the information security and personal data protection";
- „Setting up of information system of electronic prescriptions, stage I";
- „Setting up the electronic health card and integration platform information system, stage I";
- „Development of integrated e-health information system, stage II".

According to the applications for the projects implemented by the National Health Service at the stage I by December 2014 total of 26 e-services, including public administration e-services had to be introduced (see Figure 12).

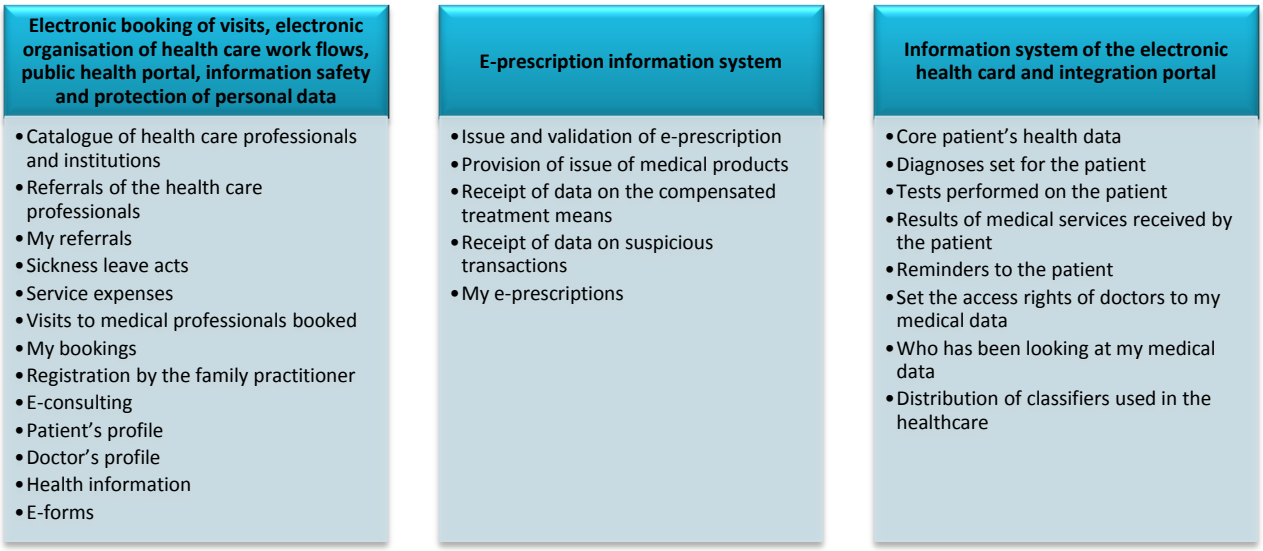



*Figure 12.* E-health **information systems and e-services of the projects of the stage I.**

According to the application of the National Health Service implementedproject of the stage II by the 28 November 2015 five new e-services, including public administration services and seven improved e-services shall be introduced (see Figure 13).

**Development of the integrated information system of the e-health, stage II (including new and improved e-services)**

- EHC notices to patients (new)
- My visual diagnostics data (new)
- Interactive consulting by the doctor (new)
- Submission of potable water testing reports to the Health Inspection (new)
- Certification on receipt of health care services in any member state of the EU, EEA or Switzerland (improved)
- Request for changed of data in the register of the licensed pharmaceutical companies (improved)
- My family practitioner (improved)
- My queues for receipt of state paid health care services (improved)
- Reporting of home care by the family practitioner/ new born (from the side of the child-birth personnel) (improved)
- Registration and request forms (improved)
- Request on actual conditions at the site supervised by the State Health Inspection (improved)

*Figure 13.* **E-services of the projects at the stage II of the e-health**

According to the information gathered within course of the audit on the completion status of the e-health projects by the National Health Service within stage I the development works of the e-health solutions have been completed, however the e-services developed were not available by the public by 1 April 2015. Service provided information[41] that these information systems and the public health portal will be available for use after preparation of the technical infrastructure of the production environment, testing and repeated safety audit, without specifying any deadlines.

According to the report of experts "Assessment of e-health information systems development efficiency" there has been performed assessment of accepttesing documentation of e-health solutions in order to verify whether the National Health Service, upon accepting and paying e-health solution development services, has verified the compliance of functionality of deliverables with the defined scope and quality. Experts identify such accepttesting documents of developed e-health solutions:

- e-prescription/e-booking and WEB platform accepttesting report - there have been established 275 issues (including errors, improvements, requests for changes, etc.), moreover during the accepttesting a part of planned inspections have not been passed, since several functions could not be verified in test environment with additional restrictions "stoppers", as well as there were established multiple issues to be precised. As it is indicated by experts, without verifying all planned functions and identifying such a major number of issues there would be necessary accepttesting;
- electronic health card information system pilot working minutes - included indications to the necessity to ensure system integration with Emergency Medical Assistance Service system and necessity to ensure accessibility of Office of Citizenship and Migration Affairs management service;
- e-health integration platform piloting summary - there are provided recommendations and indications to gaps that the National Health Service should solve in order the e-health platform could be launched with the full functionality at production environment.

[41] Letter of the National Health Service of 15.01.2015. No.07./2/7.2-2/323 „On the request for information in the audit No.2.4.1-7/2014".

According to information provided by the National Health Service the accepttesting process of e-subscription has not been taken minutes of, but the discovered gaps during the accepttesting have been processed as application of error that were notified to the contractor.

National Health Service provided an information that there were no accepttesting reports prepared for all the delivered functionality and system acceptance has not been performed, grounding upon the testing results, that were processed as minutes to the system pilot process, nevertheless the experts conclude that the pilotprocessing minutes according to their contents cannot be considered as accepttesting minutes, since they are not confirming that the technical specification requirement has been complied with, that the customer has to perform accepttesting.

In April and May 2015 experts performed practical examination of e-health solutions in the integrated test environment and during the time of inspection there were identified multiple problems that indicate to possible cooperation problems of developed solutions, for example at the working place of physician it is not possible to develop and to select prescriptions, an error is notified, attempting to register and to find referral, it is not possible to find data of sicknessleave acts, an error report is returned, it is not possible to select data in blocks “Diagnosis” and “Laboratory procedures” etc. National Health Service has provided an explanation that the cause of problems could be installation of new deliveries at the moment of carrying out of inspections, nevertheless the experts did not get a confidence on operation of system at a necessary scope and amount, since the inability of service to ensure an operating test environment during a previously agreed time of inspections indicate to a risk that due to insufficient controls of the management process the accepttesting of e-health solution and launching in production environment in defined term may be delayed.

Experts point out that the most relevant compatibility problems of e-health solutions are related directly to compatibility of semantics of information that arise of fragmentary solution conceptual architecture planning. Although e-health solutions conceptually are planned as an integrated solution, unified data architecture has not been developed, thereby solutions cannot be semantically compatible, ensuring that the development of individual solutions systematically is moving forward to achievement of e-health target architecture, thereby the developed solutions cannot be used at their full potential.

Moreover the experts indicate that there is a substantial risk for starting the e-booking information system usage, since the solution has both – technological problems and problems arising from business processes, for instance, inhabitants may perform records erroneously (for example to book a paid service instead of a service free of charge), inhabitants may not be informed about preconditions that should be observed when coming to a visit (for instance, prior to a visit not to uptake any food, etc.), as a result the service that is booked for, may not be usable. In compliance with information provided by the service in year 2016 it is planned only a partial usage of e-booking solution, namely, an electronic sickness leave act module.

The National Health Service during the implementation process has ordered to the outsourced company testing of e-prescriptions and sickness leave acts functionality to assess whether the developed functionalities correspond to respective Cabinet Regulations No.175 of March 8, 2005 “Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions” and Regulations No.152 of April 3, 2001 “Procedures for Issuance of Sickness Leave Acts”. After the performed testing it was established that the solutions do not correspond totally to respective requirements of the Cabinet of Ministers, since during the course of testing there have been successfully completed less than 40% of test examples created by the outsourced company. Service indicates that a part of requirements of the

regulations is not included in the stage I of development of solutions or is not anticipated at all. Experts also indicate that, upon using the previously mentioned solutions it would be necessary to perform individual manual activities to ensure compliance with the requirements of the Cabinet Regulations.

***Assessment of technological solutions of implemented undertakings***

Experts point out that the possibilities of adaptation of e-health standard solutions have not been evaluated (for instance, electronic health cards, e-prescriptions) and a comparison with newly developed solutions is not made. Upon evaluation from the point of view of costs, it is possible, that it would not change the total expenses of solutions, but would split their positions upon diverting the most part to licences, not to system adaptation works. Nevertheless these types of solutions would be potentially more sustainable. Upon performing analysis of standard solutions available in the market, it is established that a lot of such standard solutions exist (for instance, electronic health card solutions). In the Table 6 there is a comparison of standard solutions with newly developed solutions).

*Table 6*

**Comparison of standard solutions with newly developed solutions**

| Standard solution | Newly developed solution |
|---|---|
| ▪ Shorter implementation period<br>▪ Proved operation of solutions in other countries<br>▪ Included experience obtained during the process of development of solutions, good practice and standard processes<br>▪ Lower costs of capital<br>▪ Available extensive knowledge basis, documentation, other client's experience, etc.<br>▪ Tested standard functionality<br>▪ Updates are performed on a regular basis | ▪ Solutions are in line with specific business process necessities ( i.e., they are close to existing or planned business processes according to unique necessities of customer)<br>▪ More accessible local support<br>▪ Lower operative expenses |

The National Health Service is connecting the choice of particular solutions and grounds it with the results of respective procurements, nevertheless there is a possibility to include assessment criteria in the procurement documentation that would point to desideratum solution (standard solution or newly developed solution). Since the procurements of e-health solutions did not include such assessment criteria, the choice - standard or a newly developed solution - was substantiated solely with the offers of tenderers. Actually during the course of development of procurements there were not evaluated possibilities of the existing situation in comparison to benefits and deficiencies of other solutions.

***Undertakings the implementation of which was not commenced by the end of year 2014***

On 27 February 2015 the Ministry of Health provided information[42] on activities included in the implementation plan of the Guidelines, implementation of which has not been started by the end of 2014 by indicating that several activities have lost their topicality, their implementation is not feasible or is not currently planned, while implementation of several activities has been planned within framework of the project „Development of integrated e-health information system, stage II". Financing of 19 259 423 *euro* or 46% from the total funding required was planned for implementation of these activities. Although several planned, but actually not

[42] Letter of the Ministry of Health of 27.02.2015 No.01-15/764 „On the request for information in the audit No.2.4.1-7/2014 „Information systems in health care".

implemented activities according to the legal act[43] were included in the list of priority projects in the area of development of the electronic government and information society for the European Union Funds planning period of 2013-2017, however according to the legal act[44], additional assessment of projects was conducted considering the economic situation in the country and on the basis of the legal act[45], several activities were striked out from the list of projects to be implemented. The following activities of e-health implementation are not being performed:

- introduction of electronic European Health Insurance Card – implementation of the activity is no longer needed, as reading of electronic data from such a card is not possible in the territories of other EU member states, member states of the European Economic Area and Switzerland;
- setting up of information system of the health care providers, facilitation of development – no development of unified information system of the health care service providers is planned, but the health care institutions using their own information systems will be ensured with option of integration with the health information system, while the health care institutions without their own information system will be accessing the health information system from the e-health portal;
- setting up of central visual diagnostics (radiology) archive – the activity will not be implemented due to excessive maintenance costs. Development of the e-service "My visual diagnostics data" is planned within the frameworks of the project „Development of integrated e-health information system", which will provide people with option of viewing their visual diagnostics data at the health portal and downloading them;
- setting up of a central clinical diagnostics archive, promotion of the radiology information systems of the health care institutions, setting up of the telemedicine consulting centre – no implementation of activities is currently planned;
- setting up of a unified health care communication network (one of the activities for development of an integration platform) – implementation of the activity is no longer needed, as the Regulations of the Cabinet of Ministers[46] on a joint electronic information system of the health care sector define the overall safety and technical requirements that the external information systems shall meet in order to be allowed to establish connections to the health information system;
- inclusion of the cardio-vascular patients in the register of patients suffering from certain diseases (one of the activities for development of the statistical information system of the sector) – implementation of the activity currently is not feasible. Data collection shall be ensured in the existing register of Acute Coronary and cerebral-vascular Syndromes until

[43] Regulations of the Cabinet of Ministers of 07.10.2008 No.584 „On the list of priority Projects of the development of electronic government and information society".

[44] Protocol Decision of the Cabinet of Ministers of 25.08.2009 (prot. Nr.54 44§) to the Informative report „On development of information system, as well as knowledge obtained within the assessment process of project applications submitted within the operational programme „Infrastructure and services" 3.2.2.1.1. sub-activity „Development of information systems and electronic services" concerning efficiency of project expenses, efficient planning of tools and feasibility of performance of audits during the implementation of the project" Paragraph 3, Order of the Cabinet of Ministers of 15.03.2010 No.147 „On the priority list of the projects for development of the electronic government and information society".

[45] Order of the Cabinet of Ministers of 15.03.2010 No.147 „On the priority list of the projects for development of the electronic government and information society".

[46] Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations of the Unified Electronic Information System of the Health Care Sector".

the moment, when the health information system will be launched and data will start to accrue there from the primary registration documents provided by the health care institutions.

Within the framework of the project of the European Regional Development Fund „Development of integrated e-health information system, stage II" it is planned to introduce the data warehouse that is included in the implementation plan of the guidelines (the activity for development of information system of the industry statistics) and the electronic organisation of data exchange with insurers (although the functionality development has been included in the project category „Future").

Since the precondition of successful implementation of the e-health is awareness of the public, patients and health care service providers on implementation of the e-health, as well as improvement of information technology skills of the health care service providers, these activities have been included in the implementation plan of the guidelines, however the activities taken by the National Health Service in this area are not sufficient (see chapter 2.5 on information provided to the public and the health care services providers and their readiness to join the e-health system).

### 2.3. Does the implementation of e-health fits in the defined financial budget?

According to the Implementation plan of the Guidelines „E-health in Latvia" for years 2008-2010, the overall financing required for implementation of the plan has been set at 42 149 134 *euro*, and the fulfilment of activities listed in the plan is ensured by several subordinate institutions of the Ministry of Health.

Currently the overall budget of the e-health activities overseen by the National Health Service is 14 822 983 *euro.* Part of this financing or 10 102 002 *euro* is made up from the state budget financing assigned for the years 2007 – 2014 of 2 844 400 *euro* and the total planning financing for the stage I e-health projects completed by the end of 2014 co-financed from the European Regional Development Fund and implemented by the National Health Service for the amount of 7 257 602 *euro,* including:

- „Setting up of electronic booking system (e-booking), electronic organisation of the health care work flows (e-referrals), stage I, setting up of the public health portal, provision of the information security and personal data protection" – total financing of the project 3 150 846 *euro*;
- „Setting up of information system of electronic prescriptions, stage I" – total financing of the project 581 385 *euro*;
- „Setting up the electronic health card and integration platform information system, stage I" – total financing of the project 3 525 371 *euro*.

The rest of the implementation of the e-health funding or 4 720 981 *euro* is made up from the e-health stage II project „Development of integrated e-health information system, stage II" implemented by the National Health Service and financed by the European Regional Development Fund[47]. Implementation deadline for this project is set for the period from 29 April 2013 to 28 November 2015.

The following implementation measures of the e-health and objectives to be achieved have been provided within the framework of the stage I e-health project of the European Regional Development Fund:

[47] Conditional upon the Project being implemented at the planned volume.

- to set up the electronic booking (e-booking) information system for improvement of access to health care services and decreasing time wasted by the patients;
- to electronically organise health care work flow by setting up information system of electronic referrals (e-referrals) in order to improve productivity of medical professionals, ease information exchange and access of information during the health care process by ensuring accurate accounting and statistics of referrals;
- to set up a health portal to increase awareness of public and patients on the health care issues and motivation to maintain own health, as well as to create a patients and medical practitioners friendly environment, where personal information and electronic services would be available;
- to set up an e-prescriptions information system in order to facilitate and improve efficiency of the process of circulation, tracking and control of the prescriptions, decreasing of potential errors and promotion of decision making by issuing prescriptions, as well as by issuing medicals and thus minimising risk caused to the patient's health by application of advanced information technologies;
- to set up an information system of the electronic health cards in order to provide for a centralised storage of the health information of the patients, operational access to it by the health care professionals and patients involved in the treatment process, which in turn will improve efficiency of the work of the health care specialists, thus improving quality of health care services;
- setting up of the cooperation (integration) platform of the e-health information systems for ensuring safe and efficient exchange of information between all players of the health care system (the health care professionals, patients, policy makers, the administrative institutions of the health care sector, etc.).

Taking into account that the scope of audit does not cover all institutions implementing various activities for introduction of the e-health, information on e-health activities performed by other institutions and their costs has been included in the report on the basis of informative reports of the Ministry of Health on implementation of the Guidelines „E-health in Latvia".

***Actual costs of implementation of the e-health***

From the total cost of the stage I e-health projects implemented by the National Health Service and from the state budget allocated financing for the implementation of the e-health in total reaching 10,102,002 *euro* 9 762 697 *euro* or 97% from the available funding have been actually spent (see Table 7).

*Table 7*

**The funding actually used for implementation of the guidelines „E-health in Latvia" for the period from 2007 to the end of 2014**

| Financing | Actually used financing, *euro* |
|---|---|
| Project „Setting up of electronic booking system (*e-booking*), electronic organisation of the health care work flows (*e-referrals*), stage I, setting up of the public health portal, provision of the information security and personal data protection" | 2 946 401 |
| Project „Setting up of electronic prescriptions system, stage I" | 477 238 |

| Financing | Actually used financing, *euro* |
|---|---|
| Project „Setting up the electronic health card and integration platform information system, stage I” | 3 494 658 |
| State budget financing for implementation of the e-health Guidelines | 2 844 400 |
| **Total financing assigned for the projects implemented by the National Health Service and the state budget for implementation of the e-health guidelines** | **9 762 697** |

Analysis of funding assigned to the e-health Guidelines by years allows concluding that intense implementation of the e-health activities (according to the financing used) was started in 2011 along with launch of the projects of the European Regional Development Fund (see Figure 14).

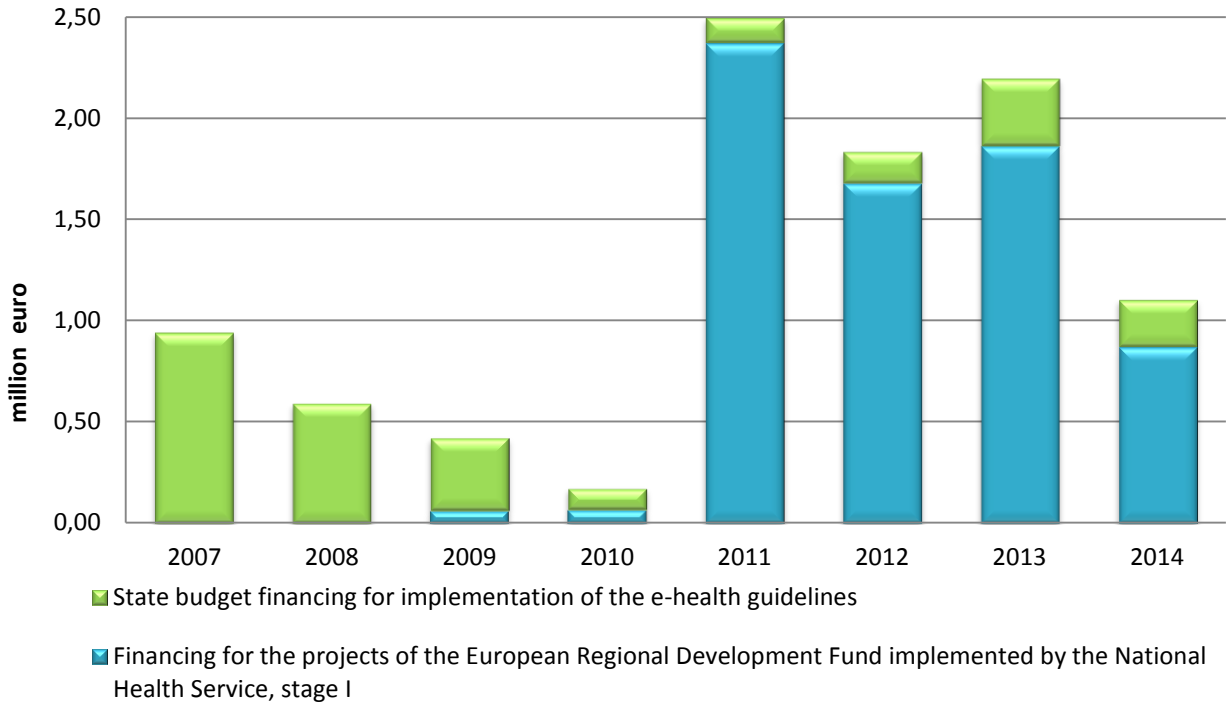



*Figure 14.* **Dynamics of the use of funding assigned to the implementation of the e-health Guidelines in years 2007 – 2014.**

Upon comparison of the actual use of funding of the European Regional Development Fund for projects implemented by the National Health Service at the stage I of the e-health it can be concluded that by the end of 2014 funding up to 82% to 99% was used in the projects, while from the total financing assigned to the project of the stage II „Development of integrated e-health information system” only 146 544 *euro* or 3% of the total project costs were used.

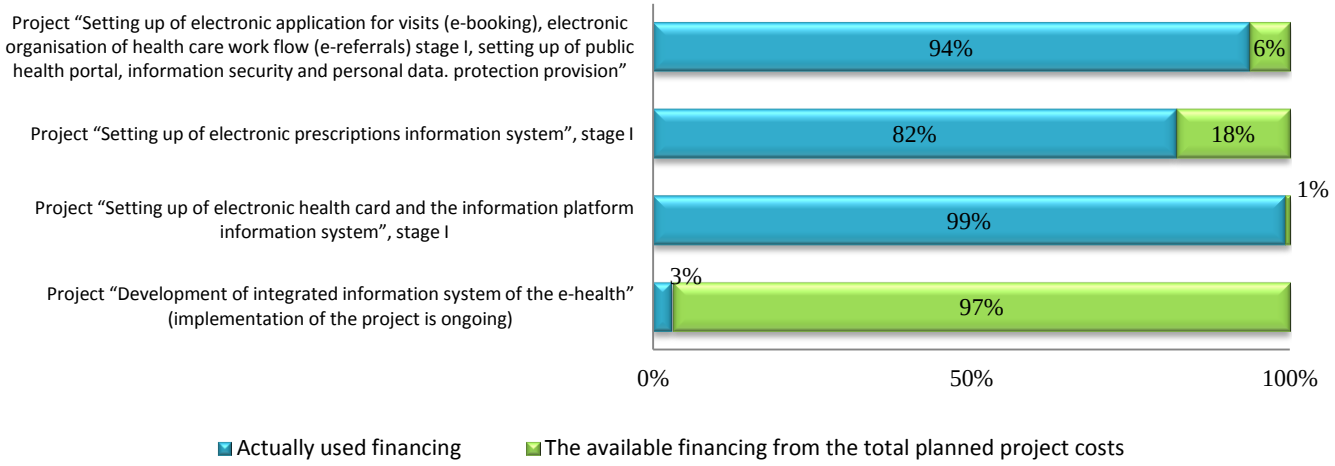



*Figure 15.* **Use of funding for the projects of the stages I and II of the e-health projects by the National Health Service in 2007 – 2014.**

Within the course of the audit comparison was done between the activities for implementation of the e-health according to the Implementation plan of the Guidelines „E-health in Latvia" for years 2008-2010 and the planning allocated to their performance against the actual expenses of the e-health activities within the period from 2007 to 2014. Assuming that the total financing assigned for the stage II of the project „Development of integrated e-health information system, stage II" will be used to full extent for implementation of the e-health, the Table 8 includes also this financing. Information on the implementation costs of the e-health activities has been summarising by applying the actually made expenses to the respective activities included in the implementation plan of the Guidelines (the remuneration expenses have been stated separately).

Implementation costs of e-health activities managed by the Ministry of Health and the National Health Service will reach 12,964,835 *euro* (including the total financing for the project „Development of integrated e-health information system, stage II" and without funding from other institutions and the costs of activities not started by the end of 2014), therefore total costs of implementation of the e-health by 154 364 *euro* exceed the funding budgeted for the respective activities of the e-health implementation (see Table 8).

*Table 8*

**E-health implementation undertakings anticipated in the implementation plan of Guidelines "E-health in Latvia" for years 2008-2010, planned and actually used funds in the time period from year 2007 to 2014 and the total planned funds of the project "E- health integrated information system development- Stage II"**

| No. of plan | Undertakings | Funds necessary in the plan, *euro* | Actually spend funds | |
|---|---|---|---|---|
| | | | *euro* | % from the planned funds |
| *Undertakings of the plan that are implemented or performed (included in the scope of the audit)* | | **12 810 471** | **12 964 835** | **101** |
| **1.1.** | Development of electronic health card information | 4 877 035 | 2 176 838 | 45 |
| **1.2.** | Information exchange standard setting | 256 117 | 155 291 | 61 |
| **1.3.** | Integration platform development (not including 1.3.5.) | 2 073 409 | 1819 411 | 88 |
| **1.5.** | Information security and personal data protection esnurance) | 398 404 | 169 181 | 42 |
| **2.1.** | Ensuring of electronical medical records usage preconditions | 56 915 | 37 484 | 66 |
| **2.3.** | Ensurance of support to treatment decisions* | 199 202 | - | - |

| No. of plan | Undertakings | Funds necessary in the plan, *euro* | Actually spend funds | |
|---|---|---|---|---|
| | | | *euro* | % from the planned funds |
| **5.1.** | Implementation of electronic prescriptions | 1 223 670 | 470 067 | 38 |
| **5.2.**<br>**5.3.**<br>**6.1.1.** | Electronic visits booking development (e-booking)<br>Electronization of work flow of healthcare services ( e-referrals)<br>Public health website development | 1 237 898 | 2 808 181 | 227 |
| **6.1.2.** | Public and patient informing (indicated solely project advertising undertakings) | 204 894 | 767 | 0 |
| **6.2.** | Raise of education in information technology area of healthcare personnel | 1 156 012 | 233 358 | 20 |
| **7.1.** | Program management structure development, including management support | 256 117 | 316 257 | 123 |
| **7.2.** | Ensurance of program implementation course supervision | 170 745 | 32 852 | 19 |
| **7.3.** | International cooperation** | 700 053 | - | - |
| ***Part of funds for development of joint health information system of "E-health integrated information system development- stage II"****** | | - | 3 513 425 | - |
| ***Actual costs for reimbursement, including agreements with companies*** | | - | 1 020 193 | - |
| ***Other costs and expenses*** | | - | 211 530 | - |
| *Plan undertakings that are implemented or are executed ( are not included in the scope of the audit)* | | **10 079 240** | **7 654 097** | **-** |
| **3.1.** | Unified emergency medical care and catastrophe medicine service IS development**** | 8 884 027 | 5 564 717 | - |
| **3.3.** | Development of industry unified supervision authority**** | 981 782 | 1 430 652 | - |
| **3.4.** | IS development of other institutions**** | 213 531 | 65 111 | - |
| ***Part of funds for development of unified supervision IS and other institutions' IS of "E-health integrated information system development- stage II"****** | | - | 593 617 | - |
| *Undertakings of the plan that are not implemented by 31.12. 2014* | | **19 259** | **752 966** | **-** |
| **1.3.5.** | Setting up of unified health care communication network | 640 292 | 0 | - |
| **1.4.** | Introduction of eHIC | 4 006 238 | 0 | - |
| **2.2.** | Setting up of the health care providers, facilitation of the setting up | 5 136 567 | 0 | - |
| **3.2.** | Development of industry statistics IS | 896 409 | 0 | - |
| **4.1** | Setting up of central visual diagnostics (radiology) archive | 4 553 190 | 139 027 | - |
| **4.2.** | Setting up of central clinical diagnostics archive | 751 276 | 0 | - |
| **4.3.** | Promotion of development of the radiology IS of the health care institutions | 2 361 967 | 0 | - |
| **4.4.** | Development of telemedicine consultation centre | 714 282 | 0 | - |
| **5.4.** | Electronization of data exchange with insurers | 199 202 | 0 | - |
| ***Respective share of the funding of the stage II project „Development of integrated e-health information system, stage II" for development of the statistics IS of the industry****** | | - | 613 939 | - |
| TOTAL | | **42 149 134** | **21 371 898** | **-** |

**The activity has been implemented within framework of the state budget financing; the amount of eligible expenses of implementation has not been identified.*

***Business travel expenses have been included in the expense group „Other expenses".*

****Share of financing of respective planned activities has been stated according to the indicative procurement plan of the project conditional upon the project being implemented to the planned extent (the completion date of the project 28.06.2015)*

*****According to the information provided by the Ministry of Health in the informative report of 02.10.2014 on the implementation of the Guidelines „E-health in Latvia" in 2008 – 2013 and the implementation plan of the Guidelines „E-health in Latvia" for years 2008 – 2010.*

If comparing the current actual costs of implementation of e-health activities managed by the National Health Service with the planned amounts it can be concluded that mostly the actual

costs were below the planned ones, while in two groups of activities the actual expenses exceeded the planned expenses:

- for setting up of electronic booking system, electronic organisation of the health care work flows and setting up of the public health portal (the activities referred to in the Paragraphs 5.2, 5.3 and 6.1.1 of the plan) the total financing of 1 237 898 *euro* was planned, however actual spending on implementation of these e-health solutions by the end of 2014 was 2 808 181 *euro* or by 127% more than planned. The largest share of expenses, i.e., 1 640 142 *euro* from the actual expenses of implementation of these e-health solutions was paid to the developer of the electronic referrals of the health care, booking information system and the e-health portal (exclusive of the training costs) and also the expenses of development of previous e-health solutions exceed the total planned financing for such activities, without counting other actual costs concerned with implementation of these e-health solutions, e.g. information and communication technology and licence or remuneration expenses. It shall be noted that in this group of activities the activity – development and introduction of the electronic organisation of the health care work flows system – were actually implemented –although no financing was planned for it according to the implementation plan of the Guidelines „E-health in Latvia" for years 2008-2010;
- the total financing planned for the programme management, including the support activities (listed in the Paragraph 7.1 of the plan) was 256 117 *euro,* however actual spending on the programme management by the end of 2014 was 316 257 *euro* or by 23% more than planed exclusive of remuneration expenses, which have been stated separately. The actual costs of various consulting and quality control service agreements were applied to the programme management expenses.

The financing actually used for implementation of various activities has been significantly lower than the initial plans (without the remuneration expenses):

- financing of 170 745 *euro* was initially planned for ensuring of the supervision of the course of the programme implementation (the programme audits as per the Paragraph 7.2 of the plan), but by the end of 2014 total of 32 852 *euro* or by 81% less than planned was spent. According to the information provided by the Ministry of Health in 2007 the assessment of the Guidelines „E-health in Latvia" was done, in 2008 - 2009 a study of potential options of activities to be performed and assessment of these for efficient application of the e-health project results and maintenance over the decades, and an audit of the e-health project. The summary does not include costs of the audit report received in 2015 „Assessment of the course of development and implementation of the unified electronic information system of the health care sector".
- financing of 1 156 012 *euro* was planned for education of the health care specialists in the area of information technologies (activities listed in the Paragraph 6.2 of the plan) while the actual amount spent by the end of 2014 was 233 358 *euro* or by 80% less than planned. The amount used is comprised of financing allocate to the Medical Professional Education Centre for improvement of expertise of the health care specialists in 2007 - 2009 and the expenses made within framework of the projects for training of users of the information system (administrators of the information system, 487 pharmacists and the health care specialists) and development of training materials.

Actually 1 020 193 *euro* have been used for remuneration of employees involved in implementation of the e-health, including[48] 66 650 *euro* for the performance contracts. The other expenses include various maintenance expenses, business travel, acquisition of computer hardware, etc.

Since the state budget funds assigned in 2015 for implementation of the e-health activities have not been included in the expenses summarised in the Table 8, the total expenses of implementation of the e-health will increase.

***Additional costs for improvement of initially developed e-health solutions***

Although according to the requirements of e-health information system development in line with the general agreements concluded on 2011-2012 the information system developers undertake to perform all the works that are necessary for information system development, including integration, testing, implementation and guarantee maintainance, nevertheless also after the information systems are accepteda substantial scope of works are anticipated to improve them and financial funds are invested:

- experts, upon performance of assessment of work assignments in the framework of the organized procurement "Performance of integration supplementing for development of unified health industry electronic information system", concluded that a part of these work assignments partially or fully comply with requirements of e-health solutions of stage I or eliminate admitted errors in designing. For instance, developers of electronichealth card are entrusted to research authentification possibilities in order the external systems (treatment institutions, pharmacies) information systems could be authentificated without the entry of personal Identity Code. The second problem clearly points to deficiencies in project planning, since as of the moment of beginning of project it was obvious that the external information systems should be integrated in the e-health system and the restrictions should be considered. Thereby a risk persists that the funds amounting to 124 206 *euro* are spent by unreasonably ordering additional work tasks;
- experts point out that previously in the indicated procurement where all the developers including had to perform migration of e-service to the new www.latvija.lv version, various developers similar tasks performed for a reimbursement that differs for many times (see Table 9). Although the National Health Service had all the three labour-consuming assessments available prior conclusion of agreements, the labour-consuming processes are not evaluated; as a result, the delivered service was overpaid.

*Table 9*

**Developers cost comparison of a single e-service migration to the new version www.latvija.lv**

| Developer | Number of e-services that should be migrated to the new www.latvija.lv | Total expenditure on service, *euro* | Expenditure for migration of one e-service, *euro* |
|---|---|---|---|
| SIA "ABC Software" | 1 | 15 266 | 15 266 |
| AS "Datorzinību centrs" | 7 | 32 256 | 4608 |
| SIA "Lattelecom Technology" | 7 | 21 991 | 3142 |

- experts have concluded that due to an incomplete documentation of procurement or non-quality development in stage II the mistakes and errors admitted in stage I shall be corrected, actually duplicating the part of requirements for stage I. For instance, in

[48] Expenses of the performance contracts classified 2232 „ Expenses of auditors, translators services, cost of studies abroad ordered by institutions"and "Other previoulsy non-classified types of services".

designing of stage I there has not been anticipated a situation where in e-prescription there could be included more than one diagnosis, or a requirement that in the screen forms of web site the information shall be automatically filled in that has already once been input, moreover, as a separate scope of work in the procurement of stage II there has been indicated applicability testing, identifying of improvements and development of improvelements of applicability of stage I. Thereby in the framework of stage II of e-health solutions the works were ordered in the amount of 59 200 *euro* to identify and to prevent deficiencies in application in solution of stage I;

- since the National Health Service points out that the developer of e-health solutions of stage II has taken over actually the guarantee liabilities of developers of solutions of stage I (that, probably, influenced the defining of contractual price of developing of solutions of stage II , amounting to 4 350 000 *euro*, including raising of price), experts point out that actually the guarantee payment of developed solutions in stage I is paid both to suppliers of stage I and to supplier for stage II (in line with the requirement included in the procurement documentation of stage II to overtake guarantee liabilities). Paid in double estimates for solution guarantees form at least 300 000 *euro*[49].

***Evaluation of e-health implementation costs***

During the audit it was established that during the process of implementation of e-health the financial means amounting to 196 292 *euro* were spent unpurposefully or non-compliant with the aims of implementation of e-health, for instance:

- In 2007 the outsourced service provider according to the instructions of the VSIA „Paula Stradiņa Klīniskā universitātes slimnīca" that was in charge of setting up of the central visual diagnostics (radiology) archive developed a development concept of the central visual diagnostics (radiology) archive and the technical specification of the data centre and the equipment solution for the total amount of 139 027 *euro*, however according to the legal acts[50], the activity „Development of central visual diagnostics (radiology) archive" on 15 March 2010 has been deleted from the list of projects to be implemented within the EU funds planning period of 2013 – 2017 and according to the information provided by the Ministry of Health on 27 February 2015[51] the activity will not be implemented due to high maintenance costs;
- concepts of several e-health solutions have been developed in 2007 and 2008, but, taking into account the economic crisis of 2008 – 2010, when no planned funding was assigned to the implementation of the e-health activities, at the moment of restarting of

[49] It is assumed that for the maintenance of guarantee annually there are reserved 12% from system development costs (assumption has been made, grounding upon to the poll of experts (3 system development service providers)). In estimate of calculation there has not been taken into account the circumstance that there has been launched a procurement on system integration improvement between solution development stage I and stage II, in the framework of which also a partial guarantee has been taken over, since actually the improvements were implemented by the same suppliers, that performed the development of solution of stage I.

[50] Protocol Decision of the Cabinet of Ministers of 25.08.2009 (prot. Nr.54 44§) to the Informative report „On development of information system, as well as knowledge obtained within the assessment pocess of project applications submitted within the operational programme „Infrastructure and services" 3.2.2.1.1. sub-activity „Development of information systems and electronic services" concerning efficiency of project expenses, efficient planning of tools and feasibility of performance of T audits during the implementation of the project" Paragraph 3, Regulations of the Cabinet of Ministers of 15.03.2010 No.147 „On the priority list of the projects for development of the electronic government and information society".

[51] Letter of the Ministry of Health of 27.02.2015 „ On the information requested in the audit case No. 2.4.1-7/2014 „Health care information system".

implementation e-health activities the concepts of 2007 and 2008 were updated. E.g., in 2007 agreements were signed for development of the concept of the electronic health card information system and the procurement documents, on development of cooperation platform (integration solution) of the e-health systems, concept of the semantic platform and procurement documents, while in 2010 the concepts and procurement documents were updated for the total amount of 27 271 *euro;*

- in July 2014 the development of e-subscription information system security policy documentation was finished for 9943 *euro* ordered by National Health Service, nevertheless the developed documentation was not approved in the Service as internal rules and regulations and there was not initiated their use in daily processes. Service points out that it was decided to create a common service information system management, without developing to every information system separate safety management documents and the deliverables prepared by the outsourced service providers would be used also for development of these new documents. Taking into account that in December 2014 the approved information system security policy by its structure and provided information differs from e-subscription information system security policy developed by outsourced service providers, a risk persists that the developed e-subscription information system security documentation will not be validly used in operation of the service;
- in addition, in June 2010 there has been completed information system security and personal data protection documentation development for patients and healthcare professionals ordered by the Health Economics Centre and amounting to 5194 *euro*-developed examples for information security and personal data protection policy for a small practice of family physician and for a medium large or large healthcare institution, as well as methodology for practical implementation of information security management process in healthcare institution, as well as informative material for patients regarding personal medical records protection. Nevertheless these developed security policy examples and the methodology of introduction for healthcare institutions, as well as informative materials for patients are not freely accessible for the use of patients on the web site of National Health Service, but the healthcare institutions may receive these, by sending an electronic request to the Service;
- in 2009 services of software maintenance and introducing of changes in the payment system of the health care services „Management Information System" were paid for the total amount of 8594 *euro;*
- in 2011 acquisition of licences for the chancellery software and related training was paid for the total amount of 5376 *euro*;
- in 2011 mandatory health checks of the employees were performed for the total amount of 887 *euro*.

During the audit there were established multiple cases where the e-health implementation measures by their nature were necessary, but they have not been implemented in the real time or at due quality, without adequately assessing various alternatives. Such cases certify on a non-effective management of e-health implementation and inefficient expenditure of financial means, for instance:

- in December 2014 in Riga and Latvian region the outsourced service providers performed unified healthcare industry information system trainings for 499 employees - healthcare professionals, pharmacists and employees of service for the total amount of 81 191 *euro*, nevertheless the employees had no possibilities to practically test the developed e-health

solutions, since the training was performed at time when the system was not working even at a test mode;

- experts point out that a part of necessary devices and facilities were purchased already in year 2012, nevertheless the production environment is not yet created, upon initiating system activity in the production environment, the guarantee time for the devices and facilities will be ended thereby creating technological risks. In overall, including for the test environment requirements, there has been purchased eight servers with the total value amounting to 66 856 *euro*, as well as two blade server chassis for the total value amounting to 55 118 *euro*, and for the purchased devices the guarantee term has expired;
- upon performance of assessment of documentation supplied by eight e-health stage I solution developers and respective quality auditors opinion, experts indicate that in general documents comply with the good practice and the available standards, nevertheless in cases where the quality controller had some uncertainties and problems are formulated with questions or in cases where corrections had not been easy to implement, they have not been made. Thereby risk persists regarding productivity and comprehensibility and quality of technical documentation of solutions, if the received recommendations on corrections have been completed only partially;
- in 2014 there has been concluded a general agreement on assessment of software and information system security and performance, as well as information system security management assessment. In the framework of the inspections was performed also the e-susbscription system performance assessment, nevertheless during the inspections, due to the functional errors it was not possible to perform multiple anticipated tasks, as well as it was not possible to perform 13 out of 30 anticipated test scenarios, paying a full initially foreseen price - 35 915 *euro*;
- experts point out that despite the fact that in the total architecture of the e-health solution there are used multiple state common use solutions, for instance State information system merging tool, Data distribution tool, authentification module, nevertheless in project the possibilities of repeated use of Latvia State information communication technology solutions were not assessed, for instance, State information system merging repeated use for integration purposes. Taking into account that in the e-health industry integration platform there is employed a standard product (*Oracle Service BUS)*, experts have not identified substantial benefits why the respective product would be adaptable to the necessities of the industry more easily than the State information system merging integrator the base of which is a standard product (Microsoft);National Health Service grounds such an approach with the industry specifics, breakdown of various target audiences, specific industry standards, as well as point out to potential State common use components performance problems and the fact that due to regulation of public procurements it would not be possible to use the existing product. Nevertheless, if the concept would anticipate to use State information system merger with e-health solution mutual integration and to adapt this solution to healthcare necessities, the experts did not identify limitations to such approach. The assessment of possibility of repeated use of Latvia State information communication technologies solutions would provide an insight to possible alternatives and their costs, as a result there would be a possibility to choose economically the most favourable development scenario and potentially reduce costs of development of stage I e-health projects;
- e-health solutions lack common technologies, since some of e-health solutions have been applied different development technologies, nevertheless good practice standards provide

for that in development of integrated solution it would be at every possibility necessary to use unified technologies. For instance, e-subscription and e-referrals information systems have been applied *Oracle* database, while for the integration platform is issued *Microsoft SQL* database.

Such situation has occurred due to planning problems, since e-health solutions have not been gradually implemented, but both paralelly within the framework of different procurements. Course of the project was not developed subsequently, i.e., upon creating initial solution that works, afterwards creating supplements that are integrated in the initial solution. Instead of this there were announced multiple parallel procurements where every developer could choose technologies that were the most suitable for him to work with, not to offer a solution, the various parts of which could have been integrated in a common solution. In case of unified technological solution it would be possible to save on expenses on various technology licences, as well as it would simplify system maintenance in future, since there would be necessary a smaller number of administrators, who supervise the system work.

***Implementation of e-health in the framework of European Regional Development Fund***

Solutions of e-health project solutions are developed in the framework of the funds granted by European Regional Development Fund according to the facility program "Infrastructure and Services" supplemental activity 3.2.2.1.1. sub-activity "Development of information system and electronical service". Implementation of sub-activity provides the responsible institution– Ministry of Environmental Protection and Regional Development and the cooperation institution – Central Finance and Contracting Agency. Resonsible institution on implementation of projects and the recipient of funds is the National Health Service.

According to the European Parliament and Council Regulation[52] the appropriations shall be used in accordance with the principle of sound financial management, namely in accordance with the principles of economy, efficiency and effectiveness:

- the principle of economy requires that the resources used by the institution in the pursuit of its activities shall be made available in due time, in appropriate quantity and quality and at the best price;
- the principle of efficiency concerns the best relationship between resources employed and results achieved;
- the principle of effectiveness concerns the attainment of the specific objectives set and the achievement of the intended results.

According to the European Council Regulation[53] 'irregularity' is any infringement of a provision of Community law resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the European Union by charging an unjustified item of expenditure to the general budget.

[52] European Parliament and Council Regulation of 25.10.2012, No.966/2012 „On the financial rules applicable to the general budget of the Union and repealing Council Regulation", Article 30.

[53] Council Regulation (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999, paragraph 7 Article 2.

Cabinet Regulations[54] provide for that the Ministry of Environmental Protection and Regional Development should assess in ten working days prior to approval of final payment request of the project the functionality of results of the project and the compliance with the project application and the Central Finance and Contracting Agency shall prepare the respective payment order on reimbursement of justified expenses or with a transfer to the state budget income shall prepare in 30 working days time after the acceptance of request of final payment.

According to Cabinet Regulations[55] if a non-conformity has been determined during on-the-spot verification of the project, the co-operation institution or the responsible institution shall notify thereof in accordance with the procedure by which shall be notified regarding the non-conformities determined in the implementation of the European Union Funds specified in regulatory enactments, shall take a management decision regarding utilisation of the allocated financing and shall recover the non-eligible expenses.

In compliance with the guidelines of the Ministry of Finance regarding application of financial adjustments[56], if as a result of implementation of project the target of the project is not achieved, the financial adjustment amounts to 100% from the justified expenses.

In compliance with the information available in the European Union structural funds and Cohesion Funds management information system[57] the requests for final reimbursement of payments of three projects of stage I of the e-health implemented by the National Health Service have been submitted in the following terms:

- Electronic subscription information system development, stage I – January 7, 2015;
- Electronic health card and integration platform information system development, stage I – January 14, 2015;
- Electronic visits booking (*e-booking)*, healthcare work-flow electronization (*e-referrals),* stage I, creation of Public health web site, information security and personal data protection ensuring – January 21, 2015.

Final payment requests up to the June 25, 2015 were accepted, but not yet approved and paid.

From the total actually used financing in stage I projects European Regional Development Fund and state budget funds amounts to 6 918 297 *euro*, the financing from European Regional Development Fund or justifiable expenses is 6 631 666 *euro*.

During the audit it was established that the final inspections of functionality of the Ministry of Environment Protection and Regional Development from February 2015 have been

[54] Cabinet Regulations No.576 of 21.07.2008 „Regulations on activity program „Infrastrucure and services" supplementing 3.2.2.1.1. sub-activity „Information system and electronical services development", paragraph 9.13 of project application selection", Paragraph 29 of Regulations No.1041 of the Cabinet of Ministers of 09.11.2010 „Procedure by which the resources are anticipated for implementation of projects confinanced from the budget resources of European Union Structural funds and Cohesion Funds, as well procedure of payment and procedure of preparation of declaration on expenses".

[55] Cabinet Regulations No.140 of 16.02.2010 „Procedures by which the Managing Authority, the Certifying Authority, the Co-operation Institution or the Responsible Institution Conducts an Inspection at the Place of Implementation of the Project Financed by European Union Structural Funds and the Cohesion Fund", paragraph 25.

[56] Appendix No.2 „Determination of scope of Financial Adjustment"of the regulation No.10 of 18.07.2014 „Guidelines on application of financial adjustment for the European Union Structural Funds, Cohesion Funds, European Economical Zone Financial instrument, Norwegian financial instrument, projects financed within the scope of the cooperation programs of Latvia and Swizterland".

[57] European Union Structural Funds and Cohesion Fund Management Informatiohn System, avaiable: https://www.visr.eps.gov.lv/visr/default.aspx?action=2&rid=181, veiwed on 25.06.2015.

suspended[58] to the month of April, since, as the production environment was not prepared yet, the functionality tests were not possible to perform.

Responding to the request of the State Audit Office to submit the planned final functionality test results on April 2015, the National Health Service informed that the tests in the environment of productions of functional testing will be possible to perform solely at the moment when the users will have really undertaken the use of system. Since after the installation of e-health system production environment it is planned to perform performance audits and safety audits, after completion of which there will be concluded agreements with the healthcare institutions on data input in production site, it is planned, that real users will be able to start using the system not sooner than on September 1, 2015.

The e-health project "Development of e-health integrated information system" of stage II implemented by the National Health Service is tightly related to the e-health projects of the stage I, since the implementation of project ensures a succession to solutions created for stage I, thereby the development of solutions of e-health of stage II is influenced by the fact how successfully have been implemented projects of the stage I of e-health. It shall be indicated that for the project of stage II of e-health, the planned justified expenses of which are 4 720 981 *euro*, deadline is prolonged from June 28, 2015 to November 29, 2015.

### 2.4. Is the implementation of e-health matching the deadline?

***Deadlines for implementation of e-health***

In the process of implementation of e-health there are defined various implementation (completion) terms:

- the deadline for implementation of guidelines „E-health in Latvia" is the end of year 2015;
- the deadline for implementation of guidelines plan for year 2008-2010 is the end of year 2010;
- in the Cabinet Regulations there have been defined e-health information system use initiation deadlines;
- in the European Regional Develoment Fund e-health projects there have been prescribed project implementation terms and individual e-service implementation terms;
- in the concluded general agreements on development of information systems, in agreements and separate tasks there have been provided their terms of execution.

According to the implementation plan of the Guidelines „E-health in Latvia" approved in 2007 completion of the activities for implementation of the e-health was planned by the end of 2010.

According to the Cabinet of Ministers Regulations of the Unified Electronic Information System of the Health Care, the health care institutions and pharmacies shall sign agreements with the National Health Service by 31 December 2015 and after signing of the agreement the health

[58] Central Finance and Contracting Agency letter No. 39-2-40/743 of 11.02.2015 „On approval of final payment requests according to agreement No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/003, No.3DP/3.2.2.1.1/09/IPIA/IUMPELS/015, No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/019."

care institutions will be obliged to use the options available in the health information system according to the specifics of the health care institution and the requirements set in the Regulations, while starting from 1 January 2016 the family practitioners will have to submit the health data of patients online to the health information system. Although the above-mentioned Cabinet of Ministers regulations ensures that pharmacies should provide data into online health information system on the medicinal products or medical devices issued on the basis of e-prescription, without delay, but no later than during three working days after service provided, meanwhile regulations do not indicate the date from which pharmacies are obliged to start data entry to the health information system.

Ministry of Health in its informative report of 2 October 2014 on the implementation of the Guidelines ”E-health in Latvia” informed that since the state budget financing assigned for implementation of the Guidelines and the implementation plan in 2008 and 2009 was significantly below the necessary amounts, and implementation of the e-health projects of the European Regional Development Fund was started only in 2009 and 2010, majority of e-health services included in the plan will now be implemented much later, i.e. in 2014.

According to final amendments of 2014 to the deadlines of the e-health projects of the European Regional Development Fund implemented by the National Health Service the deadline of implementation of e-health servicesis December 2014 (see Table 10).

*Table 10*

**Deadlines for implementation of the e-health services**

| Title of the project | Number of e-services | Implementation deadlines |
|---|---|---|
| Setting up of an electronic booking, electronic organisation of the health care work load system, stage I, development of public health portal, provision of the information security and personal data protection | 13 | 29.12.2014. |
| Setting up of electronic prescriptions system, stage I | 5 | 07.12.2014. |
| Setting up the electronic health card and integration platform information system, stage I | 8 | 10.12.2014. |

According to the plans for implementation of the e-prescriptions and electronic sickness leave act the deadline for implementation of the e-prescription and electronic sickness leave acts services in the production environment has been set by the 1 October 2015, when they will become available to health care institutions and pharmacies, while the mandatory deadline for introduction of e-prescriptions and electronic sickness leave acts is 1 January 2016 (the most recent actual implementation plans and updated deadlines of the other developed e-health services were not presented to the State Audit Office).

According to the regulations for development of the e-health information systems, the developer of the information system shall perform the actions required for development of the information system, including implementation and guarantee maintenance. The National Health Service by the set deadline approves the information system or issues a motivated refusal to approve the works completed, or informs the developer of the information system on another time, when the information system will be approved or a motive refusal to approve will be sent. Every component of the service is considered as approved if it complies with the functionality required in the work assignment and the offer for completion of works, the acceptance testing and integration test with the other components of the information system have been successful.

***Prolongation of the deadlines for implementation of the e-health and the causes thereof***

Upon summarising of the information on the planned deadlines for implementation of the e-health services it was concluded that deadlines were prolonged not only for the projects of the European Regional Development Fund within framework of which the health care e-services are developed, but also the agreements for development of information systems and for certain assignments within framework of the contracts.

Three e-health projects of the European Regional Development Fund stage I have been started in 2009 and 2010. Although the initial completion date of the project was set at 30 to 36 months, upon amendments of the project regulations, the term of the project implementation was prolonged by two years, for one of the projects – by one and half years, without changing the total costs of the projects (see Table 8). When time allocated for implementation of the project was prolonged, the deadline for implementation of the health care e-services developed within the framework of the project was also prolonged.

*Table 11*

**Projects for development of the e-health solutions by the European Regional Development Fund projects and their implementation term**

| Title of the project of the European Regional Development Fund | Length of the project implementation and total costs | | Time frame by which the length of the project implementation has been prolonged |
|---|---|---|---|
| | Initially planned | As amended | |
| Setting up of an electronic booking, electronic organisation of the health care work load system, stage I, development of public health portal, provision of the information security and personal data protection | 30.10.2009. – 29.09.2012. (35 months) | 30.10.2009. – 29.12.2014. (62 months) | 2,3 years |
| | 3 150 963 *euro* | 3 150 846 *euro* | |
| Setting up of information system of electronic prescriptions, stage I | 08.07.2010. – 07.12.2012. (30 months) | 08.07.2010. – 07.12.2014. (53 months) | 1,9 years |
| | 581 385 *euro* | 581 385 *euro* | |
| Setting up the electronic health card and integration platform information system, stage I | 11.06.2010. – 10.06.2013. (36 months) | 11.06.2010. – 10.12.2014. (54 months) | 1,5 years |
| | 3 527 850 *euro* | 3 525 371 *euro* | |
| Development of Integrated e-health information system, stage II | 29.04.2013. – 28.06.2015. (26 months) | 29.04.2013. – 28.11.2015. (31 months) | 0,4 years |
| | 4 720 981 *euro* | 4 720 981 *euro* | |

On March 12, 2015 there have been performed amendments also in the deadline of the fourth European Regional Developmenf Fund e-health project "E-health integrated information system development, stage II", by extending it from June 28, 2015 to November 28, 2015, maintaining the total costs of the project unchanged, namely, 4 720 981 *euro*.

National Health Service provided information[59] by indicating that the main causes for prolongation of the implementation deadlines of the European Regional Development Fund projects were concerned with delays in procurement procedures, including termination of the

[59] E-mail letter of the senior expert of the Division of the E-health and standarts of the National Health Service of 29.04.2015.

procurements procedures without any result in the cases when the offers received did not comply with the set requirements, changes in the procurement regulations, and also all of the projects were prolonged in order to adjust the developed e-services to the new www.latvija.lv test environment. Deadline of one project has been prolonged because additional activities were implemented, where the savings of the projects were used.

Within course of implementation of European Regional Development Fund projects of the stage I four framework agreements have been signed on development and implementation of the e-health information system and e-services. Deadlines of all of the framework agreements have also been prolonged (see Figure 16).

**11.02.2011 Framework agreement "On development of electronic health card information system"**

- Developer: SIA " Datorzinību centrs"
- The set deadline for development: 01.08.2013 (initially was 10.06.2013)
- Actual costs: 2 021 282 *euro*
- The deadline was prolonged on 31 May 2013 as the development of interactive manual provided in the framework agreement was not able due to testing e-health portal performed within framework of another project

**11.02.2011 Framework agreement "On development of information system of the integration platform"**

- Developer: SIA " ABC Software"
- The set deadline for development: 01.04.2013 (initially was 01.03.2013)
- Actual costs: 1 134 505 *euro*
- The deadline was prolonged on 25 February 2013 as the National Health Service was unable to provide for accept-testing of the developed information system by the set deadline

**28.02.2011 Framework agreement "On development, implementation and guarantee maintenance of electronic referrals/ electronic booking information system and WEB platform for users of the e-health users"**

- Developer: SIA " Lattelecom Technology"
- The set deadline for development: 01.12.2012(initially was 30.09.2012)
- Actual costs: 1 657 250 *euro*
- The deadline was prolonged on 15 June 2012 as the pilot operation of the developed information systems was not completed by the set deadline due to the course of implementation of other related e-health projects, however the pilot operations were not ordered from the developer as the developer was lagging behind the schedule in relation to the development works

**19.03.2012 Framework agreement "On development of the e-prescription information system"**

- Developer: SIA " Involv Latvia" and SIA "ABC Software"
- The set deadline for development: 02.09.2013 (initially was 07.07.2013)
- Actual costs: 148 481 *euro*
- The deadline was prolonged on 5 July 2013, since due to overload of the National Health Service, the related projects and delays of the third parties the accept testing of the information system delivered required more time

*Figure 16.* **Core information of the framework agreements on development of the information systems and reasons for prolongation of terms of execution thereof**

The implementation deadlines were also prolonged for several assignments of contracts signed within the framework agreement of 11 February 2011 „On Development of the Electronic Health Card Information System", however the National Health Service was unable to provide information on the reasons for prolongation of the deadlines, e.g. the completion deadline in the contract No.VEC 2010/2/ERAF-1 signed on 8 April 2011 was prolonged by one, two or three months for development of detailed architecture of the health care processes of the information systems of the integration platform and the electronic health card, design and development of the stage I of the information system, in the contract signed on 1 March 2012 No.VEC 2010/2/ERAF-2 the completion deadline for design and development of the stage II of the information system was prolonged by three weeks, operation of the pilot of the information system and commissioning for use – by four months.

Developer of the electronic referrals/electronic booking information system and the WEB platform for users of the e-health services has not provided for execution of the service according to the agreed calendar plan.

According to the contract for development of a component within the framework of the agreement „On development, implementation and guarantee maintenance of the information system of the electronic referrals/ electronic booking of the health care services and the WEB platform for the e-health users"[60] the contractor undertakes to develop and introduce the information system of the electronic referrals/ electronic booking of the health care services and the WEB platform for the e-health users by the set deadline – 29 June 2012. Although the initial completion date set in the contract for development of the component was prolonged[61] from 29 June 2012 to 1 November 2012, the contractor still submitted[62] the deliverables to the principal on 21 December 2012, i.e. with 50 days delay past the set deadline, for which the contractual fines of 35 680 *euro* were applied to the contractor for breach of the terms of the framework agreement.

***Long approval and implementation of the information systems developed***

It was concluded within course of the audit that the acceptance acts of the electronic health card, e-referrals / e-booking information system, e-health portal and e-prescriptions information systems are signed several months past the termination of the effective date of the framework agreements – the information system of the e-referrals / e-booking and the e-health portal were accepted within 11 months time period after the effective date of the framework agreement, the information system of the electronic health card was accepted more than four months after the effective date of the framework agreement, while the e-prescriptions information system was accepted more than three months past the effective date of the framework agreement (see Figure 17). The acceptance act of the integration platform was signed just 15 days past the effective date of the framework agreement.

[60] Contract signed between the National Health Service and SIA „Lattelecom Technology" on 31.01.2012 No. NVD 2010/6/ERAF-3 (LTT-12-000028) on development of components of service (development and training of system administrators).

[61] 15.06.2012 amendmends to the contract signed between the National Health Service and SIA „Lattelecom Technology" on 31.01.2012 No. NVD 2010/6/ERAF-3 (LTT-12-000028) on development of components of service (development and training of system administrators).

[62] Letter of SIA „Lattelecom Technology" of 21.12.2012 No.LTT2-8/12-348 „On submission of deliverable fo the system administrators training phase within the project "development, implementation and guarantee maintenance of the information system of the electronic referrals/ electronic booking of the health care services and the WEB platform for the e-health users".

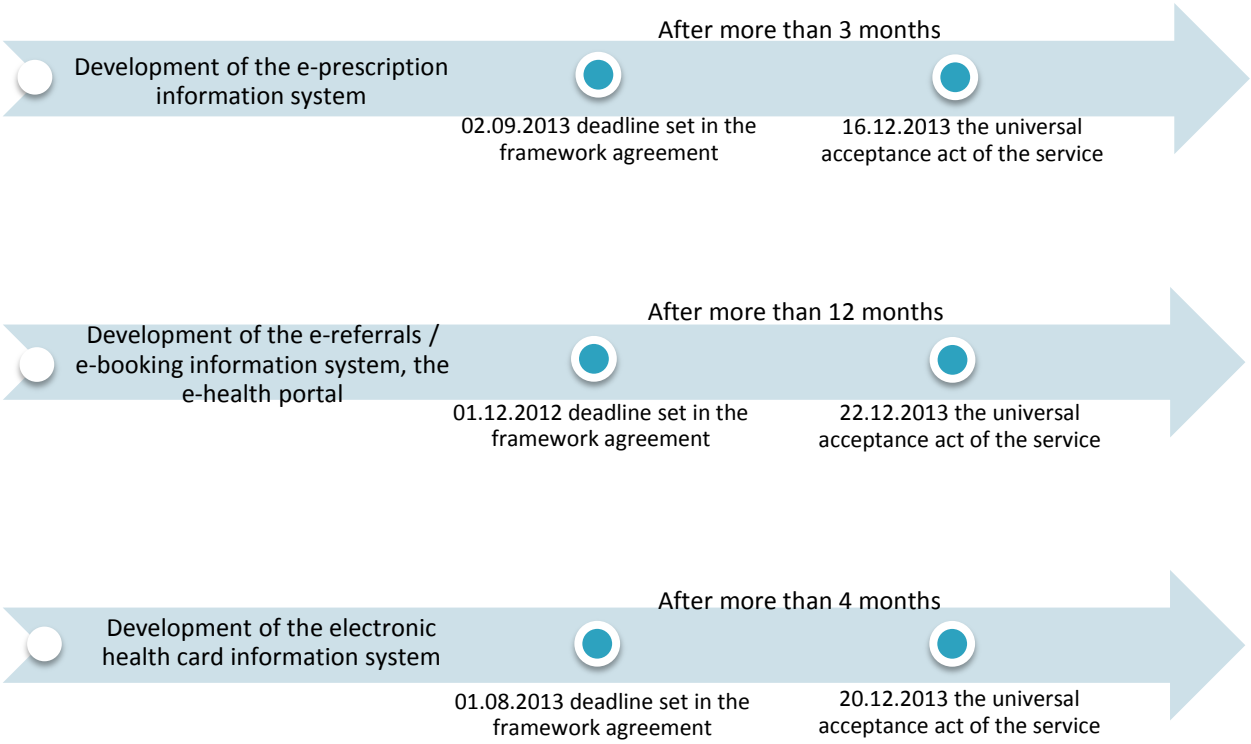



*Figure 17.* **Comparison of the deadlines set for the development of e-health information systems and the date of drafting of the unified acceptance acts of the services.**

According to the explanation provided by the National Health Service the acceptance testing of the developed information system required an integrated environment able to interact with the rest of the associated systems. At the day of delivery of the information system (termination of the effective period of the framework agreements) the Service still had not such environment at its disposal, where the associated systems would also be operating, thus ensuring thorough testing of all of the developed modules, and thus it was also impossible to perform the acceptance testing to verify complete functionality developed. The obligation of the National Health Service was to adjust on one's own account the deliverables in the accepttest environment, as well as to perform the respective configuration works for development of integrated environment. Taking into account that every system was delivered and verified separately, the systems delivered to the Service were to mount and configure at one's own account, in order the developed systems would cooperate between themselves. This process undertook more time than it was anticipated for such an installation was performed for the first time. During the installation process there were established some nuances, that the particular performer could not know and to repeat at own environment, and the consultancies of perform during the installation were provided at presence. Thereby, according to the general terms of agreement the Service notified the developers of the information system on another time, when the accetpance acts will be signed or a motivated rejection letter sent.

Although the e-health services developed within framework of the European Regional Development Fund projects had to be accessible by the public already at the end of 2014, according to the implementation of the e-prescriptions and electronic sickness leave act services the contracts on involvement in the e-health in the production environment of the e-prescriptions and electronic sickness leave act services with the health care institutions and pharmacies which were involved in testing will be signed starting from 1 September 2015.

***Financial impact, without implementing stage I of the e-health project in planned time***

National Health Service has pointed to the fact that approximately after six years starting from implementation of information system, the total amount of socioeconomical benefit occurred as a result of implementation of e-health starts to exceed the investments invested in the project.

In year 2012 the National Health Service has calculated[63] direct financial benefits from the implementation of e-health stage I for the time period from 2013 to 2027. In the calculation such indicators were used as economy of working time of physicians, upon procession documentation electronically, saving of costs from radiology process electronization, savings from unrepeated examinations, etc.

In compliance with the information of the National Health Service the projects of stage I of e-health[64] were planned to end until the end of year 2012 and the direct benefits from implementation of e-health projects of stage I were planned to receive as of year 2016, namely, it is at least three years later than initially planned (please refer to aisle 3 of the Table 12).

Thereby, not introducing the e-health projects of stage I in the planned term - up to the end of the year 2012, in the time period from 2013 to 2015 have not been obtained direct financial benefits amounting to 3 millions of *euro* (under a provision that on 1 January 2016 the stage I would be fully implemented), meanwhile in the time period up to year 2021 the non-obtained financial benefits, upon introducing the e-health projects of stage I later, the sum could amount to 16 millions of *euro* ( please refer to aisle 4 of the Table 12).

The key groups of benefit will be related with savings, upon introduction of electronic documents circulation, a centralized maintenance of patient medical records and multiple use of data, patient involvement in own healthcare processes. Relevant direct benefits would be formed in processes of healthcare organizing and management, since there will be ensured a valid information for planning of industry resources and for improvement of control processes.

*Table 12*

**Planned direct benefits after the implementation of projects of e-health stage I (EUR)**

| Year | Direct benefits, as of year 2013, if implemented during the planned term of stage I | Direct benefits, as of year 2016, if projects of stage I are implemented 3 years later | Unobtained benefits, in case of non-implementation of stage I in the planned term |
|---|---|---|---|
| 1 | 2 | 3 | 4 (3-2) |
| 2013 | 538 272 | 0 | -538 272 |
| 2014 | 1 076 403 | 0 | -1 076 403 |
| 2015 | 1 435 251 | 0 | -1 435 251 |
| **Total from 2013-2015** | **3 049 926** | **0** | **-3 049 926** |
| 2016 | 3 588 056 | 538 272 | -3 049 784 |
| 2017 | 5 382 866 | 1 076 403 | -4 306 463 |
| 2018 | 5 382 866 | 1 435 251 | -3 947 615 |
| 2019 | 5 382 866 | 3 588 056 | -1 794 810 |

[63] Report of 05.06.2012 of the National Health Service „Activity program" Infrastructure and services" supplement 3.2.2.1.1. sub-activity „Development of Information System and Electronic Services" project „Development of e-health integrated information system", e-health information system activity concept description."

[64] E-prescription stage I, E-health web site stage I, Electronic health card stage I,, Unified industry supervision information system stage I, Initial e-health infrastructure and integration platform stage I.

| Year | Direct benefits, as of year 2013, if implemented during the planned term of stage I | Direct benefits, as of year 2016, if projects of stage I are implemented 3 years later | Unobtained benefits, in case of non-implementation of stage I in the planned term |
|---|---|---|---|
| 1 | 2 | 3 | 4 (3-2) |
| 2020 | 5 382 866 | 5 382 866 | 0 |
| 2021 | 5 382 866 | 5 382 866 | 0 |
| **Total: from 2013-2021** | **33 552 312** | **17 403 714** | **-16 148 598** |

## 2.5. Are the health care service providers ready to join the e-health system?

***Planned measures for information and awareness improvement of the health care service providers***

Implementation plan of the Guidelines „E-health in Latvia" for years 2008-2010 includes activities for improvement of knowledge of the persons involved in the health care in the area of information technologies, including developing of training materials and programmes covering various user skills of information technologies by various user groups.

The Cabinet of Ministers Regulations of the Unified Electronic Information System of the Health Care[65] providethat the data is provided to the health information system online by the health care institutions (core patient's data, reports on out-patient tests/ treatment, referrals for receipt of inpatient/ outpatient services, transcripts/ epicrises, sickness leave acts, e-prescriptions etc.), family practitioners (data on the patient's health – allergies, diseased diagnosed, implants and prosthetics, surgical manipulations, diseases, medication used, etc.) and pharmacies (data on medication issued or medical devices issued on the basis of the e-prescriptions).

The health care institutions and pharmacies by 31 December 2015 shall sign contracts with the National Health Service on use of the information system.

Family practitioners as of 1 January 2016 will have to provide health data of patients online into the health information system and the health care institutions after signing of the agreement will be obliged to use options available at the health information system considering the specialisation of the health care institution and the requirements set in the Regulations. The Regulations provide that the health care institutions will provide medical documents prepared in the health information system to the patients (in printed format), including the sickness leave acts, only by 31 December 2015, but the reports on outpatient testing/treatment (in printed format) only if they are required for submission to another health care institution.

The National Health Service in its web site is inviting[66] the health care institutions, pharmacies, developers of health care information systems in testing of the e-health system (use of the test environment) in order to provide support in functionality testing of the e-health system, to identify adjustments required in the information system of its own institutions, as well as to get introduced with the e-health system.

According to the information provided by the Ministry of Health[67] the range of health care service providers which will have to operate in the e-health system is about 13,350 persons

[65] Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations on the unified electronic information system of the health care" paragraph 11.4.,11.5.,11.6.,21.1.1.,33.,36.,37.,38.
[66] Internet resource: http://www.vmnvd.gov.lv/lv/e-veseliba/e-veselibas-ieviesana (viewed on 17.02.2015.)
[67] Letter of the Ministry of Health of 13.04.2015 No. 01-15/1346 „On the information requested in the audit case No. 2.4.1-7/2014 „Health care information system".

(6909 of practising doctors excluding the dentists, interns and residents, 1424 practising dentists, 2033 practising assistant doctors, 1622 pharmacists and 1362 assistant pharmacists).

***Activities identifying readiness, informing and training health care service providers***

In order to assess and investigate the situation in the area of use of information technologies in performance of tasks of the health care institutions, as well as to identify needs of the health care institutions, the Medical Professional Education Centre in 2007 conducted the survey of health care institutions by surveying 36 health care institutions where number of employees exceeds 50. According to the survey data in 2007 computer technologies were used in performance of their tasks by 20-30% of the surveyed employees of the health care institutions, 70% of the pharmacists from the total number of pharmacists surveyed in the health care institutions. The survey revealed that training on basic knowledge of information technologies is required by 1545 of the employees of the health care institutions; in-depth training is required for 1270 employees and training on use of specific information technology products – by 306 employees. By the end of 2007 a pilot group of 110 people was trained.[68]

Within framework of the project by the European Social Fund „Enhancement of competencies of health care and health promotion professionals for sustainable development of the sector" the Ministry of Health has implemented a training programme „In depth training of health care professionals in the general information technologies skills", and in 2009 and 2011 total of 1841 of the health care specialists (doctors, assistant doctors, nurses, assistant nurses, midwives and other specialists) completed the training.

Considering the above for the period from 2007 to 2011 15% from those persons who will have to operate in the e-health system have been trained in use of information technologies.

Within framework agreement signed within the European Regional Development Fund e-health project „On Development of the Electronic Health Card Information System" by 1 August 2013 an Electronic health card end users training course was developed for health care professionals for 14 869 *euro.* According to information provided by the National Health Service[69] e-training course contains video tutorials on the e-services demonstrating nature of the e-services and the content of users of the e-services. Since the e-services are not yet available in the production environment, the material developed is not yet available to users, however at the moment when the e-services will be available, the developed e-training course will be posted at the e-health portal and the portal www.latvija.lv, where it will be available to everyone.

Within framework of the e-health projects of the European Regional Development Fund in December, 2014 training on e-health organised by the National Health Service were held in Riga and Latvian regions attended by 499 persons – health care professionals, pharmacists and representatives of the Service.

Training was organised in several modules – training for use of e-prescriptions and training for users of e-referrals, e-bookings and the health portal. Trainings on e-prescriptions information systems (50% of theoretical training, 50% of practical instruction) were attended by 16 health care professionals and 17 pharmacists. In the post-training survey on the quality of training nine respondents have admitted that a test version of the e-prescriptions information system developed just in part was presented in the training, thus it was not possible to try it in practice.

[68] Informative report of the Ministry of Health of 23 April 2008 on implementation in 2007 of the Guidelines "E-health in Latvia" and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.

[69] E-mail letters of the senior expert of the Division of the e-health and standarts of the National Health Service of 11.02.2013 and 20.03.2015.

Training on the e-referrals, e-bookings information systems and the health portal (100% of theoretical training) were attended by 454 persons (health care professionals and the support personnel). This training was organised as theoretical training, participants were not able to try in practice and to see the newly developed information system, but the screenshots of the information systems were presented in the training materials.

Considering the above, the National Health Service by the end of 2014 has provided training on the e-health information systems to 4% of the persons who will have to operate in the e-health systems.

According to the information provided by the National Health Service the Service has organised and attended meetings with the Latvian Association of Pharmacists, Latvian Association of Family Practitioners, Latvian Association of the Rural Family Practitioners and the Health Care Employers Association and provided information on latest developments in introduction of the e-health. In order to inform the users on the opportunities of processing of the patients data in the health information system, the National Health Service is planning to organise wide information campaign in the second half of 2015. The implementation plans of the e-prescriptions and electronic sickness leave acts presented to the State Audit Office contained detailed description of information and training activities.

***Does the Ministry of Health have an action plan on how to involve all of the health care service providers in the e-health information system?***

Considering that achievement of objectives and benefits set for implementation of the e-health depends on the number of users of the unified information system, the activities for involvement of the health care service providers in the use of e-health information system are of great importance.

In response to the question posed by the State Audit Office whether any particular activities have been developed for attraction and involvement of health care professionals to join and operate in the e-health system as not all of the health care institutions and persons are providing the state paid health care services and have contractual relations with the National Health Service, the Ministry of Health has not provided any detailed plans or particular planned activities for involvement of the health service providers apart from the plans for implementation of the e-prescriptions and electronic sickness leave acts, which provided for various information and training activities.

Ministry of Health informed that in order for the processing of data in the health information system to be convenient and matching needs of the users, representatives of potential users were involved in development of technical specifications of the project of the stage II of the e-health „Development of integrated e-health information system", e.g. representatives of the Latvian Association of the Family Practitioners and representatives of the Latvian Association of Pharmacists were interviewed on development opportunities of the work place of the doctor in the e-health portal, development of the functionalities of the e-prescriptions information system (doctor's and pharmacist's workplace), electronic health card, e-booking and referrals.

Also the Ministry of Health informed that planned amendments to the procedure for issue of sickness leave acts, providing as of 1 January 2016 for issue of sickness leave acts only electronically in the health information system will be a motivating factor for signing of the agreements on use of the health information system with the Service also for the health care institutions not currently having contractual relations with the Service. However it shall be noted that it is possible that not all doctors and assistant doctors are issuing sickness leave acts, thus the mandatory requirement for electronic issue of the sickness leave acts could attract

only part of potential users, and even involve them only in electronic issue of the sickness leave acts, not the entire health information system. Concerning the health care institutions providing the state paid health care services, the Ministry of Health has proposed to the National Health Service to include the requirement for use of the health information system in the contracts for provision of the state paid services.

***Opinion provided by the health care professionals and pharmacists***

In order to establish readiness of health care service providers and information level on introduction of the e-health in Latvia, in February and March 2015 the State Audit Office conducted survey of health care professionals and pharmacists by getting response from 54 health care professionals and 78 pharmacists. It was established within course of the survey that the computer equipment is available at the work places of 83% of the health care professionals and 97% of the pharmacists, thus 17% of health care professionals and 3% of pharmacies don't have access to it. The overall technical provisions of the pharmacists are slightly better than those of the health care professionals (see Figure 18).

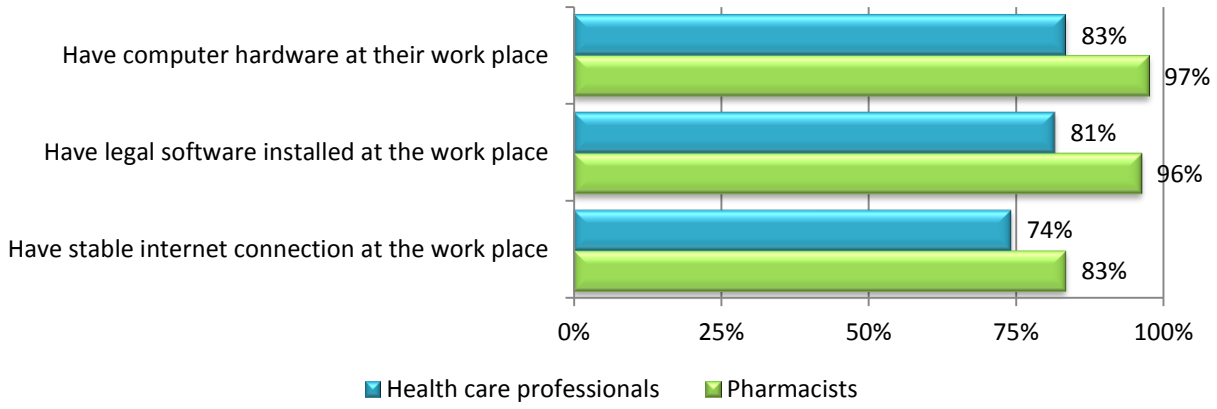



*Figure 18.* **Material-technical provisions available to the pharmacists and the health care professionals.**

To the question whether the technical provisions available at the workplace are in compliance with needs of tasks to be performed in provision of the health care or pharmacy services, 65% of the respondents considered that computer equipment is suitable, 59% believed that software was suitable for their needs and 71% of respondents considered the internet connection as adequate.

More than 60% of the surveyed health care professionals and pharmacists consider that their knowledge of computer and internet use is good and very good. Also on this issue the computer and internet user's skills of pharmacists are slightly better than those of the health care professionals (see Figure 19).


*Figure 19.* **Computer and internet literacy of the health care professionals and pharmacists.**

It was discovered within framework of the survey that 76% of the surveyed pharmacists and 46% of the surveyed health care professionals use special health care software or information systems in their work.

Concerning level of awareness of pharmacists and health care professionals on the introduction of the e-health information system in general, 11% of the respondents stated that information is sufficient, 76% of the respondents consider that they are little informed or would like to receive wider information, while 13% of respondents have replied that are not informed or are not interested.

According to the opinion of the pharmacists 10% of the respondents have sufficient awareness of the e-prescriptions information systems, 81% would like to know more, but 9% of respondents have replied that are not informed or are not interested.

The Figure 20 shows opinion provided by the health care professionals on their awareness of the e-health information systems.

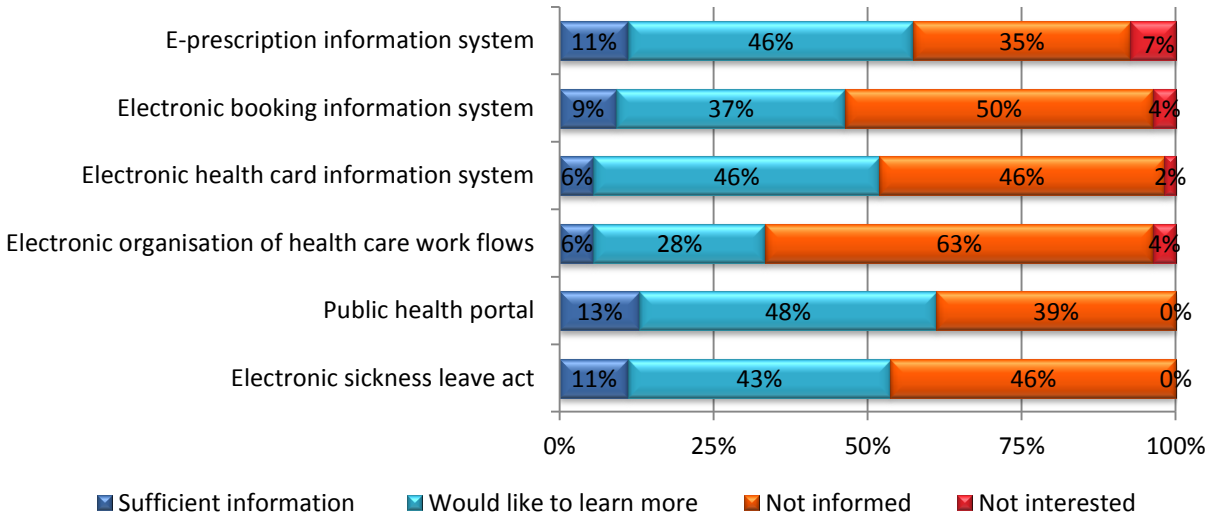



*Figure 20.* **Opinion provided by the health care specialists on general awareness of the e-health information systems.**

6-13% of respondents feel sufficiently aware of the e-health information systems, while 28-48% of the respondents would like to have more information, but 35-63% state that they are not informed on the e-health information systems. Among the sources of information on the

introduction of the e-health information system in Latvia the respondents mostly mentioned professional organisations, newspapers and magazines, TV and radio, National Health Service.

According to the opinion provided by the pharmacists 76% of the respondents are not informed on the deadline for implementation of the e-prescriptions information system, when it will be available to users, 91% of the surveyed pharmacists were not informed on the deadline by which contract has to be signed with the National Health Service on starting use of the e-prescriptions information system. The health care professionals are of similar opinion with 63% of the respondents not being informed on the deadline when the e-health information system will be introduced and 87% of respondents were not informed on the deadline by which contract has to be signed with the National Health Service.

In response to the question if the National Health Service has asked for provision of information on readiness or needs concerned with joining the e-health system 93% of the respondents had chosen the response „has not used any information". Similar answers were received to the question if the National Health Service has informed on activities necessary to start using the e-health information system – 77% of respondents replied that they are not informed.

9% of the surveyed pharmacists and health care professionals had attended special training on the e-health information system.

In March, 2015 the State Audit Office invited several health care institutions and pharmacies already using various information systems and programmes in provision of their health care services to provide their opinion on use of information technologies and implementation of the e-health. In the enquiry 6 out of 13 health care institutions and 2 out of 6 pharmacies indicated that they are sufficiently informed on the project, its objectives, expected results and benefits, while 4 of the health care institutions indicated that the single source of information in this area is the information available at the home page of the National Health Service. 9 out of 13 health care institutions and 4 of 6 pharmacies are not satisfied with communication project managers on the project progress by indicating that, e.g., that during the pilot stage of the project communication has decreased, information is missing, not responses are provided to technical queries, and communication is weak or has not occurred at all. 5 out of 13 health care institutions and 3 of 6 pharmacies do not understand actions of the project manager and actions to be taken by the institution itself in order to start mandatory use of the e-health information system as of 1 January 2016.

Within course of the audit in February, 2015 the State Audit Office invited several pharmacies and the health care institutions which have signed the agreements with the National Health Service on testing of the e-health system to provide information on their current experience from testing of the system, however 12 institutions out of 13 pharmacies and the health care institutions indicated that although the agreement has been signed with the National Health Service on testing of the e-health system, no actual testing of the e-health system has started, while one of the institutions indicated that theoretic testing of the system has been started.

### 2.6. Is the public being informed and educated on implementation and benefits of the e-health?

***Planned activities in the area of public information and education***

Implementation plan of the Guidelines „E-health in Latvia" for years 2008-2010 provides for two measures of provision of information to public and patients – setting up of the public health portal presenting the course of the e-health project, linking various health care institutions, creating a uniform source of information assisting health care professionals in

provision and receipt of better quality health care services, and measures for providing of information to various groups of the target audience.

**Actual measures taken by the National Health Service in the area of public information and education**

Within framework of the project of the European Regional Development Fund[70] on 28 February 2011 a framework agreement was signed on setting up of a public health portal and the completion deadline of this framework agreement was 1 December 2012, while the deadline of the implementation of the European Regional Development Fund project ended in December, 2014.

According to the project application the health portal will provide access to several e-services and the public will be able to receive information of health issues that every public group (youth, seniors, sugar diabetes patients, etc.) might be concerned with, information on epidemiologic situation, health promotion events, information on medications, etc. Although the National Health Service has accepted the developed health portal on 22 November 2013, by 1 April 2015 it was not publicly accessible.

Ministry of Health informed[71] that so far (15 April 2015) no informative campaigns on introduction of the e-health in Latvia aimed at wide target audience have been organised since the public section of the e-health portal is not yet open to public. Since according to the order of the Cabinet of Ministers[72] ensuring of public access to the e-health portal is planned by 31 December 2015, by providing patients with option of accessing all data stored in the health information system, registering with the family practitioner, submission of application for receipt of the European Health Insurance Card, receipt of e-prescriptions and electronic sickness leave acts, the National Health Service is planning organisation of informative campaign aimed at wide target audience (public, health care professionals, pharmacists and assistant pharmacists, employers) in the second half of 2015.

In order to inform the public on introduction of the e-health the National Health Service at its homepage in the section „Actual issues" is posting information on topical issued of the e-health and e-services of the health care. Although according to the agreements for development of the e-health solutions and their execution documents for the period from 2011 to 2014 several e-health information systems and e-services were developed, along with the progress in implementation of the e-health activities the number of publications on topical issues of the e-health in the home page of the National Health Service has significantly decreased (see Figure 21).

[70] Introduction of electronic booking of visits, electronic organisation of the health care work flow, stage I, introduction of the publicē health portal, ensurinh of information security and personal data protection (project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/015).

[71] Letter of the Ministry of Health of 13.04.2015 No. 01-15/1346 „On the information requested in the audit case No.2.4.1-7/2014 „Health care information system".

[72] Order of the Cabinet of Ministers of 16.02.2015 No.78 „On the action plan of the government for implementation of the actions planned in the Declaration on the Cabinet of Ministers lead by Laimdota Straujuma" Annex 1, Paragraph 104.2.

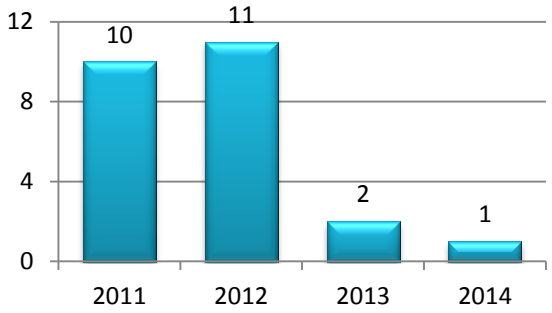



*Figure 21.* **Number of e-health activities published by the National Health Service at the home page section „Actual issues".**

On 28 September 2012 the National Health Service hosted a day of open doors within framework of which visitors were offered a presentation of the e-health, its potential use and e-services in the health care sector, representative of the National Health Service on 28 March 2012 attended conference „E-opportunities for population", where information on the e-health was presented. The auditors did not receive information on the number of participants of these events.

National Health Service had introduced a section „E-health" at its home page, where information is posted on the e-health projects, benefits to patients and the health care professionals. In the section „E-services to residents" information is provided on four e-services „My state paid health care services", „My data in the register of the sugar diabetes patients", „Data of my new-borns", „My family practitioner", which were available for the period from August, 2010 to September, 2013, when integration of these e-services in the single e-health system was started. Section "Topical issues of e-health" has been set up for purpose of publishing news feeds of the e-health developments, to provide information on the actual issues in the area of e-health, provide responses to the frequently asked questions, as well as notify on the further steps to be taken in implementation of the e-health. In the review of information available at the section "Topical issues of e-health" as at 16 April 2015 it is established that in the section by now there is only one document entered - the summary of the National Health Service of 20 August 2014 regarding the actual issues and topicalities No. 1.

Within course of the framework agreement signed in the project of the European Regional Development Fund „On Development of the Electronic Health Card Information System" on 1 August 2013 an e-training course has been prepared for the end users of the Electronic health card for 16 599 *euro.* According to the information provided by the National Health Service[73] since the services are not yet available at the production environment the materials developed are not available to users, however as soon as the e-services will become available, the prepared e-training course will be published in the e-health portal and the portal www.latvija.lv, where it will be open to everyone.

***Public survey***

In cooperation with the public research and opinion centre SKDS in February, 2015 a survey of Latvian population was performed on awareness and attitude of the Latvian population to introduction of the e-health information system in Latvia.

In order to obtain overview of the internet use skills of population, which is a critical precondition for future use of the e-health services, the residents were asked concerning their

[73] E-mail letters of the senior expert of the Division of the e-health and standarts of the National Health Service of 11.02.2013 and 20.03.2015.

habits of internet use. According to the survey results 76% of population uses the internet, and out of these 78% consider their internet usage skills as good (including 28% who stated that they were very good), while 18% of population consider their internet usage skills as weak. Analysing the survey results by the age, in the population aged from 16 to 25 years 94% considered their skills of internet use as good in general, while among the population aged from 66 to 75 years – only 55% believe their internet skills as good in general (it shall be emphasised that this question was asked to the respondents using internet).

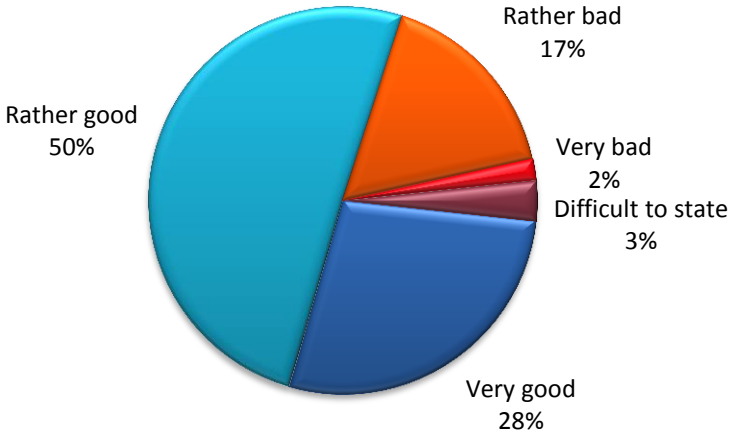



*Figure 22.* **Self-assessment of the internet literacy skills.**

Within the framework of the survey was discovered whether the people using internet were using also the e-health services offered in the portal www.latvija.lv. E-health services offered in the portal www.latvija.lv – „My family practitioner", „My state paid health care services", My data in the register of the sugar diabetes patients" and „Data of my new-borns" were available to Latvian residents for the period starting from August 2010 through to September, 2013.

In response to question whether you have used e-health services offered by the portal www.latvija.lv over the past three years, 89% of population using internet responded that they have never used any of the health e-services. Comparison of responses of various social demographic groups (by age, education, profession, residence area, etc. c.) reveals that the share of respondents stating that they have never used any of these e-services exceeded 80%.

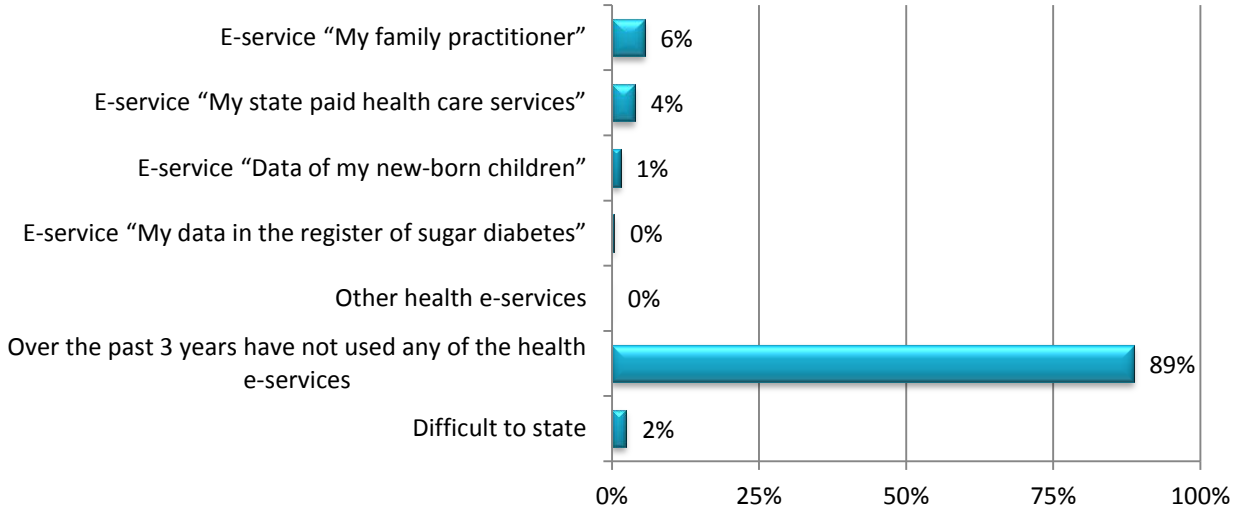
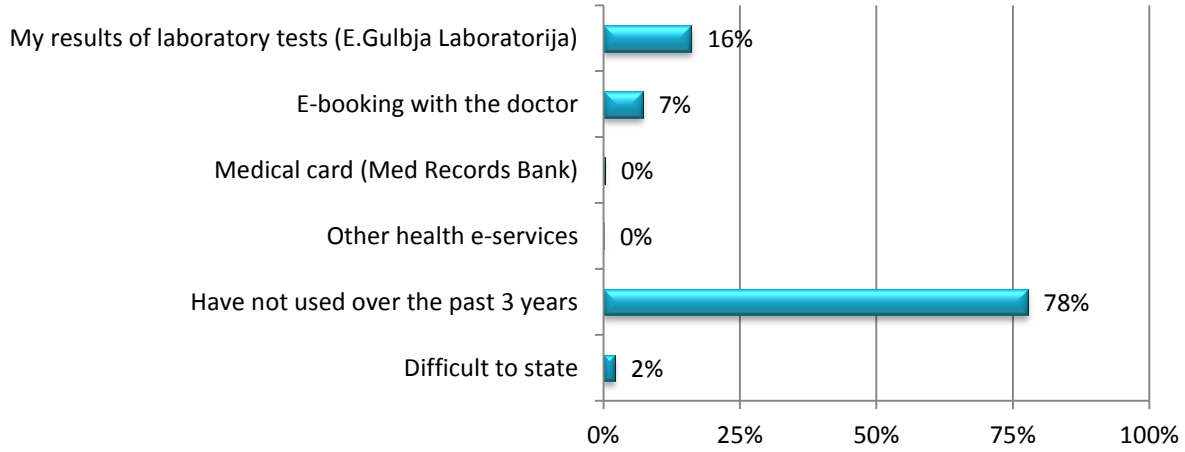



*Figure 23.* **Use of the e-health services offered at the portal www.latvija.lv.**

Taking into accounting that health e-services of various private medical institutions are available in Latvia, it was discovered in the survey whether the respondents using the internet have used alternative health e-services over the past three years period. If at least one of the e-health services available at the portal www.latvija.lv was used by 9% of the population, then alternative health e-services were used by 20% of respondents – the most often used e-service (by 16%) was „My laboratory test results in the internet (E.Gulbja laboratorija)", 7% – „Electronic booking of the doctor's appointment", but by less than one percent – „Medical card (Med Record Bank)" (0,3%) or other e-services (0,1%). 78% of the respondents have not used any of the health e-services listed or other alternative e-services over the past three years time. Detailed analysis of responses by various social demographic groups reveals that any of these services was mostly used by respondents aged 26 to 45 years, with higher education, employed in the public sector, entrepreneurs and freelancers.




*Since every respondent was allowed to check more than one answer, the total value of responses exceeds 100%.

*Figure 24.* **Use of alternative health e-services.**

Main objective of the survey was to establish awareness of Latvian population on implementation of the project „E-health in Latvia", planned e-health services and benefits brought by their introduction. The following explanations were provided to the respondents in the survey concerning every of the services:

- electronic booking by the doctor or electronic referral to the specialist (no time will be wasted by calling or contacting the health care institutions in person, the patient will be able to select specialist in the internet, see his work hours and free slots, and also the specialists will not be contacted in order to receive their conclusions, test results, etc., as everything will be stored in a unified system accessible by the patient and the treating physician);
- single electronic health card (medical history of the patient containing all information on medical records of the patient from all doctors visited (diagnoses set for the patient, treatment course prescribed by the doctors, conclusions of specialists, etc. information will be stored in a single health card, not by every of the health care institutions as it was now));
- e-prescription (prescription will not be in a printed format, but electronic – the doctors will write prescriptions in the e-prescription information system and the patient will be able to turn to every pharmacy and upon presentation of the ID document the medication prescribed will be issued);
- unified health portal www.eveseliba.gov.lv (the portal will provide complete and updated information on health improvement, health care received by the patient and medications

prescribed / issued, i.e. the internet will be used to track it and to control the own health care processes (to see the set diagnosis, treatment course prescribed by the doctor, medication and use thereof prescribed and conclusions of the specialists)).

According to the survey data 53% of the respondents had not responded for any of the services that they were informed on it (none of the following responses were checked: „very well informed", „informed, but not in detail", „have only heard, but no closer awareness"), 23% of the respondents stated that they know about all of the 4 services, 6% – on 3 services, 8% on 2 services and 10% – on 1 service.

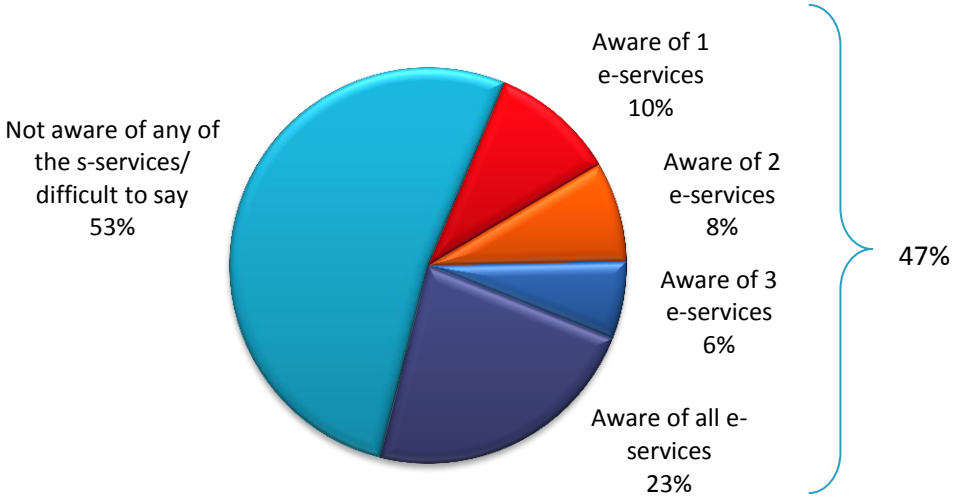



*Figure 25.* **Overall public awareness of planned e-health services.**

Analysis of overall awareness of the public by social demographic information reveals that at least one of these services was heard by those aged from 26 to 35 (58%) and from 36 to 45 (57%) years, the respondents with the higher education (59%), employees of the public sector (57%), pupils and students (53%) respondents with high income level (55%) and respondents considering their internet use skills as good (58%). Among those who never heard of any of these services respondents mostly were aged from 66 up to 75 years (70%), pensioners (70%), unemployed (57%), respondents with low income (57%).

According to the survey data the overall awareness level of public on any of the planned e-health services is the same, slightly better assessment went to the awareness on the electronic booking by the doctor or electronic referral to the specialist. 21-26% of respondents who have just heard about, but knew nothing in detail on every of the e-health services, informed, but not in detail by 7-11% of respondents, while very well informed on the planned e-health services and benefits from their introduction were 2-3% of respondents. For the detailed overview of the survey data please see Figure 26.

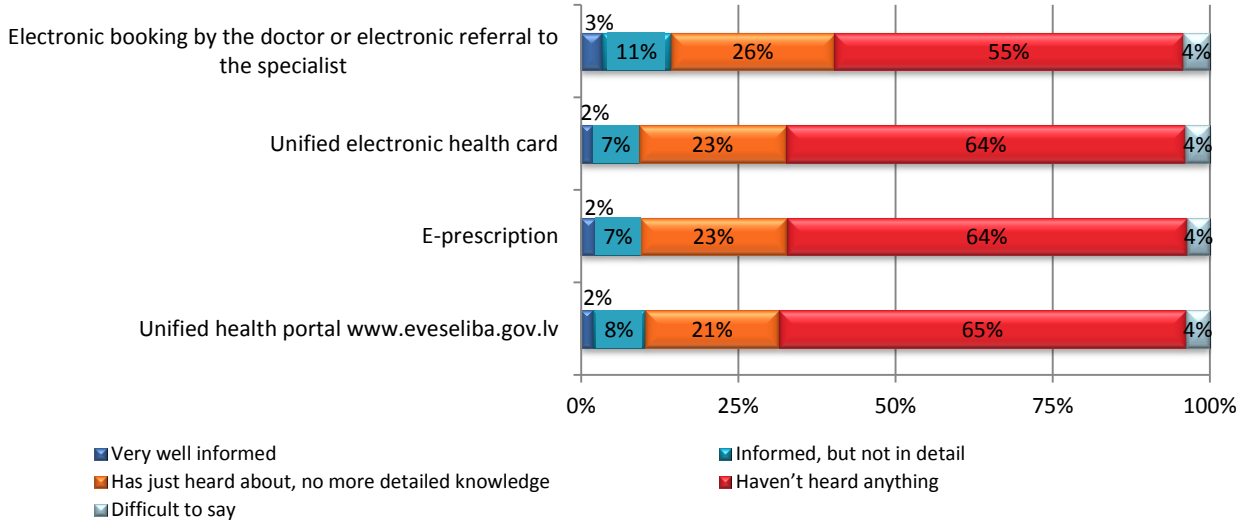



*Figure 26.* **Public awareness on planned e-health services.**

In reply on the survey question about how the respondents so far received information on the project „E-health in Latvia", 55% of the respondents replied that they haven't received any information, while 33% - that they had received and among the sources of their information had mostly mentioned television (13%), information from friends, relatives, acquaintances (10%), internet information, apart from the home pages of the Ministry of Health and the National Health Service. Notwithstanding the fact that the National Health Service has published relatively more information at its home page on implementation of the e-health services, according to the survey data a very low share of public had received information from this source, as the home pages of the Ministry of Health and of the National Health Service were referred to as the information source by respective 3% and 1% of the population.

***Public attitude towards introduction of the e-health***

Willingness of public to use various planned health care e-services was also established within course of the survey.

The respondents had to assess their interest in using the following e-services of health care:

- opportunity to obtain in one place (internet homepage) all the information on the health care (healthy lifestyle, state paid procedures, vaccines, state paid screening, copayments by the patient etc.);
- opportunity to contact health care professionals electronically over the internet (bookings of the doctor's visits or diagnostics, responses to health related questions);
- opportunity to track over the internet the funding spent on own health care (on all doctors visits, amounts paid yourself, how much has the state paid for your health care, how much the insurance costs (if you are insured));
- option of tracking over the internet the own health care (diagnosis set by the doctor, what is the prescribed treatment course, dosage and prescription of medication, conclusion of the specialists assessment, referrals by the doctors, health care manipulations performed, medication prescribed and received).

The surveyed residents have rather positive than negative views concerning the opportunities provided by the planned e-services in the health care – according to the survey data 51-54% would use the planned e-services, while 33-36% - would not use. There are no signficiant changes if use of every service is assessed separately.

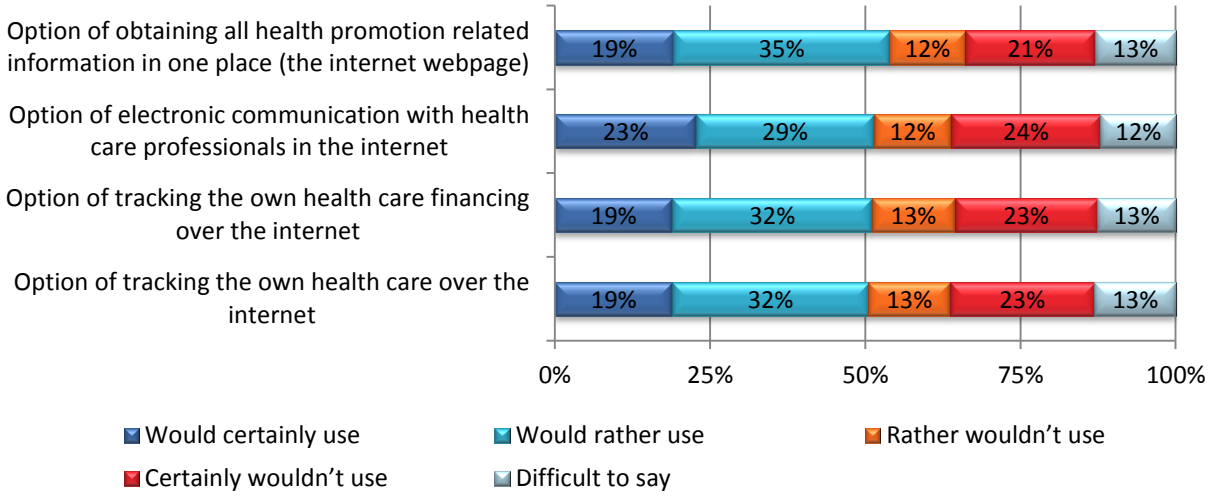



*Figure 27.* **Public willingness to use the health care e-services.**

All four of e-services would be willingly sought by 41% of the respondents, while 39% stated that they would not be using these services or refrained from answering to this question. According to the survey data internet literacy of the population affects willingness to use these services, as out of the population assessing own internet skills as good, at least one of these services offered would be used by 82%, but from those assessing own internet skills as bad – only – 53%.

In response to the question „Considering the all benefits and risks associated with the project „E-health", what would be your overall attitude towards implementation of this project in Latvia" more than half or 55% of the respondents replied that in general they would support introduction of such project, while 21% of respondents – would not support.

Comparison of responses by various social demographic groups reveals that introduction of e-health is more supported by the respondents aged from 16 to 25 years (68%) and from 26 to 35 years (72%), population with the higher education (68%) and high income (71%). Negative attitude towards implementation of the project was expressed by surveyed residents aged from 36 to 45 years (25%), from 56 to 65 years (26%), as well as those above the age of 66 years (31%), population with medium high income (27%), pensioners (34%), unemployed people (25%), people using internet only outside of the home (23%) or the ones not using internet at all (38%).

The respondents which indicated that they do not favour implementation of the project „E-health In Latvia (total of 217 persons from 1031) were asked to give three main reasons for not supporting introduction of this project. Total of 37% indicated that either themselves or other people don't have a computer, internet or skills required for using these, therefore such project shall not be supported. The second most often given range of responses was concerned with data protection and data safety risks (30%). More than 5% of respondents mentioned such reasons as wishing for more personal communication with the doctor, health care personnel by expressing concern that the doctors will be more difficult to be reached in person, as more communication will be done in the internet (13%), disliking of electronic environment in general, distrust in it (10%), opinion expressed that no such project is needed, no point in it (7%), and also stated that the system will be complex, difficult to use (6%).

## 2.7. Is the e-health web site easy to use?

The experts invited by the State Audit Office during the audit, upon performance of an inspection[74] in the National Health Service, established that the external consultants of the Service have performed in year 2013 an e-health information system applicability quality inspections on compliance of e-health web site public part with the WEB platform users interface standard of e-health users and $WCAG_2$ standard. In the opion of external consultants it was evaluated compliance of e-health portal with the WCAG lowest „A" level, including in the inspections 67 WCAG Standard requirements (20 or 30% from these due to various reasons were not verified), establishing in total 12 irregularities and 16 partial irregularities. Meanwhile in the inspections of the e-health users WEB platform users interface there were included totally 287 claims (132 or 46% from these due to various reasons were not verified), in total establishing 27 irregularities and 37 partial irregularities.

Also in the framework of the audit in May 2015 in the test environment of the e-health information system the experts invited by the State Audit Office performed various applicability tests, that included assessment of users common interface (location of information, use of unified formats, convenience of unified formats, applicability for humans with functional disorders), assessment of applicability in various anticipated workplaces (ability of users to subsequently fulfil daily tasks, without facing unforeseen complications and without devoting too much time for it), as well as assessment of user's documentation and support.

In the assessment of applicability upon performance of practical inspection of e-health information system, the invited experts established multiple problems of functionality (for instance, in the work place of a physician it is not possible to create or to read recipes, various error notices are being returned, etc.), that also this time did not allow to perform planned activities in full, at the same time observing various system usage deficiencies (please refer to examples in the Figure 28). In total from 73 performed inspections 62 inspections were not possible to carry out or there were established deficiencies in these. During the framework of the whole expert audit there have been performed inspections of applicability and the results are indicated in the Appendix No.3.

**Will the e-Health web site be easy to use?**

- To all users, irrespectively of their work place in the tool there is indicated the same information that can mislead the users about functionality that is not anticipated for the particular role
- In individual cases there is not supported usage of Internet Explorer browser
- Separate unpredictable icons and hyperlinks that can prohibit system intuitive usage (for instance, non-identifyable link to the user's profil, unexplained log-off, etc.)
- Not implemented „Easy to read" section that can prohibit an easy access to information for people with functional disturbances
- In various screen forms there is applied a different terminology and titles for the same things
- Reports are not possible to range in line with one column
- Upon closing a sickness leave act printout in PDF form, all the e-health web site is shutting down and it is necessary for the user to repeatedly connect to the system

*Figure 28.* **Examples of applicability deficiencies.**

[74] SIA „Pricewaterhouse Coopers" report of 22.05.2015 „Assessment of e-health information system development effectiveness".

National Health Service plans in the framework of the e-health project stage II to perform also a repeated testing of applicability with all the roles used in the solution, attracting also actual end users from various institutions. Nevertheless, upon reviewing the anticipated scenarios of testing and the circle of testing persons, the experts invited by the State Audit Office established that in these tests it is not anticipated to include people with functional disorders, that taking into account also the established findings during this audit, may be insufficient in order to ensure information system support for people with functional disorders.

## 3. Will safety of information data and protection of personal data be ensured in the newly developed e-health information system?

This section provides information on organisation activities performed by the National Health Service for provision of compliance at the area of management of the safety of the systems and protection of personal data processing by assessing readiness of the e-health to commission the e-health for use and start its use. Also information is provided on the data protection and confidentiality safeguarding measures planned in the e-health system in both ways – preventive ones before the data processing and after it from the analysis of the audit trail records.

***Sources of information***

- *Law of the State Information Systems and regulations issued pursuant to it.*
- *Law of Protection of Physical Persons Data and regulations issued pursuant to it.*
- *Law of the Patients Rights, Procedure for handling of medical documents.*
- *Cabinet of Ministers Order No. 560 of 17 August 2005 "The Guidelines "E-health in Latvia"".*
- *Cabinet of Ministers Order No. 660 of 24 October 2007 " The Guidelines "E-health in Latvia" implementation plan for year 2008 – 2010 ".*
- *Regulations of the Cabinet of Ministers of 11.03.2014 No.134 „Regulations of the Unified Electronic Information System of the Health Care Sector".*
- *Architecture of the health care information systems and description of the operational concept of the E-health information system.*
- *The European Parliament and the Council Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data" and documents of the task group according to its Article 29.*
- *Latvian Standard LVS ISO/IEC 27002:2013 „Information technologies. Safety methodology. Code of practice for information safety management".*
- *Internal legal acts of the National Health Service in the area of Information system security management.*
- *Information provided by the National Health Service on the e-health implementation, information system data safety and person data protection.*
- *"PricewaterhouseCoopers" Ltd. reports of 22.05.2015 "Evaluation of E-health information system development efficiency".*
- *Information provided from the State Inspection of data.*

***Audit methods***

- *Analysis of requirements of external legal acts and identification of mandatory requirements.*
- *Analysis of industry guidelines, recommendations, best practice standards and identification of recommended requirements.*
- *Analysis of reports of safety and performance audits of e-health.*
- *Interviews of the employees of the National Health Service and testing of the e-health functionality in the testing environment.*
- *Compliance assessment of the IS security management and data protection documents developed by the National Health Service and the processes implemented.*

***Evaluation criteria***

- *Have all of the required internal acts been developed in due time and in compliance with requirements of external legal acts and have all the required actions been taken in the area of IS security management and data protection, also if these are adhered to in the daily processes?*
- *Have sufficient actions been taken for assessment of the safety of e-health and for elimination of the security deficiencies?*
- *Are outsourced consulting services been ordered at the right moment and are their results used in the daily work?*
- *Does the e-health system provide for such access to health data by the health care professionals and the patients themselves, which is compliant with both - the legal acts and the interests of the patients?*
- *Does the e-health system provide for appropriate and thorough controls for identification of unauthorised processing of data and prohibition of it in a preventive way and after occurrence of the data processing?*

### 3.1. Has the system been completed from the information systems safety point of view?

***Setting up of the information systems safety management process at the National Health Service***

The description of the operational concept of the e-health information system states that data security and protection of privacy rights of the patients is one of the most challenging aspects of e-health to which special attention shall be paid throughout the course of the project implementation.

Protection of personal medical records and safety of the solutions is critical, therefore trust of public and health care professionals shall be secured and the acceptance testing of the e-health solutions as unconstrained part of the treatment process. Main aspects of safety solutions include regulation and set of procedures for access to personal data, rights of the individual to restrict access to his medical records, availability of access audit trail records, introduction of the control and supervision mechanisms, etc. aspects.

Safety management of the information systems in Latvia is regulated by several national legal acts. The State Information Systems Law provides that adherence to safety requirements shall be ensured by the holder of the state information system, which in the case of the e-health system is the National Health Service. The Cabinet of Ministers Regulations on General Safety Requirements of the Information Systems details how the holder of the system shall ensure development of various internal legal acts – safety policy of the system, internal safety rules, terms of use of the system, system's safety risk management plan, system recovery plan, as well as is in charge for adherence to these, implementation and execution.

At the beginning launch of e-health was planned to be done gradually from 1 April 2014 to mandatory use as of 1 January 2016, however by the 1 April 2015 the National Health Service had not developed all of the required internal documents in the area of e-health safety, although the Service had access to all of the requirements set for the system and the core processes to be ensured. In December, 2014 information systems safety policy was approved, serving as a basis and starting point for further development of the other internal legal acts concerning the safety of the information systems (see Figure 29).

Although the internal legal acts concerning the safety of the information systems have not been developed (incl. that no users management procedure has been developed), as of May, 2013 the National Health Service has signed at least 19 agreements with the health care institutions, pharmacies and various developers of the medical information systems on testing of the system and data exchange so that the stakeholders would have access to the test environment of the e-health for testing of the functionalities and integration of the system. However no wide access to the system has been ensured and it mostly can be used only from the restricted areas, and the e-health test environment was not launched with a test data base – actual personal names, surnames and personal identity codes are entered into it, providing only unreal medical records.

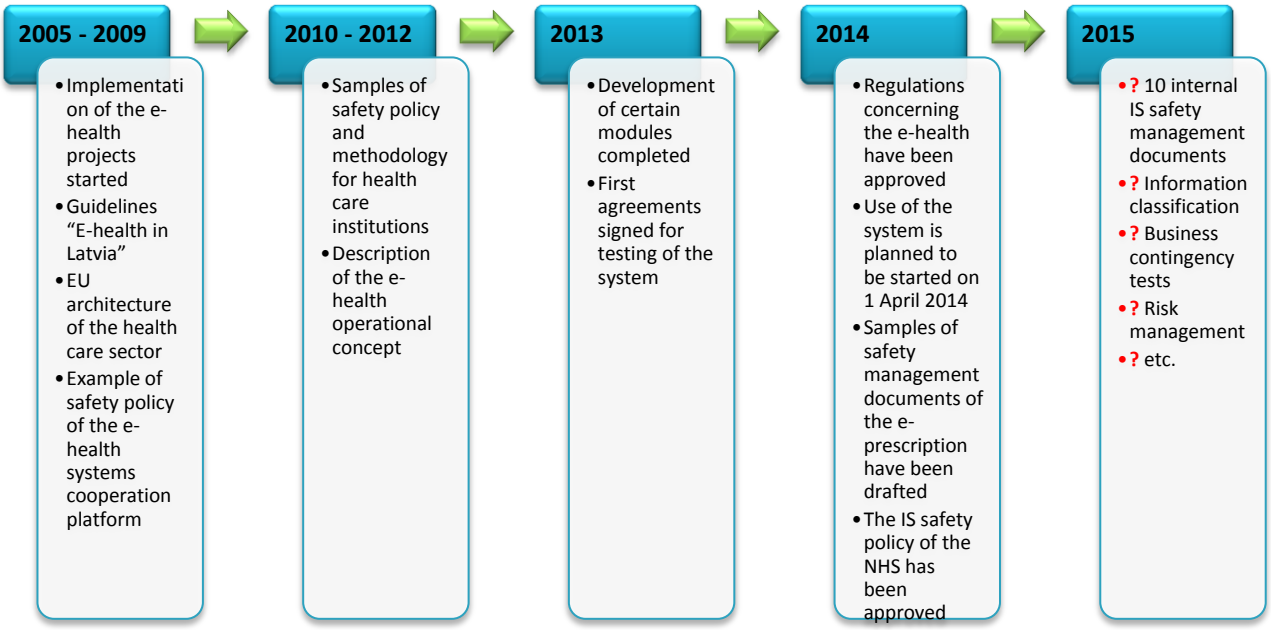



*Figure 29.* **Development of information systems safety management documents.**

Several of the external auditors hired by the National Health Service have also emphasised in their safety audit reports in November and December, 2014 on the missing safety management documents for the information systems, however these deficiencies have not been eliminated. Also in July, 2014 an outsources service provider was ordered to perform assessment of the compliance of the documentation of the e-prescriptions information system with the State Information Systems Law, and to develop safety policy of the information system, internal safety rules, terms of use of the system, system's safety risk management plan, business contingency plan and the system recovery plan for the e-prescriptions information system. Although initially the safety documentation of the information systems was developed only for the e-prescriptions information system, later the Service changed its approach and decided to build joint information systems management compliant with uniform safety management principles without developing separate safety management documents for each information system. Therefore the sample information systems safety management documents developed by the external consultant have not been internally approved in the Service.

Since not all of the safety management documents of the information systems have yet been developed in the National Health Service (currently at least 10 internal documents of safety management of information systems are being developed), the Service has not performed any information classification in regard to the e-health, development of joint risk management plan and supervision of its implementation, business contingency testing, standardised users management, etc. Thus the Service currently is at the initial stage of implementation of the safety management of the information systems in comparison against the recommended implementation process provided in the guidelines for implementation of the information systems safety management (see Figure 30).

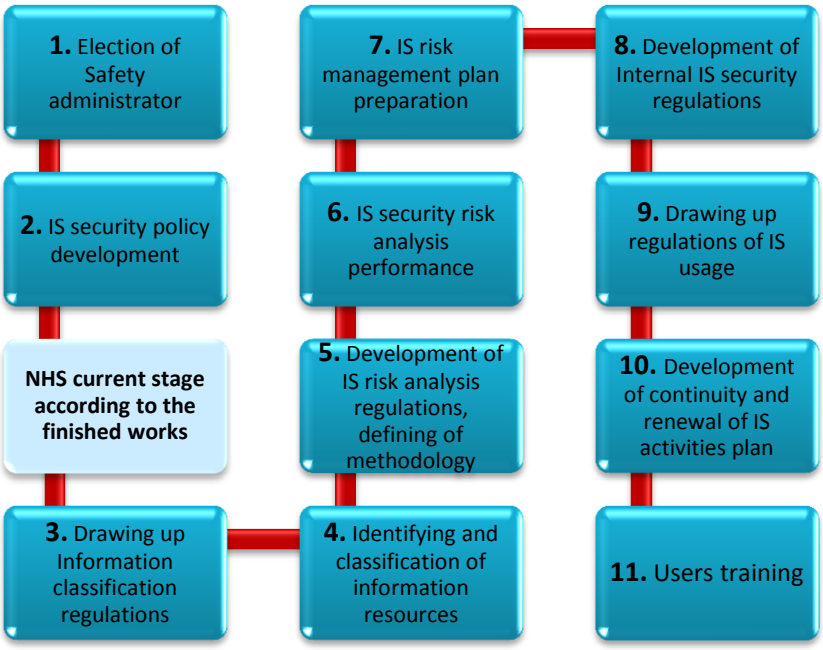



*Figure 30.* **The process of implementation of the safety management and the current stage**

Within course of the audit the National Health Service stated that internal legal acts required for launch of the e-health information system will be developed and approved, however no clear action plan with detailed deadlines for development of all of the required internal documents and their planned approval dates was presented. Also within framework of the audit the Service was also unable to present drafts of these internal legal acts in order to allow for verification of the progress of their development, scope and quality of information contained in the documents, as well as the workload still required for their completion. Nevertheless the Service indicates in the implementation plans for the e-prescriptions and electronic sickness leave act modules of the e-health system (such detailed plans are not available for the other modules) that all safety documentation and internal procedure are planned to be developed by 1 September 2015, when it is planned for several health care institutions to start using of the production environment of the e-health system in the test mode.

Thus for development of these new legal acts the three internal acts of the State Payments Centre and the Health Economy Centre are effective for the National Health Service (Internal Rules for Classification of Information, Internal Rules for Use of the Information Systems and Maintenance Rules of the Information Systems), while their contents do not fully comply with requirements set in the external legal acts and does not provide for all actions required for introduction of the e-health.

***Development of the information systems security management process in the health care institution***

Information systems security management documentation shall also be developed by the health care institutions and pharmacies, which will use their own information systems for accessing the e-health system, which will be integrated with the e-health information system. According to the requirements of the Cabinet Regulations on the Unified Electronic Information System of the Health Care Sector the health care institutions and pharmacies shall adhere to overall safety and technical requirements, incl. development of documents required for compliance of the state information systems overall requirements.

Thus the draft contract prepared by the National Health Service to be signed with the health care institution for use of the e-health system provides that the health care institution is obliged to maintain policies for safety and use of the system, regulations and procedures in compliance with the provisions of the legislative acts. The Service can request introduction of amendments to the safety policies, regulations and procedures.

Along with the standard requirements the National Health Service in the draft contract for the health care institutions has provided for higher requirements in the area of information systems security than requested by the Cabinet Regulations regulating operation of the e-health information systems and which the Service is planning to introduce into its own internal processes. The draft contract provides that the health care institution if planning to use its local information system for accessing the e-health system shall within five years period certify its information safety management system at least in relation to the segments which will be directly or indirectly involved in exchange of information with the e-health system according to the standards of the LVS ISO 27000 family. However no such requirement is currently found in any legal acts regulating the e-health system or in publicly available information in the home page of the Service concerning implementation of the e-health system in the health care institutions. At the same time such requirement is neither set for the cases when for connecting to the e-health information system the health care institutions or pharmacies will be using technical solution provided within framework of the service of the personal data operator, when the health care institutions according to contracts signed just perform processing of health records of the patients. The Service also indicated that currently there are no plans for the Service to certify its own information safety management system according to these standards.

***Registration of processing of personal data***

Since no internal document of the safety of information systems is not yet developed, the National Health Service as a holder of the e-health information system has not yet performed any registration of the processing of data of physical person according to the Law on Protection of the Physical Persons Data at the State Inspection of Data in order to be lawfully entitled to accrue and use health data of physical persons in the e-health system.

National Health Service has indicated in the implementation plans of the e-prescriptions and electronic sickness leave acts that registration of processing of data of physical persons will be done by the 1 April 2015, i.e. before launch of use of the e-health system, however so far no communication has occurred with the State Inspection of Data concerning issues of personal data of physical persons to be processed in the e-health system and no data processing registration has yet been done. The State Inspection of Data states that the latest official communication in relation to implementation of the e-health system was in 2011, when the State Inspection of Data provided information to the Health Economy Centre concerning rights of patients and data protection within the e-health context.

State Inspection of Data also indicated that processing of personal data related to processing of the health information is one of the primary areas, where also in 2015 the State Inspection of Data is conducting detailed pre-registration audits before approving any registration of the data processing. Moreover the internally developed legal acts in the area of information security and protection of data of physical persons are required for registration of data processing (the registration application shall also contain description of technical and organisation measures ensuring protection of personal data) which is planned by the Service to be ready by September, 2015.

***Performance of safety audits of the information system and elimination of deficiencies***

Legislative acts provide for need to perform various safety tests of the information systems, e.g., Mandatory Technical and Organisational Requirements for Protection of Personal Data prove the holder of the system to perform internal audit of personal data processing and to prepare a report on measures taken in the area of safety of information. The General Requirements for the State Information Systems provide for assessment of compliance of the information systems with the requirements, on the basis of the results of tests of the system's safety (audits) and the holder of the system shall ensure tests of the safety of the system (audits) at least once per year. The Safety policy of the information systems of the National Health Service also provides that tests of system's safety and personal data processing shall be performed.

Notwithstanding the role of the National Health Service as a holder of the safety of the information system, it is not actively involved in safety testing and auditing of the e-health information systems delivered, instead the audits are being outsourced. Internal legal acts of the Service provide that safety manager shall perform safety tests of the delivered information systems (incl., by involving experts), since a positive conclusion of the safety manager is a mandatory precondition for launch of use of the system. However within framework of the contract signed with external experts no all types of required tests have been ordered and performed for all of the e-health systems (e.g., no assessment of separate software codes has been performed, performance assessment has been performed only for the e-prescriptions system, physical safety has been assessed only for the integration platform, etc.).

The framework agreement signed in 2014 on assessment of the safety and performance of the software and the information systems and development of documents, and under this agreement also five safety and performance assessments of the e-health systems were performed, and the assessment of the safety management of the information system for the amount of 163 180 *euro*. The service providers had recommended elimination of all high and medium risks observed, as well as to consider elimination of he low risks observed in order to improve the overall management of the information system, to perform repeated audits after such elimination (see Figure 31).

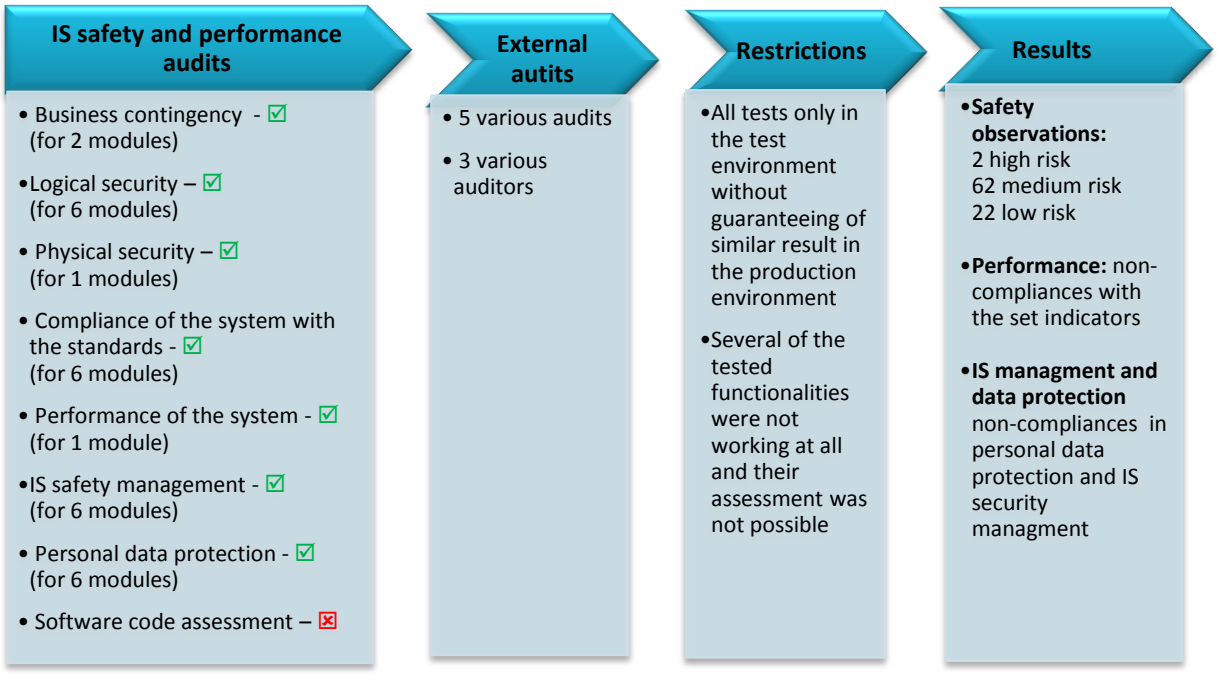



*Figure 31.* **Information system's security audits of the e-health system and the results thereof**

No thorough information was obtained within course of the audit on the progress in elimination of all of the deficiencies discovered. The safety manager of the information systems of the National Health Service explained that reports of the external safety audits are first reviewed by the holder of e-health information resources and only if necessary also by the safety manager of the information systems, although one of the tasks listed in the job description of the safety manager of the information systems is to organise elimination of deficiencies discovered by the safety audits. Meanwhile the holder of the information resources of the Service informed that the safety manager of the information systems is in charge for preparation of the plan for elimination of such deficiencies. Therefore no overall plan has been prepared for elimination of all of the deficiencies discovered with deadlines and types of actions and persons in charge. Such information will be summarised in the risk management plan of the information systems, when risk analysis of all information systems will be performed in 2015 jointly with holders of information resources (so far such analysis of the e-health information systems has not been completed and also the methodology for its performance has also not been approved).

National Health Service has set up a Safety Management Commission[75] the one of main obligations of which will be to review the safety audit reports and within two weeks time provide the Service Director with recommendation on potential implementation of the safety audit recommendations. However by April, 2015 the Safety Management Commission has not reviewed any of these reports of the external safety audits, which were submitted to the Service on November and December of 2014, thereby no recommendations have been prepared for the management of the institution on potential implementation of the safety audit recommendations.

In general after preparation and arrangement of the production environment of the e-health information systems the National Health Service is planning to order and to perform repeated safety audits in order to verify whether the deficiencies previously discovered have been eliminated. The safety manager of the Service also provided information that no coordination required by the internal legal acts for starting to use the e-health system will be given before the elimination of identified deficiencies. According to the implementation plans for the e-prescriptions and electronic sickness leave acts by the Service (such plans are not available yet to other modules) repeated safety audits for the entire e-health system are planned by 30 June 2015 and elimination of priority deficiencies will have to be eliminated by 1 July 2015 (for the electronic sickness leave acts module) and August 1 (for the e-prescriptions module).

### 3.2. Has the confidentiality of the information and respective protection of personal data been ensured?

***Management process of allocation of the access rights***

Initial implementation guidelines of the e-health contained a vision that every Latvian resident is assured that information on his health condition, diagnoses, medical record is available only in a lawful way (upon his agreement or according to procedure set by the law, when no approval of the data subject can be received). Therefore also the information systems used in the health care shall be safe and available only strictly according to the set safety requirements.

[75] Order No.4.1.-2/269 of 30.10.2014 of the National Health Service „On Development of Safety Management Commission".

The State Information Systems Law provides that in order to protect the state information systems from unauthorised access, the holder of the state information system shall ensure verification of the identity and access rights of the users of the state information systems. The general safety requirements of the state information systems provide that safety of the state information systems is ensured by a set of measures which shall be taken in order to ensure secrecy of the information among other things – disclose of information only to the persons authorised to receive or use it. While the Law on Protection of the Physical Persons Data provides that for purposes of protection of the interests of the data subject the holder ensures processing of personal data only for the set objectives and only to the required extent. The holder shall use all the necessary technical and organisational means to protect personal data and to prevent their unlawful processing.

State Inspection of Data ensuring supervision over personal data processing in Latvia indicates that processing of health information is permitted only upon ensuring special protection measures. The State Inspection of Data already in its letter to the Health Economy Centre in 2011 indicated that for processing of personal data in the health information system also other requirements of the Law on Protection of the Physical Persons Data shall be considered, incl. ensuring that the persons entitled to see the data of the particular data subject obtain such personal data only to the extent lawfully required by it, as well as to ensure audit trail registration for all of the actions taken in the system.

While the Cabinet of Ministers Regulations actually regulating operations of e-health information systems provide that the health care professional authenticated according to the procedure set in the health information system is entitled to process the restricted access data concerning the patient included in the health information system for the purpose of achievement of the treatment objectives. Main planned levels of assess rights and roles in the e-health system have been summarised in Figure 32.

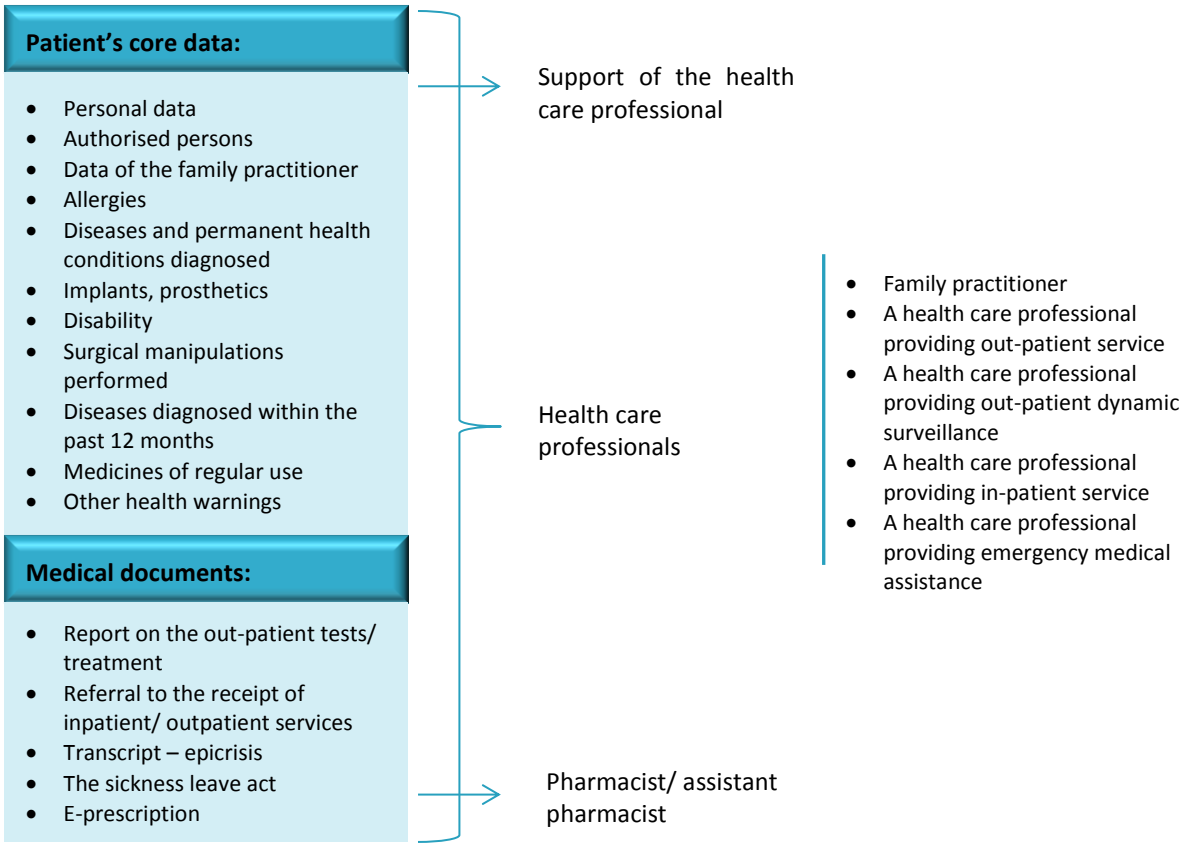



*Figure 32.* **Data available to the health care professionals on all patients.**

Also the draft contract developed by the National Health Service to be signed with the health care institutions for use of the e-health systems provides that access of the health care professionals to the health records of the persons in the e-health system is permitted only within the framework of the treatment episode.

The draft contract provides that user rights of access to the e-health system for the health care professionals and support health care personnel in the health care institutions are assigned, changed, blocked or cancelled by the administrator of the health care institution by ensuring retaining of written evidence of such decision. While the access rights of the administrator of the health care institution to the e-health system are assigned by the National Health Service. The health care institution shall immediately cancel its access rights if the user has terminated employment or contractual relations with the health care institution.

Thus according to the provisions of the Cabinet of Ministers Regulations regulating operations of the e-health after launch of operations of the e-health system all of the health care professionals aware of the personal code of the patient will have automatic access to health data of all patients until the patient himself will prohibit in the e-health access to personal data stored in the e-health information system (such approach is called an *„opt-out"* approach contrary to the *„opt-in"* approach when the user shall at first permit or approve access by other person, not prohibit it).

Already in 2011 the State Data Inspection recommended to the Health Economy Centre adhering to the recommendations[76] of the task force of the Article 29 of the Directive 95/46/EC[77] (objective being definition of data protection preconditions for development of the national level system of electronic health cards). In order to ensure the required health data protection on one side and practical considerations and flexibility of use of the system, it recommends using not only the *„opt-out"* approach in implementation of the access to the electronic health card data (which could be used for less important data), but also the *„opt-in"* methods for especially sensitive data. In the case of the Latvian e-health only the *„opt-out"* approach is used.

***Variable access rights by various roles***

Every health care specialist, e.g., family practitioner, psychiatrist, physical therapist, dentist, oculist, etc., will need access to various information in performance of the work and not always there will be necessary access to all medical records of the patients. Therefore advanced, systematic and well considered procedure for allocation of roles and rights might be required in the e-health system by assigning the access rights maybe in more detailed manner by considering the daily needs. According to the best global practice[78] the "need to know" principle is often used for control of users access, when access is assigned only for information required by the particular person in performance of its usual tasks – various roles and tasks mean different volumes of "need to know" and thus also different access profiles.

Also the State Inspection of Data already in 2011 recommended to the Health Economy Centre to adhere to the recommendations of the task force of the Article 29 of the Directive 95/46/EC (objective being definition of data protection preconditions for development of the national level system of electronic health cards), which stated that it is recommended to include in the

[76] Letter No.1-2/5736 of 15.08.2011 „On Patient's rights and data protection in the context of e-Health".

[77] Working document of the data protection task group of the European Parlament and the Council Directive, Article 29 of the 15.02.2007. Working document on the processing of personal health related data in the electronic health cards of the patient (EHC).

[78] Latvian Standard LVS ISO/IEC 27002:2013 „Information technologies. Safety methodology. Code of practice for information safety management",page 20.

electronic health cards the data access levels by various categories of the health care professionals for improvement of additional data, as well as the improved model of the access rights for purposes of data protection (this means defining categories of medical data in the system, as a result of which only data of certain category will be available to certain categories of the health care professionals or institutions).

***Rights of the patient to restrict access to his data***

Regulations of the Cabinet of Ministers regulating operations of the e-health system provide for option of the patients to prohibit access to their medical data in various ways – by prohibiting access to all or just some of his medical records or by prohibiting access only to certain health care professionals or the health care institutions (by providing partial prohibition functionality only as of 2016).

However the testing of the e-health functionality performed within the course of audit revealed that the functionality available at the test environment of the e-health allowed for the patient to prohibit access to all of his data or certain documents only for all health care professionals without allowing for variations and imposing of prohibition for certain health care institutions or doctors – e.g., by allowing access only the family practitioner and the emergency medical aid, but prohibiting access by others (see Figure 33). Therefore the patient shall entrust his medical records either to all health care professionals or none, which is contrary to the planned requirements of the Regulations of the Cabinet of Ministers regulating operations of the e-health system.

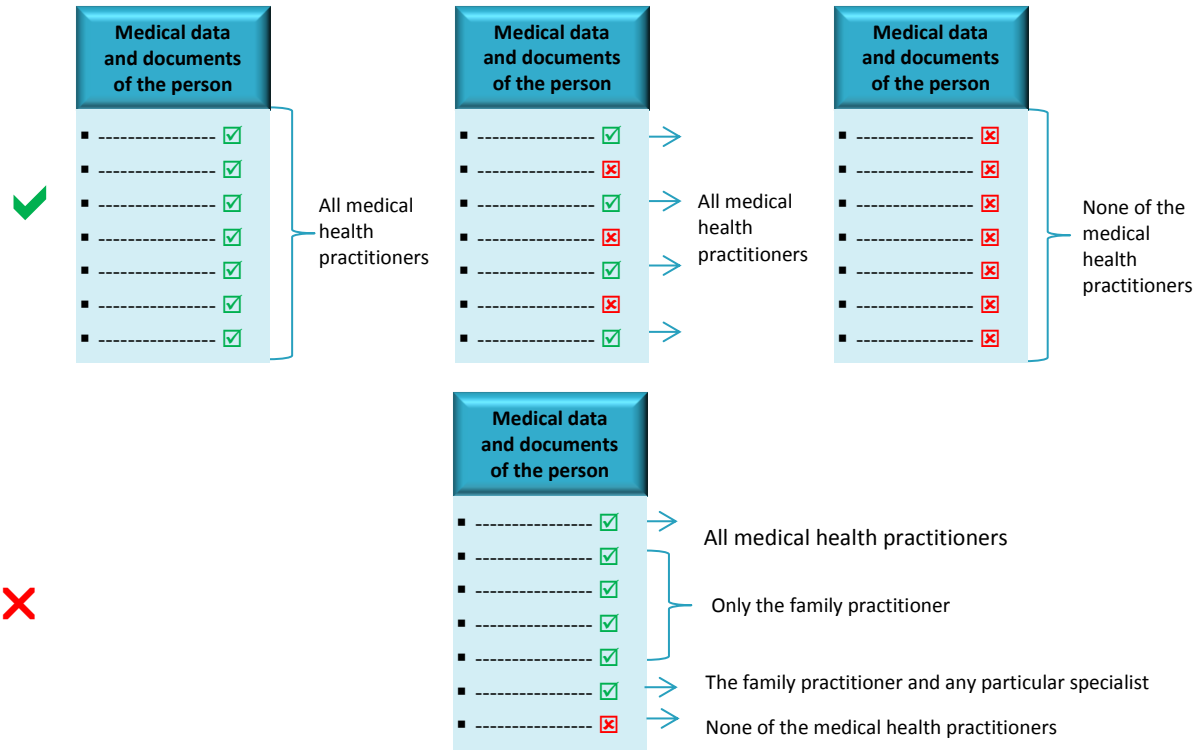



*Figure 33.* **Options of the patient to restrict access to his medical record**

Annotation to the Regulations of the Cabinet of Ministers regulating operations of the e-health system states that accrual of health data of patients in the centralised e-health system means not only access to better quality and more complete information by the persons involved in the treatment process and relieving of the administrative burden, but also higher potential harm to the person due to unauthorised and unjustified access to this information system.

***Control over unauthorised data processing provided in the system***

Although the rules regulating the operations of the e-health system provide for certain data processing restrictions, no automated controls have been provided in the e-health system for each of such planned restrictions in order to prevent access or to mark such particular data processing as risky for further verification. The National Health Service provided information that e-health system currently does not provide for more detailed inbuilt controls, which would be able to identify within description of each particular role and to prevent access to certain personal health records already before processing of the personal data, if such are being processed outside of the particular treatment episode.

Although the health care professionals have access to medical records of all patients (until such access is prohibited by the patient himself), the National Health Service believes that health care professional are liable for processing of data only within framework of the particular treatment episode and to ensure confidentiality. While the task force of the Article 29 of the Directive 95/46/EC in its recommendations directly indicated to concern that the traditional undertaking of medical professionals to maintain confidentiality is not sufficient in the case of e-health and new additional protection measures are required.

Therefore the e-health system is not automatically checking whether the family practitioner is obtaining only information on his own patients in the cases of processing of physical persons data against the data of electronic referrals/bookings, data processing cases against the created health record documents (transcripts, referrals, prescriptions, sickness leave acts etc.), data processing cases against the payment for service, patient's fee and copayment data, data processing cases against the data of patients enrolled as in-patients and the period of stay, data processing cases against the data of calls to the emergency service, data processing cases against the actually issued medicine, etc.

At the same time the Ministry of Health initially stated in the guidelines of the "Architecture of the health care information systems" and the descriptions of the solutions that access of the health care professional to the information stored by the information system in the electronic health card of the patient is authorised by the patient himself (the patient sets the type of information available to certain types of users). Organisational and technological controls also shall be provided to safeguard medical information from its inadequate use.

***Processing differences between the electronic and printed medical records***

Moreover a different approach has been discovered to the scope of access rights depending on whether the health related information is stored in the paper format or electronically in the e-health system:

- in the standard case the law on patients rights provides that information of the patient can be disclosed upon his written approval or in the cases listed in the law. Upon written request and upon receipt of written permission of the manager of the health care institution the patient's information is provided, e.g., for achievement of treatment needs of the health care institution. The procedure for handling of medical documents also provides that manager of the health care institution also ensures protection of the medical records and information contained therein from authorised access and appoints a health care professional in charge for ensuring protection of medical information. During the business hours of the health care institutions the health care professionals involved in the treatment process of the patient ensure that persons not involved in the treatment process can access medical records of the patient and information contained therein. Outside of the business hours of the health care institution the medical records of the patient and the

information contained therein are stored in a separate locked room or cabinets protected against access of persons not involved in the treatment process.

- while the information accrued in the e-health system is processed, e.g., by the health care professionals and support personnel of health care for purposes of achievement of the treatment objectives and provision of the pharmaceutical care by the pharmacists (without any reference to need for a written request from the health care institution). Moreover in the e-health system all health care professionals gain automatic access to all patients' data.

Also the preamble of the European directive on protection of processing of personal data[79] explains that protection of individuals must apply as much to automatic processing of data as to manual processing and the scope of this protection must not in effect depend on the techniques used, otherwise this would create a serious risk of circumvention.

### 3.3. Has the supervision of safety of information data and personal data safety risks and activities been ensured?

***Supervision over the IS safety processes in the health care institutions***

Regulations of the Cabinet of Ministers regulating operations of the e-health system provide that pharmacies and the health care institutions access the restricted data accrued in the e-health system after signing of contract with the National Health Service on use of the e-health system, which provides for safety and technical requirements of the use of e-health system. The health care institutions and pharmacies, intending to use for access to the e-health system their own information systems integrated with the e-health system in addition shall ensure that no mass copying of data would be possible and that a range of other certain general safety and technical requirements are adhered to (e.g., development of internal legal acts in the area of the information systems security, formation of audit trails records, infrastructure protection against unauthorised access, theft and intentional or unintentional damage, network protection by the firewall, antivirus protection, ongoing monitoring of safety threats, multi-factor authentication etc.).

The Regulations provide that the National Health Service is not signing contract for use of the e-health system with the health care institution or pharmacy if it has not fulfilled the requirements of these regulations. However the Service informed that currently no additional inspections are planned in regard to verification of actual adherence to these requirements prior to signing of the contract and thus along with signing of the contract that becomes responsibility of the health care institutions or pharmacies. Also so far the Service has not yet considered any possible inspections after signing of the contract since due to large number of contracts inspecting of the all the health care institutions or pharmacies will not be possible.

Annotation to the Regulations of the Cabinet of Ministers regulating operations of the e-health system states that target group of the e-health system is 4821 health care institutions (with which 6972 doctors, 1480 dentists, 1869 assistant doctors, 9238 nurses, 400 midwives, 508 dentistry nurses, 152 dental hygienists are associated) and 820 pharmacies (with which 1650 pharmacists and 1385 assistant pharmacists are associated). It is mandatory for all health care institution to sign contracts on use of the e-health system with the National Health Service by 31 December 2015. The Service is planning to start signing of contracts as of 1 October 2015, when according to the implementation plan of the e-prescriptions and electronic sickness leave acts the production environment of the e-health system will be available for use of all

[79] The European Parlament and the Council Directive No.95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data", Paragraph 27 of the Preamble.

interested persons. Therefore within three months period about 5641 contracts will have to be signed with the health care institutions and pharmacies, which is in average[80] 91 contracts every business day. The Service will also have to create, activate and send to the every institution the access data of the administrator of the health care institution and/ or user in charge, which in the Service can be ensured by 1-2 employees.

The draft contract developed by the National Health Service for signing with the health care institutions for use of the e-health (the final wording of the model contract was not yet coordinated and approved at the time of audit) provided, that the health care institution undertakes to ensure use of the local information system on such technical resources which are physically and logically protected from unauthorised access according to provisions of the legislative acts (at the same time no such safe exploitation is requested in the cases when the health care institution or pharmacy for connection to the e-health will be using technical solution provided within framework of the service of the personal data operator, when the health care institutions according to contracts signed just perform processing of health records of the patients). The health care institution shall upon request of the Service perform also the tests of their information systems safety (audits), while the Service is entitled to request and the health care institution is obliged to provide all the relevant information. The Service is also entitled to block the connection of the health care institution to the e-health system (should any potential threat to the system be discovered), but no rights of the Service to control or block separate users are provided.

***Data quality supervision***

The State Information Systems Law provides that the holder of the information system (in the case of the e-health information system the manager and holder is the National Health Service[81]) pursuant to legislative acts is in charge for collection, registration, entering, processing, storage, use, transmission, publishing of data, compliance with data submitted, updating, correction, as well as quality of data in the state information system.

Also the Guidelines „E-health in Latvia" provided a vision that every Latvian resident as well as health care specialists will be assured that information available on the patient's health condition and medical records is of high quality; therefore one of the objectives of development of the e-health is to ensure reliability of the health care data.

While the draft contract on use of e-health system to be signed by the National Health Service with the health care institutions provides that the Service is not liable for accuracy and justification of the bookings accrued in the e-health information system, as well as is not liable for consequences of treatment decisions passed even in the case when the decisions have been made based on the information accrued in the e-health system on the patient. The draft contract also does not provide who is liable for accuracy and justification of the patient data accrued in the e-health system. Remuneration of losses is also provided in regard to the health care institutions (not the Service), if due to their unlawful or careless actions personal data has been obtained or modified without due authorisation.

Also from the view point of the Law on Protection of the Physical Persons Data the manager of the system (thus – National Health Service) controls type of personal data entered and the time of entering, and is liable for acts of the persons performing processing of personal data.

[80] By assuming that for the period starting from 1 October 2015 to 31 December 2015 there will be 62 business days.

[81] Data from the register of the State Information Systems (Internet resource: https://www.visr.eps.gov.lv/visr/default.aspx?action=2&rid=219, viewed on 17.03.2015.).

Tests of functionality of the e-health system performed within course of the audit also revealed that the doctors are free to delete information (diagnosis) entered by another doctor. Moreover the National Health Service indicated that the e-health system does not provide for any electronic signatures being used in the records – the authors of entries will be identified from the data of authorisation and audit trail records.

***Creation and access to the audit trail records***

The Law of Patients Rights provides that the patient is entitled to know the name, surname, position, profession, specialisation and qualification of the treating physicians and other health care professionals involved in the health care process. The patient is also entitled to get introduced with his medical documents, as well as to receive information on use of information contained in his medical documents according to the provisions of this law and the Law on Protection of the Physical Persons Data.

The overall technical requirements of the state information systems provide that the holder of the state information system applies a software in relation to the system's information resources, which is performing audit trail recording by registering data on events in the system. The mandatory technical and organisational requirements for protection of the personal data provide that upon transfer and receipt of the personal data it is mandatory to save information on the time of data transfer/ receipt and the personal data of the person transferring and receiving data, the personal data transferred and received. The option of identification of the personal data which was processed without due authorisation, as well as time and person when it was performed shall also be provided.

Such requirements are also provided in the Regulations of the Cabinet of Ministers regulating operations of the e-health system - provide for saving of data in the system of the person performing processing of data in the system – name, surname, identification number, position/speciality, name of the institution, date and time, type of processing action. The person will be able to access these data through the e-health portal, thus the person will be able to control processing of its data in the e-health system and in the case of discovery of unlawful processing of data turn to the National Health Service.

National Health Service informed that in the case if the patient will have at his disposal the authentication means for logging into the e-health system, the patient will be able to submit written application to the Service and to obtain this information in writing.

However within course of the audit upon performance of the tests in the e-health portal's test environment deficiencies were discovered in performing such audit trail recordings and presentation to the patient in the e-health portal – in the audit trail registers the patient did not have access to all data processing cases, and also not all of the information was presented (e.g., name of the institution, type of data processing action, as well as data processing justification „other"). National Health Service has reported the deficiency of the software discovered within course of the audit as an error to the developer (this functionality of audit trail recording was developed and delivered already within framework of the stage I in 2013).

Also in the test environment of the e-health portal the patients don't have access to all information provided for in the documents regulating operations of the e-health system – time of data processing (only the date is available), number, speciality of position of the health care professional or pharmacist (just name, surname), number of the health care institution (only the name is seen).

***Analysis of audit trail records and identification of unauthorised data processing***

The safety policy developed by the National Health Service provides that safety manager is performing analysis of audit trail recordings. The Service also informed that a separate audit trail records module is planned for the e-health information system with options of filtering data and building various types of reports, with option of exporting audit trail records to the data warehouse solution and performing more detailed data analysis in the warehouse. However tests performed within course of the audit revealed that the audit trail recording module of the e-health system was not functioning properly (it was not possible to submit any type of request for sampling of audit trail records), but the data warehouse solution was not yet developed and available for testing, therefore no full-fledged analysis and tests of the audit trail records could be done.

National Health Service also has no access to any special software for analysis of audit trail registers, even considering the number of persons involved in and nature of the activities the potential number of audit trail recordings will be large. By now no attempts have been made to perform analysis of such audit trail records in the e-health system, no clear procedure for their analysis has been introduced and no clear criteria have been identified according to which unusual data processing cases will be identified in such audit trail records (in the interview the Service gave an example – if the data processing has been done outside of regular work hours and whether any entry has been made in the health data as a result of data processing, as well as options of the patients themselves see and control information in their own medical records).

However the State Inspection of Data indicated that the patient will have rights, not obligation to perform control after receipt of information on processing of his personal data. Therefore the holder (the National Health Service) shall implement procedure according to which it will be able to protect personal data and prevent its unlawful processing. The holder is obliged to prove and demonstrate at any time that processing of personal data is lawful. The State Inspection of Data also indicates to the judicature of the European Court of Human Rights[82] by stating that the holder is obliged to ensure operations of the system in such a manner, as to allow for identification of cases of unlawful processing.

Already in year 2011 the State Inspection of Data and the Health Economy Centre recommended to observe the recommendations of the work group of Article 29 of the Directive 95/46/EC (objective to define preconditions of data protection for creation of state level electronic health cards), that advised to especially anticipate necessity to prevent unauthorized access to the data, as well as to perform an extensive registration and documentation of activities of processing performed in the system framework that comes together with internal inspections and correct authorization inspections.

[82] The European Court of Human Rights case I. against Finland (17.07.2008. Case No.20511/03).

## 4. Has an efficient supervision and control of the project „E-health in Latvia" been set up?

In this section has been assessed the effetiveness of activity of the Ministry of Health, upon performing organizing and coordination of e-health policy, as well as supervision and control of e-health policy.

***Sources of information***

- *The Order of the Cabinet of Ministers of 17 August 2005 No. 560 "On the Guidelines "E-health in Latvia""*
- *The Order of the Cabinet of Ministers of 24 October 2007 No. 660 "On the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010"*
- *Informative report of the Ministry of Health of 23 April 2008 on implementation in 2007 of the Guidelines "E-health in Latvia" and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.*
- *Informative report of the Ministry of Health of 6 November 2014 on implementation of the Guidelines "E-health in Latvia" in years 2008 – 2013 and of the Implementation Plan of the Guidelines "E-health in Latvia" for years 2008 - 2010.*
- *Information from the Ministry of Health and the National Health Service (supportive documents, information, interviews).*

***Audit methods***

- *Legal acts of the Ministry of Health concerning the setting up of supervisory work group, committees, council, their tasks were assessed.*
- *Minutes of supervisory meetings of the Ministry of Health were assessed.*
- *The course of implementation of the e-health portal has been assessed*
- *Interviews with employees of the Ministry of Health.*

***Evaluation criteria***

- *Have the informative reports on the policy implementation been prepared in compliance with the legal acts?*
- *Is ongoing supervision ensured on the policy implementation?*
- *Is policy implementation conducted according to the approved plan (activities, deadlines, financing)?*

According to the Terms of Reference of the Ministry of Health[83] the Ministry is organising and coordinating implementation of the sectoral policy in the subordinate institutions of the Ministry as well as the overall implementation of the health promotion policy, which includes management of implementation of the guidelines „E-health in Latvia".

In the Guidelines „E-health in Latvia" and the implementation plan of the Guidelines for the years 2008-2010 the Ministry of Health was appointed as an institution in charge for implementation of the guidelines and the plan, and also as of 1 May 2008 the Ministry had to submit to the Cabinet of Ministers by the May 1 of the respective year a report (overview) on the implementation of the guidelines and the plan.

For the period from start of implementation of the Guidelines up to now four reports had to be prepared by the Ministry of Health to the Cabinet of Ministers, i.e. by the 1 May 2008, 1 May 2010, 1 May 2012, 1 May 2014, however the Ministry had prepared only two informative reports:

- informative report of 23 April 2008 on the implementation of the Guidelines „E-health in Latvia" and the implementation plan for years 2008-2010 in 2007;
- informative report of 6 November 2014 on the implementation of the Guidelines „E-health in Latvia" in 2008 – 2013 and the implementation plan for years 2008-2010.

In 2013 the Ministry of Health established the Information Technologies Council, which as of 2009 was charged with supervision over implementation of the e-health policy. Initially the terms of reference provided that the council meetings are held at least once per quarter, while as of the 2009 – at least once per year.

Information Technologies Council started its work in 2003, but no information is available on its operations in 2003 and 2004, the total of six Council meetings have been held – four in 2005, one in 2006, none in 2007 and 2008, while according to the information provided by the Ministry the last Council meeting was held in early 2009.

In order to ensure successful achievement of objectives set in the implementation plan of the guidelines and operational management and coordination of e-health implementation activities, on 1 February 2008 the Ministry of Health approved a Procedure for Performance of the e-health Project and the Sub-Projects[84], which provided for organisational and methodological framework of the implementation activities and on 21 February 2008 a task group was set up in the Ministry[85], comprising representatives of the Ministry and subordinate institutions. The task group was meeting in average once per month.

In October 2008 member of the task group – the Head of the e-health Division of the Policy Planning Department of the Ministry of Health proposed developing of a new document since the Implementation Plan of the Guidelines for years 2008 – 2010 was obsolete and not relevant at the current situation – the task group agreed with the proposal, nevertheless it was never actually implemented.

For the period from the meeting of the task group of 8 September 2009 till the next meeting of project management and supervision work group held on 15 May 2012, i.e. for more than 2.5 years not a single supervisory meeting of the e-health project supervised by the Ministry of

[83] Regulations of the Cabinet of Ministers of 13.04.2004 No.286 „Terms of Reference of the Ministry of Health".
[84] Legal act of the Ministry of Health of 01.02.2008 No.IeNA/8 „Procedure for implementation of the e-health project and its sub-projects".
[85] Order of the Ministry of Health of 21.02.2008 No.31 „On setting up of the task group".

Health was held. The dynamics of the supervisory meetings organised by the Ministry of Health are shown in the Figure 34.

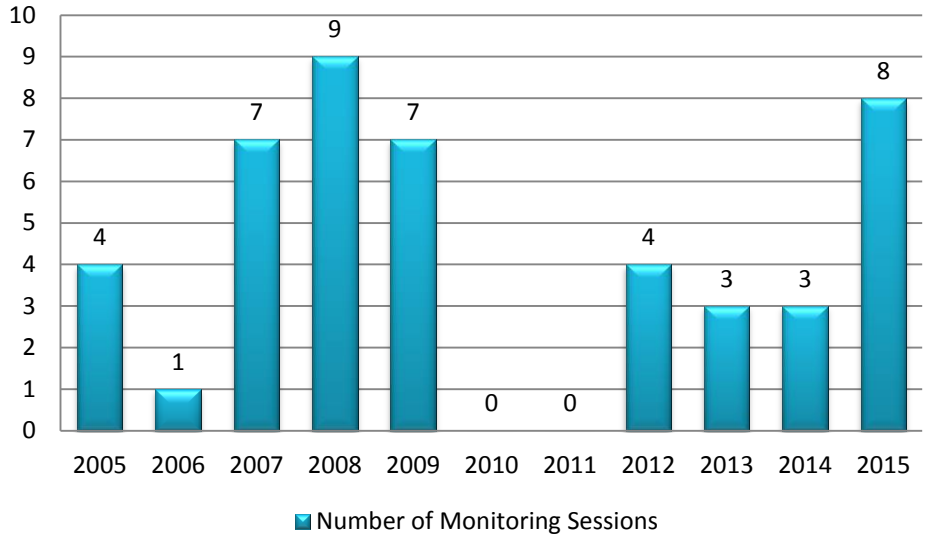



*Figure 34.* **Frequency of supervisory meetings organised by the Ministry of Health.**

In order to provide for project management of health sector investment projects funded from public sources and implementation supervision on 10 October 2011 the Ministry of Health set up a task group[86], while on 17 January 2014 an additional control work group was set for high and medium risk projects[87], which was charged with supervision and management of e-health projects financed by the ERDF.

Within the three years time members of the task group met 10 times, in average for three times per year, the main problems identified being the following:

- deadlines for implementation of the project (signing of the agreements) are being delayed as of 2012;
- starting from early 2012 use of the budget resources has been slow, even if the planned funding is brought forward to later months;
- weak communication with the National Health Service, no timely responses are provided to requests, low quality of filling in of the monthly project implementation report tables;
- already in 2013 problems identified concerned with development of an integrated environment – due to definition of classificators development of integrated test environment has been delayed;
- in early 2014 a risk was identified that in early 2015 the use of e-health system will not be launched, as the implementation deadlines have not been adhered to;
- anticipated number of persons to be trained for working in the e-health, is too low, e.g. it was planned to train for working in the e-prescriptions module only 40 health care specialist and pharmacists.

[86] Order of the Ministry of Health of 10.10.2011 No.207 „On setting up of the task group for Project management and suervision".
[87] Order of the Ministry of Health of 17.01.2014 No.17 „On setting up of the additional control work group for the high and medium risk degree projects".

Although various problems were identified during the work group meetings, no efficient solutions of the problems were sought, as these problems are still persistent.

In order to ensure efficient implementation of the e-health projects on 15 January 2015 the Ministry of Health set up the supervision committee of the implementation of the e-health projects[88], which had to ensure systematic information flow regarding the course of implementation of the project and get involved in resolution of problematic issues with the overall task being ensuring of start of pilot testing as of 1 September 2015. By the 26 March 2015 eight committee meetings have been held, in average once per week.

The supervision committee has started active cooperation with the e-health project owner National Health Service concerning operations of the e-health, whereby the following situations were analysed:

- it is possible that not all of the planned e-services in the project will be launched by the set deadline;
- the stage II of the project will not be completed by the set deadline and not all of the ERDF financing will be used, therefore all of the costs of stage II of the project will not be eligible.

Ministry of Health believes that actions taken by the Ministry for supervision and control of the e-health project are aimed at identification of operational shortcomings, analysis of risks and problematic issues, provision of recommendation of improvement of operational efficiency, elimination of deficiencies, decreasing of risks and progress of implementation of recommendations.

[88] Order of the Ministry of Health of 15.01.2015 No.2 „On setting up a supervision committee for the e-health projects".

# CONCLUSIONS AND RECOMMENDATIONS

## Conclusions

### *Drafting of the policy documents*

- Although the Ministry of Health has prepared the planning documents of the e-health development in a due time, when use of information and communication technologies in the health care sector widely expanded, the documents still are based on the analysis of the legislative acts, other policy documents and foreign experience, but no in-depth impact assessment has been done, studies and analyses of the current situation, no opinion of the health care professionals, pharmacists and information technology specialists has been established concerning development of the most efficient e-health solution, not prepared and assessed alternative solutions.
- Low quality of the planning documents of the e-health prepared by the Ministry of Health can be explained by the fact that no industry professionals were involved in development of the planning document, e.g. representatives of the health care professionals, pharmacists, pharmacies, information technology organisations, which is evidenced also by the survey results – low awareness of the project and initial actions to be taken, no thorough understanding of the benefits from the use of the e-health system, although the majority of inquired persons has positive attitude towards the introduction of the e-health system.
- Ministry of Health has not ensured updating of the Guidelines „E-health in Latvia" and the implementation plan notwithstanding the fact that outsourced experts had emphasised the need for it, the funding assigned does not comply with the plan, and also activities and priorities for implementation of the e-health had changed over the years, e.g.:
  - in 2008 the funding assigned was by 10 times lower than planned, and also the further financing was unclear;
  - in 2009 outsourced experts stated that objectives, political and operational results of the guidelines shall be updated, and also that collection and summarising of e-health data shall be started;
  - development of telemedicine has been stated in the guidelines as the main priority, while its implementation had not started by the 1 April 2015 and it is not clear when it will be started.
- The Ministry of Health has not prepared the Implementation Plan of the Guidelines for the period from 2011 to 2016, but still operates according to the implementation plan for the period 2008 – 2010 prepared in 2007.
- According to the view of the State Audit Office implementation of the project „E-health in Latvia" by the Ministry of Health will not lead to achievement of the objectives, policy and operating results set in the Guidelines because:
  - the objectives formulated in the Guidelines are incomplete, many of objective have no indicators or ratios to be achieved, meanwhile the prescribed indicators are contradictory and are not measurable, for instance a target - to improve health condition, upon performance of control of individual over his/her health condition;
  - policy result indicators will not lead to the desired effect as they cannot be assessed – only the trend of achievement and percentage rate has been set for the indicators without summarising the base data against which the trend will be compared;

- operational results indicators are incomplete and not updated, e.g. – by the 2009 eight new telemedicine centred were to be created, but by the 1 April 2015 none had been set up and it was not clear when and if ever any will be set up at all.

***Accessibility of e-health***

- There is a risk that upon implementation of the e-health information system it will not be accessible by all users as planned, since in the early 2015 not all of the health care professionals and pharmacies had the computer hardware and sufficient skills of using the special software, and also not all of the users will have access to their health data.

***Implementation of the project***

- Management of the e-health implementation is not sufficiently effective, and it is not primarily orientated to achievement of e-health objectives, because:
  - the existing management of projects is orientated to precise fulfilment of procedures of procurement and delivered product acceptance;
  - project integration management and the overall management of architecture is not implemented according to the good practice, e-health plan is not developed, upon unifying all the e-health project activities, measures for coordination of project activities are not ensured;
  - project managers have not sufficient education and experience in management of projects of similar complexity, moreover project managers have been changed for multiple times;
  - in the level of the program there is no program manager elected, the set e-health management organizational structures are implemented incompletely;
  - nevertheless according to the good practice it is recommended to introduce e-health solutions gradually, in Latvia there are simultaneously started three major e-health projects that the results of which are ensured with partial compatibility.
- The State Audit Office believes that the guidelines „E-health in Latvia" will not be introduced in Latvia in full, because the implementation period of the guidelines was by the end of the 2015 and by the late 2014 no e-health activities were even started for the implementation of which the funding amounting to 46% from the total financing of the e-health was assigned.
- National Health Service has not ensured a timely and compliant with technical specifications and good management practice accepttesting of all developed e-health solutions, since the delivered information systems are accepted even 11 months after the end of term of general agreement, not all the developed solutions accepttesting has been taken minutes of and the pilotoperation minutes that were presented instead of accepttesting minutes do not certify that the requirement of technical specification is observed and that the customer performs accepttest, thereby the delivered functionality of the solution cannot work according to the defined requirements.
- Since the developed e-health solutions are not semantically compatible and there are cooperation problems in the integrated testing environment, moreover the e-booking system does not fully encompass the specifics of health industry business processes, there is a high risk for initiation of valid system operation, qualitative use of developed e-services and ensurance of planned benefits.

- The developed e-services of e-prescription and electronic sickness leave acts do not comply with the requirements of the Regulations of the Cabinet of Ministers[89], thereby risk persists that upon using these solutions, healthcare processes will not be improved, thereby creating e-health information system users unsatisfaction and unwilling to use e-services, thereby not obtaining planned benefits.
- By the 1 April 2015 the National Health Service has not ensured users access to any of the 26 e-services notwithstanding the fact that introduction of the e-health policy was started in 2007, currently 9 762 697 *euro* have already been used for implementation of the e-health measures managed by the Service, and the Service is still improving the development of existing seven e-services and creation of five new e-services, thus attracting to the stage II of the project „Development of integrated e-health information system" funding of 4 720 981 *euro*.
- Since in disposal of the Ministry of Health there was available financing in order the solutions of the e-health project, stage I were possible to start to use (in production environment) in planned term, i.e., from year 2013, nevertheless the Ministry plans to start partially use the e-health information system by year 2016, thereby in three years time direct financial benefits have not been gained amounting to 3 millions of *euro* (under a provision that on January 1, 2016 stage I will be implemented entirely), that could have been diverted to provision of other healthcare services.
- Since the implementation plan of the Guidelines „E-health in Latvia" was developed in 2007 and has not been updated, the actual costs of implementation of the e-health activities differ from the planned ones – actual costs of some activities for implementation of the e-health are lower by 81% and even up to 127% higher than planned costs.
- Actual costs of activities managed by the National Health Service in the Guidelines „E-health in Latvia" will increase the planned costs by 154 364 *euro*, therefore there is a risk concerned with economy and productivity of funding used for implementation of the e-health.
- Due to an incomplete procurement documentations or non-quality e-health solution developed, as well as slow implementation of e-health, upon improving the initially developed e-health solutions there is a risk that financial resources amounting to at least 483 406 *euro* are spent unpurposefully, because:
  - in the procurement "Introduction of supplements of integration for development of unified health industry electronic information system" organized after acceptance of e-health solutions developed during the stage I, the ordered work assignments amounting to 124 206 *euro* partially or fully overlap with the work assignments of stage I or eliminate admitted errors in designing;
  - works ordered in stage II amounting to 59 200 *euro*, in order to identify and eliminate deficiencies in applicability in solution of stage I;
  - for suppliers of stage II there has been included a payment also for developed e-health solution guarantee in stage I, the estimate of double paid guarantee amounts to more than 300 000 *euro*, nevertheless it is also included for suppliers of stage I.

[89] Regulations No.175 of 08.03.2005 of the Cabinet of Ministers „Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions „ Regulations No.152 of 03.04.2001 of the Cabinet of Ministers „Procedures for issuance of Sickness Leave Acts"

- Risk persists that during the implementation of e-health have not been used the most beneficial and profitable information and communication technology solutions, thereby, possibly raising the price, because:
  - adaptation possibilities of standard solutions have not been evaluated and comparison with solutions that have to be newly developed has not been performed , thereby there is a risk that the accumulated experience has not been taken into account, the good practice and not employed other benefits of standard solutions;
  - there are not evaluated all possibilities of repeated use of Latvia state information and communication technology solutions;
  - due to the lack of technological unification of e-health for various e-health solutions various development technologies have been applied, thereby raising the price for their maintenance.
- Within the process of implementation of the e-health policy for the period starting from 2007 through to 2011 financial means of 196 292 *euro* have been used in vain or unpurposefully for paying for development of the concept and technical specifications for the activity which is no longer been pursued and by paying in 2010 for updating of the concept and technical specification developed in the 2007, for drawing up information system security documentation, nevertheless the documentation has not been validly used, as well as by paying for the activities which do not comply with the Guidelines „E-health in Latvia".
- Implementation of e-health has not been primarily directed to implementation of a deliberative, productive and targetful planned solutions, since in the course of implemenetation of e-health there have been different services or deliveries ordered in time, when they have not been necessary or received services are not being fully employed, for example:
  - funds amounting to 81 191 *euro* for the e-health information system training organized by the National Health Service in year 2014 have been used inefficiently, since the training was carried ot at time when the system did not operate even at test mode;
  - for a part of the purchased techniques the term of guarantee has expired, although the production environment has not yet been created;
  - ordered e-prescription information system performance assessment, although due to functional errors it was not possible to perform various anticipated tasks;
  - the amendments in documentation have not been performed according to the recommendations of quality controllers in cases where the corrections have not been easy to implement.
- Since the completion date of the project „Development of integrated e-health information system, stage II" is 28 Novmeber 2015 and by the end of 2014, i.e., more than in one and half a year since the initiation of project on April 29, 2013 actually there have been implemented e-health implementation measures, using only 3% from the planned total funding, there is a risk that the National Health Service will not be able to complete the planned project activities by the set deadline.
- Implementation process of the guidelines „E-health in Latvia" has been dragging to slowly, which will lead to objectives and received benefits for improvement of the health care quality set in the guidelines not being achieved to the full extent, as the Ministry of Health has on several occasions prolonged the deadline for implementation of the e-health system,

e.g., initially its completion was planned by the year 2010, then the implementation deadline was prolonged to 2012 and 2013, later already for 2014, when Ministry undertook that all of the realised information systems will be available at the production environment, until at the end the undertaking was issued that as of September 2015 in production environment the e-prescriptions information system will be available at the production environment, while concerning the other three realised information systems no particular deadlines are set for their launch.

- The National Health Service has not ensured implementation of the e-health information systems by the end of 2014 although the e-health solutions have been actually developed (by 2013), however they are not available to the users and there is a risk that by 1 January 2016 all planned services 31 e-service of the health care will not be available to the users.
- Risk persists that upon implementation of e-health projects co-financed by the European Regional Development Fund the requirements of European Community laws and regulations are not observed, since, although all the projects of stage I were concluded in December 2014, the final inspection of projects are suspended for multiple times, and taking into account that a successful implementation of project of stage II is closely tied with the results achieved in the stage I, there is a risk that the final inspections of projects it will be established that the aims of the projects are not achieved, thereby the funds amounting to 11 352 647 *euro* used in European Regional Development Fund may be recognized as inexpediently spent.
- Ministry of Health has not ensured preparation of the thorough action plan for involvement of the health care service providers in the e-health information system, e.g., the health care service providers not providing the state paid services, not issuing the sickness leave acts and not issuing prescriptions for medication have not been identified and contacted.
- Notwithstanding of the fast approach of the deadline for implementation of the Guidelines „E-health in Latvia" the Ministry of Health has not paid due attention to readiness and awareness of the health care service providers which is evidenced by the following data:
  - 17% of the health care professionals and 3% of pharmacists at their work place do not have access to the computer hardware, thus the users have no access to the e-health information systems;
  - self-assessment of 29%-41% of the health care professionals and pharmacists concerning their computer and internet skills are medium or low;
  - within the period of the implementation of the guidelines (9 years) only 15% of the planned training of the potential users of the e-health information system concerning use of information technologies have been conducted and 4% of those concerning use of the e-health information system;
  - only 11% of the health care professionals and pharmacists are duly informed on the implementation of the project „E-health in Latvia";
  - 12 institutions out of 13 surveyed health care professionals and pharmacies having signed agreements on testing of the e-health had not started testing yet by the February, 2015.
- The pilot project of four e-services introduced by the National Health Service in 2010 was not a success, duly announced and promoted, as, regardless of the fact that 76% of the population use internet on a daily basis, only 9% of the population had used these 4

services, while the e-services of the private health care institutions have been used by 20% of the population.

- National Health Service has not ensured due information and education of the public on implementation of e-health, including the planned health care e-services as only 47% from the 60% (the audit criteria) Latvian residents were informed on implementation of the e-health, and approximately 11% from 40% (the audit criteria) Latvian residents were informed on benefits of implementation of the e-health which indicates to low awareness level in relation to introduction of the e-health services and benefits brought by their use, which in turn increases the risk that the public will not be using the new e-health services.
- In e-health web site developed by the National Health Service more than 50% from applicability tests were not possible to perform, since the web site was available only in test environment with a limited functionality, meanwhile, upon verfification of the applicability in the limited amount, there were no material applicability problems identified, but various non-material or moderately material applicability deficiencies, for instance, non-complete assistant information, system does not support most popular internet web browsers, no activities were implemented that would ensure an easy access for information for people with functional disorders etc.). Prevention of mentioned deficiencies would improve usage of information system.

***Security of the data in the information system and protection of physical persons' data***

- Even if the e-health system according to the initial planned terms from the technical point of view would be ready for starting to use, nevertheless the National Health Service has not ensured management of e-health information system security, that does not testify about readiness of the e-health system for a safe starting to be used, thereby endangering initiation of lawful usage in planned deadlines in September and October 2015. In such way National Health Service as a curator of e-health system does not show a positive model to other healthcare institutions involved in the system operation, that the service is requiring to develop even highest quality security and IS management processes. That does not promote to public confidence both to the e-health system to be developed, and to all the healthcare system as a whole - inhabitants are not having a feeling that there is performed all the possible for the protection of medical information of patients. Thereby the planned benefits from implementation of e-health system are endangered or limited.
- National Health Service has not ensured all the necessary precodnitions in order to start a safe operation of the system and to demonstrate common comprehension of the service and attitude towards the patient sensitive data protection. Although the data security was initially defined within the e-health contact as having critical importance and the core processes and concepts of the cooperation partners were known already for years the National Health Service so far:
  - has not been able to draft and to implement all the required internal legal acts in the area of management of information systems, for instance, classification of the e-health information, risk management, business contingency testing and standardised users management, etc. Thereby the Service currently is found in the initial stage of management of the security of the e-health information system, however previously there have been even concluded agreements on the use of outsourced services on development of information security management document samples both, for the Service, and for the healthcare institutions.

- has not yet performed registration of physical entities personal data processement in the e-health system. Since the Service has not addressed the State Data Inspection on development of data in the e-health system, during the inspections of pre-registration and registration there could be discovered also previously unidentified insuffieciencies the elimination of which may require additional time, that due to nonagreed development and implementation of internal rules and regulations may hinder initiation of use in planned term;
- according to the internal procedures the National Health Service has not summarized and evaluated at the highest level the results of the external safety audits and the established deficiencies, providing to the management of the institution clear recommendations for prevention with a particular action plan, terms and responsible institutions. Moreover, by now all the safety audits have been performed in test environments and to the system that is not functioning completely.

- National Health Service has not enhanced a high personal data protection and confidentiality, ensuring controls of full and respective data protection controls, thereby enhancing the trust of society to the e-health system, since:
  - the e-health system does not ensure a respective management of access rights in order to reduce unsubstantiated processing of data and increase public trust to the system, but instead of it all the patient records by default are freely accessible to all the healthcare persons (knowing the patient's personal identity code), without assessing their daily true necessities and need to know such an extensive information that contradicts to the advices given by the European Supervising Institutions;
  - in case of printed documents patients mostly entrust their medical data to the physician and healthcare institution chosen by themselves that should also perform preventive undertaking for prevention of unauthorized physical person's data processing. In case of e-health this trust to some, most often self chosen physicians are passed to already a more extensive area of healthcare professionals and humans - actually to trust to all healthcare professionals and other healthcare personnel that has access rights to the e-health system. But prohibition of data processing in the e-health information system is possible now to the patients only in a very limited scope - either to entrust their medical record to all the healthcare professionals, or not to trust these to anyone who does not provide a midway provided for the laws and regulations, upon allowing the access to the person's health records for particular healthcare professionas or institutions.

- Being under to inbuilt controls in the automatic system, that could preventively identify and to restrict unreasoned personal data processing outside a particular treatment episode, it is very important that in the framework of the National Health Service it is supervised and identified such a possible unreasoned healthcare data processing at least after detection of such processing. In order to timely reduce the possible extent of damage and to punish the possible infringers for which the patients had not yet been reported about. Nevertheless there is still a risk that the Service is not yet able to systematically identify all the unreasoned physicial personal data processing cases, to supervise all the system users and the ensured management, as well as to respectively act, since:
  - currently the functionality of creation and reflection of the audit trail records in the e-health system is not fully operating (even if it has been developed already at the first stage of the projects and delivered in 2013), and also patients do not have free access to viewing all data processing information required in the legal acts regulating operations of the e-health system;

- there is not currently introduced any clear control tools of the e-health system, including the fact that the requirement for automated identification of unauthorised processing of physical persons data to be ensured in such audit trail records, no clear criteria is set for identification of unjustified data processing cases and thus also no lists of high risk data processing cases are being made for additional verification, no special software and human resources are planned for their analysis;
- records in the e-health information system will not be electronically signed and currently one physician is able to cancel information introduced by another physician;
- it is not clear how will the Service be able to sign high number of agreements with health care institutions on the use of e-health system in such a short time. The Service is not planning to perform and ensure the tests required prior to signing of the agreements with the health care institutions to verify implementation of the security requirements of the information systems of the health care institutions prior to beginning of use of the e-health system and accessing the medical record data of the patient, thus it depends only on the good will and sense of responsibility of the institutions themselves. Also it is not clear how these requirements will be controlled on the side of the Service after signing of the agreements during the effective use of the e-health system.

- The draft agreements that the National Health Service is planning to sign with the health care institutions on use of the e-health system (signing of such agreements is mandatory for all health care institutions) contain several unequal requirements, that do not enhance good example and ensurance of trust to healthcare institutions.
- Although the National Health Service as a manager and holder of the e-health system shall be responsible for the quality of data in the state information system and the acts of persons performing processing of personal data, the Service is planning to delegate several areas of liability to the health care institutions themselves, thus avoiding responsibility for certain critical issues, e.g., assigning of the users rights, control and revocation of such rights of the employees of the health care institutions, as well as on accuracy and justification of patient health records accrued in the e-health system.

***Supervision***

- Although within course of implementation of the e-health project the Ministry of Health has set up several supervision, control work groups, committees, councils, still the supervision of the implementation of the e-health by the Ministry of Health has not been sufficiently efficient, because, e.g.:
  - although the Guidelines „E-health in Latvia" and the implementation plan of the Guidelines for years 2008 – 2010 provide that as of 1 May 2008 the Ministry of Health shall at least once per two years provide the Cabinet of Ministers with an informative report on the course of implementation of the guidelines and the implementation plan (total of four reports) so far the Ministry has not prepared and submitted to the Cabinet of Ministers the two reports, which respectively had to be submitted by 1 May 2010 and 1 May 2013;
  - within course of implementation of the Guidelines for 2,5 years (from October, 2009 to May, 2012) the Ministry has not requested reports on the progress of implementation of the Guidelines;
  - not all of the issues included in the agenda of the supervisory council have been resolved – the implementation plan of the Guidelines has never been updated;

- introduction of the e-health is done too slowly, including several rescheduling of deadlines;
- use of the financing allocated has been insufficient – four months before its completion (not taking into account the extension of the project execution) the use of the financing for the project stage II has reached only 3% from the total financing.

## Recommendations

In order to eliminate the established crucial deficiencies and to successfully initate e-health information system usage, the Ministry of Health shall evaluate the possibility to introduce amendments in the Regulations of the Cabinet of Ministers[90], changing the deadlines for mandatory initation of usage of e-health information system to a later time period, anticipating time for prevention and elimination of all established deficiencies, including deficiencies in the data security and personal data protections, for conclusion of agreements with the healthcare service providers, as well as to define a reasonable time period - at least 6 months – as a voluntary accessing to e-health information system.

***Drafting of the policy documents***

- In order to ensure quality and topicality of the planning documents in the health care industry, as well as to set clear, realistic and achievable objectives and the results for the policy executors and the policy supervisors the Ministry of Health in preparation of new policies and updating of the current policies shallprepare guidelines in development of policy documents and define mechanism in supervision of policy implementation mechanism.
- In order to provide continuous and effective implementation of guidelines for monitoring processes, the Ministry of Health according to the laws and regulations of the Cabinet of Ministers[91] shall prepare an informative report on implementation plan of guidelines and to submit in the Cabinet of Ministers at defined terms.

***Accessibility of e-health***

- The Ministry of Health shall perform target oriented activities for creation of the preconditions for accessibility of the e-health information system by its potential users:
  - to assess justification of the legislative requirements set for the users of the e-health system to be able to connect to the system in 2017 only by use of their personal ID card (ID card) considering the actual information provided by the Authority for the Citizenship and Migration Issues on the number of ID cards issued;
  - to identify all health care service providers who will have to enter patient related data in the e-health information system and to establish readiness and ability to start working in the e-health system, e.g., presence of the computer hardware, internet access, users skills.

***Realisation of the project***

- In order to ensure further successful management of e-health projects that would be primarily orientated to the achievement of e-health objectives, the Ministry of Health shall perform the following activities, by ensuring:
  - a gradual, unified and mutually agreed e-health project and their activities development and implementation;
  - the personnel with a corresponding education and experience shall be involved in the e-health project management;

[90] Cabinet Regulations NO. 134 of 11.03.2014 „Regulations on Unifies Healthcare Industry Electronic Information System".

[91] Order No. 560 of August 17, 2005 „On guidelines „E-health in Latvia"" and order No.660 of October 24, 2007 of the Cabinet of Ministers „On implementation planof guidelines „E-health in Latvia" for years 2008-2010"".

- the organization structures of the e-health management shall be formed and operating according to their objectives of setting up.

- In order to ensure efficient and productive use of the financial resources assigned to the project thus by introducing the project end products the Ministry of Health shall ensure control over the course of the project so that the activities planned would be realised according to the implementation plans, planned financing and realistically set deadlines.
- In order to improve health care efficiency and quality of services by providing the health care service providers with a quality, precise and complete patients data, the Ministry of Health shall ensure efficient implementation of the e-health information system by ensuring:
  - implementation of the e-health information system to the set scope and deadlines;
  - accessibility and qualitative use of all of the planed e-services (31) to the users.
- In order the e-health information system could be qualitative and efficiently usable, the Ministry of Health shall ensure:
  - a timely accepttesting of developed solutions and documenting of accepttesting according to the set requirements;
  - testing of developed e-health solutions according to the set requirements, obtaining an objective solution operation assessment and providing a time for elimination of identified problems and solution for repeated testing;
  - a semantic adaptation of e-health information systems and actual common e-health solution data architecture development and maintenance;
  - e-booking solution development, upon performance of extensive business process and respective requirements analysis and implementation of solutions only after their improvement;
  - a repeated e-prescription and electronic sickness leave acts testing according to the Regulations of the Cabinet of Ministers[92] and implementation of all necessary changes in solutions or performance of amendments in the Regulations of the Cabinet of Ministers in order the use of solutions is agreed.
- In order to ensure the expenditure of financing of the European Regional Development Fund, taking into account the economy, efficiency and effictiveness principles, the National Health Service shall perform activities in order the targets set in the projects of the e-health stage I and stage II are achieved and the e-health information system is fully available to its users.
- In order to ensure in future the use of economically most efficient solutions, the Ministry of Health shall:
  - evaluate in the market available standard e-health alternative products, the benefits and deficiencies of their usage;
  - upon planning of e-health development, to assess the possibilities of usage of existing state information communication technologies solutions;

[92] Cabinet Regulations No. 175 of 08.03.2005 „Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions", Cabinet Regulations No.152 of 03.04.2001 „Procedure for Issuance of Sickness Leave Acts".

- upon performance of further development of solutions, as much as possible to unify the applied technologies.

- In order to provide e-health information system availability for data quality, accuracy and completeness e-health system should be used by all health care providers, furthermore the Ministry of Health shall ensure that all health care providers are active users in e-health system, with targeted actions:
  - identifying and analyzing the health care provider's opinion, to engage them in use of e-health system;
  - prepare an action plan on how to appeal all health service providers to engage in use of e-health system;
  - provide an opportunity for health care providers to attend trainings in information and communication technologies as well as in e-health.
- In order to improve the public health condition by facilitating individual control over the own health by providing access to own health care data and public promotion of healthy lifestyle, the Ministry of Health shall implement informative and educational campaigns for purposes of involving residents in active use of the health portal and the e-health information system.
- To let the e-health web site be easely usable, the National Health Service shall involve various groups of persons in the repeated applicability test, for instance, people with visual impairments, after these inspections perform respective changes in the information system, as well as to prevent the insufficiencies of usage and applicability detected during the audit.

***Security of the information system's data and protection of the physical person's data***

- In launching of the operations of the e-health information system in the internet environment and accessibility of e-services of all residents, the Ministry of Health shall ensure security of data stored in the existing information system and high level protection of the physical person's data, including protection of sensitive data according to legislative requirements, and thus the State Audit Office recommends assessing of option of rescheduling of the mandatory launch of use of the e-health information system for a later period past the 1 January 2016, because the National Health Service shall:
  - develop and introduce in the daily processes all of the required internal legal acts concerned with the safety management of the information system and the data protection area prior to the initiation of usage of e-health information system (in production environment);
  - perform a full system security audit, upon guaranteeing a safe e-health information system operation usage (production) environment and sensitive data protection prior to the initiation of usage of e-health information system (in production environment);
  - perform registration of the data processing to be performed in the system by the State Inspection of Data prior the initiation of usage of e-health information system (in production environment);
  - assess adequacy of requirements included in the proposed agreement to be signed with the health care institutions and to develop clear procedure for signing of the agreement by providing also the mechanism for testing of the fulfilment of the IS security requirements set for the health care institutions before the signing of the agreement, and after – within course of use of the system.

- National Health Service as the manager and holder of the e-health system shall:
  - develop clear and respective processes and tools for safeguarding accuracy and quality of data in the e-health system, as well as matching split of responsibilities;
  - assess option of reassessing the procedure for assigning of the users rights to work in e-health portal,, and as possible adjust rights of health care professionals according to their daily roles and actually required information.
- National Health Service shall ensure in the e-health system to be build the following features compliant with the legislative acts:
  - operation of the functionality of building and reflecting to patients of the audit trail bookings by developing also a full bodied auditing booking analysis process and clear criteria for the services to be able to systematically and independently identify the unjustified cases of data processing;
  - option for patients toprohibit access to their health care data , incl. also option of prohibiting part of the information concerning certain health care institutions and persons;
- rights only in special cases of one user to amend, correct and delete medical information entered by another user into e-health system.National Health Service shall assess the topicality of previously ordered and developed information system security documents sample, methodology and training materials, perform the necessary amendments, publish them at the home page of the National Health Service so that they would be freely accessible by all stakeholders, thus promoting its wider use and improvement of the understanding of the IS safety.

## OPINION OF THE MINISTRY OF HEALTH

***On the performed audit***

The task of the Ministry of Health and challenge at the same time is to modernize and to improve the healthcare system, by increasing its efficiency, making it more accessible and at the same time ensuring that all the changes are implemented by complying with the necessities of patients, as well as professionals working in the industry of healthcare. As we know, e-health is an important instrument in facilitating healthcare quality and patient safety. Thereby completion of the e-health system development and ensuring the compatibility of solutions in a unified healthcare system is one of the activities that the Ministry of Health continues to implement in situation where the state funding of the healthcare industry is insufficient, in order to improve the quality of healthcare, cost efficiency, management and supervision of the industry, that is also one of the recommendations of the European Commission for improvement of healthcare industry efficiency. Implementation of the healthcare information system affects a very expanded and complex area of activity that includes various information systems technical and data safety solutions, creation of legal framework, as well as comprehensive discussions with society, healthcare specialists, social partners and specialists from other industries. This process is not simple; thereby a detailed evaluation on system legal framework, administrative management, financial and operative results, as well as identifying the existing problems and risks is necessary. Taking into account the mentioned, the audit performed by the State Audit Office „Information Systems in Healthcare industry" was carried out for currently topical and important for healthcare industry issues and the Ministry of Health highly values the work contributed by the auditors of the State Audit Office in study and research of situation, drawing up conclusions and recommendations.

Conclusions and recommendations drawn by the State Audit Office form a material support to improvement of implementation of initiated e-health projects, as well as it is very important in further development of e-health system. Financing for years 2014-2020 of EU fund planning period is the sole available financing for development of e-health system. Thereby, by planning the necessary resources (investments) for further e-health system improvement and development, it is important that not only the previously admitted errors and deficiencies are acknowledged, but also the positive benefit from current experience. This is an important precondition in order to successfully move forward and to achieve the targeted e-health objectives. It is not easy to be done, taking into account that in healthcare industry there is always a topical issue about possibilities of financial resources, major data volume in healthcare system, as well as new trends and improvements in information and communication technology solutions.

At the same time the Ministry of Health invites to take into account that the State Audit Office performed an audit on system that is not ready for use, thereby a part of established deficiencies have already been eliminated or are being corrected. Nevertheless the established at the audit gave a possibility to correct individual steps in this process.

***On conclusions of this audit***

Nevertheless the e-health project is not yet completed and the e-health system is currently in the stage of development, the conclusions of the audit are unmistakably indicating to insufficient management and supervision of implementation of the project and the overall e-health policy. That is also certified by delayed implementation of e-health system, deficiencies in supervision and updating of e-health policy, including control of the planned and the used funding, involvement of e-health system users (inhabitants, and healthcare professionals), e-health information system safety management, as well as implementation of educative and informative measures in order to explain and popularize importance of e-health system.

At the same time it should be taken into account that the management of implementation of policy and supervision thereof was substantially influenced by economic crisis where overall capacity of project and e-health policy implementation was materially curtailed and carried out reorganizations in healthcare industry management, upon changing responsible management institutions of implementation of e-health. After the reorganization of the Ministry of Health in year 2009 the function of implementation of e-health was passed to the Centre of Health Economics, but as of the November 1, 2011 the institution responsible for implementation of e-health is the National Health Service.

***On audit recommendations***

In the opinion of the Ministry of Health the draft audit report disclosed the actual situation, outlaid recommendations are comprehensible, the implementations thereof are possible and it would enhance elimination of deficiencies.

***On implementation of audit recommendations***

It is important for the Ministry of Health to achieve that the e-health system both to the inhabitants and the providers of healthcare services and management institutions is easy to use and ensures to the patient possibilities to implement own rights and obligations as regards health. Upon evaluation of the current readiness of the e-health system to validly undertake operation, it is clear that the e-health shall be implemented gradually, defining that as of January 1, 2016 for all the healthcare institutions it will be mandatory electronic issuance of prescriptions and sickness leave acts, meanwhile other e-services shall be available for use. From October 1, 2015 in cooperation with the State Social Insurance Agency there will be implemented electronic sickness leave acts pilot-project whereof will be taking part healthcare institutions that would like to use electronic sickness leave acts functionality already prior to January 1, 2016.

National Health Service will complete prevention of deficiencies and errors that were established in testing of health information system where physicians, pharmacists, and patients took part, and immediately will undertake accept testing of all the developed e-health solutions, in order to ensure availability of developed e-services in production or work environment from the October 2015. Simultaneously the National Health Service until the October of this year will perform all e-health information system safety audit and will complete registration of personal data processing in the State Data Inspection.

Until the end of year 2015 the National Health Service shall be obliged under conducting an opinion poll to ascertain on readiness of users of e-health information system to start work and to use available e-health services, as well as to perform informative and educating undertakings for inhabitants and providers of healthcare services.

Ministry of Health in cooperation with the National Health Service shall work for the plan of development project „Development of e-health integrated information system" and ensuring implementation, as well as up to the middle of year 2016 the Ministry of Health shall develop a joint e-health implementation plan for a medium term.

For a successful supervision of implementation of e-health projects the work shall be continued by the steering committee of implementation of e-health created by the Ministry of Health that the main functions of which is upon regular requesting from the implementing institution of project - National Health Service - information (reports), to ensure a systematic circulation of information on the course of implementation of e-health projects, as well as in the competence of own skills to involve in solution of problematic issues related to e-health projects.

# DESCRIPTION OF THE AUDIT

## Objective of the audit

Objective of the audit is to verify efficiency and productivity of the actions by the institutions in charge for implementation of the e-health, as well as to audit economy and productivity of use of funds invested in the project for achievement of set objectives and gaining the planned benefits, including:

- is the policy implemented by the Ministry of Health in the area of the e-health updated and compliant with the directive of the European Parliament and the Council;
- do the activities of the National Health Service in fulfilment of the e-health policy ensure for successful and qualitative implementation by the set deadlines and achievement of objectives and results set in the guidelines;
- will the access to the e-health information system be ensured;
- have the financial means invested within course of implementation of the e-health been used in an efficient and productive manner;
- is the e-health information system set up by the National Health Service relevant (of high quality), covering the required scope and functionalities;
- is the high level information security and protection of personal data ensured in the e-health information system;
- has the Ministry of Health provided sufficient supervision over successful introduction of the e-health.

## Legal grounds

The performance audit „The Health Care Information Systems" has been conducted according to the work plan of the State Audit Office for the year 2014 and the audit assignment No.2.4.1-7/2014 of the Third Audit Department of 31 March 2014.

The audit was performed by the head of the audit group – Senior State Auditor Mareks Zvirgzdiņš, State Auditor Līga Kotāne and the Information Systems Auditor Mārtiņš Vilmanis.

## Liability of the auditors and the audited unit

Auditors of the State Audit Office are liable for provision of the audit opinion based on sufficient appropriate and reliable audit evidence.

The Ministry of Health and the National Health Service are in charge for adherence to the legal acts and accuracy of information provided to the auditors.

## Audit scope and limitations

The audit has been performed in accordance with international audit standards applicable in the Republic of Latvia. The audit has been performed as to obtain sufficient assurance on the measures taken by the audit entities included in the scope of the audit – the Ministry of Health and the National Health Service – for implementation of the health care policy, i.e. successful implementation of the Guidelines „E-health in Latvia".

The audit has been performed for the time period starting from the 1 January 2007 through to 1 April 2015.

Since the audited time period covered the day of transition from the Latvian national currency lats to the euro, all the numerical values used in the audit report have been converted into *euro* by applying the currency exchange rate of one *euro* being equal to 0.702804 lats.

The audit scope covers:

- the Ministry of Health as the leading authority of the health care sector developing the health care policy, organising and coordinating implementation of the health policy;
- the National Health Service which according to the health policy is implementing the e-health policy and is a holder of the e-health information system;
- the providers of the health care services which have to enter the patient related data in the e-health information system.

Audit limitations:

- the audit tests were performed without using sensitive data of the patients, therefore no achievement of resulting indicators of the implementation of the e-health was tested, because the majority of these are related to patients and the productively used time for obtaining of information, filling in of medical records and communication with health care professionals;
- the audit scope does not include and e-health activities were not inspected in the area of the management information systems of the emergency medical aid and catastrophe medical assistance, including the project of the European Regional Development Fund „Setting up of the Control Information System and Dispatcher's Centres of the Emergency Medical Assistance Service and Centre for Catastrophe Medical Aid (project ID No.3DP/3.2.5.2.0/09/IPIA/VSMTVA/001), that was implemented by the Emergency Medical Service, e-health activities for development of unified control information system of the health care sector, including the project of the Health Inspectorate „Development of unified control information system of the health care sector, stage I (project ID No.3DP/3.2.2.1.1/09/IPIA/IUMEPLS/006)" and in the area of development of a universal information system for supervising and monitoring of the infectious diseases there were undertakings which were involved various currently reorganized institutions, but systems maintenance is ensured by the National Health Service;
- the safety of the data of the information system in conjunction with the external factors was not assessed, e.g., unauthorised access of the third parties to the data of the system, safe data storage (protection of various levels), fragility of the software (protection against unauthorised software and malware), cryptography keys and methods;
- at the moment of carrying out the audit there was not possible an inspection of the solution in the production environment (including applicability tests, solution development scope tests, functionality and in-build control tests, etc.), thereby the inspections were carried out in integrated test environment. During the performance of audits we observed also that some functionality of solutions does not work. We received an approval that during the performance of tests in the test environments there were installed the delivered changes. This fact should be taken into account, upon analysing the conclusions of tests, that due to the changes of deliveries may not be repeatedly observable;
- along with the unstableness of the integrated system's test environment we could not fully verify all the planned inspections. The situation where it is not possible to perform all the planned tests in full, significantly increases the risk in the production environment there

could be discovered major applicability problems. It should be taken into account that the availability and the response times may differ in the production environment.

## Assessment criteria

| Audit issues | The criteria set | Criteria has been achieved/ criteria has not been achieved |
|---|---|---|
| **1. Will the e-health policy be able to solve problems and achieve the objective?** | | |
| **1.1. Has objective and high quality information been used in darfting of the policy documents?** | | |
| Development of the policy for use of information and communication technologies in the health care | Policy has been developed | Criterion has been achieved – the policy has been developed |
| Justification of the policy | Policy is prepared on a quality basis | Criterion has not been achieved – policy has not been prepared on basis of studies performed, surveys and situation analysis, no alternatives have been studied |
| **1.2. Have the policy documents been updated?** | | |
| Topicality and actual reflect of the current situation by the policy documents | Policy is updated, corresponds to the current situation | Criterion has not been achieved – the policy has not been updated |
| **1.3. Has the impact of policy documents been assessed?** | | |
| Policy impact assessment | Has been performed assessment of impact of policy | Criterion has not been achieved – no assessment of impact of policy has been performed |
| **1.4. Have the interests of all stakeholders been considered in implementation of the e-health system?** | | |
| Involvement of stakeholders in the development | Stakeholders have been involved and the interests have been safeguarded | Criterion has not been achieved – no industry professionals have been involved in drafting of planning documents |
| **1.5. Have the criteria been set for measuring of resulting indicators and achievement of objectives?** | | |
| Policy objectives and resultative indicators | Achievable objectives and measurable resulting indicators have been set | Criterion has not been achieved – the defined objectives are not detailed and measurable, the resulting indicators cannot be assessed, are incomplete and not updated |
| **1.6. Will the user's access be ensured to the e-health system?** | | |
| Accessibility of the e-health system | Has been provided accessibility to the potential users | Criterion has not been achieved – there is a risk that after introduction of the e-health information system it will not be accessible by all users |
| **2. Are the actual activities performed by the National Health Service justified for achievement of the set objectives?** | | |
| **1.1. Does the management of implementation of e-health enhance the achievement of e-health objectives?** | | |
| E-health management | Orientated to achievement of e-health objectives | Criteriaon has not been achieved – implementation of e-health is not oriented to achievement of e-health objectives |
| **2.2. Do the activities taken for development and implementation of the e-health comply with the plan** | | |
| Compliance of the activities taken for implementation of the e-health with the planned activities | Activities comply with the planned activities | Criterion has not been achieved – about 54% of the planned activities are being implemented according to the plans |

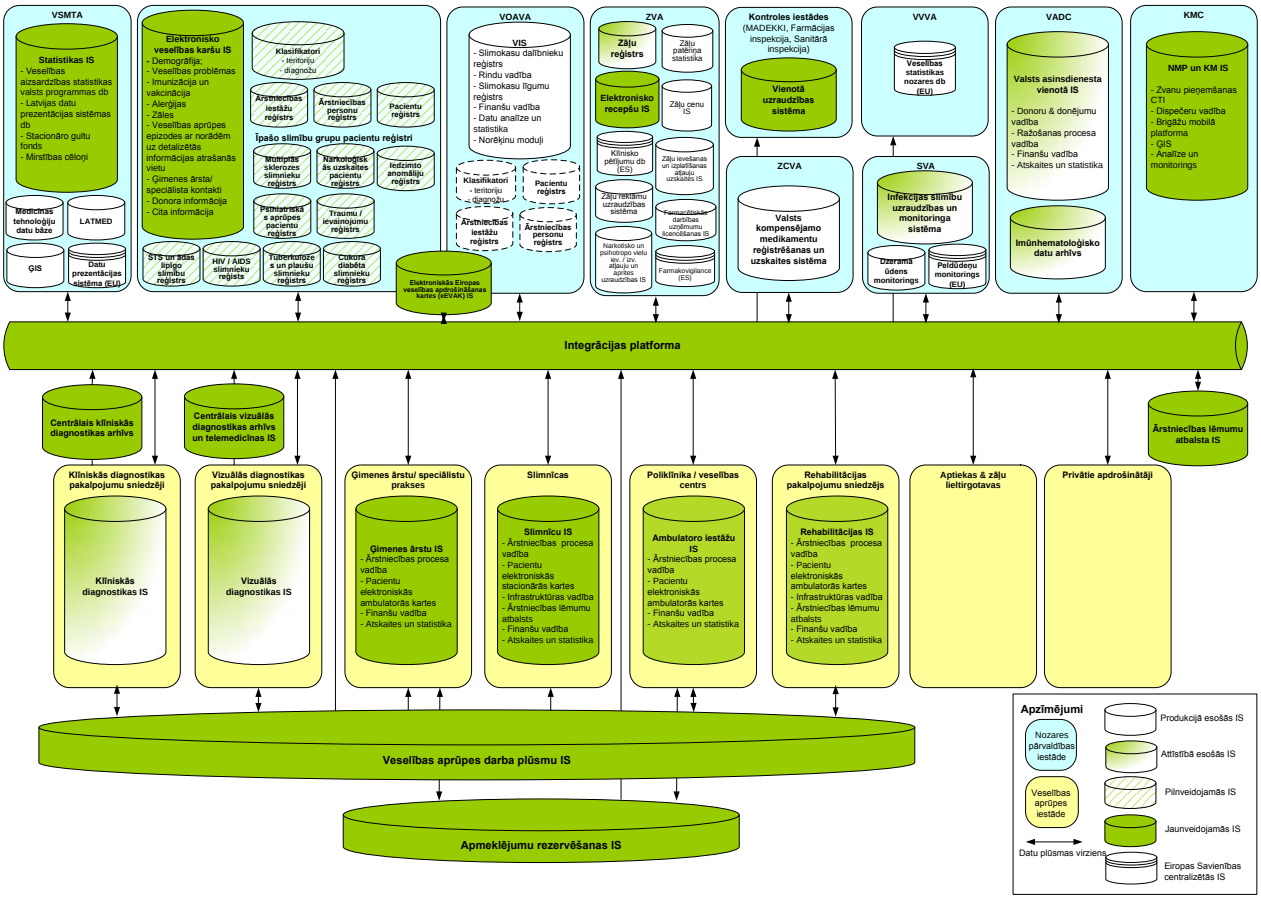
| Audit issues | The criteria set | Criteria has been achieved/ criteria has not been achieved |
|---|---|---|
| **2.3. Do the activities taken for development and implementation of the e-health comply with the financial budget?** | | |
| Acquisition of e-health implementation budget | Acquisition of the granted budget ~ 100% ( +/-5%)<br>Stage I 10 102 002 *euro*<br>Stage II 4 720 981 *euro* | Criterion has not been achieved , the acquisition of the fudning of Stage I- 97%<br>It is possible that the criterion will not be achieved- the acquisition of finances of stage II is insufficient, at the end of the project- solely 3%. |
| Financial estimated of e-health implementation | The costs of implementation of e-health activities fall under the planned financial estimates | Criterion has not been achieved – costs of implementation of the e-health activities deviate from the planned ones by - 81% to 127%<br>Criterion has not been achieved- the e-health implementation budget exceeds the defined budget for 154 364 *euro*. |
| **2.4. Is implementation of the e-health meeting the set deadlines?** | | |
| E-prescriptions implementation deadline | 07.12.2014. | Criterion has not been achieved – not implemented by the set deadline, planned to implement by 01.10.2015. |
| Electronic health card implementation deadline | 10.12.2014. | Criterion has not been achieved – not implemented by the set deadline |
| Implementation deadline for electronic booking, electronic organisation of the health care work flows and public health portal | 29.12.2014. | Criterion has not been achieved – not implemented by the set deadline |
| **2.5. Are the health care service providers ready to join the e-health system?** | | |
| Awareness and readiness of users of e-health system | Upon initiating mandatory usage of system, 100% of users shall be aware, trained and technically ensured. | Criterion has not been achieved:<br>▪ computer hardware is available only in workplaces of 83% of health care professionals and 97% of pharmacists<br>▪ computer and internet skills of 59%-71% of health care professionals and pharmacists are good and very good<br>▪ about 15% of the potential users have undergone general training of use of information technologies;<br>▪ 4% of potential users have received the training in e-health information systems<br>▪ only 11% from the health care specialists and pharmacists are informed on the implementation of the „E-health in Latvia" project;<br>▪ 12 from the 13 of the surveyed pharmacies and health care institutions having agreements on testing of the e-health, have not started testing it by the February, 2015 |
| **2.6. Is public informed and educated on implementation and benefits of the e-health?** | | |
| Awareness of Latvian population on implementation of the e-health in Latvia | 60% of Latvian population has been informed | Criterion has not been achieved – only 47% of Latvian population are informed on the introduction of the e-health |
| Awareness of Latvian population on benefits of implementation of the e-health | 40% of Latvian residents have been informed | Criterion has not been achieved– approximately 11% of the Latvian population have been informed on benefits of implementation of the e-health |
| **2.7. Is the e-health web site easy to use?** | | |
| Information system shall be used according to the intended usage | Shall be used without a particular training of users | Criterion is not achieved- during the inspections it has been observed many average or unsubstantional deficiencies of applicability, as well as could not perform all the applicability tests since the e-health system is not yet ready. |

| Audit issues | The criteria set | Criteria has been achieved/ criteria has not been achieved |
|---|---|---|
| **3. Will necessary information security and personal data protection be ensured in the newly built e-health information system?** | | |
| **3.1. Has the system been completed from the point of view of information system's security?** | | |
| Development of internal legal acts and actions in the area of management of the information systems and data protection | Internal laws and regulations have been drawn up, activities are regular and correspond to requirements of external laws and regulations | ◘ Criterion has not been achieved – not all of the required internal legal acts have been developed and not all of the actions are performed in the area of information systems safety management and data protection |
| Safety assessment of the e-health and elimination of the safety drawbacks | Activities are sufficient and in the defined scope | ◘ Criterion has not been achieved – activities for assessment and elimination of the safety deficiencies of the e-health are not sufficient |
| Outsourced consultancies | Ordered at the right moment, the results are applied | ◘ Criterion has not been achieved – the safety audits are ordered to partially operating functionality and not all the developed document samples are directly used further. |
| **3.2. Has the confidentiality of the information and respective protection of personal data been ensured?** | | |
| Access of the health care professionals and patients to data in the e-health system | Complies with legislative acts, is commensurate with the interests of the patients | ◘ Criterion has not been achieved – health data of the patients in the e-health system is freely available by default to the health care persons (having access to the personal code of the patient) and is contradictory to the advice provided by the European Consulting Institution |
| Controls for identification and prohibition of unjustified data processing (preventive) | Controls are created and operating | ◘ Criterion has not been achieved – in the system no preventive automated controls are provided for prohibition of authorised data processing and prohibition of disclosure of data to patients currently can be done only to limited extent |
| **3.3. Has supervision of safety of information data and personal data safety risks and activities been ensured?** | | |
| Controls for identification of authorised data processing identification and prohibition (after data processing) | Controls are created and operating | ◘ Criterion has not been achieved – no clear criteria has been set up for identification of unauthorised data processing, mainly by relying on the control performed by the patients themselves, and also the functionality of booking is not operating properly |
| **4. Has an efficient supervision and control of the project „E-health in Latvia" been set up?** | | |
| Informative reports on the policy implementation | Have been prepared according to the legal acts | ◘ Criterion has not been achieved – 2 out of the 4 informative reports required by the legal acts have been prepared |
| Supervision over the policy implementation | On-going | ◘ Criterion has not been achieved – supervision over policy implementation is not regular and effective, throughout the implementation time of the guidelines over 2.5 years no reports have been requested on the implementation progress of the guidelines |
| Compliance of the policy implementation with the set plan | Is going according to the set plan (activities, deadlines, financing) | ◘ Criterion has not been achieved – policy implementation is not going according to the set plan:<br>▪ Deadlines are prolonged<br>▪ Use of the financing is not sufficient<br>▪ Not all the activities have been undertaken |

*Conditional upon realisation of the project „Development of integrated e-health information system, stage II" to the full planned extent.

# ANNEXES

## Annex 1. Infrastructure of healthcare industry future information technologies



## Annex 2. E-health implementation S.W.O.T. analysis

| STRENGHTS | WEAKNESSES |
|---|---|
| ▪ **E-health is developing in the right direction,** giving patients a chance to ensure a bigger control over their health, supporting healthy lifestyle, improve decision-making validity and speed at the health care system, providing qualitative and available information. Patients will be faster and more qualitatively attended at the pharmacies, giving prescription medicine.<br>▪ **Currently, one developer develops the e-health Information System (stage II of the project).** Previously, many service suppliers performed the development works. One developer is responsible for implementation of changes in stage II of the project.<br>▪ **Currently, solution implementation planning has been actively carried out.** Every week, planning meetings have been organised, Ministry of Health and the National Health Service take part there, e-prescriptions and sickness leave acts implementation plans have been developed.<br>▪ **Financing for the development of stage I e-health information system developed is made available.** ERDF financing has been assigned to solutions of stage II of the project, additionally, a further solution development is being planned in the next period.<br>▪ **Information system applicability requirements have been defined and applicability assessment has been performed.** An e-health User Web Interface Standard, as well as assessment of e-health website public section compliance have been made; a repeated applicability testing has been planned.<br>▪ **Application Program Interface (API) is applied to the solutions.** This approach envisages a simpler integration of solutions in future, as well as potentially smaller maintenance costs.<br>▪ **A clearly defined future security management organisational structure and responsibility, several initiatives of improvements in IT security management have been started.** The regulating documentation of the existing internal information security management has been resumed, a new one is being created, and processes have been implemented and improved. | ▪ **During the documentation planning process, experts of the field were not involved, no in-depth influence assessment, health care studies and analysis had been carried out.**<br>▪ **The planning documentation does not comply with the actual situation,** all the events planned are not developed, the financing does not comply with the planned amount and schedule, e-health implementation priorities.<br>▪ **During the project planning, deficiencies have been made.** Within stage I of the e-health project, development of many complex and great solutions has been simultaneously implemented (EHR, integration platform, e-prescription, etc.) by various developers, as a result, logical integration problems of solutions exist.<br>▪ **E-health implementation administration is not efficient enough; it is not mainly oriented towards reaching e-health objectives.**<br>▪ **A timely and sufficient information flow is not provided between the stakeholders of the project, sufficient information and education has not been provided.**<br>▪ **A timely acceptance testing of all e-health solutions has not been provided in accordance with the technical specification requirements and good practice standards.**<br>▪ **None of the 26 e-health services were available to users by April 1st, 2015, although 9 762 697 EUR have already been spent.**<br>▪ **There is no chance to examine the system functionality in the production environment.** Even though the first deliveries have already been made in 2013, particular functionality does not work in the test environment, the data amount does not comply with the actual amount, besides, the tests environment of e-health website is still available only within the premises of the National Health Service; none of the developed e-services functions.<br>▪ **E-health Implementation Process is too slow, since its implementation deadlines have been extended several times.**<br>▪ **Several essential IT security management processes are still under development.** Although it is being planned to use the e-health Information System as of October 2015, several important processes related to information security and the regulating documentation are still under development.<br>▪ **The data processing registration, envisaged by the information system, has not been performed in the Data State Inspectorate.** Despite the huge amount of sensitive physical person data processing, envisaged by the system, there has been no communication with the Data State Inspectorate regarding data protection risks and data processing registration questions until now. |

| | |
|---|---|
| | ▪ **Not all prerequisites have been provided for a high-level patient data protection,** since patient data are simultaneously available to a wide range of users, there are limitations to data processing restriction, there are no clear criteria and methods for identification of unjustified data processing.<br>▪ **The amount of human resources involved in the envisaging of IT security management provision.**<br>▪ **There have not been developed clear and transparent plans for information security management improvement and prevention of identified deficiencies that would include all the manageable work, responsible persons, deadlines, and current status.** |
| **OPPORTUNITIES** | **THREATS** |
| ▪ **Prepare new or update the existing e-health policies** according to the actual situation and in-depth studies and analysis, involving experts of the field, defining clear desirable results, and perform a regular policy assessment.<br>▪ **To further provide a gradual,** united and mutually coordinated implementation of e-health solutions.<br>▪ **To improve control over implementation of e-health,** so that the events planned would be carried out according to the current plans of implementation, planned financing and reasonably set deadlines.<br>▪ **To further implement e-health solutions, based on qualitatively and fully prepared solution development documentation at the right time, amount and quality established.**<br>▪ **To pro-actively inform the society and other involved parties on the course of solution implementation.** During the communication with the society, inform it about the course of solution implementation and show the functionality that has already been implemented. Listen comments, inform about possibilities and plans of the representatives of the society on preventing the identified solution deficiencies.<br>▪ **To promote a bigger involvement of users in the solution testing.** To organise the testing of system functionality and applicability, involving all user groups of the website, including people with functional impairment.<br>▪ **To create an e-health documentation registry.** The registry would summarise and systemise all available documents, so that they would be easy to look through and manage them according to changes in the system.<br>▪ **To create a conceptual general view of the e-health system (for the external developers).** The conceptual view of the system would include a report of the external IS developers, so that they would be | ▪ **The policy in e-health field prepared by the Ministry of Health, will not be implemented within the initial amount and** time, due to which the objective – to improve the efficiency of health service rendering – is to be partially achieved.<br>▪ **The practical application of solutions may not be commenced in accordance with what has been prescribed by the normative regulation.** The time period between the available production environment and, in fact, a national transition to a production environment in January 1st, 2016, is too short. Due to a different configuration of production and test environment, problems may be identified, which could not be found in the test environment. The time necessary for testing in the production environment and prevention of the identified problems must be envisaged.<br>▪ **Adverse publicity, ignorance and insufficient knowledge of using a computer can make users be unwilling to use the system.**<br>▪ **E-health system may not be available to all planned users,** since not each and every one of patients, treatment facilities and pharmacies have a computer technique and skills to use special programmes, not each and every one of the residents have eID cards with an active electronic signature, user interface only partially provides the needs of people with functional impairment.<br>▪ **Insufficient user support.** The system does not provide a description of the respective actions at every workplace, a detailed information on how to act in case of problems. According to the information given by the NHS, the user support service has only one staff place, creating threats for official activity implementation even at the basic level, given that several hundred thousands of users have been planned for the solution.<br>▪ **Insufficient performance threats.** Given the huge data amount, solutions may have performance problems, as the amount of users increases (the biggest risk – e-registration system).<br>▪ **Third party IS holders delay the integration process.** New problems may appear when the external IS are integrated with the e-health system, which will be hard to prevent in |

| | |
|---|---|
| clear and easy to work with the integration of the system.<br>▪ **Creation of a change notification mechanism.** Define the procedure of how the cooperation with the external IS developers is going on, as well as how the developers are notified about the changes in the e-health system in order to follow and update the mutual system integration.<br>▪ **Development of iterative system additions.** Define that the additions to the system must support the interface work of the previous system.<br>▪ **Within the e-health implementation related deadlines, to develop and implement all information security management processes, as well as perform the respective actions for data processing registration.**<br>▪ **Create clear and regularly functional mechanisms to prohibit and identify unreasonable data processing.** | short-time period.<br>▪ **The planned activities of stage II of the e-health project may not be implemented, since 3% of the jointly planned financing have been spent within more than a year and a half.**<br>▪ **The unavailability of financing to the support maintenance after the end of ERDF period, as well as the risk of the practically spent productivity and economy of financing of the e-health system implementation.**<br>▪ **During the data processing registration and at the pre-registration tests may discover currently unidentified risks of physical entity data protection that may need an additional time for prevention, where the use of system may not be possible.** All the internal information security regulatory enactments that are partially necessary to register physical entity data processing, are planned to be developed only by September 2015, however, the use of the system is planned as of October. |

## Annex 3.Tests and results of the e-health information system applicability

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| **General applicability requirements** | | | |
| **1.** | Make sure that the principles of website availability are prepared and chosen, based on the WCAG (*Web Content Accessibility Guidelines*) recommendations, are in compliance with the e-health User Web interface Standard and regulatory documentation requirements, therefore providing information availability for people with vision impairment, using special tools. | A possibility of using the website for people with functional impairments was considered.<br>See the subclauses. | See the subclauses. |
| **1.1.** | In accordance with the Regulations of the Cabinet of Ministers No.171 „Procedures, by which Institutions Place Information on the Internet", a section „Easy to read" must be created on the website. The regulations apply to direct management institutions and derived public persons. | Section „Easy to read" was not implemented on the website. | Deficiencies were discovered. |
| **1.2.** | We checked whether the system supports information availability to people with vision impairment, providing a possibility to magnify the text, according to WCAG recommendations. | We made sure that the e-health solution has an implemented possibility of magnifying/demagnifying a text. | Deficiencies were not discovered. |
| **1.3.** | We checked whether the system supports information availability to people with vision impairment, providing a possibility to use specialised software ("*assistive technology*" that gives a chance to magnify the text, read the written text, use the Braille method, etc.), according to WCAG recommendations.<br>The tests have been carried out, using *„Jaws"* and *„Zoom Text"* without any adjustment of the software before the tests. | See the subclauses. | See the subclauses. |
| **1.3.1.** | Use the reading tool *"Jaws".* | Using the reading tool *„Jaws",* it was possible to magnify and read the texts, however, deficiencies were found.<br>Using the *„Jaws"* listening button, the programme reads the „code under the button", together with the text, and links – it is not possible to understand the text. | Deficiencies were discovered. |
| **1.3.2.** | Use the reading tool *„Zoom Text".* | Using the reading tool *„Zoom Text",* it was possible to magnify and read the texts, however, deficiencies were found.<br>Using the *„Zoom text",* listening button, the programme reads the „code under the button", | Deficiencies were discovered. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | | together with the text, and links – it is not possible to understand the text. | |
| **2.** | Website design | The website design is visually perceivable and intuitively understandable. See the subclauses. | See the subclauses. |
| **2.1.** | Assessment of information placement | Information is easy to find, however, deficiencies were found.<br>If a patient, a doctor or any other user has been logged on the website, the right upper corner of the screen shows a text with the user information (username and the institution). The format of the text does not imply that this is a link to the user's website profile start page. | Deficiencies were discovered. |
| **2.2.** | Assess if it is easy and convenient to orientate in the e-health WEB User Platform, if it the most frequently used links are easy to see. | E-health WEB User Platform is intuitively understandable, the user can find the necessary information fast and conveniently, however, deficiencies with the hyperlinks and buttons were found.<br>The blue button „Log Out" shows a white triangle with a circle that has a misleading influence over the user. Checking the meaning of the white arrow, the user logs out of his profile. | Deficiencies were discovered. |
| **2.3.** | Make sure whether a common format has been used to screen elements (fonts, buttons, hyperlinks, colour palette, message windows ).<br>The whole website must ensure usage of a common format screen elements. | We made sure that a common format has been used to the screen elements. See the subclauses. | See the subclauses. |
| **2.3.1.** | Screen form | See the subclauses. | See the subclauses. |
| **2.3.1.1.** | Use of terminology<br>A terminology that is understandable to the user must be used in the user screens.<br>After the name of the field it is clearly understandable what must be entered. | Several deficiencies were found in the use of terminology in various screen forms.<br>The prescription list „The given treatment medication " uses a term „medicine", but the „Giving treatment medication" uses a term „Name of the medicine".<br>Fields where a patient's personal identity number must be entered, different names have been used. The website uses terms „Patient's ID Value", „Patient", „Personal Identity Number", and „ID Value".<br>Various names have been used for buttons, which function is filter cleaning, for example, at the workplace, the button „Patient" is named „Clean the filters" and „Remove filters". | Deficiencies were discovered. |
| **2.3.1.2.** | Searching the information<br>Make sure whether the implemented possibilities of information search allow to find the necessary information according to the defined criteria. Statements are issued, if there is a necessity to specify the search criteria. | The parametres and forms, according to which the search can be made, are clear, however, it was identified that, in some cases, the necessary information has not been selected.<br>For example, at the workplace „Patient", while searching for prescriptions and services. | Deficiencies were discovered. |
| **2.3.1.3.** | Assess the complexity of reports. | The placement of report fields is clear. | Deficiencies were |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | | | not discovered. |
| **2.3.1.4.** | Assess the user interface elements. For example, to clean the filter, return, choose a date from the calendar, etc. | The System is intuitively understandable, so that the user can find the necessary data fast and easy, however, a deficiency with the filter cleaning was discovered.<br>Performing the action „clean the filter", the filters „Date from" and „to" are not cleaned. | Deficiencies were discovered. |
| **2.3.1.5.** | Notification block<br>The notification block is placed at the left upper corner of the user interface, therefore providing transparency of reflecting important information. | The notifications are easy to understand and informative.<br>Notifications are reflected at the right upper corner. | Deficiencies were not discovered. |
| **2.3.1.6.** | Filtering block<br>The filtering block is placed at the right upper corner of the user interface, therefore ensuring fast availability. The filtering block allows to show and/or hide the columns in the list, as well as filter the respective list according to specific parametres. The filtering block can be shown and/or hidden in order to give more information to the list of the block containing the most important information. | The website cannot show and/or hide the filtering block to the user. | A deficiency was discovered. |
| **2.3.1.7.** | The modal screen block<br>At the beginning, the modal screen block is not seen, it appears at the moment when the user clicks on a specific entry link in the list of the block (e-prescription identifier). | Has been implemented. | Deficiencies were not discovered. |
| **2.3.2.** | Receiving notification warnings on events<br>The patient can choose a warning notification which the patient wants to receive, their types, and define the supply channels:<br>• website;<br>• e-mail on the given address. | Notification receiving is automatic; the notification text is clearly understandable.<br>Performing a check at the patient's workplace, an error message shows, when opening the message channels. | Deficiencies were discovered. |
| **2.3.3.** | Reports | See the subclauses. | See the subclauses. |
| **2.3.3.1.** | Showing/hiding columns<br>In e-service reports, a patient must have an option to show or hide particular columns of report. | The system is intuitively understandable, so that the user can look through the necessary data in a fast and convenient manner, however, deficiencies were found.<br>It is not possible to show or hide particular columns of the report. | Deficiencies were discovered. |
| **2.3.3.2.** | Report classification<br>In e-service reports, a patient must have an option to classify the report according to one column of the report. | It is not possible for the patient to classify the report according to one column of the report. | A deficiency was discovered. |
| **2.3.3.3.** | Filter setting | No problems had been observed during the filter | A deficiency was |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | In e-service reports, a patient must have an option to set and remove filters (select entries that contain a specific value). | choice. Deficiencies in the e-prescription filter lists at the workplace „Patient" were identified. It is not indicated that a choice between the filtering parametres „Include my prescriptions" and „Include the authorisers'' prescriptions" would be obligatory. | discovered. |
| **2.3.3.4.** | The e-service must ensure that the patient's choice remains within the session. | Within the framework of the session, the patient's actions performed were saved in the reports. | Deficiencies were not discovered. |
| **2.3.3.5.** | Coding of the report entries<br>The invalid prescriptions, which are expired or all medicine has been handed, must be depicted with a different colour in the service reports. | During the test, it was not observed that the colour coding of the entries would be implemented in the prescription report list. | A deficiency was discovered. |
| **2.3.3.6.** | The list of the block is placed under the notification and filtering blocks and it takes the major part of the user interface. | Has been implemented. | Deficiencies were not discovered. |
| **3.** | Interface language | The language change buttons are placed at a clearly seen place. See the subclauses. | See the subclauses. |
| **3.1.** | Make sure that the website's interface is in Latvian language. | The interface is made in Latvian language. | Deficiencies were not discovered. |
| **3.2.** | Information about the website is available in Russian language. | Information about the website is not available in Russian language. | Deficiencies were discovered. |
| **3.3.** | Information about the website is available in English language. | Description of the website is available only in English language. | Deficiencies were not discovered. |
| **4.** | Use of browsing programmes | The configuration of the website allows to use the most popular browsing programmes, however, deficiencies were found. See the subclauses. | See the subclauses. |
| **4.1.** | We checked whether the interface provides the support of popular browsers. | While checking, we used the most popular operating systems and browsers:<br>• operating system: *Windows 7.*<br>• browsers: *IE, Firefox, Google Chrome.*<br><br>No problems were identified, using the *Firefox* un *Google Chrome* browsers.<br>Using *IE*, a deficiency was identified – it is not possible to log in as a resident or a health care expert. With *IE* it is only possible to log in only on the start page. | Deficiencies were discovered. |
| **4.2.** | It is allowed to use the following WEB technologies in the browsers (on the behalf of the client): *HTML, CSS, JavaScript, HTML5* extensions. | During the check, there were no problems with the use of WEB technologies (*HTML, CSS, JavaScript, HTML5* extensions). | Deficiencies were not discovered. |
| **5.** | Performance tests are carried out to the Doctor's workplace screen forms (the system answering time). | 07.05.2015 – according to the page's time response analysis (we checked how fast the elements were uploaded: *Scripts, Style, Images, Media, Fonts, Documents,* etc.), no deficiencies were found. The average time response - – 200- | Deficiencies were discovered. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | | 500 ms<br>08.05.2015 – from 15:00 to 17:00 a great breakdown of the website was discovered. Time response was approximately 3-7 seconds. Sometimes, *Internal Server Error – 500* occurred. | |
| **Assessment according to the user role - doctor** | | | |
| **1.** | Make sure that the user, to whom the system is new, can perform the assigned tasks. | See the subclauses. | See the subclauses. |
| **1.1.** | Write the first referral within 10 minutes. | It was possible to create a referral within less than 4 minutes. It shows a notification that the data have been successfully saved. Has been implemented. | Deficiencies were not discovered. |
| **1.2.** | Write a sik-leave certificate within 10 minutes. | It was possible to create certificate „A" and certificate „B" in less than 6 minutes, however, we cannot perform a search for sickness leave acts. | After selecting sickness leave acts < search a sickness leave act>, it is not possible to find the data. The error is returned. |
| **1.3.** | To reserve a person the service specified in the referral within 5 minutes. | It was possible to reserve the service in less than 6 minutes.<br>Has been implemented. | Deficiencies were not discovered. |
| **1.4.** | Find the referral and attach the result within 10 minutes. | It was possible to find the referral within 10 minutes, however, deficiencies were found: the search buttons for referrals and results do not function, an error is returned. | Deficiencies were discovered. |
| **1.5.** | Find and see the referral result within 5 minutes. | It was possible to find the referral in less than 4 minutes, however, a deficiency was found.<br>The referral cannot be viewed at „My written referrals", an error is returned. | Deficiencies were discovered. |
| **1.6.** | Find „New notes". | It is easy to find the section "New Notes". While trying to choose a service from the list „Search for service", it was not possible to find the data. An error is returned. | Deficiencies were discovered. |
| **1.7.** | Write a prescription. | It is not possible to write prescriptions, since it is not possible to open the section for prescriptions. | Deficiencies were discovered. |
| **1.8.** | Find and check „Planned Vaccinations". | It is easy to find the section „Planned Vaccinations", however, deficiencies were found:<br>• it is not possible to enter the „Planned Vaccinations" block, an error is shown.<br>• The function of selecting the patients for vaccination does not work. | Deficiencies were discovered. |
| **1.9.** | Add new data about the vaccination. | It is not possible to add new data in the whole vaccination section (vaccination facts, facts on complications, tests on immunity checks, infection diseases that the patient has had, additional information, tuberculin tests, waivers from vaccination, immunoglobulin tests, immunodeficient disease, immunisation card, | Deficiencies were discovered. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | | prophylactic vaccination card). | |
| **1.10.** | Preparing a report | It is easy to find and understand the section of preparing a report. | It was not possible to select data in the section „Report on immunisation and vaccination orders" (per month) – an error is shown. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | It is not possible to enter the doctor's data in the Doctor's section.<br>It was not possible to select „Diagnosis" and „Laboratory Procedures" in the data blocks. | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality.<br>Choosing<?> as a vaccination page, an error is shown.<br>Opening <?> "E-Consultation", an error notification appears. | Deficiencies were discovered. |
| **Assessment according to user roles – doctor's assistant** | | | |
| **1.** | Make sure that the user, to whom the system is new, can perform the assigned tasks. | See the subclauses. | See the subclauses. |
| **1.1.** | Create a new appointment. | It was not possible to create a new appointment, since it was not possible to choose a service, treatment facility, and the doctor in the section „Appointments -> New Appointments". | Deficiencies were discovered. |
| **1.2.** | Write a sickness leave act. | It was not possible to write a sickness leave act, since it was not possible to find the receiver of the sickness leave act, while registering acts „A" and „B". | Deficiencies were discovered. |
| **1.3.** | Register a claim for remuneration. | It is easy to find the section „Register a claim for remuneration", and it is intuitively understandable, however, deficiencies were found.<br>It was not possible to find data in the section Payment for services -> Service payment units, Register a claim for remuneration and Search for a claim for remuneration. | Deficiencies were discovered. |
| **1.4.** | Register a referral. | It was not possible to register a referral, since the system does not search teh Patient by a personal identity number in the section „Referral -> New Referral and New Result. | Deficiencies were discovered. |
| **1.5.** | Vaccination planning | The section „Vaccination Planning" is easy and intuitively understandable, however, deficiencies | Deficiencies were discovered. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | | were found:<br>• It is not possible to select data in the section Vaccination Planning -> Patients to be Vaccinated. An error is returned.<br>• It is not possible to select data in the section Vaccination planning -> Planned Vaccinations. An error is returned. | |
| **1.6.** | Preparing a report | The report preparing section is easy to understand, it has logical entry fields, however, deficiencies were found:<br>• The data are not selected in the section Vaccination Reports -> Prophylactic Vaccination History Journal Report and Immunisation and Vaccination Order Report (per month). | Deficiencies were discovered. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | The website indicates particular actions for the user to perform, however, deficiencies were found. | Using the system as a doctor's assistant, it is not possible to save the contact information in the section „Profile Information".<br>It is not possible to open sections „Applications", „Profile Information". The system is very slow, an error occurs. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality.<br>Choosing<?> as a vaccination page, an error is shown.<br>Opening <?> "E-Consultation", an error notification appears. | Deficiencies were discovered. |
| **Assessment according to user roles – general practitioner** | | | |
| **1.** | Make sure that the user, to whom the system is new, can perform the assigned tasks. | See the subclauses. | See the subclauses. |
| **1.1.** | Write the first referral. | It was not possible to write the first referral, since the system does not search the patient by its personal identity number in the section Referral -> New Referral and New Result. | Deficiencies were discovered. |
| **1.2.** | Write a sickness leave act. | It was not possible to write a sickness leave act.<br>It was not possible to write a sickness leave act, since it was not possible to find the receiver of the sickness leave act, while registering certificates „A" and „B". | Deficiencies were discovered. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| **1.3.** | Perform vaccination planning. | It is not possible to perform the vaccination planning.<br>It is not possible to select the data in the section Vaccination Planning -> Planned Vaccinations.<br>It is not possible to select data in the section Vaccination Planning -> Patients to be Vaccinated. | Deficiencies were discovered. |
| **1.4.** | Register a claim for remuneration. | It is not possible to register a claim for remuneration.<br>It was not possible to select data in sections Payment for services -> Service payment units, Register a claim for remuneration and Search for a claim for remuneration. | Deficiencies were discovered. |
| **1.5.** | Preparing a report | It is not possible to prepare a report.<br>It is not possible to select data in the section Vaccination Reports -> Profilactic Vaccination History Journal Report and Immunisation and Vaccination Order Report (per month). | Deficiencies were discovered. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | • It is not possible to save the contact information in the section "Profile Information";<br>• It is not possible to open the section "E-Consultation", an error occurs immediately;<br>• It is not possible to open the section „Mailbox", an error occurs immediately;<br>• After activating the receiving of a patient, it is not possible to enter the section „Prescription". | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality.<br>Choosing<?> as a vaccination page, an error is shown.<br>Opening <?> "E-Consultation", an error notification appears. | Deficiencies were discovered. |
| **Assessment according to user roles – treatment facility** | | | |
| **1.** | Make sure that the users can consequently perform the assigned tasks and do not deal with unplanned complexities during the execution of actions. | See the subclauses. | See the subclauses. |
| **1.1.** | Preparing a report | It is not possible to select data in the section Vaccination Reports -> Prophylactic Vaccination History Journal Report and Immunisation and Vaccination Order Report (per month), an error occurs. | It is not possible to check all reports. |
| **1.2.** | Register and find a claim for remuneration. | The data are not selected after entering the search parametres in the sections Payment for services -> Service payment units, Register a claim for remuneration and Search for a claim for remuneration. | It is not possible to perform the check. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | Opening the section „Mailbox", an error message occurs.<br>It is not possible to open „Applications" in the section „Profile Information". The system works slowly, and an error message occurs. | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality. | A deficiency was discovered. |
| **Assessment according to user roles – pharmacist** | | | |
| **1.** | Make sure that the users can consequently perform the assigned tasks and do not deal with unplanned complexities during the execution of actions. | See the subclauses. | See the subclauses. |
| **1.1.** | See the list of prescriptions | Opening the prescription list, it was not observed that expired prescriptions would be coloured. | A deficiency was discovered. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | Opening „Prescription", the names of the columns of the tables in the section „A List of the treatment medication given at the pharmacist's shop" differ from the section „A List of the treatment medication to be given at the pharmacist's shop". | A deficiency was discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality. | A deficiency was discovered. |
| **Assessment according to the user roles – investigator** | | | |
| **1.** | Make sure that the users can consequently perform the assigned tasks and do not deal with unplanned complexities during the execution of actions. | Opening the „Referrals and Results", a screen form „Create a Patient's Referral" is available to the investigator. An improper functionality has been offered to the role. | Deficiencies were discovered. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | Opening the „Referrals and Results", a screen form „Create a Patient's Referral" is available to the investigator. An improper functionality has been offered to the role. | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality. | Deficiencies were discovered. |
| **Assessment according to user roles – registration person** | | | |
| **1.** | Make sure that the users can consequently perform the assigned tasks and do not deal with unplanned | See the subclauses. | See the subclauses. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| | complexities during the execution of actions. | | |
| **1.1.** | Reserve a health care service to a person within 5 minutes. | It was possible to find the health care service section in less than 3 minutes, however, deficiencies were found.<br>The registering person cannot finish to create a new appointment, since the information corresponding to the defined selecting criteria is not found after choosing the name of the institution. | It is not possible to perform the check. |
| **1.2.** | Vaccination Planning | It was not possible to plan the vaccination.<br>No rights to plan the vaccination. After entering the information required in the Planned Vaccination List, an error occurs that there are no rights to perform such action. | It is not possible to perform the check. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | Performing a check, we observed that the patient-specific functionality is implemented. We identified particular deficiencies that may cause uncertainties to the user.<br>In case of creating notes and searching, the following problems were observed:<br>• Entering different names of doctors in the field "Choose a doctor from the list", no data have been selected;<br>• It has not been specified if the doctor should be searched by the name or surname, or a personal identity number;<br>• Searching for an appointment list, it has not been explained whether a patient's personal identity number or name, or surname should be entered in the field "Patient".<br>Saving new working hours, an error occurs.<br><br>A user has settings and notification channels. Information has been entered in the notification supply channel "E-Mail Address". Attaching an e-mail, an error occurs that "There are no rights to create a new user". | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality. | Deficiencies were discovered. |
| **Assessment according to user roles – patient** | | | |
| **1.** | Make sure that the users can consequently perform the assigned tasks and do not deal with unplanned complexities during the execution of actions. | See the subclauses. | See the subclauses. |
| **1.1.** | Reserve a health care service. | It is possible to open a screen form. After entering the information. It was not possible to perform a reservation of health care services. | It is not possible to perform the check. |

| No. | Performed test | Test result | Comments |
|---|---|---|---|
| **1.2.** | Find and print the sickness leave act within 5 minutes. | No deficiencies were found. | Deficiencies were not discovered. |
| **1.3.** | See the prescriptions. | It is not possible to see the data in the Prescription List.<br>Perhaps, the patient does not have registered prescriptions. During the checks, it was not possible to register a prescription (see "A Doctor Writes a Prescription 1.7."). | It is not possible to perform the check. |
| **1.4.** | Preparing a report | The functionality of preparing a report is convenient. It is possible to choose a report to prepare, indicate the parameters and acquire data. It is not possible to show or hide specific columns of the report. | A deficiency was discovered. |
| **2.** | Assess the user-specific functionality, whether the specific actions for the user to carry out are clearly defined (entering the data, in case of errors, etc.), as well as clearly understandable indications on how to stop or finish the action that has been started. | Performing a check, we observed that the patient-specific functionality is implemented. We identified particular deficiencies that may cause uncertainties to the user.<br>• A sickness leave act printout is opened at the existing browser in PDF format. Closing the PDF sickness leave act printout, the website also closes, and the user must repeatedly log on to the system;<br>• Opening "My Referrals and Results", a button "Create a Referral" is available to the patient. An improper functionality has been offered to the role;<br>• Performing the check for remuneration possibilities, the performed function "Clean the filters" does not clean the parameters entered in the fields. | Deficiencies were discovered. |
| **3.** | Assisting information/user documentation – the necessary information/contacts can be found (for an applicability document). | An equal assistant for all workplaces. Choosing the assistant's hyperlink in the header, an assisting screen opens, containing a description of all e-health solution workplace functionality.<br>Choosing<?> as a vaccination page, an error is shown.<br>Opening <?> "E-Consultation", an error notification appears. | Deficiencies were discovered. |

*Source of Information: SIA „PricewaterhouseCoopers" 22.05.2015. Report „Efficiency Assessment of e-health Information System Development".*

## Annex 4. Implementation deadlines of the Ministry of Health audit recommendations and reporting time schedule.

| No | The State Audit Office recommendations | Recommendation deadline set by the Ministry of Health | A deadline when the Ministry of Health reports in writing about the implementation of recommendations |
|---|---|---|---|
| 1. | In order to eliminate the established crucial deficiencies and to successfully initate e-health information system usage, the Ministry of Health shall evaluate the possibility to introduce amendments in the Regulations of the Cabinet of Ministers[93], changing the deadlines for mandatory initation of usage of e-health information system to a later time period, anticipating time for prevention and elimination of all established deficiencies, including deficiencies in the data security and personal data protections, for conclusion of agreements with the healthcare service providers, as well as to define a reasonable time period - at least 6 months – as a voluntary accessing to e-health information system. | 31.10.2015. | 01.02.2016. |
| 2. | In order to ensure quality and topicality of the planning documents in the health care industry, as well as to set clear, realistic and achievable objectives and the results for the policy executors and the policy supervisors the Ministry of Health in preparation of new policies and updating of the current policies shall prepare guidelines in development of policy documents and define mechanism in supervision of policy implementation mechanism. | 31.12.2015. | 01.02.2016. |
| 3. | In order to provide continuous and effective implementation of guidelines for monitoring processes, the Ministry of Health according to the laws and regulations of the Cabinet of Ministers[94] shall prepare an informative report on implementation plan of guidelines and to submit in the Cabinet of Ministers at defined terms. | 01.05.2016. | 01.08.2016. |
| 4. | The Ministry of Health shall perform target oriented activities for creation of the preconditions for accessibility of the e-health information system by its potential users: | | |
| | 4.1. to assess justification of the legislative requirements set for the users of the e-health system to be able to connect to the system in 2017 only by use of their personal ID card (ID card) considering the actual information provided by the Authority for the Citizenship and Migration Issues on the number of ID cards issued; | 01.06.2016. | 01.08.2016. |
| | 4.2. to identify all health care service providers who will have to enter patient related data in the e-health information system and to establish readiness and ability to start working in the e- | 31.12.2015. | 01.02.2016. |

[93] Cabinet Regulations NO. 134 of 11.03.2014 „Regulations on Unifies Healthcare Industry Electronic Information System".

[94] Order No. 560 of August 17, 2005 „On guidelines „E-health in Latvia"" and order No.660 of October 24, 2007 of the Cabinet of Ministers „On implementation planof guidelines „E-health in Latvia" for years 2008-2010"".

| No | The State Audit Office recommendations | Recommendation deadline set by the Ministry of Health | A deadline when the Ministry of Health reports in writing about the implementation of recommendations |
|---|---|---|---|
| | health system, e.g., presence of the computer hardware, internet access, users skills. | | |
| 5. | In order to ensure further successful management of e-health projects that would be primarily orientated to the achievement of e-health objectives, the Ministry of Health shall perform the following activities, by ensuring: | | |
| | 5.1. a gradual, unified and mutually agreed e-health project and their activities development and implementation; | 31.10.2015. | 01.02.2016. |
| | 5.2. the personnel with a corresponding education and experience shall be involved in the e-health project management; | 01.06.2016. | 01.08.2016. |
| | 5.3. the organization structures of the e-health management shall be formed and operating according to their objectives of setting up. | 01.06.2016. | 01.08.2016. |
| 6. | In order to ensure efficient and productive use of the financial resources assigned to the project thus by introducing the project end products the Ministry of Health shall ensure control over the course of the project so that the activities planned would be realised according to the implementation plans, planned financing and realistically set deadlines. | 31.10.2015.[95]<br>01.06.2016.[96] | 01.08.2016. |
| 7. | In order to improve health care efficiency and quality of services by providing the health care service providers with a quality, precise and complete patients data, the Ministry of Health shall ensure efficient implementation of the e-health information system by ensuring: | 31.10.2015. | 01.02.2016. |
| | 7.1. implementation of the e-health information system to the set scope and deadlines; | | |
| | 7.2. accessibility and qualitative use of all of the planed e-services (31) to the users. | | |
| 8. | In order the e-health information system could be qualitative and efficiently usable, the Ministry of Health shall ensure: | | |
| | 8.1. a timely accepttesting of developed solutions and documenting of accepttesting according to the set requirements; | 31.10.2015. | 01.02.2016. |
| | 8.2. testing of developed e-health solutions according to the set requirements, obtaining an objective solution operation assessment and providing a time for elimination of identified problems and solution for repeated testing; | 31.10.2015. | 01.02.2016. |
| | 8.3. a semantic adaptation of e-health information | 01.07.2017. | 01.08.2017. |

[95] Tiks sagatavots īstermiņa darbības plāns.
[96] Tiks sagatavots vidēja termiņa ieviešanas plāns.

| No | The State Audit Office recommendations | Recommendation deadline set by the Ministry of Health | A deadline when the Ministry of Health reports in writing about the implementation of recommendations |
|---|---|---|---|
| | systems and actual common e-health solution data architecture development and maintenance; | | |
| | 8.4. e-booking solution development, upon performance of extensive business process and respective requirements analysis and implementation of solutions only after their improvement; | 01.01.2017. | 01.08.2017. |
| | 8.5. a repeated e-prescription and electronic sickness leave act testing according to the Regulations of the Cabinet of Ministers97 and implementation of all necessary changes in solutions or performance of amendments in the Regulations of the Cabinet of Ministers in order the use of solutions is agreed. | 31.10.2015. | 01.02.2016. |
| 9. | In order to ensure the expenditure of financing of the European Regional Development Fund, taking into account the exonomy, efficiency and effictiveness principles, the National Health Service shall perform activities in order the targets set in the projects of the e-health stage I and stage II are achieved and the e-health information system is fully available to its users. | 01.03.2016. | 01.08.2017. |
| 10. | In order to ensure in future the use of economically most efficient solutions, the Ministry of Health shall: | 01.06.2016. | 01.08.2017. |
| | 10.1. evaluate in the market available standard e-health alternative products, the benefits and deficiencies of their usage; | | |
| | 10.2. upon planning of e-health development, to assess the possibilities of usage of existing state information communication technologies solutions; | | |
| | 10.3. upon performance of further development of solutions, as much as possible to unify the applied technologies. | | |
| 11. | In order to provide e-health information system availability for data quality, accuracy and completeness e-health system should be used by all health care providers, furthermore the Ministry of Health shall ensure that all health care providers are active users in e-health system, with targeted actions: | | |
| | 11.1. identifying and analyzing the health care provider's opinion, to engage them in use of e-health system; | 31.10.2015. | 01.02.2016. |
| | 11.2. prepare an action plan on how to appeal all health service providers to engage in use of e-health system; | 01.06.2016. | 01.08.2016. |
| | 11.3. provide an opportunity for health care providers to attend trainings in information and communication technologies as well as in e- | 01.06.2016. | 01.08.2016. |

[97] Cabinet Regulations No. 175 of 08.03.2005 „Regulations for Manufacture and Storage of Prescription Forms, as well as Writing out and Storage Prescriptions", Cabinet Regulations No.152 of 03.04.2001 „Procedure for Issuance of Sickness Leave Acts".

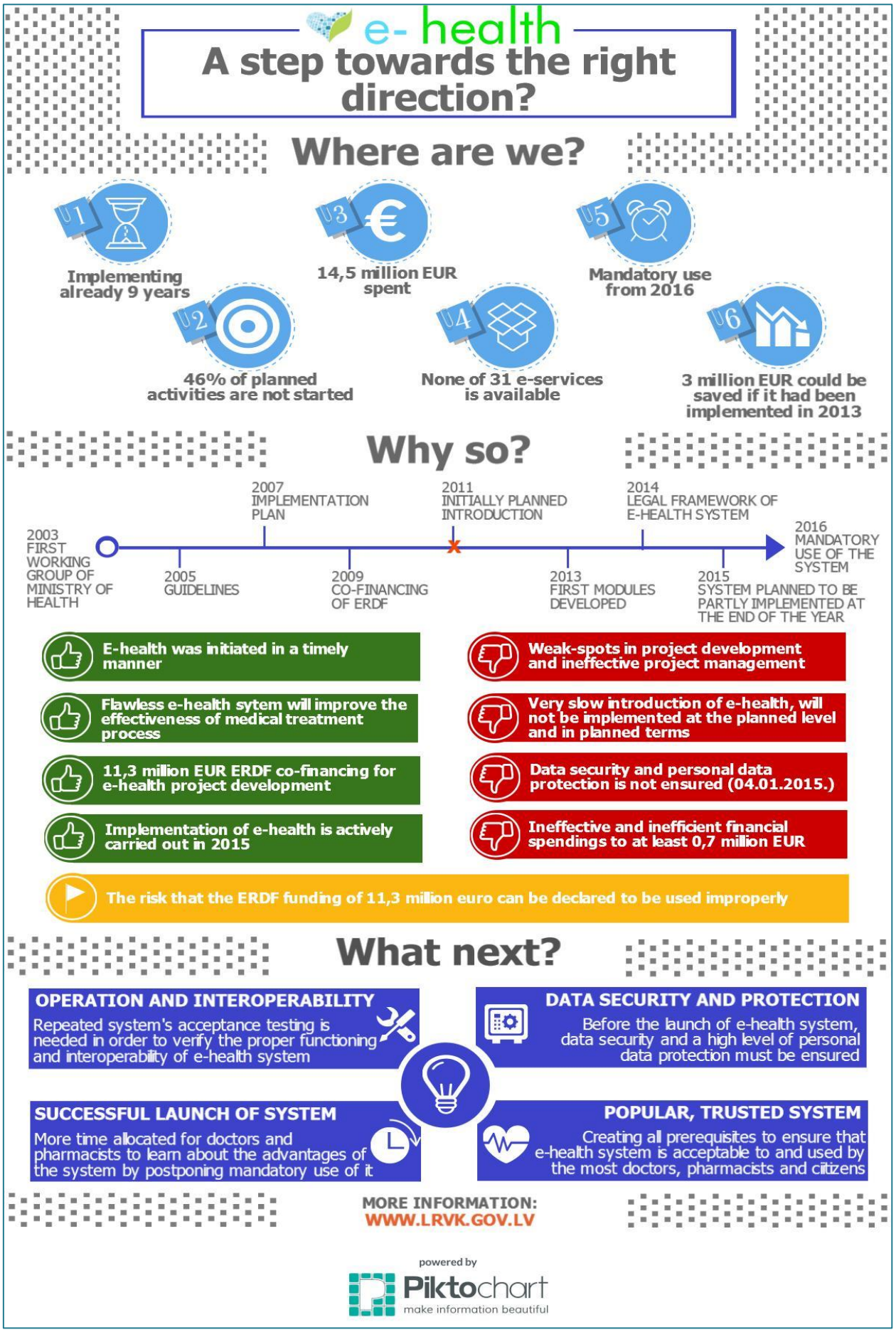
| No | The State Audit Office recommendations | Recommendation deadline set by the Ministry of Health | A deadline when the Ministry of Health reports in writing about the implementation of recommendations |
|---|---|---|---|
| | health. | | |
| 12. | In order to improve the public health condition by facilitating individual control over the own health by providing access to own health care data and public promotion of healthy lifestyle, the Ministry of Health shall implement informative and educational campaigns for purposes of involving residents in active use of the health portal and the e-health information system. | 31.10.2015.[98]<br>01.06.2016.[99] | 01.08.2016. |
| 13. | To let the e-health web site be easely usable, the National Health Service shall involve various groups of persons in the repeated applicability test, for instance, people with visual impairments, after these inspections perform respective changes in the information system, as well as to prevent the insufficiencies of usage and applicability detected during the audit. | 01.01.2016.[100]<br>01.07.2017.[101] | 01.08.2017. |
| 14. | In launching of the operations of the e-health information system in the internet environment and accessibility of e-services of all residents, the Ministry of Health shall ensure security of data stored in the existing information system and high level protection of the physical person's data, including protection of sensitive data according to legislative requirements, and thus the State Audit Office recommends assessing of option of rescheduling of the mandatory launch of use of the e-health information system for a later period past the 1 January 2016, because the National Health Service shall: | 01.10.2015. | 01.02.2016. |
| | 14.1. develop and introduce in the daily processes all of the required internal legal acts concerned with the safety management of the information system and the data protection area prior to the initiation of usage of e-health information system (in production environment); | | |
| | 14.2. perform a full system security audit, upon guaranteeing a safe e-health information system operation usage (production) environment and sensitive data protection prior to the initiation of usage of e-health information system (in production environment); | | |
| | 14.3. perform registration of the data processing to be performed in the system by the State Inspection of Data prior to the initiation of usage of e-health information system (in production environment); | | |
| | 14.4. reassess adequacy of requirements included in the proposed agreement to be signed with the health care institutions and to develop clear | | |

[98] Tiks sagatavots īstermiņa darbības plāns.
[99] ES fondu 2014.-2020.gadam plānošanas perioda veselības veicināšanas un slimību profilakses pasākumu plāns.
[100] Iepriekšējo lietojamības pārbaužu konstatēto nepilnību novēršana.
[101] Veiks atkārtotus lietojamības testus.

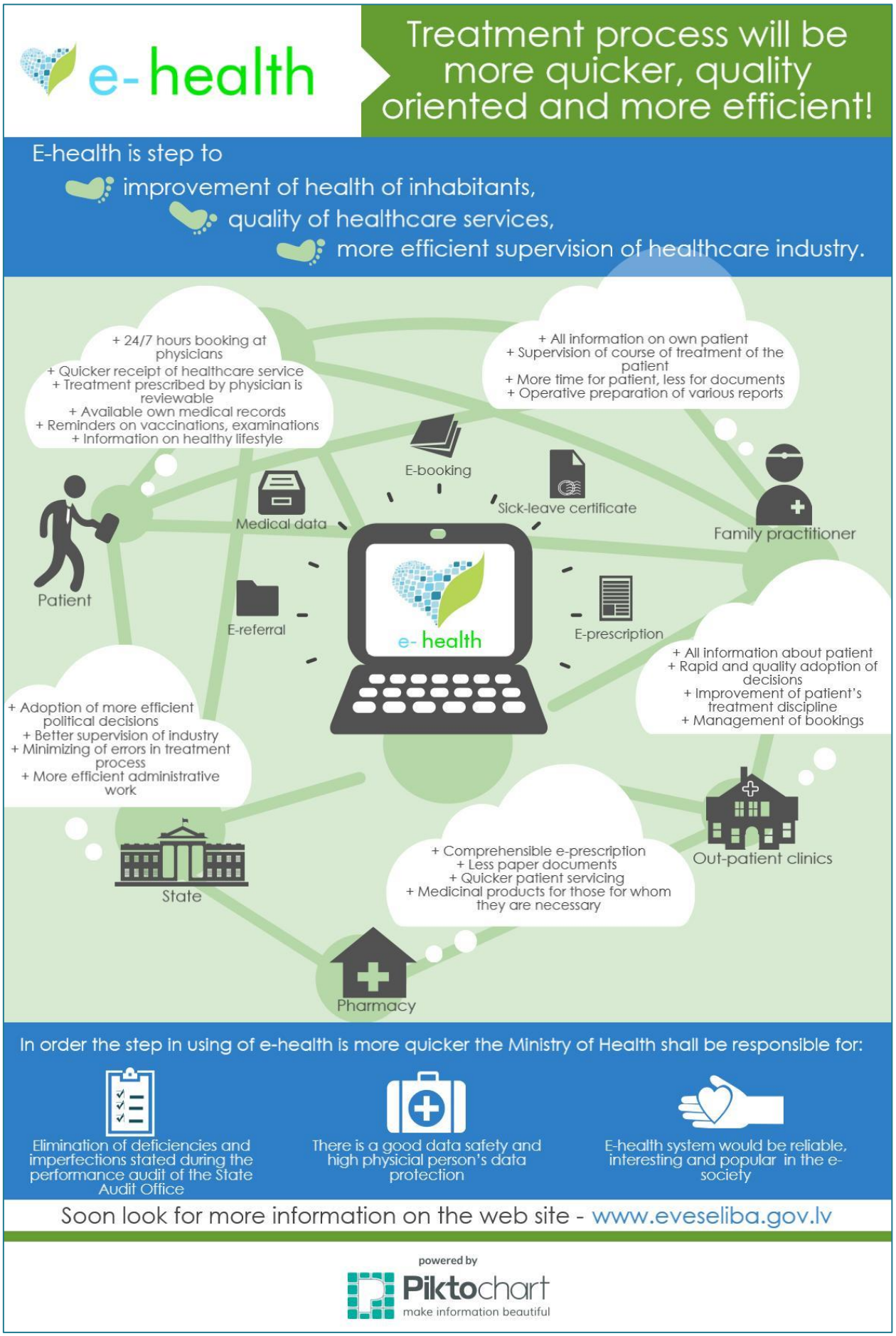
| No | The State Audit Office recommendations | Recommendation deadline set by the Ministry of Health | A deadline when the Ministry of Health reports in writing about the implementation of recommendations |
|---|---|---|---|
| | procedure for signing of the agreement by providing also the mechanism for testing of the fulfilment of the IS security requirements set for the health care institutions before the signing of the agreement, and after – within course of use of the system. | | |
| 15. | The National Health Service as the manager and holder of the e-health system shall: | 01.07.2016. | 01.08.2016. |
| | 15.1. develop clear and respective processes and tools for safeguarding accuracy and quality of data in the e-health system, as well as matching split of responsibilities; | | |
| | 15.2. assess option of reassessing the procedure for assigning of the users rights to work in e-health portal and as possible adjust rights of health care professionals according to their daily roles and actually required information. | | |
| 16. | National Health Service shall ensure in the e-health system to be build the following features compliant with the legislative acts: | | |
| | 16.1. operation of the functionality of building and reflecting to patients of the audit trail bookings by developing also a full bodied auditing booking analysis process and clear criteria for the services to be able to systematically and independently identify the unjustified cases of data processing; | 31.12.2015.[102]<br>01.07.2016.[103] | 01.08.2016. |
| | 16.2. option for patients to prohibit access to their health care data, incl. also option of prohibiting part of the information concerning certain health care institutions and persons; | 31.10.2015. | 01.02.2016. |
| | 16.3. rights only in special cases of one user to amend, correct and delete medical information entered by another user into e-health system. | 31.10.2015. | 01.02.2016. |
| 17. | National Health Service shall assess the topicality of the previously ordered and developed information system security documents sample, methodology and training materials, perform the necessary amendments and publish them at the home page of the National Health Service so that they would be freely accessible by all stakeholders, thus promoting its wider use and improvement of the understanding of the IS safety. | 01.12.2015. | 01.02.2016. |

[102] Tiks nodrošināta auditācijas pierakstu veidošana un attēlošana pacientiem.
[103] Tiks izstrādāts auditācijas pierakstu analīzes process un kritēriji.

## Annex 5. Infographic about audit



## Annex 6. Infographic about e-health

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