Kosovo eHealth Feasibility Study Development

Final Report

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Abbreviations

AIS, ASHI	The Agency for Information Society
ARBK	Business Registration Agency of Kosovo
BHIS	Basic Health Information System
CBK	Central Bank of Kosovo
COTS	Commercial off-the-shelf
CRA	Civil Registry Agency
DSHB	Prisons' Health Department
DSIS	Department of Health Information System of MoH
DWH	Data warehouse
EHR	Electronic health record
EPPV	Post-Vaccine Adverse Effects Monitoring System
ERP	Enterprise Resource Planning (is typically a software suite of integrated applications — that an organization can use to collect, store, manage and in-terpret data from these many business activities)
ESB	Enterprise Service Bus
FHIR	Fast Healthcare Interoperability Resources
FMC	Family Medical Center
FMIS	Financial management information system
GWP	Gross Weighted Premiums
HFA	Healthcare Financing Agency
HIE	Health Information Exchange
HIF	Health Insurance Fund (of Kosovo)
HIFIS	Health Insurance Fund Information System
HIIS	Health Insurance Information System
HIS	Health Information System
HMIS	Hospital Management System, Hospital Management Information System
HPM	Healthcare purchasing mechanisms
HW	Hardware
ICT, IT	Information and communications technology
KHIF	Kosovo Health Insurance Fund (same as HIF)
KHUCS	Kosovo Hospital and University Clinical Services
KMA	Kosovo Medicines Agency
MASHT	Ministry of Education, Science, Technology and Innovation
MIS	Management Information System
MLSW	Ministry of Labor and Social Welfare

FMC, MFMC	Family Medical Center, Main Family Medical Center
MOH	Ministry of Health
MDM or MDMS	Master Data Management System
MPA	Ministry of Public Administration
NCBTK	National Center of Blood Transfusion Main Center of Kosovo
NIPHK, NIPH, IKShPK	National Institute of Public Health of Rep. of Kosovo
ODS	Operational data store
OPDBS	Outpatient Drug Benefit Scheme
PAS	Patient administration system
PHC	Primary Health Care
PHF	Public Health Facility
QRShP	Regional Public Health Centers
QSHM	Mental Health Center
SIMBNJ	Human Resources Management Information System (HRMIS)
SMSF	Pharmaceutical Stock Management System
SOA	Service-oriented architecture
SW	Software
TAK	Tax Authority of Kosovo
UCCK, QKUK	University Clinical Centre of Kosovo
UP	Pristina University

1 Summary

The Ministry of Health (MoH) plans to invest in further development of national eHealth system in Kosovo. MoH needs to revise the current status of eHealth developments in Kosovo, to be able to re-think the approach, and decide about national digital health architecture and plans for future development. To trace the route for establishing the environment for such comprehensive development, the MoH started this Kosovo eHealth Feasibility Study (or Study, in this document) that is supposed to provide strategic direction of the digital health development agreed with major stakeholders (*MoH, National Institute of Public Health - NIPHK, Health Insurance Fund - HIF, Primary, Secondary and Tertiary Health Care Providers, QKUK, KMA, NCBTK, Health and Pharmaceutical Inspectorate*) in Kosovo. The Study comes up with recommendations on ways to use current and past development and plan the architecture, systems and approach in the short and long term.

Overview

With a strategic government decision to invest in a national eHealth system, Kosovo can make significant strides in improving the quality of healthcare services for its citizens in the medium-term period from 2023 to 2030. While this goal is ambitious, it is attainable with key prerequisites that need to be ensured. Most of them are emphasized in detail in the Study.

Strong political will is necessary but not sufficient, and since such national projects span beyond the timeframe of a single electoral cycle, it is important to secure national consensus among all political actors. Synergy among all stakeholders and their sincere readiness for change, coupled with clear leadership at both the strategic and operational levels, are essential. Based on the experiences of other countries successful in implementing and utilizing eHealth, **having a national eHealth body** responsible for coordinating, leading, and managing eHealth projects is crucial, making it one of the first steps we proposed. Regardless of how and where this body will be established (whether within the Ministry of Health, as an independent state agency, or as an eHealth Department inside AIS), it is important that it exists and has the authority, resources (human and financial), and expertise in managing complex healthcare IT systems.

Another important pillar for successful eHealth development is a **secure, robust, and reliable infrastructure for information and data exchange in healthcare, commonly known as Health Information Exchange (HIE).** HIE is a technology solution that enables healthcare providers and organizations to electronically share patient information between systems that are not usually connected. HIE facilitates the exchange of standardized digital documents, which may include lab results, prescriptions, or other relevant information for the treatment of individual patients.

In summary, the successful development of a national eHealth system in Europe is based on healthcare data exchange infrastructure, a **legal framework for data protection, collaboration among stakeholders, and education and training** for healthcare workers and patients.

Considering the size of Kosovo and the previous investments in building the government's state IT infrastructure (Government Gateway – GG is one part of it), as well as the existing legal frameworks promoting the use of GG in state institutions and organizations, including its current utilization in connecting hospitals, clinics, and health centers, we see the GG platform as the infrastructure for constructing a **central Health Information Exchange (HIE)**. Leveraging the GG platform and adopting interoperability standards like HL7 FHIR can enhance Kosovo's eHealth system, facilitating seamless data exchange, scalability, and future growth while considering associated complexities, costs, and required expertise. Establishing the HIE will create conditions for exchanging patient medical data among healthcare providers, where **primary, secondary, and tertiary-level public service providers must**

have their respective healthcare systems (BHIS, HMIS, LIS, RIS, etc.) capable of generating, sending, and retrieving patient data to and from the central EHR. The **national central EHR** serves as a vital building block in the first phase of establishing basic eHealth system services, expected to last until 2026. In the subsequent period from 2027 to 2030, further development should focus on introducing telemedicine systems, expert systems aiding clinical decision-making, and additional services that facilitate citizens' access to and quality of healthcare.

Action plan

Based on our analysis, experiences of other countries and considering the current state of eHealth development, aspirations, and priorities of the Ministry of Health in Kosovo, we have divided the activities for creating and implementing the national eHealth framework into the following stages:

- **Phase 0 - Capacity Building**: This phase focuses on establishing the necessary organizational requirements for successful eHealth project execution in Kosovo. Key elements include the implementation of the Kosovo eHealth Strategy, the establishment of the eHealth Body responsible for project oversight, the development of standards, procedures, and a legal framework, as well as the setup of project and product management processes. Additionally, creating the required hardware infrastructure is crucial for enabling all eHealth projects, including servers, PCs, networks, printers, etc.
- **Phase 1 – Core medical systems in public institutions and centralized EHR**: The goal of this phase is to develop a centralized EHR system and implement information systems in public healthcare institutions over a period of approximately three years. This involves installing core medical systems like Laboratory Information Systems (LIS) and Radiology Information Systems/Picture Archiving and Communication Systems (RIS/PACS) in hospitals and ambulances to collect patient medical information. It also includes implementing Hospital Management Information Systems (HMIS) and an e-Referral system. Successful completion of Phase 1 will provide essential eHealth services to citizens/patients in Kosovo, similar to successful implementations in other EU nations. Phase 1 is planned to last approximately 3 years, with an expected **completion by the end of 2026.**
- **Phase 2 - Expansion to private institutions, enhancement and telemedicine**: Phase 2 focuses on connecting private institutions, completing the EHR implementation, and introducing additional non-high-priority core medical systems such as Dentistry Information Systems and Emergency Information Systems. It also involves full implementation of eServices like e-Appointment and e-Prescription1, as well as incorporating telemedicine capabilities. Furthermore, a comprehensive Data Warehouse (DWH) system will be established to enable various analyses for improving service quality, optimizing costs, and better resource planning. Phase 2 is planned to last approximately 2.5 years, with an expected **completion by the end of 2028.**
- **Phase 3 - Artificial Intelligence (AI) and Decision Support Systems (DSS)**: The focus of this phase is on the integration of AI and DSS into the eHealth framework. The implementation of AI technologies and decision support systems aims to enhance healthcare services and improve decision-making processes. Phase 3 is projected to last for 2 years, with an expected **completion by the end of 2030.**

A major concern with this ambitious plan, in addition to the aforementioned factors, is the large number of activities to be undertaken within a relatively short period, particularly in the first three years. Coordinating and overseeing these activities with a limited number of individuals currently working on the establishment of the eHealth system poses a significant risk as to whether everything can be completed within the desired timelines. Furthermore, hiring additional resources may prove challenging

[1] The eServices can be started even in Phase 1 and implemented with some extend of functionalities, but comprehensive versions should be finished after the complete implementation of core systems in Phase 1

and time-consuming due to the scarcity of IT professionals in general, and especially those with experience in eHealth. Therefore, relying on external partners and public procurement for system acquisition and development while maintaining control over project management, IT system support, and product management is recommended.

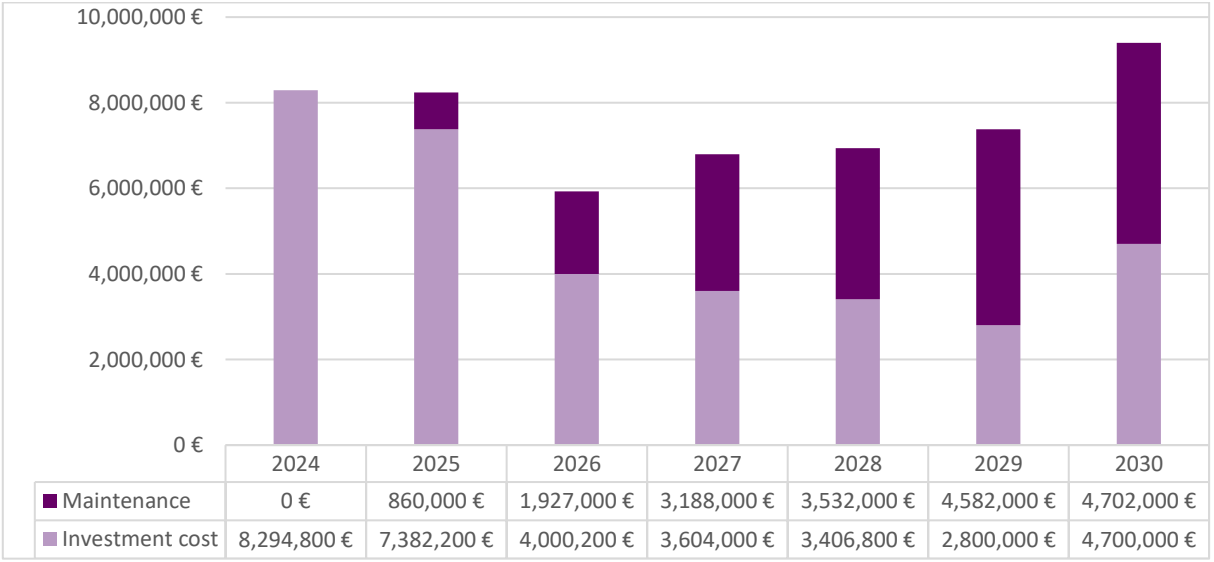
Investment plan

The financing of such healthcare infrastructure is a matter of public interest and is typically funded under healthcare financing models, regardless of the specific model in place. **Healthcare digitization usually accounts for 3-5% of the total healthcare expenditure**.[2] On other hand, the **national healthcare ICT average spend in EU is between 2-3%**[3]. However, besides the amount, it is crucial to ensure a consistent and secure source of revenue since, like any infrastructure, ongoing upgrades and maintenance are necessary to keep it useful and functional. Moreover, when aiming to rapidly address the current low level of maturity in Kosovo's eHealth sector, substantial initial investment funds need to be allocated, necessitating consideration of alternative sources of financing. While this study did not explore all potential external funding options for such projects in Kosovo, healthcare digitization and digitalization initiatives are typically eligible for financing from international financial institutions and funds (e.g., World Bank, EU funds, etc.) as well as donor organizations already present in Kosovo.

Investment plan by phases and by years are shown in the tables below.

Phase	Investment	Maintenance	Total
0	€ 5.558.000	€ 0	€ 5.558.000
1	€ 14.160.000	€ 15.539.000	€ 29.699.000
2	€ 6.970.000	€ 3.132.000	€ 10.102.000
3	€ 7.500.000	€ 120.000	€ 7.620.000
TOTAL	€ 34.188.000	€ 18.791.000	€ 52.979.000

***Note**: here "Investment" means initial project cost from initiation to production/acceptance, while "Maintenance" is in average 20% of initial cost per year over the remaining years until 2030*



	2024	2025	2026	2027	2028	2029	2030
Maintenance	0 €	860,000 €	1,927,000 €	3,188,000 €	3,532,000 €	4,582,000 €	4,702,000 €
Investment cost	8,294,800 €	7,382,200 €	4,000,200 €	3,604,000 €	3,406,800 €	2,800,000 €	4,700,000 €

Figure 1: Total cost of eHealth projects (investment + maintenance) per year

[2] Source: https://peaketechnology.com/healthcare-it-budgeting-101/

[3] Source: https://assets.gov.ie/16174/092e7c62f97b472b83cdb6dfdcdfd5c7.pdf

Risks

Implementation of a new eHealth system on a national level is a complex undertaking that bears a number of risks. These risks need to be recognized, and then managed through suitable mitigation measures. Risk assessment involves identifying and analyzing potential risks and challenges that may impact the successful implementation of eHealth initiatives in Kosovo. The planning process of the development of such large-scale projects must include a risk-assessment as there are many factors that can impede the success of the undertaking. It is important to outline key risks and ways to mitigate the risks identified. The mitigations are measures or implementation strategies, which should become an integral part of all projects' activities at different levels.

Here is the list of the high-level risks:

Risk level	Area of risk	Risk	Likelihood	Impact	Mitigation measures / strategy
High	Institutional	Insufficient number of qualified IT personnel with required knowledge	High	Medium	Develop a plan for continuous education in ICT field and eHealth solutions for healthcare professionals. Introduce direct and indirect motivation of ICT professionals working in the healthcare system: professional development and training of ICT staff at the required level, participation in specialized trainings in ICT field, encouraging the development of ICT staff and exchange of knowledge.
High	Technical	Inadequate connectivity, power outages, or lack of technical infrastructure required to support eHealth applications	High	Medium	Prepare infrastructure development plans and contingency measures and implement them continuously.
High	Institutional	Legal and managerial barriers (outside the influence of the implementers) for realization of the required changes	Medium	High	Establish strong eHealth governing body, build capacities of all stakeholders involved especially for project management, monitoring and evaluation. Engage political support. Lobby for the adjustment of the legal and regulatory framework. Make efforts to communicate plans clearly to all parties involved, including citizens.
High	Technical	Inadequate quantity and or/quality of needed IT infrastructure (hardware)	High	Medium	Invest in IT infrastructure according to investment plan and ensure additional funding for its maintenance and renewal.
High	Technical	Inadequate compatibility and interoperability of existing healthcare systems	Medium	High	Prepare and implement standards and protocols to ensure seamless data exchange and integration between different healthcare providers and their IT systems.

2 Introduction

This Final Report presents the major parts of the **Feasibility Study**, including an outline of the assessment of the Kosovo eHealth environment, as well as a quick review of the eHealth development plans, with an emphasis on the initial recommendation provided by consultant in its first report. **The main sections of the study are the eHealth Development Framework and the Action Plan for Framework Implementation**, which provide stakeholders with strategic and operational guidelines on how to establish an advanced long-term national digital health infrastructure until 2030. The initial investment plan is offered at the end, with a provisional estimate of investment for each action plan item, as well as an indication of feasibility and risk assessment.

3 Outline of the assessment of Kosovo eHealth landscape

During the initial phase of the Study, that has been concluded with "Report 1- Assessment of Kosovo eHealth landscape with initial recommendations", an evaluation was conducted on the existing ICT solutions within the main stakeholders, as well as other solutions that could be considered components of the national eHealth ecosystem. This document is a result of a brief consultant assessment based on the field visits, open discussions with responsible representatives during the visits, a couple of technical presentations of existing systems, online surveys and questioners prepared by the Consultant, and discussion with key representatives of the main stakeholder during 2 workshops.

3.1 Key findings and insights

There are important efforts and investments done in the last few years in eHealth solutions and systems in Kosovo, but these observation are still valid, "the Health Information System (HIS) is highly fragmented; data and documentation regarding the population, minorities, regional areas, and the private sector are lacking, and the country does not have a universal electronic medical record system…", "…crucial to establish a strong HIS to enable the systematic and timely collection of data, as well as the analysis of health-related data, required for the planning, implementation, and evaluation of the health status of the population. A HIS capable of generating the information required for monitoring the population's health and with strong interinstitutional cooperation, can monitor trends and track indicators that need to be reported to the WHO, CDC, EUROSTAT, and other related entities."4

The efforts to make one centralized web-based solution (BHIS) for primary health care facilities, even though without continued maintenance and support in the last years, has shown that the concept has been right and has brought some quick results.

3.1.1 BHIS

Despite the lack of proper support and maintenance for the BHIS system, it's remarkable that the MoH has managed to keep it in usage with their own limited resources. The fact that all 29 primary health medical centers, including Main Medical Family Centers and most of their Family Centers and Ambulances, are currently using the system is a testament to its importance in the healthcare system.

Usage

It's good to see that the usage of BHIS system is increasing over the years, as indicated by the rising number of registered visits in the Main Medical Family Centers (MMFC) (See Figure 2). This suggests that healthcare providers are finding the BHIS system useful and are relying on it more to manage patient care and medical records. The new BHIS' maintenance and support contract will further enhance the system's capabilities and ensure its continued success in improving healthcare outcomes.

Based on BHIS usage statistics provided by MoH, we can see that the number of patients that are the first time registered in the BHIS is rising year over year in every MMFC from 2019-2021.

[4] Berisha M, Ramadani N, Basholli FM, Jerliu N, Humolli I, Tahirukaj A, et al. Self-assessment of essential public health operations in Kosovo (Original research). SEEJPH 2022, posted: 11 May 2022. DOI:10.11576/seejph-5458

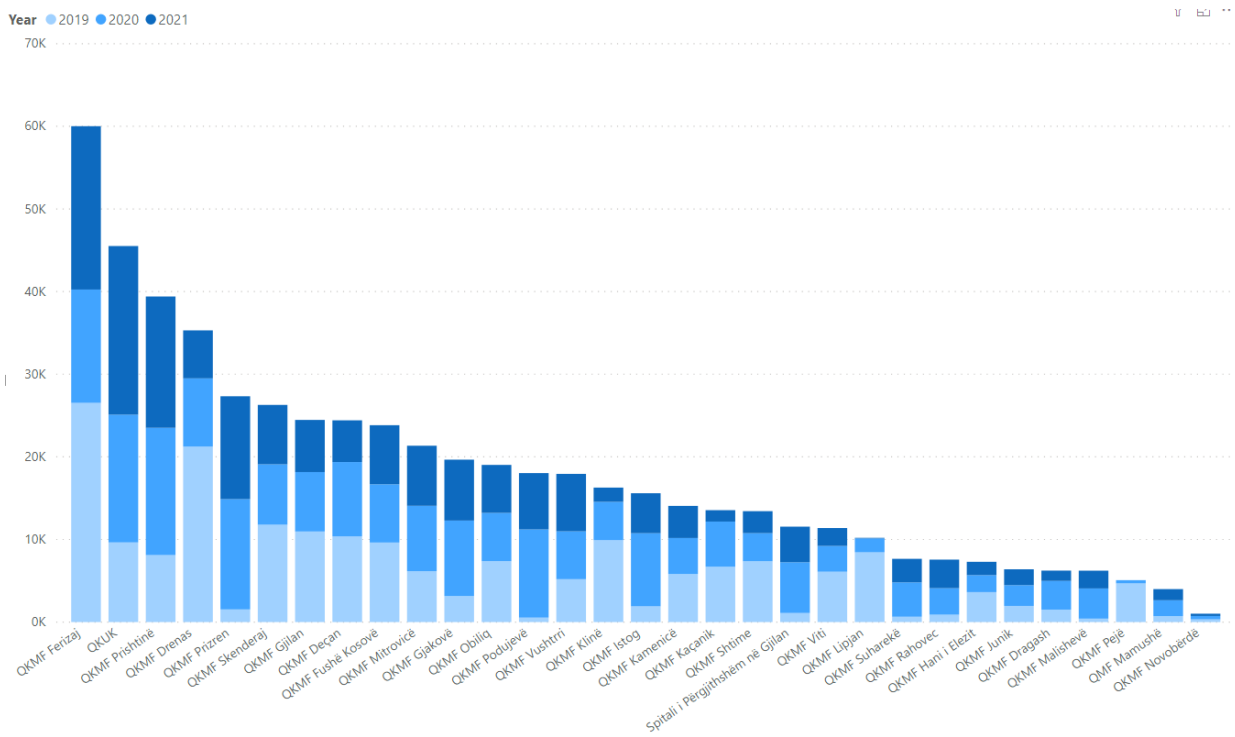


Figure 2: Registered patients in BHIS by public health providers from 2019-2021

Similarly, from usage statistics, it can be seen from the number of registered visits that MMFC are using BHIS more over the years.

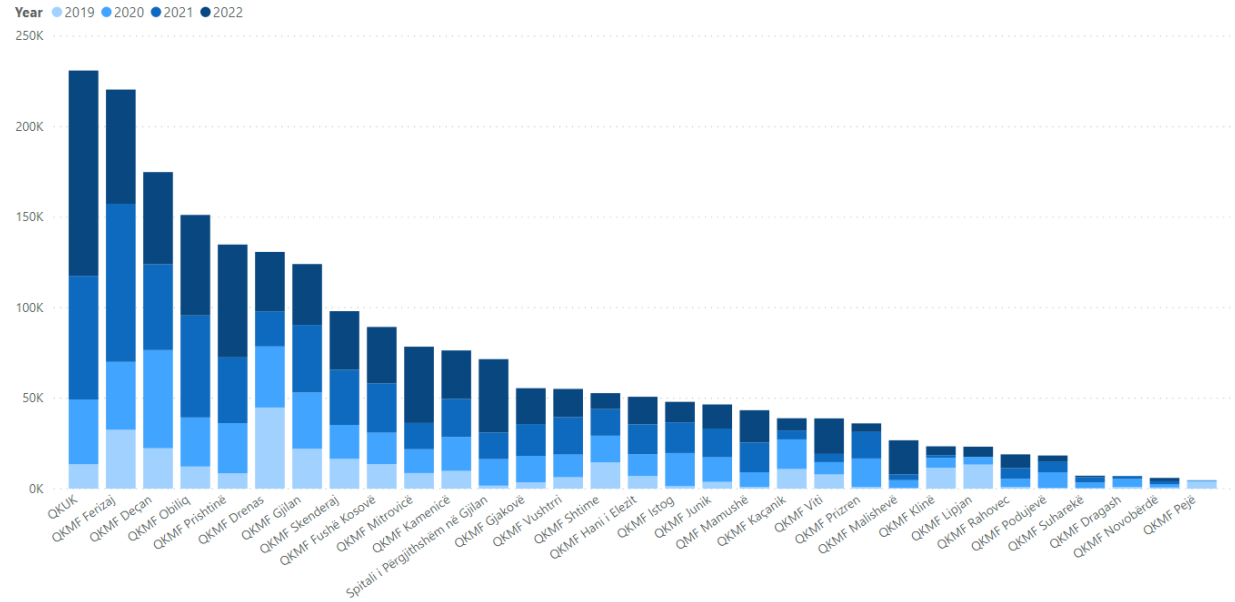
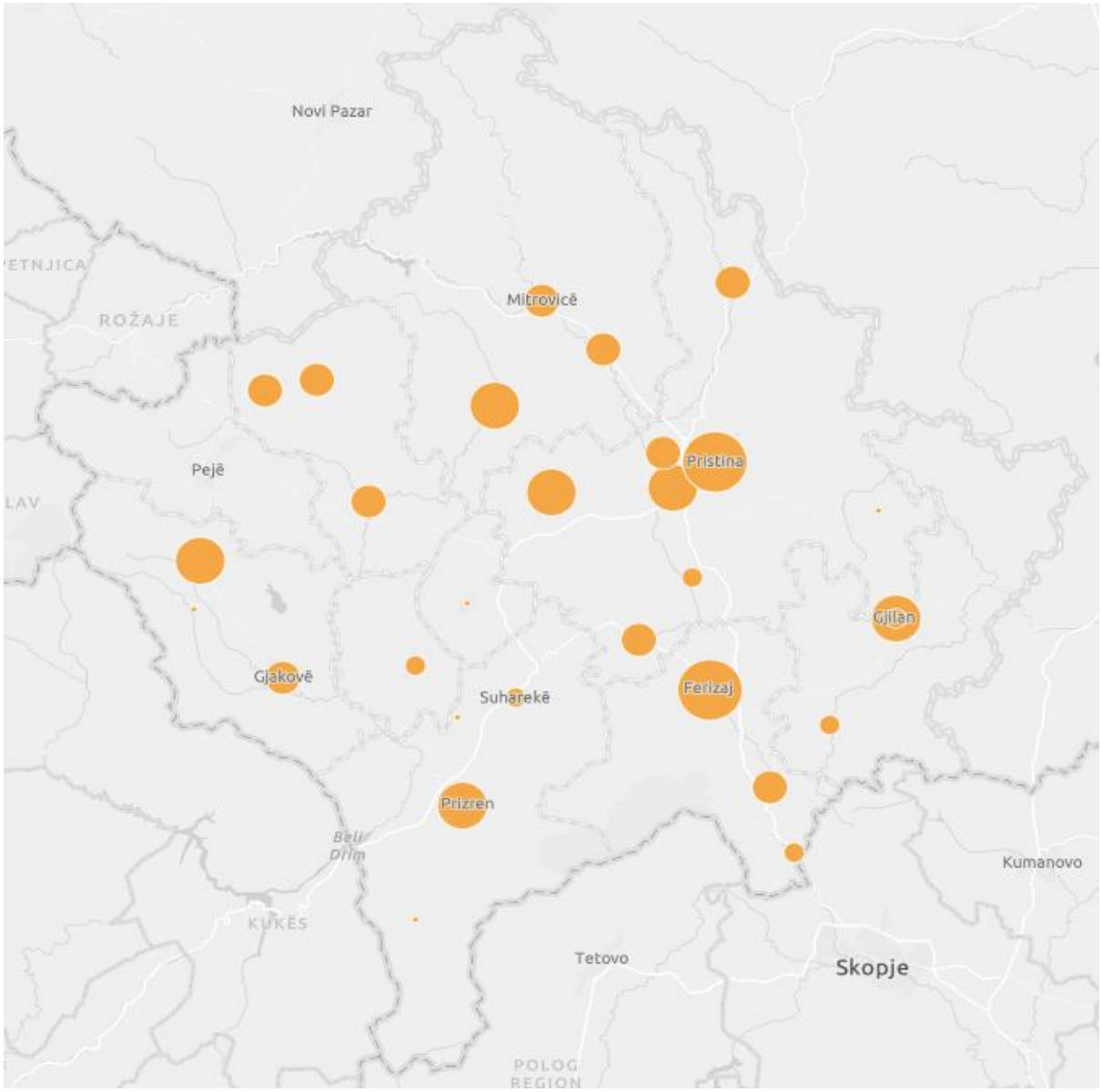


Figure 3: Registered visits in BHIS by public health providers from 2019-2022

The geographic distribution of initial patient registration in BHIS is an important indicator of the system's reach and impact on the healthcare system in Kosovo. By analyzing the distribution of initial patient registrations, we can gain insights into where the BHIS system is most widely used and where it may need more support or resources. Moreover, analyzing the geographic distribution of initial patient registration in BHIS can help healthcare providers and policymakers identify areas that may require additional resources or support to improve healthcare outcomes. For example, regions with smaller bubbles may need more outreach and education about the BHIS system to encourage more patients to register and use it, while regions with larger bubbles may need more resources to manage the increased volume of patient data and visits.



While more data such as population data, facility coverage area, and end-user training provided would have been useful to make a more precise analysis of BHIS usage by health facility, the data presented in this rapid assessment are still solid indicators of the current growth in use. The rising number of patients being registered in the system and the increasing number of registered visits over the years indicate a positive trend towards the use of the BHIS system.

Therefore, while more data would have been useful to gain a more precise analysis of BHIS usage, the available data still provide valuable insights into the current state of the system and suggest that there is potential for further growth and adoption of the system in the future.

Analyzing user feedback through a questionnaire is a valuable way to gain insights into the user experience and identify areas for improvement. While the sample size of 53 responses is relatively small, it can still provide useful information about the BHIS system from the perspective of its users.

By focusing on collecting feedback information about BHIS from the user point of view, the questionnaire can help identify issues and concerns that may not be apparent from a technical or administrative perspective. This can include usability issues, training needs, and other factors that can affect user adoption and satisfaction.

Overall, analyzing the collected responses from the questionnaire can provide valuable insights into the user experience of the BHIS system and help identify areas for improvement to enhance user satisfaction and adoption.

The major benefits are shown in the table below:

Major benefit	**Count**	
Less paperwork	6	31,6%
System is user friendly and easy to use	6	31,6%
Better service for patients	2	10,5%
More time for patients	2	10,5%
System helped me to be more efficient	2	10,5%
Data are always accessible	1	5,3%
Grand Total	**19**	**100,0%**

The major challenges are shown in the table below:

Main challenges	**Count**	
A lot of problems with printers	7	25,90%
Internet connection is not good enough and reliable enough	4	14,80%
System is nonfunctional most of the time	4	14,80%
System is not integrated with other institutions	4	14,80%
System has a lot of bugs	3	11,10%
Lack of training	2	
There is a lot of paperwork	2	
The system is not integrated in all other departments and institutions	1	
Grand Total	**27**	**100,0%**

What is your role?	Doctor	
Main challenges	**Count**	
A lot of problems with printers	1	12,5%
Internet connection is not good enough and reliab	1	12,5%
System has a lot of bugs	1	12,5%
System is nonfunctional most of the time	2	25,0%
System is not integrated with other institutions	1	12,5%
There is a lot of paper work	2	25,0%
Grand Total	**8**	**100,0%**

What is your role?	Coordinator	
Main challenges	**Count**	
A lot of problems with printers	5	38,5%
Internet connection is not good enough and reliable enough	2	15,4%
Lack of training	1	
System has a lot of bugs	1	7,7%
System is not integrated with other institutions	3	23,1%
The sistem is not integrated in all other departaments and institutions	1	
(blank)		
Grand Total	**13**	**100,0%**

It is obvious that the biggest problem is the infrastructure, in particular with printers, but there is a significant percentage of users, especially doctors, who complain about the system's malfunction, a large amount of paperwork, and bugs and lack of integration with other systems. This is not surprising considering that BHIS has not been maintained for more than 3 years.

Overall comment about technical capabilities of the system

The fact that a total of 904,270 people who received at least one dose of vaccine were registered in the BHIS vaccination module, and a total of 1,836,002 vaccinations were registered in total, is a strong indicator of the BHIS system's technical capabilities and its ability to handle large volumes of data.

The BHIS vaccination module's successful implementation and use highlights the system's reliability and efficiency. Despite certain technical problems like network issues, internet connectivity, and printer problems, the BHIS system was able to support a large number of users and effectively register vaccination data.

The successful implementation of the BHIS vaccination module can be attributed to the system's technical solution and its ability to handle large volumes of data. It's a testament to the system's scalability and ability to support a high volume of users, even in challenging circumstances.

Additionally, the lack of maintenance and support for few years has resulted in the system not having new features and not fixing all bugs, which may impact user satisfaction. The assessment also indicates that some users are not utilizing the system despite its availability, highlighting the need for better user training and promotion to increase user adoption. Overall, the successful implementation of the BHIS vaccination module demonstrates the system's technical capabilities and its ability to support critical healthcare processes like vaccination.

3.1.2 Legacy Systems

So-called legacy systems include the following systems:

- PSMS - Pharmaceutical stock management system
- HR - Human Resources
  - Health Worker (alb. Punetori shendetesor)
  - Module of Specialist Trainees
- Health Institutions Licensing

All systems are developed as web application on Microsoft technology stack (#C, ASP.NET MVC5, Net Framework 4.6.1, MS SQL Server, Microsoft Report Builder in RDL format, etc.). The application follows a three-tier architecture, which separates the application into three distinct layers: presentation

layer, business logic and data access which are located inside the same solution and hosted on the application server.

Pharmacy Inventory Management Software (PIMS)

The pharmacy inventory management software is a crucial module within the proposed Health Information System for Kosovo, designed to optimize the management of medication inventory and streamline pharmacy operations. This module encompasses various sub-modules and functionalities that support efficient inventory tracking, stock management, medication ordering, and medication safety. The implementation of the system started in January 2019.

The main modules within the pharmacy inventory management software component include:

- Pharmacy Workflow Management
- Inventory Tracking and Stock Management: The inventory tracking and stock management module enables pharmacies to monitor and track medication inventory in real-time. It provides functionalities to capture and update inventory data, including medication quantities, expiration dates, lot numbers, and storage locations.
- Medication Ordering and Replenishment
- Medication Dispensing and Barcode Scanning: The medication dispensing, and barcode scanning module ensures accurate and safe medication dispensing to patients.

Currently MoH and Healthcare institutions of all levels have this system in place with total number of 1511 active users, but what is currently missing is the integration of this system with KMA, e-Prescription and other related modules to insure the track and trace of the drugs and pharmacy inventory.

Health Worker Module

Implementation of the system started in 2019. Users of the systems are from Primary and secondary level health providers. Total number of active users: 42, Health staff: 6775, Health staff - primary level: 4493, Health staff - secondary level: 2282, Technic staff - secondary level: 339

Currently system has following main modules and functionalities:

- Registration of employee data
- Registration of licenses
- Registration of education
- Work experience
- Registration of contracts
- Reports

Health Specialist Trainees

Implementation of the system started in 2020 with redesign on 2022 with additional functionalities. Users of the systems are: Ministry of Health (1), Clinical mentors in health institutions (349 users), Committees according to types of specialization (22 users), Specialist trainees (2668 users).

The system has following main modules and functionalities:

- Opening of application period
- Application for specialization
- Acceptance of documentation
- Written test and interview
- Registration of the decision

- Registration of the contract and appointment of the clinical mentor
- Registration of the passbook
- Follow-up by committee and clinical mentor
- Colloquium evidence
- Interruption requests
  - Temporary
  - Permanent
- Completion of the syllabus
- Specialist exam

Health Institutions Licensing

System is used in Ministry of Health for supporting the processes related to Health institutions licensing and in private hospitals and non-hospital institutions. Implementation of the system started in 2020. In systems are registered: Licensed institutions; General hospital: 4, Special hospital: 8, Health institution with one activity: 836, Health institution with two activities: 121, Polyclinic: 93. Currently in the system are 1432 users.

The system has following main modules and functionalities:

- Applications
  - New Application and renewal application
    - Account opening
    - Completing the schedule of the institution
    - Selection of application category
    - Choice of services
    - Registration of personnel
    - Selection of ICD9 services
    - Documents
    - Payments
    - Case sending to board
    - Licensing/Refusal
  - Application for change of address
  - Application for additional activities
- Requests
  - Request for staff change
  - Request for change of staff schedule
  - Request for business termination
  - Request for change of business name
  - Request for activity termination
  - Request for suspension of the health institution
  - Request for cancellation of the suspension
  - Request for license revocation
  - Request for addition of ICD9 services
- Reports

Plans for further development and integration of all Legacy systems includes:

- Link with ARBK and other systems as needed
- Fully digitalized health institutions pharmacies
- Implementation in all health institutions up to the last level (patient supplies)
- Link with the Chambers systems
- Access of board members to the system Health Institutions Licensing.
- Implementation to clinical mentors and specialization committees for future application periods.
- Implementation of the Health Worker system in QKUK, DShB, Mental Health Center
- Link to e-Kosova for the specialist module.

3.1.3 NCTBK

The transfusion information system has been in use at NCBTK - Prishtina since 2005 and meets most of the NCBTK requirements. It is planned to implement the system in regional transfusion centers in 2024.

What is missing is the hospital monitoring of information on the traceability of blood products when they reach the health facilities from the transfusion centers, i.e. there is no information on where and on which patient they were used.

In the short term, the system should be improved by connecting regional transfusion centers, and in the long term, the implementation of the hospital information system must include monitoring of the traceability of transfusion procedures to the patient.

3.1.4 HIF

The HIF has invested considerable into the HIF Information System (HIFIS) development. The system has been tested and about 1.000 users are trained to use it. The system provides basic functions for maintenance of the registry of beneficiaries, revenues collection (including online tool for individual premium payments) and service payments. Connection to external systems is automatized for civil registry, exempted categories scheme, tax administration and banks. The system is based on solid architecture and technology, well tested, but considering the HIF is still not managing packages and purchasing services, the system is not in full use. It still needs to reach its mature utilization that will reveal additional functional, technical and fine-tuning requirements. Therefore, the technical assistance for health insurance reform may face the need for additional support for the HIFIS implementation.

The system consists of these modules:

- Finance and accounting,
- Register of members,
- Register of social schemes,
- Collection of Premiums from businesses,
- Individual Premiums,
- Health institutions,
- Pharmacies,
- Register of pharmacists,
- Medicines and health services,
- E-Prescription,
- E-Patient,

- Administration,
- Assets,
- Support Tickets System

Through these modules, the management and administration of the fund's finances is enabled; information about the number of insured beneficiaries; data from social schemes are provided, which according to the law are beneficiaries of health insurance; reporting and collection of premiums from businesses is enabled; issuing payment orders to all citizens who do not have the status of "insured" and wish to voluntarily be part of the insured; the contracting of pharmacies is enabled and the provision of services through E-Prescription is allowed; the service of determining the reimbursement percentage from the Fund for medicines and health services is provided; the module enables the access of all pharmacies contracted by the Fund and the provision of medicines for patients according to the defined reimbursement list; providing information to the patient regarding the status of the health insurance fund and access to the history of services and medicines received is enabled; through this module it is enabled to register, depreciate, re-evaluate and alienate assets. Also, identification is made with a unique code (barcode) for all assets that are registered; reporting problems in the system by end users and handle them by the system administrator is enabled. Also, through this module, end users have the possibility to evaluate the problem handled by the system administrators.

System is integrated through Government Gateway (GG) with external systems such as civil registry, exempted categories scheme, tax administration and banks (i.e. CRA, TAK, CBK, KMA, MFT).

The Health Insurance Fund Information System (HIFIS) was developed by a local company (DataProgNet) Although the HIFIS has been implemented, tested, and accepted, the system is not yet fully operational because the HIF is not yet fully functioning as an insurance fund, i.e., it has not yet begun collecting premiums/ contributions from businesses and individuals and paying/reimbursing local health care providers. The only business process that the HIF currently supports is treatment abroad.

An accurate evaluation of the implemented HIFIS requires that the HIF fulfil its statutory role in financing the health care system to ensure the performance and quality of the HIFIS. Nonetheless, the discussions and presentation of the system seem to indicate that the vendor is delivering a solid system based on current technology, good integration capabilities, and data security standards.

The main potential perceived risks so far detected are the lack of ICT staff in the Fund, and under capacity of Fund as organization, operational practice and experience of health insurance business processes and IT support in daily operations because the system is still in pre-production phase.

Some suggestions for additional activities to be considered before full production:

- make performance and stress testing of the system in full production with the planned number of concurrent users
- perform “dry runs” for data integration, data migrations, help and info desk procedures as organization, back-up and recovery scenarios and procedures exercise before “go-live” date whenever it would be, to be technically and operationally ready for full production start
- make refreshment trainings and education for internal and external users few weeks before production
- the additional integration of student status information, if possible API
- make plans to implement DRG payment methods in HIFIS (integration with grouper, online inpatient claim submission/intake, adjudication, business rule engine definitions, fraud detection tool, reporting and analytics
- make plans for the creation of a module to support capitation in primary care.

3.1.5 NIPHK

Center for Health Statistics is responsible for:

- Collection of health information data from health institutions of all three levels of health care (including the private one); checking, processing and presentation of data.
- Checking and guaranteeing the quality and quantity of reported data.
- Preparation of regular periodic reports which are sent to the Ministry of Health
- Preparation of additional reports according to the request of the Ministry of Health and interested agencies based on preliminary contracts.
- Preparation of specific analyzes for various problems at the request of the Ministry of Health
- Preparation of specific analyzes on various problems at the request of interested Agencies based on special contracts.
- Undertaking practical measures in the direction of advancing health information: monitoring and control of institutions, holding trainings, seminars, preparation of manuals and international classifications, etc.
- Identification and proposal of necessary measures for the advancement of SISH to the Ministry of Health and implementation of changes after approval by the Ministry of Health.

All statistical processes are done manually, collecting data either in excel forms or in paper form, cleaning it and then importing it in excel and prepare statistical reports. The process is time consuming, completely manual and they don't manage to finish it in real time due to lack of a staff.

3.1.6 KMA

The Kosovo Medicines Agency (KMA) is responsible for licensing of importers and quality control of medicines present on Kosovo market.

The main information system that supports most of the KMA's business processes is named "AKPPM – Barnatari" and support the following business functions:

- Marketing Authorizations for medicines in Republic of Kosovo (RK)
- License for wholesalers for medical products and devices in RK
- License for pharmacies in RK
- License for import of medicinal products
- License for import of medicinal devices

Most of the processes are digitalized and are realized through web application. Subjects (businesses) have their account in the system and can apply for all kinds of services depending on the type of their license via the web site application (Barnatari – extranet). All of the applications are also processed via the web application (Barnatari – intranet). The system sends data to other institutions (e.g. Customs - in which case new applications are sent in 30-minute intervals via GG).

The system is developed by local vendor, on Microsoft technologies and currently satisfy KMA's business needs.

3.1.7 eHealth Systems currently not present

Hospital Information System (HMIS)

Hospitals in Kosovo don't use any comprehensive HIS, just some parts of BHIS for keeping medical records of outpatients. Building EHR on the national level is a key strategic point for eHealth in Kosovo, and it cannot be done without HIS up and running in all hospitals. Also, hospitals are complex (number

of employees, operating costs, complexity of the processes, sophisticated equipment ...) to be managed without comprehensive HIS system that will help them to be more efficient.

Laboratory Information System (LIS)

Laboratory Information System (LIS) is an application whose main purpose is to automate processes in clinical laboratories. It is built around a centralized database of samples and any meta data, results, workflows, and instruments associated with them. This not only allows a laboratory to remain organized, but also facilitates efficiency, transparency, and compliance. We recommend implementing LIS system in all public healthcare care institutions that have clinical laboratory and integrate it with BHIS/HIS so they can act as an complete EMR system of the institution. Before integrating it, LIS can work as a standalone solution that serves only laboratory department.

Picture Archive Computer System (PACS)

A PACS is a medical imaging technology that is used to store, manage, and distribute digital medical images, such as X-rays, CT scans, MRIs, and ultrasound images. This technology replaces traditional film-based systems that are time-consuming and costly, and often require physical transportation of the images between different locations. PACS is not limited to radiology, as it is also used in *other* medical specialties that use medical imaging, such as cardiology, pathology, and dermatology. PACS systems can be customized to meet the specific needs of different medical specialties, and can be integrated with other healthcare information systems, such as Electronic Health Records (EHRs) and Radiology Information Systems (RIS), to provide a comprehensive solution for managing medical imaging data.

Radiology Information System (RIS)

A Radiology Information System (RIS) is a software that is designed to manage and automate the workflow and data associated with radiology departments in healthcare facilities. Its primary objective is to manage patient data, imaging procedures, and the distribution of diagnostic reports and images to healthcare professionals. RIS is commonly integrated with other healthcare information systems, such as Electronic Health Records (EHRs) and Picture Archiving and Communication Systems (PACS), to provide a comprehensive solution for managing medical imaging data.

3.2 Challenges

Infrastructure

The most significant issues associated with BHIS in its current operation have been highlighted through discussions with users and experts from partner companies who have built and/or maintained the system, as well as through user feedback collected via online surveys. They are related to ICT infrastructure, specifically 1) primarily the unavailability or disruptions of the network (internal and internet connections), 2) the number and reliability of printers, as well as 3) the availability of toners.

	Issues
Network	In some PHC facilities locations, LAN/WAN networks are not fully installed, while in some smaller clinics it is not at all, although in most MMC/FMC it is. Part of the PHC representatives expressed dissatisfaction with frequent Internet outages during work hours, so work with the system was disabled during that period because BHIS is an online web application that does not support offline work.

	Issues
	The VPN network is part of the government's infrastructure, which is the responsibility of the The Agency for Information Society (AIS) and health providers are just one group of the network users.
Printers	The majority of user complaints relate to problems with printers. Primarily, there are not enough of them for more efficient work (e.g. one printer in several offices, so often the patient is sent to go get a printed report/prescription and then return to doctor office with the printed report for a signature and stamp). An additional problem is that the printers are often broken, so the insufficient number of printers is further reduced when they are not working.
Toners	There were also complaints about the frequent lack of toner, so that the printers do not work. The problem is expressed by the fact that the State has entered into a service contract with two local companies responsible for the maintenance and supply of toners. While this centralized contract may be suitable for administrative bodies and agencies that operate in 8x5 mode and do not have need for higher SLA, this is a major drawback in the healthcare sector and especially in healthcare facilities that operate in 24x7 mode.

The average number of PCs per employee

The number of PCs per employee in a general hospital can vary depending on a number of factors, including the size of the hospital, the department or role of the employee, and the hospital's budget for technology.

In the EU, larger hospitals generally tend to have a higher ratio of PCs to employees, often providing each employee with their own computer for efficient record-keeping and communication. This can range from one computer per two to three employees in smaller hospitals to one computer per each employee in the larger hospitals.

It's also worth noting that some hospital employees may require access to specialized equipment, such as medical imaging workstations or research computers, in addition to their regular office computer.

In following table, between others it is presented the average number of PCs per employee in general hospital in Kosovo, based on interviews data collected in March 2023.

Table 1: General Hospitals PC statistics

General Hospital	Employees	Beds	PCs	IT staff	PC per bed	PC per employee
Ferizej	300	90	80	1	0,89	0,27
Gjakova	560	419	120	1	0,29	0,21
Gnjilani	550	360	200	2	0,56	0,36
Mitrovica	417	183	120	1	0,66	0,29
Peja	576	400	135	2	0,34	0,23
Prizren	730	550	220	2	0,40	0,30
TOTAL(s)	**3133**	**2002**	**875**	**9**	**0,44**	**0,28**

The best ratio has General Hospital Gnjilani and the lowest General Hospital in Gjakova.

Note: Consultant has not received the data for QKUK

Lack of IT staff

The health care sector in Kosovo is facing a serious challenge due to the lack of IT professionals. IT professionals are essential for the digital transformation of health care services, which can improve the quality, efficiency and accessibility of health care delivery. The reasons for this shortage include the rapid pace of technological change, the high demand for IT skills across various sectors in Europe and abroad increased "ICT brain drain", the low attractiveness of IT careers for young man and women in public sector, non-competitive payrolls levels and models in public health institutions for ICT professionals and the insufficient supply of IT education and training.

The shortage of IT professionals in the health care sector is a common challenge faced by many countries, and it can have significant implications for the quality and efficiency of health care services. Investing in attracting, retaining, and upskilling IT professionals is crucial for achieving digital transformation in health care, which can improve patient outcomes and reduce costs. Additionally, fostering collaboration and innovation among different stakeholders can help create a more supportive environment for the development and implementation of new technologies in health care. Overall, addressing the shortage of IT professionals in the health care sector requires a multi-faceted approach that involves collaboration and coordination among different actors, including government, private sector, and educational institutions.

Definitely current assessment showed limited number in all key stakeholder institutions, as well in primary health care and public hospitals. Only UCCK has a greater number of IT staff. Just as a benchmark about the number of ICT staff in health sector, based on data from Cedefop (the European Centre for the Development of Vocational Training) in 2020 in EU member states, from all employees in "health & social care" sector, there has been 0,5% employees in categories ICT professionals.[5] (0,33%) and ICT technicians.[6] (0,17%) but it is huge growth in respect to data from 2015 when there has been just 0,1% of ICT professionals and only 0,06% of ICT technicians in the in the "health & social care" sector.[7]

Main stakeholders:

Institution	ICT staff
MoH	5 (should be 24 by approved organization chart)
UCCK	20 (8 ICT professionals + 12 ICT technicians)
NIPHK	3 (in Central office)
NCBTK	1
HIF	1
KMA	1

[5] Information and Communications Technicians (ICT technicians) support the design, development, installation, operation, testing, and problem-solving of hardware and software.

[3] Information and Communications Professionals (ICT Professionals) conduct research, plan, write, test, provide advice and improve IT systems, hardware, software and related concepts for specific applications.

[7] https://www.cedefop.europa.eu/en/tools/skills-intelligence/sectors?sector=06.16#2

General Hospitals:

General Hospital	IT staff
Ferizej	1
Gjakova	1
Gnjilani	2
Mitrovica	1
Peja	2
Prizren	2
TOTAL(s)	**9**

3.3 Main risks of the current state

At this moment, we have identified the following risks that can impact the successful development of eHealth in Kosovo.

1. Implementation of health insurance law may have huge impact on HIFIS (mainly with the claim part)
2. Implementation of health insurance law may have huge impact on HIS when health institutions financing model will be changes and health facilities should issue the invoice (health insurance claims) for their services
3. The shortage of IT professionals can seriously affect the eHealth development plans
4. The incompleteness and reliability of the ICT infrastructure in PHFs can seriously affect the plan to implement BHIS in full capacity

3.4 Quick assessment of the eHealth development plans

The plan for the development of eHealth for 2023-2024 prepared by MoH appears to be very ambitious and comprehensive. MoH is planning to finish the development of the BHIS for outpatients and its full implementation on all three levels of healthcare. When BHIS is fully implemented in public healthcare institutions it is planned to start the implementation of BHIS (outpatient) in the Health Institutions of the Private sector so BHIS would become the unique EHR at the national level, containing all medical documentation except for the one created during hospital stays.

Above this, full implementation of ePrescription is planned, and also the development of several new modules (Inspectorate, Surveillance, Zoning - digital selection of the doctor, Patient portal).

The plan also poses potential risks and challenges, including the need for adequate budgets and resources that could cause delays in implementation. The extensive number of interdependent projects requires competent project management skills and additional staffing. Experience from other countries indicates that such projects may take more than five years (examples of long-lasting countries' eHealth projects development has been presented in Report 2 of the Study and also detail process of developing eHealth system in Estonia can be found in article "Ten Years of the e-Health System in Estonia"[8]). Nevertheless, with sufficient budgets and resources secured for implementation and efficient public procurement, the systems can be completed within the proposed timeframe. The plan also requires additional staffing, particularly for the Project Managers role, in the DSIS (Department of

[8] https://ceur-ws.org/Vol-2336/MMHS2018_invited.pdf

Health Information System of MoH). Although these activities are included in the plan, it is essential to begin them as soon as possible to enhance capacity.

Overall, it is important to carefully consider these potential risks and challenges, as well as the potential benefits of the plan, to make informed decisions about its implementation and priorities in implementation. A detailed and well-planned strategy, including stakeholder engagement and risk management, will be essential for the success of these projects.

In addition, we identify the following **potentially risky** decisions/choices with far-reaching consequences that might need detailed analysis before decision:

1. BHIS implementation at all three health level institutions for outpatient – Public institutions

This decision is not just a short-term solution but has far-reaching consequences for the entire future information system of the hospital and means that the medical part of HIS will be implemented by BHIS. If in the future it is decided to procure a unified HMIS and keep BHIS for outpatients, it would mean that medical documentation for outpatients would be done in one system and for inpatients in another system, which would cause difficulties for physicians who would have to use two different systems, which is not common.

2. BHIS implementation at all three health level institutions for outpatient – Private institutions

Implementing BHIS in private institutions can be one option to consider, but there is also another approach. Private institutions can be offered the BHIS as a free solution to use or be allowed to independently procure/retain the EMR system of their choice but with a duty to send defined patient data set to the central EHR.

However, private and public institutions may have different IT system's needs due to various factors, and there are few other potential issues to consider:

- **Budget**: Public institutions are government-funded and may have a limited budget for IT infrastructure and maintenance. As a result, public hospitals may not have the resources to invest in the most advanced IT systems, even if the budget comes from government funds. In contrast, private institutions may have more financial resources and can afford to invest in more advanced IT systems, giving them a competitive advantage.
- **Different complexity/different functional requirements**: Public institutions sometimes have a larger patient base and are more complex, requiring IT systems that can handle this complexity. They may also need to manage data from various departments such as laboratories, radiology, and pharmacy. The IT system used by public institutions must be able to manage and integrate data from different sources seamlessly. In contrast, private institutions may have less complex clinical processes but a more complex managerial part. Therefore, they may prioritize other functions such as customer relationship management (CRM) and enterprise resource planning (ERP), or Business Intelligence tools for financial, operational, and strategic management. Additionally, the Health Insurance Fund (HIF) requirements vary depending on the fund that is paying for the service.
- **Different regulation rules:** Although some procedures may be the same for all healthcare institutions defined by the healthcare law, public institutions may have to comply with more government regulations and standards for IT systems. Compliance with these regulations can be challenging and require significant resources. Private institutions, on the other hand, may not have to comply with all the same regulations as public hospitals.

Furthermore, private health providers might have already invested in some IT systems, sometimes even more than one (LIS, ERP, RIS, PACS). Therefore, implementing BHIS would be a difficult task requiring additional investment and effort.

4 Kosovo eHealth Development Framework

4.1 eHealth Conceptual Architecture

The building block approach within the eHealth system in Kosovo involves a comprehensive development strategy. This approach encompasses various elements, including business objectives, principles and methods of information systems design, data management, technological platforms, implementation and deployment, stakeholder analysis, requirement management, and organizational aspects. It addresses the questions of who does what, why, when, and where at different levels of granularity, such as scope, strategy, logical and physical design, implementation, and change management. Three crucial principles underpin this approach: architecture (building blocks and artifacts) repository, reusability, and standardization (interoperability).

It is crucial to highlight the evolution of different architectures and their interactions within the ecosystem. The interoperability feature of the architecture serves as the foundation for the proposed strategy, providing undeniable evidence of ICT's potential to effectively address needs. Information system architecture plays a pivotal role in the design of the architecture, particularly concerning different types of interoperability.

Seeing the current situation with health digitalization in Kosovo and the important efforts and investments done in the last few years, also seeing the challenges with highly fragmented HIS and the lack of communication and integration among different systems and modules, the figure below illustrates a selection of key processes that are essential to consider when undertaking health digitalization and defining building blocks.

Figure 4: Kosovo's proposed Building Blocks of eHealth Conceptual Architecture

This figure represents a distributed and comprehensive framework for health digitalization, consisting of interconnected sections that encompass various facets of the healthcare system. Each section represents a distinct set of processes and functions that contribute to the overall digital transformation of healthcare.

The first section: **Core Medical Systems** - focuses on the fundamental processes involved in collecting medical data and delivering basic medical services, such as collecting citizen's medical data from outpatient and inpatient healthcare visits, maintaining accurate registers of chronic diseases, contagious diseases, cancer, and other relevant health information.

Moving to the second section: **eServices** – the emphasis shifts towards digitalization of the services that enhance the organization and efficiency of health processes, remote health services, enabling better resource utilization and workflow management.

The third section: **Governance** – include processes that provide valuable support to enhance healthcare governance at various levels, from local communities to national and international settings. Examples of these include services and applications supporting Public Health Institute (NIPH), Ministry of Health and other relevant stakeholders.

And the final section: **Administration** – focuses on the Master Data Management and SSO – User management. Master Data Management ensures that information remains consistently reliable, up-to-date, and readily accessible, empowering users with the confidence to make informed decisions. Single Sign-On User Management feature orchestrates a harmonious symphony of user authentication and access control, streamlining the intricate process of managing user identities across various platforms. Administration section cements the framework's stability, elevating it to new heights of efficiency and functionality.

It is important to note that the structuring of the building blocks within these sections does not imply their isolation or varying levels of importance. On the contrary, all building blocks are interconnected and mutually dependent.

The first two sections primarily focus on centralized the **Electronic Health Record** and emphasize the significance of data integration. It is essential to ensure that the EHR contains comprehensive and accurate data about every patient, which should also be accessible for the citizens through the Patient Portal. These sections will also provide data for different medical registries like: NCD (Non-communicable Disease) Registries, Communicable Disease Registry, etc.

By establishing a strong foundation and interconnections among these processes, the healthcare system can leverage the full potential of digitalization. This includes enhancing patient care, facilitating remote healthcare services, enabling efficient collaboration between healthcare professionals, and ensuring the seamless flow of information for improved decision-making and overall healthcare outcomes.

To achieve this, it becomes crucial to establish *legal frameworks*, administrative regulations, and standardized procedures that regulate the minimal requirement dataset needed to be sent to EHR by providers, access, privacy, and security of EHR data, ownership of data, as well as define the specific data elements that should be reflected in the Patient Portal and data exchange for remote health services and collaboration of health professionals through telemedicine.

The EHR data collected through the services and applications outlined in the Core Medical Systems and eServices sections should be seamlessly shared and exchanged between public healthcare institutions and licensed/authorized private healthcare institutions with the main goal to improve the patient care.

To facilitate seamless data sharing and ensure comprehensive patient care the approach for exchanging EHR data between private health institutions and the government's Health Information System (HIS), involves private health institutions having their own Health Information Systems that are interconnected with the government HIS.

The (Figures 5-7) below illustrate the architecture and key components that are currently included and should be part of the eHealth system in Kosovo. Technically, communication between all the blocks and involved parties (private institution, pharmacy, private clinics) should be facilitated through the Government Getaway (GG), which is the national platform within the framework. Also, it is important during the implementation of the system and its individual blocks to consider that for private institutions, a communication form (API). should be created so that the data they generate can be adapted to the Healthcare provider database as an entity with the same data format in the national eHealth system. Below is a brief description of how the blocks should communicate with each other using the GG platform: (Figures 5-7).

Patients will be able to interact with the eHealth system through various channels such as the Patient portal, mobile application. They should have the ability to access their electronic health records (EHR), schedule appointment, receive e-prescriptions, and securely communicate with healthcare providers like Hospitals, Clinics, and Pharmacies, that will be connected to the eHealth system via interfaces or APIs provided by the GG platform. These interfaces should enable the exchange of data, including patient medical information, appointment scheduling, e-Prescriptions, and referral requests. The EHR system will be integrated with the GG platform through standardized protocols such as HL7 FHIR. This integration will allow for the secure exchange of patient data between the EHR system and the GG platform, ensuring that healthcare providers have access to comprehensive and up-to-date patient information. The e-Prescription system and the GG platform will involve the use of standardized protocols like HL7 messaging. When a healthcare professional generates an e-prescription, it will be securely transmitted through the GG platform to eHealth system and then be able to retrieve by the pharmacy system for processing and dispensing. The GG platform will integrate with appointment scheduling systems through APIs or standardized protocols like HL7 Appointment Scheduling. This integration will enable real-time exchange of appointment-related information, allowing patients to view available time slots and book appointments directly through the e-Kosova platform. For e-Referral system, the GG platform will facilitate data exchange of the electronic referral process by securely transmitting referral requests and patient data from healthcare providers to the referred healthcare providers' systems. Standardized protocols like HL7 Referral and Authorization should be used to ensure seamless communication and information exchange. Telemedicine systems should be integrated with the GG platform through secure video conferencing solutions or existing telemedicine platforms. The integration of telemedicine allows GG to be used solely for text-based consultations through the system, where two doctors can communicate with each other for diagnosis descriptions, reading radiological images, etc. But for video-call services, it should be used the telemedicine module that is currently being used at QKUK, where this module uses CISCO devices for video communication (with secure channel via VPN) Based on recommendations from the expert group at ASHI, GG, as a platform, does not currently support video call communication/connection.

Integration between the Blood Transfusion Information System (BTIS) and the GG platform will involve implementing standardized interfaces using protocols such as HL7. This integration will enable real-time exchange of data related to blood inventory management, compatibility testing, cross-matching, and transfusion documentation. The PHC system will integrate with the GG platform using interoperability standards like HL7 FHIR, facilitating the exchange of patient data, medical history, diagnoses, treatment plans, referrals, and other relevant information between PHC systems and the GG platform.

Integration between the HMIS and the GG platform will be achieved through interfaces or APIs for exchanging data related to patient management, discharge summaries, billing, and administrative functions. Standardized protocols like HL7 FHIR will ensure interoperability between the HMIS and the EHR. LIS will integrate with the GG platform using interfaces or APIs provided by the LIS vendors. This integration will enable the transmission of lab test orders and results between the GG platform and the LIS, ensuring seamless integration and timely reporting. Integration between the GG platform and RIS/PACS systems will involve implementing standardized protocols such as DICOM and HL7 for exchanging radiology orders, images, and reports. The GG platform will communicate with the RIS to retrieve radiology orders and with the PACS to access and display radiology images and reports. The integration between the GG platform and the Emergency Healthcare Information System will involve the use of standardized protocols like HL7 FHIR to exchange critical patient data in emergency scenarios. This integration will ensure the secure transmission of vital patient information to enable timely and informed decision-making in emergency care settings.

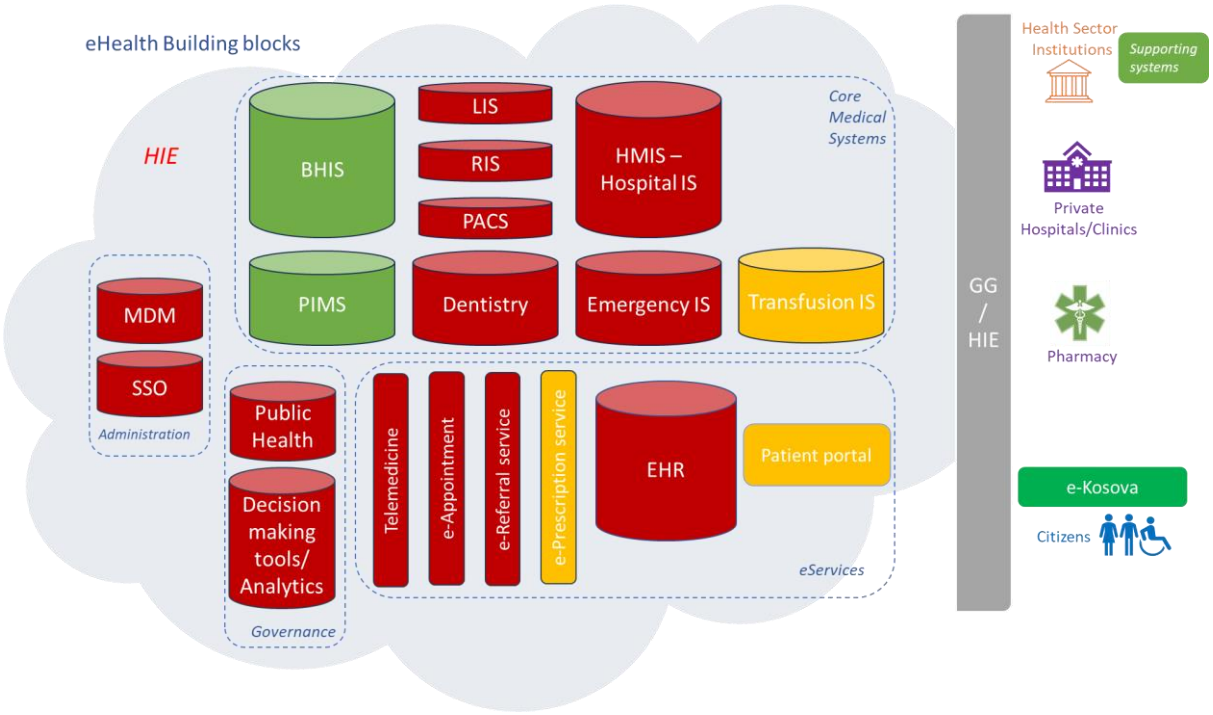


Figure 5: Conceptual design with main building blocks of the eHealth system

This would require establishing standardized, secure and reliable communication channels between these systems. To implement this option, clear legal, technical, and procedural criteria should be defined to ensure the accuracy, privacy, security, and integrity of patient data during the exchange. By enabling this connection, healthcare providers across different settings can access a complete EHR of the patient, including medical history, test results, allergies, and medications. This promotes informed decision-making, effective collaboration, and optimal patient care, regardless of the healthcare facility visited.

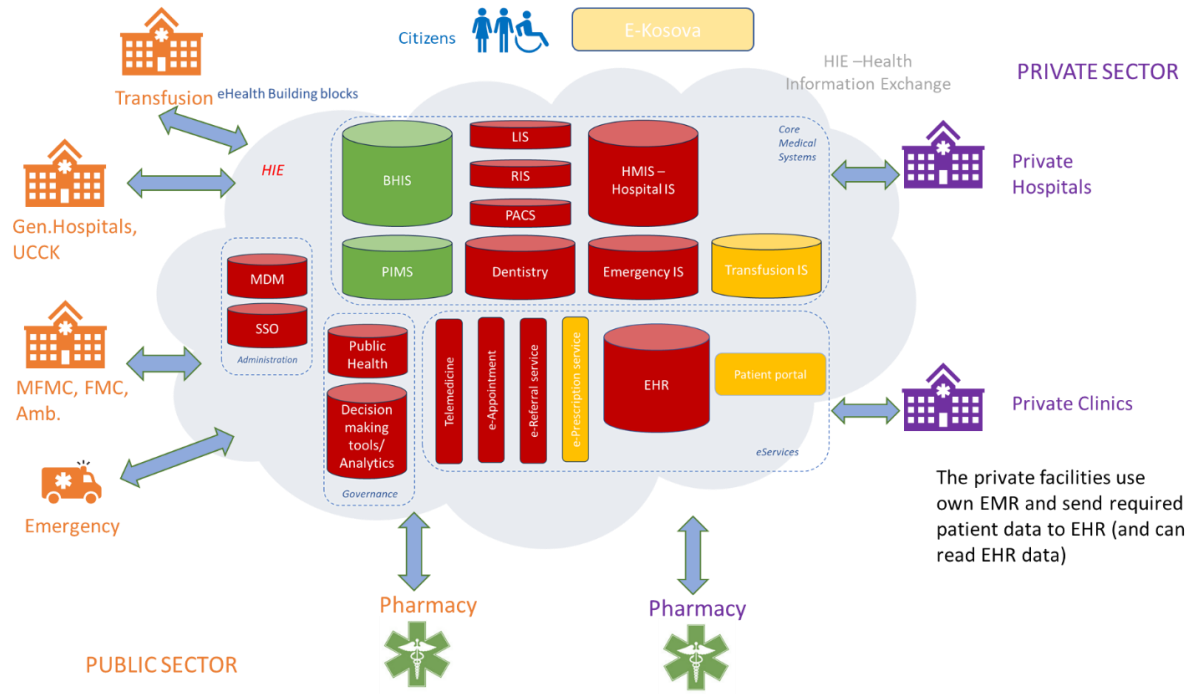


Figure 6: Conceptual design of eHealth system integrations with the main healthcare providers

It is essential to establish strong governance frameworks, standardized protocols, and data-sharing agreements to safeguard patient privacy, maintain data integrity, and comply with applicable regulations. Therefore, the applications and systems that would be interconnected with government HIS should be regularly tested and approved through application certification and accreditation process provided by eHealth body. Implementing a certification and accreditation process will ensure that eHealth solutions, vendors, and service providers meet specified quality and functional standards. It also helps ensure that the system is developed in a responsible manner, considering legal, ethical, and socio-technical factors.

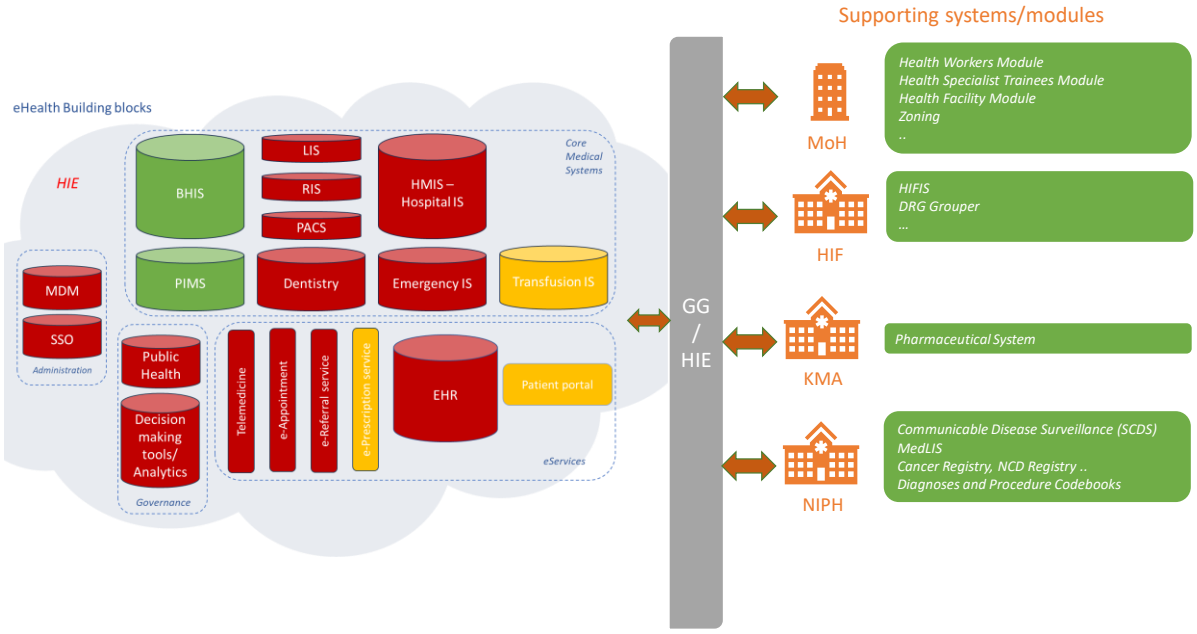


Figure 7: Conceptual design of the integration of eHealth system with supporting systems of the main health sector institutions

Supporting Systems – specifically addresses the streamlining of application procedures within central institutions responsible for healthcare governance (MoH, NIPH, KMA, etc.), this includes establishing and maintaining accurate registers of health professionals, licensed public and private health institutions, warehouse-pharmacists, tracking products with import permits in RKS, codebooks and standards (drug list, procedures, diagnosis, pricelist when the HIF will start to operate, etc.). The successful and efficient establishment of the national eHealth system rests on accurate and up-to-date registers of this type.

This underscores the significance of integrating digital solutions across various domains within the healthcare system, promoting efficient data exchange, improved service delivery, and informed decision-making to enhance overall healthcare outcomes.

Supporting systems are not a core part of eHealth but are necessary to be integrated part of eHealth system because they capture and manage vital systems, databases and registries on the national level. In the table below is a list of some current and planned services and databases with corresponding public health institutions responsible for their management as illustration.

Table 2: Supporting systems by ownership

Institution	System/Registry/Database/Service
HIF	HIFIS
MoH	Health Worker license module
MoH	Health Providers/Facility registry
MoH	Zoning
KMA	Drug Registration
KMA	Medical Devices Registration
NIPH	NCD Registry
NIPH	Cancer Registry
NIPH	Diagnoses and Procedure Codebooks
MoH	Health Professional (Specialist) module

Integrating these supporting systems is crucial to ensure comprehensive and seamless healthcare service delivery. Integrating them through a centralized infrastructure like the Government Gateway can offer several benefits, such as:

Data Sharing and Accessibility: Integrating supporting systems through a centralized infrastructure enables the exchange and accessibility of vital data across different systems. This facilitates better coordination and continuity of care, as healthcare providers can access relevant information from various sources in a timely manner.

Efficiency and Accuracy: Integration helps reduce duplication of data entry and manual processes. By linking supporting systems to the eHealth infrastructure, information can be automatically synchronized and updated, minimizing errors and improving data accuracy. This streamlines administrative tasks and allows healthcare professionals to focus more on patient care.

Interoperability: Integrating supporting systems through a common infrastructure promotes interoperability. It ensures that different systems can communicate and exchange data effectively, regardless of the platforms or technologies they use. This enhances the compatibility and connectivity of healthcare systems, facilitating seamless information flow.

Centralized Management and Governance: A centralized infrastructure provides a framework for managing and governing supporting systems on a national level. It enables standardized data management practices, data governance policies, and security measures. This centralized approach ensures consistency, security, and compliance with regulations and standards across the healthcare ecosystem.

Scalability and Future Expansion: Integrating supporting systems through a centralized infrastructure offers scalability and flexibility for future expansions. As new systems, databases, or registries are added, they can be easily integrated into the existing infrastructure, avoiding fragmented data silos and reducing implementation efforts.

Analytics and Reporting: Integrating supporting systems with the eHealth infrastructure allows for comprehensive data analysis and reporting capabilities. Aggregated data from various sources can be used for population health management, research, policy development, and decision-making purposes. It enables the generation of insights and analytics to improve healthcare outcomes.

It's important to ensure that the integration of supporting systems through a centralized infrastructure is conducted securely, with appropriate data governance, privacy protections, and adherence to relevant standards and regulations. This integration can enhance the overall effectiveness and efficiency of Kosovo's national eHealth ecosystem by connecting critical systems and databases, promoting data sharing, and facilitating informed decision-making in healthcare delivery.

4.2 Key Building Blocks

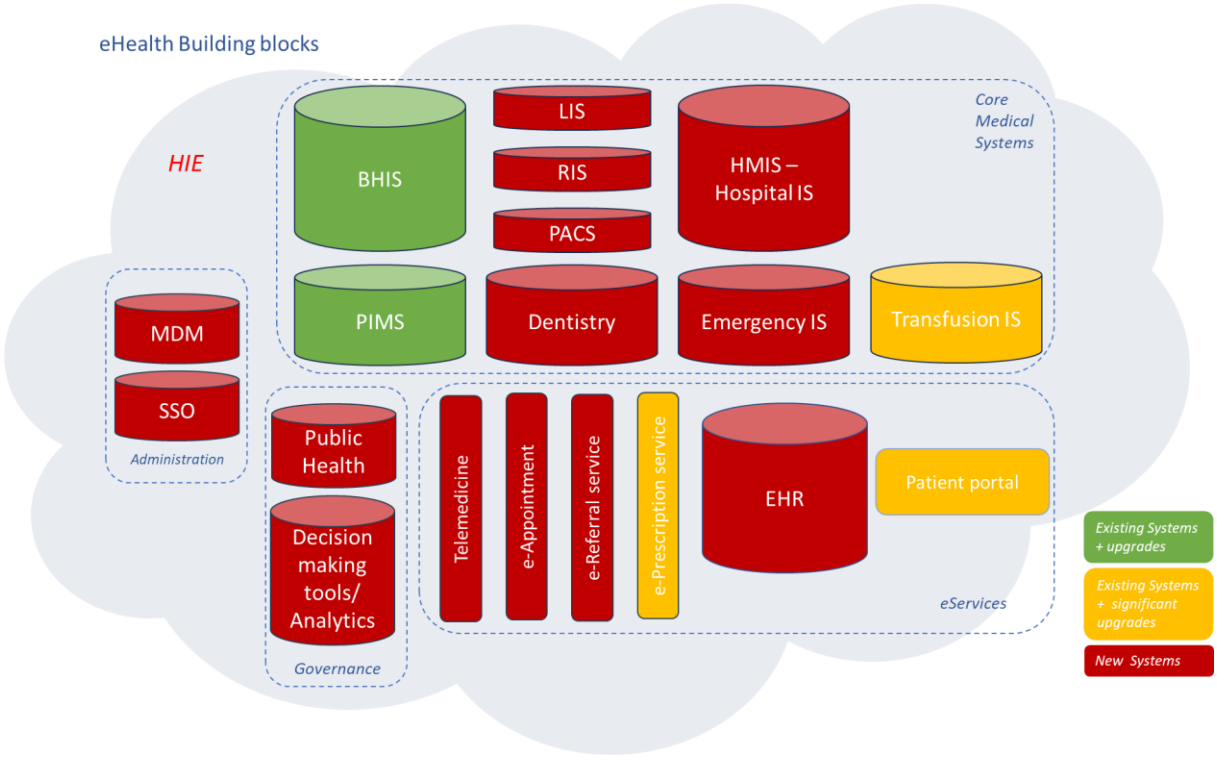


Figure 8: The main building block of Kosovo's eHealth system

Note: The existing systems that should be upgraded are indicated in green, the existing systems that require significant upgrades are indicated in yellow, and all other systems and modules that are not currently present but must be purchased or built during the development of a comprehensive national eHealth system are indicated in red.

4.2.1 Governance

Public Health

Public Health modules are dedicated to promoting and safeguarding the health of the population. It encompasses various sub-modules and functionalities that support disease prevention, health promotion, surveillance, and effective public health management.

Public health components/modules are:

- **Disease Surveillance and Outbreak Management:** The surveillance module is a critical component of the proposed Health Information System for Kosovo, designed to monitor and track disease patterns, health events, and public health indicators. The benefits of having a functional Surveillance System are:
    - Advanced algorithms and statistical techniques help analyze the collected data within the surveillance module. These algorithms can identify patterns, trends, and anomalies that may indicate the occurrence of disease outbreaks or the emergence of new health threats. By applying sophisticated analytical methods, public health officials gain insights into the dynamics of diseases, enabling timely and targeted intervention strategies.
    - Timely and Accurate Data Collection: Real-time data capture and integration with electronic health records (EHRs) ensure accurate and up-to-date information, facilitating better decision-making by healthcare professionals.
    - Early Detection of Health Risks: Digital surveillance systems enable proactive monitoring of patient health parameters, allowing healthcare providers to identify early warning signs of potential health risks or outbreaks.
    - Improved Disease Surveillance: by collecting, analyzing, and reporting health data at various levels, from individual patients to populations. This helps healthcare authorities and public health institutes monitor disease patterns, track outbreaks, and implement effective control measures.
    - Efficient Public Health Response: Health surveillance digital systems facilitate rapid communication and data sharing among healthcare providers, public health agencies, and relevant stakeholders. This enables swift response during public health emergencies, such as infectious disease outbreaks or natural disasters, allowing for coordinated efforts and timely interventions.
    - Predictive Analytics and Population Health Management: leverage advanced analytics to identify trends, patterns, and risk factors within patient populations.
    - Enhanced Patient Safety: Health surveillance systems incorporate safety alerts and risk assessment tools, promoting patient safety by preventing medication errors, adverse events, and hospital-acquired infections. Real-time monitoring of patient conditions and the integration of decision support systems further enhance patient safety protocols.

Data-Driven Research and Public Health Policy: surveillance systems generate vast amounts of data that can be anonymized and aggregated for research purposes. These data-driven insights support evidence-based decision-making, aid in the development of public health policies, and contribute to advancements in medical research and epidemiology. Key patient and treatment information can be used from HMIS and BHIS systems, to help analyse the history of the case and treatment procedures. Integrating with the e-prescription system enables the surveillance module to monitor medication prescription patterns, detect antibiotic resistance trends, and assess the impact of medication interventions on disease outcomes. Integration with laboratory information systems allows for timely and automated reporting of laboratory-confirmed cases, enhancing the accuracy and timeliness of surveillance data.

- **Immunization Management:** focuses on promoting and tracking immunization coverage within the population. Analyzing the immunization trends, schedules and catch-up plans will be based on Vaccination Module.
- **Emergency Preparedness and Response:** The emergency preparedness and response module focus on planning, coordination, and response to public health emergencies and disasters. It includes functionalities for developing emergency response plans, resource management, communication systems, and incident tracking. Integration with the surveillance module allows for early detection of potential emergencies and facilitates rapid response. This module ensures a coordinated and efficient approach to emergency preparedness, enhancing the ability to protect public health during times of crisis.
- **Quarantine Services Management:** managing quarantine services during outbreaks or pandemics. This system should enable tracking of individuals under quarantine, monitoring of their health status, contact tracing, and compliance with quarantine protocols. Additionally, it can provide essential services such as telemedicine consultations, mental health support, and access to educational resources to support individuals in quarantine.
- **Health Statistics:** a computerized platform or software application that collects, manages, analyzes, and presents health-related data and statistics. Should assist healthcare organizations, public health agencies, and researchers in gathering and interpreting information to monitor population health, identify health trends, and inform decision-making processes.

  Having a functional health statistics platform will help on improving data accuracy through automated validation checks and standardized data collection processes, timely and real time reporting which also facilitates early detection of disease outbreaks or emerging health trends but this is impacted by the data quality and standardization across different sources and systems were inconsistent data collection methods, variations in coding practices, and data interoperability issues may affect the accuracy and comparability of health statistics.

  Since health statistics often contain sensitive personal information, it should be considered and well defined the process of accessing those data and also protecting data from unauthorized access, breaches, and ensuring compliance with privacy regulations can be complex and resource intensive. Establishing robust data governance frameworks, including data ownership, consent, and ethical considerations, is essential. Balancing data access for research purposes with protecting individual privacy and confidentiality requires careful planning and policy development.

  Institutes of Public Health should have access to health statistics in order to analyze population health analysis, disease trends, conduct research and give recommendations to improving population health, preventing diseases, reducing health inequities, and promoting the overall well-being of communities.

Decision making tools / Analytics

From a technical point of view, decision support tools for eHealth systems are software applications or systems designed to assist healthcare professionals in making informed decisions by leveraging data and analytics. These tools utilize advanced algorithms and techniques to analyze large amounts of data and provide insights, recommendations, or predictions to support healthcare decision-making processes. Building a big data analytical tool for decision support in eHealth involves several technical aspects:

Data Collection: The tool needs to collect relevant data from various sources within the eHealth system. This data can include patient records, medical history, lab results, demographics, and other

clinical or administrative information. Data may be sourced from electronic health records (EHRs), medical devices, health monitoring systems, or external sources. Data Integration: Integrating disparate data sources is a crucial step. It involves transforming and harmonizing data from different formats and systems into a unified format. This process ensures that data is compatible, consistent, and accessible for analysis. Data Storage and Management: The collected and integrated data needs to be stored in a suitable infrastructure that can handle large volumes and provide efficient querying and retrieval. Big data technologies, such as distributed file systems and NoSQL databases, are commonly used for storing and managing the vast amount of healthcare data. Data Pre-processing: Before analysis, the data often requires preprocessing steps such as cleaning, filtering, and normalization to ensure data quality and remove any inconsistencies or errors that may impact the accuracy of the analytical results. Analytics and Algorithms: Big data analytics techniques, including machine learning, data mining, and statistical analysis, are applied to the preprocessed data to derive meaningful insights and patterns. These algorithms can identify correlations, trends, outliers, and predictive models that assist healthcare professionals in decision-making. Visualization and Reporting: The results of the analysis are presented through interactive visualizations, dashboards, and reports. These user-friendly interfaces allow healthcare professionals to interpret the analytical outcomes effectively and make informed decisions based on the insights provided by the tool. Scalability and Performance: Building a big data analytical tool requires considering scalability and performance aspects. The system should be designed to handle increasing data volumes, accommodate growing user demands, and deliver timely results to support real-time or near-real-time decision-making. Overall, a big data analytical tool for decision support in eHealth combines data collection, integration, storage, preprocessing, analytics, visualization, and security aspects to enable healthcare professionals to leverage data-driven insights for making informed decisions and improving patient care outcomes.

Decision support tools in healthcare provide several benefits to healthcare providers, healthcare institutions and governments in their efforts to improve healthcare systems and population health.

Ways in which decision support tools benefit governments:

- **Policy Development and Planning:** Decision support tools provide governments with valuable data and insights for policy development and healthcare planning. These tools can analyze population health data, identify patterns and trends, and help policymakers make informed decisions regarding resource allocation, preventive measures, and public health interventions.
- **Health Surveillance and Monitoring:** Decision support tools enable governments to monitor and track health indicators and disease trends at both individual and population levels. These tools can detect outbreaks, identify high-risk populations, and support early intervention strategies, helping governments respond effectively to public health emergencies and implement targeted interventions.
- **Healthcare Resource Management**: Decision support tools assist governments in managing healthcare resources efficiently. These tools can analyze data on healthcare utilization, patient flow, and resource allocation, enabling governments to optimize the distribution of healthcare services, plan for infrastructure development, and allocate budgets based on identified needs and priorities.
- **Quality Improvement and Performance Monitoring:** Decision support tools help governments monitor and assess the performance of healthcare systems, facilities, and providers. These tools can measure key performance indicators, adherence to clinical guidelines, and outcomes, enabling governments to identify areas for improvement, implement quality improvement initiatives, and ensure accountability in the delivery of healthcare services.

- **Cost Management and Fraud Detection:** Decision support tools contribute to cost management and fraud detection efforts by governments. These tools can analyze healthcare claims data, identify patterns of fraudulent activities, and detect anomalies in billing and coding practices. By leveraging decision support tools, governments can reduce healthcare fraud and abuse, leading to cost savings and more efficient use of public funds.
- **Public Health Education and Awareness:** Decision support tools support governments' efforts in health education and awareness campaigns. These tools can deliver targeted health information, preventive guidelines, and recommendations to the public, promoting healthy behaviors and empowering individuals to make informed decisions about their health. They can also facilitate communication during public health emergencies and disseminate critical information to the population.
- **Research and Evidence Generation:** Decision support tools generate valuable data and insights that can be used for research and evidence-based policymaking. Governments can leverage these tools to conduct population-level studies, evaluate the effectiveness of interventions, and generate evidence to inform healthcare policies and programs.

Decision support tools in healthcare can also refer to computer-based systems or software applications that provide healthcare professionals with relevant information, recommendations, alerts to **support clinical decision-making** like clinical decision support system (CDSS), Evidence-Based Guidance, Risk assessment and Satisfaction, Drug Interaction and Allergy Checking, Diagnostic Support, etc. Usually, those systems are incorporated in HMIS, or on the national level in primary or secondary care systems in advanced and very mature eHealth environments.

4.2.2 eServices

e-Prescription

e-Prescription process has following steps:

- **Electronic Prescription Generation**: Healthcare professionals who have the authority to prescribe medications use an electronic prescribing system to generate prescriptions for their patients. This system allows them to enter relevant details such as patient information, medication name, dosage, and instructions. – Part of BHIS
- **Transmission to the National e-Prescription System**: The e-prescription is electronically transmitted from the BHIS to a central national e-prescription system. This centralized system securely stores prescription information and makes it accessible to authorized pharmacies.
- **Retrieval by Pharmacies**: When a patient visits a pharmacy to obtain their prescribed medication, the pharmacist retrieves the patient's e-prescription from the national e-prescription system. This can be done by searching for the patient's information, such as their unique identifier or prescription code.
- **Dispensing Medication**: Once the pharmacist has retrieved the e-prescription, they can access the details of the prescribed medication, dosage instructions, and any additional relevant information. The pharmacist then dispenses the medication to the patient accordingly.

The core functionality of the e-prescription system lies in its ability to enable healthcare providers to generate electronic prescriptions and transmit them directly to central e-Prescription database to be able to retrieve and fetch from pharmacies. By eliminating the reliance on paper-based prescriptions, this system reduces errors, enhances prescription accuracy, and increases the speed of medication dispensing. Additionally, electronic prescriptions enable healthcare professionals to maintain a comprehensive record of patient medication history, allowing for improved continuity of care and informed decision-making.

Electronic prescription systems offer reporting capabilities that can assist healthcare providers in tracking and analyzing prescription trends. This data can be valuable for research, population health management, and regulatory compliance purposes.

To ensure data quality, the drug list within the e-prescription system can be sourced (but not limited to) from the KMA - Pharmaceutical System.

Integration with both HMIS and BHIS systems is essential, making e-prescription an integrated tool or module within the broader healthcare ecosystem. Furthermore, integration with the Health Insurance Fund (HIF) system is crucial to enable seamless reimbursement of medicines based on each patient's health insurance coverage.

Connecting with e-Kosova will enable patients to have their prescriptions electronically retrieved from the pharmacy of their choice. Patients can avoid paper prescriptions, wait times, and potential loss or misplacement of physical copies. Moreover, an alternative option for pharmacies to retrieve e-prescription information is by integrating their current systems with the e-prescription service using an API.

e-Referral

e-Referral, as a part of the e-health system in Kosovo, represents a significant leap forward in improving healthcare delivery and patient outcomes. It is a system that facilitates the digital referral of patients from one health care provider to another. Here's an overview:

1. **Streamlined Process**: An e-referral system can streamline the referral process by making it faster and more efficient. Healthcare providers can generate and send referrals electronically, eliminating the need for paper-based processes and reducing the risk of lost or misplaced referrals.
2. **Improved Coordination**: E-referral can enhance coordination of care between primary care physicians, specialists, and other healthcare providers. It ensures that all parties have access to the same information, leading to better, more informed decision-making and improved patient care.
3. **Patient Convenience**: With e-Referral, patients can be assured that their referral information has been transmitted directly to the specialist's office, reducing wait times and ensuring they receive care as quickly as possible.
4. **Comprehensive Tracking**: e-Referrals enable healthcare providers to maintain a record of patient referrals, allowing for improved tracking and follow-up care. It provides data on referral patterns, which could be valuable for health service planning and resource allocation.
5. **Integration**: e-Referral systems should ideally be integrated with other aspects of the e-health system, such as BHIS, HIMS, PAKS, LIS, RIS, etc. This would allow for a more holistic view of a patient's healthcare journey, facilitating better care coordination and health outcomes.

Comprehensive e-Referrals should encompass a wide range of healthcare services, both within and beyond the confines of a single institution. These referrals should seamlessly connect primary, secondary, and tertiary healthcare establishments, ensuring the smooth transfer of patients medical information. Having this said, e-Referrals should include both internal (within the same institution) and external (primary to secondary to tertiary healthcare institutions) including and not limited to diagnostics (PAKS, RIS, LIS), Dentistry, etc.

By harnessing the power of digital technology, an e-Referral system can transform the way healthcare is delivered in Kosovo, promoting more collaborative, efficient, and patient-centered care. However, it's essential to continuously monitor and evaluate the system to ensure it's meeting its objectives and contributing to improved health outcomes.

e-Appointment

e-Appointment as a component of the e-health system in Kosovo, is a significant stride toward making healthcare more accessible, efficient, and patient-centered. A web-based platform that allows patients to schedule their appointments with healthcare providers conveniently. Online appointment scheduling systems provide flexibility, reduce wait times, and streamline the appointment booking process:

1. **Scheduling Ease**: An e-Appointment system allows patients to schedule their appointments online at their convenience. This can eliminate the need for phone calls or in-person visits to schedule appointments, making the process more efficient and less time-consuming.
2. **Appointment Reminders**: The system can send automatic reminders to patients about their upcoming appointments, reducing the likelihood of missed appointments and promoting adherence to care plans.
3. **Rescheduling and Cancellation**: With e-Appointment, patients can easily reschedule or cancel their appointments. This functionality not only improves patient convenience but also allows healthcare providers to manage their schedules more efficiently.
4. **Improved Access**: By offering online scheduling, the system can make healthcare more accessible. This could be particularly beneficial in rural or underserved areas where physical access to healthcare facilities might be challenging.
5. **Waiting Time Management**: The system can provide real-time information about the expected waiting times at healthcare facilities, helping patients to plan their visits more effectively.
6. **Integration**: Like the e-Referral system, the e-Appointment system should be integrated with other components of the e-health system, such as e-Prescriptions and electronic health records (EHRs). This integration can provide healthcare providers with a more comprehensive overview of the patient's health journey.
    a) By integrating it with "Choosing Family Doctor" (which provides the option that each citizen should pick and have their own family doctor) citizens could book appointments with their family doctor.
    b) Additionally, for specialty care or referrals to secondary/tertiary institutions, the system should be connected with e-Referrals to allow patients to request schedule appointments exclusively to the specialty care specified by the family doctor. The same approach should be followed for the services that are specified by the family doctor (ex: diagnostics – laboratory, radiology, etc.).

By adopting an e-Appointment system, healthcare delivery in Kosovo can become more efficient, patient-centered, and streamlined. However, it is crucial to continually evaluate the system to ensure it meets its objectives and contributes to improved patient experiences and health outcomes.

Online Appointment Scheduling can be included in e-Kosova portal, since this portal is planned to be the entering point for other e-health services open to citizens.

EHR

Terminology (EHR/EMR/EPR)[9]

The terms EHR, electronic patient record (EPR) and EMR have often been used interchangeably, but differences between the models are now being defined. The electronic health record (EHR) is a more

[9] https://en.wikipedia.org/wiki/Electronic_health_record#Terminology

longitudinal collection of the electronic health information of individual patients or populations. The EMR, in contrast, is the patient record created by providers for specific encounters in hospitals and ambulatory environments and can serve as a data source for an EHR.

In contrast, a personal health record (PHR) is an electronic application for recording personal medical data that the individual patient controls and may make available to health providers.

"EHR means a repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent, and prospective information and its primary purpose is to support continuing, efficient and quality integrated health care."[10]

After all building blocks of eHealth system that collects patient medical data are up and running with their EMR in function, assumptions for comprehensive national electronic health records (EHR) system are fulfilled.

EHR is real-time, patient-centered records that provide immediate and secure information to authorized users. EHRs typically contain a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results. Ideally it should reflect the entire health history of an individual across his or her lifetime including data from multiple providers from a variety of healthcare settings. Implementing national comprehensive EHR is long lasting project that requires:

- Adequate resources including funding, technical expertise, and staffing, to support the EHR implementation process.
- Robust technical infrastructure including hardware, software, and network infrastructure. This can help ensure that the system is reliable, secure, and interoperable with other healthcare systems.
- Data standards and protocols for collecting, sharing, and using data within the EHR system. This can help ensure that data is accurate, complete, and accessible to those who need it.
- Legal and regulatory framework including data privacy and security regulations. This can help ensure that patient data is protected, and that the system is compliant with relevant laws and regulations.
- Patient Consent. Before granting access to EHR patient consent must be obtained.

To ensure a seamless integration between eHealth components, it is imperative that all relevant building blocks effectively populate the Electronic Health Record (EHR) with comprehensive data. This data, serving as a foundation, can then be appropriately reflected in the patient portal. However, before making this information accessible to patients, it is essential to establish legal framework that governs the specific data elements to be displayed within the patient portal. By addressing the regulatory aspects, we can ensure that patients have access to pertinent and authorized information in a secure and compliant manner.

Patient Portal

Patient portals are secure online platforms that provide patients with access to their personal health information and various healthcare services. These portals offer several features and benefits, empowering patients to actively engage in their healthcare management and improve communication with healthcare providers. Here are some key features and benefits of patient portals:

[10] ISO/TR 20514:2014, Health Informatics –Electronic Health Record –Definition, Scope, and Context

Features of Patient Portals:

- **Personal Health Records (PHR**): Patient portals allow individuals to access their personal health records, including medical history, diagnoses, medications, allergies, immunizations, and test results. This centralized and easily accessible information promotes better understanding of one's health status and facilitates informed decision-making.
- **Appointment Scheduling:** Many patient portals enable patients to schedule appointments online, offering convenience and flexibility. Patients can view available time slots, choose preferred healthcare providers, and schedule appointments that best fit their schedules, reducing the need for phone calls or in-person visits for appointment booking.
- **Medication Management:** Patient portals often include features that help patients manage their medications. This can include medication lists, reminders for medication schedules, alerts for potential drug interactions or allergies, and the ability to request prescription refills online.
- **Access to Educational Resources:** Patient portals may provide access to educational materials, resources, and health information tailored to the patient's specific conditions or needs. This empowers patients to learn more about their health conditions, make informed lifestyle choices, and actively participate in their care.

Patient portals offer convenience by providing 24/7 access to healthcare information and services. Patients can view test results, schedule appointments, or request prescription refills at their own convenience, reducing the need for phone calls or in-person visits. This saves time for both patients and healthcare providers.

Patient portals prioritize privacy and security by implementing robust encryption and authentication measures. This ensures that sensitive health information is protected and only accessible to authorized individuals, maintaining patient confidentiality and compliance with privacy regulations.

In Kosovo the patient portal can be enabled in the governmental platform e-Kosova.

In general, the Patient Portal has two choices for utilizing the eKosova platform:

a) eKosova should include a Patient Portal.

b) Patient Portal (PP) is a web portal run by the eHealth Body (or Ministry of Health), but in order to access it, a citizen must first authenticate through the eKosova authentication service. After receiving the appropriate credentials (for example, for oneself or a child or family member), the citizen should then get right to open the Patient Portal website. (Examples: Croatia https://gov.hr/en/portal-zdravlja-health-portal-is-mobile-friendly/2340, Nort Macedonia https://e-zdravstvo.mk/en/moe-zdravje)

We believe that option b) should offer more adaptability and flexibility for the long-term strategy because the development of the patient portal is a dynamic process that involves introducing new functionalities and services to citizens over a longer period of time.

Telemedicine

Telemedicine, also known as telehealth, refers to the use of technology and telecommunications to provide remote healthcare services, including medical consultations, diagnoses, monitoring, and treatment. It allows patients and healthcare providers to connect virtually, eliminating the need for in-person visits and enabling healthcare to be delivered at a distance.

Key features and benefits of telemedicine:

- **Remote Consultations:** Telemedicine enables patients to consult with healthcare providers remotely using video calls, audio calls, or secure messaging platforms. Patients can discuss their symptoms, receive medical advice, and even have virtual examinations when appropriate. It provides convenience, particularly for patients who may have difficulty traveling or accessing healthcare facilities.
- **Access to Specialists:** Telemedicine allows patients in remote or underserved areas to connect with specialists who may be located in distant medical centers. It improves access to specialized care and expertise, reducing the need for patients to travel long distances for consultations.
- **Continuity of Care**: Telemedicine promotes continuity of care by allowing patients to have follow-up appointments and regular check-ins with their healthcare providers without the need for in-person visits. It supports ongoing monitoring of chronic conditions, medication management, and care plan adjustments.
- **Remote Monitoring:** Telemedicine integrates with remote monitoring devices and wearables to collect patient data, such as vital signs, blood glucose levels, or heart rhythm. Healthcare providers can remotely review this data and make necessary adjustments to treatment plans or provide timely interventions.
- **Reduced Waiting Times:** Telemedicine helps reduce waiting times for patients, as it eliminates the need to travel, sit in waiting rooms, and spend time on administrative processes. It can improve patient satisfaction by providing timely access to healthcare services.
- **Cost Savings**: Telemedicine has the potential to reduce healthcare costs for patients. It eliminates transportation expenses, minimizes time off from work, and may reduce the need for hospital or emergency room visits for non-emergency conditions.
- **Health Monitoring in Home Environments:** Telemedicine allows healthcare providers to remotely monitor patients' health conditions and progress in their home environments. This is particularly beneficial for patients receiving palliative care, managing chronic conditions, or undergoing post-surgical recovery.
- **Education and Training:** Telemedicine platforms can be used for educational purposes, such as providing training to healthcare professionals, conducting medical conferences, or delivering health education to patients and caregivers.

The use of telemedicine services in radiology, neurosurgery, surgery, and neurology avoids unnecessary and repeated diagnostic and therapeutic procedures and shortens the patient’s stay in the telemedicine access center institution. However, based on the current situation that Kosovo is with Telemedicine, as a basic phase and the steps that could be taken right away is to launch pilot projects for the development of the simplest telemedicine services such as teleconsultation; video calls between a patient and a healthcare provider. The patient can use a smartphone, tablet, or computer with a webcam and microphone to connect to the provider, who can remotely diagnose and treat a range of common medical conditions.

4.2.3 Core medical systems

BHIS

BHIS System, referred to as a primary healthcare system, encompasses the entire spectrum of healthcare and administrative procedures offered by primary healthcare facilities. This comprehensive system revolutionizes the way patient information is gathered, organized, and leveraged, leading to streamlined workflows, enhanced care coordination, and a transformative experience for both patients and healthcare providers.

Patients visit healthcare facilities for diagnosis, treatment, preventive care, consultations, and follow-up visits. All services that are covered in primary care like medical visit, diagnostic procedures, immunization services, rehabilitation services, outpatient mental health services, home visits and palliative care should be digitalized and included in the system.

- Patient Registration: the current approach to having this interconnected with Civil Registry Agency through GG Platform it is a solid solution to ensure good quality data.
- Electronic Medical Records (EMR): A digital medical record that stores and manages patient health records, including medical history, diagnoses, treatments, medications, and test results. EMRs provide a comprehensive view of the patient's health information, facilitating efficient and accurate care delivery in one health facility.
- Screening: should support the digital process of systematic identification of individuals who may be at risk for certain health conditions or diseases. It involves conducting specific tests, assessments, or evaluations to detect early signs, risk factors, or abnormalities that may require further investigation or intervention.
- Counselling: is a professional healthcare service that aims to support individuals in addressing personal, emotional, psychological, or relationship concerns. Data about type of counselling and medical notes should be record through this module.
- Diagnostics (PACS, RIS, LIS) – the results from radiology diagnostics or laboratory test outcomes should be received in BHIS from auxiliary RIS/LIS systems.
- Immunization: A digitalized immunization schedule, including vaccines administered basing on indicators. It aims to improve the efficiency, accuracy, and accessibility of immunization data. It provides real-time tracking of immunizations, ensuring that individuals receive vaccines according to recommended schedules and can send automated reminders to healthcare providers and patients when vaccinations are due or overdue, facilitating timely immunizations.
- Home visits: module that retrieve the data about home visits (schedules, planning, management) and home visits activities and outcomes.
- Palliative care: refers to the use of technology and digital tools to support and enhance the delivery of palliative care services to patients with serious illnesses and their families.
- Remote Patient Monitoring: Connected devices and sensors that collect and transmit patient health data from home or other remote locations. This technology allows healthcare providers to remotely monitor patients' vital signs, symptoms, and medication adherence, enabling timely interventions and proactive care management.
- Pharmacy Inventory management: This module manages medication orders, dispensing, and inventory management in family medical centers with pharmacies.
- Inventory Management: This module manages the inventory of medical supplies and equipment.
- Billing: This module manages financial transactions, including billing/insurance claims from health providers to payer. This module should be in place when health insurance payment mechanism will be implemented in Kosovo.

Implementation of the Basic Health Information System (BHIS) in all primary health care units throughout Kosovo is vital to ensure comprehensive data coverage for citizens. Implementing this system to all units within the primary health care sector, can facilitate the seamless exchange of data for improved healthcare outcomes.

As the BHIS system that is implemented in PHC is centralized, the existing data exchange mechanisms between PHC units can be maintained. However, it is crucial to establish effective data exchange with

other systems (when those are in place) as HMIS, PACS, RIS, Surveillance, eServices, etc. Operationalizing these connections will enable a holistic view of patient information and promote efficient collaboration across different healthcare sectors.

The BHIS system should be used in the public healthcare system in all MFMC, FMC, and Ambulance clinics. Private institutions should be allowed to use any certified PHC (Primary Health Care) solution, as elaborated in chapters 3.4 and 7.4.2. The use of BHIS in private institutions is not recommended, due to the following. Implementing BHIS in private institutions would require extra development and support, as the private sector may have different workflows and requirements compared to the public healthcare system. With the operationalization of the HIF (Health Insurance Fund), changes in the billing process of BHIS are expected. These billing changes might differ significantly from billing processes in private institutions, making BHIS less suitable for them. Also, private providers may already have or will have their own Electronic Medical Record (EMR) systems that are designed to meet all their specific business needs. These EMRs might be more suitable for private institutions than BHIS, which may not cover all their requirements.

Hospital Management information System (HMIS)

A Hospital Management Information System (HMIS) is a software that helps managing the hospital ongoing business in all aspects (clinical, administrative, financial). It is an essential tool for managing patient information and optimizing healthcare delivery in hospitals.

By using HMIS, hospitals can improve the efficiency and quality of patient care by accessing and sharing patient data quickly and easily. HMIS also enables healthcare providers to make informed decisions based on real-time patient information, helping to improve diagnosis and treatment outcomes.

In addition to managing patient data, HMIS can also help healthcare organizations with administrative tasks such as billing, scheduling, and resource management. By automating these processes, HIS can help healthcare providers save time and reduce errors, ultimately leading to improved patient outcomes and better healthcare delivery.

System may vary depending on the specific needs of the hospital, but typically include:

- Patient Registration: the current approach to having this interconnected with Civil Registry Agency through GG Platform it is a good solution to ensure good quality data.
- Appointment Scheduling: This module is used to register patients and schedule appointments for them. It should also offer the option for Online Appointment Scheduling: A web-based platform that allows patients to schedule their appointments with healthcare providers conveniently. Additionally, for specialty care or referrals to secondary/tertiary institutions, the system should be connected with e-Referrals to allow patients to schedule appointments exclusively to the specialty care specified by the family doctor. The same approach should be followed for the diagnostics services that are specified by the specialist (ex: diagnostics – laboratory, radiology, etc.).
- Electronic Medical Record (EMR): This module manages patient medical records, including their medical history, diagnoses, test results, and treatment plans.
- Laboratory Information System (LIS): This module manages laboratory test orders, results, and reports. – the results from laboratory test outcomes should be received in HMIS from auxiliary LIS systems.
- Radiology Information System (RIS): This module manages radiology procedures, including order entry, scheduling, and result reporting. – the results from radiology diagnostics outcomes should be received in HMIS from auxiliary RIS systems

- Pharmacy Management System: This module manages medication orders, dispensing, and inventory management. This module has all the information for medication orders, dispensing, and inventory management which are received by auxiliary PIMS system
- Billing: This module manages financial transactions, including billing/insurance claims from health providers to payer. This module should be in place when health insurance payment mechanism will be implemented in Kosovo.
- Inventory Management: This module manages the inventory of medical supplies and equipment.
- Consumables and Supplies: typically includes features such as inventory management, order management, stock tracking, automated reordering, and reporting functionalities. It serves as a central hub for tracking, monitoring, and replenishing essential items necessary for patient care, such as medical supplies, surgical instruments, medications, and other consumable items.
- Sterilization: is a critical component of infection control and patient safety measures, ensuring that medical instruments, equipment, and supplies are properly sterilized to prevent the spread of infections. Key features may include barcode scanning or RFID tagging for instrument identification, tracking the status and location of instruments throughout the sterilization cycle, monitoring sterilization parameters (such as time, temperature, and pressure), documenting sterilization cycles and outcomes, and generating reports for compliance and audit purposes.
- Kitchen/Nutrition management system. The system helps dieticians and nutritionists to create customized meal plans and menus for patients, based on their nutritional needs and dietary restrictions. It is also used to manage the complete food service operations within a hospital. It is essentially an inventory management system that allows hospital staff to track food supplies, manage meal preparation, and ensure compliance with dietary requirements and regulations.
- Quality Management: This module manages the quality of care provided by the hospital, including tracking and analyzing patient outcomes and managing quality improvement projects.
- Human Resource Management and Planning Shifts: This module manages employee information, including scheduling, payroll, and benefits. These features should be provided by Medical Staff Management & HR Solutions Module
- Decision Support System: This module provides data analysis and reporting tools to support decision-making by hospital management.
- It is crucial to establish effective data exchange with other building blocks (when those are in place) as PACS, RIS, PIMS, Surveillance, eServices, etc. Operationalizing these connections will enable a holistic view of patient information and promote efficient collaboration across different healthcare sectors.

LIS

A Laboratory Information System (LIS) is a specialized healthcare software solution designed to handle and manage patient data associated with laboratory processes and testing. It serves as a comprehensive tool for healthcare providers and laboratory professionals to coordinate and streamline the workflow and quality control of medical testing, both for inpatient and outpatient settings. The LIS covers various laboratory areas, such as hematology, chemistry, immunology, microbiology, toxicology, and public health.

The primary functions of an LIS include the processing, storage, and management of clinical information related to patient testing. During a healthcare visit, the LIS tracks, stores, and updates clinical

details for each patient, ensuring the information is readily accessible in its database for future reference. It facilitates various tasks, including receiving test orders, sending orders to laboratory analyzers, tracking orders and results, implementing quality control measures, and transmitting results to other information systems like EHR or EMR.

Key features of LIS include:

- **Sample Management**: The sample management system within a Laboratory Information System (LIS) serves as its central functionality. It is responsible for maintaining accurate records of each sample, starting from its receipt in the lab and throughout its entire lifecycle. The LIS stores crucial information about each sample, including its expiration date, storage requirements, researcher names, and the sample's origin. This comprehensive data storage reduces the risks of sample expiration, contamination, and loss. The LIS enables efficient tracking of sample locations within the laboratory. It assigns samples to specific freezer locations, often with precise details down to the level of shelves or boxes. This tracking capability enhances organization and facilitates easy retrieval of samples when needed.
- **Instrument Integration:** LIS Instrument Integration is a critical functionality that enhances the integration between the LIS and laboratory instruments. It allows seamless communication and coordination between the LIS and the instruments used in the laboratory. The LIS can upload control files directly into specific laboratory instruments, enabling the LIS to control and direct their operation. This integration ensures proper instrument functionality and synchronization with the LIS. The integrated data is readily available for analysis and reporting.
- **Result File Import**: The LIS can import instrument-generated result files, extracting relevant data for quality control assessment and further analysis. This streamlined process eliminates the need for manual data entry and ensures accurate and efficient reporting.

By utilizing a dedicated and flexible LIS, laboratories can enhance workflow efficiency, minimize errors, aid in decision-making processes, ensure consistent adherence to procedures, and increase overall productivity. Additionally, an LIS can automate proper billing practices, leading to optimized reimbursement processes.

RIS

A Radiology Information System (RIS) is an advanced database system utilized by radiology professionals to manage patient data and the large image files generated during diagnosis and treatment. It serves as a specialized electronic medical record (EMR) system tailored specifically for radiology, enabling the manipulation and distribution of patient data. Implementing a RIS offers several benefits, including improved accuracy, reduced medical errors, and fewer transcription mistakes in patient charts. It aids in developing more precise diagnoses and plays a crucial role in coordinating care across different healthcare services, facilitating seamless communication between the imaging department and the patient's primary healthcare provider.

A RIS integrates multiple functions into a comprehensive system, eliminating redundant actions and enhancing staff efficiency through easy access to critical data. It streamlines operations from registration and scheduling to billing and results reporting, empowering the staff to serve more patients effectively.

- **Registration and Scheduling**: With a RIS in place, the time-consuming and cumbersome process of registering new patients using paper documents becomes streamlined. Instead of redundant information on paper intake forms, staff can enter data once, eliminating the need for repetitive data entry.

- **Storage and Tracking of Documents and Images**: Radiology practices generate a significant volume of documents, particularly in digital form. A robust RIS is essential for securely storing and tracking these records, ensuring compliance with HIPAA guidelines to safeguard patient confidentiality.
- **Interactive Documents**: RIS leverages computerized medical systems and networking technology to enable interactive documents. Healthcare professionals are prompted to provide specific data, ensuring comprehensive and accurate patient charting.
- **Results Reporting and Delivery**: The RIS simplifies reporting tasks, whether it's generating monthly progress reports on unpaid bills or tracking last-minute cancellations. It streamlines the process, ensuring timely delivery of reports with minimal time constraints.
- **Medical Billing**: The revenue cycle of a radiology practice heavily relies on efficient billing processes. A RIS accelerates billing by enabling faster and more efficient document processing, reducing staff effort compared to paper-based systems.
- **Material Management**: Managing materials in a radiology practice becomes more efficient with a computerized system. A RIS provides real-time visibility into inventory levels, facilitating informed decision-making on reordering supplies and improving budget control.

Overall, a Radiology Information System optimizes the management of patient data, enhances workflow efficiency, ensures compliance with regulations, improves reporting capabilities, streamlines billing processes, and enables effective material management.

PACS

A Picture Archiving and Communication System (PACS) is a computer system utilized in healthcare settings to capture, store, distribute, and display medical images for interpretation and review. It enables the transmission of electronic images and reports, digitally connecting healthcare professionals involved in patient care.

PACS consists of four major components:

- **Imaging Modalities**: Various imaging devices such as X-Ray, CT, MRI, Ultrasound, and Nuclear Medicine equipment, which capture medical images.
- **Secure Network**: A secure network infrastructure facilitates the transmission of patient information, ensuring data privacy and confidentiality.
- **Workstations**: Specialized workstations are used by radiologists and other medical professionals for interpreting and reviewing medical images, providing tools for digital enhancement and manipulation.
- **Image Archives**: PACS incorporates both long-term and short-term archives for the storage and retrieval of medical images and associated reports.

Through the integration of web technology, PACS enables timely and efficient access to images, interpretations, and related data. It can be further enhanced by integration with other healthcare systems such as the Radiology Information System (RIS), the Hospital Management Information System (HMIS), and Speech Recognition Systems.

Benefits of PACS include:

- **Digital Enhancement and Manipulation**: PACS allows for the digital enhancement and manipulation of medical images, aiding in improved diagnosis and analysis.
- **Seamless Image Accessibility**: As patients move between different healthcare facilities, their medical images can be accessed at multiple organizations. This reduces the need for patients to undergo duplicate imaging procedures.

- **Easy Access to Historical Images**: PACS provides easy access to a patient's historical images, supporting radiologists in performing more comprehensive interpretations and facilitating informed decision-making.
- **Accurate Patient Identification and Data Integration**: PACS ensures accurate identification of patient exams and seamless integration with clinical data. This, coupled with high-level integration with reporting systems, helps reduce the potential for errors in reporting.

Overall, PACS revolutionizes medical image management by offering enhanced image manipulation capabilities, improved accessibility across healthcare facilities, efficient retrieval of historical images, and streamlined patient data integration.

Blood Transfusion IS

The blood transfusion system is a vital component of the proposed Health Information System for Kosovo, focusing on the safe and efficient management of blood products within the healthcare system. This module encompasses a range of functionalities that ensure the availability of compatible blood for patients in need, accurate documentation of transfusion processes, and adherence to stringent quality and safety standards.

One of the primary objectives of the blood transfusion module is to track and manage the entire lifecycle of blood products. This includes monitoring blood inventory levels, ensuring appropriate storage conditions, and tracking the movement of blood units from donation to transfusion. By implementing a comprehensive inventory management system, the module helps prevent shortages and wastage, optimizing the utilization of this critical resource.

Compatibility between blood donors and recipients is of utmost importance to ensure safe transfusions. The blood transfusion module incorporates features such as blood grouping and cross-matching functionalities. These functionalities enable healthcare providers to accurately determine the compatibility of donor blood with the recipient, minimizing the risk of adverse reactions or transfusion-related complications.

To maintain a complete record of transfusion events and ensure traceability, the module allows for detailed documentation of each transfusion process. This includes capturing information such as patient details, blood component details, transfusion date and time, administering healthcare provider, and any adverse reactions or observations during the transfusion. This should support Electronic patient identification systems (including bar codes and Radio Frequency Identification tags).

Integration with laboratory information systems enables seamless transmission of test results, ensuring timely availability of blood units meeting the required safety standards. To support for real-time communication and coordination between blood banks, healthcare providers, and transfusion services this module should be connected with HMIS system. This facilitates the efficient request and delivery of blood products, especially in emergency situations. By enabling electronic communication and automating processes such as blood product ordering, verification, and delivery, the module minimizes delays and enhances the overall transfusion workflow.

Emergency healthcare information system

Emergency Healthcare Information System (EHIS) is aimed to support functioning of emergency medical service that at the same time enables the medical professionals to control their activities, the patients to obtain care within "a golden hour", and the management to track and monitor business processes in emergency medicine.

EHIS main components:

- Triage Management: enables efficient triage by categorizing patients based on the severity of their condition, ensuring that critical cases receive immediate attention.
- Patient Tracking: It allows healthcare providers to track and monitor patients throughout their emergency care journey, providing real-time updates on their location, treatment status, and medical interventions.
- Vital Signs Monitoring Module: This module integrates with medical devices to capture and display real-time vital signs data, such as heart rate, blood pressure, oxygen saturation, and temperature. It helps healthcare providers closely monitor patients' conditions and detect any changes or deterioration promptly.
- Communication Module: This module facilitates secure and efficient communication among healthcare team members involved in emergency care. It may include features like instant messaging, voice calls, video conferencing, and alerts to ensure effective collaboration and timely response.
- Information Exchange: The EHIS facilitates the secure exchange of patient data, including medical history, allergies, medications, and diagnostic results, ensuring that healthcare providers have access to comprehensive and up-to-date information.
- Resource Management: The EHIS helps optimize resource allocation by providing visibility into available staff, equipment, medications, and other critical resources. It ensures efficient utilization and minimizes delays in providing emergency care.

The implementation of an Emergency Healthcare Information System enhances the overall effectiveness and efficiency of emergency care delivery. It enables healthcare providers to make timely and well-informed decisions, improves patient safety, and facilitates coordinated efforts among multiple stakeholders involved in emergency healthcare services.

Pharmacy Inventory Management Software (PIMS)

The pharmacy inventory management software is a crucial module within the proposed Health Information System for Kosovo, designed to optimize the management of medication inventory and streamline pharmacy operations. This module encompasses various sub-modules and functionalities that support efficient inventory tracking, stock management, medication ordering, and medication safety.

The main modules within the pharmacy inventory management software component include:

- Pharmacy Workflow Management
- Inventory Tracking and Stock Management: The inventory tracking and stock management module enable pharmacies to monitor and track medication inventory in real-time. It provides functionalities to capture and update inventory data, including medication quantities, expiration dates, lot numbers, and storage locations.
- Medication Ordering and Replenishment
- Medication Dispensing and Barcode Scanning: The medication dispensing, and barcode scanning module ensures accurate and safe medication dispensing to patients.

Currently MoH and Healthcare institutions of all levels have this system in place, but what is currently missing is the integration of this system with KMA, e-Prescription and other related modules to insure the track and trace of the drugs and pharmacy inventory.

Dentistry

This module encompasses various sub-modules and functionalities that facilitate the management of dental records, treatment planning, communication between dental professionals, patient education, and quality assurance.

The main modules within the dentistry component include:

- Patient Records Management: The dentistry module enables the digital storage and management of comprehensive dental patient records. It allows dental healthcare providers to capture and store essential information, including dental history, radiographic images, treatment plans, and progress notes. By centralizing these records, the module ensures easy access, accuracy, and the ability to track changes over time.
- Treatment Planning and Progress Monitoring: This module supports dental professionals in creating treatment plans, scheduling appointments, and tracking the progress of each patient's dental care journey. Treatment planning tools enable dentists to document diagnoses, develop customized treatment plans, and set milestones for achieving optimal oral health. Dental staff can efficiently coordinate appointments, monitor treatment progress, and record outcomes within the system. Integration with imaging technologies allows for visual documentation of treatment progress, aiding in comprehensive care delivery.
- Inter professional Collaboration: Efficient communication and collaboration between dental professionals is crucial for delivering comprehensive oral healthcare. The dentistry module provides secure communication channels, enabling intra-office and inter-office collaboration. Dentists and dental staff can securely exchange messages, share digital images, refer patients to specialists, and consult on complex cases. This collaborative feature enhances interdisciplinary coordination, facilitates knowledge sharing, and ensures seamless continuity of care.
- Patient Education and Oral Health Promotion: The dentistry module includes tools for patient education and oral health promotion. It provides resources such as educational materials, preventive care guidelines, oral hygiene instructions, and videos on dental procedures. Dental professionals can leverage these resources to educate patients about maintaining oral health, preventing dental diseases, and adopting healthy oral hygiene practices. Patient education modules contribute to empowering individuals to take an active role in their oral health management, leading to improved overall oral health outcomes.

The integration of the dentistry module with other components of the e-Health, such as the electronic health record system, enhances the overall efficiency and effectiveness of oral healthcare services. Seamless data exchange between different healthcare modules ensures comprehensive patient care, promotes interdisciplinary collaboration, and enables a holistic approach to healthcare management.

4.2.4 Administration

Master Data Management

Master data management system (MDM) is a comprehensive software platform crafted to handle the management and governance of master data within organizations. It seamlessly integrates and consolidates data from diverse sources, guaranteeing a unified and precise view. With its array of features encompassing data integration, governance, quality management, and relationship management, MDM elevates data quality, operational efficiency, and regulatory compliance. Its versatile applications span across industries, benefiting customer management, supply chain optimization, and adherence to regulatory requirements.

Key features of MDM software are:

- Patient Identification and Matching: One of the critical challenges in eHealth is accurately identifying and matching patient records across various systems and healthcare organizations. MDM helps resolve this challenge by establishing a single, trusted patient identifier that enables accurate patient matching and eliminates duplicate records.
- Data Integration: In eHealth, there is a wide variety of data sources and systems that need to be integrated, such as electronic health records (EHRs), health information exchanges (HIEs), laboratory systems, and more. MDM helps integrate these diverse data sources, ensuring a unified view of patient and healthcare-related data.
- Data Quality and Consistency: Accurate and consistent data is crucial in eHealth to support clinical decision-making, patient safety, and continuity of care. MDM software provides data cleansing, validation, and enrichment capabilities, improving data quality and ensuring consistency across different healthcare systems.
- Interoperability and Data Exchange: Interoperability is essential in eHealth to enable seamless data exchange between different healthcare entities, systems, and regions. MDM plays a crucial role in harmonizing data formats, standardizing terminology, and facilitating data sharing and interoperability across disparate systems.
- Analytics and Insights: Effective data management and integration provided by MDM enable healthcare organizations to derive meaningful insights from aggregated data. This data can be used for population health management, clinical research, quality improvement initiatives, and healthcare analytics.

SSO

Single sign-on, or SSO, is a secure and convenient way for users to access all their authorized applications with one credential. SSO eliminates the need to remember and enter multiple passwords during a user's shift. Users can simply sign in once and then tap their badge to authenticate themselves for any subsequent applications.

This feature is especially important for healthcare technology, as it enables clinical users to focus more on their patients and less on the technical issues. SSO helps healthcare professionals save time, reduce errors, and improve security.

With single sign-on (SSO), users can securely log in once within a specified time frame, usually the duration of their work shift. SSO uses one credential to grant access to all the applications that users are authorized to use, without requiring them to remember multiple passwords. After the initial "single sign-on", any further authentication can be done easily with the SSO solution. SSO solutions can enhance security and user efficiency, and when combined with strong authentication methods, they can eliminate the need for passwords altogether.

It would be good to use SSO as a service from GG, if GG can provide SSO for all users in eHealth systems, otherwise, eHealth Body needs to plan to implement such SSO solution for all users of eHealth systems.

4.3 Critical relationships between building blocks

4.3.1 The current situation of the systems in terms of technology and law

One of the key decisions for developing a healthcare information system is whether to adopt interoperability standards like HL7 FHIR (Fast Healthcare Interoperability Resources) or to use a non-standard format. Additionally, the connection and communication within a national platform not only requires technological requirements for data security, but also legal aspects oblige us to align with the state-

level requirements. Interoperability requirements can be understood and interpreted through the typology of ICT-supported decisions as prerequisites for a coherent system design. These prerequisites encompass aspects such as patient access to the system, the safety of system approaches, the implementation of data exchange channels between information systems, the use of communication technology and web-based platforms, and the organization of databases. Since the architecture is based on microservices, the exchange of data between these modules (blocks) is facilitated by implementing standardized protocols and interfaces. This en-sures seamless communication and interaction, allowing for efficient and coordinated healthcare services. The healthcare database must establish standardized protocols and interfaces that enable the seamless exchange of data between these modules (blocks). This can be achieved using interoperability between GG national platform and standards such as HL7 and FHIR, that facilitate the sharing and integration of healthcare data.

Based on discussions with experts from the ASHI and relevant individuals, GG architecture promises a full integration of the eHealth system in Kosovo. This integration is not only mandatory in the legal context but also feasible in the technological aspect. There is a possibility for the eHealth system to find support for data interoperability among healthcare institutions. Below you will find the current state in terms of the legal aspect, along with recommendations, as well as the technological aspect.

Kosovo has approved the Interoperability Framework (https://gzk.rks-gov.net/ActDocumentDetail.aspx?ActID=8669), which is transposed from the European Interoperability Framework. According to the Law on Governmental Institutions of Information Society (https://gzk.rks-gov.net/ActDocumentDetail.aspx?ActID=8669), Article 5, paragraph 2 states that "the Agency is the central state administration body for the development and implementation of information and communication technology for the institutions of the Republic of Kosovo." All institutions are required to coordinate their activities and synchronize their systems with the central state infrastructure of information systems.

An important legal act that obliges institutions in the country to develop IT projects in full coordination with central assistance and obtain approval from the special commission within ASHI is Regulation: Regulation (QRK) No. 06/2018 on Project Management in the Field of Information and Communication Technology, which can be downloaded (https://gzk.rks-gov.net/ActDocumentDetail.aspx?ActID=18781). Based on the mentioned legislation and other legal acts, all institutions are required to design and develop their systems in a way that:

- Utilizes the central infrastructure of the state computer network
- Utilizes the State Data Center, including aspects of central cybersecurity managed by ASHI
- Utilizes connections with various systems through the existing Interoperability/Intercommunication Platform (GG Microsoft platform).

All systems provided for citizens and officials must utilize the GG Interoperability platform and be published on the Central eKosova Platform, which was designed for this purpose and has been functioning as the central gateway for online services since 2020. The authentication module (for officials and citizens) is offered through the interoperability platform (GG platform), through which each system interacts with multiple other systems, such as the Civil Registry, where the eHealth system in Kosovo retrieves vital data.

Based on the legislation highlighted above, the Government of the Republic of Kosovo issued a decision in 2021, stating that all public institutions in the Republic of Kosovo are obliged to coordinate their activities with the Information Society Agency in the Ministry of Internal Affairs (ASHI/MPB) for the development of electronic systems and their integration into the infrastructure and central platforms of information systems in accordance with the current legislation. It is worth noting that the National Audit Office identifies and marks observations for all those institutions that do not utilize GG and eKosova for online services.

Regarding the eHealth Information System and the Interoperability Platform (GG platform), the recommendations are based on instructions of ASHI – eKosova staff, stating that all central state systems must communicate through the GG platform. In this case, the eHealth Information Systems will utilize services through the GG platform, where all data of citizens and healthcare professionals are obtained from the central Civil Registry through GG. Additionally, GG is designed to be integrated so that all registers and systems receive data directly from GG, as it has previously established connections with over 20 central data exchange systems/registers.

4.3.2 Technical solution interoperability with HL7 FHIR and GG Platform

The Government Gateway (GG) solution adopted by the Government of Republic of Kosovo is a system that establishes a standardized protocol for communication, including data exchange and authentication. GG serves as a mediator between different governmental systems by providing a standardized way to authenticate and consume services. To integrate new services within Government Gateway, "integration libraries" are developed which fetch data from end-system APIs and the returned data is encapsulated in a standard GG XML Envelope. This XML envelope can contain data in several formats, one of which can be HL7 Fast Healthcare Interoperability Resources (FHIR). When another system fetches data from eHealth, it is encapsulated in the GG XML Envelope which the system then has to "unpack" to extract and parse the data. In other words, GG does not make any assumptions about the format of the enclosed data. All it does is it provides authentication and communication standards between different systems. The main difference between FHIR and HL7 is that FHIR leverages RESTful web services and open web technologies such as XML, JSON, and RDF, while HL7 only supports XML. FHIR builds on previous standards, including HL7 CDA, V2, and V3, but is easier to use since it covers a broader range of technologies. Communication technology formats are acceptable for GG, and it is worth noting that GG is only the HUB service that does not store data, but only enables interaction between systems (synchronous and asynchronous) in a safe way, through the digital certificate that serves as authentication of the systems. GG encrypts the traffic and sends it encrypted to the end system. Consequently, GG bears the responsibility of ensuring that the communication technology formats are compatible and suitable for its operations. It is important to emphasize that GG functions solely as a HUB service, refraining from data storage, facilitating secure interactions between systems in both synchronous and asynchronous manners. This security is guaranteed through the implementation of digital certificates, that serve to authenticate the involved systems. Moreover, GG employs encryption to secure the transmitted traffic, ensuring that it reaches the end system in an encrypted form. (Ref: IT ASHI group, developer team from company who developed GG)

Refer to (expert from Microsoft) HL7 provides a framework and standards for structuring, encoding, and transmitting health-related data, ensuring that the information is understood and interpreted consistently across different systems. It covers various aspects of healthcare data, including clinical and administrative information.

GG uses GovTalk protocol, which is considered as a one level above of HL7. That means, GovTalk can carry HL7 messages in case there is created wrapper, which can encapsulate HL7 messages into GovTalk envelope. In general, GovTalk is designed to carry any type of message and data structure. The benefit of GG in this case is that it can be used for integration of different systems, regardless of the lower-level protocols like HL7. On the other side it means, that pieces of SW, that will be able to wrap/unwrap such messages, are needed. In general, if there is only just one system based on HL7 (typical system in Hospital) then there is no benefit using GG as an integration platform, because it adds complexity. In case there is a need to get or send data between institutions then usage of GG as a universal integration platform makes sense.

Of course, there could be aspects that can be considered when selecting an integration platform. When selecting an HL7 integration hub, it's essential to consider factors such as compatibility with existing systems, scalability, security features, support for different HL7 versions and messaging formats, ease of configuration, and overall reliability. Some integration hubs are specifically designed for HL7 Version 2 messaging, while others also support newer standards like HL7 Version 3 and FHIR. Many modern integration hubs embrace FHIR standards due to its growing popularity and adoption in the healthcare industry. (Ref: recommendations from Microsoft expert) https://azure.microsoft.com/en-us/blog/microsoft-launches-azure-health-data-services-to-unify-health-data-and-power-ai-in-the-cloud/

Integrating HL7 FHIR into the eHealth system in Kosovo is a crucial step towards improving healthcare data exchange, interoperability, and patient care. FHIR's flexible and standardized data representation allows for seamless integration with existing health information systems, fostering efficient and secure data sharing across healthcare providers and organizations. As for the HL7 FHIR (Fast Healthcare Interoperability Resources) protocol, which is a standardized framework for data exchange specifically created for healthcare systems, If we use separate services FHIR, similar to how GG Microsoft provides general data exchange, the HL7 FHIR standard aims to improve interaction and facilitate data exchange in healthcare between providers, systems, and applications, with a particular focus on healthcare. However, in Kosovo, there hasn't been a requirement for GG to interact with technologies like HL7 FHIR. Nevertheless, some research indicates that GG enables interaction and provides services according to this methodology, especially for healthcare systems and healthcare data security.

References:

- https://learn.microsoft.com/en-us/azure/healthcare-apis/fhir/overview
- https://azure.microsoft.com/en-us/blog/microsoft-launches-azure-health-data-services-to-unify-health-data-and-power-ai-in-the-cloud/

Integrating HL7 FHIR into the eHealth system in Kosovo is a crucial step towards improving healthcare data exchange, interoperability, and patient care. FHIR's flexible and standardized data representation allows for seamless integration with existing health information systems, fostering efficient and secure data sharing across healthcare providers and organizations.

Understanding FHIR Standards: The technical team should start by gaining a comprehensive understanding of the HL7 FHIR standard, including its data models, resources, and API structures. This understanding will form the foundation for the subsequent steps in the integration process.

Assessment of Existing eHealth Systems: Conduct a thorough assessment of the current eHealth systems in Kosovo. Identify the data formats, protocols, and technologies in use. This assessment will help identify potential challenges and compatibility issues that may arise during the integration.

Selecting the Appropriate FHIR Version: Choose the most suitable version of HL7 FHIR for integration. Consider factors such as the existing health system's capabilities, future requirements, and support for backward compatibility. Versions like DSTU2, STU3, and R4 should be evaluated, and the most appropriate one should be selected.

Designing FHIR APIs: **Develop FHIR-compliant APIs** that facilitate data exchange between the eHealth systems and other healthcare systems. These APIs should adhere to the FHIR standards, enabling seamless data retrieval and updates while ensuring data privacy and security through authentication and access controls.

Data Mapping and Transformation: Map the data elements from the existing eHealth system to the corresponding FHIR resources. Ensure that data transformation is accurate and follows the FHIR data models. This step is crucial for maintaining data consistency and integrity during integration.

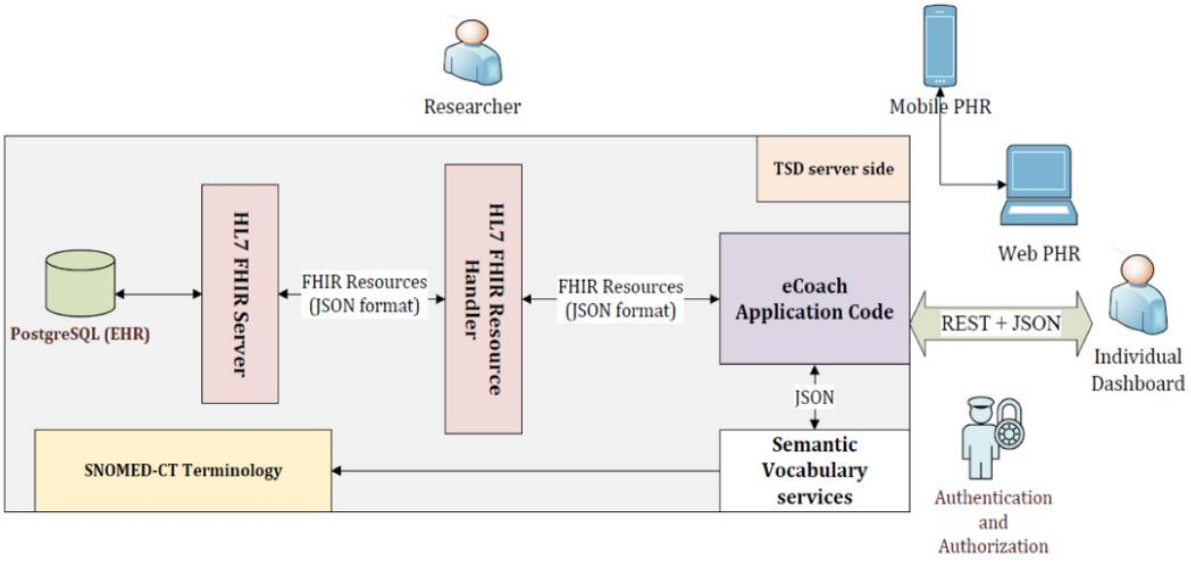


Figure 10: HL7 FHIR with SNOMED-CT to Achieve Semantic and Structural Interoperability in Personal Health Data[11]

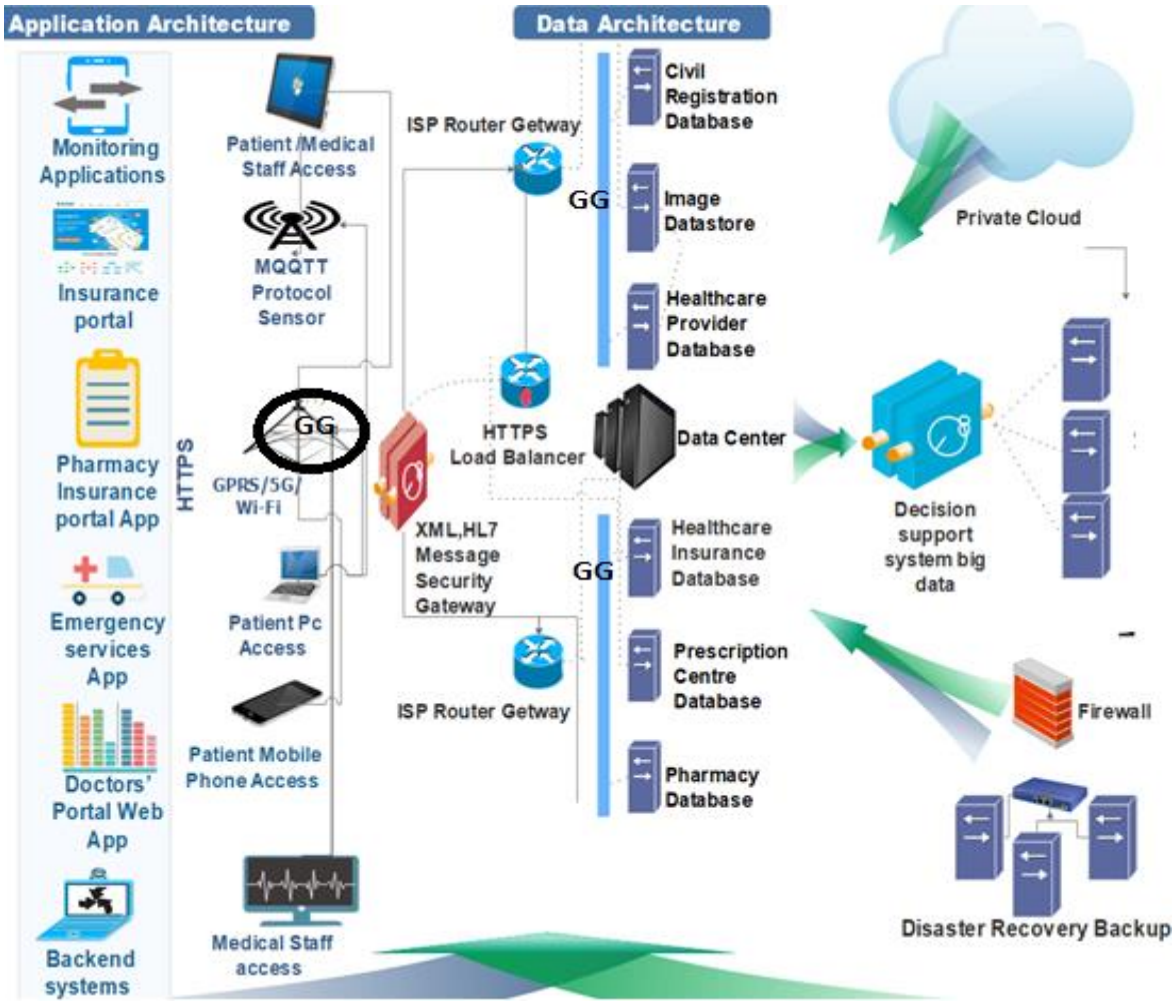


Figure 9: Example of Data Exchange in eHealth architecture (GG, HL7 FHIR)

[11] A Proof-of-Concept Study (https://www.mdpi.com/1424-8220/22/10/3756)

This choice has several implications for the system's performance, usability, and sustainability. Here are some of the pros and cons:

Pros:

- **Interoperability**: Standards like HL7 FHIR promote interoperability, enabling seamless data exchange and communication between different healthcare systems and applications.
- Standardized Communication: The GG solution establishes a standardized protocol for communication, including data exchange and authentication.
- Mediator Between Governmental Systems: GG serves as a mediator between different government systems, providing a standardized way to authenticate and consume services.
- HL7 FHIR Integration: GG enables interaction and provides services according to the HL7 FHIR methodology, improving interaction and facilitating data exchange in healthcare systems
- **Scalability**: Interoperability standards provide a scalable foundation for health information systems, accommodating future growth, and technological advancements.

Cons:

- **Implementation Complexity**: Implementing interoperability standards can be complex and require technical expertise, especially during the initial stages of adoption and communication between (ASHI – eKosova) Staff and MoH IT team.
- **Learning Curve**: Development teams and healthcare providers may need to invest time and effort in understanding and adopting the standards, potentially resulting in a learning curve.
- **Potential Limitations**: Interoperability standards may not cover every specific use case or domain, leading to potential limitations or gaps in certain areas of healthcare information exchange.
- **Cost**: Adhering to interoperability standards may involve additional costs, such as training, licensing, and implementation support.
- **Local experts**: the challenge of finding and retaining local experts with knowledge and experience in implementing HL7 standards.

Case study in different countries

Based on the case studies, we do not have a specific case that GG has been implemented as a platform for eHealth systems in a country. Studies show that FHIR, HL7 are adaptable to most platforms in eHealth systems. Below you have some scientific research related to two standards on how they can be integrated in different health systems.

1. https://www.sciencedirect.com/science/article/pii/S1532046419302291
2. https://www.mdpi.com/1424-8220/22/10/3756
3. https://www.semanticscholar.org/paper/HL7-FHIR%3A-An-Agile-and-RESTful-approach-to-exchange-Bender-Sartipi/1303cba4966df8aefb696b288ba06e1438f3d109
4. https://www.mdpi.com/1660-4601/17/1/73

Using a Nonstandard Format

The choice of format plays a crucial role in the design and implementation of healthcare systems, particularly in the realm of e-health. While standardized formats offer a common framework for interoperability and data exchange, there are instances where using a nonstandard format may present certain advantages. In this discussion, we will explore the pros and cons of using a nonstandard format in healthcare systems.

Pros:

- **Flexibility**: Choosing a nonstandard format provides greater flexibility to tailor the system to specific requirements without being bound by predefined standards.
- **Customization**: A nonstandard format allows for customization and optimization of data structures and messaging protocols based on the specific needs of the organization or system.
- **Quick Implementation**: Developing a system based on a nonstandard format may expedite the initial development process, as there may be no need to conform to existing standards.
- **Cost**: Lower the implementation cost, as the system can leverage existing components or interfaces that already support nonstandard format.

Cons:

- **Limited Interoperability**: Using a nonstandard format can hinder interoperability with other systems, making it challenging to exchange data and collaborate with external stakeholders.
- **Higher Integration Effort**: Integration with other healthcare systems or external applications may require custom interfaces and extensive development effort due to the lack of standardized formats. Also impose the cost of certification or accreditation that may be needed for nonstandard systems to ensure their safety and reliability.
- **Data Silos**: Nonstandard formats may lead to data silos within the organization, impeding the sharing and utilization of data across different departments or healthcare settings.
- **Long-term Sustainability**: Nonstandard formats may become outdated or unsupported over time, making it difficult to maintain the system and adapt to evolving requirements.

Recommendation

Developing a healthcare information system in Kosovo requires careful consideration of interoperability standards and the choice between adopting standardized formats like HL7 FHIR or using nonstandard formats. The current situation in Kosovo emphasizes the utilization of the Government Gateway (GG) platform as a central infrastructure for seamless data exchange and interoperability among healthcare institutions. The GG platform facilitates standardized communication, acts as a mediator between different systems, and enables integration with other central data exchange systems/ registries.

Technical integration: To integrate new services within Government Gateway, "integration libraries" are developed that fetch data from end-system APIs and the returned data is encapsulated in a standard GG XML Envelope. This XML envelope can contain data in several formats, one of which can be HL7 Fast Healthcare Interoperability Resources (FHIR). When another system fetches data from eHealth, it is encapsulated in the GG XML Envelope that the system then must "unpack" to extract and parse the data. In other words, GG does not make any assumptions about the format of the enclosed data. All it does is it provides authentication and communication standards between different systems.

- **Interoperability Standards:** Consider adopting interoperability standards like HL7 FHIR to promote seamless data exchange and communication between different healthcare systems and applications. This will enhance interoperability and facilitate the sharing and integration of healthcare data.
- **GG Platform Utilization**: Leverage the GG platform as a central infrastructure for connecting healthcare providers, hospitals, clinics, laboratories, and pharmacies. Establish standardized communication protocols and data formats to ensure compatibility and interoperability among different systems.

- **Legal Compliance**: Align with the legal requirements set forth by the Interoperability Framework, the Law on Governmental Institutions of Information Society, and other relevant regulations. Coordinate activities and synchronize systems with the central state infrastructure of information systems, utilizing the GG Interoperability platform.
- **Long-term Sustainability**: Ensure that the chosen approach, whether it's utilizing GG or implementing an HIE architecture, can be maintained, upgraded, and adapted to evolving technologies and interoperability standards. Develop a comprehensive plan for ongoing maintenance, updates, and investments to ensure the long-term sustainability and effectiveness of the system.
- **User Acceptance and Training:** Consider the needs and concerns of healthcare providers and other stakeholders. Provide sufficient training and support to facilitate the adoption of interoperability standards or the chosen system, addressing potential resistance and ensuring smooth workflow integration.

Conclusion: leveraging the GG platform and potentially adopting interoperability standards like HL7 FHIR can enhance the eHealth system in Kosovo, enabling seamless data exchange, scalability, and future growth while considering the associated complexities, costs, and expertise required.es, can be adapted to the local context. Leveraging the GG platform and potentially adopting interoperability standards like HL7 FHIR can enhance the eHealth system in Kosovo, enabling seamless data exchange, scalability, and future growth while considering the associated complexities, costs, and expertise required. Regarding the **GG platform, both from a technical and legal standpoint, it remains that all current and future systems should be adapted to this platform** for communication since it is the only platform currently supporting the healthcare system in Kosovo.

Integrating HL7 FHIR into Kosovo's eHealth system is essential for enhancing healthcare data exchange, interoperability, and patient care. FHIR's standardized data representation enables seamless integration with existing health information systems, promoting efficient and secure data sharing among healthcare providers. To achieve successful integration, the technical team should understand FHIR standards, assess the current eHealth system, select an appropriate FHIR version, design FHIR-compliant APIs, and perform data mapping and transformation. Implementing these steps will foster improved healthcare services and data security in Kosovo's healthcare ecosystem.

4.3.3 Critical Relationship and Data Exchange between Building Blocks

As we elaborate in **chapter 4.1** figure (2-4) critical relationships and data exchange between building blocks, the integration between various building blocks in the healthcare ecosystem, including the eHealth system in Kosovo, and the Government Getaway (GG) platform, with the support of standardized protocols like HL7 FHIR, should enable seamless data exchange and interoperability. The eHealth system in Kosovo connects with the GG platform, should ensuring secure transmission of patient data and facilitating access to electronic health records (EHR). e-Prescriptions should be transmitted through standardized protocols, enabling efficient processing and dispensing by pharmacies. Appointment scheduling systems should integrate with the GG platform, allowing patients to book appointments and providing real-time availability information. Referral requests and patient data are securely should be transmitted between healthcare providers in Kosovo using the GG platform. Telemedicine allows GG to be used solely for text-based consultations through the system, where two doctors can communicate with each other for diagnosis descriptions, reading radiological images, etc. But for video call services, it should be used the telemedicine module that is currently being used at QKUK, where this module uses CISCO devices for video communication (with secure channel via VPN). Based on recommendations from the expert group at ASHI, GG, as a platform, does not currently support video call communication/connection.

The Blood Transfusion Information System in Kosovo should be exchanges data with GG, enhancing blood inventory management and ensuring timely transfusions. Primary Healthcare Systems and Hospital Management Information Systems in Kosovo need to integrate with GG, enabling seamless data exchange for patient management, billing, and administrative functions. Laboratory Information Systems transmit lab test orders and results through GG, facilitating efficient diagnostic processes. Radiology Information Systems and PACS exchange radiology orders, images, and reports via GG, enhancing radiology services and collaboration. Emergency Healthcare Information Systems securely need to transmit critical patient data through standardized protocols, enabling timely and informed decision-making during emergency care situations. Pharmacy Information Management Systems in Kosovo should be connected with GG for the exchange of patient and prescription data, ensuring accurate and up-to-date medication information. Public Health Information Systems in Kosovo may need to integrate with GG to exchange relevant public health data, enhancing disease surveillance and management. Decision-making tools and analytics can access data from the eHealth system in Kosovo through GG, supporting evidence-based healthcare practices. Central registries in Kosovo ensure accurate and synchronized master data management, improving data quality and consistency across the healthcare ecosystem. Overall, the integration between these building blocks, including the eHealth system in Kosovo, and the GG platform fosters efficient data exchange, collaboration, and improved healthcare outcomes in the country.

In the context of healthcare, there are several building blocks or components that need to work together to support the delivery of efficient and effective care. These building blocks typically include healthcare providers, patients, electronic health records (EHRs), health information exchange (HIE) systems, and various healthcare applications. Critical Relationships and Data Exchanges are:

- **Provider-to-Patient:** Providers share medical information with patients, including diagnoses, treatment plans, and educational materials. Patients provide their medical history, symptoms, and self-reported data to their healthcare providers.
- **Provider-to-EHR:** Healthcare providers input patient data into EHR systems, ensuring the information is accurately documented and updated. EHRs may also integrate with other clinical systems, such as laboratory information systems, radiology systems, and pharmacy systems, to receive test results and medication information.
- **EHR-to-Healthcare Applications:** EHR systems exchange patient health data through HIE communication platforms, allowing healthcare organizations to share information across different systems and facilitate care coordination. HIEs provide a standardized framework for data exchange and ensure data security and privacy.
- **Patient-to-Healthcare Applications**: Patients interact with healthcare applications, such as patient portals or mobile health apps, to access their health records, schedule appointments, communicate with providers, and receive personalized health information. These applications may retrieve patient data from EHRs to provide accurate and up-to-date information.

Health Information Exchange (HIE) systems, interoperability, and APIs are related concepts but have some distinct differences:

- **Health Information Exchange (HIE) Systems** HIE systems are the infrastructure and technology platforms that enable the secure exchange of patient health information between different healthcare organizations, systems, and stakeholders. HIEs facilitate the sharing of electronic health records (EHRs), lab results, imaging reports, medication data, and other clinical information. They provide the framework and standards necessary for data exchange, ensuring data integrity, privacy, and interoperability among participating entities.

- **Interoperability**: Interoperability refers to the ability of different healthcare systems, applications, and devices to exchange and use health information effectively, accurately, and consistently. It involves the harmonization of technical, semantic, and organizational aspects to ensure seamless data exchange and meaningful use of the information. As an example of usage of Interoperability in Kosovo it can be considered the GG platform.
- **Application Programming Interfaces** (APIs): APIs are sets of rules and protocols that enable software applications to interact and communicate with each other. In the context of healthcare, APIs provide a standardized way for different systems, applications, and platforms to exchange data and services. APIs provide a flexible and scalable approach to data exchange and integration, allowing developers to build new applications or extend the functionality of existing systems. They enable interoperability by providing standardized interfaces for data exchange and ensuring seamless communication between different components of the healthcare ecosystem.

Several European Union (EU) countries have implemented advanced health information exchange platforms. Here are a few examples:

Estonia: *Estonia is known for its advanced digital health infrastructure. They have implemented an integrated health information system called "e-Health" that enables seamless sharing of patient data across healthcare providers. The system includes a digital health record, e-prescription, and secure data exchange between healthcare institutions.*

Finland: *Finland has developed an extensive health information exchange platform known as Kanta, which connects different healthcare organizations, such as hospitals, clinics, pharmacies, and laboratories. Kanta provides a centralized repository for patient data, including electronic prescriptions, medical records, and imaging results.*

Denmark: *Denmark has established a nationwide electronic health record system called "Sundhedsplatformen." It allows healthcare professionals to access patient data, including medical history, test results, and medication information. Sundhedsplatformen promotes data sharing and collaboration among healthcare providers.*

Netherlands: *The Netherlands has implemented the National Exchange Point for Healthcare (LSP - Landelijk Schakelpunt). LSP facilitates the secure exchange of patient information among healthcare professionals, such as general practitioners, hospitals, pharmacies, and specialists. It enables real-time access to essential medical data across different care settings.*

Sweden: *Sweden has developed a comprehensive health information exchange platform called "National Patient Overview" (NPÖ). NPÖ allows healthcare providers to access patient summaries, medical history, medication lists, and diagnostic reports from various care settings. It aims to enhance care coordination and improve patient safety.*

For effective interoperability and centralized data management, seamless data exchange is essential among all healthcare systems and modules. This requires the establishment of robust data integration mechanisms to ensure accurate and consistent information flow across the entire healthcare ecosystem.

Interoperability requirements can be understood and interpreted through the typology of ICT-supported decisions as prerequisites for a coherent system design. These prerequisites encompass aspects such as patient access to the system, the safety of system approaches, the implementation of data exchange channels between information systems, the use of communication technology and web-based platforms, and the organization of databases. The architecture is based on several essential aspects to ensure the sustainability of the system in line with the objectives.

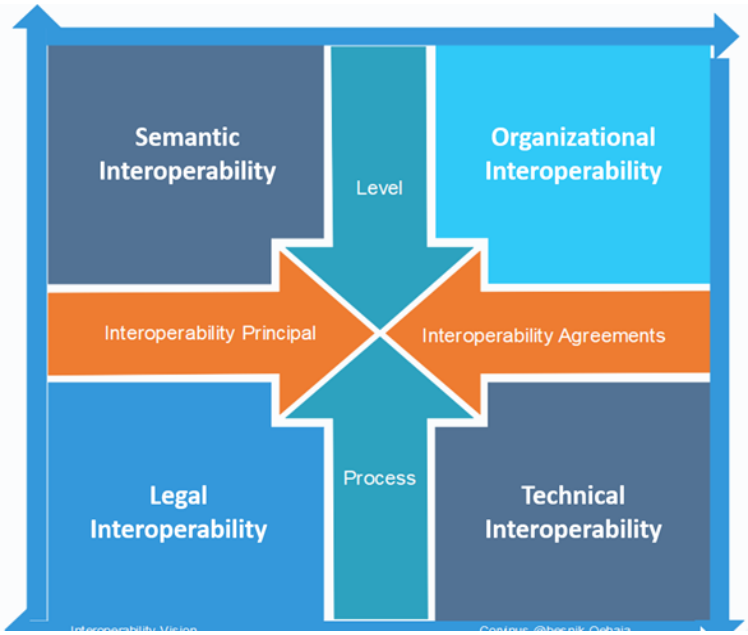


Figure 11: Interoperability rules

1. **Semantic Interoperability**: This refers to the ability of information shared by systems to be understood at the meaning and context level. For health systems, this is critical because it ensures that medical terms, patient data, diagnoses, and treatment plans are universally understood, regardless of the software used. Techniques such as using standardized medical terminologies (SNOMED CT, LOINC, etc.), coding systems as agreed by the institution (ICD-10, ICD-11, etc.), and healthcare data exchange standards (like HL7 FHIR) can be used to achieve semantic interoperability.
2. **Organizational Interoperability**: This refers to the coordination of processes in which information is used. In the context of the e-health system, organizational interoperability might involve ensuring that various healthcare entities such as hospitals, clinics, pharmacies, and administrative bodies have processes in place to handle shared information appropriately. This includes ensuring consistent procedures for data sharing, usage, and privacy protection. It requires creating rules and guidelines about how, when, and by whom information can be accessed and used.
3. **Legal Interoperability**: This refers to the ability of different systems to exchange data while adhering to a set of common legal guidelines or frameworks. It's crucial in healthcare because it deals with sensitive patient data. In Kosovo's case, the e-health system should adhere to both local and EU laws and regulations related to data privacy and protection, such as GDPR. Legal interoperability also includes ensuring the system follows guidelines related to patient consent and the ethical use of data.
4. **Technical Interoperability**: This aspect refers to the ability of two or more systems to exchange information at a technical level. In an e-health system, this can involve using common protocols and data formats for information exchange, enabling different systems to "talk" to each other effectively. Techniques to achieve technical interoperability include using common standards (like HL7, FHIR, DICOM for images) and APIs to allow systems to interact seamlessly.

The key to successful interoperability in the eHealth system of Kosovo would be an effective balance between these four aspects, ensuring a seamless and efficient data flow while protecting the privacy and security of patient data.

4.4 Technical Infrastructure

4.4.1 Databases and Systems Hosted

The conceptual architecture of the E-health system, as outlined in Chapter 4.1, features individual blocks with dedicated databases. These blocks can communicate through the GG platform, facilitating the exchange of information using APIs tailored to each system's requirements. Besides systems and databases communicating through GG, this communication allows them to also contribute to the Electronic Health Record (EHR) registry, ensuring real-time updates with patient information.

The EHR registry encompasses essential medical data such as medical history, diagnoses, treatments, medications, allergies, immunizations, radiological images, and laboratory results. This secure and immediate access to information is limited to authorized users. The ultimate goal of the architecture is to ensure that every system will communicate with each other, and all systems will contribute to updating the EHR registry with accurate and relevant patient details.

Hosted systems

One critical aspect to be meticulously managed is the infrastructure for publishing systems, considering security, service quality, implementation cost, and maintenance considerations. After thorough analysis, the most feasible option is ASHI's Datacenter, which comes highly recommended for its comprehensive support, ranging from hosting to security management and other essential aspects. Utilizing their services provides a reliable point of reference and valuable opportunity for the success of the E-health system. Furthermore, it is noteworthy that the Ministry of Health (MoH) already has their equipment placed in the ASHI data center, which adds to the suitability and integration of the chosen infrastructure.

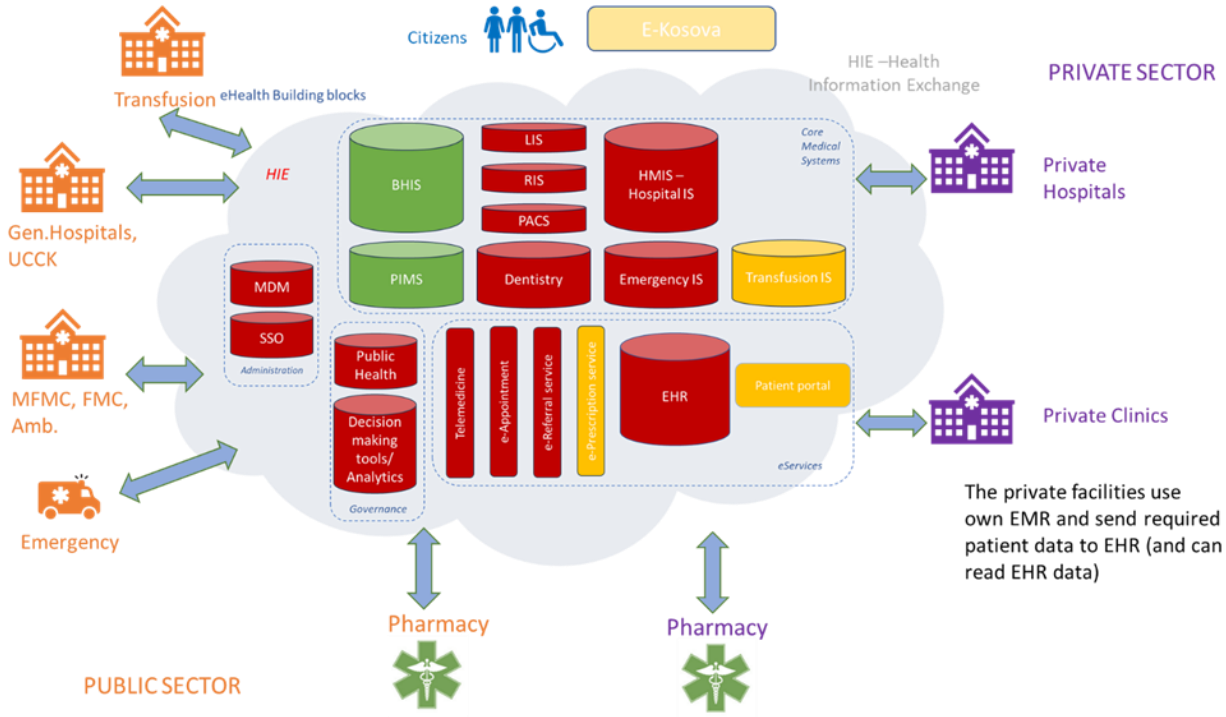


Figure 12: eHealth Conceptual Data Architecture

4.4.2 HW/NW Infrastructure

Data center & network

Current network solutions presented demonstrate a well-designed architecture that adheres to best practices. The centralization of resources within the Data Centre offers numerous benefits, including enhanced security, cost reduction, and streamlined technological requirements for hospitals.

The Data Centre comprises servers hosted in a virtualized environment, ensuring a secure and centralized location for databases and systems. This virtualization concept optimizes resource utilization and facilitates efficient management. Additionally, the Storage Area Network (SAN) serves as a physical communication medium within the Data Centre, providing consolidated and flexible storage solutions. It enables high-speed access to data on disk arrays, facilitating smooth transactional exchanges.

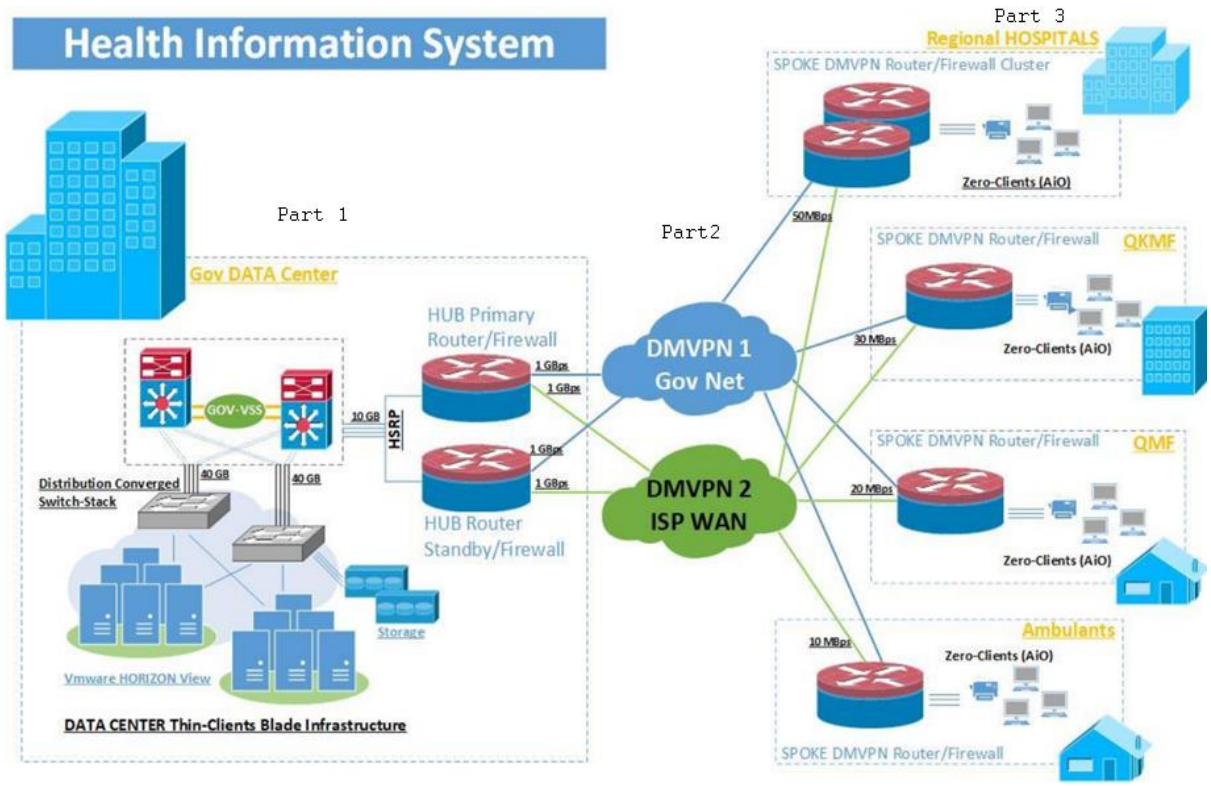


Figure 13: Current Health Information System Infrastructure

To facilitate communication between servers, a separate LAN or VLAN is established, physically isolated from the SAN. This LAN or VLAN is connected to the Wide Area Network (WAN) through a router, safeguarded by a firewall. Furthermore, a Load Balancer plays a crucial role in distributing workload across Web application servers, ensuring optimal resource utilization, minimal response time, and avoidance of overload.

Currently, each facility has its own LAN network equipped with routers, switches, and zero clients. These routers feature DHCP servers to manage LAN-connected devices, and VPN connectivity allows communication with the Data Centre. The WAN infrastructure employs L3 IPsec VPN technology, specifically DMVPN, which is maintained by the Government network or private ISP.

To safeguard against unauthorized access, stringent security rules are configured on network devices protecting all network access points. End users access the system through zero clients within the Local Area Network (LAN) of the healthcare provider, ensuring secure and controlled access.

End-user client HW

Zero client technology refers to a computing model in which the end-user device, known as a zero client, has minimal processing power and relies heavily on a central server or cloud infrastructure for its computing resources. This solution/device offer minimal local processing, centralized computing, increased security, scalability and flexibility, energy efficiency, and simplified management and maintenance.

The average number of PCs per employee

The number of PCs per employee in a general hospital can vary depending on a number of factors, including the size of the hospital, the department or role of the employee, and the hospital's budget for technology.

In the EU, larger hospitals generally tend to have a higher ratio of PCs to employees, often providing each employee with their own computer for efficient record-keeping and communication. This can range from one computer per two to three employees in smaller hospitals to one computer per each employee in the larger hospitals.

It's also worth noting that some hospital employees may require access to specialized equipment, such as medical imaging workstations or research computers, in addition to their regular office computer.

In following table (extracted from Table 1- General Hospitals PC statistics), it is presented the average number of PCs per employee in general hospital in Kosovo, based on interviews data collected in March 2023.

General Hospital	PC per employee
Ferizaj	0,27
Gjakova	0,21
Gjilan	0,36
Mitrovica	0,29
Peja	0,23
Prizren	0,30
TOTAL(s)	**0,28**

Additional steps to be considered:

Currently there are healthcare institutions that do not have the governmental network installed, the process of having all healthcare institutions of all levels with up and running governmental network should continue as this is the base to having systems in place. In line with this activity, all healthcare institutions should have physical network and necessary equipment in place.

Another issue reported by all municipalities and healthcare institutions was lack of printers and toners, it should be considered to place additional printers in the healthcare institutions and to provide them additional toners in stock.

For increased system reliability and availability, it is recommended to establish a backup Data Centre in a separate location via a Virtual Private Network (VPN). This redundancy measure ensures system continuity and should be given priority to minimize downtime and data loss.

4.4.3 Disaster recovery plan architecture

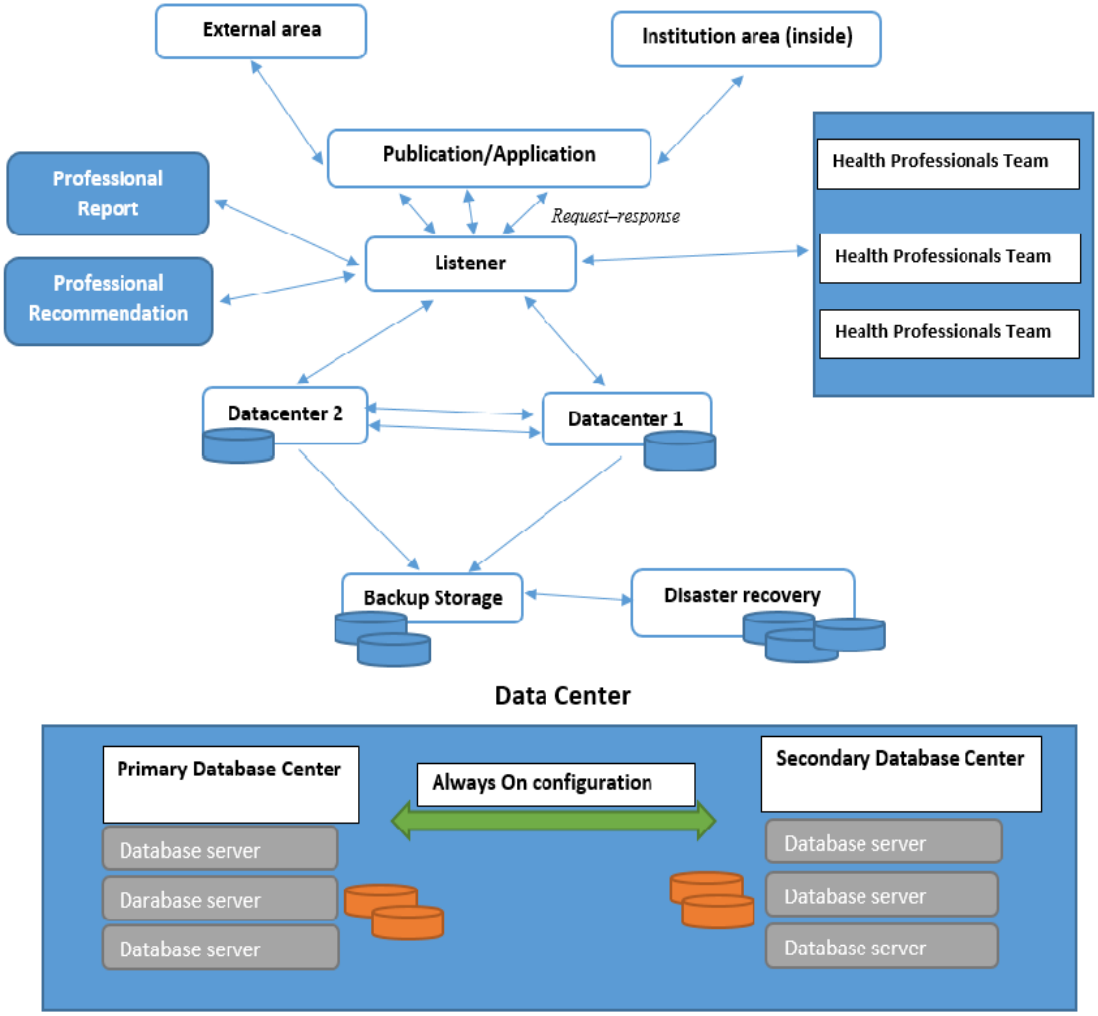


Figure 14: Database Disaster recovery plan architecture

Example: **Always-on Database Configuration** - helps the services to be uninterrupted, meaning that communication between end-users and the information base will be possible for each one. For this purpose, functionality, accuracy, speed, security, and availability are very important components. This technology has begun to evolve and for this purpose has been named as HADR:

- H-High
- A-Available
- D-Disaster
- R-Recovery

Always On is based on:

- Database Mirroring, and
- Failover Clustering.

Cluster technology is used to protect against three main types of failures:

- For the failure of applications and services,
- Hardware system failures,
- Failure of sites in multi-site organizations that may occur due to power cuts, communications, or natural disasters.

Disaster recovery should be a system independent of the primary system in a different geographic location in physical or natural disasters; this system must be ready to access and take the role of the primary system as soon as possible. Disaster recovery should be updated with the latest data on regular daily basis or even more often depending on what type of information is found in the databases. The above figure shows the primary data center and the disaster recovery data center where the synchronization between of data centers is done synchronously and asynchronously. Synchronous between the databases in the primary datacenter and asynchronously between the primary and the disaster datacenter.

Data security has the highest priority, because health records are classified and confidential, data encryption should be applied to the database. Backup copies must be also encrypted. According to EU rules, any information identifying an individual should be protected and coded against free reading and understanding (GDPR). Encryption can be done in several methods by deleting the rules and procedures that differ from which method is omitted.

Among others, Always Encryption enables information to be generated from the database even it is transmitted over the network from the database to the client and is deciphered only in the relevant client application, which means that the data is also protected from administrators of the system.

All e-Health components should be hosted in the Agency for Information Society as is defined by current laws and procedures. AIS manages IT infrastructure of governmental institutions, it is responsible for security and protection of electronic communication infrastructure and data and helps the relevant institutions in the fight against electronic crime (cyber-crime).

Regarding security, it is essential to implement industry-leading authentication practices. As an example, it is presented the Two-factor authentication (2FA) which adds an extra layer of protection against unauthorized access by requiring users to provide additional proof of their identity beyond a password, such as a unique verification code or biometric authentication, the security posture of the system is significantly enhanced. Furthermore, organizations should adopt secure authentication protocols, such as OAuth or OpenID Connect, which provide standardized and secure methods for authentication and authorization. These protocols ensure that user credentials are securely transmitted and verified between different systems, reducing the risk of interception or tampering.

Efficient access management practices for healthcare workers should be carefully reviewed to ensure streamlined workflows and user satisfaction. Requiring users to access each module or system separately can lead to frustration and inefficiencies. Therefore, it is crucial to establish a seamless and secure access framework that caters to the specific roles and responsibilities of healthcare professionals.

4.5 Architecture Implementation Strategies

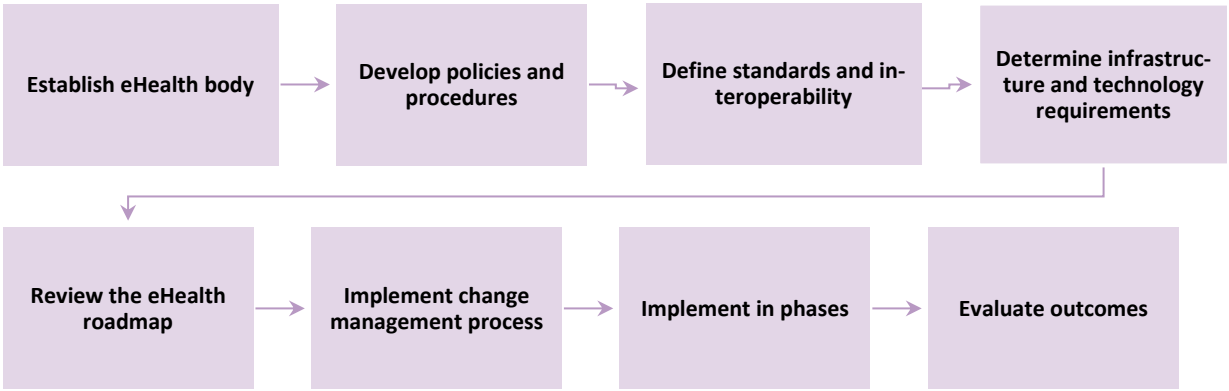
This chapter defines the strategy for implementing the eHealth system in Kosovo, which includes all relevant elements such as transition strategy, governance strategy, contracting strategy, change management strategy, monitoring strategy, standards enforcement strategy etc. In the table below, the basic elements of the implementation strategy are listed for each eHealth building block:

Building blocks	Type of institution	Basic implementation strategy	How many separated systems?	Who will implement it?	Who is responsible for the functioning of it?	Who is responsible for the content of databases?
EHR		Centralized one solution	1	eHealth body	eHealth body	Institutions
e-Prescription		Centralized one solution	1	eHealth body	eHealth body	Institutions
e-Appointment		Centralized one solution	1	eHealth body	eHealth body	Institutions
e-Referral		Centralized one solution	1	eHealth body	eHealth body	Institutions
Patient portal		Centralized one solution	1	eHealth body	eHealth body	Institutions
Telemedicine						
Blood transfusion IS		Centralized one solution	1	eHealth body	NCBTK	Institutions
PHC system	Public institutions	Centralized one solution	1	eHealth body	eHealth body	Public institutions
	Private institutions	Open market model	n	Private institutions	Private institution	Private institutions
HMIS (Hospital management information system)	Public institutions	Centralized one solution	1	eHealth body+ hospitals	eHealth body	Hospitals
	Private institutions	Open market model	n	Private institutions	Private institution	Private institutions
LIS (Laboratory information systems)	Public institutions	One solution	1	eHealth body	eHealth body	Public institutions
	Private institutions	Open market model	n	Private institutions	Private institution	Private institution

Building blocks	Type of institution	Basic implementation strategy	How many separated systems?	Who will implement it?	Who is responsible for the functioning of it?	Who is responsible for the content of databases?
RIS radiology information systems (including PACS),	Public institutions	One solution	1	eHealth body	eHealth body	Public institutions
	Private institutions	Open market model	n	Private institutions	Private institution	Private institution
Emergency healthcare information system		Centralized one solution	1	eHealth body	eHealth body	Institutions
Pharmacy information management system	Public institutions	Centralized one solution	1	eHealth body	eHealth body	Public pharmacies
	Private institutions	Open market model	n	Private pharmacies	Private pharmacies	Private pharmacies
Public health IS		Centralized one solution	1	NIPHK	eHealth body	NIPHK
Decision making tools / Analytics		Centralized one solution	1	MoH	eHealth body	MoH
Master data management		Centralized one solution	1	eHealth body	eHealth body	eHealth body
SSO		Centralized one solution	1	eHealth body	eHealth body	eHealth body

4.5.1 Transition strategy

Transitioning to eHealth depends on factors like existing infrastructure, available resources, stakeholder engagement, and goals. To ensure a successful and sustainable implementation of eHealth solutions, it is important to address technical, operational, cultural, and regulatory aspects. Here are key steps for a smooth transition to eHealth:



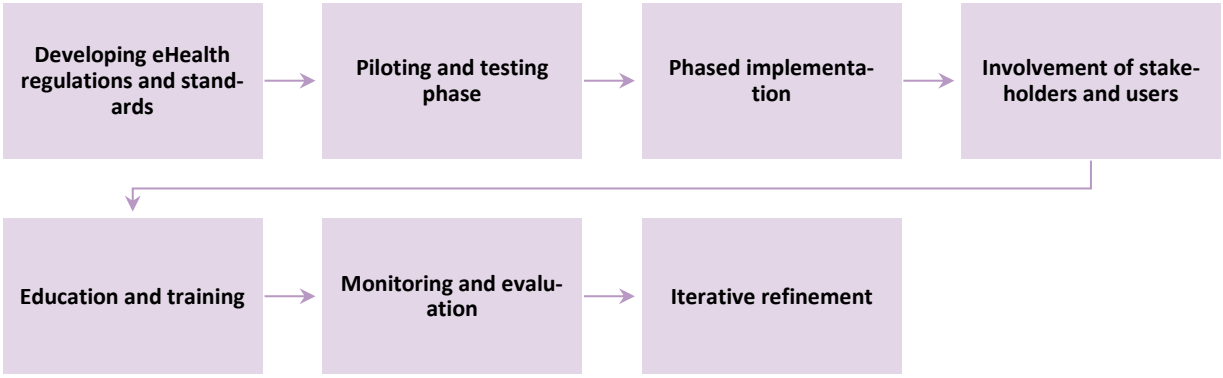
- **Establish eHealth body**: Formulate a formal structure that outlines roles, responsibilities, and decision-making authority for eHealth initiatives. This body will provide oversight and coordination for the planning, implementation, and management of eHealth projects, ensuring clear accountability among stakeholders.
- **Develop policies and procedures**: Create comprehensive guidelines and protocols to direct the implementation and utilization of eHealth solutions. This includes privacy and security policies to safeguard patient data, frameworks for data governance to ensure data integrity and quality, consent management procedures for handling patient permissions, and adherence to applicable regulations and legal requirements.
- **Define standards and interoperability**: Ensure that eHealth systems and solutions conform to industry standards and facilitate interoperability. Establish a framework for seamless exchange and integration of data across various systems. This enables efficient and secure sharing of information and collaboration among healthcare providers.
- **Determine infrastructure and technology requirements**: Conduct a thorough assessment of the existing IT infrastructure and identify necessary upgrades or investments to support eHealth solutions. Consider factors like hardware prerequisites, software applications, network infrastructure, data storage capacities, and security measures necessary for the reliable and secure operation of eHealth systems.
- **Review the eHealth roadmap**: Review the eHealth roadmap defined in Feasibility Study and adjust based on the previous steps and new findings and define detailed steps, timelines, and milestones for the transition to new eHealth. Break down the implementation process into smaller manageable phases, considering organizational priorities and available resources. Identify areas or functionalities that yield the greatest value and address critical needs, ensuring a strategic and phased approach to implementation.
- **Implement change management process**: Establish a change management process to address the cultural and organizational shifts accompanying the transition to eHealth. Effectively communicate the benefits of eHealth to stakeholders, address concerns or resistance, and actively manage the change process. Engage champions and advocates within the organization to promote adoption and facilitate a seamless transition, providing training and support to staff throughout.

- **Implement in phases:** Option for a gradual approach instead of an all-encompassing transition. Roll out eHealth solutions in stages, beginning with a specific department or service area. This method allows for controlled implementation, minimizing disruptions and facilitating continuous learning. Gather feedback from users and stakeholders and make necessary adjustments before proceeding to full-scale implementation. This approach ensures gradual adaptation, smoother workflows, and easier troubleshooting.
- **Evaluate outcomes**: Continuously monitor and evaluate the implementation of eHealth systems. Collect feedback from users, measure performance metrics, and assess the impact on healthcare outcomes. Utilize this information to identify areas for improvement and refine the eHealth strategy over time. Regular evaluation guarantees alignment with organizational goals and enables data-driven decision-making for future enhancements.

4.5.2 Gradual introduction of regulations and standards

IT is important to take a gradual approach to the introduction of eHealth regulations and standards. This approach will allow for the development of regulations and standards that are effective, cost-effective, evidence-based, and flexible.

The plan for the gradual introduction of eHealth regulations and standards, as well as the involvement of stakeholders and users, can vary depending on the specific country or healthcare system. However, here are some common approaches and considerations:



- **Developing eHealth regulations and standards:** The responsible entity, often a government or health ministry, establishes a framework for eHealth regulations and standards. This involves defining legal requirements, privacy and security guidelines, interoperability standards, data exchange protocols, and technical specifications for eHealth systems. Initial step should be establishment of the eHealth standardization working group. The development process should involve collaboration with relevant stakeholders, including healthcare professionals, industry experts, legal experts, and patient advocacy groups.
- **Piloting and testing phase**: Before implementing eHealth regulations and standards nationwide, a pilot phase should be conducted. This involves selecting specific regions, healthcare facilities, or specific use cases to test the effectiveness and feasibility of the proposed regulations and standards. Feedback from stakeholders and users is collected during this phase to identify any challenges or areas for improvement.
- **Phased implementation**: To ensure a smooth transition, eHealth regulations and standards are typically introduced in a phased manner. This allows healthcare organizations and providers to gradually adapt and comply with the new requirements. The implementation plan should prioritize specific aspects of eHealth, such as electronic health records, interoperability, health data exchange or telemedicine, based on the Kosovo's healthcare priorities and resources.

- **Involvement of stakeholders and users**: Engaging stakeholders and users is crucial for successful eHealth implementation. The responsible entity conducts consultations, workshops, and meetings with various stakeholders, including healthcare providers, professional associations, patient representatives, technology vendors, and regulatory bodies. Their input is sought to understand their needs, concerns, and expectations regarding eHealth regulations and standards. Regular communication and feedback mechanisms are established to ensure ongoing engagement throughout the implementation process.
- **Education and training**: As eHealth regulations and standards are introduced, training and capacity-building programs are developed to educate healthcare professionals, administrators, and other users on the new requirements. Training may cover areas such as data privacy and security, proper use of eHealth systems, interoperability standards, and compliance with regulations. Stakeholders and users are involved in the design and delivery of these training programs to ensure relevance and effectiveness.
- **Monitoring and evaluation**: Once eHealth regulations and standards are in place, a monitoring and evaluation framework is established to assess their impact and effectiveness. Key performance indicators (KPIs) are defined to measure progress in areas such as improved healthcare outcomes, patient satisfaction, efficiency gains, and cost-effectiveness. Stakeholders and users are involved in the data collection and evaluation process to provide insights and feedback for continuous improvement.
- **Iterative refinement**: As eHealth systems evolve and new technologies emerge, the regulations and standards need to be periodically reviewed and updated. The responsible entity, in collaboration with stakeholders and users, conducts periodic reviews to identify areas for refinement, address emerging challenges, and incorporate advancements in technology and healthcare practices.

The involvement of stakeholders and users should be an ongoing process throughout the planning, implementation, and evaluation stages to ensure that eHealth regulations and standards align with their needs and contribute to the overall success of the eHealth system.

Roles and responsibilities

The Ministry of Health of Kosovo must have the main responsibility and influence in the implementation of standardization from the political, legislative and management level, and the eHealth standardization working group for defining and managing standards should be operational in the definition and achievement of national consensus. In the actual implementation, control, certification, the central eHealth body should play a leading role, as well as in documentation and assistance during implementation and training.

4.5.3 Governance strategy

The role of the leadership and governance is fundamental for the sustainability of eHealth. The desired outcomes of an eHealth implementation will not be feasible unless there is a governance structure that ensures its correct development and implementation by guaranteeing a global coordination, monitoring and evaluation of the strategy and the respective action plan.

Looking into successful countries confirms that digitization is not an end in and of itself. Necessary processes must be geared towards the benefits they can deliver. There is no simple recipe for success for digitalizing a healthcare system (**Error! Reference source not found.**).

However, a clear pattern can be identified in the success stories of different countries in Europe and worldwide. Digital solutions have been achieved on a national level in those countries where an

effective strategy can be found, where the political leadership is showing the way forward and which features either one or a number of institutions with the political mandate to coordinate the process.

Successful digitalization requires a trio of factors: effective strategies, political leadership and coordinating national institutions.

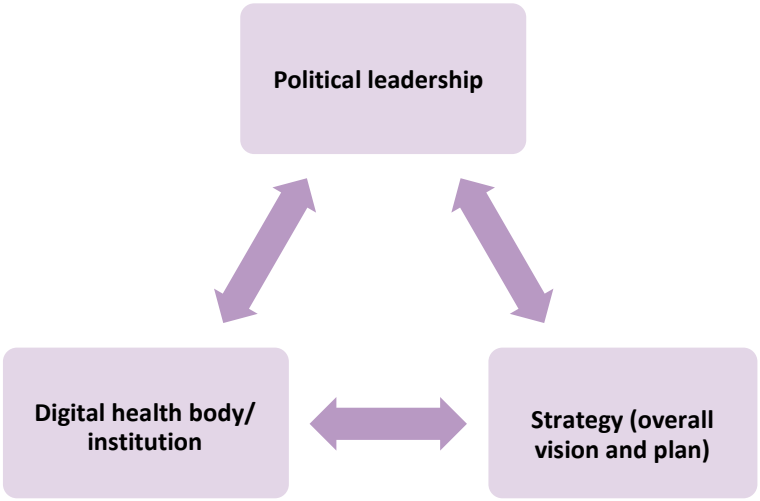
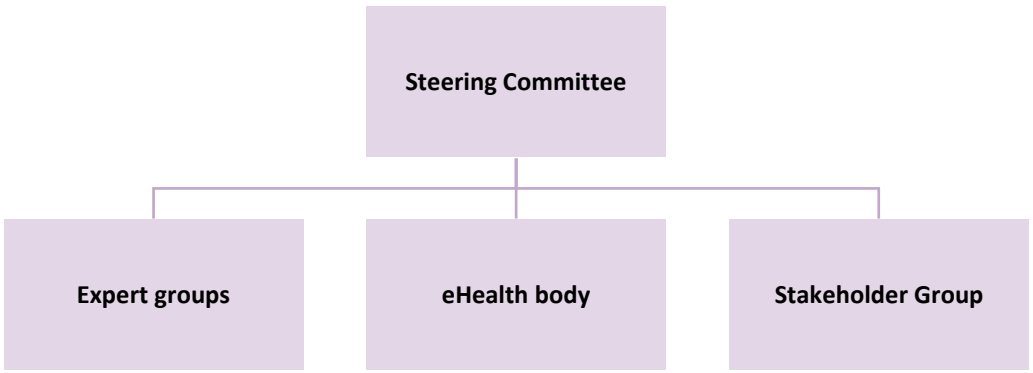


Figure 15: Successful national digitalization of health requires three key factors

To achieve successful national eHealth initiatives, strong leadership and commitment from senior government officials and health sector leaders are essential. The development of a national eHealth vision marks the beginning of the formal eHealth program. Having a credible and respected leader or leadership team actively supporting and championing the effort is crucial. They secure funding, address major challenges, and ensure the vision is driven by the health sector for the health sector.

First step in successful eHealth implementation is to establish eHealth governance bodies. Governance bodies are organizational structures and entities tasked with decision-making, policy-setting, and oversight in a particular domain. Their purpose is to facilitate collaborative decision-making, incorporate expert input into policy development, and ensure the successful implementation of eHealth projects in alignment with strategic objectives and stakeholder interests. In the context of eHealth governance, multiple governance bodies can be established to achieve these goals and effectively manage eHealth initiatives.

Here are some common governance bodies in eHealth:



Group	Responsibilities	Composition

Steering committee	• Gives overall direction, oversight and mandate • Secures spending authority and resources • Assists with resolution of major issues, problems, conflicts and other challenges • Approves, endorses and owns the national eHealth vision	• Senior level health sector decision makers
Stakeholder groups	• Provide input to the development of the national eHealth vision • Provide feedback on deliverables that have been socialized or published	• Individuals or organizations who are affected by or have a specific interest in eHealth and its outcomes.
Expert groups	• Provide guidance on the development of outcomes and recommendations, and supports the development of the national eHealth vision • Assist in identification of existing or planned eHealth components, and their re-use or sharing • Provide input into the development of eHealth governance model • Provide insights into the implications of strategic directions and recommendations for the stakeholder groups • Review and provide feedback on findings, conclusions, and draft deliverables	• Academics, thought leaders, and representatives from the health sector are influential individuals who may not be directly involved in decision-making but possess expertise and can influence key decision-makers through their knowledge and advisory roles. • An expert advisory group consists of a select few industry, sector, or subject matter experts who are invited to provide technical input and advice.
eHealth body	• Plans and manages of the eHealth vision development process. • Manages all eHealth projects • Manages daily operations of centralized eHealth systems	• Individuals skilled and experienced in the management and delivery of largescale health sector strategy. • Individuals skilled and experienced in the IT operations

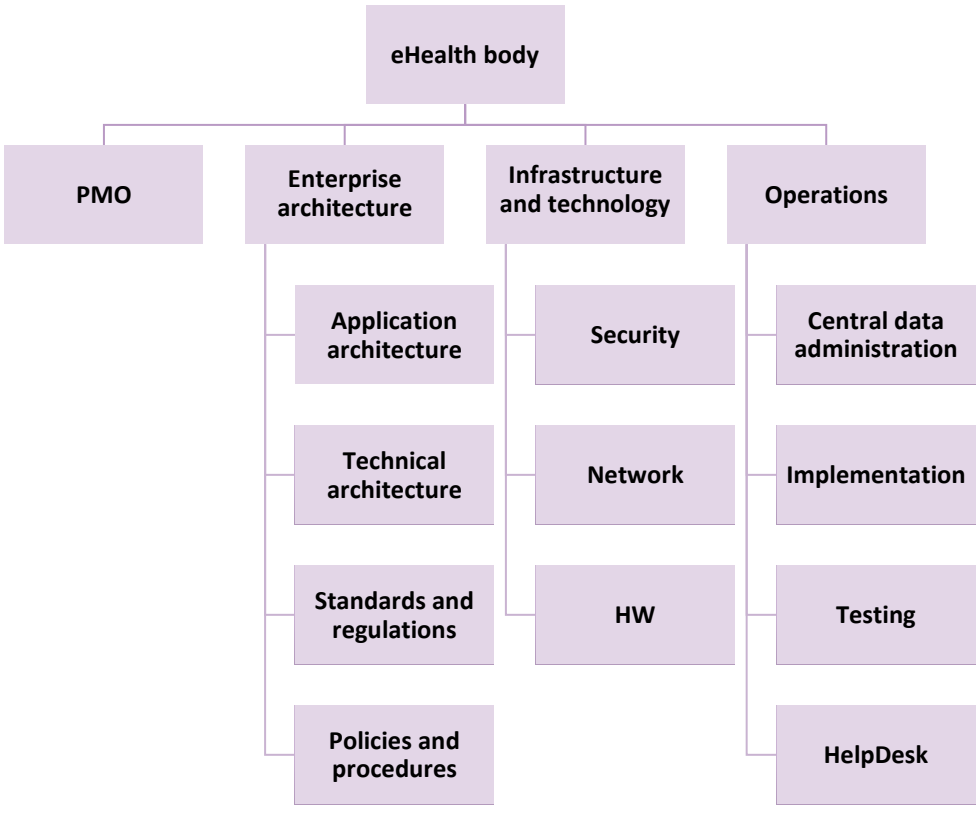
The sustainable establishment and implementation of digital health systems requires an appropriately authorized institution with sufficient powers. This should be an organizational unit that holds overall responsibility for the establishment, management and maintenance of the digital health platform and its infrastructure services. Depending on the national situation, this entity may have to work closely and cooperatively with other specialized organizations. Within the governmental sphere, these may be bodies dealing with cyber-security issues, for example, or specialized national / regional organizations for the management of electronic identities for citizens, physicians and other health professions. Whether the entity takes the form of a department within a ministry, an independent eHealth institute or a department in a national health agency appears to be of secondary importance.

The **creation of an independent national body (eHealth body)** for digital health should be the ultimate goal, but the organizational structure and implementation process can be carried out gradually and pragmatically to avoid political and legal restrictions from preventing or limiting the operational introduction of digital health due to the lack of an institutional operational body. Therefore, we suggest that in the initial phase the existing Department of Health Information System of MoH (DSIS) be given more authority and responsibilities so that it can serve as a coordinating body for the future national body for digital health. These responsibilities include:

- **Strategic Planning**: Developing and implementing a strategic plan for digital health initiatives at the national level.
- **Coordination**: Coordinating efforts and collaborations among various stakeholders involved in digital health, including healthcare providers, government agencies, technology vendors, and research institutions.
- **Policy Development**: Formulating policies and guidelines related to the implementation and use of digital health technologies, data privacy, security, interoperability, and standards.
- **Standards and Interoperability**: Establishing and maintaining national standards for data exchange, interoperability, and technical infrastructure to ensure seamless communication and integration of digital health systems.
- **Governance and Oversight**: Providing governance and oversight of digital health initiatives, including monitoring compliance, evaluating outcomes, and ensuring ethical use of health data.
- **Capacity Building**: Promoting training and capacity building programs to enhance digital health literacy among healthcare professionals and other stakeholders.
- **Stakeholder Engagement**: Facilitating engagement and collaboration with healthcare providers, patients, industry partners, and other relevant stakeholders to ensure their involvement in the development and implementation of digital health strategies.
- **Evaluation and Research**: Conducting evaluations, research, and assessments to measure the effectiveness and impact of digital health initiatives and inform future decision-making.
- **International Collaboration**: Engaging in international collaborations and partnerships to exchange best practices, learn from other countries' experiences, and contribute to global digital health advancements.

To accomplish a long-term goal of having independent digital health body, in parallel with empowering DSIS, start to work on legal and political prerequisites for establishing national Digital Health Agency in the next few years.

We recommend following organization of the eHealth body:



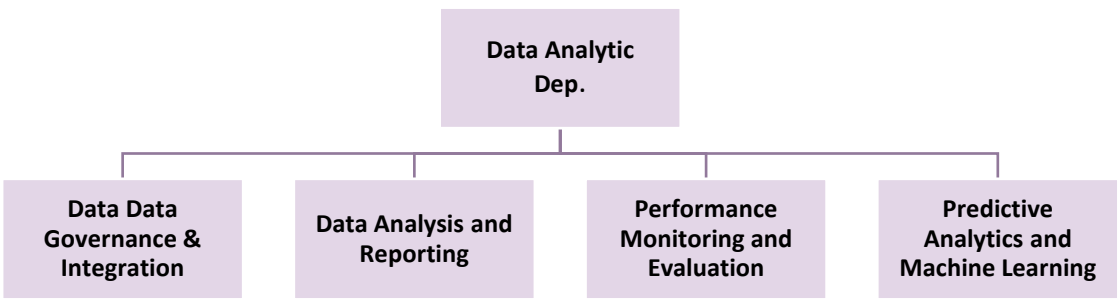
Besides the classic IT roles that depend on IT operations performed by eHealth body, key roles that eHealth body should have, are listed in the table below:

Key role	Responsibilities	Job description
Project manager	The Project Manager holds the responsibility of effectively coordinating all activities, schedules, and human resources associated with the implementation of eHealth projects. Acting as a liaison, they facilitate communication and collaboration between the eHealth body and the project managers or focal points of other stakeholders involved in the initiative.	• Creating business cases, project charters, and project status reports for eHealth projects. This involves outlining the rationale, objectives, and expected outcomes of the projects, as well as providing regular updates on their progress. • Developing, maintaining, and updating comprehensive project plans, schedules, and human resource requirements specifically tailored to eHealth projects. This ensures that all aspects of the projects are well-coordinated and properly resourced. • Monitoring, updating, and reporting on issues and risks associated with eHealth projects. This includes identifying potential challenges or obstacles that may arise during project implementation and communicating them to the relevant stakeholders for timely resolution.
Health Information Systems Analyst	The Health Information Systems Analyst possesses a deep understanding of the healthcare system, including health programs and other related business processes. Their expertise enables them to analyze and comprehend clinical and business challenges, allowing them to make recommendations for solutions that align with the organizational objectives of clinical and business units. By providing a secure and efficient patient care delivery system, they contribute to improving outcomes, reducing costs, enhancing efficiency, and ultimately enhancing the overall patient experience.	• Facilitating the collaborative process of identifying, documenting, and prioritizing strategic, business, clinical, functional, and technical requirements in consultation with key stakeholders. These requirements are crucial for the selection, design, and implementation of clinical and business information systems. • Offering support in identifying and selecting solutions that align with the organization's needs. This includes aiding in the development of business cases, evaluating information technology solutions, and contributing to the creation of functional and non-functional requirements within procurement documents. • Conducting in-depth analysis of workflows, data collection methods, reports, and other aspects of clinical and business processes for the Ministry of Health (MOH) and other key stakeholders. This analysis is essential in facilitating the successful implementation and optimal utilization of information technology solutions.
eHealth Policy Analyst	The eHealth environment operates within a framework of legal, ethical, and policy considerations to address important matters like safeguarding personal health information, regulating secondary data usage, and mandating health information reporting by service providers and national stakeholders. The	• Identifying the legal, regulatory, and policy requirements that are relevant to the implementation of eHealth systems. • Conducting thorough research to identify the best practices in legal, regulatory, and policy frameworks across all strategic areas of eHealth. • Identifying and devise appropriate approaches to address any gaps in legal, regulatory, and

Key role	Responsibilities	Job description
	role of the eHealth Policy Analyst is vital in identifying any policy gaps and requirements. They play a crucial role in facilitating the development of necessary legislation, regulations, and policies to ensure the smooth and complete implementation of the national eHealth strategy.	policy requirements in collaboration with key stakeholders. • Coordinating and oversee the implementation of these approaches, ensuring that they effectively address the identified gaps. • Facilitating the drafting of necessary legislation, regulations, and policies to support the implementation of eHealth systems, as needed.
Change manager	The role of a Change Manager is crucial in ensuring the successful achievement of project objectives within the allocated time and budget. They are responsible for increasing stakeholder adoption and usage by addressing the people aspect of change, which includes modifications to business processes, systems and technology, job roles, and organizational structures. The main focus of the Change Manager is to create and execute effective change management strategies and plans that maximize stakeholder adoption while minimizing resistance. Their primary goal is to ensure smooth and successful transitions throughout the change initiatives.	• Implementing a systematic methodology and oversee change management activities by utilizing appropriate processes and tools. This includes devising a strategy to facilitate the adoption of necessary changes. • Supporting effective communication among stakeholders and teams by creating, developing, delivering, and managing communication messages and materials. • Generating practical outcomes for the five change management levers, namely the communications plan, sponsor roadmap, coaching plan, training plan, and resistance management plan. • Identifying and proactively address any expected resistance to change. • Providing consultation and guidance to project teams, offering support and coaching throughout the change management process.

At a later stage, when a comprehensive data warehouse (DWH) with advanced analytics tools is implemented, the organizational structure of the eHealth body should also include a Data analytics department/sector focused on data integration and management, data analysis and reporting, business intelligence (BI) with predictive analytics and machine learning.

Possible organizational structure of future Data Analytic Department is shown on the following org-chart.



4.5.4 Change management strategy

In general terms, change management is about supporting people through change. Typical requirements of successful change management include processes, tools, and techniques to proactively manage the human elements of change to achieve desired business results. The result of effective change management is a change in behaviors, attitudes and/or work processes to achieve business objectives.

In the world of eHealth, successful change implementation results in solution adoption and other long-term benefits such as improved patient care and organizational efficiencies. In other words, successful implementation of change is achieved when the systems, processes, tools, and technology of the change initiative are embedded in the new way health care providers do their work. Conversely, ICT project failures often have root causes associated with change management shortfalls.

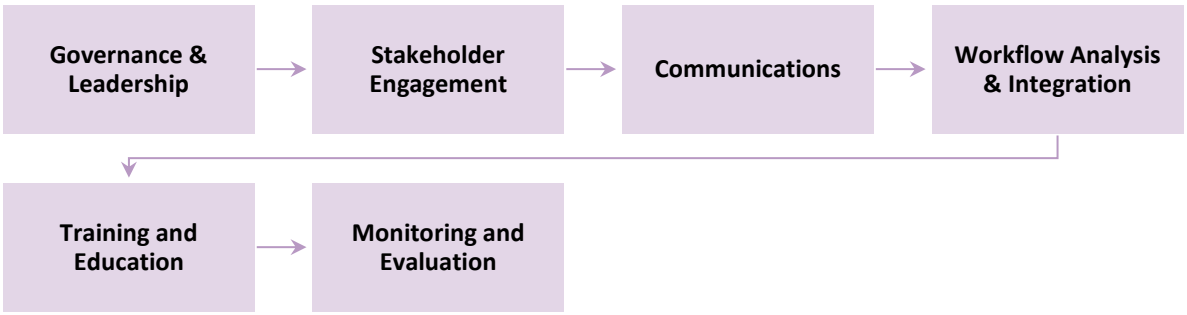
Implementing information and communications technologies (ICT) in health care is not easy, requiring organizational commitment, strong leadership, adequate resources (capital and human), sound project methods, a skilled team, and the utilization of appropriate change management techniques. As such, change management is an integral part of project management processes, impacting project scope, time, cost, quality, risk, contract/procurement, human resources, communications and more. Ultimately, change management activities result in solution adoption and use, transforming health care quality and efficiency.

Change management plans must try to anticipate the various individual reactions of people to new and often stressful situations, and as such, must remain fluid and dynamic. Poorly managed change can result in negative consequences including: turnover of valued employees; lower productivity; resistance in all forms (passive, overt, mild, serious); disinterested, unengaged, detached employees; increased absenteeism; cancellation of projects; and slow or non-adoption of new methods and procedures.

Organizational change management is focused on supporting people to change their behaviors in specific, desirable ways, by providing them with the right tools and supports. Effective leadership that clearly communicates this vision is a critical first step. One must also understand and appreciate the political environment and culture within the organization and the degree of alignment between any new ideas and the organization's perceived "real needs".

Change management is a necessary component of all aspects of eHealth initiatives, including project planning, project management and effective use of cross-functional teams.

Within the context of planned eHealth projects on Kosovo, we suggest the following framework for describing change management activities, that consists of six core elements:



This framework helps to proactively focus attention to these core and vital activities, aiming to minimize negative consequences. Thoughtful contemplation of these undertakings, both in planning and in execution, proactively considers users of eHealth solutions and presents communication opportunities. It also supports the integration of technology into practice; and overall, supports people and their organizations as they transition from the current state to the newly desired state.

Governance & Leadership

These are mechanisms used to guide, steer, or regulate the course of a project, including how stakeholders can affect the priorities and progress of a project as well as the CM activities occurring within a project. Without an effective governance structure, the strategic view that links project tasks together – the "what are we doing" and "why are we doing it," never gets answered and the project risks loss of aim, direction, and successful execution. Without an engaged leadership structure supporting the change activities, as well as desired future state, there is risk of discord and negative impact to organizational culture, failure to obtain buy-in from stakeholders and overall loss of productivity.

Governance concerns the mechanisms that are used to guide, steer, or regulate the course of an organization or system. Strong governance leads to better decisions, greater alignment with organizational priorities and more buy-in from stakeholders. With respect to eHealth projects, it is important to establish formal arrangements for governance (and management) of change programs to clearly establish roles, responsibilities and "who does what" throughout the program or project. Governance structure identifies the mechanism by which stakeholders can affect the priorities and progress of a project.

Effective project planning, stakeholder analysis and engagement at the outset of a project can contribute to successful governance and long-term project success. Engaging end users/stakeholders when defining governance structures has been shown to contribute to successful outcomes in complex solution projects. For example, the initial planning process may reveal key partners that, if included in the governance structure, may result in benefits to the project later.

There is no single best model for governance; it will look different in each organization. Indeed, one of the most critical success factors of effective governance is that the model must match the unique culture and objectives of each organization. However, we can approach identify three key elements of a governance model in terms of principles, structure, and processes, as follows:

- **Principles**: the guiding policies to which the governance model(s) should adhere. Simplicity, efficiency, clarity, and transparency are identified as useful principles for a complex environment such as eHealth.
- **Structure**: the roles, responsibilities, and relationships among the major participants in the information management / information technology governance model, including individuals, committees, and organizational units.
- **Processes**: the operating modes and "ground rules" for operating the model and making decisions.

Having effective governance mechanisms in place to support change management is an important contributor to project success. In a project-based environment, governance mechanisms and project management structures work together to ensure that projects progress as expected.

Clearly defined **leadership** and accountability structures at the outset of the project will motivate others to adopt change. Successful change management requires that a variety of governance structures and roles be in place to provide the leadership and accountability for ICT projects.

Every project needs to have strategic, operational, and tactical level leadership and direction to achieve the required balance of decision making, change progress, and project success.

Although there is no exact formula to follow in implementing an eHealth system, one key ingredient for success appears to be the complete support of the senior executive team, beginning with the head of the organization. Senior leadership needs to support not only the objectives of the project, but also the activities that are required to meet them, including change management. In this context,

leadership is distinct from management, although effective management is an important characteristic of success. Many projects lack change leadership and accountability. A "guiding team" of change leaders and change agents is required to translate the vision into a reality.

Guiding team often includes multiple levels of leadership and management, including:

- **The Initiating Sponsor** – executive who launched the idea. Usually remains committed but is a little more removed from the daily leadership and accountability.
- **The Sustaining Sponsor** – could be the program or project steering committee, and a group of local leaders who are accountable for successfully implementing change.
- **The Target Sponsor** – local level leader of the change.

In practice, change management initiatives require highly integrated teams involving a number of distinct roles. Based on best international practice of implementing change management strategy for eHealth projects, we offer the following framework of examples for (potential) **Change Leadership Roles:**

Description	Examples
Executive Sponsor(s) The executive's representative for ensuring that: • appropriate resources are committed; • problems are solved; and • the program succeeds.	Program Sponsor, i.e. Chief Information Officer, Chief Nursing Officer, Chief Medical Officer, Chief Technology Officer
Change Leader(s) A senior member of the organization who: • is able to command resources and the attention of the executive team; • has a strong personal commitment to the success of the program; and • is the principal trouble-shooter.	Business Sponsor, i.e. Medical Director, Allied Health Director, Clinical Informatics Director, Information Technology Director
Change Agent(s) Members of the project team who are seen to be implementers and enablers of change. i.e. these individuals: • manage and perform tasks to bring about change; • set up environments so change can happen; and • maintain the overall responsibility for detailed planning and implementation of one or more components of the change program.	Project Manager, Transition & CM Lead, CM Specialist
Advocates Individuals who: • are responsible for supporting and communicating change initiatives; • allocate required resources within their area of control; • use their influence with others to support the initiatives; and • support, console and coach others through the change process.	Middle managers, Front line supervisors, Team leaders
Stakeholders Individuals who are: • directly affected by, participate in, and will benefit from the change; • expected to behave differently in the 'changed' organization; and • will be accountable for sustaining future state performance.	Front line clinicians, i.e. physicians, nurses, health professionals, administrative staff, researchers, "users" of the solution

In any case, clinician leaders who embrace the change contribute to the project vision through their advocacy, demonstrated use, and by creating a sense of urgency around the need for adoption. Governance structures, as well as roles and responsibilities for all positions including change leaders, agents and advocates must be well articulated and agreed to by those fulfilling the roles. Champions of the change need to be cultivated across all aspects of the organization / initiative. Leadership is required at all levels of participating stakeholders.

Stakeholder Engagement

It is the process by which the perceptions, issues and expectations of stakeholders are learned and managed. Stakeholder engagement includes focused attention on the individuals who are expected to change. Their behaviors and needs must be defined, understood, and considered when implementing eHealth projects.

Without considering stakeholders, particularly the actual people who need to make the change, there is risk of failed solution uptake, creation of angst and emotional upset, loss of respect for leaders and project implementers, as well as failure to achieve any return of investment or value.

Term "stakeholder" is used frequently but is often confused and interchanged with partners and customers. Stakeholders are persons, groups or organizations that must somehow be considered by leaders, managers, and front-line members. They can be internal or external to an organization. Stakeholders can be considered as any group or individual who can affect or is affected by the achievement of the organization's objectives.

Stakeholder behaviors and needs must be defined, understood, and considered when implementing eHealth projects. Often, one of the most important stakeholders is the end user of the solution being implemented. Stakeholder engagement strategies are then defined in response to these needs, with the goal of creating stakeholder commitment, involvement, and trust. Overall purpose of stakeholder engagement is to drive strategic direction and operational excellence for organizations, and to contribute to the kind of sustainable development from which organizations, their stakeholders and wider society can benefit.

Stakeholders may be involved for any one or combination of the following: for the purposes of sharing information, providing education, seeking feedback, developing consensus, creating an involved or shared resolution, or being empowered to devolve decision-making. Stakeholder engagement goes beyond informing and consulting. Stakeholder engagement requires, at a minimum, some degree of involvement or collaboration during the change process.

All initiatives can derive benefit or be put at risk through the degree to which stakeholders are engaged and involved. Ideally, stakeholder involvement will:

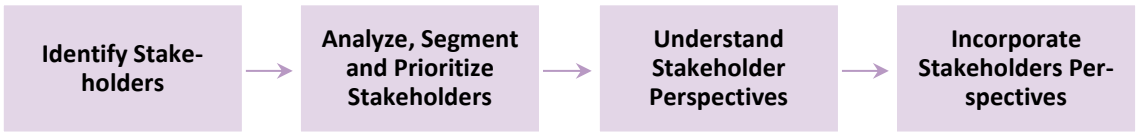
- ensure stakeholder input into the project;
- prepare stakeholders for the work necessary to complete the project;
- increase the likelihood of an initiative's success and minimize the risk of failure;
- ensure long-term viability of organizations, policies, plans and programs;
- mitigate risk – time investment is minimal compared with costs of not involving stakeholders;
- provide access to a wide range of views, expertise, values and beliefs that can be integrated into the change program;
- help stakeholders understand the value proposition and specifically their "what's in it for me"; and
- support the incorporation of a wide range of views into developing a case for change and in articulating both clinical and patient benefits.

There may be different considerations for individual stakeholders compared with organizational stakeholders. Stakeholders must be identified at the outset of change projects. Their expectations with respect to benefits and timelines should be anticipated, ascertained, and managed from the beginning to avoid misunderstanding and/or disappointment. Successful implementation projects must have structured processes and approaches to engage and involve key clinical end user groups.

Stakeholders can be engaged and participate in several ways, including:

- as champions and super-users, supporting and promoting the change initiative;
- through regularly scheduled work group sessions;
- at structured sessions during strategy, planning, requirements gathering, prototype and build, and testing of the solution phases;
- in formal project leadership roles to engage other end users across the jurisdictions;
- for ad hoc information and feedback sessions; and
- as participants in formal and informal clinical advisory groups.

There are four key components of any good stakeholder engagement process:



- **Identify Stakeholders:** First step to any stakeholder engagement process is stakeholder identification during project initiation. Although self-evident, many projects either neglect this altogether or limit the attention paid to even the most obvious stakeholders. Frameworks for categorization may vary by project, but often include: internal stakeholders, external stakeholders, and key partners.
- **Analyze, Segment and Prioritize Stakeholders:** This step attends to the issues and concerns of stakeholders throughout the project duration. Investing time near the beginning of a project and re-visiting this assessment at regular intervals throughout the project lifecycle improves the likelihood of success. There are three key components to this step:
    - Analysis: Understanding the issues that matter most to stakeholders will assist project teams to better prioritize, understand and mitigate engagement risks.
    - Segmentation: Identifying the difference between stakeholder groups will provide an opportunity to target messages and methods of engagement.
    - Prioritization: Some stakeholders have a higher degree of influence. In fact, some projects may have “super-stakeholders” who are particularly invested in a project’s outcome and who are highly influential. These “super-stakeholders” must be identified early on, with specific engagement and management strategies identified for each.
- **Understand Stakeholder Perspectives:** Anticipating and understanding stakeholder perspectives is another key step in the engagement process. Specific questions can be unique to each project. This is an opportunity to reach out to solicit views about the project, and how stakeholders wish to participate.
- **Incorporate Stakeholder Perspectives:** Extent to which stakeholder perspectives are incorporated into projects will vary. Ideally, the “ground rules” for such involvement will be made explicit at the outset. Stakeholders need to know their voices have been heard, even if their recommended courses of action are not adopted. Regular feedback will make stakeholders feel valued and more inclined to participate in future projects as well as much more likely to support, adopt and champion the change.

Most major change processes elicit some or all of the following reactions:

- Initial disbelief – "it won't happen!"
- Anger – "it won't happen if I can help it!"
- Acceptance – "if it's going to happen then I might as well do it!"
- Accommodating new reality – "that works quite well, and I wouldn't want to change it."

As such, any change will have its supporters and its resistors depending on where your organization is at in implementing a change and where the individuals within the organization are at with accepting the change.

Change is often met with resistance for a variety of reasons. Stakeholders can feel they:

- have not been consulted or involved in the change or its design, nor have any shared opinions or views been considered;
- cannot identify "what's in it for me";
- do not feel the wider community would see the value of the proposed change;
- like the present status quo and question their confidence and competency in the new context;
- do not trust/do not respect/do not like the person/group proposing the change;
- have not been given the support or time to adjust to the changes;
- are expected to change too many things at the same time;
- do not have clarity about change aims and objectives;
- believe other things need changing more urgently; and
- do not think the time is right for this particular change.

Considering the above, planning for change involves not only generating enthusiasm for the change process and working with the early adopters and converts, but being prepared to challenge and win over the skeptics. Here are some suggestions for dealing with resistance:

- Acknowledge that managing resistance can require the need to both challenge and change an individual's perceptions and beliefs.
- Work with the early adopters and then move onto the main group of staff. Recognize that there will always be some staff that finds change difficult. Identify and work with this group to minimize their impact by ensuring the majority are on board.
- Confront the sceptics head on.
- Reflect on activities and processes undertaken to date. Question if there are other ways to achieve the desired outcomes.

Communications

It is a process of providing stakeholders with what they need to know, in order to prompt appropriate responses and/or actions. Consistent and repeated communication about the strategy or project and the desired end goals and objectives is vital. Without it, information would not reach those who need to know. Value of what is trying to be achieved may not be recognized, stakeholders would not be aware or engaged in the process, innovation and creative ideas would never be shared, and the required education and training would not be successfully delivered.

Ability to deliver the right message, by the right person, through the right channel, to the right audience, at the right time is very important. Communications serve to inform diverse stakeholders and prompt appropriate responses and/or actions. Targeted approaches to communications are defined in response to the stakeholder analysis. Change leaders and implementers need to understand their respective roles in communicating with a broad range of stakeholders.

As applied to the eHealth context, the goals of communication include:

- soliciting feedback – engaging in two-way communication and dialogue;
- providing people with what they need to know to make informed choices about whether/how to comply with or commit to the initiative;
- building trust with candid information about the need for change and the difficulty of changing, including the consequences of not changing; and
- reporting progress – or lack of – so people can be responsible contributors to success.

Minimum core components of communications plans include the following:

- definition of target audience;
- information requirements;
- key messages;
- required frequency and format; and
- responsibility for the provision of information.

Communications planning builds upon stakeholder analysis and change management planning exercises to identify messages for specific stakeholder groups and various ways to deliver messages to these audiences.

Communication approaches that promote awareness and understanding of the expected change by all affected stakeholders are required. Specifically, the approach to communications should:

- start early in a project and describe the why, what and how;
- consider the audience (messages, format, language, outlet, frequency, etc.);
- consider who the message is coming from;
- make use of a variety of tools and outlets;
- provide a mechanism for sharing project information;
- ensure there are two-way dialogue and feedback mechanisms;
- organize the content of messages after consulting the users and other stakeholders;
- identify and gather knowledge objects;
- manage rumors and handle misinformation;
- create a feeling of belonging; and
- evaluate the effectiveness of the communications approach.

Workflow analysis can also contribute to communications activities by identifying the magnitude of the change required from stakeholders. Significant changes will require a heightened communications effort over a longer period. Change leaders should report achievements regularly and widely to keep people motivated and involved and the initiative moving forward.

Workflow Analysis & Integration

process of understanding current work processes and opportunities for improvement, so that new processes using eHealth solutions can be sustainably embedded into the culture, as evidenced through their presence within steady-state operations. Without considering the ways that people work and how business is conducted, it is not possible to incorporate a new tool or practice, disrupting the workplace and potentially duplicating efforts. If people are unable to easily use the technology or fail to see its value, it will not get used, wasting valuable resources and halting progress.

Objective of workflow analysis and integration is to embed new processes using eHealth solutions into the operations of health service delivery organizations. Analyzing and integrating work processes prior

to implementing new technologies will stimulate critical analysis on how work is performed in the current environment, the ways in which these current processes can be improved and identify further opportunities for progress by new or enhanced technology.

Project team makes full use of stakeholder working groups to discuss and create workflow integration, communications, knowledge management and training plans to create a collective vision to direct the change process. Typically, the business analysis team conducts the process mapping with the stakeholder working group and then transitions the information to the change management team for further consideration and integration into change management plans.

Often, the implementation of new systems focuses on training users rather than examining how the new systems can impact workflow. Implementing new systems provides an opportunity to reexamine workflows and processes so that they may take full advantage of capabilities of these new systems. For example, implementing a new electronic medical record into a physician office environment represents an opportunity to think about processes that might have been in place for many years, or processes that have been adapted to meet the demands of other technologies or systems (e.g., manual scanning of documents, physical location of equipment, etc.).

There is often a struggle between technical and clinical requirements when implementing new solutions. Ideally, designing new work ow processes should incorporate best practices from both the clinical and technological requirements. Teams are often pressured to change their workflows solely to meet the requirements of the system. Change management leaders play an important role in ensuring stakeholder-identified clinical needs are represented in the newly designed workflows.

Integrating people, process and technology through coordinated implementation plans, communications plans, workflow redesign efforts, training and other change management tactics ensures that all activities contribute to a successfully aligned implementation and appropriate communications at all stages of implementation. Accomplishing this can be done by involving team members in a variety of planning activities and by producing an integrated deployment plan that can ensure timely delivery of related project activities.

Integrating workflow improvements and technology adoption into operations that become engrained in organizational culture over time can be particularly challenging. Sustainable culture change is one of the last things to occur and is highly dependent on results that add lasting value. Clinician champions play a significant role here, as they can provide insight into how work gets done using the new systems.

Training & Education

This is an act of imparting both knowledge and specific skills among key stakeholders to promote adoption. An education plan that considers approaches to prepare the organization and users for the upcoming change is critical. It forms the foundation upon which solution training occurs, and continues over the longer term, ensuring sustainability and optimal use. Without execution of comprehensive education and training plans, few, if any of the project goals can be achieved.

When implementing new eHealth systems, approaches to user education, training, knowledge development and capacity will have to be specific, practical, and offered on the job in a timely fashion. Education and training are sometimes simply described as the difference between “knowing” and “doing”.

Education refers to a program of instruction in which knowledge or skill is developed or obtained through a learning process. Overall goal is to know more at the end of the process than you did at the start. Knowledge tends to be focused more on the longer- term tenure. As such, it is a key influencer of project sustainability. Key elements of education include:

- Provision of a broad perspective
- Flexibility of approach
- Measured by tenure
- Encourages general approaches to problem solving

Training is defined as an organizational activity aimed at imparting information or instructions to improve a recipient's performance or to help him/her attain a required level of knowledge or skill. One of the main objectives of a training encounter is the ability to perform a skill to a specified standard at the end of a session. Key attributes of training include:

- Tends to be narrowly focused; leads to a high proficiency in a specific skill
- Effectiveness is measured by what you can do when you have completed it
- Focuses on doing and improvement in performance

While educational initiatives should begin early in a project and be tightly linked with communications messaging (i.e., clearly and consistently delivered, relevant to the target audience, frequently delivered), training activities are often most successful (in terms of improving retention of both knowledge and skill) when offered through 'just in time' delivery.

When planning for education and training, remember to take the time to do the education (i.e., educate on process and procedure) prior to the training. Dedicating time and resources to produce quality education and training materials presented by qualified instructors, is also critical for reducing as much stakeholder angst and adoption risk as possible.

Standardized plans, tools, resources, and media should be in place to meet initial needs prior to and during implementation to ensure sustainability of adoption. Content and delivery of these resources should have consistent core components, while allowing for customization where necessary.

Educational programs can make use of tools like videos, manuals, web-based programs, workshops and seminars, but should focus on giving an individual the information needed to promote a particular topic or idea. is could be as simple (but important) as the reason behind a process change. While the individual may not be ready to take the controls, they know what needs to be done; they just may not have yet developed the necessary skills.

Training strategies should focus on achieving skills through, for example, putting education into practice, with an instructor standing back, monitoring and correcting. Common mantras like "tell, show and do" are effective strategies in supporting individuals to implement and achieve new skills.

An effective long-term training strategy needs to incorporate the concept of maturity of use. Users have different needs at different stages: new users need to be acquainted with the basic functionality, while advanced users should be empowered to use technology as a tool for innovation.

Key components of an integrated and effective training strategy include:

- analyzing learning needs regarding the new clinical work ow and system functionality;
- linking stakeholder analysis and communications plan;
- linking changes to what we are changing, why we are changing and how we are changing;
- determining learning objectives and content;
- developing appropriate methods to deliver content;
- assessing the results of education delivery approaches and methods; and
- offering a means of continuous learning (continuous improvement and ongoing learning for new staff).

Monitoring & Evaluation

This is the process of reviewing whether change management activities took place as planned; and the extent to which they were effective. Paying attention to process through ongoing monitoring and evaluation provides opportunity to identify risks. Without focusing on these issues, opportunities to improve process, to identify gaps or to recognize success do not take place. Ongoing monitoring and evaluation are essential to understand and manage progress toward the future state. Lessons learned and process improvements need to be integrated in real-time, to avoid repeated mistakes.

Monitoring and evaluation are important concepts that extend throughout the lifecycle of eHealth projects and into the operational life of the solution. Benefits, stemming from the use of information and communications technologies (ICT) for health in delivering and supporting health care, need to be established during the planning phase of major projects. A sustained effort is required to ensure these benefits can be realized over the longer-term.

Methods and timeframes for monitoring and evaluation differ depending upon the context of the change initiative. Concepts of formative and summative evaluation provide a foundation for differentiating between process-related evaluation of change management activities and benefits-focused outcomes evaluation.

Formative evaluation helps to confirm if goals and objectives are being achieved across the continuum of the project – from key milestones at the outset through to mid- and later phases of implementation and solution integration. For eHealth projects, formative evaluation offers a means of examining the form and content of the implementation plan, including communications, training, education etc., and assures the technology is meeting all levels of requirement, such as usability, functionality, and instructional effectiveness.

Conducted at every stage of the project lifecycle and across all key mechanisms including governance structure and leadership support, formative evaluation provides an opportunity to engage those leading, managing and affected by the solution. It also provides a structure to implement and test innovative ideas to support effective ongoing rollout and solution integration. Additionally, evaluation also provides an opportunity to assess project risks, identify issues and develop mitigation plans. Earlier formative evaluation begins, the more likely an effective project that achieves its intended objectives will result.

Formative evaluations are intended to be built into the overall components of a change management approach but are often ad hoc and not always part of an integrated evaluation plan. Ideally, a change management plan will contain a comprehensive approach to measuring the effectiveness of change activities, interventions, and processes. Formative or process evaluations can evaluate whether targeted users are actually using the solution, and if so, how – and also identify opportunities to engage and enhance user optimization of the solution.

Test methods (e.g. surveys, interview questions) should be developed to best align with the following types of questions:

- Did I achieve my goals and objectives?
- What were the obstacles?
- Did the users bene t in the way I intended?
- What were the unintended consequences?

Key questions evoked by formative evaluations include:

- Are the CM activities being effectively executed?

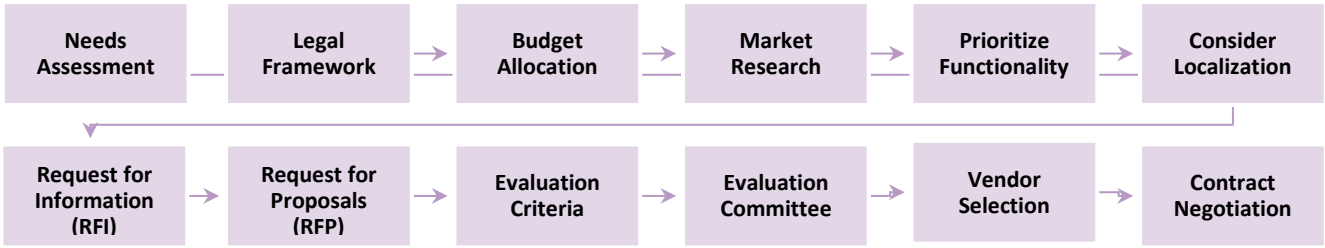
- Does your solution accomplish what it is supposed to, or is anticipated to?
- Does it impose minimum obstacles between the user and use?
- Does it ensure the interface doesn't get in the way of the learning (use)? i.e.,
  - Are users able to understand instructions?
  - Are users able to navigate through the solution?
  - Are the headings and buttons clearly labeled?
  - Is it visually appealing and easy to read?
- Has the communications strategy influenced the target audience (e.g., measuring awareness of the initiative through a survey or key informant interviews)?
- Have users been satisfied with the training (e.g., training evaluation survey)?

Examples of commonly used testing methods include:

- Electronic communications with stakeholders (i.e., asynchronous discussion) via list servs or bulletin boards
- Focus groups or one-on-one interviews
- Observation: This is usually done by observing two or more people using the solution. Record where they click, how long things take to finish, at what point they ask questions, etc. Observer should ask questions upon completion
- Online chat interview: Conduct one-on-one or group discussions for direct feedback.
- Pre- and post-tests: Test people before and after using the solution (or participating in educational session, etc.) to measure strengths and weaknesses, as well as whether the instruction is necessary
- Surveys: Users can complete a survey to indicate their expectations, rate the communications, educational instruction, etc. Surveys are particularly useful if you are doing mass testing of a solution and are looking for trends (e.g., in things like appeal of the course, anticipated benefits, first impressions, etc.)

4.5.5 Software solutions contracting strategy

We propose that the following steps should be considered as key parts of strategy for public procurement and contracting of software solutions in the e-health system of the Republic of Kosovo:



- **Needs Assessment**: Conduct a comprehensive needs assessment involving relevant stakeholders, such as healthcare professionals, government officials, IT experts, and patient representatives. Identify the specific requirements and challenges of the e-health system in Kosovo, considering factors such as interoperability, data security, scalability, and local language support.
- **Legal Framework**: Ensure compliance with the legal framework throughout the procurement process, including transparency, fairness, and accountability.

- **Budget Allocation**: Determine a realistic budget for the procurement process. Consider the financial constraints of Kosovo and allocate funds for software licenses, customization, implementation, training, and ongoing maintenance and support. Seek funding options from international development organizations or consider public-private partnerships to enhance financial resources.
- **Market Research**: Conduct market research to identify software vendors that offer solutions aligned with the requirements of the e-health system in Kosovo. Assess the capabilities and credibility of software vendors. Consider factors such as their financial stability, reputation, customer references, technical support, and ability to provide training and ongoing maintenance. Look for vendors with experience in the healthcare sector, a proven track record, and the capacity to meet the specific needs of the country. Consider open-source solutions, as they can offer cost-effective alternatives.
- **Prioritize Functionality**: Identify the key features and functionality required for your e-health system. Prioritize essential functionalities such as electronic medical records (EMR), appointment scheduling, billing, reporting, and telemedicine capabilities. Ensure that the software can be customized and scaled to meet future needs.
- **Consider Localization**: Ensure that the software can be easily localized and translated into the local language(s). Also, check if it supports local health protocols, standards, and regulatory requirements.
- **Request for Information (RFI)**: Prepare an RFI document to gather information from potential vendors. Include specific questions regarding their software solutions, previous experience, technical expertise, scalability, and interoperability capabilities. Use the responses to shortlist vendors for the next phase.
- **Request for Proposals (RFP):** Develop a comprehensive RFP document that outlines the project scope, technical requirements, implementation timeline, evaluation criteria, and contractual terms. Ensure that the RFP reflects the unique needs of the e-health system in Kosovo and allows for customization and scalability. Invite selected vendors to submit detailed proposals that outline their software solution, implementation plan, timeline, and cost breakdown. Request references from their previous clients to verify their claims.
- **Evaluation Criteria**: Establish clear and transparent evaluation criteria to assess the proposals from vendors. Consider factors such as functionality, scalability, interoperability, security measures, customization options, user experience, training and support services, cost and the financial sustainability of the proposed solution. Consider conducting product demonstrations and seeking user feedback.
- **Evaluation Committee**: Form an evaluation committee consisting of experts from relevant fields, including healthcare professionals, IT specialists, and legal advisors. Ensure the committee members have the necessary expertise and impartiality to evaluate the proposals objectively.
- **Vendor Selection**: Evaluate the proposals based on the predefined criteria and select the vendor that best meets the requirements of the e-health system in Kosovo. Conduct due diligence on the selected vendor, including financial stability, references, and legal compliance.
- **Contract Negotiation**: Negotiate the contract terms with the selected vendor, including pricing, licensing, implementation timeline, training, and ongoing support. Ensure that the contract includes provisions for future upgrades, data ownership, confidentiality, technical support, and compliance with local regulations.

By following these steps, a robust public procurement strategy can be established for software solutions in the eHealth system of the Republic of Kosovo. It is crucial to involve key stakeholders through-

out the process to ensure the software solution meets the requirements and contributes to improving healthcare services in Kosovo.

Then, regarding the choice between a monopoly or a liberalized market, it depends on several factors:

- **Competition and Innovation:** A liberalized market encourages competition among software vendors. This competition can drive innovation, quality improvement, and cost efficiency. Multiple vendors can offer a variety of solutions, providing you with a broader range of options to choose from. It also incentivizes vendors to continuously improve their offerings to gain a competitive edge.
- **Customization and Flexibility:** A liberalized market often provides more flexibility in terms of software customization and integration. Different vendors may specialize in specific modules or functionalities, allowing you to select the best fit for your specific requirements. This can lead to a more tailored solution that meets your unique needs and workflows.
- **Pricing and Cost Considerations:** In a liberalized market, competition can lead to competitive pricing. With multiple vendors competing for contracts, you may have more negotiating power and the ability to secure more favorable pricing and contract terms. This can be advantageous in terms of budget management, especially for a small, low-income country like Kosovo.
- **Vendor Lock-In and Dependency:** Choosing a monopoly supplier may result in vendor lock-in, where you become heavily dependent on a single vendor for ongoing support, upgrades, and maintenance. This can limit your ability to switch vendors or negotiate favorable terms in the future. In a liberalized market, you have the freedom to switch vendors if needed, fostering a more balanced relationship, and reducing dependency.
- **Local Capacity Building:** A liberalized market can promote local capacity building and foster the growth of domestic software development and IT expertise. By engaging multiple vendors, you create opportunities for local companies to participate in the e-health system's development, potentially contributing to economic growth and job creation within Kosovo.
- **Risk Mitigation:** Relying on a single monopoly supplier carries the risk of potential service disruptions or vulnerabilities. If the monopoly vendor faces financial, technical, or operational challenges, it could significantly impact the continuity of your e-health system. A liberalized market with multiple vendors can mitigate this risk by providing alternative options and redundancy.

Ultimately, the decision between a monopoly or a liberalized market should be based on a careful analysis of the specific circumstances in Kosovo. Factors such as the existing market landscape, the capabilities of local vendors, the complexity of your requirements, budget constraints, and the long-term sustainability of the eHealth system should also be considered.

4.5.6 Quality and functional standards enforcement strategy

The enforcement strategy for eHealth quality and functional standards takes into account several important regulatory environments, maturity of eHealth system, budget for eHealth projects, stakeholder collaboration etc. To ensure the enforcement of eHealth standards, the following approaches can be taken:

- **Laws and Regulations**: Implement regulations that mandate compliance with eHealth standards. This includes legislation that requires healthcare providers, vendors, and stakeholders to adhere to specific standards when exchanging health information. The strategy should outline clear enforcement actions, such as warnings, penalties, suspension of certifications, or license revocation, for non-compliance. In serious cases, legal actions may be pursued to address violations or breaches.

- **Public Awareness** Campaigns: Launch public campaigns to educate citizens and patients about the significance of eHealth standards. These campaigns should focus on raising awareness about data privacy, security, and the benefits of standardized health information exchange. By fostering public support for eHealth standards, governments can encourage their widespread adoption.
- **Financial consequences:** Provide incentives, such as financial rewards, grants, or other benefits, to organizations that adopt and comply with eHealth standards. Conversely, impose disincentives, penalties, or consequences for non-compliance. By offering rewards for compliance and penalties for non-compliance, organizations are motivated to prioritize adherence to the standards.
- **Procurement regulations**: Include adherence to eHealth standards as a requirement in government procurement policies for acquiring healthcare IT systems and services. By making compliance with standards a prerequisite for government contracts, it creates a strong market demand for standardized solutions and encourages vendors to comply with the specified standards.
- **Certification**: Establish a certification and accreditation process to ensure that eHealth solutions, vendors, and service providers meet the specified quality and functional standards. This process may involve third-party evaluation, independent audits, and formal recognition of compliance. Organizations that meet the requirements can receive certification or accreditation, demonstrating their adherence to the standards and building trust among users and stakeholders.

To effectively enforce eHealth standards, it is crucial to employ a combination of these strategies.

4.5.7 IT service delivery options

IT service delivery is the way a organization provides users access to IT services, such as applications, data storage and other business resources. IT service delivery covers design, development, deployment, operation and retirement. Many IT professionals play a role in the various stages of service delivery. Quality of IT service delivery is gauged by metrics included in a service-level agreement (SLA). Here are some common IT service delivery options:

- **In-sourcing IT Service Delivery**: In this model, the organization establishes an internal IT organization to handle all aspects of IT service delivery. This includes managing the infrastructure, applications, networks, and user support. The organization has direct control over the IT services and can tailor them to their specific needs. However, it requires significant investment in resources, expertise, and infrastructure.
- **Outsourcing IT Service Delivery (Managed services):** IT outsourcing is a specific type of business process outsourcing that involves contracting IT functions to external service providers. It can be categorized into two primary types: infrastructure outsourcing and application outsourcing. Infrastructure outsourcing entails handing over the management and operation of IT hardware, software, networks, or security systems to a managed service providers (MSPs). On the other hand, application outsourcing involves delegating the development, maintenance, testing, or implementation of software applications to a MSP. In addition to these traditional forms of IT outsourcing, there is a growing trend towards cloud-based services, such as software-as-a-service (SaaS), infrastructure-as-a-service (IaaS), and platform-as-a-service (PaaS). These services are delivered over the internet by a variety of providers, including both traditional outsourcing firms and specialized software vendors, or even industrial companies that offer technology-enabled services. It's important to recognize that successful IT outsourcing

relies not only on the actual IT services or transactions but also on the relationships established between the outsourcing parties. Therefore, outsourcing governance plays a crucial role in determining the success of an outsourcing arrangement. Without proper governance, even carefully negotiated and documented rights in the outsourcing contract may not be effectively enforced, and the resulting relationship may deviate significantly from the initial vision.

- **Hybrid Model:** Many organizations adopt a hybrid model, combining in-house IT capabilities with external service providers. Maintaining a fully in-sourcing model can present increasing challenges for public sector institutions primarily due to the scarcity of qualified and affordable technology professionals in the current market. Identifying, hiring, and retaining such talented staff members often proves to be a significant challenge, resulting in notable gaps in the internal IT support and knowledge base. Consequently, companies are turning to trusted IT managed service providers (MSPs) to overcome these risks. MSPs possess the expertise and resources to create a cohesive strategy for technology operations, helping companies navigate the complexities of their IT needs. Organizations may choose to keep critical or sensitive services in-house while outsourcing non-core services to external providers. This model provides flexibility, cost-effectiveness, and the ability to leverage specialized expertise as needed. Engaging an MSP allows companies to benefit from their established certifications, ensuring adherence to industry standards. Furthermore, MSPs maintain the agreed-upon service level agreements (SLAs) to deliver reliable and consistent IT support. They also play a critical role in providing technology training to staff members, keeping them up-to-date with the latest developments. Regular upgrades and maintenance, which can be a challenge when internal resources are insufficient, are handled by MSPs as part of their comprehensive support offerings. By partnering with trusted MSPs, companies can bridge the resource gap and alleviate the strain on internal IT support. This approach enables businesses to focus on their core competencies while relying on the expertise and experience of MSPs to manage and maintain their technology infrastructure effectively.

Considering the state and specificity of the healthcare system in Kosovo and the healthcare strategy, we propose a **hybrid approach** as follows:

1. **In-sourcing IT Services** for
   a) project management
   b) product management
   c) user support for IT systems
2. **Out-sourcing IT Services** for
   a) application development
   b) network & infrastructure services.

4.5.8 Planning horizons and implementation monitoring (indicators)

We suggest starting with simple set of indicators like:

Stakeholder	eHealth outcomes	Indicators
Patients	Improve the ability for patients to access healthcare services	• Average reduction in time for a patient to access health services • Patients satisfaction regarding role of technology in improving their access to health services • Percentage increase in the number healthcare consultations conducted via telemedicine

Stakeholder	eHealth outcomes	Indicators
	Improve access to knowledge resources for better management of their chronic conditions	• Percentage increase in patients visits to knowledge portal • Patients satisfaction of using knowledge portal to improve access to knowledge for better management of their chronic conditions
Healthcare providers	Improve the ability of providers to access health information at the point of care.	• Percentage of health-care providers that have standards compliant software systems • Percentage of health-care providers that have access to fit-for-purpose data/telecommunications connectivity • Percentage of health-care providers that have access to fit-for-purpose computing infrastructure • Percentage increase in the number of healthcare professionals using EHR data on a regular basis • Healthcare professional's satisfaction of using eHealth to access healthcare information using EHR
	Improve the ability of providers to exchange patient information with other providers.	• Percentage increase in the number of electronic health information transactions between healthcare providers • Percentage increase in the number of discharge summaries being received by primary care providers • Provider satisfaction of using eHealth to improve information sharing with other providers
	Enable healthcare professionals to access clinical knowledge, evidence sources and expertise to assist with skills development.	• Percentage increase in visits to knowledge portal • Provider satisfaction of using eHealth to improve access to knowledge and expertise to support them in delivering care
Healthcare administrators	Enable healthcare authorities to monitor and respond to emergencies more quickly	• Percentage reduction in time to report and analyze disease outbreaks to support decision-making • Perceptions of issues/challenges affecting use of eHealth for monitoring and response
	Support the education, training and development of the health workforce.	• Percentage increase in the number of health workers entering the health workforce that have been trained in part through eLearning and other similar e-based training • Percentage growth in the number of people enrolling for electronic-based education and training programs

4.6 Set of Standards and Regulations

Standards and regulations are playing a crucial role in shaping and governing the eHealth system in Kosovo. They establish a framework of guidelines and requirements that ensure the quality, safety,

interoperability, and ethical use of digital technologies in healthcare. These standards and regulations provide a common language and set of expectations for all stakeholders involved in the development, implementation, and operation of the eHealth system. By adhering to these standards and regulations, the eHealth system in Kosovo aims to deliver efficient, secure, and patient-centered care while safeguarding privacy, data integrity, and compliance with legal and ethical principles.

4.6.1 Terminology/Health Data Dictionary

In the eHealth system of Kosovo, codes and directories play a crucial role in organizing and standardizing health information. These technical components ensure consistency, interoperability, and efficient data exchange within the system. Here are some key points related to codes and directories in the eHealth system of Kosovo:

- **Standardized Coding Systems**: The eHealth system in Kosovo employs standardized coding systems, such as ICD-10 (International Classification of Diseases, 10th Revision), SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms), and LOINC (Logical Observation Identifiers Names and Codes). These coding systems provide a uniform and internationally recognized framework for classifying and encoding medical diagnoses, procedures, laboratory results, and other relevant healthcare data.
- **Diagnosis and Procedure Codes**: The system incorporates standardized diagnosis and procedure codes to ensure accurate and consistent representation of clinical information. Diagnosis codes, based on ICD-10, enable classification of diseases, injuries, and health conditions, while procedure codes, such as ICD-10-PCS (Procedure Coding System), facilitate the coding of medical interventions and treatments.
- **Medication and Pharmacy Codes**: To streamline medication management and facilitate interoperability, the eHealth system in Kosovo incorporates standardized medication codes, such as the WHO's ATC (Anatomical Therapeutic Chemical) classification system. These codes enable the identification and classification of medications based on their therapeutic properties, facilitating accurate prescription, dispensing, and monitoring of medications across healthcare settings.
- **Terminology and Vocabulary Standards**: The eHealth system utilizes standardized terminology and vocabulary standards, such as SNOMED CT, to ensure consistent representation and understanding of clinical concepts and terms. This promotes semantic interoperability and facilitates effective communication and information exchange among different healthcare stakeholders.
- **Health Provider Directories**: The eHealth system maintains directories of healthcare providers, including hospitals, clinics, laboratories, and pharmacies. These directories contain essential information, such as contact details, specialties, and services offered, allowing easy access to healthcare resources and facilitating efficient referral and collaboration among providers.
- **Data Exchange Standards**: The eHealth system adheres to data exchange standards, such as HL7 (Health Level Seven) and DICOM (Digital Imaging and Communications in Medicine), for the interoperable exchange of clinical data and medical images. These standards define the structure, format, and protocols for secure and efficient data transmission between different healthcare systems and devices.

By implementing standardized coding systems, directories, and data exchange standards, the eHealth system in Kosovo ensures accurate, consistent, and interoperable representation and exchange of health information. These technical components support improved healthcare delivery, data analytics, and decision-making, ultimately contributing to enhanced patient care and outcomes.

4.6.2 Codes and directories

Codes and directories related to classification of diseases and health conditions is the key aspect related to building a health information system.

In this regard, it is recommended that International Classification of Diseases (ICD) is used in Kosovo. The ICD is a globally recognized coding system used to classify and code diseases, injuries, and other health conditions. It provides a standardized way to record and analyze health information.

The current version of ICD is called ICD-10, was introduced in 1992. It consists of alphanumeric codes that represent specific diagnoses, symptoms, procedures, and other health-related information. The codes are used by healthcare providers, researchers, statisticians, and other stakeholders to accurately document and communicate health conditions and related data.

The ICD is regularly updated and revised to reflect advances in medical knowledge and changes in healthcare practices. In fact, an updated version, ICD-11, was released by the WHO in 2018 and is being implemented by various countries around the world.

Further, Kosovo should also consider adoption of similar unified codes and directors to ensure compliance and data comparability with other countries and internationally accepted standards.

Kosovo needs to adopt this a key tool for ensuring reliable data in the health information sector.

4.6.3 Business Processes/Functional Standards

Business processes and functional standards that are commonly implemented to ensure efficient operations and interoperability of the health information standards. Some examples of such business processes and functional standards include:

- Electronic Health Record (EHR) Systems:
- Health Information Exchange (HIE): HIE involves the secure sharing of patient health information across different healthcare organizations and systems. In the case of Kosovo this is relevant in relation to public/private healthcare institutions.
- Interoperability: Interoperability standards, such as Health Level Seven (HL7)
- Clinical Coding and Classification Systems: As mentioned earlier, coding systems like the International Classification of Diseases (ICD)

4.6.4 Basic data semantics/structures standards

The interoperability of the eHealth system operates only when the data architecture allows transmitting information between two or more systems allowing one another to process the information in an independent manner and with a single standard. In the eHealth system of Kosovo, the implementation of basic data semantics and structures standards is of utmost importance to achieve a coherent and interoperable representation of healthcare data. These technical standards establish the guidelines, formats, and structures necessary for organizing and exchanging information within the system. Here are some essential technical aspects related to the basic data semantics and structures standards in the eHealth system of Kosovo:

- **Data Modelling**: The standards provide guidelines for data modelling, defining the entities, attributes, and relationships relevant to the eHealth domain. This includes determining the appropriate data types, constraints, and semantics for each attribute, ensuring data consistency and integrity across different systems.
- **Terminology and Coding Systems**: Basic data semantics and structures standards incorporate standardized terminology and coding systems, such as SNOMED CT, LOINC, and ICD, to

ensure consistent representation and communication of clinical concepts, procedures, and diagnoses. These standards facilitate semantic interoperability, enabling accurate and meaningful exchange of healthcare data.

- **Data Element Definitions**: The standards define the specific data elements required within the eHealth system, along with their definitions, characteristics, and allowable values. This ensures a common understanding and consistent usage of data elements across different healthcare entities and systems.
- **Structured Data Formats**: The standards specify structured data formats, such as XML or HL7 FHIR, for organizing and encoding healthcare information. These formats provide a standardized framework for data representation, facilitating data exchange, storage, and retrieval across different systems and platforms.
- **Data Integration and Interoperability**: Basic data semantics and structures standards promote data integration and interoperability by establishing common data structures and interfaces. These standards enable seamless exchange and sharing of healthcare information among various stakeholders, such as hospitals, clinics, laboratories, and pharmacies.
- **Metadata and Data Governance**: The standards outline requirements for metadata management and data governance, ensuring the proper documentation, versioning, and governance of data elements and structures. This enhances data quality, traceability, and accountability within the eHealth system.
- **Compliance and Conformance**: Adherence to basic data semantics and structures standards is enforced through compliance and conformance mechanisms. Compliance assessments and conformance testing ensure that healthcare entities and systems meet the prescribed standards, promoting data consistency, integrity, and interoperability.

The eHealth system in Kosovo need to hold the principles of basic data semantics and structures standards to guarantee the consistent and interoperable representation of healthcare data. By complying with these standards, the system enables smooth data exchange, seamless integration, and effortless sharing, thereby enhancing the efficiency of healthcare delivery, enabling informed decision-making, and ultimately improving the quality of patient care.

4.6.5 Identification and authentication services

Protecting the confidentiality of patient information in a common healthcare environment is one of the most complex and demanding tasks. Accurately identifying users, assigning access permits, and complexity becomes even greater when it comes to providing a solution for sharing data between healthcare providers. Traditional approaches such as Mandatory Access Control, Discretionary Access Control and Role-Based Access Control. Identification and authentication services within the eHealth system of Kosovo are of utmost importance for ensuring robust security measures and safeguarding the privacy of health information. These technical components serve as dependable mechanisms for verifying user identities and controlling their access to sensitive healthcare data. Here are some crucial aspects to consider regarding the identification and authentication services in the eHealth system of Kosovo:

- **User Identification**: The eHealth system employs unique identifiers, such as usernames or personal identification numbers, to uniquely identify users accessing the system. Each user is assigned a distinct identifier that allows for accurate tracking and auditing of their activities within the system.
- **Authentication Methods**: To verify the identity of users, the eHealth system supports various authentication methods. These methods may include username and password authentication, two-factor authentication (2FA), smart card authentication, or biometric authentication

(e.g., fingerprint or iris recognition). By combining multiple factors, such as something the user knows (password) and something the user possesses (smart card or mobile device), the system enhances security and reduces the risk of unauthorized access.

- **Role-Based Access Control (RBAC):** The eHealth system implements RBAC to control user access based on predefined roles and permissions. Each user is assigned a specific role that determines their level of access to different functionalities and health data within the system. RBAC ensures that users can only access the information relevant to their roles and responsibilities, promoting data privacy and confidentiality.
- **Secure Single Sign-On (SSO)**: The eHealth system may employ a secure SSO mechanism, allowing users to access multiple healthcare applications and services with a single set of credentials. SSO simplifies the login process for users and improves usability while maintaining security by centrally managing user authentication and access control.
- **Identity Federation**: In cases where multiple healthcare organizations or systems are involved, the eHealth system may utilize identity federation protocols, such as SAML (Security Assertion Markup Language) or OpenID Connect. These protocols enable seamless and secure user authentication across different systems, ensuring consistent access control and eliminating the need for separate login credentials for each system.
- **Audit Trails and Logging**: The eHealth system maintains detailed audit trails and logs of user activities, including login attempts, access requests, and modifications to health records. These logs provide a record of user actions and support accountability, enabling administrators to monitor system usage, detect potential security breaches, and investigate any unauthorized access or data breaches.
- **Secure Communication Channels**: The eHealth system utilizes secure communication channels, such as encrypted connections (e.g., HTTPS) and virtual private networks (VPNs), to protect the confidentiality and integrity of data during transmission. Secure communication channels prevent unauthorized interception or tampering of sensitive health information.

The eHealth system in Kosovo incorporates robust identification and authentication services to ensure that only authorized users have access to and can interact with health data. Through these technical measures, data security, privacy, and compliance with regulatory requirements are strengthened, instilling trust in the system and safeguarding the confidentiality of patient information.

4.6.6 Messaging standards

Messaging standards are essential in the eHealth system of Kosovo as they enable secure and standardized communication among various healthcare entities and systems. These technical standards promote interoperability, maintain data integrity, and facilitate efficient exchange of information. Here are some important aspects to consider regarding messaging standards in the eHealth system of Kosovo:

- **Health Level 7 (HL7)**: HL7 is a widely adopted messaging standard in healthcare. The eHealth system in Kosovo utilizes HL7 messaging standards, such as HL7 v2.x and HL7 FHIR (Fast Healthcare Interoperability Resources), for the exchange of clinical and administrative data. HL7 defines message formats, communication protocols, and data structures, enabling seamless interoperability between disparate systems.
- **Message Exchange Patterns**: The eHealth system supports various message exchange patterns, including point-to-point messaging, publish-subscribe, and request-response. These patterns allow healthcare providers, laboratories, pharmacies, and other stakeholders to exchange messages in a standardized and structured manner, ensuring efficient and reliable communication.

- **Clinical Document Architecture (CDA)**: CDA is a messaging standard that defines the structure and encoding of clinical documents. The eHealth system utilizes CDA to exchange clinical summaries, discharge summaries, lab reports, and other medical documents. CDA ensures consistent data representation, enabling healthcare providers to access and interpret information accurately.
- **XDS (Cross-Enterprise Document Sharing)**: XDS is a messaging standard specifically designed for sharing healthcare documents across different organizations. It allows secure and standardized exchange of patient information, including clinical documents and images, between healthcare providers within the eHealth ecosystem in Kosovo. XDS ensures data privacy, access control, and reliable document retrieval.
- **Secure Messaging Protocols**: To ensure the confidentiality and integrity of healthcare messages, the eHealth system employs secure messaging protocols, such as HTTPS (Hypertext Transfer Protocol Secure), SFTP (Secure File Transfer Protocol), and SMTP with TLS (Transport Layer Security). These protocols encrypt data during transmission and provide authentication mechanisms, safeguarding sensitive patient information.
- **Message Validation and Error Handling**: The eHealth system incorporates mechanisms for message validation and error handling. Messages are validated against predefined schemas or profiles to ensure adherence to messaging standards and data integrity. Error handling mechanisms allow for the identification, reporting, and resolution of data validation errors or discrepancies in message content.
- **Integration Engines**: Integration engines are utilized in the eHealth system to facilitate message routing, transformation, and workflow management. These engines interpret incoming messages, map data to the appropriate format, and route them to the intended recipients. Integration engines support the seamless integration of various systems and enable interoperability within the eHealth ecosystem.

Through strict adherence to messaging standards, the eHealth system in Kosovo establishes a robust framework for secure, standardized, and efficient communication between healthcare entities. These technical standards form the foundation for reliable data exchange, fostering seamless care coordination and empowering informed decision-making. By facilitating effective communication, the system enhances the delivery of healthcare services and contributes to improved patient outcomes.

4.6.7 Software certification standards

Software certification standards in the eHealth system of Kosovo have a significant impact on guaranteeing the quality, dependability, and security of healthcare software applications. These technical standards define the criteria and procedures for certifying software used within the eHealth ecosystem. Here are some important technical considerations regarding software certification standards in the eHealth system of Kosovo. Depending on the method chosen by the Ministry of Health in Kosovo, if applications are purchased or developed, they should follow certain steps, such as:

- **Compliance with Regulatory Requirements**: Software certification standards in the eHealth system of Kosovo ensure compliance with relevant regulatory requirements and guidelines. These standards define the necessary features, functionalities, and security measures that software applications must meet to be certified for use in healthcare settings.
- **Quality Assurance**: Software certification standards include rigorous quality assurance processes to assess the overall quality, performance, and reliability of the software. This includes testing the software for functionality, interoperability, usability, and adherence to coding and documentation standards.

- **Security Assessments**: Software certification standards in the eHealth system of Kosovo also include security assessments to identify and address vulnerabilities and ensure the software's ability to protect sensitive health data. This involves evaluating the software's security features, access controls, encryption, and protection against unauthorized access or data breaches.
- **Interoperability Requirements**: Interoperability is a crucial aspect of software certification standards. The eHealth system ensures that certified software applications adhere to interoperability standards, enabling seamless integration and data exchange with other systems and healthcare providers within the eHealth ecosystem.
- **Maintenance and Updates**: Software certification standards may include requirements for regular maintenance and updates to ensure that the software remains up to date with the latest security patches, bug fixes, and regulatory changes. This helps to address any identified vulnerabilities and ensure the ongoing security and performance of the software.
- **Documentation and Reporting**: Certified software applications within the eHealth system of Kosovo are required to provide comprehensive documentation and reporting. This includes documentation of design, development, testing processes, security measures, and compliance with certification standards. It enables transparency and accountability and facilitates effective troubleshooting and auditing of the software.
- **Continuous Monitoring and Evaluation**: Once certified, software applications are subject to continuous monitoring and evaluation to ensure ongoing compliance with certification standards. This may involve periodic audits, security assessments, and user feedback to identify any emerging issues and ensure the software's continued effectiveness and safety.

By adhering to software certification standards, the eHealth system in Kosovo promotes the use of high-quality, secure, and interoperable software applications in healthcare. These standards contribute to improved patient safety, data security, and the overall efficiency of healthcare services within the eHealth ecosystem.

4.6.8 Changes of laws and internal rules/rulebooks needed for the implementation

Overview of the Legal Framework

The health information system in Kosovo has evolved in a haphazard and fragmented way, following major political, administrative, economic, legal and donor policy changes. This has involved termination of specific projects, changes into the national policies for healthcare digitization, and partial modules being currently developed.

From one perspective, Kosovo legal system does not address and does not regulate the basic and minimum requirements for building a health information system. As such it is not adequate and does not support and regulate a proper health information system. To address this, key minimum requirements for development of the legal acts are elaborated in this feasibility study.

From another perspective, Kosovo has had two (2) major projects in the health information system. First, there was a project to build a wide range of health information systems. However, in 2018 MoH has decided to terminate and close the implementation of the project, which was supported by LuxDev as a donor. While the reasoning for the termination of the project have not become public, this decision has resulted in major practical changes regarding the digitalization of the healthcare sector. Second, after termination of the holistic health information system, and as a matter of urgency, MoH has proceeded with the development of Basic Health Information System (BHIS). BHIS provided minimal functionality of registration of patients in the PHC centers and basic ADT function (admission, discharge, transfer) to be used by hospitals.

Therefore, a major and highly important failure of all such initiatives has been legal and regulatory compliance. The required legislation required for implementation of such initiates has not been developed and was not being considered a priority. As an illustrative example, the regulatory framework regarding health information systems is limited to a few very short articles under the LAW No. 04/L-125 ON HEALTH ("Kosovo Law on Health") and is limited in simply authorizing the establishment of the health information system. This has resulted in a lack of clear legal basis for such projects, including establishing the obligations for the purpose of data entry or data sharing with other entities and institutions. Further, the consultant was not able to identify any proper legal analysis to ensure compliance with the existing legislation, especially with respect to the changes into the applicable laws on personal data protection and principles.

Synopsis of the Current Applicable Legislation in Kosovo

With the exception of the protection of personal data, Kosovo legal system does not address and does not regulate the basic and minimum requirements for building a health information system. The applicable laws in Kosovo are limited to authorizing the establishment of the centralized health information system, whereas the Government of Kosovo and MoH have failed to pass the foreseen sub-legal acts for the purpose of functionalizing it. Therefore, it is assumed that previous projects in this regard, including BHIS, are functioning under a vacuum without the proper legal basis.

Part III of this Chapter provides an in-depth analysis of the key legal aspects which need to be legislated by the Assembly of Kosovo the MoH and Kosovo as part of building an effective HIS. This is made without prejudice to the model of health information system that the MoH decides to implement. In summary, these include the requirements for data collection, reporting, ownership, access, and supervision, roles in ensuring the operational functioning and financing of the system, responsibilities regarding accurate data reporting, confidentiality, and data protection.

In addition, Part IV outlines the sub-legal acts and compliance reminder to ensure compliance in protection of the personal data which is collected and processed under the health information systems.

Inadequacy of the current legislative framework of Kosovo for health information systems

The key provisions regarding the health information systems are found in Kosovo Law on Health, and Law No. 04/L -249 On Health Insurance in Kosovo **("Kosovo Law on Health Insurance").** Both laws are insufficient and address and authorize simply the health information system. Both laws have been adopted in 2013/2014 and are currently under the legislative programs of being replaced with new laws.

The solutions to the inadequacy of the current legal framework includes two (2) options. The first option is to develop a specific and separate law on Health Information Systems. This is a solution is adopted by countries such as Germany (Digital Healthcare Act (Digitale-Versorgung-Gesetz or DVG)), Austria (Electronic Health Record Act (EHR-Act) and is a dominant solution within EU. The second option is to legislate the rules and principles of the Health Information Systems within the existing laws (such as Kosovo Law on Health, Kosovo Law on Health Insurance).

Whichever option is selected by Kosovo, the new and update legislative framework should address and include the topics and principles elaborated in the section below "Principles and overview of the required legal instruments for developing and implementing a health information system", proving an overview of the aspects which should be addressed in the primary legislation (laws).

First point of analysis is the insufficiency of the Kosovo Law on Health.

The Kosovo Law on Health has five (5) short articles regarding establishment of the health information system. It simply provides that it authorizes the establishing and maintaining a comprehensive and integrated system for healthcare data management and that the MoH is tasked with ensuring the development, implementation, and operation of the HIS throughout the entire healthcare sector, regardless of ownership or organization. Finally, the Kosovo Law on Health provides that the data collected within the system, which pertains to the health status of the population, should be accessible to the National Institute of Public Health for analysis and the preparation of specific reports.

Further, the Kosovo Law on Health provides that the system shall be governed by the norms and standards set by the MoH. However, MoH has failed and did not adopt the required sub-legal acts for the purpose of functionalization of the HIS.

Finally, Kosovo Law on Health also provides that data collection, management, analysis, usage, and reporting within the HIS are to be defined by the sub-legal acts to be developed by MoH. However, MoH also has failed to develop such legal acts, therefore these crucial operations are not defined.

Second point of analysis is the Kosovo Law on Health Insurance Fund.

Kosovo Law on Health Insurance has no substantive provisions or regulatory aspects related to health information systems. The law establishes the Kosovo Health Insurance Fund (KHIF), which serves as the main financing mechanism for healthcare services. The KHIF is responsible for collecting contributions from citizens, employers, and the government, and using these funds to cover the cost of healthcare services for insured individuals. The law defines the rights and obligations of insured persons, healthcare providers, and the KHIF, ensuring transparency and accountability in the management of healthcare funds.

In relation to the health information system, the only applicable provision in the law is the one which authorizes the KHIF to access the health information system.

The expected reform of the Kosovo legal system concerning healthcare

The Legislative Program for the year 2023, was approved on the 121 meeting of the Government of the Republic of Kosovo with the Decision No. 02/121, dated 25.01.202312, and includes major reform in the healthcare sector. Among other things, it foresees the replacement of all existing laws in the healthcare sector with new laws. Among others, this foresees:

- Draft Law on Health - expected to be passed to the Assembly of Kosovo by June 2023,
- Draft Law on Health Insurance - expected to be passed to the Assembly of Kosovo by June 2023
- Draft Law on Medicinal Products and Medical Devices - expected to be passed to the Assembly of Kosovo by September 2023
- Draft Law on Regulation of Price of Medicinal Products

Based on the established practices, in cases where the Government foresees a completely new text of the law, it means that there is a major policy change which requires a completely new legal framework. Therefore, we can expect major changes in the near future (3-4 months).

However, this also has a very positive side. The proposed principles on how to structure and legally regulate the health information systems, as elaborated below, can be incorporated within the new expected changes easily.

[12] Available at: https://kryeministri.rks-gov.net/wp-content/uploads/2023/05/Programi-Legjislativ-per-vitin-202325.5.2023.pdf

The legislative structure and practices in the Republic of Kosovo

Following the Administrative Instruction No. 03/2013 On Standards for The Drafting Of Normative Acts ("**AI on Drafting Normative Acts**"), the recommended legislative steps in ensuring the establishment and regulation of the health information systems should be divided between the:

- The applicable laws, as the primary source of the regulations
- Administrative instructions, as sub legal acts to be approved by the Government of the Republic of Kosovo.

In Kosovo, the legislative framework is established by developing governing principles into laws, which provide the overarching legal framework for various sectors and areas of governance. However, the detailed rules and regulations, as well as practical implementation guidelines, are often formulated through Administrative Instructions (AI).

Administrative Instructions serve as supplementary regulations that provide detailed guidance on how to interpret and implement the provisions outlined in the laws. They are issued by relevant government institutions or authorities responsible for specific sectors or areas, and they aim to ensure consistent application of the laws and facilitate their effective implementation on a day-to-day basis.

The use of Administrative Instructions allows for a more flexible and responsive approach in addressing specific administrative procedures, technical requirements, and operational aspects within different sectors. It enables the government to adapt and respond to changing circumstances, emerging challenges, and evolving best practices without the need for frequent amendments to primary legislation.

Therefore, the recommendation remains that the applicable guiding rules, as elaborated below, are included in the applicable laws. This can be as a special new law on health information systems, or as part of the Law on Health. Further, the technical and other detailed regulation aspects should be regulated by the virtue of by-laws.

One advantage to this proposal is the fact that the technical part of the solutions foreseen under administrative instruction is easier to implement. Procedurally, this can be updated and adopted by the MoH, without the need to go to the lengthy parliamentary procedures of changing the law.

I. PRINCIPLES AND OVERVIEW OF THE REQUIRED LEGAL INSTRUMENTS FOR DEVELOPING AND IMPLEMENTING A HEALTH INFORMATION SYSTEMS

The development and implementation of health information systems depend largely on the legal and institutional environment, and include the rules and principles on coordination, sharing, and dissemination of data. The legal and regulatory contexts play a crucial role in generating and using health information. They establish mechanisms to ensure that data is available, exchanged, of high quality, and shared.

There is a general consensus that the following elements represent minimum requirements that are required to be specifically addressed in the applicable legislation[13]:

- [13]Health information systems – past, present, future, International Journal of Medical Informatics, Volume 75, Issues 3–4, March–April 2006, Pages 268-281
- Health indicators in Europe: availability and data needs, Katri Kilpeläinen et al European Journal of Public Health, Volume 22, Issue 5, October 2012, Pages 716–721

A. Governance and leadership

Refers to overall management and decision-making processes that ensure the effective and responsible use of health information system. This requires development of clear governance structures and accountability mechanisms to oversee the implementation, operation, and management of the health information systems. Under Kosovo Law on health, this institution was designed to be MoH. While it can remain the same choice, the basic principles require that the role of MoH is more clearly defined.

One aspect of the Governance involves developing policies and guidelines that define how health information should be managed, including data privacy and security, data quality standards, interoperability requirements, data sharing protocols, and related. This includes defining roles and responsibilities, establishing oversight bodies, and ensuring compliance with relevant standards and regulations.

This would also be the body that will have the responsibility to finance the system and also maintain the same.

Based on the current legislative approach in Kosovo, the governance and leadership part of the health information systems would need to be addressed through laws directly (primary legislation). Depending on the option selected, whether it is a completely new Law on Health Information Systems or it is amendment of the Law on Health, the governance and ownership part should be addressed within the text of such law. Once the ownership and governance is defined by a primary law, subsequently, it will be the role of the government to further define the technical standards using sub-legal acts. Sub-legal acts may address the organizational issues of the teams employed, roles and responsibilities and similar technical and organizational aspects.

B. Mechanisms to be established to ensure data availability, exchange, quality and sharing

Legislation and regulations are particularly important in enabling the health information system to access data from both private and public healthcare services, as well as non-health sectors. It is essential to pay attention to legal and regulatory issues to integrate non-state healthcare providers into the health information system.

As such, irrespective of whether Kosovo would make it compulsory for the privately owned healthcare institutions (private hospitals, private laboratories, private clinics) to use the national health system, or integrate their systems within the national healthcare sector, these requirements would need to be specifically addressed in the legal acts.

Similarly, feeding information from civil registry or other sources, also requires specific legal basis for access to such data and the manner of access, together with allowed processing requests. In Kosovo, this legal basis can be created by either introducing the same in one comprehensive new Law on Health Information Systems, or by amendment of the Law on Health.

C. Data privacy and security

This is one of the areas where Kosovo legislation is compliant with EU legislation. However, despite that it has an advanced legal framework for protection of personal data, Kosovo institutions and MoH need to be careful in ensuring full implementation of rules on data protection.

- Design and implementation of health information systems, World health Organization (Edited by Theo Lippeveld)

Kosovo has adopted LAW NO. 06/L –082 ON PROTECTION OF PERSONAL DATA ("**Kosovo Law on Data Protection**") is in full compliance and almost a verbatim adoption of the Regulation 2016/679 - Protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("General Data Protection Regulation" or "**GDPR**").

When dealing with health information systems, data privacy and security concerns are of paramount importance. The sensitive and personal nature of health information necessitates robust measures to protect patient confidentiality and prevent unauthorized access or breaches. Here are some key data privacy and security concerns that need to be addressed by the legislation to be enacted by the Ministry:

- **Patient Confidentiality**: Health information systems must ensure that patient data remains confidential and is only accessible to authorized individuals. Measures like encryption, strong access controls, and user authentication protocols should be implemented to safeguard patient privacy.
- **Data Access Controls**: Access to patient data should be limited to authorized personnel who have a legitimate need for it. Role-based access controls should be implemented, granting different levels of access based on job roles and responsibilities. This ensures that only authorized individuals can view, modify, or share patient information.
- **Data Integrity**: Health information systems should employ mechanisms to ensure the integrity of data, preventing unauthorized modification, deletion, or tampering. This can be achieved through measures like data backups, audit logs, data validation checks, and data encryption.

From the perspective of implementation and compliance with Kosovo Law on Data Protection, all the above-mentioned principles need to be defined in the respective law regulating the Health Information Systems (either a new Law on Health Information System, or amendment to the Law on Health.

D. Patient authorizations and consent

The legislation should address requirements for obtaining informed consent from individuals for the collection, use, and sharing of their health information. It should also establish rules for obtaining authorization when sensitive or identifiable information is involved.

The principles of consent and authorization by patients are fundamental to establishing and maintaining a trustworthy health information system. These principles ensure that individuals have control over the use and disclosure of their personal health information, promoting autonomy, privacy, and transparency. Here is an overview of these principles:

- **Informed Consent**: Informed consent requires that patients be provided with clear and comprehensive information about how their health information will be collected, stored, used, and shared within the system. Patients should have a full understanding of the purposes, risks, and benefits associated with the system and provide their consent voluntarily.
- **Authorization for Disclosure**: Patients should have the ability to authorize the disclosure of their health information to specific individuals or organizations. This ensures that sensitive information is shared only with the appropriate parties and for legitimate purposes, such as healthcare provision, research, or coordination of care.
- **Revocation of Consent**: Patients should have the right to revoke their consent or authorization at any time. This empowers individuals to exercise control over their health information and make decisions about its use and disclosure.
- **Privacy Safeguards**: Health information systems must implement robust privacy safeguards to protect patient data. This includes encryption, access controls, audit trails, and regular security assessments to prevent unauthorized access, breaches, or misuse of personal health information.

E. Interoperability

Legislation should emphasize interoperability standards to ensure that different health information systems can seamlessly exchange data. This includes adopting common data standards, coding systems, and protocols for data sharing to enable smooth communication between different healthcare providers and systems.

This would be especially important if the private healthcare providers (hospitals, laboratories and similar), would be authorized to develop and implement their own health information system, with a duty to report some parts of the data to the national healthcare standards. Legislation that emphasizes interoperability standards is essential for the efficient and effective functioning of health information systems.

To achieve interoperability, it is crucial to establish and adopt common data standards. These standards define how data is structured, formatted, and represented, ensuring that information can be understood and utilized across different systems.

Additionally, standardized coding systems, such as International Classification of Diseases (ICD) or Systematized Nomenclature of Medicine (SNOMED), play a vital role in ensuring consistency and clarity in medical terminology and coding. Using common coding systems enables healthcare providers to accurately document and share information, facilitating effective communication and enhancing patient safety.

In conclusion, legislation that emphasizes interoperability standards is crucial for enabling the exchange of health data across different systems and providers. By adopting common data standards, coding systems, and protocols for data sharing, healthcare organizations can achieve seamless interoperability, leading to improved patient care, care coordination, and research outcomes. Legislative support for interoperability standards paves the way for a more interconnected and data-driven healthcare ecosystem, ultimately benefiting patients, healthcare providers, and the overall healthcare system.

F. Data integrity and quality

The legislation should outline requirements for data quality, accuracy, and integrity to ensure that health information stored within the system is reliable and can be effectively used for decision-making. This may include guidelines for data validation, verification, and auditing processes.

This would be the main role of the MoH, if the current model of governance is maintained, or would require appointment of a new institution in Kosovo.

Legislation plays a crucial role in outlining requirements and guidelines for maintaining high standards of data quality, accuracy, and integrity within the system. By establishing guidelines for data validation, verification, and auditing processes, legislation can promote the use of trustworthy health information for improved healthcare outcomes.

Legislation should outline clear requirements for data quality, establishing guidelines and standards that healthcare organizations must adhere to. This includes guidelines for data validation, verification, and auditing processes. Data validation ensures that the entered data conforms to predefined rules and formats, reducing errors and ensuring consistency. Verification processes involve cross-checking and validating data against reliable sources to ensure accuracy. Auditing processes, on the other hand, involve regular reviews and assessments of data to identify discrepancies, errors, or inconsistencies.

Additionally, legislation can require the implementation of robust security measures to protect data integrity. This includes safeguards against unauthorized access, data tampering, or malicious activities. Encryption, access controls, and regular security assessments can help ensure that health information remains intact and trustworthy.

G. Health information exchange between different institutions

Legislation should address the legal framework for health information exchange across different healthcare entities, such as hospitals, clinics, laboratories, and public health agencies. In the case of Kosovo, this would involve MoH, primary, secondary and tertiary care, private hospitals, public and private laboratories, and many others.

As such, developing concise legislation defining the rights, responsibilities, and obligations of these entities when sharing health information is crucial.

H. Patient rights

Legislation should clarify individuals' rights to access and control their health information. It should establish mechanisms for individuals to request access, correction, or deletion of their health records, as well as the right to restrict the sharing of their information in certain circumstances. In this case, it is advisable that the institution authorized to address and manage the individuals' rights to their health information is the one responsible for managing the same. In the case of Kosovo, this would likely be MoH.

To achieve this goal, there are some specific requirements. First, legislation should outline clear guidelines for individuals to request access to their health records. This process should be simple, secure, and readily accessible through electronic means. Patients should have the right to obtain their records in a format of their choice and which is convenient.

Furthermore, the legislation should establish mechanisms for individuals to correct inaccuracies or omissions in their health records. Mistakes in medical records can have serious consequences, potentially leading to misdiagnosis, improper treatment, or delays in care. By giving patients the ability to review, correct, and update their health information, the legislation promotes accuracy and enhances the overall quality of healthcare delivery.

Individuals should have the right to request the deletion of their health records under certain circumstances. This may include situations where the information is no longer relevant, inaccurate, or violates their privacy. However, there may be limitations to this right, such as legal requirements for data retention or public health considerations.

I. Allocation of the appropriate resources, training and education

The legislation should foresee two final things: a) proper allocation of the staff to achieve its mission and goal, and b) encourage training and education.

In the case of Kosovo, it is of paramount importance to foresee and ensure financial and human resource independence of the institutions responsible for healthcare. This is ensuring independence and encouraging training and education programs to ensure that healthcare professionals, system administrators, and other relevant stakeholders are equipped with the necessary knowledge and skills to effectively use and manage the system.

J. Compliance and penalties

The legislation should outline consequences for non-compliance with the requirements, such as administrative fines, penalties, or legal actions. It should also establish processes for auditing, monitoring, and enforcing compliance.

Compliance with data protection regulations is of utmost importance when it comes to the health information systems and ensuring compliance. This includes non-state actors which are required to feed in the data to the national health information systems.

4.6.9 Privacy policies

Kosovo has adopted LAW NO. 06/L –082 ON PROTECTION OF PERSONAL DATA ("**Kosovo Law on Data Protection**") is in full compliance and almost a verbatim adoption of the Regulation 2016/679 – Protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ("General Data Protection Regulation" or "**GDPR**").

As such, the protections offered by the Kosovo Law on Data Protection are identical to the protections of the GDPR applicable within the European Union. Due to the fact that this part of the legislation is developed, the key focus is to ensure compliance from the MoH.

This requires the MoH, or any other public body in Kosovo, with the obligation to ensure the following specific requirements related to health information systems:

- **Personal Data**: Health information, including medical records, is considered personal data under the Kosovo Law on Data Protection. This includes any information that can directly or indirectly identify an individual, such as names, contact details, health conditions, treatment information, or genetic data. Therefore, such personal data becomes under the protection of the applicable law and requires the MoH to observe and comply with specific requirements.
- **Lawful Basis for Processing**: The Kosovo Law on Data Protection requires a lawful basis for processing personal data. In the context of health information systems, this could be based on the necessity of processing for the performance of a medical service or treatment (e.g., providing healthcare services), compliance with legal obligations (e.g., health regulations), consent, or legitimate interests pursued by the data controller or a third party.
- **Data Subject Rights**: The Kosovo Law on Data Protection grants individuals several rights regarding their personal data. These rights include the right to access their health information, rectify inaccuracies, erase data under certain circumstances (e.g., when the data is no longer necessary), restrict processing, object to processing, and data portability.
- **Consent**: When relying on consent as a lawful basis for processing health information, the Kosovo Law on Data Protection sets strict requirements. Consent must be freely given, specific, informed, and unambiguous. It should be obtained through clear affirmative action, and individuals have the right to withdraw consent at any time.
- **Privacy by Design and Default**: The Kosovo Law on Data Protection, similar to GDPR, promotes the concept of privacy by design and default. Health information systems should implement privacy-enhancing measures from the inception of the system and default settings should prioritize privacy. This includes measures such as data anonymization, pseudonymization, access controls, encryption, and regular privacy impact assessments.
- **Data Transfers**: The Kosovo Law on Data Protection imposes restrictions on the transfer of personal data outside the Kosovo and EU/EEA. Such limitations should be imposed also on the legislation related to health information systems.
- **Data Protection Officer (DPO)**: Organizations involved in health information systems may be required to appoint a Data Protection Officer. The DPO is responsible for ensuring compliance with the Kosovo Law on Data Protection and acting as a point of contact for individuals and supervisory authorities.

4.6.10 Compliance to other privacy policies (national, international)

One of key goals in developing a Health Information System is ensuring compliance with GDPR. Kosovo Law on Data Protection, being almost a verbatim adoption of the GDPR, offers the safety of being GDPR

compliant. Therefore, the only remaining task is to ensure full compliance with Kosovo Law on Data Protection, which effectively ensures GDPR compliance. **GDPR** compliance process requires specific tailoring of the health information system to match its requirements. In the case of Kosovo, the system should comply with basic requirements set in section 8.9 and other privacy requirements elaborated herein. On the other hand, good examples of ensuring GDPR compliance within the health information systems are Estonia and Denmark – Estonian e-Health System: Estonia has a well-known e-Health system that integrates various healthcare databases and services. The system ensures GDPR compliance by implementing strong security measures, providing transparent information to patients about data processing, obtaining informed consent, and granting individuals control over their health data. - Danish Health Data Authority: The Danish Health Data Authority is responsible for the collection and management of health data in Denmark. It has implemented GDPR-compliant processes to ensure the lawful and transparent processing of health data. They provide clear guidelines to healthcare providers on data protection, consent management, and secure data sharing.

4.6.11 Access and consent policy

The principles of consent and authorization by patients are fundamental to establishing and maintaining a trustworthy health information system. These principles ensure that individuals have control over the use and disclosure of their personal health information, promoting autonomy, privacy, and transparency and include:

- **Informed Consent**: Informed consent requires that patients be provided with clear and comprehensive information about how their health information will be collected, stored, used, and shared within the system. Patients should have a full understanding of the purposes, risks, and benefits associated with the system and provide their consent voluntarily.
- **Authorization for Disclosure**: Patients should have the ability to authorize the disclosure of their health information to specific individuals or organizations. This ensures that sensitive information is shared only with the appropriate parties and for legitimate purposes, such as healthcare provision, research, or coordination of care.
- **Revocation of Consent**: Patients should have the right to revoke their consent or authorization at any time. This empowers individuals to exercise control over their health information and make decisions about its use and disclosure.

Access to patient data should be limited to authorized personnel who have a legitimate need for it. Role-based access controls should be implemented, granting different levels of access based on job roles and responsibilities. This ensures that only authorized individuals can view, modify, or share patient information.

A good example in this regard is Estonia. In Estonia, health information systems are governed by the Estonian Health Services Organization Act and the Personal Data Protection Act. Some key aspects related to access and consent in health information systems in Estonia:

- Patients in Estonia have the right to access their health information held by healthcare providers and health information systems. They can request access to their medical records and other relevant health data. Healthcare providers are required to provide access to this information within a reasonable timeframe.
- Estonia has implemented a nationwide digital health record system known as the Estonian Electronic Health Record (EHR) system. This system allows authorized healthcare professionals to access and exchange patient health information securely. Patients can also access their own EHR through a secure online portal called the "Patient Portal."

- In Estonia, patients have control over the sharing of their health information. They can provide consent for healthcare providers to share their health data electronically through the EHR system. Consent can be given explicitly or, in some cases, may be implied if sharing is necessary for providing medical treatment.
- The Personal Data Protection Act in Estonia requires healthcare providers and health information systems to implement appropriate technical and organizational measures to ensure the security and confidentiality of personal data, including health information. Measures such as data encryption, access controls, and audit trails should be in place to protect patient data.
- Healthcare providers are responsible for managing patient consents for the processing and sharing of health information. Patients should be informed about their rights regarding consent and the purposes for which their data may be used. Healthcare providers must ensure that consent records are maintained accurately and updated when necessary.
- Estonian laws do not specify a specific retention period for health records. However, healthcare providers are expected to retain health data for a reasonable period, taking into account the applicable medical and legal requirements. When data is no longer needed, it should be securely deleted or anonymized.

Different practices can be noticed in different EU country in regulation about patient consent for using EHR. Here is a short overview of some practice and implementations (based of the findings of Consultant's expert from status in 2018.)

EHR in EU - overview

Country	Estonia	Finland	Germany * (2018 19)	Poland * (2018)	Sweden	Great Britain(England)	Croatia
Patient/citizen consent	OPT-OUT	OPT-IN	OPT-IN	OPT-OUT	YES/NO	OPT-IN for Portal,OPT-OUT fordata collection	OPT-IN
Access to EHR for medic professionals	all the time	until revocation	for each access, the patient must give the consent of the	On request	with the agreement of patient	for each access, the patient must give the consent of the	with the agreement of patient
The patient may	Hide data	Limit access rights	?	?	Opt-out from national dana exchange platform	Opt-out	Define who should have access
EHR	Centralized at the national level	National Register	will not be centrally stored	Distributed Data	Distributed Data National Portal	SCR Only (Summary Care Records)	Centralised at the national level
Name of the Patient Portal		Kanta	EPF	TBD	My healthcare contacts, MVK	Patient Online (NHS)	PortalZdravlja
Link	https://www.digilugu.ee/login?locale=en	https://www.kanta.fi/en/citizens			http://www.minavardkontakter.se/	https://www.nhs.uk/using-the-nhs/nhs-services/gps/gp-online-services/	https://portal.zdravlje.hr

4.6.12 Audit policy

An information systems (IS) audit is an independent review and examination of system records, activities, and related documents. These audits are intended to improve the level of information security, avoid improper information security designs, and optimize the efficiency of the security safeguards and security processes.

There are three main forms of IS audit, depending on the relationship between the auditor and the auditee parties:

- **First-party audit** is defined in every internal procedure handled by an internal member or group of members within an organization. The purpose of the first-party audit is to ensure that a process, or set of processes in the quality management system, meets the procedure requirements specified by the enterprise. If the audit is performed by the owner(s) of the process(es) then the audit process is called a self-assessment, which is a commonly accepted procedure of the audit preparation. On behalf of the enterprise, the auditor acts internally and inspects in depth for problematic areas where processes possibly do not comply and identifies opportunities for improvement.
- **A second-party audit** takes place when the organization performs an audit of a vendor/supplier to ensure that all the requirements specified in the contract between the two parties exists.
- **A third-party audit** occurs when an organization's decision concerns the creation of a quality management system (QMS) that conforms to a standard set of requirements. In this case, an independent company is required to perform an audit to verify and validate the conformity and compliance of the organization with the necessary requirements. These certification bodies conduct audits to compare and verify that the QMS of the enterprise meets all the criteria and requirements of the standard of interest and continues to meet the requirements on an ongoing basis. Once the QMS meets the requirements, the certification body approves and delivers the certificate to the organization.

The scope of an IS audit includes various elements such as the description of the physical locations, the organizational units, the related activities and processes, as well as the timeline needed for conducting the audit. Determining the scope of the audit procedure is the most vital element of the overall audit planning; therefore, the audit scope should be based on, but not limited only to the followings:

- risk exposures, regulatory guidelines and focus to high-risk areas as they deserve closer attention and a broader scope to cover all the identified risk factors;
- critical components that directly contribute to recovery capability and operations resilience; and
- the nature of the business operations and the impact on operations of the audit process.

One of the primary goals of the audit, is to assess the design and operating effectiveness of the implemented controls on all layers, organizational, procedural and/or technical. An additional key outcome/goal would be the assessment of the implemented controls' efficiency towards minimizing the identified risk. Finally, the following outcomes, is expected to be achieved during the IS audit:

- information and evidence about conformity or non-conformity to all the requirements of the legislative context or/and standards;
- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;
- auditee management systems and performance regarding the legal compliance;
- review of design and operational effectiveness for all organizational and/or technical controls;
- management responsibility for auditee policies;
- review links between the normative requirements, policy, performance objectives and targets;
- review any applicable legal requirements, responsibilities, competence of personnel; and
- review operations, procedures, performance data and internal audit findings and conclusions.

Key IT controls should be in place to mitigate the IT-related risks and thus ensure the confidentiality, availability and integrity of data and the efficiency and effectiveness of business processes. The following table gives examples of risks and their IT sources:

Risk	IT-related risk source
Individual errors become systematic	Automation replacing manual operations
Failure to identify the performer of the transaction	Electronic transactions not logged
Unauthorized access and changes to data	Electronic data not properly secured
Loss (destruction) of data	Electronic data not protected (backups and archiving)
Disclosure of confidential information	Electronic data not properly secured
Control weaknesses undetected	IT risks and controls not (adequately) considered in audit

The use of IT systems in business processes changes the nature of audit evidence, the audit trail and the internal control environment. It also creates new vulnerabilities to irregularities and fraud, and new audit procedures are therefore necessary to deal with these challenges.

The evaluation of internal controls should vary according to the type of audit and the degree of reliance the auditor wishes to place on them.

When IT systems data are an important part of the audit and data reliability is crucial to accomplishing the audit objective, auditors need to satisfy themselves that the data are reliable and relevant. Data produced, stored, or provided to the auditor by means of IT should not be treated as reliable until the auditor has convincing evidence that this is so. The components of reliability are accuracy, completeness, and validity. The quality of the data received from the auditee may significantly influence whether the audit objectives are achieved.

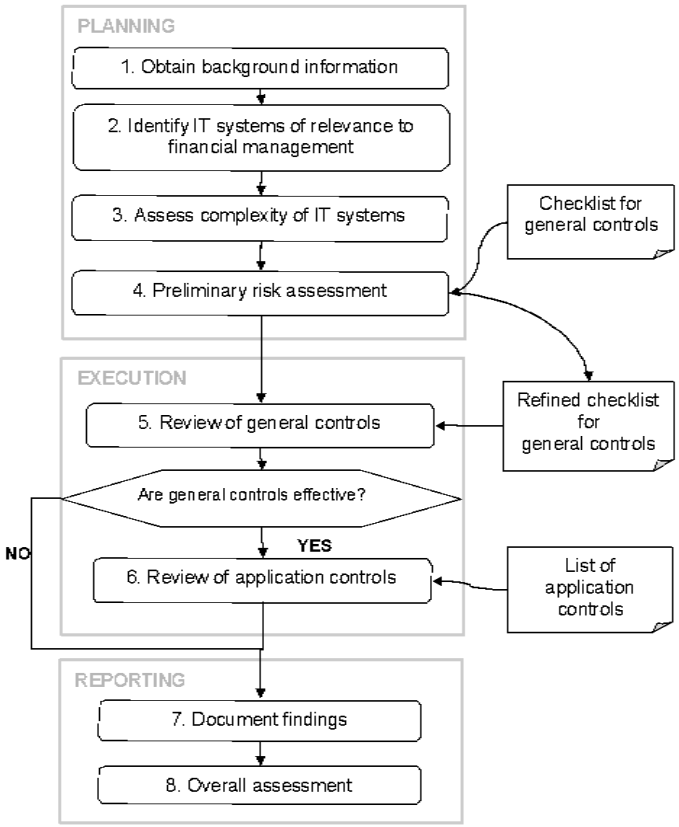
Evidence for the reliability of the computerized data provided by an auditee may come, depending on the nature of the data, from assurance that internal controls on IT are functioning securely and correctly, from cross-checking of the data (e.g. by reconciling them with data from other sources), or from a combination of the two.

The absence of appropriate IT controls may give rise to conditions and events indicating a risk of material misstatement. This in turn would influence the nature, timing, and extent of subsequent IT-related audit procedures.

IT audit may be used in the context of a performance audit when:

- The audit focuses on the performance of IT systems;
- The audit examines the efficiency and effectiveness of a business process and/or program where IT is a critical tool for the organization managing these processes or programs;
- Data reliability is to be assessed.

IT audit work consists of the following steps:



The objective of the planning phase is to identify risks that are relevant to the audit goals and determine which controls will be assessed during the execution phase:

- General controls (as for the IT control environment);
- Application controls (in IT applications of relevance to financial management).

During the planning phase it is important for the auditor to obtain an understanding of the auditee's IT systems, an inventory of the auditee's IT systems and resources (IT budget and staffing, IT organization, software and hardware) and a statement of the concerns arising from previous internal or external audits of IT systems.

The purpose of assessing the complexity of IT systems is to:

- Identify risks - complex systems are more risky than simple ones;
- Decide whether there is a need for external assistance. In principle, auditors are competent to carry out IT audit tasks in relation to simple systems, with the IT audit team providing support in the audit of more complex systems.

The following factors will influence this assessment:

- Hardware and network complexity;
- IT applications and data entry methods;
- IT organization;
- The presence of systems under development or recently subject to change;
- The sensitivity of the processed data;
- Any specific difficulties affecting the audit trail;
- The auditor's technical knowledge and skills.

Using all the information obtained in the previous steps, the auditor will then make a preliminary risk assessment.

Just as in the more general audit context, internal control in IT comprises two elements:

- the internal control environment, i.e. the overall attitude, awareness and actions of management;
- internal control procedures, i.e. procedures complementary to the control environment which contribute to the entity's achievement of its objectives.

General controls relate to the environment within which automated application systems are developed, maintained, and operated. They are concerned with IT-related policies, procedures and working practices. They are used to ensure the proper development, implementation and maintenance of all automated applications and the integrity of data files. They therefore minimize risks to the functioning of the organization's IT systems and infrastructure and specific risks to applications.

General controls include:

- IT governance and management controls: These are high-level controls designed to provide a formal IT governance framework aligned with the business strategy. IT strategic planning and monitoring, IT policies and procedures, IT roles and responsibilities, the segregation of duties, IT risk, project and investment management, and legal and regulatory compliance can all be considered IT governance and management controls;
- Data management controls ensure that data are properly stored, archived, and disposed of. They also help ensure the reliable production of financial and management information;
- Business continuity planning addresses the scenario of a computer systems breakdown and concerns the organization's arrangements for protecting data and continuing or restarting operations in that situation;
- Information security controls help organizations establish and maintain IT security roles, responsibilities, policies, standards and procedures. They include logical access controls aimed at ensuring that data can only be seen or altered by authorized persons, inside or outside the organization, and in accordance with data protection requirements. Information security controls are also concerned with preventing unauthorized access to and interference with IT systems;
- Change management controls provide assurance that systems and controls continue to function as designed;
- Outsourcing controls: Given that more and more organizations now prefer to outsource IT services, it has become crucial to manage service-level agreements. Depending on the scope of outsourcing, inappropriate management could be detrimental to the IT areas subject to control.

The effectiveness of IT controls will depend on the strength of the general controls. If the auditor concludes that the general controls are effective, he should then assess the effectiveness of application controls. However, ineffective general controls will render application controls ineffective (or severely limit their effectiveness) since they act as a foundation on which specific application controls are built. Application controls are to be considered ineffective when, for instance, the necessary logical or physical access controls are not functioning adequately.

The auditor may obtain audit evidence by observation, inspection, inquiry, and confirmation, reperformance, recalculation, computation, analytical procedures, or other generally accepted methods.

Following the assessment of IT controls, the findings should be documented, with a general conclusion on the effectiveness of IT controls. The auditor should document each significant finding, with a statement of the regulatory framework, facts, conclusion, and IT risks.

Auditors should explain each control weakness in relation to the IT risks. They should also determine which areas of the accounts could be negatively affected by a control weakness.

In addition to the individual findings, the auditors should reach an overall conclusion about IT controls.

The assessment may lead to three possible conclusions in the context of the audit:

- IT controls functioned effectively, consistently and continuously during the period under review;
- weaknesses are noted in the effectiveness and continuity of IT controls, but the overall system is considered reliable;
- IT controls are unreliable, i.e. they did not function as expected and/or they did not function continuously during the period under review and/or they could not be tested.

The auditor must consider whether the cost of obtaining audit evidence is reasonable. As already stated, adequate assurance can often be obtained from a more limited examination of general controls and by drawing upon other sources of information.

The audit of application controls is not necessarily highly technical. Many applications are designed to give definite assurance to management that data and processing are in order, without the need for IT experts. In such cases, the checks and procedures (including manual procedures) routinely carried out by regular users may give satisfactory assurance that data and output are reliable. This level of assurance will also be adequate for auditors – except in the case of specific IT audits.

When technical expertise is necessary for specific IT audit testing tasks (network performance, penetration tests, security issues, user rights, change management, technical documentation, etc.) and the necessary skills and resources are not available in-house, external expertise should be organized to collect the required audit evidence.

In the following section, a guidance on how to facilitate the IS audit is provided. The guidance follows the categorization of the security measures. More specifically, it provides a list of questions categorized per security measure and each question is accompanied by indicative pieces of evidence, which enable the body that performs the audit, to assess whether each control is implemented as intended.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
1 GOVERNANCE AND ECOSYSTEM			
1.1 INFORMATION SYSTEM SECURITY GOVERNANCE & RISK MANAGEMENT			
1	Information System Security Risk Analysis	Are the key personnel aware of the main information security risks and the relevant mitigations?	Evidence of personnel attendance to the training (e.g. accepted invitation, date and agenda of training, signed participation list during the awareness workshop etc.).
		Is there a mechanism for ensuring that all security personnel use the risk management methodology and tools?	Guidance for personnel on assessing risks and list of risks and evidence of updates/reviews documented.
		Is the risk management methodology and/or tools, periodically	Documentation of the review process and updates of the

	SECURITY MEASURES	QUESTIONS	EVIDENCE
		reviewed, taking into account changes and past incidents?	risk management methodology and/or tools. Timetable and overall plan of the review cycle.
2	Information System Security Policy	Is there an information security policy (ISSP) and an information security management system (ISMS) in place?	Documented ISS policy in place (dated and signed).
		Are there any certifications in place for specific security risk management standards?	Certification against information security risk management standards (for example ISO 27001), including scope statement.
		Are the information security processes reviewed at regular intervals, while taking into account violations, exceptions and incidents which affected other essential operators?	Documentation of review process, taking into account changes and past incidents. Timetable and overall plan of the review cycle.
3	Information System Security Accreditation	Have the systems supporting essential services been regularly subjected to security scans and have they been integrated within the risk management framework of the organization?	Reports from past security scans and security tests.
		Are there policy/procedures in place for the performance of security assessments and security testing?	Documented policy/procedures for security assessments and security testing, which include at least: • which assets should be assessed, • under what circumstances, • the type of security assessments and tests, • frequency, • approved parties (internal or external), • confidentiality levels for assessment, • test results and the objectives security assessments and tests.
		Has the effectiveness of policy/procedures for security testing been evaluated?	List of reports about security assessment and security tests.
4		Are KPIs implemented in systems supporting essential services to	Documentation of KPIs and mapping with the Critical

	SECURITY MEASURES	QUESTIONS	EVIDENCE
	Information System Security Indicators	be able to assess their effectiveness at all times?	Information System in which they are implemented.
		Are there any policy/procedures in place for the implementation of security indicators for testing the systems supporting essential services?	Policy/procedures for testing critical information systems, including when tests must be carried out, test plans, test cases, test report templates, desired KPI values.
		Are the policy/procedures reviewed and updated?	Updated policy/procedures for testing critical information systems, review comments, and/or change logs.
5	Information System Security Audit	Is there an updated policy and/or procedure for performing information system security assessments and audits of systems and assets supporting essential services?	Information security audit policy and/ or procedures, formally documented and regularly maintained.
6	Human Resource Security	Are the professional references of key personnel (system administrators, security officers, guards, etc.) validated?	Documentation of checks of professional references for key personnel.
		Is training material on security issues provided to key personnel?	Evidence of personnel attendance to the training (e.g. accepted invitation, date and agenda of training, signed participation list during the awareness workshop etc.)
		Are key personnel formally appointed in necessary security roles?	List of appointments and description of responsibilities and tasks for security roles. Organization's organigram in place, job descriptions signed by key personnel, relevant role trainings attended.
		Are the policies/procedures for the Human Resource security regularly reviewed and updated, taking into account possible changes?	Comments or change logs of the policy/procedures. Review time-plan versions of the policies/procedures providing the changes that took place.
7	Asset Management	Are lists of critical assets and configurations of systems supporting essential services maintained?	Lists of centrally managed critical assets and critical system configurations managed and maintained.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
		Is there a policy/procedures in place for asset management configuration control?	Documented policy/procedures for asset management, including roles, responsibilities, assets, and configurations that are subject to the policy along with the objectives of the asset management
		Is the asset management policy regularly updated, based on changes and past incidents?	Up to date asset management policy/procedures, review comments and/or change logs.
1.2 ECOSYSTEM MANAGEMENT			
1	Ecosystem Mapping	Are the contract relationships with third parties properly documented and listed?	Lists of all contracts with third parties
2	Ecosystem Relations	Are the security requirements included in the contracts with third parties?	Explicit security requirements in the contracts with third parties supplying IT products, IT services, outsourced business processes, helpdesks etc.
		Is a security policy for third parties in place?	Documented security policy for contracts with third parties.
		Is the security policy for third parties reviewed following incidents or changes?	Documented comments or change logs of the policy.
		Are there any residual risks associated to third parties and their services not addressed/mitigated?	Vendor Risk Assessment/ Management policy/ procedure in place and maintained. Documented amendment or termination of relationships with high-risk third parties.
		Is a periodic review and update performed to the security policy of third parties, taking into account past incidents, changes, etc.?	Documentation of review process of the ecosystem relations policy.
2 PROTECTION			
2.1 IT SECURITY ARCHITECTURE			
1	Systems Configuration	Are networks and systems supporting essential services configured with information security in mind?	System configuration policy and/ or procedure in place and maintained. System configuration tables. Timetable and plan of system configuration review cycles.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
		Is the effectiveness of the security configurations to protect the integrity of systems evaluated and reviewed?	Documented past exercises/ tests of critical information systems in place. Timetable and plan of security configuration reviews.
2	System Segregation	Are the information systems properly segregated in order minimize the potential consequences when risks occur?	Documentation about how the system segregation of CISs and data is implemented.
3	Traffic Filtering	Is there a monitoring mechanism of the systems supporting essential services in place?	Monitoring reports of critical network and information systems.
		Is there a traffic monitoring policy of the systems supporting essential services in place?	Documented policy for monitoring procedures, including minimum monitoring requirements.
		Are there tools in place for supporting the traffic monitoring of the systems supporting essential services?	Proof of existing tools for monitoring systems.
4	Cryptography	Are there cryptographic mechanisms in place to protect the confidentiality and integrity of information stored in or out of the company boundaries (digital facilities)?	Appropriate cryptographic processes exist.
		Are there implemented cryptographic mechanisms such as digital signatures and hashes to detect unauthorized changes to critical data at rest?	Safeguards to protect the secrecy of secret (private) key(s) are in place.
2.2 IT SECURITY ADMINISTRATION			
1	Administration Accounts	Does the operator set up specific administration accounts, to be used only for administrators that are carrying out specific operations (e.g. installation, configuration, management, maintenance, etc.) on the systems supporting essential services?	Tailored and documented administration accounts with specific access rights given to the relevant personnel.
		Are the administrator accounts solely used to connect to administration information systems?	Documented management of administrator accounts process. Logs of administrator account activity available.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
2	Administration Information Systems	Are hardware and software resources, used for administration purposes?	Detailed inventory with hardware and software resources used for administration purposes.
		Are administration information systems solely used for administration purposes and not mixed up with other operations?	Administration information systems isolated and segregated from the rest of the infrastructure for enhanced resilience.
		Are the resources managed and configured by an authorized operator?	Responsible specialized personnel for the management and configuration of the resources.
2.3 IDENTITY AND ACCESS MANAGEMENT			
1	Authentication and Identification	Are there any access control mechanisms in place, for network and information systems, to allow only authorized use?	Access control policy including description of roles, groups, access rights, procedures for granting and revoking the right to access the information systems.
		Are unused or no longer needed accounts deactivated?	Rule definition for deleting no longer used accounts after a short period of time.
		Is there a mechanism in place for monitoring access to network and information systems and for approving exceptions and registering access violations?	Access control related matrices (e.g. segregation of duties control matrix, remote access control, etc.)
2	Access Rights	Are access rights granted in a structured and monitored manner? Are they granted automatically when applicable?	Access right section included in access control policy/procedures.
		Does the operator define access rights to the multiple functionalities of the resource?	Access rights mapping register to relevant resources and/or processes included in access control policy.
2.4 IT SECURITY MAINTENANCE			
1	IT Security Maintenance Procedure	Has a procedure been established for security maintenance in accordance with the security policy?	Maintenance security procedure properly documented and approved by senior management.
		Are the conditions for enabling the minimum security level for systems supporting essential services resources defined?	Clearly defined minimum security maintenance process.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
		Are software and hardware resources regularly maintained and updated?	Formally documented software and hardware requirements for ensuring compatibility. Software/ hardware asset management formally documented and maintained.
2	Industrial Control Systems	Considering that the proper operation of many essential services depend on functioning and secure industrial control systems (ICS), does the operator, if applicable, take the particular security requirements for ICS into account?	Formally documented ICS requirements
2.5 PHYSICAL AND ENVIRONMENTAL SECURITY			
1	Physical and Environmental Security	Is unauthorized physical access to facilities and infrastructure prevented and have environmental controls, for the protection against unauthorized access (such as burglary, fire, flooding, etc.) been implemented?	Basic implementation of physical security measures and environmental controls, such as door and cabinet locks, burglar alarm, fire alarms, fire extinguishers, CCTVs, etc.
		Has only a limited number of authorized personnel with authorized access and appropriate authorization credentials access to premises containing information systems?	List of personnel with authorized access and authorization credentials.
		Is there a policy for physical and environmental security measures implemented?	Documented policy for physical security measures and environmental controls, including description of facilities and systems in scope.
3 DEFENCE			
3.1 DETECTION			
1	Detection	Is there a policy and related procedures for incident detection and analysis in place?	Documented incident detection and analysis policy, addressing purpose, scope, roles and responsibilities and coordination among all related entities, including clients.
		Is there a mechanism to ensure that the personnel are available and properly trained to detect, understand, and report a security incident?	Reports from related awareness and training exercises.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
2	Logging	Is there a mechanism in place for tracking and documenting information security incidents through an incident monitoring process?	Inventory of major past incidents detected and escalated, including all related information (cause, impact, order of actions taken).
		Have the systems been configured in a way that the automatically registering and escalating of incidents, to the appropriate people, is possible?	Systems, tools and procedures for Incident detection and analysis.
3	Logs Correlation and Analysis	Are the information security incidents investigated and are the relevant reports addressed to the organization's management created?	Up to date documentation of the incident detection policy and related procedures and systems
		Is the policy along with the procedures, related to incident detection, updated in regular intervals?	Evidence of reviews of the incident detection policy and the related procedures and systems.
		Do you conduct information security exercises?	Evidence of past related cyber exercises conducted, including the dates they were conducted.
3.2 COMPUTER SECURITY INCIDENT MANAGEMENT			
1	Information System Security Incident Response	Is there a policy, along with related processes or systems, in place for incident response?	Documented incident detection and analysis policy, addressing purpose, scope, roles and responsibilities and coordination among all related entities, including clients.
		Is there a mechanism to ensure that the incident response personnel is available and properly trained to manage and handle incidents?	Records of incident response related training sessions to the appropriate personnel.
		Is the incident response policy and procedures reviewed following an incident?	Systems, tools and procedures for Incident detection and analysis.
		Are there any incident handling processes in place in accordance with industry standards and good practices?	Management commitment with the incident response policy, guidelines and procedures.
2	Incident Report	Is there a register of past security incidents in place?	Existence of reports related to the detection and escalation of past security incidents.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
		Is the policy and procedures related to incident response reviewed regularly and updated accordingly?	Up to date documentation of the incident detection policy and related procedures and systems
		Are reviews performed to the incident detection policy and to related procedures and systems?	Evidence of reviews of the incident detection policy and the related procedures and systems.
		Does the organization perform cyber exercises in a regular basis?	Evidence of past cyber exercises conducted, including the dates they were conducted.
4 RESILIENCE			
4.1 CONTINUITY OF OPERATIONS			
1	Business Continuity Management	Has a business continuity strategy for the critical services provided by the organization been implemented?	Formally documented service continuity strategy, including recovery time objectives for key services and processes.
		Are contingency plans for the systems supporting essential services implemented in the organization?	Contingency plans for critical systems, including clear steps and procedures for common threats, triggers for activation, steps, and recovery time objectives.
		Are all personnel involved in the continuity operations properly trained in their roles and responsibilities with regards to the information system?	Records of individual training activities as well as post- exercise reports.
2	Disaster Recovery Management	Is the organization prepared for recovery and restoration of the services affected by following disasters?	Measures in place for dealing with disasters, such as failover sites in other regions, backups of critical data to remote locations, etc.
		Is there a policy in place along with related procedures for deploying disaster recovery capabilities?	Formally documented policy/procedures for deploying disaster recovery capabilities, including list of natural and/or major disasters that could affect the services, and a list of disaster recovery capabilities (either those available internally or provided by third parties).
		Is all the personnel involved in the disaster recovery operations?	Records of individual training activities.

	SECURITY MEASURES	QUESTIONS	EVIDENCE
4.2 CRISIS MANAGEMENT			
1	Crisis Management Organization	Is there a crisis management policy in place for managing and responding to IT security incidents?	Formally documented crisis management policy which shall at least include critical CIS, information assets, roles and responsibilities in the event of an IT security incident.
2	Crisis Management Process	Does the operator define in its security policy the processes for crisis management which the organization will implement in case of IT security incidents?	Formally documented crisis management procedure

The product of an audit is the report which outlines all observations / recommendations / non-conformities depending on the scope and approach of the conducted audit exercise. The audits should also include an implementation roadmap for the auditee, with proposed corrective actions and an implementation timeframe. The auditee must accept responsibility for the implementation of the corrective actions before the agreed timeframe.

4.6.13 Software certification and licensing policy

Designing a software certification and licensing policy for eHealth in Kosovo requires careful consideration of various factors. The MoH, as the central body of the state administration responsible for managing the entire health system, establishes a system of standard development and certification procedure through which devices, organization, processes, and IT solutions in health care are certified with the aim of improving the management, interoperability, cost-effectiveness, and efficiency of the health system of the Republic of Kosovo. That can be achieved through better resource management, reduction of interventions for adaptation of solutions, shortened procurement procedures and preparation of adequate and standardized IT solutions.

The key recommendation, when it comes to software certification and licensing policy, as well as software accreditation standards and quality frameworks, is to align current initiative with the industry best practices, or international standards. There is a major need to establish the proper activities and initiatives to govern the quality, accreditation, and certification standards in Kosovo. This is not an easy process, and requires multi-stakeholder engagement, which should seek the right balance of quality vs accreditation and certification. Here, an opportunity mostly sits with using similar expertise from other European countries. Examples could include UK DCB0129/DCB0160 standard for clinical safety (https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems). As general advice, in order to protect the sustainability of eHealth solutions, as well as stimulate competitiveness and innovation, the accreditation framework should be aligned with international practice.

In accordance with that recommendation, we propose the following key components to include in software certification and licensing policy:

- **Certification Process:** Define a certification process that software vendors must undergo to ensure the quality, functionality, and security of their eHealth solutions. Specify the criteria,

standards, and requirements that vendors need to meet to obtain certification. This may include compliance with international standards, interoperability, data security measures, and adherence to best practices.

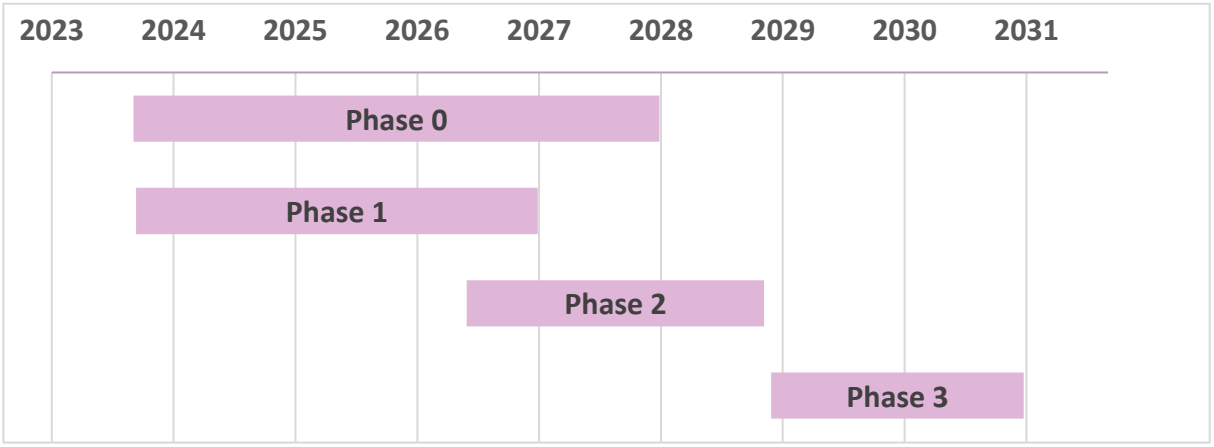
- **Evaluation Criteria**: Establish clear evaluation criteria that will be used to assess software solutions during the certification process. Consider factors such as functionality, performance, usability, interoperability, security, scalability, and compatibility with existing healthcare systems and standards.
- **Accredited Certification Bodies:** Designate and accredit independent certification bodies responsible for evaluating and certifying eHealth software solutions. These bodies should have the expertise and impartiality to conduct thorough assessments and ensure compliance with the certification requirements.
- **Recertification and Maintenance:** Specify the duration of the certification validity and establish recertification processes to ensure that certified software solutions continue to meet the required standards over time. Define the frequency and scope of recertification assessments. Additionally, outline the obligations for vendors to maintain and update their certified software solutions to address any identified vulnerabilities or shortcomings.
- **Licensing Framework:** Develop a licensing framework that outlines the legal requirements and obligations for software vendors to operate in the eHealth sector in Kosovo. Define the licensing categories, fees, and application procedures. Consider the different types of licenses, such as for commercial vendors, open-source software, or custom-built solutions.
- **Intellectual Property Rights:** Address intellectual property rights related to eHealth software solutions. Specify ownership rights, licensing agreements, and the use of proprietary or open-source components. Clearly define the intellectual property rights of both the software vendors and the government or healthcare institutions using the software.
- **Compliance and Monitoring:** Establish mechanisms for monitoring and enforcing compliance with the certification and licensing requirements. Outline the responsibilities of relevant regulatory authorities or oversight bodies in conducting regular audits, inspections, and assessments to ensure ongoing adherence to the policy. Implement sanctions or penalties for non-compliance, if necessary.
- **Transparency and Public Information**: Promote transparency by providing accessible and up-to-date information about certified software solutions, licensed vendors, and the certification process. Create a publicly available registry or database that lists the certified eHealth software solutions and licensed vendors, along with relevant details and documentation.
- **International Standards and Harmonization:** Align the certification and licensing policy with relevant international standards and best practices in eHealth. Consider adopting recognized standards for interoperability, data security, privacy, and ethical considerations. Foster collaboration and harmonization with regional or international organizations working on eHealth certification and licensing.
- **Stakeholder Engagement:** Involve relevant stakeholders, such as healthcare professionals, IT experts, government representatives, and patient organizations, in the development and review of the certification and licensing policy. Seek their input to ensure that the policy addresses their needs, concerns, and the unique context of Kosovo's healthcare system.

Regularly review and update the certification and licensing policy to keep pace with technological advancements, changing industry standards, and emerging challenges in eHealth. This will help maintain a robust and effective framework for ensuring the quality and reliability of eHealth software solutions in Kosovo.

5 Action plan for the Framework implementation

This action plan lists recommendations for Kosovo e-Health implementation activities for the next several years. It describes a comprehensive set of activities, the main action lines, timelines, and responsible parties with the indication of financial resources.

This list of action lines is a **living document** that needs to be constantly updated, depending on the dynamics of existing projects, because it can significantly be affected by the availability of planned resources, primarily human resources and of course financial resources. As is always the case in life, priorities will change over time, especially in the healthcare system, which the World has especially experienced since 2020, so external influences and changing priorities will affect the current view of possible projects. Therefore, it is necessary to keep the action plan in focus and updated at least once in two years.



This current plan includes ideas for the years 2023-2030 and is separated into three time periods: the first (2023-2026), the second (2026-2028), and the third (2028-2030). An additional phase, designated as phase 0, will begin in 2023 and will last until 2027, and will contain numerous strategic projects that should actualize strategic efforts surrounding the organization and successful administration of eHealth projects.

5.1 High Level Overview of Action Plan

Here is a consolidated work of action plan items (projects) with current timelines for the next 7 years:

This list gives an overview with a description and activities of planned and future potential e-Health projects in the period 2023-2030. The projects are numbered based on the initial project list developed by the Consultant, considering the comments and inputs of stakeholders, and potential priority and phase of implementation.

The list of Action plan Items:

Project ID	Project Name	Building Block	Priority (High/ medium/Low)	Phase
1	E-health strategy	NA	High	0
2	eHealth Body Setup Consultancy	NA	High	0
3	Define and optimize processes in eHealth project implementations and supervision	NA	High	0

Project ID	Project Name	Building Block	Priority (High/ medium/Low)	Phase
4	Development of healthcare call center (HCCC)	NA	Medium	0
5	Development of Digital Health Innovation Center (DHIC)	NA	Low	0
6	HW renewal and new purchase	NA	High	0
7	BHIS upgrade + maintenance	BHIS	High	1
8	HMIS (Hospital Management Information System)	HMIS	High	1
9	LIS (Laboratory Information System)	LIS	High	1
10	RIS (Radiology Information System) including PACS (Picture Archiving and Communication Systems)	RIS/PACS	High	1
11	SMSF upgrade + maintenance	PIMS	High	1
12	Blood Transfusion IS, connecting regional TC	Blood Transfusion IS	Medium	1
13	EHR + HIE	EHR	High	1
14	Patient portal	Patient portal	High	1
15	e-Referral	e-Referral	High	1
16	Master Data Management	MDM	High	1
17	Statistical Public Health System (SPHS)	Public Health	High	1
18	Surveillance system of communicable diseases	Public Health	High	1
19	Legacy Systems upgrade (Health Worker, Specialist, Licensing)	NA	High	1
20	Zoning	NA	High	1
21	Capitation support in HIFIS	NA	High	1
22	DRG support in HIFIS	NA	High	1
23	Inspectorate IS	NA	High	1
24	Data integration of KMA database with MDM	NA	Medium	1
25	Dentistry	Dentistry	Medium	2
26	Emergency healthcare information system (EHIS)	EHIS	Medium	2
27	Transfusion module in hospitals	Blood Transfusion IS	Medium	2
28	Microbiology Information Management System (MIMS) upgrade (NIPHK)	LIS	High	2
29	e-Appointment	e-Appointment	Medium	2

Project ID	Project Name	Building Block	Priority (High/ medium/Low)	Phase
30	EHR Integrations with private providers	EHR	Medium	2
31	e-Prescription	e-Prescription	High	2
32	e-Visits	Telemedicine	Medium	1
33	Teleconsultations (between medical staff)	Telemedicine	Medium	2
34	Telemonitoring	Telemedicine	Low	2
35	Statistical Public Health System (SPHS) 2.0	Public Health	Medium	2
36	Analytical System (DWH)	Decision making tools/Analytics	High	2
37	Track&trace	PIMS	Medium	2
38	National public health registries (diabetes, cancer, HIV, TBC, ...)	Public Health	Medium	2
39	Call center software (CCS)	NA	Medium	2
40	e-Radiology - Central national repository of digital radiology images	RIS/PACS	Low	3
41	Development of AI solution for triage of patients	Decision making tools/Analytics	Low	3
42	e-Pathways: healthcare guidelines information system	Decision making tools/Analytics	Low	3
43	Clinical Decision support systems (CDSS)	Decision making tools/Analytics	Low	3
44	Drugs Decision support systems (DDSS)	Decision making tools/Analytics	Low	3
45	Imaging Decision support systems (IDSS)	Decision making tools/Analytics	Low	3
46	e-Medication: integrated information system for professional and economical medication management	Decision making tools/Analytics	Low	3
47	Cross Border Patient Data Exchange	EHR	Low	3

Buy or Build for the proposed Action Item of the Software projects

The "Buy/Build" assumption refers to a software project initiative and the decision of whether to develop a custom solution or purchase a ready-made standard product that can be configured to meet the needs of the eHealth project in Kosovo. The "Build" option has been chosen for all software solutions that are already in use, such as BHIS, legacy systems, etc., and it is proposed to retain them with upgrades. It is also chosen for options where there is no standard solution due to the highly specific

nature of the area (e.g., DWH/BI). For all software solutions for which multiple standard options exist on the market, the recommendation is to buy a ready-made solution because it incorporates standard business practices used by a large number of users in the same domain, and it also provides speed as the software already exists and only needs to be configured.

Project ID	Category	Sub-Category	Project Name	Type	New/ Upgrade
7	Software	Core medical systems	BHIS upgrade + maintenance	Build	Upgrade
8	Software	Core medical systems	HMIS (Hospital Management Information System)	Buy	New
9	Software	Core medical systems	LIS (Laboratory Information System)	Buy	New
10	Software	Core medical systems	RIS (Radiology Information System) including PACS (Picture Archiving and Communication Systems)	Buy	New
11	Software	Core medical systems	SMSF upgrade + maintenance	Build	Upgrade
12	Software	Core medical systems	Blood Transfusion IS, connecting regional TC	Build	Upgrade
13	Software	eServices	EHR + HIE	Build	New
14	Software	eServices	Patient portal	Build	New
15	Software	eServices	e-Referral	Build	New
16	Software	Administrative	Master Data Management	Buy	New
17	Software	Governance	Statistical Public Health System (SPHS)	Build	New
18	Software	Governance	Surveillance system of communicable diseases	Build	New
19	Software	Supporting systems	Legacy Systems upgrade (Health Worker, Specialist, Licensing)	Build	Upgrade
20	Software	Supporting systems	Zoning	Build	New
21	Software	Supporting systems	Capitation support in HIFIS	Build	New
22	Software	Supporting systems	DRG support in HIFIS	Build	New
23	Software	Supporting systems	Inspectorate IS	Build	New
24	Software	Supporting systems	Data integration of KMA database with MDM	Build	Upgrade
25	Software	Core medical systems	Dentistry	Build	New

Project ID	Category	Sub-Category	Project Name	Type	New/ Upgrade
26	Software	Core medical systems	Emergency healthcare information system (EHIS)	Buy	New
27	Software	Core medical systems	Transfusion module in hospitals	TBD	Upgrade
28	Software	Core medical systems	Microbiology Information Management System (MIMS) upgrade (NIPHK)	Buy	New
29	Software	eServices	e-Appointment	Build	New
30	Software	eServices	EHR Integrations with private providers	Build	Interoperability
31	Software	eServices	e-Prescription	Build	New
32	Software	eServices	e-Visits	Build	New
33	Software	eServices	Teleconsultations (between medical staff)	Build	New
34	Software	eServices	Telemonitoring	Buy	New
35	Software	Governance	Statistical Public Health System (SPHS) 2.0	Build	New
36	Software	Governance	Analytical System (DWH)	Build	New
37	Software	Governance	Track&trace	Build	New
38	Software	Governance	National public health registries (diabetes, cancer, HIV, TBC, ...)	Build	New
39	Software	Administrative	Call center software (CCS)	Buy	New
40	Software	Core medical systems	e-Radiology - Central national repository of digital radiology images	Buy	New
41	Software	Core medical systems	Development of AI solution for triage of patients	Buy	New
42	Software	eServices	e-Pathways: healthcare guidelines information system	Build	New
43	Software	eServices	Clinical Decision support systems (CDSS)	Buy	New
44	Software	eServices	Drugs Decision support systems (DDSS)	Buy	New
45	Software	eServices	Imaging Decision support systems (IDSS)	Buy	New
46	Software	eServices	e-Medication: integrated information system for professional and economical medication management	Build	New
47	Software	eServices	Cross Border Patient Data Exchange	Build	New

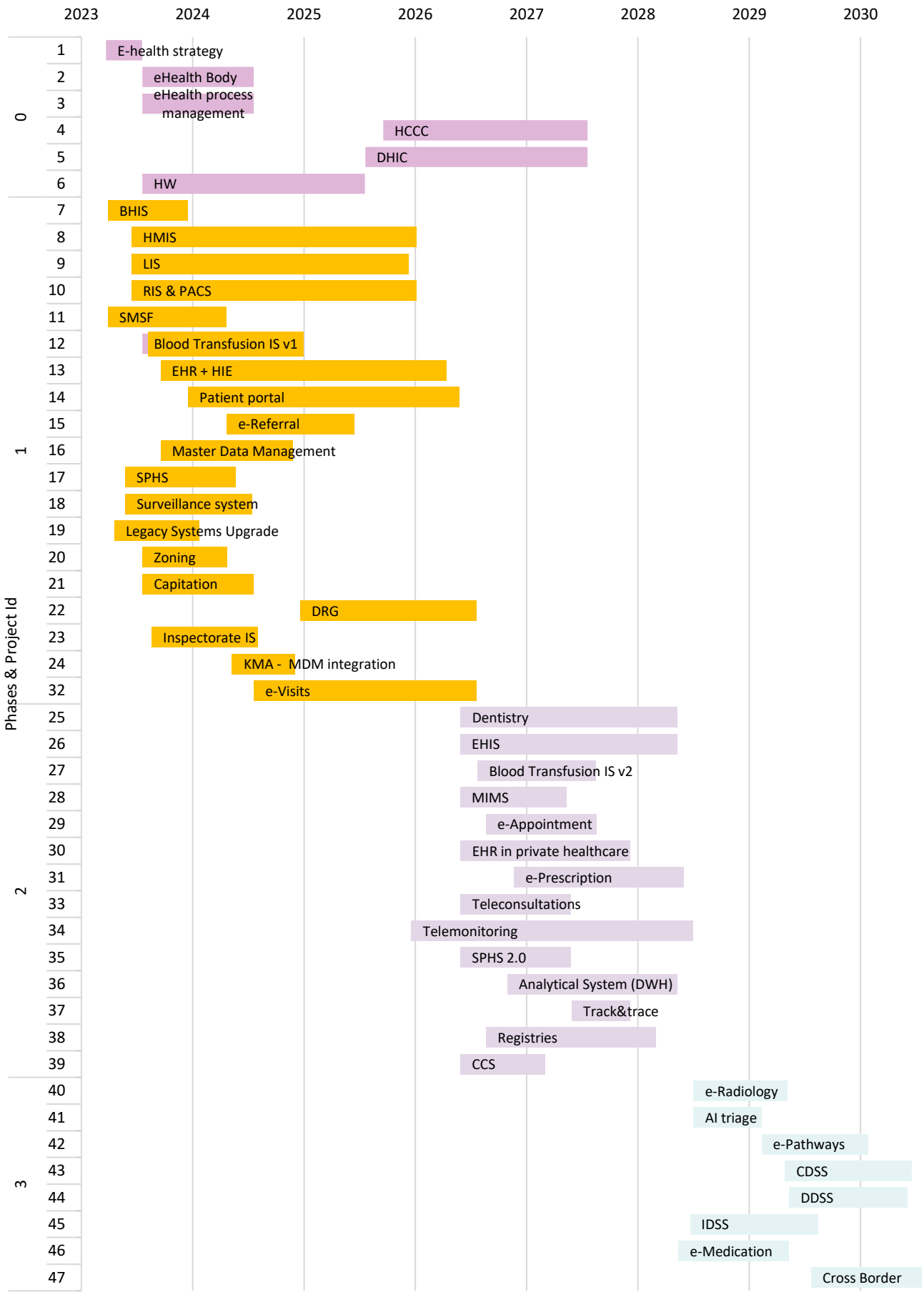
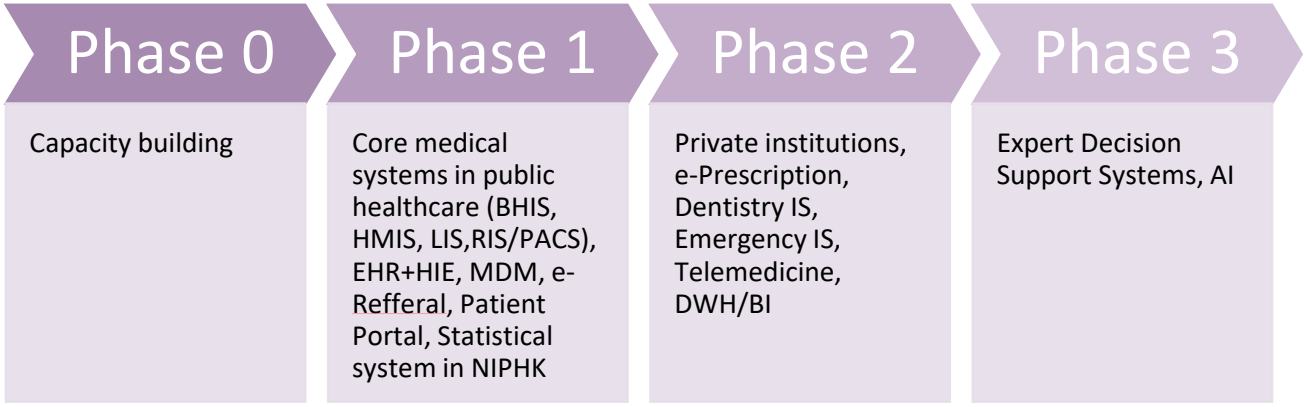


Figure 16: Gantt chart of all proposed projects

Based on our observations of other nations and the current state of Kosovo's eHealth development, aspirations, and Ministry of Health priorities, we have divided the creation and implementation of the national eHealth framework's activities into the following stages:



- **Phase 0** can be called a **Capacity Building phase,** and it is responsible for ensuring the organizational requirements for the successful execution of eHealth projects in Kosovo. In addition to the Kosovo eHealth Strategy, which is critical, the **primary focus is on establishing the eHealth Body**, which will be in charge of overseeing all eHealth projects. This excludes projects from the Supporting Systems category because they are not part of eHealth, but rather back-office software required for the operation of other projects, for which the respective institutions will remain accountable. Standards and procedures, a legal framework, project and product management processes, and change management processes must all be established. Creating the **appropriate hardware infrastructure** (servers, PCs, networks, printers, etc.) is another key enabler for all eHealth project. The development of a health Call center, which acts as a one-stop shop for patients and is crucial for the successful adoption of telemedicine, is also carried out during this phase in the later stage. In order to build a critical mass of knowledge for the long-term sustainability of digital health in Kosovo, the Digital Health Innovation Center should be developed during this phase.
- **Phase 1** of the project aims to develop a centralized Electronic Health Record (EHR) system and implement information systems in various public healthcare institutions over a period of approximately three years. This phase involves the installation of core medical systems, such as LIS and RIS/PACS, in hospitals and ambulances to gather patient medical information, as well as the implementation of Hospital Management Information Systems (HMIS), e-Referral system. The successful completion of Phase 1 will provide essential eHealth services to citizens/patients in Kosovo, similar to successful implementations in other EU nations.
- **Phase 2** is focused on **connecting private institutions**, **finishing EHR** (implementing other non-high-priority core medical systems such as Dentistry IS and Emergency IS, introducing additional eServices (e-Appointment, e-Prescription), and **implementing telemedicine**. Additionally, a comprehensive Data Warehouse (DWH) system will be built, enabling various analyses aimed at improving service quality, optimizing costs, and better resource planning. This phase is planned to last almost 2,5 years, with an expected completion by the end of 2028.
- **Phase 3** is focused on **artificial intelligence (AI) and Decision Support Systems (DSS).** This phase is planned to last for 2 years, with an expected completion by the end of 2030.

It's important to note that the Supporting Systems category, which consists of back-office software from several stakeholder institutions, falls outside the scope of eHealth and remains the responsibility of respective institutions.

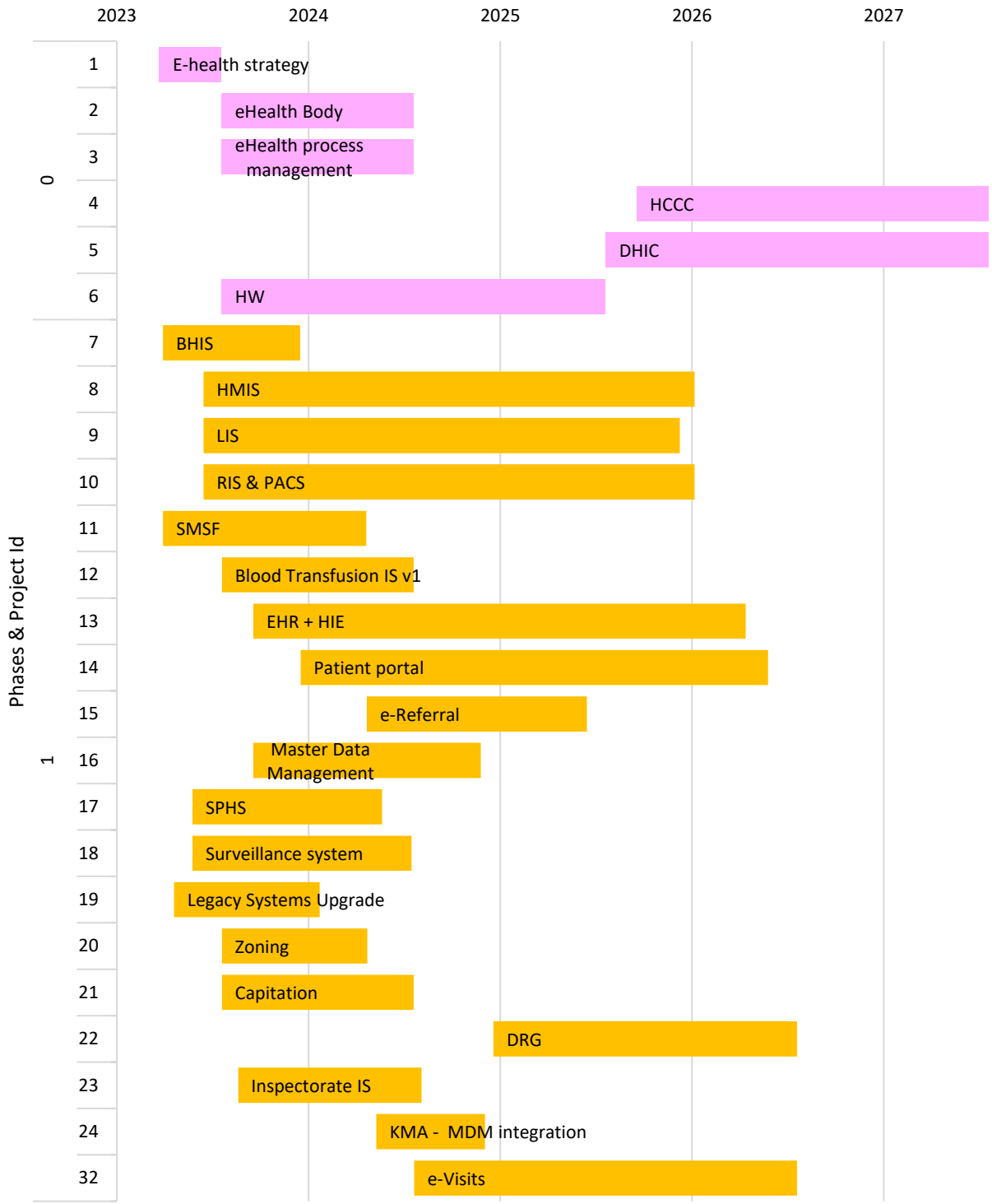


Figure 17: Gantt chart of project in Phase 0 & 1

Phase 1 should concentrate on **developing a centralized Electronic Health Record (EHR) system and implementing information systems in primary, secondary, and tertiary public healthcare institutions**. Phase 1 is anticipated to last for about three years. To guarantee the efficiency of Electronic Medical Records (EMR) in MFMC, FMC, Ambulances, and public hospitals, important core medical systems will be installed throughout this phase. This makes it possible to gather patient medical information from public healthcare facilities. In addition to the installation of LIS and RIS/PACS for institutions with laboratory and radiological diagnostics, BHIS upgrade and further implementation are planned for MFMC, FMC, and ambulances. Implementation of Hospital Management Information Systems (HMIS), LIS, and RIS/PACS will take place at UCCK and regional hospitals.

The deployment of the **e-Referral system** and the implementation of **HMIS in all hospitals, the completion of the EHR, and the construction of the HIE platform**. In order to assure interoperability across construction components, a master data management system should also be implemented. The National Institute of Public Health and Communicable Diseases' (NIPHK) statistical system will start to be developed, and ongoing modifications to the BHIS system and its supporting systems (Legacy system, Inspectorate), should be finished. **A functional EHR with data from public healthcare institutions (apart from dentistry and outpatient emergency treatment) as well as a functioning patient portal and an e-Referral system** should be in place by the phase's conclusion, which is set for 2026.

The **core services for citizens/patients – e-Referral, Patient Portal, systems to support the work of medical workers in primary, secondary, and tertiary care – as well as the basic infrastructure for the national eHealth system can be provided to Kosovo with the successful implementation of projects from Phase 1**. The majority of the EU nations that are now having success implementing eHealth have followed the same steps (e-Prescription, primary care, EHR), including Estonia, Denmark, and Croatia. Due to the ambitious and the number of concurrent initiatives, the primary risks in this phase are the limited human resources that are now accessible.

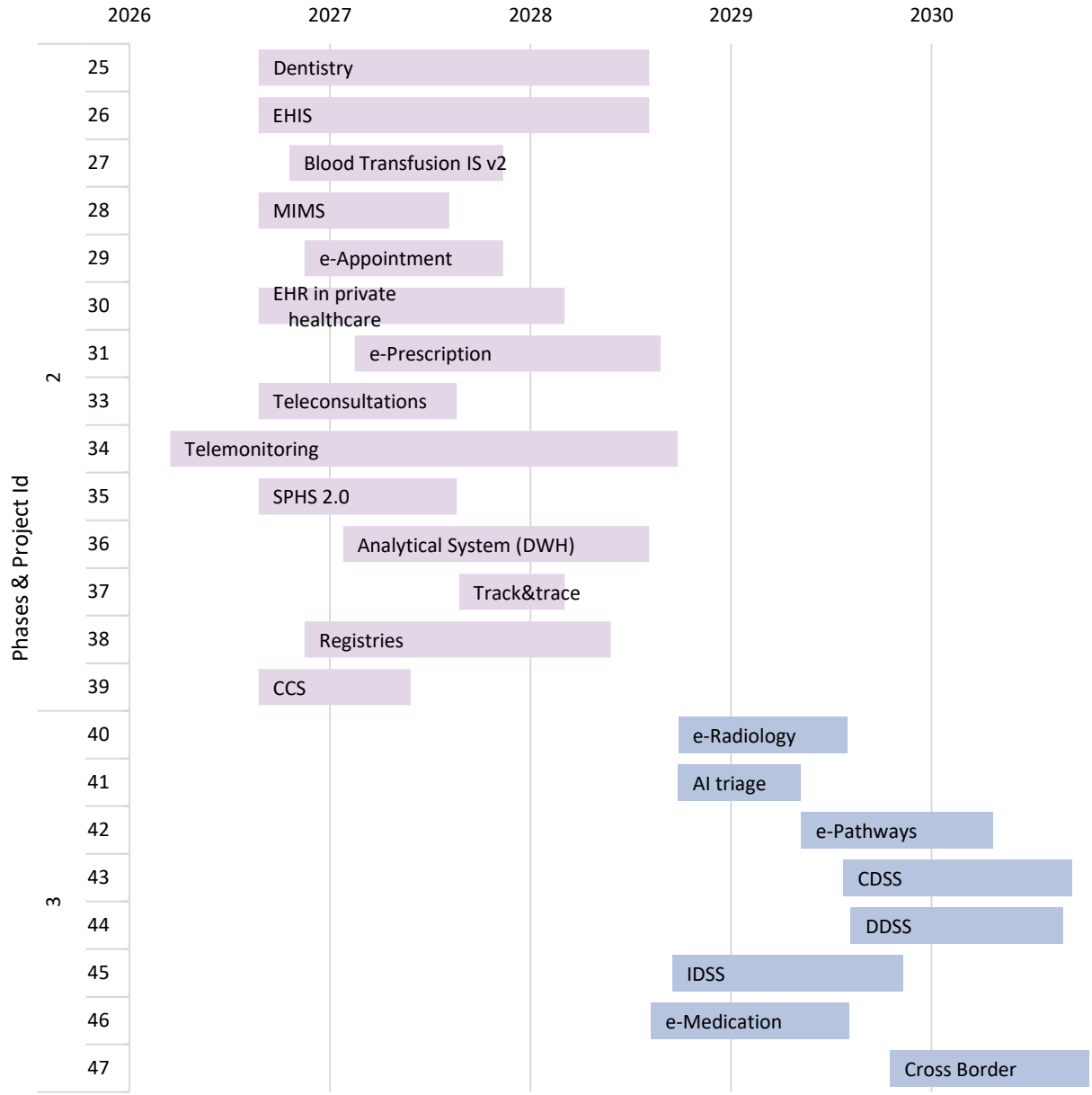


Figure 18 - Gantt chart of project in Phase 2 & 3

The next **Phase 2** should focus on building advanced systems and solutions that add value to patients and healthcare professionals as well as executive and public health authorities. Full integration with private healthcare providers of health services, and expand e-Prescription services, introduce electronic appointment scheduling, further development of telemedicine and systems that were not built in Phase 1 (Transfusion, Dentistry, Track & Trace, Emergency), and create a DWH system with advanced analytics. This phase should take about 2 years and would be a step forward to fully leverage the investments made so far in eHealth services in Kosovo.

Phase 3 should lay the groundwork for the first cutting-edge systems that would support doctors' clinical judgments and the introduction of cutting-edge artificial intelligence tools in healthcare that, based on structured and unstructured data sets, would aid in the analysis of cases, and provide recommendations for the patient's individualized care. To aid medical personnel in making wise choices when treating patients, three decision support systems (Clinical, Drug, and Imaging) should be created.

The EHR should be linked to the central system of e-Radiology, which should create a unique metabase of linkages for all radiological images. The e-Medication system would assist physicians and pharmacists in learning about potential drug interactions at the time of prescription or dispensing. At this point, infrastructure development for potential cross-border health information exchange partnerships with other EU countries can also be envisaged.

5.2 List of Action Plan Projects

Each project, initiative, or program is briefly described here with a short card that includes the name, proposed beginning and end, projected costs, including initial investment and maintenance costs (if any or if it is possible to project them at this time), a brief description of the project and its goals as well as a list of project activities.

5.2.1 E-health strategy

Project Id**: 1**	Phase #: **0**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

Developing and accepting a National eHealth strategy of the Republic of Kosovo as one of the first and crucial steps in the systematic realization of the development of eHealth services.

The e-Health Strategic Development Plan 2024-2028 shall represent a comprehensive e-Health development strategy with an operational level action plan that includes a clear set of priorities, measurable time-bound performance indicators. The strategy should include detailed governance mechanisms with defined roles/responsibilities for the various actors, to address quality gaps and bring about sustainable quality improvements including interoperability in the e-Health domain.

Activities

Use international consultancy to deliver the Kosovo national eHealth Strategy Plan based on WHO's National eHealth Framework.

Delivery working plan:

1. Deliverable 1. Inception report
2. Deliverable 2. Situation analysis of e-Health development and implementation in Kosovo
3. Deliverable 3. Kosovo e-Health Strategic Development Plan 2024-2028

4. Deliverable 4. Kosovo e-Health Business Implementation Plan 2024-2026
5. Deliverable 5: Dissemination event report

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	9/4/2023	12/31/2023	€ 120.000	€ 0	MoH

5.2.2 eHealth Body Setup Consultancy

Project Id**: 2**	Phase #: **0**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

Establishment of a central body responsible for planning, implementing and coordinating all measures within eHealth, i.e. a central place for managing all information systems in health in accordance with the Strategic Plan for the Development of eHealth

Activities

1. Analysis of the current state and needs of the eHealth system;
2. Elaboration of the business plan (including personnel and financial plans);
3. Elaboration of business processes;
4. Development of ordinances and internal regulations;
5. Establishment of the organization;
6. eLearning programme for civil servants and users;
7. Awareness raising and training for civil servants;
8. Raising citizens' awareness;
9. Organize the governance body for continuous monitoring, quality checking and management of key health informatics standards that are used in practice;
10. Organize training facility for stakeholder education and engagement;
11. Publish necessary implementation guidelines.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	1/1/2024	12/31/2024	€ 180.000	€ 0	MoH

5.2.3 Define and optimize processes in eHealth project implementations and supervision

Project Id**: 3**	Phase #: **0**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

Since a large number of parallel and related projects are expected, especially in the first phase of implementation, it is important to have a firm control over the supervision of project execution in order to reduce risks. For successful ehealth implementation some processes need to be defined/ optimized

i.e. Project Management, Product Management, Change Management, Procurement Management and those skill set need to be acquired by the eHealth Body.

Activities

1. Assess Current Skill Gaps
2. Hire an eHealth Consultancy Firm
3. Conduct a Needs Analysis
4. Create a Training Strategy
5. Select Training Providers
6. Implement Training and Assess Progress
7. Encourage Knowledge Sharing and Keep an Eye on Implementation

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	1/1/2024	12/31/2024	€ 144.000	€ 0	MoH

5.2.4 Development of healthcare call center (HCCC)

Project Id**: 4**	Phase #: **0**	Priority level: **Medium**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

Development of sophisticated call center for health sector is essential for better utilization of healthcare staff. It provides services such as appointment scheduling, prescription refills, and general inquiries. It will also support citizens in crisis situations such as COVID-19 pandemic and enable health professionals to manage these kinds of situations with predefined scripts, guidelines, trainings etc., enabling better efficiency and communication between citizens and health sector. Healthcare systems have been designed with focus on acute care and triage processes, which typically involve the immediate access to "physical gateway" – either the GP or ER services. In number of cases however, citizens could be triaged in virtual settings (over phone, chat, email, mobile app etc.), which could provide proper advice without necessary physical visit to the doctor's office.

Activities

1. Identify Goals and Objectives: Determine the specific goals and objectives of the call center
2. Define Service Offerings: Identify the range of services the call center will provide, including appointment scheduling, prescription refills, general inquiries, crisis support, and virtual triage.
3. Establish Technology Infrastructure: Assess and define necessary technology infrastructure to support the call center operations. This includes call center software, customer relationship management (CRM) tools, telephony systems, chat and email platforms, and mobile applications.
4. Develop Predefined Scripts and Guidelines: Create predefined scripts and guidelines for call center staff to follow when interacting with callers.
5. Provide Training: Train call center staff on the specific skills and knowledge required to handle calls effectively.

6. Integrate with Healthcare Providers: Collaborate with healthcare providers, including general practitioners (GPs), specialists, and pharmacies, to ensure seamless integration of the call center with their systems.
7. Define Quality Assurance Measures: Establish quality assurance processes to monitor and evaluate the performance of the call center staff.
8. Continuously Improve and Innovate: Regularly review call center operations and gather feedback from callers, staff, and healthcare providers to identify areas for improvement.
9. Monitor Performance Metrics: Track and analyze key performance indicators (KPIs) to measure the effectiveness and efficiency of the call center.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	3/1/2026	12/31/2024	€ 264.000	€ 0	MoH

5.2.5 Development of Digital Health Innovation Center (DHIC)

Project Id**: 5**	Phase #: **0**	Priority level: **Low**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

The Digital Europe program is focus on strengthening European capacities in the areas of high-performance computing, artificial intelligence, cyber security and advanced digital skills, and on ensuring their widespread use in sectors such as health. It is necessary to enhance cooperation between public and business sectors in the field of Digital Health, so the establishment of digital innovation centers in the field of digital Health is an effective way to encourage innovation, especially in the application of artificial intelligence or blockchain technology in the health system. The Ministry of Health, through e-Health body, should encourage and record the launch of digital innovation centers in existing health institutions or innovation centers of the business sector, with the aim of achieving the necessary synergy and solutions that improve the health system. It is crucial to employ existing nationwide resources and establish digital innovation centers in the field of Digital Health to share initiatives about the creation of solutions and methodologies to assess and evaluate e-health benefits for the main stakeholders on a specific initiative, taking also into account an optimal resource allocation, and risk optimization.

Activities

1. Inception
2. Status analysis of Kosovo (resources, needs, capabilities, stakeholders; academia, education, private sector, industry)
3. Establishment of Digital Health Innovation Center
   a) Organizational structure and governance
   b) Financing (self-sustainable)
   c) Objectives (vision/mission)
   d) Business model
   e) Legal framework
   f) Sustainability
   g) Investments/Funding
   h) Human resources

4. Collection of feedback of stakeholders
5. Final proposal wrapping-up
6. Dissemination activities/public communications

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	1/1/2026	12/31/2027	€ 150.000	€ 0	EU fund/donation

5.2.6 HW renewal and new purchase

Project Id**: 6**	Phase #: **0**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Current**

Short description of the project

All eHealth projects beside SW applications, necessary HW infrastructure (PC, Servers, Network, printers) for efficient and secure functioning of eHealth system. Also it is very important to have multiyear support and maintenance services for all key HW components in place.

Activities

1. Keep up-to-date record of all HW equipment and define a list of equipment for maintenance and for write-off
2. Make a list of necessary HW equipment procurement for all public health facilities, and list for locations for update/upgrade HW capacities
3. Make public procurement for HW equipment with strict SLA ("fix or replace") in warranty period - for Servers, NW, Printers and PCs/laptops
4. Distribute, install, test equipment
5. Public procurement for multiyear maintenance (3-5 years) agreement with stick SLA ("fix or replace") for Servers, NW, Printers and PCs/laptops

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	1/1/2024	12/31/2025	€ 4.700.000	€ 0	MoH

Breakdown of HW investment projects in the 2024-25.

Project Name	Description	Activities	Starting Date	End date	Estimated budget
Network equipment procurement	The connection of all public HC institutions is a necessary prerequisite for the construction of the entire national eHealth system. Most institutions are connected, but there are problems in connecting smaller and remote locations of PHC, while in some locations the equipment is outdated or of poor quality and needs to be replaced. At the same time, the LAN/WAN network is not implemented everywhere or needs to be renewed.	1. Keep up-to-date record of all NW equipment and define a list of equipment for maintenance and for write-off 2. Make a list of necessary NW equipment procurement for all public health facilities, and list for locations for update/upgrade NW capacities 3. Make public procurement for NW equipment with stick SLA ("fix or replace") 4. Distribute, install, test equipment	01/01/2024	31/12/2025	1.000.000,00
Printers procurement	As one of the main current complains in usage of BHIS is insufficient number and quality of printers in the PHC, this project should address that issue and provide necessary printing capabilities to all PHC in the public healthcare network	1. Keep up-to-date record of all printers and define a list of equipment for maintenance and for write-off 2. Public procurement for printing services with minimal 2 providers with 24x7 multiyear maintenance (3-5 years) agreement with stick SLA ("fix or replace")	01/01/2024	31/12/2025	500.000,00
Servers + PCs Procurement	For development and production of eHealth systems and services it is required addition servers, storage and PC infrastructure	1. Keep up-to-date record of all server/storage/PC (HW) equipment and define a list of equipment for maintenance and for write-off 2. Make a list of necessary HW equipment procurement for all public health facilities 3. Make public procurement for HW equipment with stick SLA ("fix or replace") 4. Distribute, install, test equipment	01/01/2024	31/12/2025	2.000.000,00
Maintenance PC/Printer/ servers	On going HW maintenance for PC/Printers/Servers equipment for eHealth network	1. Keep up-to-date record of all HW equipment and define a list of equipment for maintenance and for write-off 2. Public procurement for multiyear maintenance (3-5 years) agreement with stick SLA ("fix or replace") for Servers, NW, Printers and PCs/ laptops	01/01/2024	31/12/2025	1.200.000,00

5.2.7 BHIS upgrade + maintenance

Project Id**: 7**	Phase #: **1**	Priority level: **High**
Building Block: **BHIS**	Project type: **Upgrade**	Project status: **Ongoing**

Short description of the project

BHIS needs to be improved to become a comprehensive EMR (Electronic Medical Record) for primary and secondary healthcare provided in health centers. This includes preparing all specialist reports, relevant code sets for diagnoses and procedures, and full implementation in all public institutions. Additionally, paper-based records such as protocol books need to be digitized to reduce/eliminate the amount of external records. Integration preparation with SMSF-of for ePrescription implementation, as well as integration preparation with RIS/PACS and LIS systems, is required. Within the project, it is necessary to further develop the Vaccination module, EPPV module, and home visit module.

Activities

1. Analyzing the usage of BHIS
2. Reviewing the standard operating procedures and identifying the gaps and needs for digitization and integration of the systems and processes.
3. Development of functional and technical specifications
4. Accept and approve Change Requests
5. BHIS Development
6. UAT
7. Training and piloting BHIS with selected users and locations.
8. System verification and validation;
9. Full implementation OF BHIS

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	9/11/2023	5/29/2024	€ 360.000	€ 2.160.000	eHealth body

5.2.8 HMIS (Hospital Management Information System)

Project Id**: 8**	Phase #: **1**	Priority level: **High**
Building Block: **HMIS**	Project type: **New**	Project status: **Future**

Short description of the project

A Hospital and Clinical Management Information System (HMIS) is a software that helps managing the hospital ongoing business in all aspects (clinical, administrative, financial). In it's medical part it is acting like complete EMR system inside the hospital. It is an essential tool for managing patient information and optimizing healthcare delivery in hospitals. Unique HMIS should be implemented in all public hospitals in Kosovo. It should include Administration module, Clinical module, Pharmacy module, Billing module. implement ERP system for managing the hospital (Accounting, Inventory management, Human Resource Management, Payroll). Integrate them together and with other systems (LIS, RIS/ PACS).

Activities

1. Identify and document the specific requirements of the HMIS
2. Analyze UCCK and regional hospital needs, processes, and workflows to determine how the HMIS will address those requirements;

3. Research and evaluate different HMIS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the HMIS;
5. Configuration and Customization;
6. Data Migration;
7. System Testing;
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/27/2023	6/19/2026	€ 3.500.000	€ 3.150.000	eHealth body

5.2.9 LIS (Laboratory Information System)

Project Id**: 9**	Phase #: **1**	Priority level: **High**
Building Block: **LIS**	Project type: **New**	Project status: **Current**

Short description of the project

Laboratory Information System (LIS) is an application whose main purpose is to automate processes in clinical laboratories. It is built around a centralized database of samples and any meta data, results, workflows, and instruments associated with them. This not only allows a laboratory to remain organized, but also facilitates efficiency, transparency, and compliance. It should be implemented in all public institutions and integrated with BHIS (MFMC; FMC) or HMIS (Hospitals) so complete EMR is available in those institutions. Standard HL7 protocols should be used for integration.

Activities:

1. Identify and document the specific requirements of the LIS
2. Analyze UCCK, regional hospitals' and primary laboratory needs, processes, and workflows to determine how the LIS will address those requirements;
3. Research and evaluate different LIS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the LIS;
5. Configuration and Customization;
6. System Testing;
7. User Training;
8. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/27/2023	5/22/2026	€ 1.110.000	€ 999.000	eHealth body

5.2.10 RIS (Radiology Information System) including PACS (Picture Archiving and Communication Systems)

Project Id**: 10**	Phase #: **1**	Priority level: **High**
Building Block: **RIS/PACS**	Project type: **New**	Project status: **Current**

Short description of the project

A Radiology Information System (RIS) is a software that is designed to manage and automate the workflow and data associated with radiology departments in healthcare facilities. Its primary objective is to manage patient data, imaging procedures, and the distribution of diagnostic reports and images to healthcare professionals. It is always integrated with PACS system. A PACS is a medical imaging technology that is used to store, manage, and distribute digital medical images, such as X-rays, CT scans, MRIs, and ultrasound images. RIS/PACS should be implemented in all public institutions with radiology department and integrated with BHIS (MFMC; FMC) or HMIS (Hospitals) so complete EMR is available in those institutions. Standard HL7 protocols should be used for integration.

Activities

1. Identify and document the specific requirements of the RIS&PACS
2. Analyze UCCK, regional hospitals' and primary radiology department needs, processes, and workflows to determine how the RIS&PACS will address those requirements;
3. Research and evaluate different RIS&PACS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the RIS&PACS;
5. Configuration and Customization;
6. System Testing;
7. User Training;
8. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/27/2023	6/19/2026	€ 1.480.000	€ 1.332.000	eHealth body

5.2.11 SMSF upgrade + maintenance

Project Id**: 11**	Phase #: **1**	Priority level: **High**
Building Block: **PIMS**	Project type: **Upgrade**	Project status: **Ongoing**

Short description of the project

SMSF should be upgraded with a possibility to manage donations of drugs and pharmaceutical products. It should be implemented in the remaining MFCM. Before HMIS procurement it should be decided whether to keep SMSF in hospitals or to change it with HMIS Pharmacy module due to specific needs of hospitals and demand for integration with Hospital ERP and Clinical module. Also, all necessary improvements should be made to prepare for e-Prescription and Track&Trace implementation.

Activities

1. Analyzing the usage of SMSF system
2. Reviewing the standard operating procedures and identifying the gaps and needs for digitization and integration of the systems and processes.
3. Development of functional and technical specifications
4. Accept and approve Change Requests
5. SMSF System Development
6. UAT
7. System verification and validation;
8. Deploy and go-live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	9/11/2023	10/2/2024	€ 120.000	€ 720.000	eHealth body

5.2.12 Blood Transfusion IS, connecting regional TC

Project Id**: 12**	Phase #: **1**	Priority level: **Medium**
Building Block: **Blood Transfusion IS**	Project type: **Upgrade**	Project status: **Ongoing**

Short description of the project

Existing Blood Transfusion IS should be improved immediately by connecting regional transfusion centers.

Activities:

1. Analyze UCCK's and regional hospitals' needs, processes, and workflows in segment of blood transfusion process
2. Identify and document the specific requirements of the BT system including HMIS and ERP integration in hospitals
3. Develop functional and technical specifications for BT system
4. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations;
5. Decide whether to implement HMIS module for BT or upgrade current system in NCBTK
6. BT system development
7. UAT
8. Training and piloting with selected hospitals
9. System verification and validation;
10. Full implementation od BT system in public hospitals in Kosovo

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
NCBTK	1/1/2024	12/31/2024	€ 140.000	€ 28.000	NCBTK

5.2.13 EHR + HIE

Project Id**: 13**	Phase #: **1**	Priority level: **High**
Building Block: **EHR**	Project type: **New**	Project status: **Future**

Short description of the project

EHR is real-time, patient-centered records that provide immediate and secure information to authorized users. EHR contains a patient's medical history, diagnoses and treatment, medications, allergies, immunizations, as well as radiology images and laboratory results. It should reflect the entire health history of an individual across his or her lifetime including data from multiple providers from a variety of healthcare settings. It should be built together with Health Information Exchange (HIE). HIE is a system that enables the secure electronic sharing of healthcare-related information among various healthcare institutions like hospitals, clinics, laboratories, and pharmacies. The primary objective of HIE is to facilitate the seamless exchange of patient health information, encompassing medical records, test results, medication history, and other pertinent data.

It is recommended that the development of these two building blocks, EHR and HIE, should be done as one project with two deliverables. The EHR should be built as part of the HIE development and function as a central database that extracts medical data, organizes it on the patient level, and sends it from providers through the HIE.

Activities

1. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
2. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information.
3. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations.
4. Define the rights and responsibilities of healthcare providers, patients, and other stakeholders involved in the EHR+HIE system.
5. Procurement of the EHR+ HIE system
6. Development of EHR +HIE system
7. System verification and validation;
8. Implement the EHR+HIE system in a phased approach
9. eLearning programme for end users;
10. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	3/1/2024	9/24/2026	€ 3.500.000	€ 3.150.000	eHealth body

5.2.14 Patient portal

Project Id**: 14**	Phase #: **1**	Priority level: **High**
Building Block: **Patient portal**	Project type: **New**	Project status: **Current**

Short description of the project

Patient portals are secure online platforms that provide patients with access to their personal health information and various healthcare services. These portals offer several features and benefits, empowering patients to actively engage in their healthcare management and improve communication with healthcare providers. Key features of a patient portal are: Personal Health Records (PHR), Appointment Scheduling, Opt in/Opt out decisions, Zoning, Communication with doctor regarding administrative and medical issues,..)

Activities

1. Based on business process analysis design the Patient portal system with a degree of flexibility that will reduce the system's own dependence on changes to the policy;
   - Incorporate regulations based on defined opt-in/opt-out model;
   - Share Patient portal information to relevant health systems (e-Referral, e-Prescription, e-Appointment, EHR);
2. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible;
3. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information;
4. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations;
5. Procurement of the Patient portal system;
6. Development and implementation of Patient portal system;
7. System verification and validation;
8. Establishment of the Patient portal system;
9. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	5/30/2024	11/6/2026	€ 750.000	€ 600.000	eHealth body

5.2.15 e-Referral

Project Id**: 15**	Phase #: **1**	Priority level: **High**
Building Block: **e-Referral**	Project type: **New**	Project status: **Future**

Short description of the project

Comprehensive e-Referrals should encompass a wide range of healthcare services, both within and beyond the confines of a single institution. These referrals should seamlessly connect primary, secondary, and tertiary healthcare establishments. e-Referrals should include both internal (within the same institution) and external (primary to secondary to tertiary healthcare institutions) including and not limited to diagnostics (PACS, RIS, LIS), Dentistry, etc.

Activities

1. Based on business process analysis design the e-Referral system to cover common referral usage scenarios, but with a degree of flexibility that will reduce the system's own dependence on changes to the referral policy;

- Eliminate patient's duplicate unnecessary examinations by saving information of internal e-Referrals in central database;
- Incorporate regulations through which patient should receive medical service within the agreed period for each procedure;
- Share e-Referral information to relevant health systems (e-Appointment, EHR, Patient Portal)

2. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
3. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information;
4. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations;
5. Procurement of the e-Referral system
6. Development and implementation of e-Referral system
7. Verification of specifications by running a pilot on a limited set of referral processes;
8. System verification and validation;
9. Establishment of the e-Referral system;
10. eLearning programme for end users;
11. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	10/3/2024	11/26/2025	€ 250.000	€ 250.000	eHealth body

5.2.16 Master Data Management

Project Id**: 16**	Phase #: **1**	Priority level: **High**
Building Block: **MDM**	Project type: **New**	Project status: **Future**

Short description of the project

Multiple building blocks of eHealth are interconnected while adhering to defined interoperability standards. Successful data transfer largely relies on a set of codebooks (Patients, ICD, Drugs and Materials, Health Workers...). It is essential to ensure centralized management of registries (codebooks) by establishing a master data management system (MDM). MDM's goal is to establish consistency, accuracy, completeness, and currency of master data throughout various systems, departments, and applications. This is accomplished by establishing a central and trusted repository known as a master data hub, where authoritative master data is stored.

Activities

1. Define sets of codebooks that need centralized data management. For each codebook define owner.
2. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
3. Procurement of the MDM system
4. Implementation of MDM system
5. Verification of specifications by running a pilot on a limited set of codebook and building blocks;

6. System verification and validation;
7. Establishment of the MDM system;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	3/1/2024	5/8/2025	€ 500.000	€ 600.000	eHealth body

5.2.17 Statistical Public Health System (SPHS)

Project Id**: 17**	Phase #: **1**	Priority level: **High**
Building Block: **Public Health**	Project type: **New**	Project status: **Future**

Short description of the project

Statistical Public Health System should be used in Health Statistics Department of NIPHK for collecting medical and other data from all three level institutions (i.e. human resources, indicators, activities, morbidity, births, malignant diseases, non-communicable diseases ...) and preparation of annual reports and all other analysis. System should be integrated with BHIS and HMIS for all the data that are being collected. If integration is not possible Robotic Process Automation (RPA) solution for collecting data in excel form should be used.

Activities

1. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
2. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information.
3. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations.
4. Define the rights and responsibilities of healthcare providers and other stakeholders involved in the SPHS system.
5. Procurement of the SPHS system
6. Development of SPHS system
7. System verification and validation;
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
NIPHK	11/6/2023	11/1/2024	€ 400.000	€ 480.000	NIPHK

5.2.18 Surveillance system of communicable diseases

Project Id**: 18**	Phase #: **1**	Priority level: **High**
Building Block: **Public Health**	Project type: **New**	Project status: **Current**

Short description of the project

Development of risk stratification tool related to communicable diseases and national health GIS system. The surveillance module is a critical component of the proposed Health Information System for Kosovo, designed to monitor and track disease patterns, health events, and public health indicators.

Activities

1. Assess the current HIS and identify the gaps and needs for surveillance
2. Design of process flow algorithms that enable early detection of diseases/outbreaks, as well as for response, prevention and control, which should be digitized and an integral part of the Surveillance System
3. Digitalization of processes and their verification/acceptance if they conform to requirements and specifications
4. Define the core indicators and data sources for surveillance
5. Design and implement the surveillance module using digital solutions and integrating it with other HIS modules
6. Train the staff and users on how to use the surveillance module and ensure data quality and protection
7. Monitor and evaluate the performance and impact of the surveillance module

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
NIPHK	11/6/2023	12/27/2024	€ 250.000	€ 300.000	NIPHK

5.2.19 Legacy Systems upgrade (Health Worker, Specialist, Licensing)

Project Id**: 19**	Phase #: **1**	Priority level: **High**
Building Block: **NA**	Project type: **Upgrade**	Project status: **Ongoing**

Short description of the project

The Health Worker system should be upgrade with the digitization of the transfer/termination/contract change/vacation request management process. Also, integration with other institutions is planned to enable accurate and up-to-date data on the education and licensing of each health worker. Health Specialist module should be integrated with other institution to enable accurate and updated education and licensing data of each health professional. Also, the liaison with eKosova to enable the use of the system by specialists (application to competitions, requests for leave, for change or interruption of specialization).

Activities

1. Analyzing the usage of Legacy modules
2. Reviewing the standard operating procedures and identifying the gaps and needs for digitization and integration of the systems and processes.
3. Development of functional and technical specifications
4. Accept and approve Change Requests
5. Legacy modules Development
6. UAT
7. System verification and validation;
8. Deploy and go-live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	10/2/2023	7/5/2024	€ 250.000	€ 300.000	ehealth body

5.2.20 Zoning

Project Id**: 20**	Phase #: **1**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Current**

Short description of the project

In the context of the primary healthcare system, zoning refers to the practice of organizing geographic areas or regions into different zones or zones to efficiently distribute and manage healthcare resources and services. Zoning is primarily used to ensure equitable access to healthcare services, particularly in areas with diverse population densities or geographical challenges. A zoning application or solution in the context of the primary healthcare system should encompass various components to effectively allocate healthcare resources and improve service delivery.

The zoning application or solution can effectively analyze, allocate, and optimize healthcare resources in the primary healthcare system, leading to improved access, enhanced service delivery, and better health outcomes for the population.

Activities

1. Needs Assessment: Conduct a comprehensive needs assessment to understand the current state of the primary healthcare system, identify gaps in healthcare access and service delivery, and determine the specific objectives and requirements for the zoning application.
2. Data Collection and Analysis: Gather relevant data, including demographic information, health indicators, healthcare facility locations, transportation infrastructure, and other pertinent datasets. Analyze and integrate the data using appropriate tools and techniques to inform the zoning application's development.
3. GIS Development: Develop a Geographic Information System (GIS) platform tailored to the needs of the zoning application. Design and implement the necessary features and functionalities to support data visualization, spatial analysis, mapping, and resource allocation.
4. Zoning Framework Design: Define the zoning framework based on the objectives and requirements identified in the needs assessment. Establish the criteria for zone delineation, such as population size, demographics, health indicators, and geographical factors. Determine the number and boundaries of zones for efficient resource allocation.
5. Resource Allocation Modeling: Develop models or algorithms to optimize resource allocation based on the zoning framework. Consider factors like population needs, healthcare workforce availability, infrastructure capacity, and accessibility to determine the appropriate distribution of healthcare resources within each zone.
6. Application Interface Design and Integrations: Design a user-friendly interface for the zoning application. Ensure that stakeholders can easily navigate and interact with the system, visualize data, access reports and analytics, and provide feedback. Recognize all integration point with other health and government systems for integrations
7. Piloting and Testing: Conduct pilot tests of the zoning application in a representative area or region with integration tests. Collect feedback from users and stakeholders to identify areas

for improvement, address usability issues, and refine the system's functionality and performance.

8. Implementation and Training: Roll out the zoning application across the targeted areas or regions. Provide training and support to stakeholders involved in using and managing the application. Ensure that healthcare administrators, planners, and decision-makers are equipped with the necessary skills to effectively utilize the system.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	1/1/2024	10/4/2024	€ 150.000	€ 180.000	MoH

5.2.21 Capitation support in HIFIS

Project Id**: 21**	Phase #: **1**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Current**

Short description of the project

There is a decision for Kosovo to introduce a capitation method of payment in primary healthcare. Therefore, IT support for flexible and easy to adapt capitation model should be implemented in HIFIS.

Activities

1. Elaboration of the concept and specifications of the Kosovo's capitation payment model
2. Define process, technical and functional specification for development and implementation of capitation module
3. Development of the capitation module
4. Verification of specifications by running a pilot on few primary health facilities with integration test with other eHealth systems (i.e.. Zoning);
5. System verification and validation;
6. Establishment of the capitation module;
7. eLearning program for civil servants and users;
8. Awareness raising and training for civil servants;
9. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
HIF	1/1/2024	12/31/2024	€ 50.000	€ 60.000	HIF

5.2.22 DRG support in HIFIS

Project Id**: 22**	Phase #: **1**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Current**

Short description of the project

There is a decision for Kosovo to introduce a DRG method of payment for in-patient services in hospitals. Therefore, IT support in HIFIS should be provided. Software that, based on input data (age, gender, primary and secondary diagnoses, procedures, discharge diagnosis, etc.), determines for each

patient the DRG category in which the episode of treatment belongs is called "DRG Grouper" because it groups cases into certain DRG categories/groups. The DRG Grouper SW should be made on the basis of the DRG model that Kosovo accepts for the national model (e.g. Australian DRG as one of the most dominant in the surrounding countries). DRG Grouper should have access for the hospitals with bulk import data options and generate DRG codes for bulk of cases/invoices. DRG Grouper need to be integrated with HIFIS as part of the claim adjudication process.

Activities:

1. Elaboration of the concept and specifications of the Kosovo DRG system of payment for hospital in-patient services rendered;
2. Procurement of an DRG grouper and make integration with HIFIS
3. Verification of specifications by running a pilot on a limited set of processes;
4. System verification and validation;
5. Establishment of the DRGs system;
6. eLearning programme for civil servants and users;
7. Awareness raising and training for civil servants;
8. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
HIF	6/1/2025	12/31/2026	€ 300.000	€ 240.000	HIF

5.2.23 Inspectorate IS

Project Id**: 23**	Phase #: **1**	Priority level: **High**
Building Block: **NA**	Project type: **New**	Project status: **Current**

Short description of the project

Inspectorate Information System should support business processes of Department of health inspectorate of MoH health.

Health inspectorate exercises the following functions: oversees the implementation of relevant legislation; provides technical and professional advice and information to health institutions on achieving standards and interpreting relevant legislation; notifies the Ministry of Health and other relevant institutions about the illegal work of health institutions and takes measures according to law; and promotes good practices in the provision of health services among health institutions.

Activities

1. Analyze and identify Health Inspectorate processes and document the specific requirements of the Inspectorate IS
2. Research and evaluate different document management and workflow vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
3. Procurement of the platform for document management or procure solution based on standard platform;
4. Solution Development/Configuration and Customization;
5. Data Integration with other eHealth systems;

6. System Testing;
7. Verification of specifications by running a pilot on a limited set of prescription processes
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
MoH	2/1/2024	1/15/2025	€ 300.000	€ 360.000	MoH

5.2.24 Data integration of KMA database with MDM

Project Id**: 24**	Phase #: **1**	Priority level: **Medium**
Building Block: **NA**	Project type: **Upgrade**	Project status: **Future**

Short description of the project

As one of the important data set of national eHealth system is common medication(drug) code list that should be used and propage through all key eHealth systems (BHIS, HMIS, HIFIS, ePrescriptions, etc.). KMA as national authority for authorization and licensing of medicines and medical product in Republic of Kosovo, keep all data about medicine, medical products and devices, pharmacies, etc. To have that data available for other systems in eHealth ecosystem it is necessary to establish data integration with Master Data Management (MDM) system. This will enable the availability and propagation of medication data across key eHealth systems, promoting interoperability, data consistency, and efficient management of medication information in the healthcare ecosystem.

Activities

1. Identify Data Requirements: This may include medication names, codes, classifications, dosages, indications, and other relevant information.
2. Define Data Standards and Formats: Establish data standards and formats that will be used for the common medication code list to ensure consistency and interoperability across different eHealth systems.
3. Establish Data Integration Channels: Establish data integration channels between the MDM system and KMA databases
4. Data Mapping and Transformation: Map the data elements, mapping and transformation methods from the common medication code list to the respective data structures and formats used in each eHealth system.
5. Implement Data Integration: Implement the data integration processes and mechanisms to transfer the medication data to the MDM system.
6. Test and Validate Data Integration: Verify the accuracy, completeness, and timeliness of the medication data in each system to ensure successful integration.
7. Monitor and Maintain Data Integration: Establish monitoring mechanisms to track the performance and quality of the data integration processes.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
KMA	10/21/2024	5/16/2025	€ 150.000	€ 150.000	KMA

5.2.25 Dentistry

Project Id**: 25**	Phase #: **2**	Priority level: **Medium**
Building Block: **Dentistry**	Project type: **New**	Project status: **Future**

Short description of the project

Dentistry system enables the digital storage and management of comprehensive dental patient records. It allows dental healthcare providers to capture and store essential information, including dental history, radiographic images, treatment plans, and progress notes.

Activities

1. Identify and document the specific requirements of the Dentistry system
2. Analyze user needs, processes, and workflows to determine how the Dentistry system will address those requirements;
3. Research and evaluate different Dentistry vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the Dentistry system;
5. Configuration and Customization;
6. Data Migration;
7. System Testing;
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	10/20/2028	€ 500.000	€ 200.000	eHealth body

5.2.26 Emergency healthcare information system (EHIS)

Project Id**: 26**	Phase #: **2**	Priority level: **Medium**
Building Block: **EHIS**	Project type: **New**	Project status: **Future**

Short description of the project

In addition to the health module of the system, which is extremely important for the patient, the integrated system would consist of modules that would cover the business processes of all activities performed by county institutes of emergency medicine.

Activities

1. Identify and document the specific requirements of the EHIS
2. Analyze emergency centers' needs, processes, and workflows to determine how the EHIS will address those requirements;
3. Research and evaluate different EHIS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the EHIS;

5. Configuration and Customization;
6. Data Migration;
7. System Testing;
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	10/20/2028	€ 1.000.000	€ 400.000	eHealth body

5.2.27 Transfusion module in hospitals

Project Id**: 27**	Phase #: **2**	Priority level: **Medium**
Building Block: **Blood Transfusion IS**	Project type: **Upgrade**	Project status: **Ongoing**

Short description of the project

Existing Blood Transfusion IS used in NCBTK. But hospital processes of blood transfusion are missing and should be implemented as a module of HMIS Blood Transfusion IS should be upgraded to collect data from hospital transfusion.

Activities

1. Analyze UCCK's and regional hospitals' needs, processes, and workflows in segment of blood transfusion process
2. Identify and document the specific requirements of the BT system including HMIS and ERP integration in hospitalsv
3. Develop functional and technical specifications for BT system
4. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations;
5. Decide whether to implement HMIS module for BT or upgrade current system in NCBTK
6. BT system development
7. UAT
8. Training and piloting with selected hospitals
9. System verification and validation;
10. Full implementation od BT system in public hospitals in Kosovo

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
NCBTK	1/4/2027	1/28/2028	€ 280.000	€ 168.000	NCBTK

5.2.28 Microbiology Information Management System (MIMS) upgrade (NIPHK)

Project Id**: 28**	Phase #: **2**	Priority level: **High**
Building Block: **LIS**	Project type: **New**	Project status: **Current**

Short description of the project

Microbiological analyses are conducted by hospitals and the National Institute of Public Health and Communicable Diseases (NIPHK). The way they operate differs. In the hospital, the Microbiology Information Management System (MIMS) is an integral part of the Hospital Management Information System (HMIS). It performs tests based on internal referrals and returns the results to the hospital's Electronic Medical Record (EMR). It does not directly communicate with the Electronic Health Record (EHR) or handle billing tasks. On the other hand, the MIMS in the NIPHK must have billing functionality and integration with the EHR system, as patients arrive with referrals from primary care physicians. For the needs of the NIPHK, a MIMS system that enables all functions should be procured.

Activities

1. Identify and document the specific requirements of the MIMS
2. Analyze NIPHK laboratory needs, processes, and workflows to determine how the MIMS will address those requirements;
3. Research and evaluate different MIMS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation;
4. Procurement of the MIMS;
5. Configuration and Customization;
6. System Testing;
7. User Training;
8. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	10/22/2027	€ 240.000	€ 144.000	eHealth body

5.2.29 e-Appointment

Project Id**: 29**	Phase #: **2**	Priority level: **Medium**
Building Block: **e-Appointment**	Project type: **New**	Project status: **Future**

Short description of the project

A web-based online platform that should allows patients to schedule their appointments with healthcare providers conveniently. It should enable patients to request appointment for the certain medical procedures (based on e-Referral system), as well as review existing scheduled orders and cancel them if needed, without any medical staff interactions. Part of e-Appointment serves should be patient's remainder service for the scheduled appointments.

Activities

1. Based on business process analysis design the e-Appointment system to cover common usage scenarios, but with a degree of flexibility that will reduce the system's own dependence on changes to the policy;
    - Eliminate patient's duplicate booking (i.e. patients direct booking into institution calendar;
    - Incorporate regulations through which patient should receive medical service within the agreed period for each procedure;

- Share e-Appointment information to relevant health systems (e-Referral, EHR, Patient Portal)

2. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
3. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information;
4. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations;
5. Procurement of the e-Appointment system
6. Development and implementation of e-Appointment system
7. Verification of specifications by running a pilot on a limited set of procedures and institutions;
8. System verification and validation;
9. Establishment of the e-Appointment system;
10. eLearning programme for end users;
11. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	2/1/2027	1/28/2028	€ 400.000	€ 240.000	eHealth body

5.2.30 EHR Integrations with private providers

Project Id**: 30**	Phase #: **2**	Priority level: **Medium**
Building Block: **EHR**	Project type: **Interoperability**	Project status: **Future**

Short description of the project

After EHR is up and running and data from public institutions are being collected, all other IT systems in private institutions that keep patient medical data should be integrated with EHR using HIE infrastructure. So all patient medical data is kept in one place and using opt in, opt out consent from patient available to medical professionals.

Activities

1. Determine the scope of integration, including the types of data to be exchanged and the functionality to be shared between the systems;
2. Evaluate the technical compatibility and interoperability capabilities of the EHR and other IT systems;
3. Identify any potential limitations or gaps in system functionalities that need to be addressed during the integration process;
4. Determine the most suitable integration methods and protocols based on the capabilities of the EHR and other IT systems;
5. Develop integration Interfaces;
6. Test and validate Integration;
7. Deploy and monitor.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	5/19/2028	€ 200.000	€ 80.000	eHealth body

5.2.31 e-Prescription

Project Id**: 31**	Phase #: **2**	Priority level: **High**
Building Block: **e-Prescription**	Project type: **Upgrade**	Project status: **Current**

Short description of the project

ePrescription i.e. electronic prescribing, is the process of generating and transmitting prescriptions electronically. Instead of using traditional paper prescriptions, healthcare providers use a secure electronic system to send prescriptions directly to a patient's pharmacy of choice. E-prescribing can help improve patient safety by reducing errors related to handwriting or other manual processes, and can also help streamline the prescription process by eliminating the need for patients to bring paper prescriptions to the pharmacy.

Activities

1. Develop functional and technical specifications for upgrading e-Prescription system for including private pharmacies
2. Procurement of upgrade of the e-Prescription system;
3. Verification of specifications by running a pilot on a limited set of prescription processes;
4. System verification and validation;
5. Establishment of the e-Prescription system;
6. eLearning programme for end users;
7. Training of the end-users
8. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	5/3/2027	11/10/2028	€ 600.000	€ 240.000	eHealth body

5.2.32 e-Visits

Project Id**: 32**	Phase #: **1**	Priority level: **Medium**
Building Block: **Telemedicine**	Project type: **New**	Project status: **Future**

Short description of the project

Similar to the eConsultations, COVID-19 outbreak has surfaced an immediate and high priority need for enabling virtual visits to the care practice. Currently, patients are advised to "call their doctors" in case of need, rather than physically visit the office. In the case of secondary and tertiary services, many elective procedures and follow ups have been postponed or cancelled due to pandemic measures. This will have a possible major impact in high incidents of complications for chronic diseases long-term; cancer incidences late diagnosis; psychological problems in perceiving healthcare as non-accessible, and inability to consume services due to self-isolations or positive tests to COVID-19 virus.

Activities

1. Identify the necessary infrastructure, software platforms, and communication tools needed to support virtual visits.
2. Procurement of eVisits system (infrastructure, software platforms, and communication tools)
3. Select specific use cases where virtual visits can provide value and improve patient care.

4. Identify disciplines and medical specialties that are suitable for virtual visits
5. Evaluate the impact on reimbursement policies and ensure that appropriate mechanisms are in place for healthcare professionals to be fairly compensated for virtual visits.
6. Align the implementation with the legal and regulatory frameworks governing telemedicine and patient privacy to ensure compliance.
7. Pilot the system
8. System verification and validation;
9. Establishment of the eVisits system;
10. Monitoring the satisfaction levels of healthcare professionals and patients engaging in virtual visits.
11. eLearning programme for medical end users;
12. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	1/1/2025	12/31/2026	€ 600.000	€ 480.000	eHealth body

5.2.33 Teleconsultations (between medical staff)

Project Id**: 33**	Phase #: **2**	Priority level: **Medium**
Building Block: **Telemedicine**	Project type: **New**	Project status: **Future**

Short description of the project

With the rise of COVID-19 pandemic in the H1 of 2020, and the risk of new wave re-emerging, the MoH should consider the platform for Teleconsultations as one of top priorities. Teleconsultations would allow for communication between doctors, nurses and other medical personnel without need to be physically present in the same location. That could be of particular use for medical professionals who have been dislocated, are visiting remote facilities or engaged with outpatient services, or in case of COVID-19, have been issued with self-isolation measures. These should include virtual consultations between GPs and secondary care for patients that may be admitted to a hospital; online exchange of information; and 2nd opinion. The communication should be safe, secured, and easy to use.

It is also vitally important that any implementation of Teleconsultations platform and solutions becomes sustainable initiative rather than pure COVID-19 response. That assumes carefully designing use cases, clinical areas and disciplines, and technology to be applied, so that the initiative delivers benefits in efficiency, clinical outcomes and doctors/patient experiences.

Activities

1. Identify the necessary infrastructure, software platforms, and communication tools needed to support virtual visits.
2. Procurement of Teleconsultations system (infrastructure, software platforms, and communication tools)
3. Select specific use cases where teleconsultations can provide value and improve patient care.
4. Identify disciplines and medical specialties that are suitable for teleconsultations
5. Evaluate the impact on reimbursement policies and ensure that appropriate mechanisms are in place for healthcare professionals to be fairly compensated for teleconsultations.
6. Align the implementation with the legal and regulatory frameworks governing telemedicine and patient privacy to ensure compliance.

7. Pilot the system
8. System verification and validation;
9. Establishment of the Teleconsultations system;
10. Monitoring the satisfaction levels of healthcare professionals engaging in Teleconsultations.
11. eLearning programme for medical end users;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	11/5/2027	€ 300.000	€ 180.000	eHealth body

5.2.34 Telemonitoring

Project Id**: 34**	Phase #: **2**	Priority level: **Low**
Building Block: **Telemedicine**	Project type: **New**	Project status: **Future**

Short description of the project

Telemonitoring is a part of Telemedicine that involves the remote supervision of patients' health using technology. It utilizes devices like wearable sensors, mobile apps, or connected medical devices to collect and transmit patients' vital signs, symptoms, and health data to healthcare professionals. This enables continuous monitoring of patients' well-being from a distance, allowing for early detection of potential issues and timely interventions. Telemonitoring is particularly beneficial for individuals with chronic conditions or those in post-surgery recovery, as it improves patient outcomes and reduces the need for frequent hospital visits or readmissions. Telemonitoring project should carefully select the use cases, disciplines and areas of applicability, infrastructure availability and target sustainable implementation in context of clinical outcomes, reimbursement and legal framework.

Activities

1. Identify the necessary infrastructure, software platforms, and communication tools needed to support Telemonitoring.
2. Procurement of Telemonitoring system (infrastructure, software platforms, and communication tools)
3. Select specific use cases where telemonitoring can provide value and improve patient care.
4. Identify disciplines and medical specialties that are suitable for telemonitoring
5. Evaluate the impact on reimbursement policies and ensure that appropriate mechanisms are in place for healthcare professionals to be fairly compensated for telemonitoring.
6. Align the implementation with the legal and regulatory frameworks governing telemedicine and patient privacy to ensure compliance.
7. Pilot the system
8. System verification and validation;
9. Establishment of the Telemonitoring system;
10. Monitoring the satisfaction levels of healthcare professionals and patients engaging in telemonitoring
11. eLearning programme for medical end users;
12. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	6/1/2026	12/11/2028	€ 800.000	€ 320.000	eHealth body

5.2.35 Statistical Public Health System (SPHS) 2.0

Project Id**: 35**	Phase #: **2**	Priority level: **Medium**
Building Block: **Public Health**	Project type: **New**	Project status: **Future**

Short description of the project

SPHS 2.0 should be implemented as new and improved version on initial SPHS systems based on data collected from eHealth systems that would be develop in the meantime. Implementation of the analytics and reporting services by using the data collected in eHealth. A statistical system can help an NIPHK to monitor the health status and trends of the population, identify and respond to emerging threats and challenges, evaluate the effectiveness and impact of interventions and policies, and inform decision-making and planning.

Activities

The implementation of analytics and reporting services should involves several steps:

1. Defining the objectives and scope of the SPHS 2.0 project
2. Identifying the data sources and methods for data collection (based on eHealth Data Warehouse system)
3. Developing and testing the analytics models and algorithms
4. Selection of the analytics and reporting platform
5. Designing and deploying the reporting dashboards and visualizations
6. User Training;
7. Deployment and Go-Live;
8. Evaluating and monitoring the impact and outcomes of the project

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	11/5/2027	€ 200.000	€ 120.000	NIPHK

5.2.36 Analytical System (DWH)

Project Id**: 36**	Phase #: **2**	Priority level: **High**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

A data warehouse is a centralized repository of integrated data from various sources, such as electronic health records, clinical registries, e-Prescriptions, administrative databases, insurance claims, etc. A data warehouse can support the analysis and reporting of health information for various purposes, such as quality improvement, performance measurement, research, and policy making. Implementation of DWH should enable a comprehensive and longitudinal view of the health status and outcomes of the population and subgroups, as well as should enhance the collaboration and coordination among different stakeholders in the health sector, such as policymakers, researchers, clinicians, managers, and patients.

Activities

The implementation of analytics and reporting services for eHealth involves several steps:

1. Defining the objectives and scope of the eHealth project

2. Identifying the data sources, data elements, data quality standards, data governance, and data security requirements
3. Designing the data warehouse architecture, such as the data model, data integration, data storage, data access, and data presentation layers
4. Developing and testing the analytics models and data warehouse components, such as the extract-transform-load (ETL) processes, data validation rules, data quality checks, data analysis tools, and data visualization dashboards
5. Deploying and maintaining the data warehouse, such as the data refreshment schedules, data backup and recovery procedures, data audit and monitoring mechanisms, and
6. User training and support

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	4/12/2027	10/20/2028	€ 700.000	€ 280.000	eHealth body

5.2.37 Track&trace

Project Id**: 37**	Phase #: **2**	Priority level: **Medium**
Building Block: **PIMS**	Project type: **New**	Project status: **Future**

Short description of the project

Track and Trace for pharmaceutical/health products is a system that allows the tracking of the movement and location of medical products along the supply chain, from the manufacturer to the dispenser. This system helps to prevent counterfeit and substandard medicines from entering the market and to ensure patient safety.

Activities

1. Analyzing the existing systems and processes for data collection and storage, such as BHIS, ePrescription, SMSF, Pharmacist and Customs systems.
    - Reviewing the standard operating procedures and identifying the gaps and needs for digitization and integration of the systems and processes.
    - Determining the standards for identification of medical products, such as generic names, dosage forms, packaging, manufacturers, etc.
2. Development of functional and technical specifications
3. Accept and approve Change Requests
4. Development, implementation and testing
5. UAT
6. Training and piloting the Track and Trace system with selected users and locations.
7. Evaluating and scaling up the Track and Trace system to cover all medical products and supply chain actors.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2027	5/19/2028	€ 800.000	€ 320.000	eHealth body

5.2.38 National public health registries (diabetes, cancer, HIV, TBC, ...)

Project Id**: 38**	Phase #: **2**	Priority level: **Medium**
Building Block: **Public Health**	Project type: **New**	Project status: **Future**

Short description of the project

National digital registries for common and severe illnesses are implemented to monitor disease trends, support research, inform healthcare planning, and improve patient outcomes, while facilitating collaboration and knowledge sharing among stakeholders. These registries provide a centralized repository of data, enabling evidence-based decision-making, quality improvement, and targeted public health interventions. Most common national registry are: Cancer Registry, Diabetes R., Cardiovascular R., Rare Disease R., Organ Transplant R., Infectious Disease R., Mental Health R.

Implementing common digital platform and data collection model should improve establishment of such registries and collect necessary data directly form providers eHealth systems (BHIS, HMIS, EHR).

Activities

1. Define Objectives and Scope: Clearly define the objectives of establishing the national digital registries and determine the scope of illnesses to be included.
2. Engage Stakeholders: Involve relevant stakeholders such as healthcare providers, medical professionals, researchers, public health agencies, and patient advocacy groups.
3. Identify Data Elements: Determine the specific data elements that need to be collected and included in the registries for each identified illness.
4. Design Data Collection Processes: Develop standardized data collection processes to ensure consistent and accurate capture of information for each illness.
5. Implement Data Governance: Establish a data governance framework to ensure data quality, security, and privacy.
6. Develop IT Infrastructure: Implement the necessary IT infrastructure to support the national digital registries.
7. Monitor and Evaluate: Continuously monitor and evaluate the registries to assess their effectiveness, data quality, and impact on healthcare outcomes.
8. Continuous Improvement: Regularly update and enhance the registries based on evolving medical knowledge, advances in technology, and changing healthcare needs.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	2/1/2027	8/11/2028	€ 650.000	€ 260.000	NIPHK

5.2.39 Call center software (CCS)

Project Id**: 39**	Phase #: **2**	Priority level: **Medium**
Building Block: **NA**	Project type: **New**	Project status: **Future**

Short description of the project

Call center solutions offer a range of communication channels to establish connections with patients, simplifying the process of reaching out to providers whenever assistance is required. Call center software has become crucial in the healthcare industry due to the increasing prominence of telehealth and

the demand for seamless patient communication. This software enables healthcare providers to efficiently handle a substantial influx of calls, deliver tailored support to patients, optimize their operations, and improve the management of patient information.

Activities

1. Develop functional and technical specifications for scalable system which can be upgradable, updatable and flexible
2. Establish the necessary legal and regulatory framework to govern the collection, storage, sharing, and protection of health information.
3. Address issues related to privacy, security, consent, data ownership, and confidentiality in compliance with applicable laws and regulations.
4. Define the rights and responsibilities of healthcare providers and other stakeholders involved in the CCS system.
5. Procurement of the CCS system
6. Development of CCS system
7. System verification and validation;
8. User Training;
9. Deployment and Go-Live;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	11/9/2026	8/13/2027	€ 300.000	€ 180.000	MoH

5.2.40 e-Radiology - Central national repository of digital radiology images

Project Id**: 40**	Phase #: **3**	Priority level: **Low**
Building Block: **RIS/PACS**	Project type: **New**	Project status: **Future**

Short description of the project

Establishing a central national repository of metadata for retrieving and accessing digital radiology images from the source of data (the place where the images are produced) should be an integral part of patients' EHR and available along with other clinical information.

There is a need to create a single system that will enable the rapid and purposeful exchange of medical information between different electronic systems and different institutions. This need is particularly pronounced in diagnostic methods with the application of ionizing radiation and with a high cost of inspections, such as examinations in radiology and nuclear medicine.

Dosage of ionizing radiation must also be part of patients' EHR since it is an important factor when referring patients to new diagnostic procedures that include additional doses. Collection of dosage should be supported in an automated manner and with a manual entry (for older radiology machines) for all patients including radiology staff.

This project should bring great benefits to patient safety but also should increase efficiency and reduction of costs.

Activities

1. Elaboration of the concept and specifications of the e-Radiology system;

2. Procurement of the central national e-Radiology information system;
3. Verification of specifications by running a pilot on a limited set of locations;
4. System verification and validation;
5. Establishment of the national e-Radiology system;
6. Training and e-Learning programme for medical professionals and users;
7. Awareness raising and training for medical professionals and users;
8. Raising citizens' awareness of the new solution and benefit of e-Radiology.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	12/12/2028	10/15/2029	€ 600.000	€ 120.000	eHealth body

5.2.41 Development of AI solution for triage of patients

Project Id**: 41**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

Development of AI solution for triage of patients to unburden health system in crisis situations and provide patients with better/on-time communication with health system.

There is a growing body of evidence that AI holds a great potential to release the burden on the health workers and improve not only the risk stratification and early notifications, but very much so patient safety in general. In this context in particular, the aim is to analyze different algorithms that could be used to triage patients, especially in out-of-office hours, so that some of less urgent cases are solved remotely or deferred to in-office hours.

This project should serve as a high-level analysis of potential usage of AI based solutions across healthcare system, before wider implementation and investments are taken forward.

Activities

1. Identify cases and medical specialties that are suitable for AI triage;
2. Analyze the use case for implementation of AI based solution in patient triage;
3. Investigate the security, privacy, ethical and compliance framework. Adjust the policy accordingly;
4. Design and develop a test solution;
5. Pilot the system and measure the impact;
6. System verification and validation;
7. Monitoring the satisfaction levels of healthcare professionals and patients engaging in AI triage;
8. eLearning program for medical end users;

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	12/12/2028	7/23/2029	€ 500.000	€ 0	eHealth body

5.2.42 e-Pathways: healthcare guidelines information system

Project Id**: 42**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

Implementing the e-Pathways in the health system and ensuring availability through IT tools are key instruments for improving and equaling the quality of healthcare and improving system management for the benefit of patients, healthcare professionals and society as a whole. Their purpose is to standardize and optimize diagnostic, treatment and monitoring criteria, treatment and monitoring of patients, as well as achieve more effective and safe healthcare and rationalization of health system costs. e-Pathways, implemented in the IT system, define specific, practical recommendations and standard procedures in selected topics of clinical work and treatment of physicians in certain clinical fields.

Activities

1. Define Objectives and Scope: Clearly define the objectives of implementing e-Pathways and identify the specific clinical fields or topics where e-Pathways will be developed. Determine the scope of the project and the resources required for successful implementation.
2. Engage Stakeholders: Involve key stakeholders in the process, including healthcare professionals, clinicians, IT specialists, policymakers, and administrators. Establish a multidisciplinary team to ensure diverse perspectives and expertise are represented throughout the implementation.
3. Conduct Needs Assessment: Conduct a thorough needs assessment to identify the gaps and challenges in the current clinical practices and treatment protocols. Gather feedback from healthcare professionals and clinicians to understand their specific needs and requirements.
4. Develop e-Pathways: Collaborate with healthcare professionals and clinicians to develop specific recommendations and standard procedures in the selected clinical fields. Ensure that the e-Pathways are evidence-based, practical, and aligned with best practices.
5. Design IT Tools: Work with IT specialists to design and develop the necessary IT tools to support the implementation of e-Pathways.
6. Ensure Accessibility and Integration: Ensure that the e-Pathways and IT tools are easily accessible to healthcare professionals at the point of care.
7. Pilot Testing: Conduct pilot testing of the e-Pathways and IT tools in selected healthcare settings.
8. Refine and Iterate: Incorporate feedback from the pilot testing phase and refine the e-Pathways and IT tools accordingly.
9. Training and Education: Provide comprehensive training and education to healthcare professionals and clinicians on how to effectively use the e-Pathways and IT tools.
10. Continuous Monitoring and Evaluation: Establish a system for ongoing monitoring and evaluation of the e-Pathways' impact on clinical outcomes, patient safety, and cost-effectiveness.
11. Regular Updates and Maintenance: Regularly update the e-Pathways to incorporate new clinical evidence, guidelines, and best practices and ensure the IT tools supporting the e-Pathways are regularly maintained, updated, and secured to ensure optimal performance and data privacy.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	7/24/2029	7/8/2030	€ 400.000	€ 0	eHealth body

5.2.43 Clinical Decision support systems (CDSS)

Project Id**: 43**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

Clinical Decision Support Systems (CDSS) are software applications that aid healthcare professionals in clinical decision-making by delivering pertinent information, knowledge, and recommendations during patient care. These systems amalgamate patient-specific data, medical expertise, clinical guidelines, and other pertinent information to generate customized alerts and suggestions. CDSS can analyze patient symptoms, signs, and test results, facilitating the diagnostic process by presenting potential diagnoses based on the provided data. This assists healthcare professionals in considering various possibilities and enhancing clinical reasoning capabilities. Typically, these systems are integrated into Hospital Management Information Systems (HMIS) or are implemented at the national level in advanced eHealth environments.

Activities

1. Define Objectives and Scope: Clearly define the objectives of implementing CDSS and identify the specific clinical fields or topics where CDSS will be developed. Determine the scope of the project and the resources required for successful implementation.
2. Engage Stakeholders: Involve key stakeholders in the process, including healthcare professionals, clinicians, IT specialists, policymakers, and administrators. Establish a multidisciplinary team to ensure diverse perspectives and expertise are represented throughout the implementation.
3. Conduct Needs Assessment: Conduct a thorough needs assessment to identify the gaps and challenges in the current clinical practices and treatment protocols. Gather feedback from healthcare professionals and clinicians to understand their specific needs and requirements.
4. Research and evaluate different CDSS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation.
5. Procurement of the CDSS
6. Configuration and Customization
7. Ensure Accessibility and Integration: Ensure that the CDSS are easily accessible to healthcare professionals at the point of care.
8. Pilot Testing: Conduct pilot testing of the CDSS in selected healthcare settings.
9. Refine and Iterate: Incorporate feedback from the pilot testing phase and refine the CDSS accordingly.
10. Training and Education: Provide comprehensive training and education to healthcare professionals and clinicians on how to effectively use the CDSS.
11. Continuous Monitoring and Evaluation: Establish a system for ongoing monitoring and evaluation of the CDSS' impact on clinical outcomes, patient safety, and cost-effectiveness.
12. Regular Updates and Maintenance: Regularly update the CDSS to incorporate new clinical evidence, guidelines, and best practices and ensure CDSS is regularly maintained, updated, and secured to ensure optimal performance and data privacy.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	10/8/2029	11/29/2030	€ 2.000.000	€ 0	eHealth body

5.2.44 Drugs Decision support systems (DDSS)

Project Id**: 44**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

Drug Decision Support Systems (DDSS) focus specifically on medication-related decision support. They provide information on drug interactions, contraindications, dosages, and potential adverse effects. DDSS can provide treatment recommendations based on the patient's specific condition, medical history, and current guidelines. These recommendations assist healthcare professionals in selecting appropriate medications, therapies, or interventions tailored to each individual patient. Typically, these systems are integrated into HMIS and BHIS or are implemented at the national level in advanced eHealth environments.

Activities

1. Define Objectives and Scope: Clearly define the objectives of implementing DDSS and identify the specific clinical fields or topics where DDSS will be developed. Determine the scope of the project and the resources required for successful implementation.
2. Engage Stakeholders: Involve key stakeholders in the process, including healthcare professionals, clinicians, IT specialists, policymakers, and administrators. Establish a multidisciplinary team to ensure diverse perspectives and expertise are represented throughout the implementation.
3. Conduct Needs Assessment: Conduct a thorough needs assessment to identify the gaps and challenges in the current clinical practices and treatment protocols. Gather feedback from healthcare professionals and clinicians to understand their specific needs and requirements.
4. Research and evaluate different DDSS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation.
5. Procurement of the DDSS
6. Configuration and Customization
7. Ensure Accessibility and Integration: Ensure that the DDSS are easily accessible to healthcare professionals at the point of care.
8. Pilot Testing: Conduct pilot testing of the DDSS in selected healthcare settings.
9. Refine and Iterate: Incorporate feedback from the pilot testing phase and refine the DDSS accordingly.
10. Training and Education: Provide comprehensive training and education to healthcare professionals and clinicians on how to effectively use the DDSS.
11. Continuous Monitoring and Evaluation: Establish a system for ongoing monitoring and evaluation of the DDSS' impact on clinical outcomes, patient safety, and cost-effectiveness.
12. Regular Updates and Maintenance: Regularly update the DDSS to incorporate new clinical evidence, guidelines, and best practices and ensure CDSS is regularly maintained, updated, and secured to ensure optimal performance and data privacy.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	10/22/2029	11/13/2030	€ 1.500.000	€ 0	eHealth body

5.2.45 Imaging Decision support systems (IDSS)

Project Id**: 45**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

Imaging Decision Support Systems (IDSS) are software applications designed to assist radiologists and other healthcare professionals in interpreting and analyzing medical images, such as X-rays, CT scans, MRIs, and ultrasounds. These systems utilize advanced algorithms and image processing techniques to provide additional insights, support diagnosis, and improve accuracy in image interpretation. Typically, these systems are integrated intoRIS/PACS or are implemented at the national level in advanced eHealth environments, serving primary or secondary care systems.

Activities

1. Define Objectives and Scope: Clearly define the objectives of implementing IDSS and identify the specific clinical fields or topics where IDSS will be developed. Determine the scope of the project and the resources required for successful implementation.
2. Engage Stakeholders: Involve key stakeholders in the process, including healthcare professionals, clinicians, IT specialists, policymakers, and administrators. Establish a multidisciplinary team to ensure diverse perspectives and expertise are represented throughout the implementation.
3. Conduct Needs Assessment: Conduct a thorough needs assessment to identify the gaps and challenges in the current clinical practices and treatment protocols. Gather feedback from healthcare professionals and clinicians to understand their specific needs and requirements.
4. Research and evaluate different IDSS vendors and solutions that meet the identified requirements and check various factors such as functionality, scalability, support, pricing, and vendor reputation.
5. Procurement of the IDSS
6. Configuration and Customization
7. Ensure Accessibility and Integration: Ensure that the IDSS are easily accessible to healthcare professionals at the point of care.
8. Pilot Testing: Conduct pilot testing of the IDSS in selected healthcare settings.
9. Refine and Iterate: Incorporate feedback from the pilot testing phase and refine the IDSS accordingly.
10. Training and Education: Provide comprehensive training and education to healthcare professionals and clinicians on how to effectively use the IDSS.
11. Continuous Monitoring and Evaluation: Establish a system for ongoing monitoring and evaluation of the IDSS' impact on clinical outcomes, patient safety, and cost-effectiveness.
12. Regular Updates and Maintenance: Regularly update the IDSS to incorporate new clinical evidence, guidelines, and best practices and ensure IDSS is regularly maintained, updated, and secured to ensure optimal performance and data privacy.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	12/1/2028	1/24/2030	€ 1.200.000	€ 0	eHealth body

5.2.46 e-Medication: integrated IS for medication management

Project Id**: 46**	Phase #: **3**	Priority level: **Low**
Building Block: **Decision making tools/Analytics**	Project type: **New**	Project status: **Future**

Short description of the project

The purpose of the project is to achieve integrated drug data management at the national level in order to enable a simple and safe exchange of drug information among various stakeholders of the health system, rationalize resources, improve the safety of drug administration and contribute to the further improvement of the entire health system. The scope of the project includes all medicines that are on the market in Kosovo, regardless of the method of obtaining approval for placing on the market and regardless of whether these medicines are financed from compulsory health insurance funds or not. Project delivery should cover 3 main functionalities:

- creation of a unique national base of medicines integrated with main stakeholders' systems (MoH, eHealth services and systems, KMA, HIFIS)
- introduction of a system for checking interactions in real-time when drug is prescribing. A commercial interaction verification system will be integrated into the e-Prescription mechanism through the prescribing and dispensing process.
- development of the functionality of direct reporting of side effects from the eHealth system to the KMA. For citizens, the same functionality should be developed within the Patient Portal.
- The eHealth Digital Service Infrastructure (eHDSI) facilitates the cross-border exchange of health data including patient summaries and e-prescription. Through 'core services', the European Commission is providing a common ICT infrastructure and crosscutting services (terminology, interoperability etc.) to EU countries. They can then set up 'generic services' to connect national eHealth systems through 'National Contact Points for eHealth (NCPeH)', with financial assistance from the Connecting Europe Facility Telecom Programme (2015-2020) and from the EU4Health Programme (2021-2027

Activities

1. Elaboration of the concept and specifications of the e-Medication system;
2. Procurement of an integrated information system for professional and economical medication management;
3. Verification of specifications and integration with other eHealth systems by running a pilot on a limited scope;
4. System verification and validation;
5. Establishment of the e-Medication system;
6. e-Learning programme for civil servants and users;
7. Awareness raising and training for civil servants;
8. Raising citizens' awareness.

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	10/23/2028	10/19/2029	€ 800.000	€ 0	eHealth body

5.2.47 Cross Border Patient Data Exchange

Project Id**: 47**	Phase #: **3**	Priority level: **Low**
Building Block: **EHR**	Project type: **New**	Project status: **Future**

Short description of the project

EU Commission Recommendation on a European Electronic Health Record exchange format (EEHRxF) sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union. Based on Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU, EU and non-EU member states can use the Guideline to set common semantic strategy for adoption of standards facilitating exchange of health information across EU. The following 2 electronic cross-border health services are currently being introduced in all EU countries: "ePrescription and eDispensation" and "Patient Summaries".

Kosovo in the long term should make efforts in providing those services for own citizens and for the EU citizens who will be visiting Kosovo.

Activities

1. Establish technical working group and get agreement with EU eHeatlh Network to participate in eHealth Digital Service Infrastructure
2. Get technical assistance or consultancy service for technical guidelines and knowledge transfer
3. Define scope and technical assessment based on gap analysis for 2 electronic cross-border health services
4. Make National Contact Points for eHealth (NCPeH)
5. Develop NCPeH infrastructure and cross-border interoperability capabilities
6. Verification of specifications and integration with EHR systems by running a pilot on a limited scope;
7. Establishment of the NCPeH system
8. e-Learning programme for civil servants and users
9. Awareness raising and training for civil servants
10. Raising citizens' awareness

Project owner	Planned start date	Planned end date	Estimated initial investment cost	Estimated maintenance until 2030	Main source of funding
eHealth body	1/1/2030	12/30/2030	€ 500.000	€ 0	eHealth body

6 Investment plan

Key remarks

- All the planned/projected numbers in this plan are based on our best knowledge and the data available to Consultant during the preparation of this document.
- In case of software (build or purchased), we estimated yearly cost of maintenance at 20% of total planned value of investment, as common standard in SW industry.
- HW investment projection is based just on the information provided from MoH for the initial two years. For the following years it will be necessary to make HW assessment based on SW application technical requirements during procurement applications process.
- Due to its size and complexity, full combination of action and investment plan is delivered in Excel format table as an annex to this document.

Key figures

Total projected (build/purchase) investment	**34.188.000 €**
Total projected (software) maintenance costs	**18.791.000 €**
Total projected mid-term (2024-2027) investment/costs	**29.256.200 €**
Total projected long-term (2024-2030) investment/costs	**52.979.000 €**

Investment Plan per projects (in Euro)

Project ID	Project Name	Estimated budget		Total costs	
		Initial investment	Mainte-nance	Mid-term (2024-2027)	Long-term (2024-2030)
1	E-health strategy	120.000	0	120.000	120.000
2	eHealth Body Setup Consultancy	180.000	0	180.000	180.000
3	Define and optimize processes in eHealth project implementa-tions and supervision	144.000	0	144.000	144.000
4	Development of healthcare call center (HCCC)	264.000	0	211.200	264.000
5	Development of Digital Health Innovation Center (DHIC)	150.000	0	120.000	150.000
6	HW renewal and new purchase	4.700.000	0	4.700.000	4.700.000
7	BHIS upgrade + maintenance	360.000	2.160.000	1.440.000	2.520.000
8	HMIS (Hospital Management In-formation System)	3.500.000	3.150.000	4.550.000	6.650.000
9	LIS (Laboratory Information Sys-tem)	1.110.000	999.000	1.443.000	2.109.000
10	RIS (Radiology Information System) including PACS (Picture Archiving and Communication Systems)	1.480.000	1.332.000	1.924.000	2.812.000

Project ID	Project Name	Estimated budget		Total costs	
		Initial investment	Mainte-nance	Mid-term (2024-2027)	Long-term (2024-2030)
11	SMSF upgrade + maintenance	120.000	720.000	480.000	840.000
12	Blood Transfusion IS, connecting regional TC	140.000	28.000	168.000	168.000
13	EHR + HIE	3.500.000	3.150.000	4.550.000	6.650.000
14	Patient portal	750.000	600.000	900.000	1.350.000
15	e-Referral	250.000	250.000	350.000	500.000
16	Master Data Management	500.000	600.000	800.000	1.100.000
17	Statistical Public Health System (SPHS)	400.000	480.000	640.000	880.000
18	Surveillance system of communi-cable diseases	250.000	300.000	400.000	550.000
19	Legacy Systems upgrade (Health Worker, Specialist, Licensing)	250.000	300.000	400.000	550.000
20	Zoning	150.000	180.000	240.000	330.000
21	Capitation support in HIFIS	50.000	60.000	80.000	110.000
22	DRG support in HIFIS	300.000	240.000	360.000	540.000
23	Inspectorate IS	300.000	360.000	480.000	660.000
24	Data integration of KMA data-base with MDM	150.000	150.000	210.000	300.000
25	Dentistry	500.000	200.000	250.000	700.000
26	Emergency healthcare infor-mation system (EHIS)	1.000.000	400.000	500.000	1.400.000
27	Transfusion module in hospitals	280.000	168.000	196.000	448.000
28	Microbiology Information Man-agement System (MIMS) up-grade (NIPHK)	240.000	144.000	240.000	384.000
29	e-Appointment	400.000	240.000	280.000	640.000
30	EHR Integrations with private providers	200.000	80.000	120.000	280.000
31	e-Prescription including private pharmacies	600.000	240.000	240.000	840.000
32	e-Visits	600.000	480.000	720.000	1.080.000
33	Teleconsultations (between medical staff)	300.000	180.000	300.000	480.000
34	Telemonitoring	800.000	320.000	400.000	1.120.000
35	Statistical Public Health System (SPHS) 2.0	200.000	120.000	200.000	320.000

Project ID	Project Name	Estimated budget		Total costs	
		Initial investment	Maintenance	Mid-term (2024-2027)	Long-term (2024-2030)
36	Analytical System (DWH)	700.000	280.000	280.000	980.000
37	Track&trace	800.000	320.000	80.000	1.120.000
38	National public health registries (diabetes, cancer, HIV, TBC, ...)	650.000	260.000	260.000	910.000
39	Call center software (CCS)	300.000	180.000	300.000	480.000
40	e-Radiology - Central national repository of digital radiology images	600.000	120.000	0	720.000
41	Development of AI solution for triage of patients	500.000	0	0	500.000
42	e-Pathways: healthcare guidelines information system	400.000	0	0	400.000
43	Clinical Decision support systems (CDSS)	2.000.000	0	0	2.000.000
44	Drugs Decision support systems (DDSS)	1.500.000	0	0	1.500.000
45	Imaging Decision support systems (IDSS)	1.200.000	0	0	1.200.000
46	e-Medication: integrated information system for professional and economical medication management	800.000	0	0	800.000
47	Cross Border Patient Data Exchange	500.000	0	0	500.000
TOTAL		**34.188.000**	**18.791.000**	**29.256.200**	**52.979.000**

Investment plan per phases

Phase	Investment	Maintenance	Total
0	€ 5.558.000	€ 0	€ 5.558.000
1	€ 14.160.000	€ 15.539.000	€ 29.699.000
2	€ 6.970.000	€ 3.132.000	€ 10.102.000
3	€ 7.500.000	€ 120.000	€ 7.620.000
TOTAL	€ 34.188.000	€ 18.791.000	€ 52.979.000

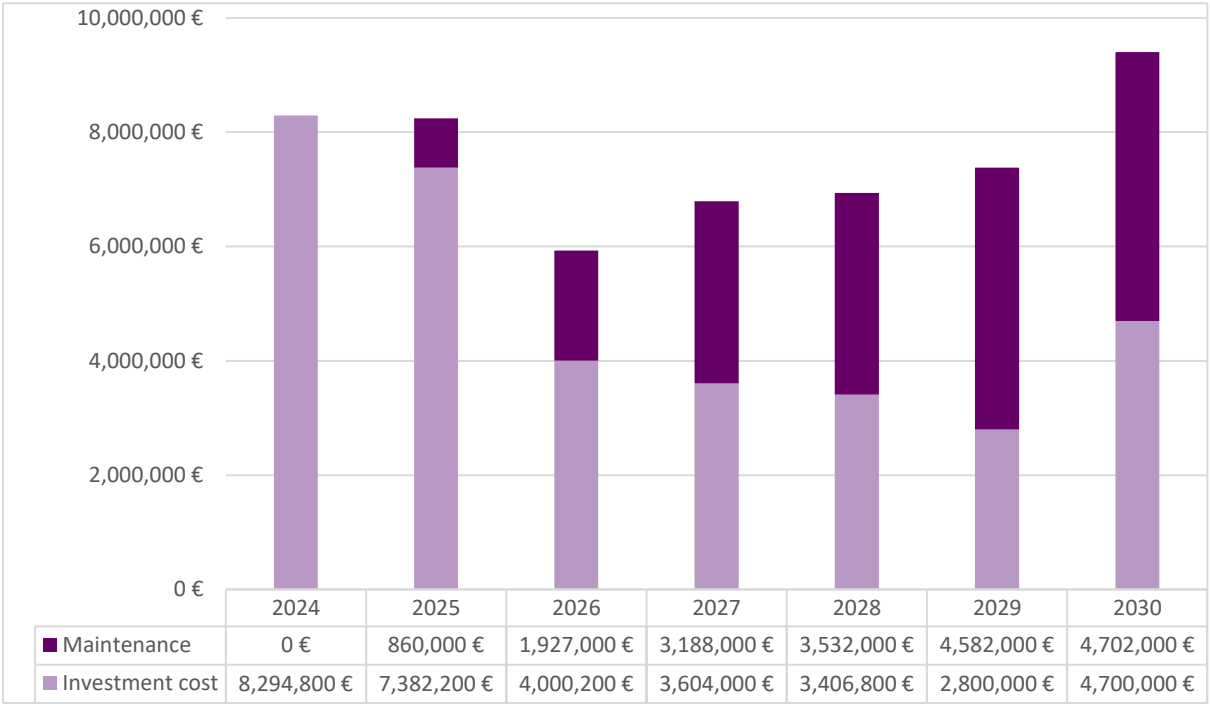
Investment Plan per years (in Euro)

Project Id	Project Name	Financed by	2024	2025	2026	2027	2028	2029	2030
1	E-health strategy	MoH	120.000	0	0	0	0	0	0
2	eHealth Body Setup Consultancy	MoH	126.000	54.000	0	0	0	0	0
3	Define and optimize processes in eHealth project implementations and supervision	MoH	100.800	43.200	0	0	0	0	0
4	Development of healthcare call centre (HCCC)	MoH	0	0	79.200	132.000	52.800	0	0
5	Development of Digital Health Innovation Center (DHIC)	EU fund/donation	0	0	60.000	60.000	30.000	0	0
6	HW renewal and new purchase	MoH	1.974.000	2.726.000	0	0	0	0	0
7	BHIS upgrade + maintenance	eHealth body	360.000	360.000	360.000	360.000	360.000	360.000	360.000
8	HMIS (Hospital Management Information System)	eHealth body	1.400.000	1.050.000	1.400.000	700.000	700.000	700.000	700.000
9	LIS (Laboratory Information System)	eHealth body	444.000	333.000	444.000	222.000	222.000	222.000	222.000
10	RIS (Radiology Information System) including PACS (Picture Archiving and Communication Systems)	eHealth body	592.000	444.000	592.000	296.000	296.000	296.000	296.000
11	SMSF upgrade + maintenance	eHealth body	120.000	120.000	120.000	120.000	120.000	120.000	120.000

Project Id	Project Name	Financed by	2024	2025	2026	2027	2028	2029	2030
12	Blood Transfusion IS, connecting regional TC	NCBTK	98.000	42.000	28.000	0	0	0	0
13	EHR + HIE	eHealth body	1.050.000	1.400.000	1.400.000	700.000	700.000	700.000	700.000
15	Patient portal	eHealth body	225.000	225.000	300.000	150.000	150.000	150.000	150.000
16	e-Referral	eHealth body	50.000	200.000	50.000	50.000	50.000	50.000	50.000
17	Master Data Management	eHealth body	250.000	350.000	100.000	100.000	100.000	100.000	100.000
18	Statistical Public Health System (SPHS)	NIPHK	400.000	80.000	80.000	80.000	80.000	80.000	80.000
19	Surveillance system of communicable diseases	NIPHK	250.000	50.000	50.000	50.000	50.000	50.000	50.000
20	Legacy Systems upgrade (Health Worker, Specialist, Licensing)	eHealth body	250.000	50.000	50.000	50.000	50.000	50.000	50.000
21	Zoning	MoH	150.000	30.000	30.000	30.000	30.000	30.000	30.000
22	Capitation support in HIFIS	HIF	35.000	25.000	10.000	10.000	10.000	10.000	10.000
23	DRG support in HIFIS	HIF	60.000	150.000	90.000	60.000	60.000	60.000	60.000
24	Inspectorate IS	MoH	210.000	150.000	60.000	60.000	60.000	60.000	60.000
25	Data integration of KMA database with MDM	KMA	30.000	120.000	30.000	30.000	30.000	30.000	30.000

Project Id	Project Name	Financed by	2024	2025	2026	2027	2028	2029	2030
26	Dentistry	eHealth body	0	0	50.000	200.000	250.000	100.000	100.000
27	Emergency healthcare information system (EHIS)	eHealth body	0	0	100.000	400.000	500.000	200.000	200.000
28	Transfusion module in hospitals	NCBTK	0	0	0	196.000	140.000	56.000	56.000
29	Microbiology Information Management System (MIMS) upgrade (NIPHK)	eHealth body	0	0	24.000	216.000	48.000	48.000	48.000
30	e-Appointment	eHealth body	0	0	0	280.000	200.000	80.000	80.000
31	EHR Integrations with private providers	eHealth body	0	0	20.000	100.000	80.000	40.000	40.000
32	e-Prescription including private pharmacies	eHealth body	0	0	0	240.000	360.000	120.000	120.000
33	e-Visits	eHealth body	0	240.000	240.000	240.000	120.000	120.000	120.000
34	Teleconsultations (between medical staff)	eHealth body	0	0	30.000	270.000	60.000	60.000	60.000
35	Telemonitoring	eHealth body	0	0	80.000	320.000	400.000	160.000	160.000
36	Statistical Public Health System (SPHS) 2.0	NIPHK	0	0	20.000	180.000	40.000	40.000	40.000
37	Analytical System (DWH)	eHealth body	0	0	0	280.000	420.000	140.000	140.000
38	Track&trace	eHealth body	0	0	0	80.000	720.000	160.000	160.000

Project Id	Project Name	Financed by	2024	2025	2026	2027	2028	2029	2030
39	National public health registries (diabetes, cancer, HIV, TBC, ...)	NIPHK	0	0	0	260.000	390.000	130.000	130.000
40	Call center software (CCS)	MoH	0	0	30.000	270.000	60.000	60.000	60.000
41	e-Radiology - Central national repository of digital radiology images	eHealth body	0	0	0	0	0	600.000	120.000
42	Development of AI solution for triage of patients	eHealth body	0	0	0	0	0	100.000	400.000
43	e-Pathways: healthcare guidelines information system	eHealth body	0	0	0	0	0	160.000	240.000
44	Clinical Decision support systems (CDSS)	eHealth body	0	0	0	0	0	600.000	1.400.000
45	Drugs Decision support systems (DDSS)	eHealth body	0	0	0	0	0	300.000	1.200.000
46	Imaging Decision support systems (IDSS)	eHealth body	0	0	0	0	0	240.000	960.000
47	e-Medication: integrated information system for professional and economical medication management	eHealth body	0	0	0	0	0	800.000	0
48	Cross Border Patient Data Exchange	eHealth body	0	0	0	0	0	0	500.000
	TOTAL		**8.294.800**	**8.242.200**	**5.927.200**	**6.792.000**	**6.938.800**	**7.382.000**	**9.402.000**



	2024	2025	2026	2027	2028	2029	2030
Maintenance	0 €	860,000 €	1,927,000 €	3,188,000 €	3,532,000 €	4,582,000 €	4,702,000 €
Investment cost	8,294,800 €	7,382,200 €	4,000,200 €	3,604,000 €	3,406,800 €	2,800,000 €	4,700,000 €

Figure 19: Total cost of eHealth projects (investment + maintenance) per year

Financing plan structure

We plan that, during the whole observed period (2024-2030), about 39% of the total costs should be spent on *eServices* projects, with most of them being implemented towards the end of the period, after more urgent projects have been completed, including hardware (HW), that we propose to be purchased/installed during first two years of observed period, for about 9% of the total projected costs. Relatively most important and most urgent parts of the whole eHealth ecosystem – Core medical systems, should encompass about 33% of the total projected costs (including maintenance after the software has been build/purchased and implemented).

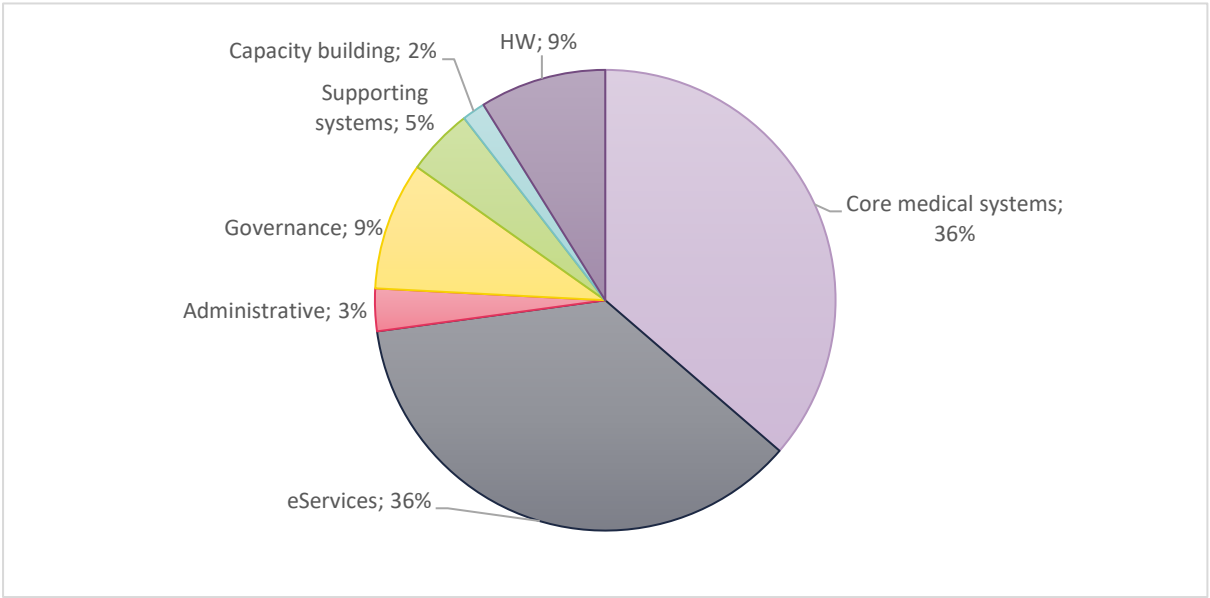


Figure 20: Total cost of eHealth projects per sub-categories

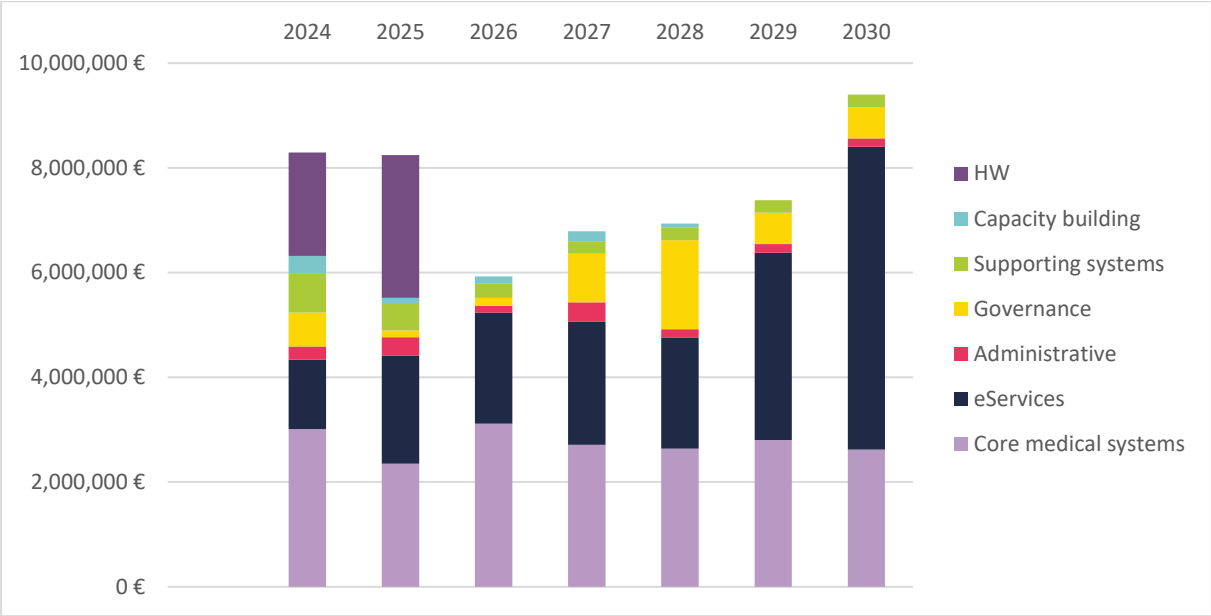


Figure 21: Total cost of eHealth projects per year per sub-categories

At the same time, we propose/predict that by far the most (about 79%) of the total costs of eHealth projects should be financed by/through the budget of newly formed *eHealth body*, followed with about 13% by/through *MoH*, and about 5% by/through *NIPHK*, and the rest 3% by/through others.

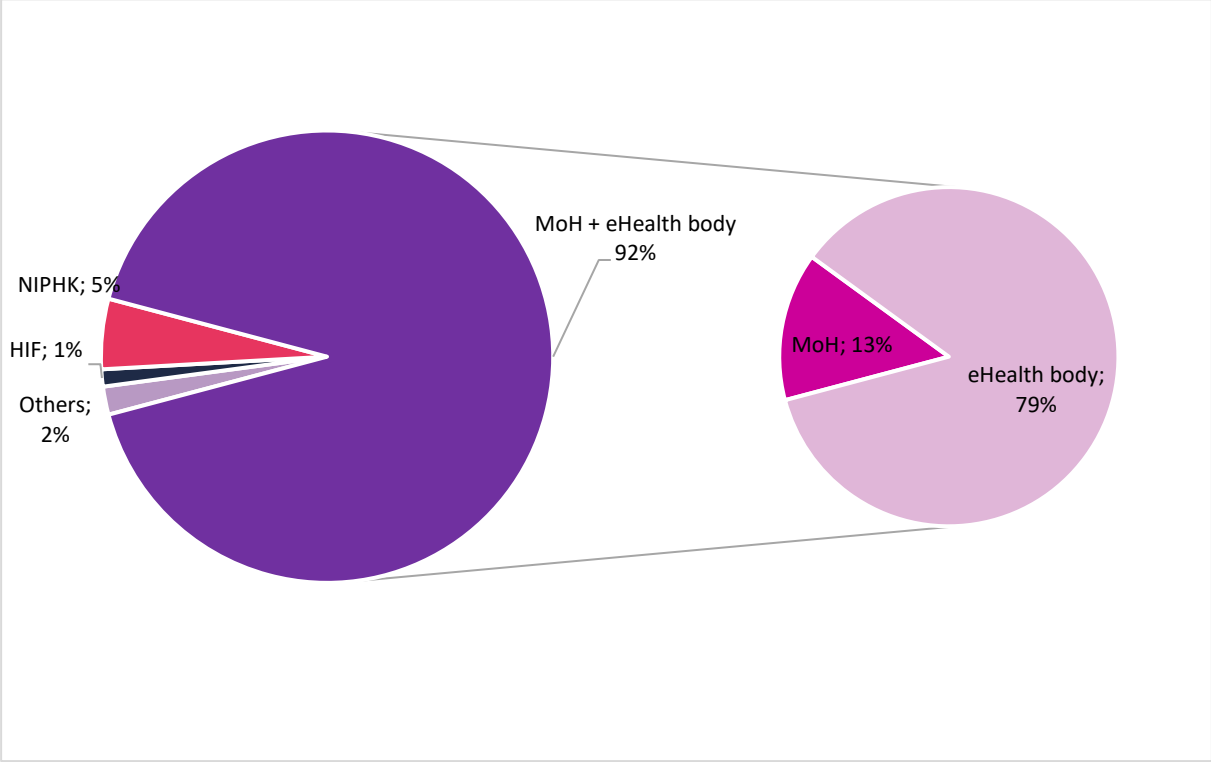


Figure 22: Total cost of eHealth projects per institution (responsible for financing)

Recommendations for sustainability of financing

The amount spent on Information and Communication Technology (ICT) as part of national healthcare expenditure can vary depending on the country and its specific healthcare system. However, on average, healthcare ICT spending typically accounts for around 3-5% of the total healthcare expenditure in many countries. It is important to note that this percentage is an estimate and can vary based on

various factors, including the level of healthcare digitization, the size and complexity of the healthcare system, and the country's overall healthcare budget. Some countries with more advanced eHealth systems may allocate a higher proportion of their healthcare expenditure to ICT, while others with less mature systems may allocate a smaller percentage. Furthermore, as healthcare systems continue to evolve and digital transformation efforts increase, the proportion of healthcare expenditure allocated to ICT may also change over time. Governments and healthcare organizations recognize the importance of investing in ICT to improve healthcare delivery, enhance efficiency, and achieve better patient outcomes.

Considering the current and planned organization of public healthcare system in Kosovo, as well as its financing sources and overall capacity, and to assure the sustainability of financing, we plan/propose that most of the planned eHealth projects should be publicly financed by central government (from state budget through responsible institutions). Such way, in principle there is also no need for immediate legislative changes and all the projects need for their start and implementation is political will and organizational capacity. However, to assure eHealth projects' financing further formally from public sources (through yearly state budgets), we highly suggest preparing national eHealth strategy, which would provide additional formal basis for mid- and long-term development of eHealth system. Such strategy can also be a valuable basis for any potential Kosovo's application for possible international financing of eHealth projects.

Furthermore, as Kosovo's National Health Accounts Report for 2021 states that total expenditure on health from public sources (government grant) amounted to about 279 million Euros, that makes yearly amounts of total investment/costs of eHealth projects proposed in this document at about 3% of current public spending on healthcare, which we think is minimum needed to keep the momentum of continuous build-up of eHealth system towards its full functionality. At the same time, this is a reasonable and sustainable percentage which any modern healthcare system should be able to finance in order to ensure basis for the efficient functioning of the whole healthcare system.

Therefore, we believe that the investment plan proposed in this document is necessary, ambitious, as well as realistic for Kosovo to implement and sustain eHealth system on the national level.

7 Feasibility and Risk Assessment

The issue of investing in e-Health, as one of the pillars of any country's modern health system, has become unquestionable today, and especially in times of global pandemic it has proved to be an indispensable and, in some cases, the only possible solution in providing a specific health care. Therefore, eHealth is usually seen as an intelligent investment in the health sector by using information and communications technologies that efficiently enable changes and improvements in healthcare both at the operational and managerial levels in order to support the health sector and citizens directly and indirectly.

7.1 Institutional feasibility

Institutional feasibility refers to the readiness of institutions, policies, and regulations to support the implementation of eHealth in Kosovo. Key factors to consider are:

Government Support

- government's commitment and support for eHealth initiatives
- national strategies, policies, and plans that prioritize the development and implementation of eHealth
- level of collaboration between different government departments and agencies involved in healthcare and IT

Regulatory Framework

- existing regulatory framework that supports the implementation of eHealth solutions
- data protection, privacy, telemedicine regulations, interoperability standards, and licensing requirements

Stakeholder Collaboration

- level of collaboration and coordination among stakeholders in the healthcare sector, including healthcare professionals, IT experts, government institutions, and patient organizations
- strong collaboration ensures that diverse perspectives are considered and helps in the successful implementation of eHealth solutions

Capacity and Expertise

- availability of skilled professionals, including healthcare IT specialists, project managers, and administrators, who can lead and manage eHealth projects effectively

Change Management

- readiness of healthcare organizations and professionals to adapt to eHealth solutions
- culture, attitudes, and willingness to embrace technological changes
- change management strategies to address resistance and ensure smooth adoption of eHealth technologies

7.2 Financial feasibility

Financial feasibility assesses the availability of financial resources to implement and sustain eHealth initiatives. The following factors are crucial to consider:

Funding Sources

- potential funding sources, such as government budgets, international development organizations, grants, and public-private partnerships
- availability and reliability of these funding sources for supporting eHealth initiatives in Kosovo

Budget Allocation

- ability of the government to allocate sufficient funds for eHealth initiatives within the healthcare budget
- Prioritization of eHealth investments based on the strategic goals and potential impact on healthcare delivery and outcomes

Sustainability

- financial sustainability of eHealth solutions beyond the initial implementation phase
- potential revenue streams, such as user fees or insurance reimbursements, that can support the long-term operation and maintenance of the eHealth system

7.3 Technical feasibility

Technical feasibility focuses on the availability and readiness of technical infrastructure and resources for implementing eHealth solutions. Key factors to consider are:

ICT Infrastructure

- existing information and communication technology (ICT) infrastructure, including internet connectivity, broadband penetration, and reliability
- infrastructure that supports the bandwidth requirements of eHealth applications, data transmission, and real-time communication

Interoperability

- compatibility and interoperability of existing healthcare systems and data repositories
- standards and protocols in place to ensure seamless data exchange and integration between different healthcare providers, including hospitals, clinics, laboratories, and pharmacies

Data Security and Privacy

- existing data security and privacy measures in the healthcare sector
- ability to protect sensitive patient information, comply with data protection regulations, and implement robust security measures, such as encryption, access controls, and secure authentication

Considering all of the above, we prepared the risk assessment to identify potential challenges and offer strategies to mitigate risks and ensure the successful implementation of eHealth initiatives in Kosovo.

7.4 Feasibility analysis of key strategic topics in developing eHealth system on Kosovo

This feasibility study defines the target state of Kosovo's eHealth framework, taking into consideration various factors such as global standards in the field, experiences of other countries in building their national eHealth systems, and the specificity of the healthcare system in Kosovo.

Many systems, whether eHealth or supporting systems, are already in use in Kosovo and have been analyzed during this study to assess whether they need replacement or can be retained and adapted to the new eHealth framework. Generally, there is no need to retire any existing system, as no major problems or risks requiring retirement have been identified. The assumption is that they can be integrated with new systems while adhering to all interoperability standards.

Regarding new systems that need implementation, we analyzed the **build/buy option and made the following assumptions:**

- For all solutions with standard options available in the market that do not require significant customization, the recommendation is to acquire standard solutions primarily for the

embedded know-how and faster implementation. This primarily applies to core medical systems (HMIS; LIS, RIS/PAC, emergency IS, DSS).

- On the other hand, for eService solutions (EHR, HIE, e-prescription, e-referral, e-Appointment), we propose a custom approach primarily to retain control and flexibility. This approach is characteristic of most national eHealth systems. Detailed analysis for each system is provided below, and a summary is presented in the table below.

eHealth Building block	Build/Buy	Benefits	Risks
BHIS	Build (based on BHIS)	Ownership, control, time to market	Vendor lock-in, IT vendor abandonment of projects
HMIS	Buy	Built know how, Roadmap, Ready for future use	Vendor lock-in, limited customization, on-going cost
PIMS	Further development	Ownership, control, time to market,	Vendor lock-in , IT vendor abandonment of projects
EHR	Build	Ownership, control, customization, integration with HIE	Time-consuming development and implementation, lack of internal knowledge
HIE	Build	Ownership, control, customization, integration with HEI	Time-consuming development and implementation, lack of internal knowledge
Patient portal	Build using eKosova authentication services	Ownership, control, customization, integration with EHR, availability of development teams	Time-consuming development and implementation
e-Appointment	Build	Ownership, control, customization, integration with other eHealth systems, availability of development teams	Time-consuming development and implementation
e-Refferal	Build	Ownership, control, customization, integration with EHR, availability of development teams	Time-consuming development and implementation
e-Prescription	Build	Ownership, control, customization, integration other eHealth systems, availability of development teams	Time-consuming development and implementation
MDM	Buy	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost
EHIS	Buy	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost
DSS	Buy	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost
Legacy systems	Further development	Ownership, control, time to market,	Vendor lock-in, IT vendor abandonment of projects

7.4.1 Primary Healthcare Information System implementation strategy for public institutions

In general, there are 3 different options to consider: a) further development based on BHIS, b) build a new solution, c) Buy a new solution

Option a) – Further development based on BHIS

Despite the lack of proper support and maintenance for the BHIS system, it's remarkable that the MoH has managed to keep it in usage with their own limited resources. The fact that all 29 primary health medical centers, including Main Medical Family Centers and most of their Family Centers and Ambulances, are currently using the system is a testament to its importance in the healthcare system.

The fact that a total of 904,270 people who received at least one dose of vaccine were registered in the BHIS vaccination module, and a total of 1,836,002 vaccinations were registered in total, is a strong indicator of the BHIS system's technical capabilities and its ability to handle large volumes of data. The BHIS vaccination module's successful implementation and use highlights the system's reliability and efficiency.

Despite certain technical problems like network issues, internet connectivity, and printer problems, the BHIS system was able to support a large number of users and effectively register vaccination data.

Pros:

- **Complete Control:** MoH has complete control to this solution (BHIS), which gives MoH full control over the system, allowing the healthcare organization to customize it according to the specific needs.
- **Greater Flexibility**: can be designed to incorporate emerging technologies, giving the healthcare organization greater flexibility in the long run.
- **Lower Long-term Costs**: there may be lower long-term costs that includes not buying additional licensing fees. The costs might be for maintenance and building/developing new modules and features
- **Implemented healthcare code standards** (ICD9 for procedures, ICD10 for diagnoses and ATC for medicine)
- **Trained Users**: TOTs and current users among 29 municipalities have been trained and are more familiar to use and work with BHIS.

Cons:

- **Lack of Maintenance:** Insufficient maintenance and support over an extended period have resulted in the absence of new features and unresolved bugs within the system, potentially impacting user satisfaction. This lack of maintenance can lead to various technical issues, including system instability, compromised data quality, performance degradation, system instability, and security vulnerabilities.
- **Coverage:** Challenges related to infrastructure, such as network, printers, and PCs, have impacted the utilization of the BHIS system. Presently, it is being used in 29 MMFCs and a limited number of MFCs.
- **Usage:** The fact that some doctors use the BHIS system while others do not is an issue that needs to be addressed to ensure that the system is being used to its full potential. However, it is positive that the Health Law obliges all health professionals to use HIS systems, including BHIS.

Option b) – Build a new solution

Building a new solution for the healthcare information system (BHIS) has its own set of pros and cons.

Pros:

- **Reduced Technical Debt:** Legacy systems often accumulate technical debt over time due to patches and modifications. By starting afresh, technical debt can be minimized or eliminated, leading to a more maintainable and sustainable solution in the long run.
- **Meeting User Needs**: Building a new solution allows for direct feedback from end-users, including doctors, nurses, administrators, and SHI coordinators. This means the solution can be tailored to their specific needs, potentially improving overall user satisfaction and efficiency.
- **Improved Security and Privacy:** Starting anew allows for a thorough assessment of security measures and privacy protocols. The new system can be built with the latest security standards in mind, helping safeguard sensitive patient data and protecting against potential cyber threats.
- **Innovative Features**: A new solution allows for innovative features and functionalities that may not have been possible or practical to implement in the current BHIS. These innovations can lead to improved patient care, streamlined processes, and enhanced analytics for decision-making.

Cons:

- **Time to market**: Developing a new solution from scratch is a time-consuming process. The projected minimum 24-month duration without considering the procurement process could mean a significant delay in implementing the solution and addressing the current system's limitations.
- **Project Complexity and Risk**: Developing a new solution is a complex undertaking that involves various stakeholders, such as software developers, healthcare professionals, and IT personnel. The project's complexity increases the risk of delays, technical issues, and unforeseen challenges.
- **High Development Cost**: Creating a new solution from scratch can be significantly more expensive than upgrading or customizing an existing system. The cost of development, implementation, and training can strain the organization's budget, potentially leading to financial challenges.
- **Data migration challenges**: Migrating data from the current BHIS to the new solution could pose significant difficulties. There is no guarantee that all data will be correctly migrated, potentially leading to data loss or corruption, which could negatively impact patient care and administrative processes.
- **User acceptance**: Introducing a completely new solution will require additional training for end-users and administrative staff. This could lead to resistance from some users who are accustomed to the current system and may be reluctant to adopt the new one. The potential for passive or active resistance could impede the successful implementation of the new solution.
- **Short Lifecycle**: Considering that a third solution is expected to be introduced within a few years, implementing a completely new solution now could lead to another major transition in the near future. This could create further disruptions and potentially increase resistance from users who might prefer to wait for the third solution.

Option c) – Buy a new solution

Here are some of pros and cons of the option to "Buy a new solution" for public primary health providers.

Pros:

- **Faster Implementation**: Buying a new solution can significantly reduce the time needed to implement an "built solution". The procurement process may take some time, but it is generally faster than building a new solution from scratch. This means that the organization can start benefiting from the new system sooner.
- **Established Features**: A commercially available solution is likely to come with a set of established features and functionalities that have been tested and refined in real-world scenarios. This can provide a comprehensive and robust system right out of the box.
- **Vendor Support**: When purchasing a solution from a reputable vendor, the organization gains access to technical support, maintenance, and updates. This can be crucial in ensuring the system's smooth operation and the prompt resolution of any issues that may arise.
- **Reduced Development Costs**: Buying a pre-existing solution can be more cost-effective than building a new one, especially when considering the development, testing, and quality assurance expenses associated with a custom solution.
- **Training and Documentation**: Vendors typically provide training and comprehensive documentation for their solutions. This can ease the learning curve for end-users and administrative staff, facilitating quicker adoption and proficiency.

Cons:

- **Limited Customization**: While commercial solutions offer established features, they may not fully align with the organization's specific needs. Customization options might be limited or require additional costs, potentially resulting in compromises on certain requirements.
- **Integration Challenges**: The new solution may need to integrate with existing systems and workflows within the organization. Ensuring seamless integration might be complex and time-consuming, depending on the compatibility between the new and current systems.
- **Vendor Dependency**: Relying on a third-party vendor means the organization becomes dependent on their support and availability. Any issues with the vendor, such as financial troubles or changes in service offerings, could negatively impact the organization's operations.
- **Ongoing Costs**: While buying a solution may have lower upfront costs compared to building one, there are ongoing licensing fees, maintenance charges, and potential upgrade expenses to consider. Over time, these costs can add up significantly.
- **Learning Curve and User Acceptance**: A new solution, even if it is commercially available, may still require training and adaptation by end-users and administrative staff. User acceptance might be a concern, especially if the new system significantly deviates from the current BHIS.

Discussions and recommendations

In summary, we believe that the best option is to continue investment in the BHIS system, coupled with module improvements, functional upgrades, and infrastructure enhancements.

Building block	Option	Features	Benefits	Risks	TCO	Time
BHIS	Further development based on BHIS	++	Ownership, control, time to market,	Vendor lock-in, IT vendor abandonment of projects	$	⧗
BHIS	Build	+++	Ownership, control	Time consuming with implementation and user adaption risks, data migration	$$	⧗
BHIS	Buy	+++	Built know how, Roadmap, Ready for future use	Vendor lock-in, IT vendor abandonment of projects, on-going cost, user acceptance	$$$	⧗

To ensure optimal performance and user satisfaction, it is essential to prioritize the enhancement of existing modules based on user feedback and the resolution of reported bugs. Addressing these issues will contribute to an improved user experience and streamline workflow efficiency within the BHIS system.

Additionally, investing in the development of new modules and functional upgrades is crucial for realizing the full potential of the BHIS. By expanding its capabilities, the system can offer a comprehensive range of features that cater to the specific needs of healthcare providers, enabling them to deliver high-quality care and optimize their operational processes.

Legacy system	General remarks	Positive aspects	Possible cautions	Recommendations for further steps
BHIS (Primary care)	Continue with investment in BHIS	MS technology stack, code ownership, implemented healthcare code standards (ICD9 for procedures, ICD10 for diagnoses and ATC for medicine), integration with e-Kosovo, large number of users, performance	Vendor lock-in, IT vendor abandonment of projects	FHIR API integration, functional upgrades

In parallel with module improvements and functional enhancements, it is imperative to address infrastructure challenges promptly. Expanding the network infrastructure and resolving issues related to printers and PCs should be prioritized to create a solid foundation for the successful implementation of the BHIS system.

7.4.2 Primary Healthcare Information System implementation strategy for private institutions

Here, we elaborate 2 different concepts that could be options for the informatization of private primary health providers: a) private institutions also use central national BHIS, b) private institutions choose EMR solutions on open market.

Those concepts have some technical but also organizational, legal and investment differences.

Option a) – Private institutions also use central national BHIS

In this concept, private primary health providers must use a centralized National BHIS that is managed and operated by the government (or designated authority at the national level – eHealth body). The BHIS serves as a standardized web-based solution that facilitates information exchange and interoperability among all healthcare providers, including public and private institutions. Private providers become integrated into the larger national healthcare ecosystem, sharing patient data, medical records, and other relevant information across the healthcare network.

Technical Aspects:

- **Data Interoperability**: The central national BHIS is built as one web application to ensure standardized data formats and functionalities, enabling seamless communication and data access and exchange among different healthcare providers.
- **Data Security and Privacy**: BHIS must adhere to robust data security and privacy standards to protect sensitive patient information from unauthorized access and breaches.
- **Health Information Exchange (HIE):** The system incorporates Health Information Exchange infrastructure that allows authorized healthcare providers to access patient data securely and in real-time.

Organizational Aspects:

- **Governance and Regulation:** The central BHIS is governed and regulated by the government or a designated authority to ensure compliance with national healthcare standards and regulations.
- **Data Sharing Agreements:** Private primary health providers are required to enter into data sharing agreements with the central BHIS, specifying the terms and conditions for data exchange and usage.
- **Training and Adoption:** Private institutions need to provide training to their staff members to ensure smooth adoption and effective use of the central BHIS.

Legal Aspects:

- **Data Ownership and Consent**: Legal agreements must define data ownership and patient consent protocols for data sharing within the national BHIS.
- **Data Access and Audit Trails:** Regulations should outline who has access to patient data, how access is granted, and maintain audit trails to track data usage.
- **BHIS Usage and Data Quality:** It should be legal enforcement for all private provider in Kosovo to use BHIS for all services provided to patients with defined standard quality of data and clear penalties measures for non-compliances

Investment Aspects:

- **Implementation Costs:** Private primary health providers may need to invest in hardware, software, and staff training to align their systems with the central BHIS, and government needs to invest in data center infrastructure, and SW development of BHIS
- **Maintenance and Support:** Ongoing maintenance costs and support fees may be incurred to ensure the proper functioning and compatibility with the BHIS.
- Reimbursement of investment/maintenance costs: Should the private providers pay for the usage of the BHIS or not.

Option a) – Private Institutions use BHIS

Pros:

- **Interoperability:** Integration with the central national BHIS allows seamless data exchange and interoperability among all healthcare providers, improving care coordination and patient outcomes.
- **Standardization:** The use of a centralized system promotes data standardization, leading to more consistent and reliable data across the healthcare network.
- **Government Support:** The central national BHIS may receive government backing and resources, ensuring continuous development, updates, and improvements.
- **Improved Public Health:** The central BHIS enables data aggregation and analysis, facilitating public

Cons:

- **Limited Autonomy:** Private institutions may have less control over customization and configuration of the central BHIS to fit their specific needs.
- **Lack of Flexibility:** The central BHIS may not cater to specific requirements or unique workflows of certain private healthcare providers.
- **Implementation Challenges:** Resistance of the private provider (in particular the large and mature providers) to use BHIS as web-based solution without integration with their current information systems.
- **Data Security Concerns:** Depending on the central BHIS's security measures, there may be concerns about data breaches or unauthorized access to sensitive patient information by the staff members of private providers.
- **Compliance Burden:** Private institutions must adhere to strict regulations and data sharing agreements, which could increase administrative burdens.
- **Cost recovery:** Private providers could ask for the cost recovery from the government (ie. MoH) because of their investment or cost related to the usage of BHIS
- **Potential legal questions** – about public financing of private entities or discussion of amount for cost of services and who should cover that cost

b) Private institutions choose EMR solution on open market:

Pros:

- **Customization**: Private institutions have the freedom to select a healthcare information system that can be tailored to their specific needs and workflows.
- **Flexibility:** Choosing a solution on the open market allows private providers to switch vendors or systems if needed, providing flexibility for future changes.
- **Vendor Selection:** Private institutions have the opportunity to choose a reputable and reliable vendor that aligns with their values and priorities.
- **Local market:** Private sector is investing in development of local EMR market
- **Integration Control:** Private institutions can have more control over integrating the chosen system with their existing IT infrastructure and other systems.

Cons:

- **Higher Costs:** Customization and integration expenses could be higher compared to a centralized solution, especially if multiple systems need to be integrated.
- **Support and Maintenance:** The institution becomes solely responsible for maintaining the chosen system and ensuring it remains up-to-date and functional.

- **Data Security Risks:** The level of data security in the chosen system might vary, posing potential risks if not adequately addressed by the vendor.

Discussions and recommendations

Most countries have left it to healthcare service providers to buy their EMR solutions on the market, but such solutions need to be certified by a public body that sets standards for EMR solutions and methods of integration with the national EHR and other national eHealth services.

For Kosovo, we propose as the long term the better solution is **option b)** (**private providers choose and buy EMR solutions on the open market**). Therefore, should be needed for the establishment of standards for a set of healthcare data and methods of sending them to the EHR, as well as specifying which eHealth services (e-Prescription, e-Referral, etc.) must be used and how. A minimum period of 18 months should be given for adaptation, procurement of certified solutions, user training, and implementation of the solutions at private healthcare service providers.

7.4.3 Buy/Build general consideration for the new eHealth components

For **all new eHealth systems** there are different options to consider:

a) Build a new solution
b) Buy off-the-shelf solution

Option a) – Build a new solution

Pros:

- **Complete Control:** Building a new solution gives full control over the system, allowing the healthcare organization to customize it according to their specific needs.
- **Greater Flexibility**: An own solution can be designed to incorporate emerging technologies, giving the healthcare organization greater flexibility in the long run.
- **Lower Long-term Costs**: Once the new solution is built, there may be lower long-term costs compared to buying an off the shelf solution, such as no licensing fees.

Cons:

- **Higher Upfront Costs**: Building a new solution can be expensive, especially for smaller countries with limited resources as it requires a significant investment in software development, hardware infrastructure, and personnel.
- **Slower Development Time**: Developing a new solution can take time, which may delay the deployment of the system and disrupt hospital operations. This can be a significant disadvantage, especially if there is a need to implement the new solution quickly.
- **Resource Intensive**: Building a new solution requires a significant amount of resources and expertise, which may not be readily available in a small country. Without this expertise, the development of the system can be challenging, and the resulting system may be less reliable or secure.
- **Maintenance and support**: Once the new solution is built, ongoing maintenance and support are required to keep the system running smoothly. This can be challenging and expensive, especially if the organization does not have the necessary expertise or resources.
- **Integration with other systems**: Building a new solution in-house can make it difficult to integrate the system with other systems used by the organization or other healthcare providers. This can limit the ability to share data and coordinate care effectively.

- **Experts**: Finding and retaining subject matter experts in the development of new and modern eHealth solution can be a challenge. It requires a lot of time, resources, and successful project implementations to develop such expertise. Moreover, it can be difficult to retain these experts in public health provider organizations, as they may be attracted to other opportunities in the private sector or in other countries. This can lead to knowledge gaps and difficulty in maintaining and updating the solution over time. Additionally, the cost of hiring and training staff can be a significant expense for organizations that choose to build their own eHealth solution

Option b) – Buy new ("off she shelf") solution

Pros:

- **Faster Implementation**: Buying a new solution can significantly reduce the time needed to implement an "built solution". The procurement process may take some time, but it is generally faster than building a new solution from scratch. This means that the organization can start benefiting from the new system sooner.
- **Established Features**: A commercially available solution is likely to come with a set of established features and functionalities that have been tested and refined in real-world scenarios. This can provide a comprehensive and robust system right out of the box.
- **Vendor Support**: When purchasing a solution from a reputable vendor, the organization gains access to technical support, maintenance, and updates. This can be crucial in ensuring the system's smooth operation and the prompt resolution of any issues that may arise.
- **Reduced Development Costs**: Buying a pre-existing solution can be more cost-effective than building a new one, especially when considering the development, testing, and quality assurance expenses associated with a custom solution.
- **Training and Documentation**: Vendors typically provide training and comprehensive documentation for their solutions. This can ease the learning curve for end-users and administrative staff, facilitating quicker adoption and proficiency.

Cons:

- **Limited Customization**: While commercial solutions offer established features, they may not fully align with the organization's specific needs. Customization options might be limited or require additional costs, potentially resulting in compromises on certain requirements.
- **Integration Challenges**: The new solution may need to integrate with existing systems and workflows within the organization. Ensuring seamless integration might be complex and time-consuming, depending on the compatibility between the new and current systems.
- **Vendor Dependency**: Relying on a third-party vendor means the organization becomes dependent on their support and availability. Any issues with the vendor, such as financial troubles or changes in service offerings, could negatively impact the organization's operations.
- **Ongoing Costs**: While buying a solution may have lower upfront costs compared to building one, there are ongoing licensing fees, maintenance charges, and potential upgrade expenses to consider. Over time, these costs can add up significantly.
- **Learning Curve and User Acceptance**: A new solution, even if it is commercially available, may still require training and adaptation by end-users and administrative staff. User acceptance might be a concern, especially if the new system significantly deviates from the current BHIS.

- **Alignment with Long-Term Goals**: The purchased solution might not fully align with the organization's long-term strategic goals. It could become outdated or insufficient to meet future healthcare requirements, leading to the need for further upgrades or replacements.

Discussions and recommendations

Taking into considerations all pros/cons we suggest buying off-the-shelf eHealth solutions when

- there is mature market and there is no need for a lot of customization due to policies and regulations like (LIS, RIS/PACS, HMIS) or
- there is lack of internal knowledge to build such solution (i.e. DSS, CDSS, IDSS, DDSS, Emergency healthcare IT system)

In the following subchapters we give more detail analysis for each building block.

7.4.4 HMIS implementation strategy for public institutions

A Hospital and Clinical Management Information System (HMIS) is a software that helps managing the hospital ongoing business in all aspects (clinical, administrative, financial). In its medical part it is acting like complete EMR system inside the hospital. It is an essential tool for managing patient information and optimizing healthcare delivery in hospitals. Unique HMIS should be implemented in all public hospitals in Kosovo. It should include Administration module, Clinical module, Billing module. HMIS implementations should also include ERP system for managing the hospital (Accounting, Inventory management, Human Resource Management, Payroll). It should be Integrated with other systems in hospital (LIS, RIS/ PACS, PMIS). Choosing the appropriate HMIS strategy is a long-term decision for national healthcare systems. Hospitals need to operate with a high level of accuracy, efficiency, and reliability. Therefore, they must decide whether to buy a ready-made HMIS or build their own solution that meets their specific requirements. There are key differences to consider when deciding whether to buy or build the Hospital Management Information System (HMIS) on a national level in a small country.

- **Specialist Knowledge**: HMIS involves highly specific and critical medical processes, and building a custom solution would require extensive specialist knowledge. Purchasing a pre-existing HMIS solution from experienced vendors would ensure that the system is designed and tested with the necessary expertise in mind.
- **Time Efficiency**: Developing a comprehensive HMIS from scratch would be a time-consuming process, while ready-made solutions are already available and can be implemented more quickly. This would allow emergency medical services to benefit from the system sooner and improve patient care in a timely manner.
- **Cost-Effectiveness**: Building a custom HMIS would involve significant development costs, ongoing maintenance, and updates. By purchasing a pre-existing solution, the initial investment might be more cost-effective, particularly considering the need for specialized knowledge and resources.
- **Proven Functionality**: Established HMIS solutions are likely to have a track record of successful implementation in various hospitals. This ensures that the functionalities of the system have been tested and optimized for efficiency and reliability.
- **Regulatory Compliance**: Ready-made HMIS solutions are often designed to meet regulatory requirements and industry standards, reducing the risk of non-compliance and ensuring patient data security.

Building block	Options	Features	Benefits	Risks	TCO	Time
HMIS	Build within BHIS	++	Ownership, control, time to market	Time-consuming development and implementation, resource intensive, lack of available subject experts, integrations with other systems	$	
HMIS	Build	++	Ownership, control	Time-consuming development and implementation, resource intensive, lack of available subject experts, integrations with other systems	$$$	
HMIS	Buy	+++	Built know how, Roadmap, Ready for future use	Vendor lock-in, limited customization, on-going cost	$$	

In summary, deciding whether to buy or build a centralized HMIS solution in a Kosovo should require careful consideration of the pros and cons that are listed in chapter 7.4.3Factors such as upfront costs, customization, time of implementation, flexibility, long-term costs, and resource availability should be weighed to determine the best approach. Taking into considerations all pros/cons we suggest **buying off the shelf HMIS solutions** because

- there is mature market of HMIS solutions and there is no need for a lot of customizations due to policies and regulations and
- it will take too long to build comprehensive HMIS

We believe that **the best option is to select a standard HMIS** that has been tried and tested in practice in hospitals of similar size and supporting the processes of all the necessary specialties that exist in UCCK and other hospitals in Kosovo. This is based on above mentioned factors and the desire of the ministry to speed up the computerization of hospitals after decades of failed attempts. A solid solution may be ensured, project risks can be minimized, and vendor lock-in problems can be mitigated by firm project management, and with strong tender documentation through detailed technical specifications, strict deadlines, and explicit contractual duties in the implementation and post-production phases.

While purchasing a ready-made HMIS is recommended, it's crucial to assess various vendor offerings and choose a solution that aligns closely with the specific needs and workflows of the emergency medical service. Customization options might still be available to tailor the solution to suit the unique requirements for Kosovo hospitals.

7.4.5 Pharmacy Inventory Management Software (PIMS) implementation strategy for public institutions

The PIMS enables the management of the supply process of medicines and medicinal materials, starting from central level institutions to health institutions, and up to distribution to the patient.

The purpose of the PIMS, in addition to enabling better management of pharmacies/warehouses of Health Institutions, is to provide transparency in the supply of medicines and medical consumables.

PIMS has been implemented in health institutions of Primary, Secondary and Tertiary Health Care, as well as in the Pharmacy Division - PD.

Kosovo could choose between 2 options: a) Further development of PIMS) Retirement of PIMS and replacement with new system. Finding a commercial solution that meets all the needs MoH is almost impossible. Although there are various pharmacy solutions available on the market, they lack the component related to the central drug management from the MoH's side.

Option a) – Further development of PIMS

Pros:

- **Complete Control:** MoH has full control over the system
- **Greater Flexibility**: can be designed to incorporate emerging technologies, giving the healthcare organization greater flexibility in the long run.
- **Lower Long-term Costs**: there may be lower long-term costs for maintenance and building/developing new modules and features
- **Trained Users**: Current users have been trained and are familiar with the system.

Cons:

- **Coverage:** Challenges related to infrastructure, such as network, printers, and PCs, have impacted the utilization of the Legacy systems.
- **Integration:** with BHIS, HMIS, KMA is currently missing.

Option b) – Retirement of PIMS and replacement with new system

Building a new solution has its own set of pros and cons.

Pros:

- **Reduced Technical Debt:** Legacy systems often accumulate technical debt over time due to patches and modifications. By starting afresh, technical debt can be minimized or eliminated, leading to a more maintainable and sustainable solution in the long run.
- **Meeting User Needs**: Building a new solution allows for direct feedback from end-users. This means the solution can be tailored to their specific needs, potentially improving overall user satisfaction and efficiency.
- **Improved Security and Privacy:** Starting anew allows for a thorough assessment of security measures and privacy protocols. The new system can be built with the latest security standards in mind, helping safeguard sensitive patient data and protecting against potential cyber threats.
- **Innovative Features**: A new solution allows for innovative features and functionalities that may not have been possible or practical to implement in the current PIMS. These innovations can lead to improved patient care, streamlined processes, and enhanced analytics for decision-making.

Cons:

- **Time to market**: Developing a new solution from scratch is a time-consuming process. The projected minimum 24-month duration without considering the procurement process could mean a significant delay in implementing the solution and addressing the current system's limitations.
- **Project Complexity and Risk**: Developing a new solution is a complex undertaking that involves various stakeholders, such as software developers, healthcare professionals, and IT personnel. The project's complexity increases the risk of delays, technical issues, and unforeseen challenges.

- **High Development Cost**: Creating a new solution from scratch can be significantly more expensive than upgrading or customizing an existing system. The cost of development, implementation, and training can strain the organization's budget, potentially leading to financial challenges.
- **Data migration challenges**: Migrating data from the PIMS to the new solution could pose significant difficulties. There is no guarantee that all data will be correctly migrated, potentially leading to data loss or corruption, which could negatively impact patient care and administrative processes.
- **User acceptance**: Introducing a completely new solution will require additional training for end-users and administrative staff. This could lead to resistance from some users who are accustomed to the current system and may be reluctant to adopt the new one. The potential for passive or active resistance could impede the successful implementation of the new solution.

Discussions and recommendations

There is no urgent need to retire PIMS due to technology or functional needs. Also, there is no high risk for keeping it that cannot be managed. Retiring PIMS and investing in new solution should be time and cost consuming with any actual benefit.

So, in summary, we believe that the **best option is to continue investment in PIMS**, coupled with module improvements, functional upgrades, and infrastructure enhancements.

To ensure optimal performance and user satisfaction, it is essential to prioritize the enhancement of existing modules based on user feedback and the resolution of reported bugs. Addressing these issues will contribute to an improved user experience and streamline workflow efficiency within the PIMS system.

Building block	Options	Features	Benefits	Risks	TCO	Time
PIMS	Further development	+++	Ownership, control, time to market,	Vendor lock-in, IT vendor abandonment of projects	$	⧖
PIMS	Build	+++	Ownership, control	Time consuming with implementation and user adaption risks, data migration	$$$	⧗

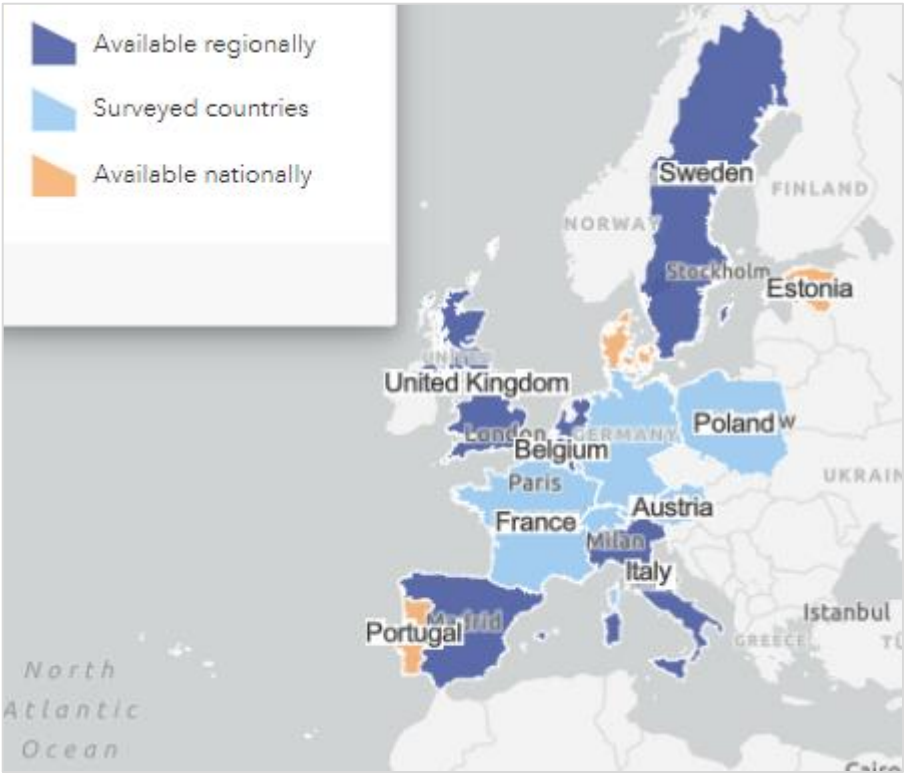
7.4.6 EHR implementation strategy

A national Electronic Health Record (EHR) is a centralized and interoperable digital repository that stores comprehensive health information of individuals within a country. It aims to facilitate secure data exchange and seamless access to patient information by authorized healthcare providers across different healthcare settings.

Here are some key concepts of a national EHR:

- **Centralized Database**: A national EHR system maintains a single, central database that securely stores health information of all citizens. This ensures that patient data is accessible from anywhere within the country's healthcare network. For example, Estonia's national EHR system, called "eHealth," has a centralized data repository that stores patient health records, including medical history, prescriptions, allergies, and test results, accessible to authorized healthcare professionals across the country.

The same centralized concept is developed and implemented in most of the small and mid-size countries in the EU (Croatia, Denmark, Finland, North Macedonia, Portugal among others) and larger countries are implementing EHR on the regional levels.



Source: https://www.bertelsmann-stiftung.de/de/publikationen/publikation/did/smarthealthsystems-1

- **Interoperability**: National EHRs prioritize interoperability, enabling seamless data exchange between different healthcare institutions and systems. This allows healthcare providers to access comprehensive patient information regardless of where the patient received treatment. For instance, Denmark's "Sundhedsplatformen" integrates EHRs from various hospitals and clinics, allowing clinicians to access patient data regardless of the care facility they visit.
- **Privacy and Security**: Privacy and security measures are crucial in national EHR systems to protect patient data from unauthorized access. Robust encryption, access controls, and authentication protocols are implemented to ensure the confidentiality of sensitive health information. The United Kingdom's "Summary Care Record" system provides patients with the option to control access to their health records and specify who can view their information.
- **Patient Access and Empowerment**: A well-designed national EHR should offer patients access to their own health information, empowering them to take an active role in their healthcare decisions. Patients can view test results, medication history, and other relevant health data through secure online portals. Croatian “Portal zdravlja” and N.Macedonia “Moj termin” are examples of a national EHR system that allows patients to access their health information and share it with healthcare providers as needed. (Examples: Croatia https://gov.hr/en/portal-zdravlja-health-portal-is-mobile-friendly/2340, Nort Macedonia https://e-zdravstvo.mk/en/moe-zdravje)
- **Data Analytics and Public Health**: National EHR systems can contribute valuable data for public health research and surveillance. Aggregated and anonymized data from EHRs can be used to monitor disease outbreaks, assess population health trends, and design targeted

healthcare interventions. On the other hand, there are still significant barriers that need to be overcome for efficient secondary use of health data through EU (https://tehdas.eu/app/uploads/2022/08/tehdas-report-on-secondary-use-of-health-data-through-european-case-studies-.pdf)

- **Scalability and Sustainability**: A national EHR system must be designed with scalability and sustainability in mind, considering the future growth of the healthcare system and technological advancements. Upgrades and expansions should be feasible to accommodate increasing data volumes and evolving healthcare needs.

Approaches

In the implementation of national EHR in Kosovo, it is clear that a **centralized model** should be implemented, but Kosovo could choose between 2 options:

a) To Build EHR or
b) to Buy EHR solution

a) Building a National EHR Solution:

Pros:

- **Customization**: Building a custom EHR allows for tailoring the solution to the specific needs and workflows of the country's healthcare system, ensuring a better fit for the unique requirements.
- **Control**: Developing EHR solution provides the country with greater control over its features, functionalities, and security measures.
- **Long-term Flexibility**: A custom-built EHR can be easily adapted and scaled as the healthcare system evolves and technology advances.
- **Intellectual Property**: The country retains ownership of the developed software and can potentially generate revenue by licensing it to other regions or countries.

Cons:

- **Time and Cost**: Building a national EHR system from scratch is a time-consuming and expensive process, involving significant development, testing, and maintenance costs.
- **Expertise Requirements**: Developing and maintaining a complex EHR system requires a skilled team of IT professionals and healthcare experts, which may be a challenge to assemble and retain.
- **Delayed Implementation**: The time needed for development and testing might delay the implementation of the EHR system, potentially impacting patient care and healthcare efficiency.

b) Buying a Commercial National EHR Solution:

Pros:

- **Faster Implementation**: Commercial EHR solutions are readily available, allowing for quicker implementation and deployment compared to building from scratch.
- **Established Features**: Commercial EHRs often come with a wide range of features and functionalities that have been tested and proven in real-world healthcare settings.
- **Vendor Support**: EHR vendors provide ongoing support, maintenance, and updates, ensuring the system remains up-to-date and compliant with regulatory changes.
- **Cost Predictability**: The pricing structure of commercial EHRs is usually more predictable, helping to manage costs more effectively.

Cons:

- **Limited Customization**: Commercial EHR solutions may not perfectly align with the country's specific requirements, leading to limitations in customization.
- **Vendor Dependency**: The country becomes dependent on the EHR vendor for support, updates, and any future enhancements.
- **Data Ownership and Privacy**: The country needs to ensure data ownership and privacy compliance, especially if the EHR is hosted on the vendor's servers or cloud infrastructure.
- **Integration Challenges**: Integrating a commercial EHR with existing healthcare systems and other eHealth services may require additional effort and resources.

Discussions and recommendations

The implementation of a national EHR involves more than just selecting an EHR solution from the market. The primary challenge lies in integrating the EHR with various existing systems, databases, registries, and codebooks both within and outside the healthcare ecosystem. Many countries have chosen to develop their own national EHR systems in collaboration with experienced solution providers and implementors to mitigate implementation risks effectively.

One of the crucial factors in building a national eHealth infrastructure is having full control over the systems. This means that a build approach is preferred over buying a ready-made solution. By building the national EHR system, a country like Kosovo should retain control over its features, functionalities, and security measures. This control is essential for ensuring the system aligns with the specific needs and requirements of the healthcare ecosystem in Kosovo.

Additionally, building the national EHR provides the flexibility to customize and tailor the system to meet the unique demands of the country's healthcare environment. Integration with existing systems and databases can be more seamless and efficient when the EHR is designed to work cohesively with them from the beginning.

While building a national EHR may involve higher initial costs and development efforts, the long-term benefits of having a fully controlled and customized system outweigh the potential drawbacks.

In conclusion, the integration complexity and the importance of having full control over the national eHealth infrastructure make **the build approach the preferred option for implementing a national EHR system in Kosovo**. Collaboration with experienced solution providers can help mitigate risks and ensure the successful development and deployment of a robust and tailored EHR solution that aligns with the country's healthcare needs and objectives.

Building block	Options	Features	Benefits	Risks	TCO	Time
EHR	Build	++	Ownership, control, customization, integration with HIE	Time-consuming development and implementation, lack of internal knowledge	$$	
EHR	Buy	+++	Built know how, Roadmap, Standards	Vendor lock-in, limited customization, on-going cost	$$$	

7.4.7 HIE implementation strategy

Discussions and recommendations

Integration is a key element of the functionality of HEI project so good synergy could be made with the joint development of EHR and HIE as one project effort. Therefore, it is recommended that the development of these two building blocks, EHR and HIE, should be done as one project with two deliverables. The EHR should be built as part of the HIE development and function as a central database that extracts medical data, organizes it on the patient level, and sends it from providers through the HIE.

Similar reasoning Build vs Buy as described in the previous subchapter **Error! Reference source not found.**, lead us to recommend build own HIE with selected experienced solution providers / implementors who should significantly reduce the implementation risk.

One additional reason for choosing this approach is the utilization of Government Gateway (GG) as the foundation for the HIE platform. By using GG as the communication platform, it provides a solid infrastructure and groundwork on which the HEI platform can be built. This means that the functionalities and capabilities of GG can be leveraged to facilitate the secure electronic exchange of healthcare-related information among various healthcare institutions.

The HIE platform should be designed to adhere to healthcare message standards (Ie. HL7). By implementing HL7 and other relevant healthcare message standards, the HIE platform can ensure that the data exchanged between healthcare providers is consistent, standardized, and easily interpretable by all parties.

In summary, **building the HIE platform on top of the GG communication platform**, while incorporating healthcare message standards like HL7, can result in a robust and interoperable system that enables seamless and secure sharing of patient health information across the healthcare network, ultimately leading to improved patient care and healthcare outcomes.

Building block	Options	Features	Benefits	Risks	TCO	Time
HIE	Build	++	Ownership, control, customization, integration with HEI	Time-consuming development and implementation, lack of internal knowledge	$$	⧗
HIE	Buy	+++	Built know how, Roadmap, Standards	Vendor lock-in, limited customization, on-going cost	$$$	⧗

7.4.8 Patient portal implementation strategy:

In Kosovo the patient portal can be enabled through the governmental platform e-Kosova. In general, the Patient Portal has two choices for utilizing the eKosova platform:

a) eKosova could include a Patient Portal as part of eKosova services.
b) Patient Portal (PP) is a web portal and mobile app run by the eHealth Body (ie. Ministry of Health), but in order to access it, a citizen must first authenticate through the eKosova authentication ser-vice. After receiving the appropriate credentials (for example, for oneself or a child or family member), the citizen should then get right to open the Patient Portal website. (Examples: Croatia https://gov.hr/en/portal-zdravlja-health-portal-is-mobile-friendly/2340 , Nort Macedonia https://e-zdravstvo.mk/en/moe-zdravje)

We- believe that option b) should offer more adaptability and flexibility for the long-term strategy because the development of the patient portal is a dynamic process that involves introducing new functionalities and services to citizens over a longer of time.

The decision to build or buy a patient portal involves various considerations. While both options have their merits, building a custom-made solution (building) may be the preferred approach for several reasons:

- **Scalability and Customization**: A patient portal is a dynamic service that is likely to grow over time, incorporating different services and functionalities as other eHealth systems evolve. Building a custom solution allows for greater flexibility and scalability to accommodate future changes and tailor the portal to meet specific requirements.
- **Integration with Other Systems**: A custom-built patient portal can be seamlessly integrated with other eHealth systems and databases, primarily with EHR.
- **Control and Ownership:** By building the national patient portal, the MoH retains full control over its features, data security, and future updates. There is no dependency on third-party vendors, providing greater autonomy in managing and enhancing the portal.
- **Technical Complexity**: Developing a patient portal is generally less technically complex compared to building other eHealth systems. With the abundance of common development frameworks and resources available, finding a skilled software development team for the task is more manageable.
- **Tailored User Experience**: A custom solution allows for a personalized and user-friendly interface, tailored to the specific needs and preferences of the patients and healthcare providers who will be using the portal.

However, it's essential to consider some potential challenges of the build approach:

- **Time and Cost**: Building a custom patient portal requires time and financial investment for development, testing, and ongoing maintenance.
- **Expertise and Resources**: While developing a patient portal may not be as technically complex as other eHealth systems, it still requires a skilled development team with knowledge of healthcare regulations, security protocols, and user experience design.

On the other hand, buying a pre-existing patient portal solution may offer quicker implementation and initial cost savings, but it might not provide the level of customization and future scalability that a custom solution offers.

Discussions and recommendations

So, our recommendation, for a national patient portal, **the build approach** seems reasonable due to its dynamic nature, scalability requirements, and the availability of skilled development teams.

Building block	Options	Features	Benefits	Risks	TCO	Time
Patient portal	Build using eKosova authentication services	+++	Ownership, control, customization, integration with EHR, availability of development teams	Time-consuming development and implementation	$$$	⧗
Patient portal	Buy a new solution	++	Built know how, Roadmap	Vendor lock-in, limited customization, on-going cost	$$	⧗

7.4.9 e-Appointments implementation strategy

Approaches

e-Appointment system is online platform that should allow primary care doctors and patients to schedule appointments with healthcare providers conveniently. It should enable patients to request appointment for the certain medical procedures (based on e-Referral system), as well as review existing scheduled orders and cancel them if needed, without any medical staff interactions. Part of e-Appointment serves should be patient's remainder service for the scheduled appointments.

Kosovo could choose between 2 options:

a) To Build e-Appointment system or
b) to Buy e-Appointment system

a) Building an e-Appointment system:

Pros:

- **Customization**: Building an e-Appointment system allows for tailoring the solution to the specific needs and workflows of the country's healthcare system, ensuring a better fit for the unique requirements.
- **Control**: Developing an e-Appointment system provides the country with greater control over its features, functionalities, and security measures.
- **Long-term Flexibility**: A custom-built e-Appointment system can be easily adapted and scaled as the healthcare system evolves and technology advances.
- **Intellectual Property**: The country retains ownership of the developed software and can potentially generate revenue by licensing it to other regions or countries.

Cons:

- **Time and Cost**: Building an e-Appointment system from scratch is a time-consuming and expensive process, involving significant development, testing, and maintenance costs.
- **Expertise Requirements**: Developing and maintaining an e-Appointment system requires a skilled team of IT professionals and healthcare experts, which may be a challenge to assemble and retain.
- **Delayed Implementation**: The time needed for development and testing might delay the implementation of an e-Appointment system, potentially impacting patient care and healthcare efficiency.

b) Buying a Commercial e-Appointment system:

Pros:

- **Faster Implementation**: Commercial e-Appointment systems are readily available, allowing for quicker implementation and deployment compared to building from scratch.
- **Established Features**: Commercial e-Appointment systems often come with a wide range of features and functionalities that have been tested and proven in real-world healthcare settings.
- **Vendor Support**: e-Appointment system vendors provide ongoing support, maintenance, and updates, ensuring the system remains up-to-date and compliant with regulatory changes.
- **Cost Predictability**: The pricing structure of commercial e-Appointment system is usually more predictable, helping to manage costs more effectively.

Cons:

- **Limited Customization**: Commercial e-Appointment systems may not perfectly align with the country's specific requirements, leading to limitations in customization.
- **Vendor Dependency**: The country becomes dependent on the e-Appointment system vendor for support, updates, and any future enhancements.
- **Data Ownership and Privacy**: The country needs to ensure data ownership and privacy compliance, especially if the e-Appointment system is hosted on the vendor's servers or cloud infrastructure.
- **Integration Challenges**: Integrating a commercial e-Appointment system with existing healthcare systems and other eHealth services may require additional effort and resources.

The decision to build or buy e-Appointment involves various considerations. While both options have their merits, building a custom-made solution (building) may be the preferred approach for several reasons:

- **Integration with Other Systems**: A custom-built e-Appointment can be seamlessly integrated with other eHealth systems and databases, primarily with EHR.
- **Control and Ownership**: By building the e-Appointment system the MoH retains full control over its features, data security, and future updates. There is no dependency on third-party vendors, providing greater autonomy in managing and enhancing the portal.

However, it's essential to consider some potential challenges of the build approach:

- **Time and Cost**: Building an e-Appointment system requires time and financial investment for development, testing, and ongoing maintenance.
- **Expertise and Resources**: Developing an e-Appointment requires a skilled development team with knowledge of healthcare regulations, security protocols, and user experience design.

On the other hand, buying a pre-existing e-Appointment system solution may offer quicker implementation and initial cost savings, but it might not provide the level of customization and future scalability that a custom solution offers.

Discussions and recommendations

The **implementation of eServices** (EHR, e-Appointment, e-Referral, e-Prescription) **as a crucial part** of national eHealth system is more than just selecting solution from the market. The primary challenge lies in integrating eServices with various existing systems, databases, registries, and codebooks both within and outside the healthcare ecosystem. Many countries have chosen to develop their own platform in collaboration with experienced solution providers and implementors to mitigate implementation risks effectively.

One of the crucial factors in building a national eHealth infrastructure is having full control over the systems. This means that a build approach is preferred over buying a ready-made solution. By building a national eHealth infrastructure a country like Kosovo should retain control over its features, functionalities, and security measures. This control is essential for ensuring the system aligns with the specific needs and requirements of the healthcare ecosystem in Kosovo.

Additionally, building a national eHealth infrastructure provides the flexibility to customize and tailor the system to meet the unique demands of the country's healthcare environment. Integration with existing systems and databases can be more seamless and efficient when the national eHealth infrastructure is designed to work cohesively with them from the beginning.

While building eServices may involve higher initial costs and development efforts, the long-term benefits of having a fully controlled and customized system outweigh the potential drawbacks.

In conclusion, the integration complexity and the importance of having full control over the national eHealth infrastructure make **the build approach the preferred option for implementing eServices as a crucial part of eHealth system in Kosovo**. Collaboration with experienced solution providers can help mitigate risks and ensure the successful development and deployment of a robust and tailored EHR solution that aligns with the country's healthcare needs and objectives.

Building block	Options	Features	Benefits	Risks	TCO	Time
e-Appointment	Build	+++	Ownership, control, customization, integration with other eHealth systems, availability of development teams	Time-consuming development and implementation	$$$	⧗
e-Appointment	Buy	++	Built know how, Roadmap	Vendor lock-in, limited customization, on-going cost	$$	⧗

7.4.10 e-Referrals implementation strategy

Approaches

e-Referral, as a part of the e-Health system in Kosovo, represents a significant leap forward in improving healthcare delivery and patient outcomes. It is a system that facilitates the digital referral of patients from one health care provider to another.

Kosovo could choose between 2 options:

a) To Build e-Referral system or

b) to Buy e-Referral system

a) Building an e-Referral system:

Pros:

- **Customization**: Building an e-Referral system allows for tailoring the solution to the specific needs and workflows of the country's healthcare system, ensuring a better fit for the unique requirements.
- **Control**: Developing an e-Referral system provides the country with greater control over its features, functionalities, and security measures.
- **Long-term Flexibility**: A custom-built e-Referral system can be easily adapted and scaled as the healthcare system evolves and technology advances.
- **Intellectual Property**: The country retains ownership of the developed software and can potentially generate revenue by licensing it to other regions or countries.

Cons:

- **Time and Cost**: Building an e-Referral system from scratch is a time-consuming and expensive process, involving significant development, testing, and maintenance costs.
- **Expertise Requirements**: Developing and maintaining an e-Referral system requires a skilled team of IT professionals and healthcare experts, which may be a challenge to assemble and retain.
- **Delayed Implementation**: The time needed for development and testing might delay the implementation of an e-Referral system, potentially impacting patient care and healthcare efficiency.

b) Buying a Commercial e-Referral system:

Pros:

- **Faster Implementation**: Commercial e-Referral systems are readily available, allowing for quicker implementation and deployment compared to building from scratch.
- **Established Features**: Commercial e-Referral systems often come with a wide range of features and functionalities that have been tested and proven in real-world healthcare settings.
- **Vendor Support**: e-Referral system vendors provide ongoing support, maintenance, and updates, ensuring the system remains up-to-date and compliant with regulatory changes.
- **Cost Predictability**: The pricing structure of commercial e-Referral system is usually more predictable, helping to manage costs more effectively.

Cons:

- **Limited Customization**: Commercial e-Referral systems may not perfectly align with the country's specific requirements, leading to limitations in customization.
- **Vendor Dependency**: The country becomes dependent on the e-Referral system vendor for support, updates, and any future enhancements.
- **Data Ownership and Privacy**: The country needs to ensure data ownership and privacy compliance, especially if the e-Referral system is hosted on the vendor's servers or cloud infrastructure.
- **Integration Challenges**: Integrating a commercial e-Referral system with existing healthcare systems and other eHealth services may require additional effort and resources.

The decision to build or buy e-Referral involves various considerations. While both options have their merits, building a custom-made solution (building) may be the preferred approach for several reasons:

- **Integration with Other Systems**: A custom-built e-Referral can be seamlessly integrated with other eHealth systems and databases, primarily with EHR.
- **Control and Ownership**: By building the e-Referral system the MoH retains full control over its features, data security, and future updates. There is no dependency on third-party vendors, providing greater autonomy in managing and enhancing the portal.

However, it's essential to consider some potential challenges of the build approach:

- **Time and Cost**: Building an e-Referral system requires time and financial investment for development, testing, and ongoing maintenance.
- **Expertise and Resources**: Developing an e-Referral requires a skilled development team with knowledge of healthcare regulations, security protocols, and user experience design.

On the other hand, buying a pre-existing e-Referral system solution may offer quicker implementation and initial cost savings, but it might not provide the level of customization and future scalability that a custom solution offers.

Discussions and recommendations

The **implementation of eServices** (**EHR, Patient Portal, e-Appointment, e-Referral, e-Prescription**) **as a crucial part** of national eHealth system is more than just selecting solution from the market. The primary challenge lies in integrating eServices with various existing systems, databases, registries, and codebooks both within and outside the healthcare ecosystem. Many countries have chosen to develop their own platform in collaboration with experienced solution providers and implementors to mitigate implementation risks effectively.

One of the crucial factors in building a national eHealth infrastructure is having full control over the systems. This means that a build approach is preferred over buying a ready-made solution. By building a national eHealth infrastructure a country like Kosovo should retain control over its features, functionalities, and security measures. This control is essential for ensuring the system aligns with the specific needs and requirements of the healthcare ecosystem in Kosovo.

Additionally, building a national eHealth infrastructure provides the flexibility to customize and tailor the system to meet the unique demands of the country's healthcare environment. Integration with existing systems and databases can be more seamless and efficient when the national eHealth infrastructure is designed to work cohesively with them from the beginning.

While building eServices may involve higher initial costs and development efforts, the long-term benefits of having a fully controlled and customized system outweigh the potential drawbacks.

In conclusion, the integration complexity and the importance of having full control over the national eHealth infrastructure make **the build approach the preferred option for implementing eServices as a crucial part of eHealth system in Kosovo**. Collaboration with experienced solution providers can help mitigate risks and ensure the successful development and deployment of a robust and tailored EHR solution that aligns with the country's healthcare needs and objectives.

Building block	Options	Features	Benefits	Risks	TCO	Time
e-Refferal	Build	+++	Ownership, control, customization, integration with EHR, availability of development teams	Time-consuming development and implementation	$$$	⧗
e-Refferal	Buy	++	Built know how, Roadmap	Vendor lock-in, limited customization, on-going cost	$$	⧗

7.4.11 e-Prescriptions implementation strategy

Approaches

ePrescription i.e. electronic prescribing, is the process of generating and transmitting prescriptions electronically. Instead of using traditional paper prescriptions, healthcare providers use a secure electronic system to send prescriptions directly to a patient's pharmacy of choice. E-prescribing can help improve patient safety by reducing errors related to handwriting or other manual processes, and can also help streamline the prescription process by eliminating the need for patients to bring paper prescriptions to the pharmacy.

For Kosovo, the financial model of covering medicine and how prescription drugs are funded plays a significant role in the decision-making process for implementing a national ePrescription system/solution. The financial considerations can have a profound impact on the design, scope, and implementation approach of the ePrescription system. Here are some main factors to consider:

- **Public or Private Healthcare System Funding**: In countries with a predominantly public healthcare system, where the government or state funds healthcare services and prescription drugs for the population, the implementation model may focus on a centralized approach. In countries where healthcare services are primarily provided by private

institutions, and individuals or private insurance companies bear the cost of prescription drugs, the implementation model might be more diverse.

- **Health Insurance Coverage**: The presence of health insurance schemes can also impact the implementation model. If there are multiple health insurance providers, each with their own requirements and processes, healthcare facilities might opt for systems that can accommodate various insurance billing and claims procedures.
- **Prescription Drug Reimbursement Policies**: The reimbursement policies for prescription drugs can vary widely. Some countries have comprehensive drug reimbursement schemes, while others may have more limited coverage. The chosen implementation model should be able to handle the complexities of reimbursement and billing for prescribed drugs.
- **Patient Affordability**: The financial burden on patients can also impact the design of the ePrescription system. If patients are responsible for a significant portion of the drug costs (like it is now in Kosovo), the system might include features to help them compare drug prices, choose cost-effective alternatives, or access information about drug discounts or subsidies.

Kosovo is trying to implement mandatory Health insurance coverage model but still there is no clear indication when that will finally happen but on the other hand there is strong will to develop modern national eHealth system and this Study is one of that significant step forward in that direction.

The establishment of a Fund for healthcare and achieving quick, tangible results in eHealth can create a gap in making long-term and well-informed decisions about the method and dynamics of ePrescription implementation. This gap can have similar implications for other eServices like eReferral and eAppointment, and it's essential to emphasize the importance of careful planning and decision-making. Here are some key points to consider:

1. **Immediate vs. Sustainable Solutions**: The pressure to show quick results in eHealth can lead to the implementation of immediate, short-term solutions for ePrescription and other eServices. While these quick wins may demonstrate progress, they might not be the most sustainable or optimal solutions in the long run.
2. **Interoperability and Integration**: Implementing various eServices (like ePrescription, eReferral, and eAppointment) in isolation can lead to fragmented systems that lack interoperability. It's essential to consider the integration of these eServices to create a seamless and efficient digital healthcare ecosystem.
3. **Stakeholder Engagement**: The success of eHealth initiatives depends on the engagement and collaboration of various stakeholders, including healthcare providers, technology vendors, government agencies, and patients. In the rush to achieve quick results, it's vital not to overlook the importance of involving all relevant parties in the decision-making process.
4. **Standardization and Regulations**: Ensuring standardization and adherence to regulations is crucial for the successful implementation of eServices in healthcare. Quick decisions without proper consideration for standards and regulations may lead to inconsistencies and compatibility issues in the future.
5. **Data Security and Privacy**: As eHealth initiatives involve the handling of sensitive patient data, data security and privacy must be at the forefront of decision-making. Rushed decisions may inadvertently compromise data security, leading to potential risks for patients and healthcare providers.
6. **User Experience and Training**: Providing a positive user experience for healthcare professionals and patients is crucial for the successful adoption of eHealth services. Adequate training and support should be considered as part of the implementation process to facilitate a smooth transition.

In conclusion, while the establishment of a healthcare fund and achieving quick results in eHealth are commendable endeavors, decision-makers must also prioritize making informed, long-term decisions about ePrescription and other eServices. It's crucial to recognize the interconnectedness of these services and the importance of a holistic approach to digital healthcare transformation. Emphasizing careful planning, stakeholder engagement, interoperability, security, and scalability will contribute to the successful and sustainable implementation of eHealth initiatives.

Based on these considerations we suggested that all eServices should be done after implementation of the basic eHealth infrastructures (HEI, EHR, HMIS, BHIS, etc.) because of the long-term approach. Then again, we recognize and understand political pressure for quick wins and eServices are those that can bring more visible benefit to the citizens and patient in Kosovo, so some hybrid approach could be done as intermediate or initial solutions.

Kosovo could choose between 3 options:

a) Using existing developed ePrescription module in HIFIS
b) To build new e-Prescription
c) to Buy e-Prescription system.

a) Using existing developed ePrescription module in HIFIS

Pros:

- **Low risk: S**olution is already developed; around 1000 pharmacies have been trained.
- **Control**: Source code is owned by HIF and local partner developed solution
- **Intellectual Property**: The country retains ownership of the developed software and can potentially generate revenue by licensing it to other regions or countries.

Cons:

- **Full implementation of HIF is required:** Uncertainty when the legal framework be accepted in parliament. Without fully functioning HIF it is not clear if current ePrescription module in HIFIS can be used as solution because HIFIS is integrated health insurance solution.
- **Time and Cost**: If the ePrescription module without full functionalities of HIFIS could be used as intermediate solution, detail project definition and solution redesign should be done and could be a time-consuming and expensive process, testing, and retraining.

b) Building a new ePrescription system

Pros:

- **Full implementation of HIFIS is not required**: Not need to wait for HIF to start to operate.
- **Customization**: Building an e-Prescription system allows for tailoring the solution to the specific needs and workflows of the country's healthcare system, ensuring a better fit for the unique requirements.
- **Control**: Developing an e-Prescription system provides the country with greater control over its features, functionalities, and security measures.
- **Intellectual Property**: The country retains ownership of the developed software and can potentially generate revenue by licensing it to other regions or countries.

Cons:

- **Temporary Solution:** When HIF will start to operate, integration with HIFIS or migration to HIFIS ePrescription module will be needed.
- **Time and Cost**: Building an e-Prescription system from scratch is a time-consuming and expensive process, involving significant development, testing, and maintenance costs. It may be preserved as double investment because HIF already invested in ePrescription development.

- **Resistance of private providers**: If there is no reimbursement or payment from Fond for the medicine, there is not clear motivation for private providers (pharmacies, private health providers) to use the ePrescriptions.
- **Delayed Implementation**: The time needed for development, testing and training might delay the implementation of an e-Prescription system.

c) Buying a Commercial e-Prescription system:

Pros:

- **Faster Implementation**: Commercial e-Prescription systems are readily available, allowing for quicker implementation and deployment compared to building from scratch.
- **Established Features**: Commercial e-Prescription systems often come with a wide range of features and functionalities that have been tested and proven in real-world healthcare settings.
- **Vendor Support**: e-Prescription system vendors provide ongoing support, maintenance, and updates, ensuring the system remains up-to-date and compliant with regulatory changes.
- **Cost Predictability**: The pricing structure of commercial e-Prescription system is usually more predictable, helping to manage costs more effectively.

Cons:

- **Limited Customization**: Commercial e-Prescription systems may not perfectly align with the country's specific requirements, leading to limitations in customization.
- **Vendor Dependency**: The country becomes dependent on the e-Prescription system vendor for support, updates, and any future enhancements.
- **Data Ownership and Privacy**: The country needs to ensure data ownership and privacy compliance, especially if the e-Prescription system is hosted on the vendor's servers or cloud infrastructure.
- **Integration Challenges**: Integrating a commercial e-Prescription system with existing healthcare systems and other eHealth services may require additional effort and resources.

The decision to build or buy e-Prescription involves various considerations. While both options have their merits, building a custom-made solution (building) may be the preferred approach for several reasons:

- **Integration with Other Systems**: A custom-built e-Prescription can be seamlessly integrated with other eHealth systems and databases, primarily with EHR.
- **Control and Ownership:** By building the e-Prescription system the MoH retains full control over its features, data security, and future updates. There is no dependency on third-party vendors, providing greater autonomy in managing and enhancing the portal.

However, it's essential to consider some potential challenges of the build approach:

- **Time and Cost**: Building an e-Prescription system requires time and financial investment for development, testing, and ongoing maintenance.
- **Expertise and Resources**: Developing an e-Prescription requires a skilled development team with knowledge of healthcare regulations, security protocols, and user experience design.

On the other hand, buying a pre-existing e-Prescription system solution may offer quicker implementation and initial cost savings, but it might not provide the level of customization and future scalability that a custom solution offers.

Discussions and recommendations

As we pointed out in "Discussions and recommendations" in the previous subchapters 7.4.9 and 7.4.10, all of that applies also here for e-Prescription, why the build is more preferable solution for Kosovo.

Building block	Options	Features	Benefits	Risks	TCO	Time
e-Prescription	Further development based existing e-Prescription	+++	Ownership, control, time to market,	Time-consuming development and implementation	$$	⧗
e-Prescription	Build	+++	Ownership, control	Time-consuming development and implementation	$$	⧗
e-Prescription	Buy	+++	Built know how, Roadmap, Ready for future use	Vendor lock-in, limited customization, on-going cost	$$$	⧗

Some additional consideration should be take in account regarding option a) or b). The primary factor influencing the decision on the implementation model is the financial model of covering medicine, specifically addressing who bears the cost for prescribed drugs and how they are funded. As a result, the timing of the Health Insurance Fund's (HIF) initiation becomes a critical consideration for determining the most suitable approach for the ePrescription solution.

If the HIF is expected to commence operations within the next 12 months, it would be prudent and advantageous to utilize an existing, developed ePrescription solution. Implementing an already established system can lead to quicker deployment and integration with the forthcoming HIF, ensuring a smooth transition and timely access to ePrescription services.

On the other hand, if there is uncertainty about the HIF starting its functions within the 12-month timeframe, developing a new ePrescription solution might become a practical option. Building a custom solution allows for tailored features and functionalities that can align precisely with the specific needs of the healthcare system. This approach grants greater control over the implementation process, even if the HIF's operational timeline is uncertain.

7.4.12 MDM implementation strategy

Master data management system (MDM) is a comprehensive software platform crafted to handle the management and governance of master data within organizations. It seamlessly integrates and consolidates data from diverse sources, guaranteeing a unified and precise view. With its array of features encompassing data integration, governance, quality management, and relationship management, MDM elevates data quality, operational efficiency, and regulatory compliance. Its versatile applications span across industries, benefiting customer management, supply chain optimization, and adherence to regulatory requirements.

Based on the specific requirements and complexity of the MDMD it appears that **the buy approach**, which involves purchasing ready-made solutions, **would be more effective than building a custom MDM solution**. Several reasons support this decision:

- **Time Efficiency**: Developing a comprehensive MDM from scratch would be a time-consuming process, while ready-made solutions are already available and can be implemented more

quickly. This would allow emergency medical services to benefit from the system sooner and improve patient care in a timely manner.

- **Cost-Effectiveness**: Building a custom MDM would involve significant development costs, on-going maintenance, and updates. By purchasing a pre-existing solution, the initial investment might be more cost-effective, particularly considering the need for specialized knowledge and resources.
- **Proven Functionality**: Established MDM solutions are likely to have a track record of successful implementation in various industries including healthcare. This ensures that the functionalities of the system have been tested and optimized for efficiency and reliability.

While purchasing a ready-made MDM is recommended, it's crucial to assess various vendor offerings and choose a solution that aligns closely with the specific needs and workflows of Kosovo eHealth system. Customization options might still be available to tailor the solution to suit the unique requirements of MoH.

Overall, option to buy a ready-made MDM solution can streamline the implementation process, provide access to specialist knowledge, and potentially offer cost and time savings.

Building block	Options	Features	Benefits	Risks	TCO	Time
MDM	Build	++	Ownership, control, customization	Time-consuming development and implementation, lack of specific knowledge	$$$	
MDM	Buy	+++	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost	$$	

7.4.13 Emergency IS implementation strategy

As we pointed out before, Emergency Healthcare Information System (EHIS) is aimed to support functioning of emergency medical service that at the same time enables the medical professionals to control their activities, the patients to obtain care within "a golden hour", and the management to track and monitor business processes in emergency medicine. Main components of EHIS are: Triage Management, Patient Tracking, Vital Signs Monitoring, Communication module, Information Exchange and Resource Management.

Based on the specific requirements and complexity of the Emergency Healthcare Information System (EHIS), it appears that **the buy approach**, which involves purchasing ready-made solutions, **would be more effective than building a custom EHIS solution**. Several reasons support this decision:

- **Specialist Knowledge**: EHIS involves highly specific and critical medical processes, and building a custom solution would require extensive specialist knowledge in emergency medicine and healthcare regulations. Purchasing a pre-existing EHIS solution from experienced vendors would ensure that the system is designed and tested with the necessary expertise in mind.
- **Time Efficiency**: Developing a comprehensive EHIS from scratch would be a time-consuming process, while ready-made solutions are already available and can be implemented more quickly. This would allow emergency medical services to benefit from the system sooner and improve patient care in a timely manner.

- **Cost-Effectiveness**: Building a custom EHIS would involve significant development costs, on-going maintenance, and updates. By purchasing a pre-existing solution, the initial investment might be more cost-effective, particularly considering the need for specialized knowledge and resources.
- **Proven Functionality**: Established EHIS solutions are likely to have a track record of successful implementation in various emergency medical service settings. This ensures that the functionalities of the system have been tested and optimized for efficiency and reliability.
- **Regulatory Compliance**: Ready-made EHIS solutions are often designed to meet regulatory requirements and industry standards, reducing the risk of non-compliance and ensuring patient data security.

While purchasing a ready-made EHIS is recommended, it's crucial to assess various vendor offerings and choose a solution that aligns closely with the specific needs and workflows of the emergency medical service. Customization options might still be available to tailor the solution to suit the unique requirements for Kosovo emergency medical care.

Overall, option to buy a ready-made EHIS solution can streamline the implementation process, provide access to specialist knowledge, and potentially offer cost and time savings.

Building block	Options	Features	Benefits	Risks	TCO	Time
EHIS	Build	++	Ownership, control, customization	Time-consuming development and implementation, lack of specific knowledge	$$$	⧗
EHIS	Buy	+++	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost	$$	⧗

7.4.14 Decision making tools (DSS) implementation strategy

Decision Support Systems (DSS) are software applications that aid healthcare professionals in clinical decision-making by delivering pertinent information, knowledge, and recommendations during patient care. These systems amalgamate patient-specific data, medical expertise, clinical guidelines, and other pertinent information to generate customized alerts and suggestions. DSS can analyze patient symptoms, signs, and test results, facilitating the diagnostic process by presenting potential diagnoses based on the provided data. This assists healthcare professionals in considering various possibilities and enhancing clinical reasoning capabilities.

Based on the complexity of the DSS, it appears that **the buy approach**, which involves purchasing ready-made solutions, **would be more effective than building a custom DSS solution**. Several reasons support this decision:

- **Regulatory Compliance**: Ready-made DSS solutions are often designed to meet regulatory requirements and industry standards, reducing the risk of non-compliance.
- **Specialist Knowledge**: Building a custom solution would require extensive specialist knowledge all field off medicine and healthcare regulations. Purchasing a pre-existing DSS solution from experienced vendors would ensure that the system is designed and tested with the necessary expertise in mind.

- **Time Efficiency**: Developing a comprehensive DSS from scratch would be a time-consuming process, while ready-made solutions are already available and can be implemented more quickly. This would allow MoH to benefit from the system sooner and improve patient care in a timely manner.
- **Cost-Effectiveness**: Building a custom DSS would involve significant development costs, on-going maintenance, and updates. By purchasing a pre-existing solution, the initial investment might be more cost-effective, particularly considering the need for specialized knowledge and resources.
- **Proven Functionality**: Established DSS solutions are likely to have a track record of successful implementation. This ensures that the functionalities of the system have been tested and optimized for efficiency and reliability.

Overall, option to buy a ready-made DSS solution can streamline the implementation process, provide access to specialist knowledge, and potentially offer cost and time savings.

Building block	Options	Features	Benefits	Risks	TCO	Time
DSS	Build	++	Ownership, control, customization	Time-consuming development and implementation, lack of specific knowledge	$$$	⧗
DSS	Buy	+++	Built know how, Roadmap, Training and documentations	Vendor lock-in, limited customization, on-going cost	$$	⧗

7.4.15 Business model of the eHealth core systems

In the discussion about today's main business models in acquiring software solutions, three primary models were addressed: owning a software solution, building a software solution, and Software as a Service (SaaS).

- **Using a Standard Software Solution** -This model involves purchasing standard software solutions and acquiring a license for their use . There are initial procurement costs, as well as on-going expenses for maintenance and support.
- **Building a Software Solution** - The build approach entails developing a custom software solution tailored to the specific requirements of the national eHealth system. This model allows for full control and customization but may involve higher initial costs and a longer development timeline. While it can be effective for highly specialized and complex systems, it requires expertise in both software development and domain-specific knowledge.
- **Software as a Service (SaaS**) - SaaS is a model where software applications are delivered to end-users over the Internet on a subscription basis. With SaaS, the end-user does not own the software but instead pays for its use as a service. This model offers advantages in cost and flexibility, as there are no upfront license fees, and updates and maintenance are typically handled by the SaaS provider. SaaS is generally faster to deploy and allows for scalability based on user demand. However, it may have certain drawbacks, such as a lack of control over the software, potential data security concerns, and dependency on the SaaS provider's infrastructure.

Here we are exploring the characteristics, benefits and disadvantages of **SaaS model for eHealth**. SaaS is a software licensing and delivery model in which software is:

- licensed on a subscription basis - usually monthly or annually
- centrally hosted in the cloud
- accessed via a browser over an internet connection

SaaS (Software as a Service) offering **several advantages** that align well with the requirements of large-scale healthcare initiatives:

- **Cost-Effectiveness**: National eHealth systems can benefit from the cost-effectiveness of SaaS. As a subscription-based model, it reduces the need for significant upfront investments in software licenses and infrastructure. This is especially beneficial for countries with limited IT budgets, allowing them to allocate resources more efficiently.
- **Scalability**: National eHealth systems often need to cater to a large number of healthcare providers, patients, and other stakeholders. SaaS provides scalability, enabling the platform to accommodate varying user demands and easily expand as the system grows in scope and user base.
- **Quick Deployment**: SaaS applications are already pre-configured and hosted in the cloud, which significantly speeds up the deployment process. This ensures that critical healthcare services can be rolled out faster, benefiting patients and healthcare providers sooner.
- **Accessibility and Mobility**: SaaS applications are accessible through web browsers, making them available to users with internet access on various devices, including desktop computers, laptops, tablets, and smartphones. This accessibility allows healthcare professionals and patients to access health information and services from anywhere, improving patient care and efficiency.
- **Expert Support:** SaaS providers typically offer professional support and regular updates, reducing the burden on national eHealth system administrators and ensuring that the platform remains up-to-date with the latest features and security enhancements.
- **Interoperability:** Many SaaS providers design their applications with interoperability in mind, making it easier to integrate the national eHealth system with existing healthcare infrastructures and exchange data with other healthcare providers and institutions.
- **Disaster Recovery and Redundancy**: SaaS providers often have robust disaster recovery measures and redundancy options in place, ensuring that data and services remain available even in the event of unexpected failures or outages.

Despite the numerous advantages, **some challenges** and considerations should be taken into account when adopting SaaS for national eHealth systems:

- **Data Privacy and Sovereignty**: For sensitive healthcare data, it is essential to ensure that data privacy and sovereignty regulations are met, especially when dealing with cross-border data storage in the cloud.
- **Connectivity**: SaaS relies on internet connectivity; thus, uninterrupted access to critical healthcare services requires reliable and stable internet connections.
- **Integration and Interoperability**: Integration with existing healthcare systems and data sharing with various stakeholders may require careful planning and standardization to ensure smooth interoperability.
- **Customization**: While SaaS platforms often offer customization options, some national eHealth systems may have unique requirements that may necessitate custom development or additional configuration.

As one of the main concerns and showstopper for wilder implementation of SaaS in the core national eHealth systems are **data security, data privacy related to (public) cloud services**. Even though the EU promotes the benefits of cloud computing in the healthcare since 2014 (https://digital-strategy.ec.europa.eu/en/library/what-are-benefits-cloud-computing-healthcare-sector) there are still a lot of barriers to overcome. One of the important steps has been initiated in 2021 by The European Union Agency for Cybersecurity (ENISA) that published the **Cloud Security for Healthcare Services report**, which provides **cybersecurity guidelines for healthcare organizations** to help further digitalize with cloud services. In particular – "*The report addresses these concerns by providing security guidelines for three main areas in which cloud services are used by the healthcare sector, namely for:*

- ***Electronic Health Record** (EHR), i.e. systems focusing on the collection, storage, management and transmission of health data, such as patient information and medical exam results;*
- ***Remote Care**, i.e. the subset of telemedicine supporting remote patient-doctor consultations;*
- ***Medical Devices**, i.e. cloud services supporting the operation of medical devices such as making medical device data available to different stakeholders or for device monitoring.*

For each of these use cases, the report highlights the main factors to be considered when healthcare organizations conduct the relevant risk assessment – for example, in terms of risk to sensitive patient data or availability of a medical service. These guidelines, however, are only a first step for healthcare providers to adapt securely to the cloud. More support is needed, such as established industry standards on cloud security, specific direction from national and EU authorities, and further guidelines from Data Protection Authorities on transferring healthcare data to the cloud.

The report also proposes a set of security measures for healthcare organizations to implement when planning their move to cloud services, such as establishing processes for incident management, defining data encryption requirements, and ensuring data portability and interoperability. The measures are proposed taking into consideration the draft candidate EU Cybersecurity Certification Scheme on Cloud Services (EUCS) to ensure compatibility and requirements mapping. The Agency's draft scheme is part of the cybersecurity certification framework aimed at enhancing trust in ICT products, services and processes across Europe. The draft scheme is open for public consultation until 7 February 2021."

(https://digital-strategy.ec.europa.eu/en/library/study-cloud-security-healthcare-services)

In summary, SaaS can be a compelling option for national eHealth systems, offering cost-effectiveness, scalability, quick deployment, and accessibility but for now main core systems should be buy or build and owned, and SaaS model can be used for some standard eHealth solutions (ie. EHIS, DSS, HMIS, …), but for the core components, still because of undefine security guidelines, we will recommend to monitor the development in that area and migrate eventually in the years to come.

7.4.16 Analysis of Legacy systems

The legacy systems, including Health Worker Module, Licensing of Private Health Institutions Module, and Health Professional (Specialist) Module, have been developed to cater to the specific needs and operational workflows of the Ministry of Health (MoH) and various health institutions. These systems have been implemented across a wide range of healthcare facilities and are actively utilized by users in their daily work activities.

In general, there are 2 different options to consider **for each Legacy system**:

a) further development of current systems
b) Retirement of current system and replacement with new ones

Option a) – Further development of current systems

Pros:

- **Complete Control:** MoH has complete control to this solution, which gives MoH full control over the system, allowing the healthcare organization to customize it according to the specific needs.
- **Greater Flexibility:** can be designed to incorporate emerging technologies, giving the healthcare organization greater flexibility in the long run.
- Lower Long-term Costs: there may be lower long-term costs that includes not buying additional licensing fees. The costs might be for maintenance and building/developing new modules and features
- **Trained Users:** TOTs and current users among 29 municipalities have been trained and are more familiar to use and work with BHIS.

Cons:

- **Coverage:** Challenges related to infrastructure, such as network, printers, and PCs, have impacted the utilization of the Legacy systems.
- **Integration:** with BHIS, between Legacy systems itself and other current systems like KMA, Medical Chambers, Universities, etc. is currently missing.

Option b) – Retirement of Legacy systems and their replacement with new ones

Pros:

- **Reduced Technical Debt:** Legacy systems often accumulate technical debt over time due to patches and modifications. By starting afresh, technical debt can be minimized or eliminated, leading to a more maintainable and sustainable solution in the long run.
- **Meeting User Needs**: Building a new solution allows for direct feedback from end-users. This means the solution can be tailored to their specific needs, potentially improving overall user satisfaction and efficiency.
- **Improved Security and Privacy:** Starting anew allows for a thorough assessment of security measures and privacy protocols. The new system can be built with the latest security standards in mind, helping safeguard sensitive patient data and protecting against potential cyber threats.
- **Innovative Features**: A new solution allows for innovative features and functionalities that may not have been possible or practical to implement in the current BHIS. These innovations can lead to improved patient care, streamlined processes, and enhanced analytics for decision-making.

Cons:

- **Time to market**: Developing a new solution from scratch is a time-consuming process. The projected minimum 24-month duration without considering the procurement process could mean a significant delay in implementing the solution and addressing the current system's limitations.
- **Project Complexity and Risk**: Developing a new solution is a complex undertaking that involves various stakeholders, such as software developers, healthcare professionals, and IT personnel. The project's complexity increases the risk of delays, technical issues, and unforeseen challenges.

- **High Development Cost**: Creating a new solution from scratch can be significantly more expensive than upgrading or customizing an existing system. The cost of development, implementation, and training can strain the organization's budget, potentially leading to financial challenges.
- **Data migration challenges**: Migrating data to the new solution could pose significant difficulties. There is no guarantee that all data will be correctly migrated, potentially leading to data loss or corruption, which could negatively impact patient care and administrative processes.
- **User acceptance**: Introducing a completely new solution will require additional training for end-users and administrative staff. This could lead to resistance from some users who are accustomed to the current system and may be reluctant to adopt the new one. The potential for passive or active resistance could impede the successful implementation of the new solution.

Discussions and recommendations

There is no urgent need to retire any Legacy system due to technology or functional needs. Also there is no high risk for keeping those solutions that cannot be managed. Retiring those solutions and investing in new ones should be time and cost consuming with any actual benefit.

So, in summary, we believe that the **best option is to continue investment in all Legacy systems**, coupled with module improvements, functional upgrades, and infrastructure enhancements.

To ensure optimal performance and user satisfaction, it is essential to prioritize the enhancement of existing modules based on user feedback and the resolution of reported bugs. Addressing these issues will contribute to an improved user experience and streamline workflow efficiency. Ensuring the seamless exchange of data between systems is of utmost importance. It is essential to prioritize the implementation and interconnection of Legacy systems across all health institutions and units to achieve comprehensive coverage and successful implementation.

Legacy system	General remarks	Positive aspects	Possible cautions	Recommendations for further steps
Health Worker Module	Continue with investment in Health Worker Module	MS technology stack, mobile compliant	Vendor lock-in, IT vendor abandonment of projects,	FHIR API integration, functional upgrades, Integrations with MDM and FHIS
Licensing of Private Health Institutions Module	Continue with investment in Private Health Institution Module	MS technology stack, mobile compliant	Vendor lock-in, IT vendor abandonment of projects,	FHIR API integration, functional upgrades, integrations with FHIS
Health Professional (Specialist) Module	Continue with investment in Health Professional (Specialist) Module	MS technology stack, mobile compliant	Vendor lock-in, IT vendor abandonment of projects,	FHIR API integration, functional upgrades, Integrations with MDM and FHIS

Building block	Options	Features	Benefits	Risks	TCO	Time
Legacy systems	Further develop-ment	+++	Owner-ship, control, time to market,	Vendor lock-in, IT vendor abandonment of projects	$	⧗
Legacy systems	Build	+++	Owner-ship, control	Time consuming with imple-mentation and user adaption risks, data migration	$$$	⧗

7.5 Risk Assessment

Implementation of a new eHealth system on a national level is a complex undertaking that bears a number of risks. These risks need to be recognized, and then managed through suitable mitigation measures. Risk assessment involves identifying and analyzing potential risks and challenges that may impact the successful implementation of eHealth initiatives in Kosovo. The planning process of the development of such large-scale projects must include a risk-assessment as there are many factors that can impede the success of the undertaking. It is important to outline key risks and ways to mitigate the risks identified. The mitigations are measures or implementation strategies, which should become integral part of all projects' activities at different levels.

When assessing the influence of possible risks, we used the basic risk assessment matrix, which simultaneously assesses the level of **likelihood** (that a certain risk will actually occur) and the level of **impact** (seriousness/severity) of possible consequences (in the event that the risk actually occurs), after which the possible total negative influence of a potential event/circumstance is assessed as a combination of those two aspects. Individual risks are then divided into three possible categories according to their overall/combined **risk level**:

- High risk (H / red);
- Medium risk (M / yellow):
- Low risk (L / green).

Risk assessment matrix

Impact (of possible cosequences)				
	High	M	H	H
	Medium	L	M	H
	Low	L	L	M
		Low	Medium	High
		Likelihood (of risk realization)		

At this moment, we have identified several risks that can impact the successful development of eHealth in Kosovo. These are summarized in the following table. Overall, without underestimating these risks, we believe they are manageable and will not jeopardize the successful outcome of the eHealth implementation.

Risk level	Area of risk	Risk	Likelihood	Impact	Mitigation measures / strategy
High	Institutional	Insufficient number of qualified IT personnel with required knowledge	High	Medium	Develop a plan for continuous education in ICT field and eHealth solutions for healthcare professionals. Introduce direct and indirect motivation of ICT professionals working in the healthcare system: professional development and training of ICT staff at the required level, participation in specialized trainings in ICT field, encouraging the development of ICT staff and exchange of knowledge.
High	Institutional	Legal and managerial barriers (outside the influence of the implementers) for realization of the required changes	Medium	High	Establish strong eHealth governing body, build capacities of all stakeholders involved especially for project management, monitoring and evaluation. Engage political support. Lobby for the adjustment of the legal and regulatory framework. Make efforts to communicate plans clearly to all parties involved, including citizens.
Medium	Institutional	Lack of clear direction or focus leading to inefficient use of resources	Medium	Medium	Prepare and adopt eHealth Strategy as a fundamental document with clear goals and direction, which all other plans and actions can relate to.
Medium	Institutional	Resistance to change from individual users (medical staff)	Medium	Medium	Develop change management strategies, provide adequate training and support, and communicate the benefits of eHealth.
Medium	Institutional	Impossibility to ensure the continuity of the implementation and sustainability of projects due to political issues and/or poor commitment and involvement of stakeholders	Low	High	eHealth is already considered priority of Government. Reduction of risk by involvement of large stakeholder groups including decision-makers in health institutions. Build sustainable eHealth governance with a technical structure that is politically neutral.
Low	Institutional	Resistance to change from decision makers, managers, service providers and other sector stakeholders	Low	Medium	Early inclusion and regular sharing of information and asking for feedback.

Risk level	Area of risk	Risk	Likelihood	Impact	Mitigation measures / strategy
Low	Institutional	Needed legislation not in place	Low	Medium	Follow recommendations for needed legislation change according to provided analysis. Ensure compliance with relevant regulations and work towards resolving any legal challenges.
Low	Institutional	Political acceptance of reforms not ensured	Low	Medium	Strive to achieve broader consensus amongst the participating stakeholders, to ensure larger ownership and sustainable implementation.
Low	Institutional	Other health reforms are not in line with eHealth development	Low	Low	Coordinate all strategic activities within the MoH and adjust all plans simultaneously. The eHealth governing body has to be informed of innovative initiatives from the stakeholders.
Medium	Financial	Discrepancy between the need to rationalize expenses while increasing quality and preserving the accessibility to health system	Medium	Medium	When needed, conduct cost-benefit analyses that will help to achieve a balance between cost savings and improvement of quality.
Medium	Financial	Imbalance of needs in financial resources with the planned budget execution	Medium	Medium	Adequate budgetary planning, investment attracting and monitoring of disbursement. Identify and participate in international donors' calls for projects.
Medium	Financial	Vendor lock-in	Medium	Medium	Have a clear eHealth strategy, and what should be part of the strategy is certainly the availability of data. Correct contractual documentation should clearly define what should be included and what should be excluded from delivery. Public procurement should support and insist on purchasing solutions based on open standards and/or open-source software. Take special attention to the development of neutral functional and technical specifications and well-balanced contracts during tendering. Develop common guidelines for bids for different projects. Open standards also support competition, helping to avoid supplier-based inference and can save costs.

Risk level	Area of risk	Risk	Likelihood	Impact	Mitigation measures / strategy
High	Technical	Inadequate quantity and or/quality of needed IT infrastructure (hardware)	High	Medium	Invest in IT infrastructure according to investment plan and ensure additional funding for its maintenance and renewal.
High	Technical	Inadequate connectivity, power outages, or lack of technical infrastructure required to support eHealth applications	High	Medium	Prepare infrastructure development plans and contingency measures and implement them continuously.
High	Technical	Inadequate compatibility and interoperability of existing healthcare systems	Medium	High	Prepare and implement standards and protocols to ensure seamless data exchange and integration between different healthcare providers and their IT systems.
Low	Technical	Unauthorized access to patient data, data breaches, and privacy violations	Low	Medium	Implement robust data security measures, conduct regular security audits, and ensure compliance with data protection regulations.

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