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## AUDIT REPORT

# EFFICIENCY AND EFFECTIVENESS IN IMPLEMENTATION OF UNIFIED AND INTEGRATED HEALTH INFORMATION SYSTEM

*Performance audit*

Prishtina, December 2017

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The Auditor General has decided related to this report "Efficiency and Effectiveness in Implementation of Unified and Integrated Health Information System" in consultation with the Assistant Auditor General, Vlora Mehmeti who supervised the audit.

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<sup>1</sup> Economy -Principle of economy means minimising the cost of resources. The resources used must be available in a timely manner, in the right quantity and quality and at the best price possible

<sup>2</sup> Efficiency - The principle of efficiency means getting the most out of the available resources. It has to do with the link between the resources involved and the outcome given in terms of quantity, quality and time.

<sup>3</sup> Effectiveness - The principle of effectiveness implies achievement of predetermined objectives and achievement of expected results.

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## List of abbreviations

<b>CRA</b>	Civil Registration Agency
<b>AIS</b>	Agency for Information Society
<b>NAPDP</b>	National Agency for Personal Data Protection
<b>KNDC</b>	Kosovo National Data Centre
<b>DHIS</b>	Department of Health Information System
<b>KAS</b>	Kosovo Agency of Statistics
<b>EURSOTAT</b>	Statistical Office of the European Union
<b>NIPHK</b>	National Institute of Public Health of Kosovo
<b>HI</b>	Health Institutions
<b>SHC</b>	Secondary Health Care
<b>NCHIS</b>	National Council for Health Information System
<b>HPC</b>	Professional Health Cards
<b>PHC</b>	Primary Health Care
<b>THC</b>	Tertiary Health Care
<b>MPA</b>	Ministry of Public Administration
<b>MoF</b>	Ministry of Finance
<b>MIA</b>	Ministry of Internal Affairs
<b>MoH</b>	Ministry of Health
<b>OECD</b>	Organization for Economic Cooperation and Development
<b>WHO</b>	World Health Organization
<b>EO</b>	Economic Operator
<b>AP</b>	Action Plan
<b>MFMC</b>	Main Family Medicine Centre
<b>UCCK</b>	University Clinical Centre of Kosovo
<b>FMC</b>	Family Medicine Centre
<b>CR</b>	Civil Registry
<b>PSMS</b>	Pharmaceutical Stock Management System
<b>HIS</b>	Health Information System
<b>RHPE</b>	Regional Hospital Peja
<b>RHPZ</b>	Regional Hospital Prizren
<b>SHISK</b>	Strategy for Health Information System in Kosovo
<b>KHUCS</b>	Kosovo Hospital and University Clinical Service
<b>AI</b>	Administrative Instruction
<b>NAO</b>	National Audit Office

## Executive Summary

The Ministry of Health as the institution that is legally responsible to ensure that all citizens and residents of the Republic of Kosovo have the right to access equally healthcare services, should implement a proper system for planning, coordination and management and provision of healthcare services.

In order to improve the health services to Kosovo citizens, the Ministry of Health in 2011 has started implementation of the Health Information System. Implementation of the system is foreseen to be implemented in three stages (A, B and C). The first two stages include piloting and implementation of the system that covers 30% of Country's territory and assessment of piloting at the end of 2014. While the third stage consists of system implementation across the Country foreseen to be implemented by 2020.

However, many electronic media, research reports and auditor reports of previous years have highlighted that the Kosovo Health Information System is being implemented with difficulties. Given the importance of health services for Kosovo citizens, the National Audit Office has carried out the performance audit "Efficiency and Effectiveness in Implementation of Unified and Integrated Health System".

The objective of this audit is to assess whether the Ministry of Health and responsible parties involved in this project have managed to coordinate necessary activities, starting from planning, provision of legal and physical infrastructure, of financial and human resources, establishment of monitoring and reporting mechanisms that are prerequisites that ensure efficient and effective implementation of Health Information System.

Since many health information systems operate within the Ministry of Health, the system that we have audited is the Health Information System, which in this audit report is referred to as the Health Information System (HIS).

The subject of the audit was the Ministry of Health and five Health Institutions that are in the pilot project stage: tertiary healthcare University Clinical Centre of Kosovo - Paediatric Clinic, secondary healthcare - Regional Hospital Prizren, primary healthcare - Family Medicine and two Family Medicine Centres in Prishtina. Furthermore, in order to evaluate coordination of activities with external parties we have included in our audit: Ministry of Internal Affairs - Civil Registry Agency, the Ministry of Public Administration - State Information Agency and the State Agency for Protection of Personal Data.

The purpose of this audit is to provide adequate recommendations that will enable the Ministry of Health and relevant stakeholders to use all legal instruments and resources appropriately, so that they are responsible related to their obligations, adhere to timeframes so that the Health Information System functionalised, and to ensure that the current system is functional and enables its wide use by being implemented throughout the country with the sole purpose of providing health services to every citizen.

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## **Overall conclusion**

Complete functionalization of the Health Information System besides being a legal obligation for the Ministry of Health, is also important for achievement of this Ministry's main objective, which is provision of equal services to all citizens and residents of the Republic of Kosovo.

Implementation of the Health Information System in Kosovo is not fully functional and it results that it has not been efficient and effective. Based on the planning done in the Action Plan for implementation of the Health Information System for its wide use and implementation in 30% of the Country's territory, we have concluded that the Ministry of Health has not managed to implement it by the end of 2014. Moreover, until May 2017, the Ministry of Health has not managed to implement the project in 30% of Country's territory. In five audited institutions, we have found that only 39% of patients were recorded in the Health Information System, which is considered low percentage of system use due to the fact that only certain departments use it and not in all departments planned for the pilot stage.

These setbacks have caused a number of barriers for citizens of the Country, one of which is development and implementation of the Health Insurance Information System. Delays in implementation of the Health Information System is one of the reasons behind the prolongation in implementation of the health insurance project, as the Health Information System is a prerequisite for proper functioning of this project.

Despite the efforts and costs incurred, implementation of the Health Information System project continues to have lag in implementation and is deficient as a result of which piloting has not been finalised in all Health Institutions and was not assessed.

## **Key recommendations**

The Government of Kosovo should prioritize implementation of the Health Information System by assessing it up to the current stage of implementation through the Ministry of Health, and addressing current setbacks in order to continue with its efficient and effective implementation in the rest of the Country.

The Ministry of Health should establish legal preconditions as soon as possible - update the Administrative Instruction on the Health Information System and approve the same, update the Action Plan based on the strategy, and create physical preconditions - provide equipment, networks and software in order to make the Health Information System functional and operational.

The National Council for Health Information System should take concrete actions to coordinate activities with relevant stakeholders in order to make the system fully operational.

*(For more detailed conclusions and recommendations, see further in the report).*

## **The response of the parties involved in the audit**

The Ministry of Public Administration and the State Agency for the Protection of Personal Data have agreed with the audit findings and recommendations. Whilst we did not receive answers from: Ministry of Internal Affairs, Ministry of Health and five Health Institutions. We encourage the institutions involved in this audit to make every effort to address the recommendations given.

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# 1 Introduction

Accurate and timely information on the health status of country's population has impact on making the right decisions regarding necessary improvements to provide health services and to lead a Health Institution efficiently.

To achieve this, the Ministry of Health (MoH) has drafted and approved the strategy for the Health Information System (HIS) in Kosovo (2010-2020). The strategy aims to identify manners in which within the defined period will be created the necessary infrastructure for the development of health intelligence and that decision-making is based on evidence through the health care system and by analysing the statistical health system.

Part of the HIS strategy is the Action Plan (AP) for its implementation, which is broken down into activities that relate to: what is done, what are the verification tools, factual situation at the beginning of the activity, objectives aimed, institutions responsible for implementation, institutions that should support the responsible entity, the timetable and the approximate budget foreseen for implementation of each activity. The amount needed to implement AP is €15.9million.

In order to implement the strategy in the health sector, the Republic of Kosovo and the Republic of Luxembourg have signed the bilateral agreement KSV/014: "Support Program for Health in Kosovo". The agreement foresees obligations and responsibilities of each party. The Luxembourg Government will meet its financial obligations for implementation of the project in the amount of €6,500,000, while the Government of the Republic of Kosovo will provide the support and monitoring of the project implementation and has to contribute in the amount of €1,300,000.

The specific objective of this agreement is to strengthen the capacities of MoH to implement the strategy in the health sector. This agreement foresees achievement of results that are closely related to the implementation of the HIS.

The HIS is a system that generates, compiles, analyses, communicates and uses the data for the public and private health sector. This data is converted into information that has decision-making impact for parties involved in the health system, such as:

- population as a party that demands accountability from (Health Institutions) HI for provision of quality services;
- patients as selectors of the institution to obtain health services;
- health managers to make the right decisions to provide quality services; and
- policy-makers to issue adequate laws and regulations to regulate the national health system.

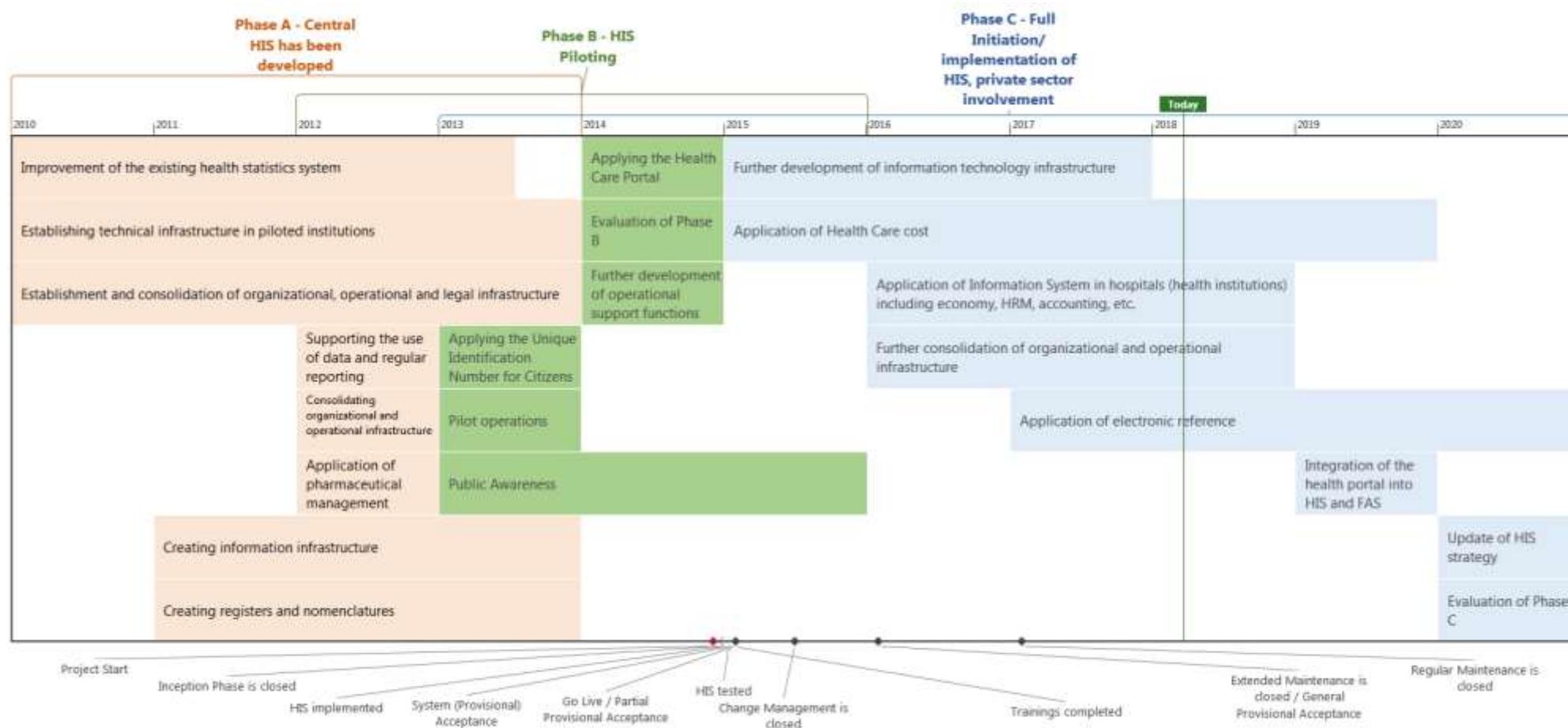
This data relates to HIs, management of resources, management of patients, management of diseases, management of populations health, pharmaceutical management, participation in international organisations, and meeting EU social cohesion requirements, public health and participation in open market<sup>4</sup>.

In the following are presented main activities of the AP for the implementation of HIS.

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<sup>4</sup> Strategy for the systeminformation of information in Kosovo 2010-2020

Graph 1- Key activities of the AP



According to Graph 1 and the AP, implementation of HIS is foreseen in the following three stages:

*Stage A (2010-2013)* is the first phase of implementation of HIS. At this stage, the financial implications and responsibilities of implementing parties are foreseen;

*Stage B (2012 -2014)* is the piloting stage wherein are also foreseen financial implications and monitoring of pilot project. Pilot projects include the HIS software which will be obtained by 73 HIs, 7 Main Family Medicine Centres (MFMC), 53 Family Medicine Centres (FMC), 10 Outpatient care, 1 Secondary Health Institution (Regional Hospital of Prizren RHPE), 1 Tertiary Health Institution, University Clinical Centre of Kosovo (UCCK) and 1 central HI the National Institute of Public Health (NIPHK).

*Stage C (2013 - 2020)* foresees full implementation of HIS, including the private sector.

Stage A and B include piloting and full implementation of HIS, in 30% of the Country's territory and pilot assessment by the end of 2014. In Annex A are presented implementation stages of HIS.

### Current health information systems in the MoH

The MoH for several years has developed and implemented various information systems for decision-making and data management and. These systems are presented below:

- a) System for licensing of private health institutions;
- b) Inspection system;
- c) System for health human resources;
- d) System for pharmaceutical stock management;
- e) Information system of health statistics;
- f) Health information system for detainees.

A more detailed description of these systems is given in Annex B.

### Health Information System and its functions

In addition to the approval of the HIS strategy, in 2012, with the approval of the Law No. 04/L-125 on Health, was foreseen establishment of a unified and integrated information system that would cover the entire health sector of all levels. For this purpose, in February 2014, a contract was signed between the MoH as the Contracting Authority on behalf of the project KSV/014 and an Economic Operator to provide and implement the HIS software within a period of 36 months in the pilot HIs. In addition, the purpose of this contract was to provide a new platform with all its functions,

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including the establishment of HIS, establishment of the network operations centre, provision of Professional Health Cards (HPC)<sup>5</sup>, provision of user training, etc.

The scope of software implementation in the HIs pilot, up to this stage intends to involve HIs of central and local level.

The HIS for patient treatment provides several functions: registering patients in HIs, management of pharmaceutical stock and management of human resources. Treatment procedures of patients begin with their registration in the HIS, wherein is set the treatment appointment in the nursing room. Depending on the case, the case is referred to for treatment to the professional physician. A professional physician is the person who has access to all patients' records including the diagnosis.

The contracting company sets all access privileges of health personnel, which means that healthcare personnel (nurses) that register patients have limited access to patients' data. A professional physician has access to all patients' records. The system administrator provides access authorisations for healthcare personnel.

The Economic Operator contracted for implementation of HIS<sup>6</sup> has produced an implementation timeframe and based on this plan has established key implementation points which are presented in Graph 1.

Parties responsible for implementing the HIS are classified into two groups<sup>7</sup>:

(a) Internal parties responsible for the HIS are: MoH, NCHIS, Telemedicine Centre of Kosova - Department of HIS (DHIS), NIPHK, Health Institutions (HIs) and KHUCS; and

b) External parties that have indirect impact and provide support in implementation of the system are: Ministry of Public Administration (MPA) - State Information Agency (SAI), Ministry of Internal Affairs (MIA) through the Civil Registration Agency (CRA), National Agency for Personal Protection of Data (NAPDP).

Relevant documents for the implementation of HIS are: the Law on Health (LH), Administrative Instruction (Health) on the Health Information System and the Reporting of Statistical Data, as well as the law and regulation related to protection of personal data<sup>8</sup>.

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<sup>5</sup> Health Professional Cards - cards are a standardized and safe element for identifying and authorizing healthcare professionals.

<sup>6</sup> Because most of the information systems so far set up as HIS, the unique integrated Avicena system, this report is referred to as HIS.

<sup>7</sup> See Appendix C

<sup>8</sup> See Appendix D

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## Audit problem

According to studies conducted related to large information systems it turns out that organizations face different challenges during their implementation. This particularly happens because government organizations undertake initiatives for purchase and establishment of information systems without conducting a prior assessment of risks to their implementation<sup>9</sup>.

In order to ensure overall coordination at the national level and to assist in drafting of technical, legal and organizational principles for HIS is needed the engagement and involvement of some parties that have impact on functioning of this system.

Our assessments have revealed lack of data on patients, medicine, treatment, illnesses, and resource management due to which has resulted in inefficient and ineffective delivery of health services and treatment of patients. Report<sup>10</sup> KSV/014 "Program for Health Support in Kosovo" discloses an assessment on achievements and delays in implementation and functioning of the HIS. According to this assessment, there are several factors that have led to an inoperable HIS, which are mainly of organizational nature (communication, effective staff training, segregation of duties and responsibilities among relevant parties, poor monitoring over implementation, etc.).

Issues that relate to the current manner of functioning of HIS are also mentioned in regularity audit reports for MoH (2014 and 2015) that mainly relate to the aspect of revenue recording. According to this report<sup>11</sup> HIS is considered a tool to carry out this function. Another issue that requires improvement is also the pharmaceutical stocks management, which represents one of the functions of HIS.

Another report of the National Audit Office (NAO) states that there are significant discrepancies in the current data on pharmaceutical stocks available and the stocks data produced by HIS.<sup>12</sup>

Indicators mentioned above demonstrate lack of a unique and integrated HIS. The condition of the health sector in the Country is considered the most disadvantaged sector in the region and in the Eastern Europe, and this indicator shows the importance that a functional HIS would have in improvement of current situation.<sup>13</sup> A similar condition was also recorded in the report drafted by the Kosovo Democratic Institute.<sup>14</sup> Our research during the pre-study phase has identified that the physical infrastructure of HIS has started being distributed during 2013 to the selected institutions for the pilot stage of the project. During this stage is noticed lack of monitoring mechanisms over the distribution of infrastructure, therefore based on these problems we have defined our audit objective.

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<sup>9</sup> The Challenges of Complex IT Systems, The Royal Academy of Engineering and The British Computer Society April 2004

<sup>10</sup> The report is a research conducted by LUX DEV which provided technical and financial support for the implementation of the HIS.

<sup>11</sup> Audit Report on the Ministry of Health financial statements for the year ended 31 December 2015, page 28.

<sup>12</sup> Performance Audit Report, Health Sector Procurement Systems, 2015

<sup>13</sup> Strategy on health information system in Kosovo 2010-2020

<sup>14</sup> [http://www.kdi-kosova.org/publikime/1-KDI\\_QLPO\\_002\\_SHQ\\_ENG\\_WEB.pdf](http://www.kdi-kosova.org/publikime/1-KDI_QLPO_002_SHQ_ENG_WEB.pdf)

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## Audit objective

The objective of this audit is to evaluate the efficiency and effectiveness of the implementation of the Health Information System in the Country. Furthermore, the objective of this audit is:

- To provide a view over the functioning of instruments and policies and procedures used to implement the HIS;
- To assess whether the activities undertaken at central and local level are coordinated and consistent to achieve effective implementation of the HIS; and
- To assess whether the resources used and control systems established are sufficient and functional to ensure efficient and effective implementation and functioning of the HIS.

Our aim is to provide recommendations on improvement of the implementation process and effective functioning of the Health Information System. These recommendations will be addressed to the central and local level as well as other responsible parties so that they improve their approach when implementing this system.

## Audit questions

In order to respond to the audit objective we have posed the following audit questions and sub-questions:

*First key audit a question is:*

1. *Has HIS been implemented in an effective and efficient manner?*
  - 1.1 *Has the MoH created adequate preconditions for functional implementation of HIS?*
  - 1.2 *Has the MoH coordinated activities for complete and functional implementation of HIS with external parties?*

*Second key audit question is:*

2. *Is the HIS functioning effectively?*
  - 2.1 *To what extent has the HIS been implemented?*
  - 2.2 *What are the challenges that HIS has faced in terms of functioning?*
  - 2.3 *To what extent have MoH's mechanisms of monitoring, assessment, and reporting been functional?*

## Audit criteria

The definition of audit criteria was done based on the strategy and the AP which lay out the requirements and the process that needs to be followed and at the same time the cooperation between the MoH and other relevant responsible institutions involved in implementation of this system.

When setting the criteria we have also consulted official documents<sup>15</sup> that define key parties and other parties responsible for implementation of the HIS that also define procedures and guidelines that these parties should follow in order to functionalise the system.

The MoH as a party that is responsible for the functionalization process of the HIS in Kosovo should propose, draft, approve and ensure implementation of policies, strategies and legislation that relate to development of this system by:

- Establishing, developing, and functionalising a unique and integrated health information system throughout the country, especially in HIs selected for the pilot stage;
- Establishing and consolidating legal, physical, organizational, and operational infrastructure;
- Conducting needs assessment in order to provide preconditions for functionalization of the HIS through coordination of its activities with its internal and external stakeholders;
- Establishing monitoring, assessment and reporting mechanisms on the progress of implementation of HIS;
- Carrying out the testing process of pilot project, including infrastructure, functionality and usability of the HIS.

The MoH should also coordinate its activities with implementing institutions of HIS such as the Municipal Health Directorate and the University Clinical Centre of Kosovo (UCCK).

Municipal Directorates are responsible for providing conditions and coordination with the MoH and to oversee implementation of HIS across subordinate HIs of the primary healthcare, while the UCCK is responsible for all activities of secondary and tertiary healthcare.

## Audit Scope

In this audit, we have focused on coordinating HIS activities, distribution of physical infrastructure, training of HIC personnel, development, functionality, and use of HIS, its monitoring and testing to ensure a functional HIS that supports the right decision-making.

Subject to audit are internal parties such as: Ministry of Health, University Clinical Centre of Kosovo - Paediatric Clinic, secondary healthcare - Regional Hospital of Prizren, Main Family Medicine

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<sup>15</sup> List of relevant laws and documents presented in Appendix E

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Centre and two Family Medicine Centres of primary healthcare. External parties involved are the Ministry of Internal Affairs, Ministry of Public Administration - State Information Agency, National Agency for Protection of Personal Data. The audit covers the period 2010-2017.

The audit team as part of its scope has selected as a case study of HIs<sup>16</sup> in three healthcare levels. Selected HIs are: tertiary healthcare - UCCK, namely the Paediatric Clinic, secondary healthcare - RHPZ and primary healthcare – MFMC Pristina, FMC 5 - Dardania and FMC 6 - Kodra e Diellit.

Selection of these HIs was done because the UCCK covers two levels of HIS, the secondary and tertiary level, while the MFMC and two other FMCs cover the primary healthcare.

The largest number of patients in these centres and the largest coverage of hospital wards within these centres has been the indicator for selection of these samples. At the same time, the MFMC is selected as coordinator of all FMCs in the municipality of Prishtina and as a representative institution of primary healthcare.

## Audit Methodology

To respond to audit questions we have conducted several activities, by:

- Analysing the legal framework;
- Analysing the creation of preconditions and coordination of activities by MoH for development and functioning of HIS;
- Interviewed leading structures of responsible institutions;
- We were also present in the role of the observer, during the fifth NCHIS meeting;
- Analysing minutes of all NCHIS meetings in order to understand achievements and setbacks identified in these meetings regarding the progress of HIS;
- Analysing contracts of EOs responsible for infrastructure, training and software of HIS;
- Analysing training provided to key users and system support staff and the importance of these trainings;
- Analysing the functionality and usability of the programme;
- Analysing the communication form of MoH with parties involved in the HIS as well as correspondences;
- Analysing causes and reasons for non-integration of different systems into the HIS as foreseen;
- Observing and analysing delays in the implementation of the HIS by identifying key causes and addressing of these setbacks by the MoH and relevant stakeholders.

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<sup>16</sup> Certain pilot institutions are listed in Appendix C

## 2 Key findings

### 2.1 Planning, coordination and organising of activities in the MoH for implementation of HIS

#### National Council for Health Information System

To ensure general coordination at national level of relevant partners and to assist in drafting of technical, legal and organizational principles for HIS was proposed establishment of NCHIS, which will be the highest advisory body on issues of national importance as well as for inclusion of organizations outside the health sector. NCHIS consists of representatives of all relevant partners for HIS such as MoH, service buyers, patients' associations, MPA, NIPHK, Municipalities, HIs.

NCHIS was established in 2015, while according to the AP is foreseen to be established in 2011, namely with a four year delay. Due to which all activities under the AP were implemented late. NCHIS consists of 13 members from various institutions that are responsible for the implementation of HIS.

Taking into account the responsibilities of NCHIS regarding the adoption of regulations and standards, this council has failed to review the Administrative Instruction (AI) No. 11/2013 on the Health Information System and update it in accordance with the strategy and the AP. This AI does not make clear the responsibilities and obligations of the parties that are responsible for implementation of the HIS under the new action plan. According to this AI, personal health records are administered and managed by HIs. This form of data handling by HIs is in disagreement with the objective of HIS, considering the aim of creating a centralized (unique and integrated) data system. NCHIS as a monitoring and reporting body for the overall process, due to delays in establishment has failed to establish a monitoring mechanism to follow up and monitor closely the implementation of the HIS.

After its establishment, the NCHIS has managed to draft the regulation of this council. In this regulation, among other things are also foreseen regular meetings, but was not specified their schedule. Nevertheless, meetings so far have been held on an ad-hoc basis. From March 2015 until April 2017, NCHIS has held five meetings. The last meeting was held in April 2017. This meeting was held late for more than a year, while the previous meeting was held in March 2016. As a result, has failed to address achievements and delays of the implementation. While analysing minutes of meetings held by NCHIS, we noticed that most of the recommendations were repeated. This shows that they were not addressed and questions achievement of objectives of this council.

Furthermore, the coordination of activities between MoH and NCHIS is deficient due to which have resulted a series of setbacks that had negative impacts on the efficiency and effectiveness of project implementation. Failure to include the NIPHK as one of the key stakeholders in the pilot stage of implementation of the HIS is another important indicator that shows lack of coordination between the activities of NIPHK and MoH.

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In 2011, after the adoption of the strategy as an initial step was planned reorganisation of available data so that this data is transferred from the old HIS to the new HIS which provides security and accuracy. For implementation of this activity, the key responsible institution is NIPHK.

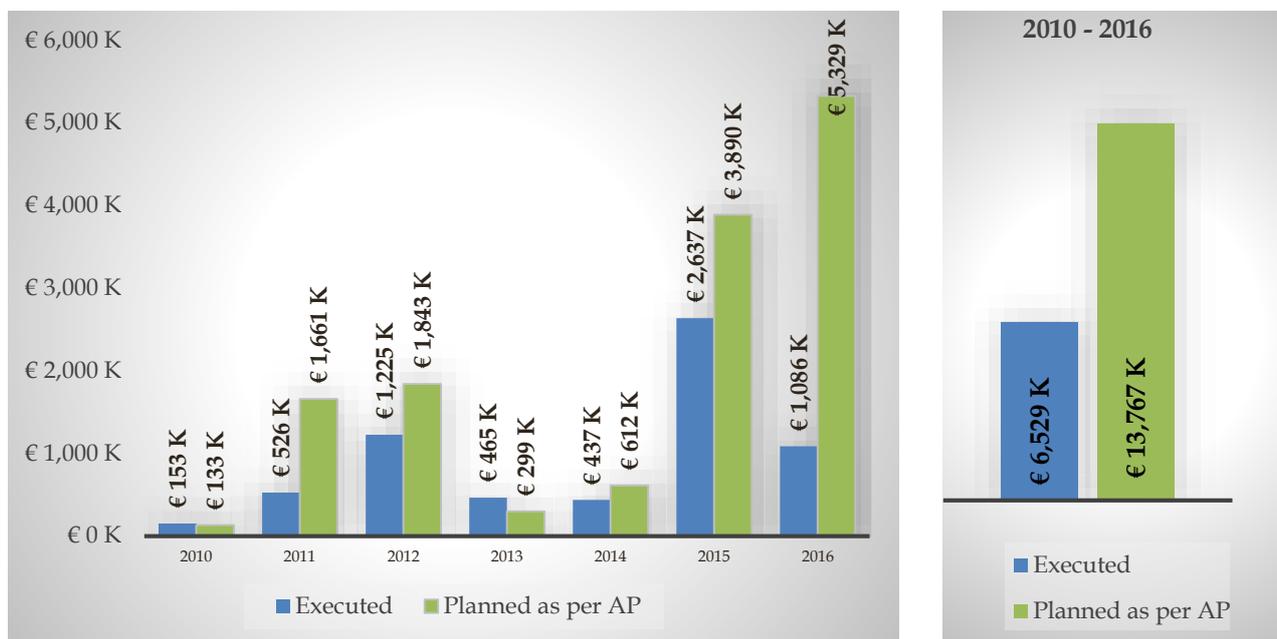
Given the importance of this institute, in the national strategy of the HIS and the AP is foreseen involving this party in first activities of HIS implementation. Until May 2017, this institute was not involved in any activities to contribute to development and implementation of the HIS. This institute continues to generate reports manually, based on the data that it collects from its local offices. Based on computer sheets, HIs report to these local NIPHK offices. Use of HIS in this pilot stage by NIPHK is impossible due to its lack involvement in its development and implementation activities. Despite the requests of the NIPHK addressed to the MoH regarding its involvement in implementation of the HIS, the MoH has not yet taken any concrete steps for this.

Furthermore, it should be noted that the data of the old HIS are processed by the HI to the NIPHK with several months of delay due to their large volume, although the deadline for their processing is specified under the AI No. 11/2013. All activities planned under the AP have been carried out with a delay, while there was no involvement of NIPHK as an important party in implementation.

## Planning and use of financial and human resources

The AP foresees a cost of €15.9m for the overall implementation of the HIS during the period 2010-2020. As shown in the figure below in the period 2010 - 2016 according to the plan were foreseen to be spent €13.7mil, while until December 2016 only €6.5mill were spent, which shows that from the financial aspect only 47% of the project was implemented, which is a significant setback.

Figure 2 – Expenditures incurred against those planned (K=1000)

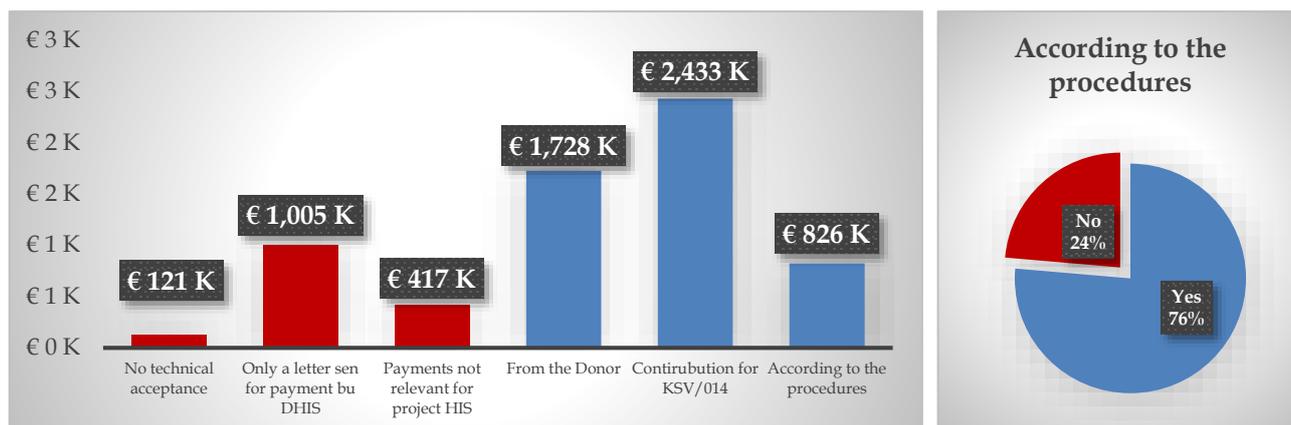


In addition, we have found deficiencies in financial control, in contract management as well as their implementation. From the financial management and control information system, have been generated reports of all payments carried out over the years, based on which we have assessed their designation.

From payments carried out, we noticed that some contracts were executed without establishing a receiving committee, the evidence of the receipt of goods or services was done with a letter from the DHIS, received only by one person, or without determining their technical condition.

Based on Figure 3, we consider that 76% of payments were carried out for activities related to HIS, while 24% of payments that amount to €417,000 were carried out for other projects that were not foreseen with the HIS project. In addition, out of the HIS budget were carried out payments for: court decisions in the amount of €201,000, €77,000 for purchase of X-Ray in UCCK, €59,000 for purchase of "Digital Ultrasound Imaging System", €70,000 for "Preparation of Terms of Reference, conceptual project and renovation and rehabilitation of elevators in UCCK" and €9,000 for "Integration of the Database into the E-Government Portal".

Figure 3 – Financial execution from the code of project 721(K=1000)



Furthermore, setbacks in securing sufficient personnel to support the project by MoH, namely the DHIS. In general, all institutions involved in this project have had lack of human resources that are necessary for implementation. This activity is planned in the AP, by evaluating recruitment needs of each institution for professional staff for carrying out certain activities in implementation of HIS.

The MoH has submitted a request for the necessary support staff to implement the HIS program. Initially, some of the requests were approved but with the growing need for implementation support MoH did not find support from the MPA and the Ministry of Finance (MoF) to secure this staff. Taking into account the insufficient support staff for implementation of HIS, most institutions have made recruitment requests regarding this, including DHIS, HIs, and others, but this has not happened due to budget limitations and other limitations by responsible ministries.

All these activities are preconditions for an effective start of implementation of the HIS program, which were not implemented according to the plan.

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## 2.2 Planning, coordination and organization of the Ministry of Health with external parties for implementation of HIS

In order to enable implementation and functionalization of the HIS, the MoH should provide preconditions through external parties. MAP through AIS provides server and electronic infrastructure for the data of HIS in the Country. At the same time, the civil registry, which provides data of citizens to the MoH on recording and provision of other services to patients in HIs, is indispensable. In this process for exchange of data, processing, securing of their confidentiality, it is necessary implication of NAPDP as an oversight party that ensures quality and protection of data. In the following, we have presented planning, coordination and organization of MoH activities with external parties.

### Ministry of Public Administration/Agency for Information Society (AIS)

AIS manages and oversees the implementation of information technology related projects in public institutions. It covers the security and protection of electronic communications and data infrastructure, provides space and conditions for proper functioning of HIS equipment and systems which are under the care of AIS.

Since the beginning of HIS implementation, AIS supported processes for proper progress and implementation, providing the necessary professional advice and technical infrastructure within its capacities and capabilities.

One of the most important processes allowing proper functioning of the HIS was the activation of the national data center. The deployment of central devices for processing, transmitting and storing data from HIS was planned for this data center. This data center, after various delays, was put into operation in February 2014. In addition, MoH did not plan to purchase equipment for this center which introduced first barriers to operation. This is because AIS, in addition to providing hosting services (provision of equipment) and provision of working conditions (supply with electricity, proper refrigeration of space, physical security in AIS spaces) did not plan to supply main equipment appropriate for HIS.

In April 2014, as a temporary solution, AIS secured a working environment for temporary use for launching of the HIS implementation where the MoH was provided with "Blade Server" for data processing, "External SAN Switch" - to enable communication between equipment, as well as data storage devices, along with the supporting infrastructure.

Due to lack of proper definition of responsibilities, these devices were not activated until October 2014, meanwhile there was a need for purchasing disks and additional licenses from AIS in the amount of approximately €120,000.

Although by the end of 2015, the Ministry of Health purchased the equipment required for proper functioning, including 28 servers and disks with total capacity of 30-Terrabyte, HIS continues today to use equipment given by the AIS with limited capacity (only 7 servers). Officials in charge have

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informed us that the reasons for not using these 28 servers are due to lack of defining responsibilities for obtaining licenses.

Lately, AIS notified the MoH that it does not have sufficient capacity to enable data storage outside the main location at a data recovery location, but can only secure the space for their deployment.

For the services provided by AIS, no Memorandum of Understanding or something similar has been in place to determine the roles and responsibilities of the parties involved.

### Civil Registration Agency (CRA)

CRA is responsible for providing the civil registry with the data of the citizens to the MoH in order for the latter to use this data for the operation of the HIS.

Based on the agreement arising from the need for exchange of data between MoH, CRA-MIA and NAPDP, the latter being responsible for the protection of personal data of the citizens of the country based on the Law on Protection of Personal Data 03- L-172<sup>17</sup> and based on the standard operating procedures between these parties we have ascertained how this agreement started to be implemented in February 2015. Referring to AP which foresees the finalisation of the system pilot testing in 2014, this indicates that there are delays and negligence in ranking of activities with key stakeholders included in the HIS project by the MoH.

The agreement also foresees the exchange of data in a mutual manner, in this case the MIA from the exchange of data with the MoH such as birth and death facts is the beneficiary of this agreement. At the meeting held with the Head of CR we found that despite this, no data was not sent from the MoH until the audit period regarding the facts of births and deaths.

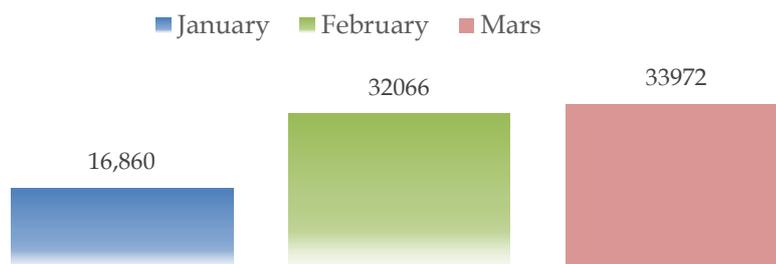
According to the MIA-CRA work reports, during the first quarter of 2017, 82,898 requests for personal data were made for MH, respectively HIS. Figure 4 shows an increase in requests made by the HIS showing that its utilization has increased significantly since February 2017 and that data exchange from MIA-VRA to MoH is successfully completed.

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<sup>17</sup> Law on Personal Data Protection, Law no. 03/L-172

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Figure 4 - Q1-2017 requests executed in MIA-CRA



### National Agency for Personal Data Protection (NAPDP)

It is an independent state institution, established under the Law on Personal Data Protection, which is responsible for overseeing the legitimacy of processing personal data.

MoH in 2016 sent a memo to NAPDP where it requested legal interpretation and consultancy on the processing of personal data that will be made by the health insurance fund. However, it has never requested legal interpretation or consultancy on data processing for HIS based on the importance of information that contains personal health data.

NAPDP did not make any assessment when it comes to proper handling of data by the Ministry of Health through HIS. In certain the “main user” level at the HIS have access to personal medical records, data that should only be accessible to “medical personnel” level of users. Further on, we have not noticed that the processing and protection of data by EO is evaluated and data is circulated without a certain procedure despite the fact that patient data is categorized as personal data and as such should be handled according to the defined rules<sup>18</sup>.

## 2.3 Implementation, Functioning and Utilization of HIS

### Department of HIS

Department of HIS<sup>19</sup> is a department created for smooth functioning of HIS systems such as pharmaceutical stocks, human resources, statistics system etc. as well as hosting and securing them in the data center located on the telemedicine. It should monitor and report on a regular basis on the implementation of the HIS including its maintenance and operation. DHIS continues to offer this support despite having many problems due to lack of proper definition of roles and

<sup>18</sup> [http://www.amdp-rks.org/repository/docs/2015\\_03\\_ashmdhp\\_rregullore.pdf](http://www.amdp-rks.org/repository/docs/2015_03_ashmdhp_rregullore.pdf)

<sup>19</sup> MoH has established DHIS for the support and implementation of HIS. The operation of this department is regulated by AI No.11/2013 It should first be noted that the director of this department has moved to another position within the MoH, since June 2016 in this position has been appointed another person who since that time continues to function in the capacity of the acting director.

responsibilities, taking into account the inclusion of IT unit within KHUCS, EO contracted for developing an application, network problems in HIS etc.

There are no policies, procedures or guidelines for user management - users to use the HIS password and share their rights.

Despite this, DHIS is also responsible for the implementation and maintenance support of HIS. Taking into account staffing constraints, engagement of additional staff and the required professional training, this department faced numerous stumbling blocks in fulfilling the responsibilities that they are entitled to.

However, the implementation of the process on appointing health care users is managed currently by the contracted economic operator for maintenance and implementation services.

Figure 5 shows the roles and responsibilities of health personnel in using HIS.

*Figure 5 - Logical roles in HIS*



These roles are not exactly defined, but according to the interviewed personnel, the functions of the above mentioned roles are:

**Main User** - has the possibility to modify physical locations (clinics, FMC, etc.) to which other users have access to;

**Medical staff** - have the same access as those of nursing staff and in medical records of patients;

**Nursing staff** - have access to basic patient records (personal data, blood group, blood pressure, weight, height, allergies, etc.) as well as limited printing functions (discharge papers);

**Administrator** - has full access in the administration of the system, but not the data of patients.

The segregation between the first three groups is based on the contract that the user possesses, there is no definition of the services or rights that one of these groups should have. While the administrative access is only available to the EO, and DHIS does not have information on the activities of this group.

When it comes to the management of the users, during the interviews with responsible officials of DHIS we have concluded that the information on suspension or eventually termination of access for health personnel will be based on information transmitted from the human resources system, but this link has not yet been put in place and as such it was impossible to verify.

Contractual based HIS functional domains have not yet been developed or implemented in its entirety. This has resulted in the inability to coordinate the activities and their functional setting or even the division of the scope within the health personnel. The following table presents some of the functional domains of HIS.

Figure 6 - Functional Domains of HIS

Functional Domains of HIS		Status
a	Acceptance, Issuance and Transfer	Partially Implemented
b	Patient Relationship Management	Uncompleted
c	Hospital, Outpatient and Emergency Care	Partially Implemented/Only Hospital Part
d	Management of Medical Treatment and Planning Orders	Uncompleted
e	Electronic medical record	Partially implemented
f	Acceptance/approval management	Uncompleted
g	Management of identity and access	Partially implemented
h	Register of medical professionals	Uncompleted
i	Register of medical care institutions	Uncompleted
j	Patient Register	Uncompleted
k	Medicament Registry	Partially implemented
l	Procedure and Laboratory Catalogue	Partially implemented/only part of the of procedures catalogue where ICD9 procedures are established
m	Diagnostic Catalogue	Uncompleted and ICD10 Procedures have been implemented
n	Billing Support	Uncompleted
o	Capacity Management, Personnel Scheduling and Planning	Uncompleted
p	Medical Statistics and Public Health Reporting System	Uncompleted

HIS possesses more than 120 different sub-functional operations, these functions which have functional domains as basis shown in the table above, but their division and provision is not defined. The possibility to use some of them for healthcare staff is given on an ad hoc basis or based on the knowledge that the DHIS system operator possesses. This division is not structured and as such the same medical staff in different clinics can be offered access to different functions.

To identify functional needs based on medical personnel, different working groups (focus groups) have been established. This action has managed to identify functional needs only for some organizational units.

Delays caused by the implementation and functionalization of KNDC have also influenced the process of deploying equipment at the Centre for the needs of HIS. Further on, after activating this center, not being able to get equipment from MPA - AIS due to budget constraints and lack of planning, the MoH has been forced to supply the main equipment for the data center. This procedure has been extended and the contract has been signed on 20.12.2015.

Nevertheless, in activating these devices, MPA-AIS has offered in use some equipment with limited capacity to enable activation and testing of HIS. It should be noted that this temporary environment enabled by MAP-AIS is in use and that MoH failed to activate equipment purchased for this purpose. One of the reasons for this failure is improper planning to obtain the required licenses to enable server virtualization. These licenses are later provided by the Lux-Dev Supporting Project for the MoH.

As far as the backup of the HIS is concerned, responsibility has been transferred to the contracted EO for "NOC-Outsource" and that DHIS has no knowledge on execution of this activity. DHIS also assigns MPA-AIS responsibility for execution of backup copies outside the location of KNDC although there is no agreement concluded on this.

This department has recently begun drafting policies and procedures which after our evaluation have a character of standard operating procedures and as such do not determine the roles and responsibilities of participants in the system

## HIS Infrastructure

The Municipality of Prishtina together with 15 HIs, and 45 other His in the Prizren region are primary health care providers, while Prizren Hospital is a secondary healthcare provider. The Pediatric Clinic within the UCCK is a provider of tertiary health service. All these HIs are designated as pilot institutions for implementing HIS.

Alongside the PA which has foreseen the distribution of physical infrastructure in 2011 in these pilot HIs, until 2013 there was no distribution from EO contracted by MoH. After the distribution to pilot His started, the infrastructure distribution was not executed in all departments within HIs.

After the contracting of the new EO due to the ending of the maintenance contract with the EO which aimed at maintenance of the equipment and network, in 2014 to put HIS into operation, the new EO made an assessment of the infrastructure that was set up in 2013 to continue with the deployment and operation of the system.

Based on this evaluation report, EO has evidenced a lack of different hardware equipment throughout HIs. The lack of such equipment was confirmed by the director of the clinic as well.

EO reported on the lack of infrastructure in the HIs, however MoH did not take any concrete steps to monitor and identify these losses at the same time providing the HIs with the necessary infrastructure and continued putting HIS into operation within ISHs but not in all their departments.

Based on the fact that the infrastructure distribution was completed in 2013 while the use of this infrastructure started in 2016 in the pilot HIs, we have concluded that these devices were not used for a period of three years and as a result these devices result to be amortized.

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## HIS Software

MoH is responsible for providing HIS software which is a prerequisite in addition to the physical infrastructure that enables health personnel in HIs a range of different functions for proper delivery of health service to citizens. HIS software is an application that enables the implementation of integrated and unique HIS across the country.

Due to delays in drafting the terms of reference, the tendering procedures for providing HIS software have been delayed. Upon completion of these procedures in February 2014 a contract was signed with EO for providing HIS software.

Based on the signed contract, the process of piloting or operating the system is planned to be executed within 36 months period. However, the implementation of this process has not started until June 2016. For carrying out this activity, the MoH has not rightly and timely coordinated the internal and external parties.

Up to May 2017, piloting has not yet been completed and no assessment of the pilot phase has been made to identify the achievements and setbacks in software by the MoH. If we refer to the above-mentioned piloting timelines planned by the EO for service delivery we may conclude that these objectives have not been met. We have also noticed some shortcomings that were due to inadequate management by HIs within their structures and failure to put the program into operation properly due to hardware aging.

HIS is not functional in all HIs of the primary level. It is only functional in MFMC and six other FMCs in the Municipality of Prishtina.

When it comes to the implementation and activation of HIS functionalities:

- All functions from patient registration to diagnosis descriptor prescribed by the physician are active and can be executed through the program;
- Issuance of the final report by the physician is not active; and
- Integration of systems such as the patient treatment system, the human resources system and the pharmaceutical stock system have not been implemented and are not available from HIs. The exception is the patient's treatment system which is integrated into the HIS, but its utilization compared with the planned planning is below the required level.

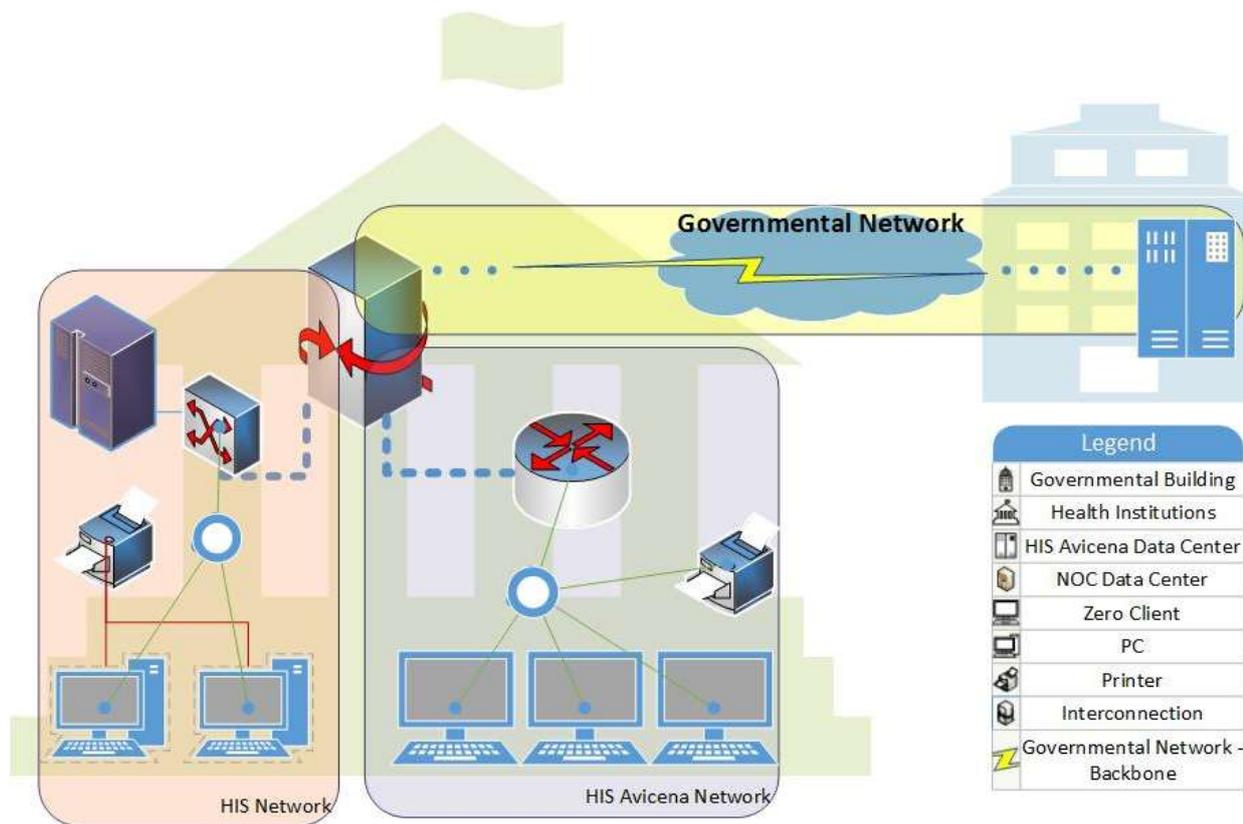
### HIS Computer Network

Prior to the implementation of HIS, a computer network assessment was carried out, which enabled the operation of old HISs and the telemedicine data center which processes and stores the health data of these systems. This network was enabled by MPA. Due to the failure to maintain the IT unit in UCCK, it is crucial that this network is replaced with a completely new network, which will be referred to as the HIS network.

HIS network is used to enable interconnection of terminal equipment (zero-clients, printers, barcode readers) with the HIS data center located at the National Data Center (KNDC). It should be noted that the responsibility for the maintenance of the HIS network up to the interconnection point belongs to the MoH, respectively the DHIS who have contracted an EO to execute this service. From interconnection point to KNDC, this service is provided by MPA-AIS and falls under their responsibility. The interconnection of these networks is shown in Figure 7.

For the services provided by MPA-AIS, regardless of the manner in which it was implemented, the MoH did not execute any type of service level agreement that would determine the detailed responsibilities of the service, such as and the mandatory capacity to provide security, and other details to enable the provision of quality and measurable service. It should be noted that DHIS uses the SolarWinds application to monitor HIS network points but does not perform performance measurements since maintenance belongs to a contracted EO "NOC-Outsource".

Figure 7 - Logical Network Topology



### Network Operations Center – NOC

Not being able to provide customer support services due to limited capacities in the Network Operations Center - NOC, technical and personnel staff, the MoH in January 2016 contracted one EO to provide these services.

One of the services to be provided by this EO is support for users when they encounter problems or improper operation of HIS. To facilitate easier communication with the NOC, a free number is provided by Kosovo Telecom. However, in this number, free calls were possible only from landline telephones, not from mobile phones.

This inefficient service has caused additional costs to medical staff and at the same time this led to failure to use this service permanently to seek assistance in cases when problems encountered during the HIS operation.

For the first quarter of 2017 (Q1-2017) a total of 927 cases were reported in NOC, and the main grouped problems are presented in the figure below:

Figure 8 - Cases presented at NOC for Q1-2017<sup>20</sup>

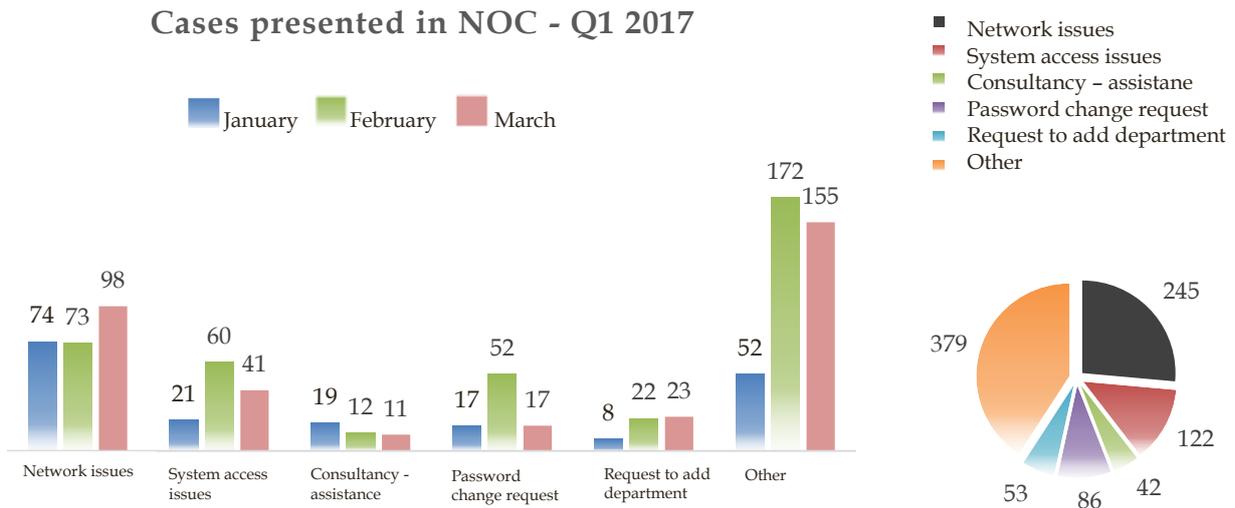
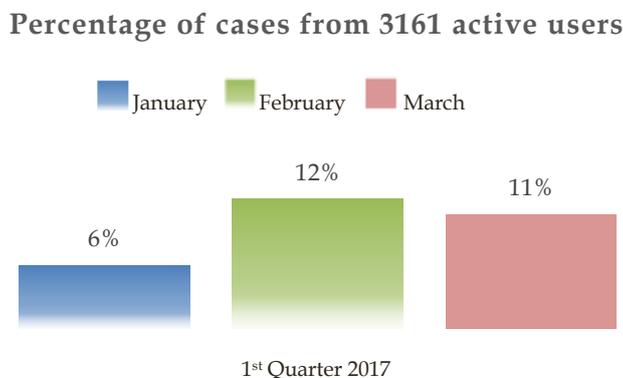


Figure 8 clearly shows that the main problems presented are classified as network problems of 245, system access problems 122, password change requests 86, request for adding a department 52, request for consultant 42, and other problems are 379 cases.

Further on, as shown in Figure 9 of a total of 3161 currently active users in the HIS<sup>21</sup>, at best case scenario (if a user has filed only one case) on average, 9.6% of them have filed cases to the customer support service. Given many problems, this is a very small number. It should also be noted that we did not notice either from DHIS or NOC that these data have been processed in order to improve or identify the main causes of the cases filed.

Figure 9 - Cases filed in %



<sup>20</sup> HelpDesk calls report

<sup>21</sup> HIS Users\_20.03.2017

It should be highlighted that the process from case reporting until its closure is not clarified, although the EO for project support recommended to implement a framework for management and handling cases, including the management of the provided services.

During the field visit we noticed that to file a case, the user was instructed to contact the NOC again later and will be guided for further steps. After some phone calls, the case filed was adjusted but the user was not notified of this until he tried to execute the process, and thus realized that the obstacles were cleared<sup>22</sup>.

The contract for the maintenance and implementation of the HIS expires in September 2017 and the MoH did not plan nor decided how to proceed further.

### Professional Health Cards (PHC)

PHCs - cards are a standardized and safe element for the identification and authorization of healthcare professionals. This is a “smart” card that should be compatible with integrated readers in all workstations (zero-client) where HIS is used.

The intention was to supply all users of the HIS card with this card which would enable an easier and safer authentication and management of all users. For the implementation and supply of the PHCs - cards, contract was initially concluded with the EO. In the absence of DKNDC for their implementation and testing, but also for not being able to provide trainings for all healthcare staff, this component has been changed and replaced with the provision of training for the use of the HIS program by EO in agreement with MoH.

In addition, MoH signed another contract with the EO for facilitating and implementing the PHC card. Despite the signing of this contract, its implementation has not yet been achieved as a result of the uncertainties and difficulties of the EO. Further on, other causes were technical barriers and as a contract it has not yet been executed despite the delays caused.

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<sup>22</sup> In our presence, a total of five (5) calls were made from 11:17 to 14:23 on 17.03.2017.

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## Pharmaceutical Stock Management Information System (PSMIS)

Given the importance of the data processed by the PSMIS, we have made an assessment of it. It should also be noted that data from PSMIS should be transferred to the new HIs after the activation of its function to enable its proper operation.

PSMIS although system is implementable as such does not meet the needs of institution. Some of its shortcomings are:

- Inability to register medicines that are accepted as a donation;
- Inability to generate reports as needed by the institution although this has been requested several times by management and operating officers;
- Classification by type, manufacturer or quantity
- Putting in place the medicaments from the essential list
- Equalization of the stock, etc.

It should be noted that for the registration of donated medicaments, their purchase value should be zero (0.00€), but the developed application does not allow setting the zero value. PSMIS operators have found the way of reporting and not putting the purchasing value of the medicine, completely bypassing the field. In addition to the PSMIS operators at the central pharmacy of UCCK/KHUCS, this system's 'omission' also utilizes the PSMIS operators of Gjakova Regional Hospital to register medicines received as donations.

This is a glitch in this application, made it an impossible to override the completion of this field by the data validation function in this area. As such, it is impossible to classify data based on purchases and generate reports from the PSMIS if we consider the criteria for donated medicines.

Further on, there have been numerous problems in support provided by DHIS about system functions, as well as those problems appeared with the HIS network.

KHUCS Central Pharmacy contracted an Economic Operator for the development and implementation of a secondary system, which they use currently in order to meet the unrealized functional requirements of the MoH regarding the PSMIS.

The implementation of a secondary stock management system was also done within the Peja Regional Hospital.

Implementing double systems, though it may be more than necessary for internal use by HIs due to the inability to provide functions and operations of the PSMIS, makes it even more difficult to link or import data to the HIS. This is because the division of roles and responsibilities in these systems is not done correctly, data backups are not properly managed, as well as the deployment and processing of data from these secondary systems. Therefore, the reliability of data from these secondary systems should be evaluated if decided to be used for HIS.

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## Training of health personnel for using HIS

Training of users (health personnel) for using HIS program started to be held by EO to 2015. This training was initially conducted through DHIS officials. However, due to inadequate planning by the MoH, DHIS failed to provide training to all health personnel in the pilot HIs. Consequently, EO continued to hold training until the end of 2016 for the institutions in which HIs was implemented. Further on, trainings with “key users” of HIS in pilot HIs were held in this year. And by the end of 2016, all trainings with health personnel were performed in all HIs by EO. Based on the AP, the trainings were scheduled to be completed in 2014 and their testing phase completed, while it was completed with two years of delay.

The trainings provided for the use of the program were basic trainings held on a two day and three day basis depending on the position of health personnel. In the evaluation lists filled out by the staff who have benefited from these trainings we found that most of them answered “satisfied with the training”. On the other hand, we have found that in the Pediatric Clinic trained health personnel have no basic knowledge about system use. This indicates that the two-day training is insufficient to understand and learn the basic functions of the HIS program.

Further on, a number of health personnel, in certain cases, neglected to record the data, while others due to the lack of basic knowledge for the program did not use it at all even though they had attended the trainings offered. Most staff did not have basic knowledge starting from access to the program. This negligence is due to the lack of follow-up and personnel responsibility by the management of the clinic on the use of HIS.

## HIS usability

Considering all the obstacles and shortcomings in the infrastructure, HIS is managed to be put in place and operation but not in all departments within the pilot HIS, in this case within the Pediatric Clinic. Distribution of equipment and network was not executed in all departments and consequently this system was only functional at the patient registration desk, the nursery room, and in the main clinic room within this clinic. Other important departments within the Pediatric Clinic such as: Pediatric Emergency Department, Intensive Care, Hematology, Neurology, Dialysis Nephrology, etc., are not included in the HIS.

At the beginning of the system’s implementation at the Pediatric Clinic, patients’ registration started on a regular basis. From the information we received, we found that nurses and physicians have overlooked data registration in the system for various reasons, such as barriers to 24/7 network delivery, as this system works through the “online” platform. Another problem we have identified as a cause for not using it is the limitations on system functions. The function of issuing a physician report from HIS is an important activity which at this stage is not functional and forces physicians to use other forms to release the patient's report. In this case, the medical staff, in particular the physician, is obliged to record the diagnosis in the HIS and also issue the same completed form manually.

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The duplicate data is a burden for the health personnel and one of the main causes which resulted in failure to use HIS.

The lack of such functions in the HIS system is evident in all HIs in which we conducted the audit, and as a result HIs maintains duplicate data.

RHPZ uses three forms of data retention including here use of HIS. In this HI there are setbacks in using HIS. During the audit, and conducted interviews,<sup>23</sup> we have found that health personnel are reluctant to use this program. Healthcare personnel who uses the HIS at least in this HI, are the main physicians. The reason is because they are obliged to keep data in other forms than their reporting to the HIS. This burden on recording data in many forms resulted in its failure to use due to insufficient time available.

Keeping records in other forms is also intended to generate complete and accurate data.

Problems related to the non-operation of the program are directly addressed to the "help desk", while the technical issues related to the infrastructure in this case with the equipment and other technical problems are addressed within DHIS.

Challenges regarding the operational problems of the HIS system, are addressed by the EO and generally solves the problems of this nature while addressing technical issues such as hardware and network problems and problems with the provision of internet service are still evident. These problems are the responsibility of the MoH specifically DHIS and remain unaddressed.

To prove this, we have visited the "help desk" offices<sup>24</sup>, carrying out interviews with the supporting staff of this office and at the same time we have received reports from them to evaluate the HIs requirements with setbacks on program running. We have found that most of the requirements of health personnel result in obstacles in providing Internet service which is not the responsibility of the EO. In conclusion, we have found that this is the responsibility of the MoH in cooperation with MPA to find permanent solutions of providing 24/7 network connectivity so that there will be no interruption of system operation since the HIS program platform is grounded on a client-server platform and for its proper functioning, one of the basic conditions is the access to the server devices located in MPA.

To determine the usability of the program, we have analysed the data recorded since the beginning of 2017 until April 2017 throughout audited HIs. After comparing the data recorded in the HIS and those recorded in the health protocols, we found that in the RHPZ approximately 28% of patients were registered in the HIS. Approximately 11% of patients in the HIS were recorded in the pediatric clinic. Meanwhile, two FMCs and one MFMC in the Municipality of Pristina recorded

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<sup>23</sup>Prizren Regional Hospital, interview with hospital director and coordinator of HIS (03 April 2017), examination of the program and its use by health personnel.

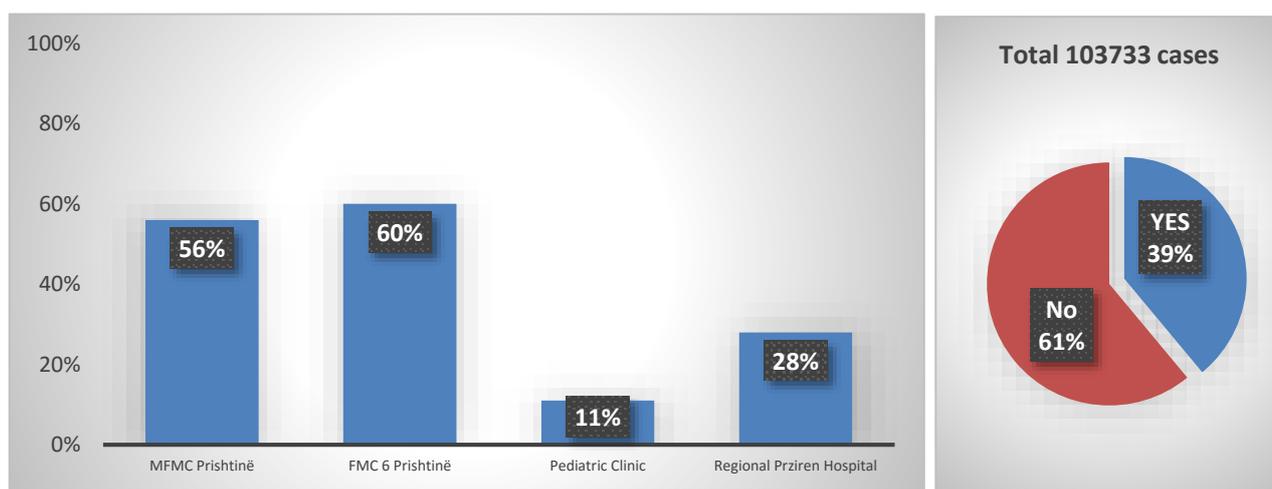
<sup>24</sup> Help-Desk interview with the head of this office (March 22, 2017); the examination of the functions released for the HIS program by the EO, and access privileges to the system by health personnel.

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approximately 60% of patients in the HIS. This low percentage indicates the level of use for the HIS program until May 2017, the period when the audit was completed.

The comparison of the data recorded in the HIS with those recorded in the health protocols has disclosed that in MFMC and two FMC in Pristina were recorded around 60% of patients in HIS. Compared with HIs which we have audited at the secondary and tertiary level, primary HIs in Prishtina use the most satisfactory level of HIS.

Figure 10 - Overall Patient Record Report at HIS in HI Pilots for the Period January-March 2017<sup>25</sup>

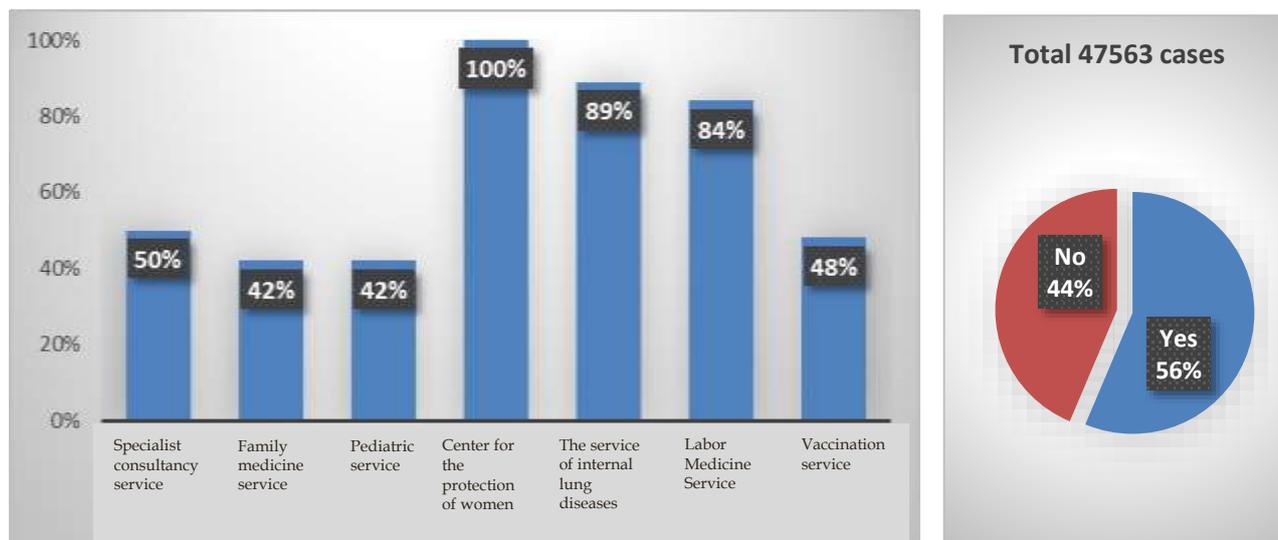


Referring to the above table, these data recorded in the HIS totaled approximately 39% of the recorded cases, while 61% reported to be recorded only in the protocols and not in the HIS in all audited HIs. Based on this percentage of its use by HIs which is not satisfactory for this pilot phase, it should be noted that at the same time these data are not accurate. This is because in certain cases we have noticed that patients have been recorded more than once in the HIS. This is because in the area for the personal number of the patient, the validation is not executed and as such can be left empty or other numbers added that do not belong to the patient's personal number.

Deficiency would be avoided if the field for the registration of the patient ID card would be mandatory and the application would not allow patient registration more than once. The lack of accuracy and completeness of data as a phenomenon is evident even in the old HIS system. This setback is attributed to negligence by the management and by staff within HIs who are responsible for recording accurate data as well as due to the ineffective functions of the program that we have evidenced during the audit.

To illustrate the percentage of HIS utilization in the units within the MFMC, we have shown the figure below.

<sup>25</sup> Patient Protocol and HIS Report - through HIS, March 2017

Figure 11 - Patient Record Report within HIS in MFMC for the period January-March 2017 <sup>26</sup>

In the table above we noticed that during the identification of patients at HIS within HIs for the period January - March 2017, in the total number of departments there are 47563 cases in MFMC - Prishtina. Out of these, three departments that are most prudent in recording data at the HIS are the center for the protection of women, the service of the internal lung diseases and the service of the medical work where the percentage of recording ranges from 84% to 100% , while in other departments recording rate of cases is 42% to 50%. In total, in these seven wards, 56% of data are recorded in HIS, while 44% remain recorded in the protocols. From this we understand that except that HIS is not functional in all departments within IHIs at the same time and in those where it is still functional is used at an unsatisfactory level by HIs.

Despite the fact that HIS is functional at the Pediatric Clinic providing Tertiary Health Service, which is also functional in the PHC and SHC, these three levels of healthcare provision do not have communication between them through HIS, a communication which would also enable the transfer or referral of patients between these levels.

In regard to this, the integration of the patient's treatment system is only the data population the HIS program although these data are inaccurate and are considered unreliable.

If we refer in general to the percentage of HIS utilization by His where we carried out the audit we can say that this percentage is below the right level.

<sup>26</sup> Patient Record Report in Protocol and HIs, MFMC Pristina - March 2017

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## 2.4 Monitoring, Coordination and Follow-up of HIS Implementation

Monitoring is a very important process which depends on the data, the means of verification, the available sources of data to be used and the methodologies to be used. The efficient monitoring and evaluation process provides a clear picture of the achievement of intended outcomes and objectives.

RHPZ management, UCCK management, PHC management in the Municipality of Prishtina and MoH as important factors have not put sufficient effort to encourage health personnel to use HIS despite the functional capabilities of the system. HIS Management did not establish mechanisms for monitoring and following-up the implementation of HIS. Despite these stagnation in monitoring the implementation of HIS, RHPZ management has taken a positive step to oversee system work. The director of the hospital, in January 2017, appointed a working group for overseeing the HIS works. RHPZ internal initiative, though late, can be considered as a good practice for pilot His involved in this stage of implementation.

According to AI No.11/2013, RHPZ appointed a HIS coordinator who addresses the problems and delays DHIS when it comes to using the HIS program by health personnel. Further on, the PHC in the Municipality of Prishtina and the UCCK - specifically the Pediatric Clinic appointed a coordinator to follow up the HIS system in all FMCs. The Coordinator addresses the issues of health personnel related to stagnation and barriers during the implementation of the DHIS system. If we refer to Table 9, we can notice the difference between the management of HIS, which despite all the assigned coordinators have not put sufficient effort to use HIS by health personnel.

It is important to note that during the distribution of hardware and network equipment, the process of handing over these equipment was done to the HIS coordinator within the pilot HIS and in special cases the HIS director also took part in handing-over event. The distribution of equipment directly to HIS indicates the lack of monitoring for this process by the MoH.

These setbacks have caused a number of other important barriers for the citizens of the country, where one of the most important is the development and implementation of the Health Insurance Fund System (HIFS). In this case, the delays in the implementation of the HIS are one of the reasons for delaying the implementation of the health insurance project as the HIS is a condition for the proper functioning of this project.

In May 2015, within the KSV/014 Project, a Lux-Dev evaluation of the implementation of the Health Sector Strategy in Kosovo was conducted. This report has generally highlighted the achievements and setbacks in the health sector within in the country. The assessment includes four components and one of these was the HIS assessment. Lags and delays were identified in the implementation of the HIS in this assessment as well. Further on, in this assesment report recommendations were given on how to act in the future.

Based on the strategy and AP for the implementation of the HIS, MoH as a responsible stakeholder was obliged to carry out the implementation for the HIS pilot phase at the end of 2014. Such an assessment by the MoH for the implementation of HIS in HIS has not been accomplished until May 2017 when the field audit work was completed.

A final assessment of the current implementation of HIS during the period 2010-2017 is indispensable in order to identify and address the setbacks to continue its implementation in the rest of the country. Its prioritization by the Government is necessary by creating working groups to eliminate obvious errors in order not to continue with these shortcomings in its overall implementation.

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### 3 Conclusions

The implementation of HIS in Kosovo is not fully functional and it results that it was not efficient and effective. Based on the planning made in the HIS Action Plan for its deployment and implementation in 30% of the country's territory, we have ascertained that MoH failed to put it in place by the end of 2015. The MoH stalled in reaching its objectives in terms of its implementation, from the five audited institutions we found that only 39% of patients were identified in the HIS and it is considered a low percentage of usability considering the fact that it is used only in certain departments and not in all departments planned for the pilot phase.

These setbacks have caused a number of other important barriers for the citizens of the country, where one of the most important is the development and implementation of the Health Insurance Fund System. In this case, the delays in the implementation of the HIS are one of the reasons for delaying the implementation of the health insurance project as the HIS is a condition for the proper functioning of this project.

Despite the efforts and costs incurred, implementation of the Health Information System project continues to have lag in implementation and is deficient as a result of which piloting has not been finalised in all HIs and was not assessed.

#### **NCHIS**

NCHIS is established with four years of delay and as a consequence failed to initiate the establishment of a working group for the AP review which was intended to address the setbacks and adaptation alongside the unfinished activities. Failure to update the AI for HIS and report on statistical health data causes ambiguity in the allocation of roles and responsibilities to relevant implementing parties, monitoring, evaluation and reporting as well as administrative and financial sanctions of HIS.

NCHIS did not develop monitoring mechanisms and procedures for coordination of activities between relevant institutions and stakeholders in the field of HIS. Also, it did not hold regular meetings to identify and address the gaps during the implementation. The meetings were held on an ad-hoc basis.

Failure to involve the NIPHK in the HIS has made it impossible to produce the required health reports for decision making and in general for the health system in the country.

Spending only 47% of the budget, including many payments in this spending which did not relate to HIS project shows the shortcomings in the overall budget process. In all HIs there was a lack of human capacities that were necessary for the implementation of HIS. Based on this, the prerequisites for the efficient implementation of the HIS have not been provided.

The allocated funds for the functionalization of the HIS project, MoH has spent for other purposes, approximately €407 thousand, or about 6% of the funds allocated for the purpose of functionalizing the HIS spent on other purposes.

Shortcomings in the coordination of activities between MoH and other parties such as: failure to coordinate with AIS to provide data center equipment for the implementation of HIS, NAPDP have made it impossible to update the data in the HIS.

In the absence of budget and inadequate planning, MPA failed to provide all equipment to MoH for the data center, it has offered for use some limited capacity equipment for HIS, therefore MoH has been obliged to implement this procedure which has lasted until the end of 2015. Although the MPA has provided services, the MoH has not implemented any agreement through which the responsibilities and obligations for service delivery would be determined.

MoH failed to develop policies, procedures or guidelines for user management. There is no definition and division of roles and responsibilities of users as well as their description as a result of lack of definition of role and responsibilities, users of the same level have different access rights to system functions. Failure to determine responsibilities may result in compromising data.

HIS possesses several domains but not all are functional as they are under development. Failure to functionalize the domains has prevented the coordination of the activities and their functional determination.

The support of the users for the services provided was not done by the network operating center but by the EO contracted by MoH. This service was not used efficiently, and one of the reasons was the restriction of free calls from Kosovo Telecom that was only for landline telephones and not for mobile phones and consequently no assistance was requested in all cases. Out of 3161 active users, only 9.6% have submitted cases for customer support.

PSMIS does not meet the needs of the institution even though as a system is implementable, this due to the impossibility of registering medications, generating reports, reconciliation of stock etc. The MoH has not yet put in place the PHCs needed to identify and authorize health care professionals.

Distribution of Physical infrastructure by 2013 was not done in all HIs where it was foreseen, even in HIs where the distribution did not cover all wards. We have noticed deficiencies in the financial control and management of contracts by the MoH during their implementation. Delivery of computer equipment in certain cases is done directly by the economic operator to the HIs, without being received by the MoH. Failure to provide the data center and software at the same time have made the hardware equipment unused and remain passive for a period of three years, resulting in amortization.

The reorganization of the preliminary data from the old systems to integrate into the HIS which would enable its full functionality was not in place. PSMS and human resources are not integrated into the HIS and as such disable the interaction between them. Failure to link with the human resources system also prevents proper tracking and identification of users, including their creation, suspension or de-activation. Failure to integrate PSMS causes inadequate planning of providing medication and prevents the provision of adequate service to patients. All this brings HIS to have partial information, functions resulting in its limited use.

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HIS is not functional in all primary HIs, it is only functional in MFMC, six other FMCs in the Municipality of Prishtina and some pilot HIs, but not in all departments within the pilot HIs in our case is within the Pediatric Clinic. While RHPZ experienced setbacks in use, health personnel do not fully use the system. They also do not report on a regular basis and do not use the “help desk” when facing obstacles and lags to address them when using the system.

HIS for internal needs use, dual systems, one of the reasons is the malfunction of HIS 24/7 which has directly affected its low utilization. Obstacles and frequent technical problems, mainly networking, were one of the main factors that impacted the low share of HIS utilization by HIs.

The HIS program is not being used at the appropriate level by medical personnel. The functions that this program offers are largely usable with some exceptions. The management of HIs did not hold accountable health personnel for the HIS utilization. Further on, the trainings organized for this program did not give the proper effect as in some His, trained health personnel have no basic knowledge about the use of the system.

The total number of patients in the HIS totaled 39% of registered cases while 61% only recorded in the protocols. Therefore, utilization of this program by HIs pilot is considered low. It should be noted that these data are not accurate and complete since there are cases when the same patients are registered more than once.

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## Recommendations

The recommendations below are intended to ensure that the responsible parties take the necessary steps to implement HIS properly

We recommend the MoH to ensure that:

- NCHIS updates the administrative guide for HIS in order to avoid uncertainties for relevant parties for more efficient implementation of HIS;
- NCHIS initiates working groups for revision of current AP in order to address the identified setbacks. With emphasis on creating monitoring and reporting mechanisms on the implementation of HIS. These mechanisms continuously monitor the work and report on a regular periodic basis to the responsible lines on achievements and setbacks during implementation;
- NCHIS meets on a regular basis to identify, review and address delays during the implementation of HIS in a timely manner;
- NIPH is involved in the pilot phase of the implementing HIS in order to utilize the data for drafting the necessary and general reports on HIS;
- Review the reasons for non-implementation of the HIS project according to the foreseen plan and receive adequate measures in order to increase the efficiency in using this fund and make this system operational as soon as possible;
- Whether the financial means intended for the HIS project, such as donors or the Kosovo budget, are used for this project only;
- Bring together and coordinate activities with internal and external stakeholders in order to provide legal and physical infrastructure and create the necessary prerequisites for more effective functioning and utilization of HIS so that there are no delays as they were evident in the pilot phase of the project;
- Address the human capacity issue in MoF and MPA to analyze and consider the requests addressed by the MoH to avoid obstacles for execution of the HIS;
- The agreement between CRA data exchange to be implemented fully, MoH to provide birth and deaths data for the CRA in order to enable data update;
- Consult with the NAPDP for the collection, processing, storage, and transfer of personal data for HIS needs, as well as based on the recommendations given, rules of procedure for their handling;
- NAPDP will carry out an assessment on using of citizen data by MoH and at the same time to assess whether this data is being used only by authorized users within CRA, MoH and His;

- Review the whole process of user management starting with their creation, handing over credentials, suspend and de-activate them and increase the level of security in terms of user management;
- Develop and implement the procedures and guidelines needed for the use and maintenance of HIS as well as determine roles and responsibilities of users;
- Functionalize the domains in a timely manner so that the activities are more coordinated;
- Plan the smooth running of services that expire in September 2017, regardless of whether they will be carried out by internal MoH capacities or outsourced;
- Distribution of physical infrastructure is done in all planned HIs. Evaluate the activities undertaken for implementation and identify all deficiencies and obstacles throughout the implementation of the HIS. These shortcomings should be identified and addressed in order to avoid the continuation of the project during its extension in the rest of the country;
- PSMIS and the HR will be integrated into the HIS to enable interaction between them through this we will have full and functional use of this program;
- Complete testing of HIS operation (processing, transmission and storage of data) will be carried out and the necessary measures will be taken to address the setbacks as a prerequisite for broad use in the rest of country;
- Hold HIs into account for using HIS, to oblige health personnel within HIs to use HIS as the primary health care system and at the same time to use the “Auxiliary Table” during obstacles and lags to address them during use of HIS system and report on a regular basis. Further on, the establishment of measuring indicators for the provision of services should be carried out and measurements and evaluations based on them should be executed;
- Identify and address all technical and operational obstacles to HIS use in order to eliminate the use of other systems;
- Training for HIS is organized in order to achieve the appropriate effect on the use of this program;
- Identify all patients at HIS in HIs Pilots. Review and restructure patient records that are registered more than twice in the HIS until this stage, in order to avoid duplicate registration, and continue registering patients only by personal number, not in other forms;
- To make regular registration and inventory of dedicated equipment for the HIS project according to legal obligations; and
- Notwithstanding the contract manager, MoH establish monitoring mechanisms that follow the execution of the services from the EO according to the contractual obligations.

## Appendix A –Agreement between Lux-Development and MoH and the HIS implementation phases

Based in the agreement between Lux-Development and MoH for Kosovo Health Support Program KSV/014 and after the approval of SHISK and AP, on behalf of this project a contract was signed between the contracting authority MoH/Lux-Development and the Economic Operator (EO), to provide the service for further development and institutionalization of HIS in Kosovo. This contract was signed in June 2011. The EO aims to support and develop the unique HIS. This objective of the project is planned to be achieved by considering the following three phases:

PHASE A - HIS development (201-2013), starting from the needs assessment to improve the existing health system, the establishment of technical infrastructure in pilot projects, and organizational, operational and legal infrastructure strengthening, putting in place electronic registers and nomenclatures and creating information infrastructure.

PHASE B - Pilot Implementation (2012-2014), pilot operation, support for data usage and regular reporting, strengthening of organizational and operational infrastructure, introduction of pharmaceutical management, introduction of health service portal, awareness raising and assessment Phase B.

Phase C - Deployment of HIS - in the country and the private sector involvement (2013-2020), which includes the further development of the technical information infrastructure, the integration of the human resource system, the presentation of the cost of care, the integration of the unique ID for the citizens, the continuous strengthening of the infrastructure organizational and operational, integration of health portal with HIS, further development of operational support operation, Phase C assessment and updating of HIS.

AP foresees all HIS implementation activities ranging from needs assessment, restructuring of the base data on existing data, preparation of infrastructure, preparation of HIS software, training of personnel directly involved in the use of HIS and other activities to the testing and evaluation of pilot phase which is scheduled to be implemented by the end of 2014.

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## Appendix B - Current Information Systems in MoH

Based on current information, MoH has for several years developed and implemented various information systems for data management and decision-making. These systems are presented below:

- a) The system for licensing private health institutions - is mainly used by the MoH in order to follow-up, issue and/or withdraw the licenses of private institutions providing health services;
- b) Health Inspection System - used for inspecting institution's compliance;
- c) Medical human resource system - used for:
  - Manage the licensing of professional medical personnel;
  - Manage and register the medical personnel specialization;
  - Manage and register the continuing professional education of medical personnel;
  - Manage the contracts of medical personnel.
- d) Pharmaceutical Inventory Management System - a system that should provide accurate information on the pharmaceutical stock, its scope has recently been modified and is divided into two (2) parts:
  - Primary health care - falling under the responsibility of the Ministry of Health, and
  - Secondary and tertiary Health care - falling under the responsibility of the Kosovo Hospital and University Clinic Service (KHUCS) and the Health insurance agency.
- e) Health Statistics Information System - used by NIPHK to collect statistical data,
- f) The health information system for detainees - is a modified HIS system used by the service to manage prisoner health information. It includes several functionalities and combinations of:
  - Human resources system;
  - Pharmaceutical stock management system;
  - Information system for health statistics.

But since it is an independent system due to its nature and the sensitivity of information, it is unclear how and to what extent information is exchanged.

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## Appendix C Responsibilities of internal and external stakeholders

Internal parties or those directly related to the implementation of the HIS

### **Ministry of Health**

In accordance with the provisions of the Law on Health (LoH) and the supplementary documents issued on the basis of this law, as well as ISHIS, MoH is responsible to:

- Provide the establishment, development and functioning of a unique and integrated health information system throughout the health sector;
- Propose, draft and ensure implementation of policies/strategies and legislation related to the development of HIS;
- Provide health care institutions (His) as well as responsible legal and physical persons who are required to collect health records, keep them and report them to the HIS, in accordance with the sub-legal act issued by the Ministry;
- Monitor and coordinate HIS of activities with different parties such as Pilot HISs that are responsible for the implementation of HIS within their organizational structure;
- Provide from the Ministry of Internal Affairs the transfer of the civil registry system as an important system with the data of citizens which is directly related to the population of HIS - with personal data;
- Provide the Ministry of Public Administration, respectively the information society agency, the space for the safe deployment of HIS equipment, the provision of equipment and related licenses, and to provide computer networking;
- Provide the state agency for the protection of personal data that personal data of citizens for medical needs from the MoH are used in accordance with the requirements based on the relevant legislation.

### **National Council for the Health Information System**

Responsibilities of NCHIS:

- NCHIS is an inter-institutional body and the highest body responsible for providing advice on policies, legislation and other issues related to HIS;
  - NCHIS is responsible for the coordination and development of HIS. It is a compilation of strategies and policies. Develops and supervises the implementation of the HIS program, Government advice on priorities and allocation of resources for the development and implementation of HIS, adoption of regulations, standards, technical regulations and guidelines for the development and implementation of HIS;
  - Establishes mechanisms and procedures for coordinating activities between state institutions and other relevant stakeholders that are related to HIS;
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- NCHIS also monitors and prepares reports to the Government on developments in this area;
  - NCHIS should draft a work regulation through which the responsibilities of council members, quorums, meetings, participation and agendas, meeting procedures, voting procedures, minutes of meeting etc. are foreseen;
  - NCHIS establishes working groups including qualified and experienced experts to assist NCHIS in the implementation of its functions and responsibilities.

**National Telemedicine Center of Kosovo** - monitors and reports on regular basis on the implementation of the HIS - including its maintenance and operation. It plans financial, human and technological resources on regular operation, as well as initiates procedures for the engagement of the economic operator for maintenance. It contributes to the data being secure and qualitative.

It provides access authorizations on data sources and registers as required and relevant data protection legislation.<sup>27</sup>

At the beginning of 2016, EO is contracted to provide full system maintenance and implementation services. This six-month contract was extended in September 2016 for an additional one-year period. After the contracting of the EO, DHIS members were appointed to the commission for evaluation and monitoring of contract execution by the EO. This contract is referred to as NOC<sup>28</sup>-Outsource and we will use the same reference below.

Under this contract, DHIS sends to the EO for NOC Outsource the list of health personnel generated by the Human Resources system. In this case, in cooperation with the Heads of the HIS Sector, clinics directors are contacted within the KHUCS and the staff to attend the training is selected, a list which is forwarded to the EO for NOC Outsource, which executes the training of the personnel.

**Health Care Institutions** monitor the workflow of the HIS unit and take all measures to ensure full and accurate records of the data. They provide the optimal working conditions for the HIS unit (offices, equipment required for the smooth running of all applications, staff required for HIS operation and job description of staff). HI prepares reports on the progress of the system. It ensures full confidentiality of the data. It ensures the issuance of periodic reports. Ultimately with all these duties and responsibilities, the assessment of HIs is done<sup>29</sup>.

**National Institute of Public Health of Kosovo** - It reorganizes the data source, reorganizes the central database, develops procedures for consistent data collection. After their reorganization and completion in order to be (accurate, complete, timely and complete) they are made ready for integration into HIS.

In addition, NIPHK is the primary healthcare institution responsible for issuing accurate data reports and qualitative towards the MoH for national needs and decision-making as well as against

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<sup>27</sup> AI (Health) No.11/2013 Health Information System and Statistical Reporting in Kosovo

<sup>28</sup> NOC - Network Operations Center

<sup>29</sup> ibidem

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national and international health organizations such as the Statistical Office of Kosovo (SOK), the World Health Organization (WHO), the European Community Statistical Office (Eurostat), and other health institutions. In this institute there is a HIS department that collects the data generated by HIs. These Institutions report based on AI No.11/2013 on a monthly basis<sup>30</sup>.

The reporting method of HIs to the NIPHK is executed through the forms named HIS 001, HIS 002 and HIS 003, but this form of reporting is manual.

The quality of data interpretation is crucial for determining and identifying indicators and regular reports on morbidity, mortality, malignant and chronic non-communicable diseases, and so on.

**Kosovo Hospital and University Clinical Service** - It is a unique, integrated healthcare institution that consists of public secondary health care institutions (General Hospitals and UCCK) as its organizational units including professional services as organizational and functional units.<sup>31</sup> Responsible clinics report to UCCK, while UCCK, together with general hospitals, report to KHUCS.

**Public primary health care institutions** such as: Main Family Medicine Centers and Family Medicine Centers are responsible for the implementation of HIS and to report to the Municipal Health Directorates.

External parties that have an indirect impact and provide support for the implementation of the System.

**The Ministry of Public Administration**, namely AIS - manages and oversees the implementation of information technology related projects in public institutions<sup>32</sup>. It ensures the security and protection of electronic communications and data infrastructure, provides space and conditions for proper functioning of HIS equipment and systems placed under the auspices of AIS.

**The Ministry of Internal Affairs** - through the Civil Registration Agency (CRA) is the owner and a civil registry administrator who contains personal data. Citizens' Civil Register (RC) is one of the key elements as a prerequisite for initiating the HIS. Along with the MoH they have drafted an agreement for access and exchange of data from the civil registry for the needs of MoH, which will be used for HIS, but will also exchange data from MoH for the needs of MIA. Part of this agreement is also NAPDP having an independent status, which has legal responsibility for overseeing the implementation of rules on personal data protection.

**National Agency for Personal Data Protection** - is an independent state institution, established on the basis of the Law on Protection of Personal Data. It is responsible for overseeing the legitimacy

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<sup>30</sup> Administrative Instruction (Health) No.11/2013 Health Information System and Reporting of Statistical Health Data. Article 7, According to this instruction, HIs are obliged to send data through the electronic network (internet) from every HIS unit in each institution, every month no later than the 5th of the following month, unless this operation is defined in a special way.

<sup>31</sup> The Charter of the Kosovo Hospital and University Clinical Service, Chapter 5, p.3

<sup>32</sup> Law no. 04/L-145 on governmental bodies for information society

of processing personal data. It guides on issues related to the protection of personal data, including the interpretation and implementation of relevant laws regulating the processing of personal data.

#### **The agreement between the MoH, CRA and NAPDP for the use of personal data of citizens**

There is a need for the use of data of the citizens for the provision of health services by the MoH and the need for providing these data has urged these parties to enter into an agreement between MoH, CRA and NAPDP defining their responsibilities and obligations. At the same time, along with this agreement, standard operating procedures have been drafted. These procedures correctly foresee the extent to which personal data of citizens received from CR can be used, and provide data during their exchange, provide traces and other functions.

This agreement also defines the use of CR by the MoH for the needs of HIS functionality - - using this registry through an electronic web service that enables electronic exchange between the systems of the parties involved.

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## Appendix D Relevant Infrastructure for the HIS

### Law on Health

Law 04/L-125, aims to provide a legal basis for maintaining and improving the health of citizens of the Republic of Kosovo through the promotion of health, prevention activities and the provision of comprehensive and qualitative services.

This law also defines health institutions as data owners and among other things responsible for maintaining and managing data in a regular and safe manner.

### Administrative Instruction (Health) No.11/2013 on Health Information System and Statistical Data Reporting

The purpose of this AI is to regulate how the HIS functions as well as the reporting of statistical data collected with this system in function of adequate planning, program and rapid and efficient quality management of health services.

Public and private HIs are obliged to implement AI No.11/2013. In addition, this AI defines the location of the central base in the HIs, the communication between HIS database levels, data usage, access, confidentiality and reliability, data collection, responsibilities of each HIs, responsibilities of each healthcare staff within HIs, time limits, inspections and administrative and financial sanctions.

### European directive, law and regulation regarding personal data protection

The European Commission Directive No. 95/46/EC<sup>33</sup>, according to the recommendations published in the “Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services<sup>34</sup>” from the European Union Health Program at the Point of Rights on Patient Data states that ‘data subject’ enables a range of rights to their data. These include the right to access the data, the right to be deleted and corrected, and the right to be informed of who is accessed by these data”.

Law no. 03 / L-172<sup>35</sup>, defines personal and sensitive data, defines the subject’s rights in relation to personal data, but does not specifically address personal health data.

Regulation No.03/2015<sup>36</sup> on security measures in the processing of personal data, approved by the state agency for personal data protection, defines appropriate organizational and technical measures as well as logical technical protection of personal data and the prevention of unauthorized

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<sup>33</sup> [http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46\\_part1\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf)

<sup>34</sup> [https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws\\_report\\_recommendations\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_report_recommendations_en.pdf), faqe 10

<sup>35</sup> Law on Personal Data Protection

<sup>36</sup> [http://www.amdp-rks.org/repository/docs/2015\\_03\\_ashmdhp\\_rregullore.pdf](http://www.amdp-rks.org/repository/docs/2015_03_ashmdhp_rregullore.pdf)

or deliberate destruction, detection, alteration, unauthorized access and use of data or their sudden or intentional loss of personal data processing by public and private bodies.

### **Strategy for HIS in Kosovo and Action Plan**

The main objectives of HIS strategy are:

**Objective 1:** To create and develop HIS infrastructure, including legal infrastructure, organizational infrastructure, human resource structure and economic resource structure.

**Objective 2:** To create and further develop electronic processes and methodologies for collection, storage and analysis of data, and creation of information technology infrastructure.

**Objective 3:** Further develop the evidence-based decision-making method at all levels of the healthcare sector and for all participants in the healthcare system.

**Objective 4:** Full integration of the private sector, creation of a patient's electronic file and preparations for the establishment of hospital information systems.