PUBLISHING A “BUILDABLE” DIGITAL HEALTH BLUEPRINT FOR KOSOVO

Developing an implementable, conformance-testable, standards-based digital health infrastructure that operationalizes person-centric, guideline-adherent care at national scale.

List of Figures

Introduction

This section describes the document's purpose and intended audience, a summary of key takeaway messages, and the layout of the document including its sections and appendices.

Document purpose and intended audience

This blueprint document is intended to augment the e-health feasibility study conducted in 2023. It goes into detail on the structure of the national HIE proposed in the feasibility study, and documents solutions for the challenges around governance and capacity that were documented in the feasibility study. Further it provides a full cost estimate for setting up and running the HIE for a period of 10 years and models the benefits that can be accrued from the improved the quality of care that will result from this.

This document is intended principally for the Kosovo Ministry of Health. However, the technical sections, especially those on HIE Components will be useful for firms or consultants engaged by the Ministry of Health to set up the various HIE components or bring existing systems into conformance with the HIE. Finally, this document will be useful for development partners who may, in future, assist Kosovo with various aspects of the HIE.

Key takeaway messages

Following are the document's key takeaway messages.

1 Kosovo is very well positioned to launch the process of setting up a Health Information Exchange

The TWG agreed on the priority areas of disease burden, and this maps very well to the health and digital health strategies in the country. Further, Kosovo is in a high state of digital readiness in terms of infrastructure, connectivity, and the usage of the Internet to seek information about healthcare. The foundations are therefore in place to start to the process.

2 The use of global standards for health information exchange provides reliability and risk mitigation

Global standards like FHIR, SNOMED, ICD10, LOINC and others have been extensively tested, are widely used, and have had years of expertise go into developing and maintaining them. The use of these global standards, as opposed to developing standards specific to Kosovo, will mean that Kosovo is taking advantage of the experience of several other implementations and wide global expertise. This will mitigate risk and allow the Ministry of Health to focus on the business of providing healthcare as opposed to standards development.

3 The data in existing systems can be leveraged to provide a running start for the implementation

A number of existing point of service applications in Kosovo have reached scale and, while these systems will remain point of service applications, the data that has been collected using these systems over time can be fed into the HIE to give the implementation a running start

4 The use of Computable Care Guidelines will allow for improved quality of care and lead to a healthier population

Computable Care Guidelines allow for guideline-based care to be implemented in digital systems. This results in improved quality of care and helps to lower the disease burden in the country. For diseases like diabetes, guideline-adherent can result in a dramatic lowering of the disease burden. This, in turn, means a healthier and more productive population and an improved GDP.

5 An effective mechanism of governance for digital health is critical for the success of the implementation

It will be critical that Ministry of Health is able to exert governance over the implementation and to ensure that all digital health initiatives adhere to the norms and standards for Kosovo and align with national health and digital health strategies.

6 The adoption of Kosovo's digital health norms and standards by the private sector will be key to the success of the implementation

Kosovo has a significant private sector for healthcare and a number of citizens seek care in the private sector. To gain maximum benefit from the national digital health roll-out, it will be critical for the private sector to adopt and adhere to the digital health norms and standards for Kosovo. If this does not happen, patient data will be fragmented across multiple disconnected systems and continuity of care will be lost.

7 The implementation of a conformance-testable, standards-based, Health Information Exchange in Kosovo is cost effective and will result in real economic benefits

As shown by the investment case model in Appendix 2, the setup and maintenance over 10 years of a national Health Information Exchange in Kosovo can be done in 0.95% of the total

health expenditure and will begin to return economic benefits owing to healthier population within 4 years. This makes it a very worthwhile investment.

Layout of this document and its sections

This document is prepared in six sections and two appendices:

- **Introduction**: this section – which includes the purpose and intended audience, key takeaway messages, and the layout of the document.
- **National Burden of Disease**: a high-level summary and analysis of the key burdens of disease in Kosovo as extrapolated from data from neighboring countries made available by the Institute for Health Metrics and Evaluation (retrieved: April 20th, 2024).
- **National Digital Health Readiness:** a summary of the country's scoring across the key metrics of the digital health readiness and the anticipated implications for the national infrastructure project.
- **National Health and Digital Health Strategies**: a summary overview of the elements of the national health strategy and the national digital health strategy that directly apply to shared infrastructure (the national Health Information Exchange, HIE) and a mapping of key strategic goals to operational workflows.
- **Components of a Health Information Exchange**: a description of architectural actors in a national HIE and the roles they play in operationalizing key workflows. This section articulates a conformance-testable set of national digital health norms and standards.
- **Digital Health Landscape and Quick-win Opportunities**: a high-level overview of existing solutions deployed at scale that can be quickly leveraged to give a "running start" towards a national infrastructure.
- **Digital Health Governance**: a recommended governance structure that may be leveraged to ensure coordination and resource pooling across the various disparate digital health activities. A suggested policy structure is also described that supports national scale health data exchange across both private and public sector care providers.
- **Appendix-1: Example Use Case**: this section provides a worked example of digitally enabled care workflows using Diabetes as the target. This example generically references WHO's recommended care guidelines and maps these guideline-based care pathways to the blueprint's architectural actors and the care delivery workflows they support.
- **Appendix-2: Exemplar 10-year Digital Health Investment Plan**: this section leverages a digital health investment tool to develop a 10-year cost-utility analysis (CUA). The model's assumptions are documented, and a sensitivity analysis illustrates the impacts of key implementation-related variables on cost-effectiveness, as measured against the national Cost-effectiveness Threshold (CET).
- **Appendix-3: Inputs for National Level Health Data Governance Roles**: this section describes the responsibilities typically associated with key roles related to health data governance

National Burden of Disease

KEY MESSAGES: There is a strong opportunity to ameliorate Kosovo's burden of disease through investments in national-scale digital health infrastructure.

- Content from peer neighbor countries was used to model Kosovo's burden of disease. This burden is dominated by NCDs, and addressing these must drive the target use cases for our digital health infrastructure investments.
- Digital health investments should focus on increasing systemic adoption of guideline-based care across the healthcare delivery network.

RECOMMENDATIONS: Kosovo will be well-served by timely and rigorously developed metrics related to health and digital health metrics.

- Adopt and operationalize a methodologically sound method for measuring burden of disease in disability-adjusted life-years (DALYs). Regularly publish these.

This section summarizes disease burden data for Kosovo, estimated from data on neighboring countries provided by the Institute for Health Metrics and Evaluation) IHME[1] . IHME is a global repository of health metrics and indicators. It develops and reports metrics based on the country content found at the Global Health Data Exchange.[2] Additionally World Bank[3] data on demographics and health system operations for Kosovo is also covered. The following content is from the most recent statistics published by IHME and the World Bank. IHME and World Bank graphics are included in this document without alteration.

[1] https://www.healthdata.org
[2] https://ghdx.healthdata.org/countries
[3] https://data.worldbank.org/country/kosovo?view=chart

Demographics

Figure 1 – Current population and growth forecast

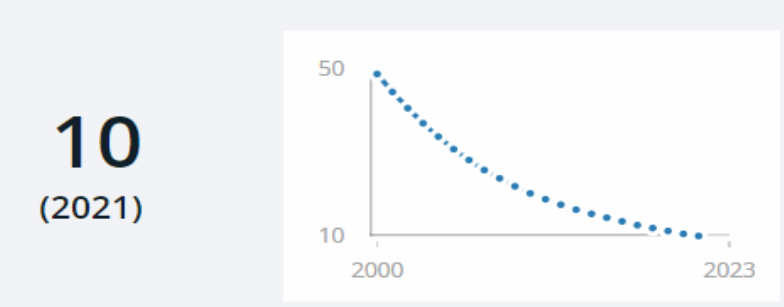

Figure 2 – Mortality Rate – under (-5 per 1000 live births)

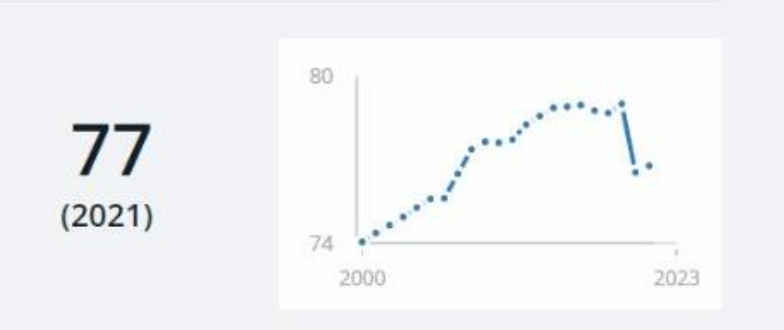

Figure 3 - Life Expectancy, current and forecast

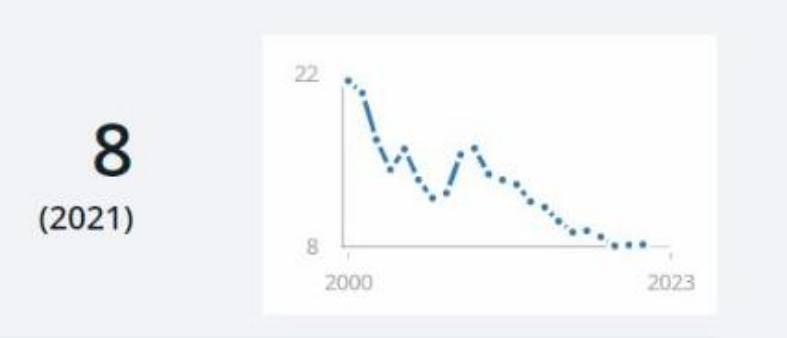

Figure 4 - Adolescent Fertility Rate (births per 1000 women ages 15-19), current and forecast

Burden of disease

Since the IHME website did not have data for Kosovo, and other data sources were also not available, IHME data from neighboring countries was used to estimate the Top 10 burden of disease for Kosovo.

Figure 5 - IHME disease burden data for Kosovo's neighboring countries

DALYs Cause	DALYs total across peers	Estimated DALYs (Kosovo)
Ischemic heart disease	721,312	107,152
Stroke	706,750	104,989
Low back pain	272,658	40,504
Tracheal, bronchus, and lung cancer	230,330	34,216
Diabetes mellitus	230,147	34,189
Chronic obstructive pulmonary disease	109,650	16,289
Colon and rectum cancer	101,645	15,100
Age-related and other hearing loss	99,439	14,772
Headache disorders	94,516	14,040
Hypertensive heart disease	91,850	13,644
Falls	87,360	12,977
Breast cancer	80,169	11,909
Cardiomyopathy and myocarditis	75,101	11,156
Neonatal disorders	70,934	10,537
Self-harm	61,922	9,199
Road injuries	52,762	7,838
Populations		
Kosovo	1,800,000	
Montenegro	617,000	
Serbia	6,660,000	
North Macedonia	2,060,000	
Albania	2,780,000	
Ratio: Kosovo / peers	**0.148551622**	

Figure 6- Estimating Kosovo's Top Ten Disease Burden using population and disease burden data from neighboring countries

In order to estimate Kosovo's top disease burden based on DALY's (see yellow shaded cells in Figure 6), the top total DALYs for Kosovo's neighbors were calculated from IHME data. These were then pro-rated based on the ratio of Kosovo's population to the total population of the peer countries to obtain estimates for Kosovo's DALYs.

Discussion regarding implications of the IHME indicators

The TWG's input around the Top 10 burden of disease largely aligned with the estimates presented above, with Ischemic Heart Disease, Lung Cancer, and Diabetes being the top areas of concern with Stroke, and Hypertensive Heart Disease following. This indicates that the primary disease burden in Kosovo is driven by non-communicable disease as indicated by several different data sources. Further, the increasing life expectancy and decreasing population growth rate mean that the population, in general, is aging. All of this highlights the need for a shift towards integrated care, and digital health interventions tailored to supporting long term and chronic care. This, in turn, indicates that a Health Information Exchange would be a key component of the digital health landscape going forward, allowing for patient data to be available across providers at different levels of the health system, supporting longitudinal care, and tracking visits, referrals, and drug dispensation ultimately leading to digitally enabled continuity of care across the life course of a citizen of Kosovo

Further, Quality of Care and a Focus on Health Outcomes were seen as the top 2 priorities as regards reportable indicators. This lends itself to the use of Computable Care Guideline, as discussed in later sections of this document.

There was no reliable data to be found on health expenditures but given the absence of a national health insurance scheme, patients have the option to choose between free care provision in the public sector or out of pocket payments for private sector care. With a new Health Insurance Law in the pipeline, the digitalization of healthcare is critical as Kosovo proceeds on the path to Universal Health Coverage.

In general, given the above context, digital health investments tailored towards treating chronic disease can certainly help to address Kosovo's disease burden.

Finally, given that data for Disability Adjusted Life Years (DALY's) for Kosovo is today not readily available, Kosovo would be well-served by developing a methodologically sound method of determining DALY's and publishing these regularly.

National Digital Health Readiness

KEY MESSAGES: Kosovo is in a high state of digital readiness to launch the HIE

- Kosovo is well served by its existing digital infrastructure, including the eKosova platform and existing eGovernment datacentre hosting infrastructure.
- The citizenry is relatively digital-savvy and already uses the Internet and Internet enabled devices to access information including for healthcare

RECOMMENDATIONS: Kosovo needs to leverage this readiness by a cohesive implementation strategy.

- A focus on applying technology to maximize the benefit to patients and healthcare providers is needed
- As a purely practical matter, MOH should submit an official survey response on the Global Digital Health Monitor. This should be refreshed every two years.

Digital Readiness Overview

Given that Kosovo is not represented at the Global Digital Health Monitor (GDHM), digital health readiness data was gleaned from other sources.

Kosovo has a high degree of digital health readiness. Cellular coverage is widespread, investments in data center infrastructure are being leveraged, smartphone use is high, and citizens use the Internet to access information including about health

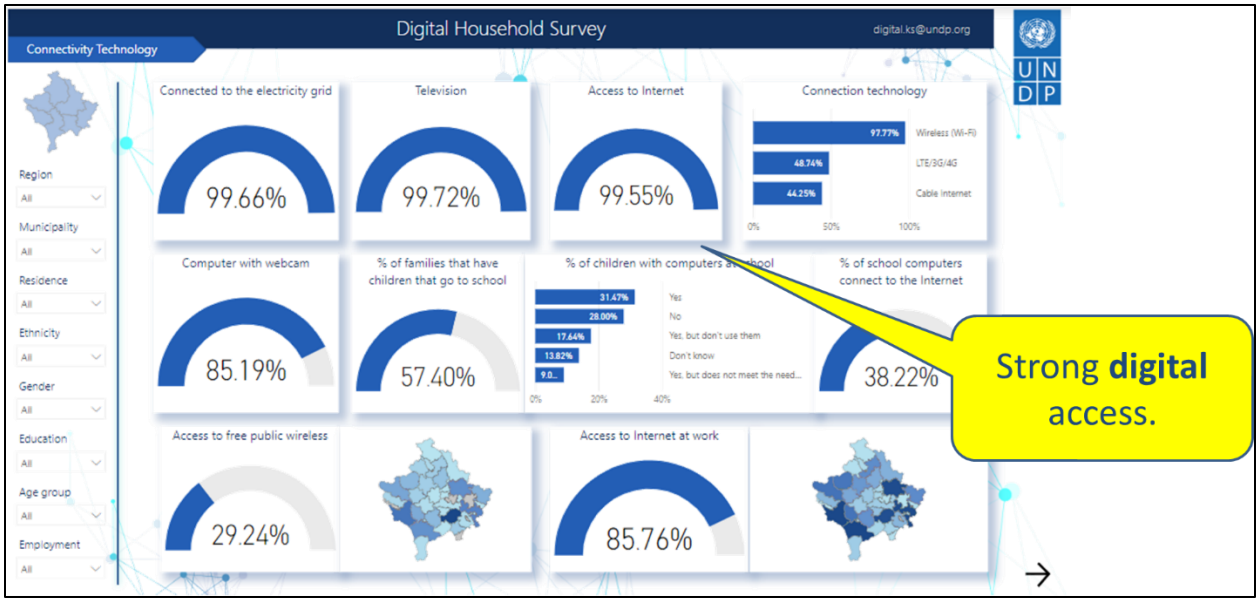

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Figure 7 - Widespread access to the Internet in Kosovo

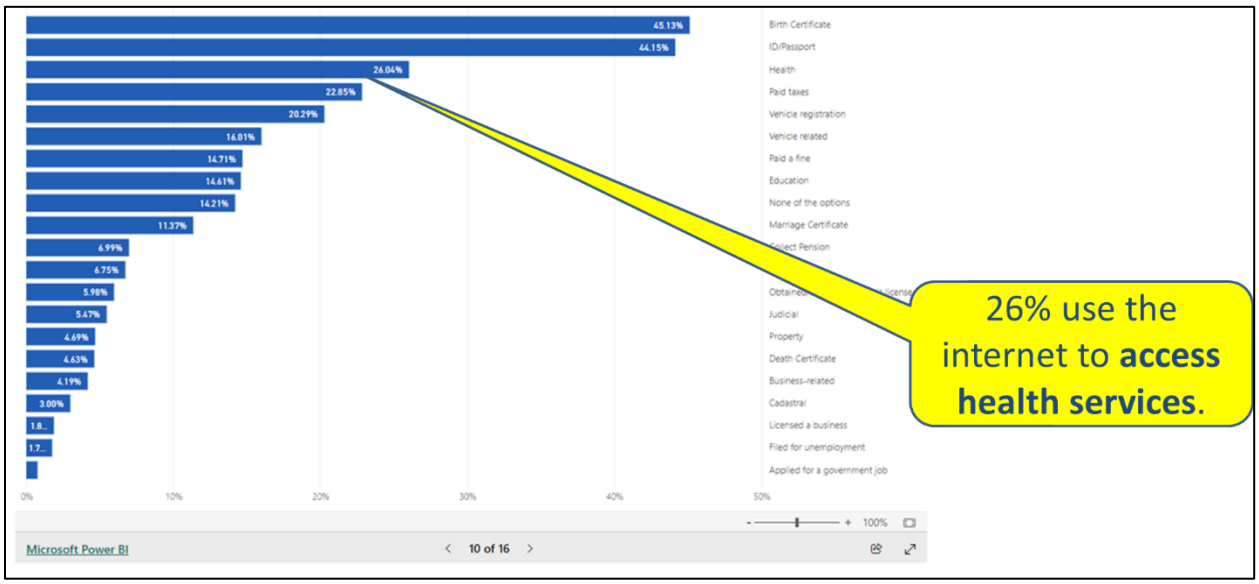

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Figure 8 - 26% of respondents use the Internet to access health services

Further, the existing eKosova mobile application offers citizens access to their own data and can become a means for citizens to access and control their own health data.

[4] https://www.undp.org/kosovo/digital

The TWG was also surveyed to obtain their responses to questions would otherwise inform the score on the GDHM. It should be noted that only 8 members of the TWG responded to the questionnaire. The results are shown below.

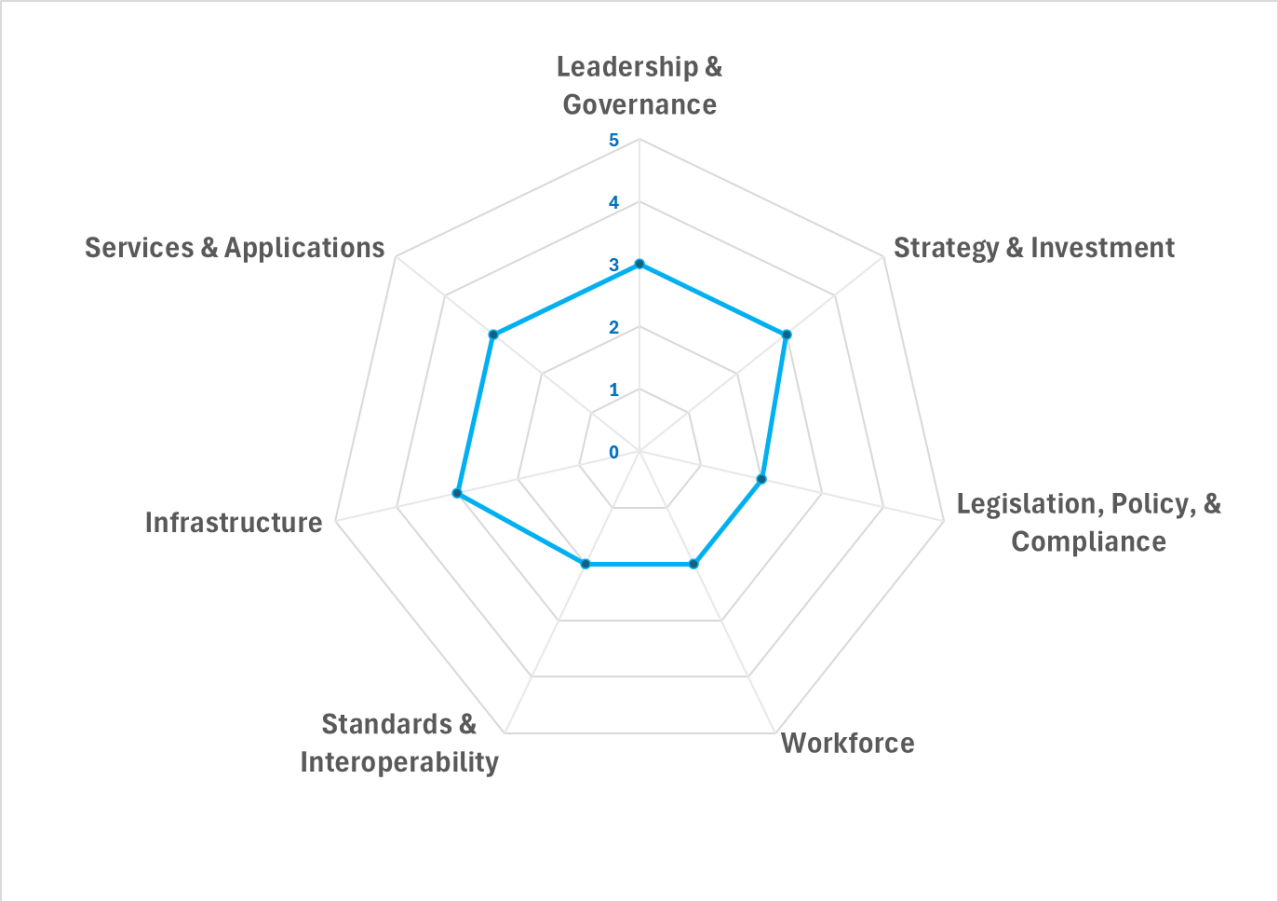


Figure 9 - Spider Graph of TWG Responses to GHDM questions

The above graph indicates that respondents felt that Kosovo ranked relatively higher on Leadership and Governance, Strategy and Investment, Services and Applications, and Infrastructure, but lower on Standards and Interoperability, Workforce, and Legislation, Policy and Compliance. While the sample size is admittedly small, this largely aligns with other sources of information e.g. the UNDP study referenced above. Kosovo would be well served by submitting an official response to the GDHM periodically so that it is able to understand both its own digital readiness, as well as where it stands relative to peers and neighbors.

A 2021 World Bank report on Digital Readiness in the Civil Service in Kosovo[6] had findings that also largely aligned with the above graph. It found that while most public officials were satisfied with infrastructure and with the IT services being provided, there were significant challenges with recruiting qualified and trained staff, and with the legislative and policy landscape to allow for effective e-governance to be implemented.

[6] https://documents1.worldbank.org/curated/en/156601632212564932/Key-Findings-and-Recommendations-from-a-Survey-of-Public-Officials-in-Kosovo-Report.docx

Discussion and Implications of the GDHM indicators

It can be concluded from the previous section that, despite challenges with workforce capacity, Kosovo owing to its infrastructure, digitally savvy population, availability of funding, and political will is well-placed to start its HIE journey. However, to avoid challenges down the road, capacity building is a critical requirement, along with policy and legislative changes to support the exchange of data in a standardized way. Both these issues are addressed in the section on Governing the National HIE later in this document. It will be important to invest in these areas to ensure that Kosovo can maximize the benefit of being well placed from a digital readiness perspective.

The use of the eKosova application can be an accelerator for the digitalization process in healthcare and a powerful way to grant citizens access to, and control over, their own health data.

National Health and Digital Health Strategies

KEY MESSAGES: Kosovo's existing health strategies are generally well focused on the NCD-dominated disease burden, but digital health strategies and investments to date do not cohesively address it.

- There is a clear role for the blueprint in helping inform and coordinate digital health investments that target the dominant disease burden: NCDs.
- The private sector remains largely outside regulation as far as digital health is concerned.

RECOMMENDATIONS: Key strategic course-changes should be informed by the recent blueprint workshop process.

- A policy and legislation-supported strategy for increasing MOH governance over private sector care delivery should be implemented. The national digital health infrastructure can and should play a key role as an expected "instrument" of this strategy.
- The national digital health strategy should be revisited to embrace the benefits that can be realized from the standards-based approach. Regarding digital health solutions, a preferential hierarchy of adopt-adapt-develop should be officially articulated. Kosovo is not well-served by large public investments in custom-built, non-standard digital health solutions.

Overview and background

Kosovo's draft Health Sector Strategy for the years 2023-2030 aims at developing a health system capable of providing high quality and safe health services to the population. Specifically, the Health Sector Strategy has the following major objectives:

- Improved infrastructure
- Strengthened Family Medicine
- An improved process of drafting clinical guidelines, and the use of clinical audits to maintain quality.
- Regulation of drug prices and the development of an Essential Medicine List

- Implementing a new law on Health Insurance
- Implement ICD11 and ICHI via electronic modules for health reporting.
- Promote health education.
- Target Non-Communicable Diseases by reducing risk factors.
- Improve regular immunization.
- Strengthen maternal, adolescent and child health.
- Address oral and mental health issues.
- Improve tracking and assess impact of Environmental Health issues.
- Establish partnerships and participation in regional and international initiatives.
- Strengthen monitoring.

Specifically, the Health Sector Strategy points to a "full functionalization of health information system" as a way to improve the health of the population.

It is worth noting that the disease areas identified as areas of focus by the Health Sector Strategy align well with the burden of disease and the notions of quality and safety that were identified by the TWG as priorities.

Aligned with the Health Sector Strategy, the Strategic Plan for the Development of the Health Information System 2024-2030, published in March 2024, states that:

"The available analytical data imposed the necessity to recommend investment in a national health information system, which will enable important steps in improving the quality and safety of health services for its citizens in the medium term from 2024 to 2030"

The above echoes that quality and safety of health services for the population are key pillars of the way forward for healthcare in Kosovo.

The Strategic Plan for the Development of the Health Information System aims at continued investment in legacy systems, including the Basic Health Information System (BHIS), and a focus on interoperability so that these systems may be used more effectively. Further it envisages the need to develop new systems including HMIS, LIS, EHR, e-prescription, and e-referral. The Strategic Plan further stresses the need to develop governance and administrative capacities, patient facing portals and applications, and improved cybersecurity. Finally, capacity building of staff in areas of health informatics and cybersecurity is highlighted as key to achieving the strategic goals.

A feasibility study was commissioned in 2023 by the World Bank and served as an early version of the national digital health blueprint. The study laid out a high-level analysis of the digital health landscape in Kosovo and recommended ways forward to operationalize the Strategic Plan for Development of the Health Information System. This study highlights the following key areas of focus for Kosovo:

- The need for strong political will
- The establishment of a central eHealth body to coordinate and lead developments in the space
- A secure, robust Health Information Exchange based on the Government Gateway

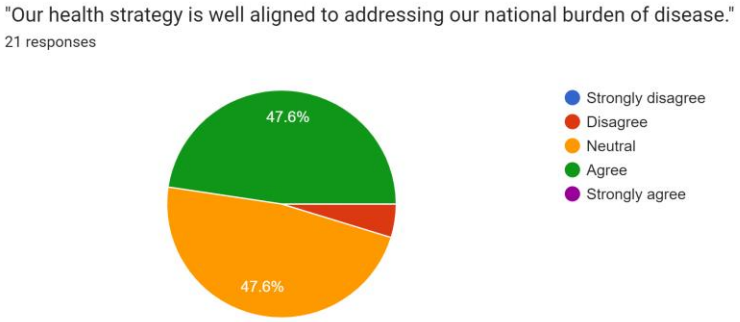
- Development of a legal framework, improved stakeholder collaboration, and education and training
- The need for a central Electronic Health Record

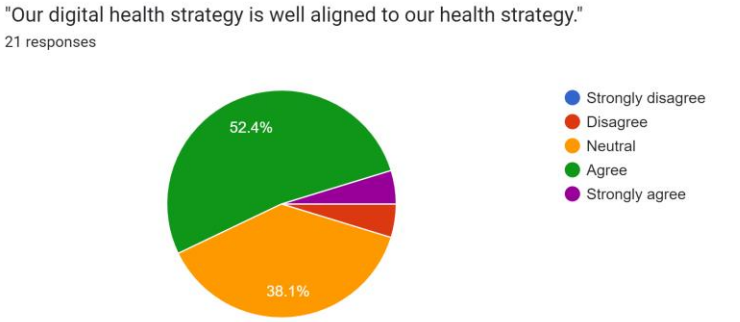
One important point to highlight is that the digital health strategy notes that investing in existing health information systems is a priority. It is critical to point out that the decision around continued investment in any of the already developed systems needs to be based on whether or not that system is functioning well, can be brought into conformance with the digital health norms and standards, and is not overlapping with or duplicating the functionality of either an existing or planned POS application or HIE role. It is worth noting here that POS applications and HIE applications are distinct and should ideally remain distinct.

Discussion related to the country's strategic plans

This blueprint document builds upon the above areas of focus considering the burden of disease and the digital context in Kosovo. It can serve as an instrument to inform and coordinate digital health investments to address NCDs as the dominant burden of disease in the country. Strategic alignment and a focused implementation plan will be key for the success of this work, and these are explored further in the document

The TWG generally agreed that there was some degree of alignment between the health and digital health strategies (see Figure 10 below), from the discussion it was also concluded that while there was general alignment it would be beneficial to have the digital health strategy focus on similar outcomes to the health sector strategy especially when it comes to non-communicable disease.





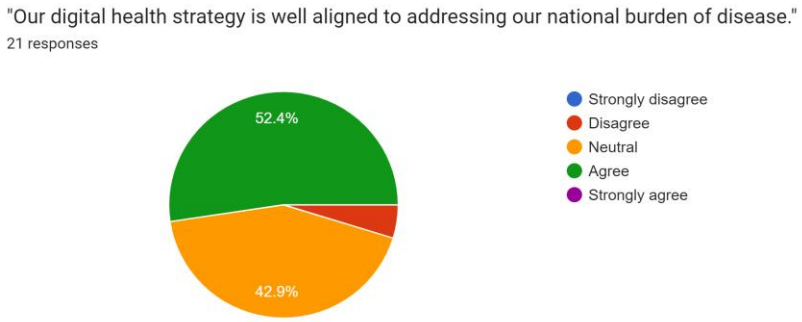


Figure 10 – TWG responses to queries around strategic alignment

Specific areas of alignment include

- An emphasis on quality and safety
- A need for better governance
- A need for capacity building
- A need for better infrastructure
- The importance of a central EHR and HIE
- The important of data for informed decision making

Further, the digital health strategy should be re-visited to introduce a more standards-based approach. Kosovo's digital health investments to date have largely been focused on custom-built point of service applications that are not standards compliant. These applications are at varying degrees of maturity and scale, but this level of investment could potentially have been avoided by the adaptation of readily available and widely deployed software (either free and open source or commercial) that can be adapted or configured for the Kosovo context. It is recommended that Kosovo adopt a policy of adopt-adapt-develop when considering digital health investments. This means that the first preferred option should be to be to adopt an existing software application as-is provided that it meets Kosovo's requirements. The next priority, if an existing ready-to-use application is not available should be to adapt an existing solution to meet Kosovo's needs. Developing custom software should ideally be the last resort when neither adoption not adaptation of existing software is possible to address health system needs. Regardless of which option is chosen however, the software should be compliant with Kosovo's norms and standards for digital health – this is further explored in a future section of this document.

A further key point around digital health investments is that the feasibility study proposed a considerable investment in data center infrastructure. However, the investment case model (see Appendix 2), developed as part of this Blueprint indicates that while data center expenses are by no means trivial, it is setting up the Shared Health Record and nationwide implementation of Point of Service applications that will by far account for the largest budget. This is quite a common scenario because the data centers and the HIE itself are standard components that rarely need much customization. The true complexity of digital health implementation lies in rolling out

Point-of-Service applications, and the change management, training, and planning that are all critical parts of that. The implementation level is where country context factors in the most and tailoring of applications and approaches to country context is required.

Regarding governance around strategies and blueprints, a majority of the TWG felt that the national health strategy should be updated between every 3 and 5 years, the national digital health strategy between every 2 and 3 years, and the burden of disease between every 2 and 3 years. In general, while the burden of disease can be refreshed on a 2-to-3-year time horizon, health and digital health strategies can be refreshed every 5 years barring a dramatic change in either the health or digital health context that would necessitate an update before this time. As a practical matter, it is unwise to change the national digital health blueprint on a shorter timeframe than that of a national deployment project.

A final key consideration is around the private sector. Most TWG members agreed that an HIE would help to address the burden of disease and to achieve strategic goals. However, given that many citizens seek care in the private sector, it is vital to consider the role of the private sector in achieving these goals. If the private sector is not conformant to Kosovo's norms and standards for digital health, patient data will remain fragmented and disconnected, and this will detract from the aims of supporting continuity of care, improving quality of care, and patient safety. It is therefore critical that the Ministry of Health put in place policy and legislation to increase oversight over the private sector, and to bring it into conformance with the national HIE.

Mapping strategic goals to HIE design specifications

The strategic documents point to several areas where components of the HIE can be leveraged to support the achievement of strategic objectives

The Health Sector Strategy specifically mentions the transition from ICD10 to ICD11 – something that would be supported by a Terminology Service. Similarly, the current Lab Information System in use does not employ LOINC codes. A Terminology Service would support this as well.

Both Health and Digital Health Strategies mention the need for a system to register patients. This points to the need for a Client Registry – something that can be leveraged by multiple point of service applications including an insurance system. The Client Registry in question would need a way to assign a unique health identifier to any individual seeking care in Kosovo (including those who are not nationals of Kosovo). Also, both the central EHR and any eventual insurance, claims management, or e-referral systems would be well-supported by the presence of Facility and Provider Registries.

The Health Sector Strategy also points to an Essential Medicines List. Both this and e-prescription would also benefit from the use of a Terminology Service. As a practical matter, a terminological map is needed between the International Non-proprietary Names (INN, as coded by WHO's Anatomical Therapeutic Chemical (ATC) codes) used for prescribing and the GS1 Global Trade Item Number (GTIN) used for dispensing.

Finally, the notion of a patient portal and patient facing mobile applications points to the need for a Shared Health Record. This can be supported by enabling patients to view their own medical record on the already widely used eKosova application

Components of a "buildable" Health Information Exchange

KEY MESSAGES: To mitigate risk and accelerate its pace of implementation, Kosovo should embrace best practices regarding health enterprise architecture and adopt as its norms and standards for digital health a conformance-testable set of IHE Profiles based on the HL7 FHIR v4 specification and companion international terminologies.

- Kosovo's health information exchange (HIE) requirements are consistent with those of European Union peers.
- To connect, eventually, into Europe's eHealth Digital Services Infrastructure (eHDSI), Kosovo will be well-served to adopt domestic norms and standards consistent with the new European EHR exchange Format (EEHRxF) specifications.
- Conformance-testability is essential to exerting governance over the care delivery network and ensuring interoperability. To support this, Kosovo should adopt and operationalize the same IHE-supported testing frameworks currently used by European peers.
- Adoption of modern, global standards increases the market options (both commercial and open source) that Kosovo can employ as "Lego® Blocks" in constructing its national digital health infrastructure. This can fundamentally reduce risk, cost, and implementation time.

RECOMMENDATIONS: The new blueprint document provides a policy foundation for Kosovo's norms and standards for digital health.

- MOH should enact a policy to adopt the conformance-testable specifications named in the most current published version of its "blueprint" as Kosovo's national norms and standards for digital health.
- The blueprint document's technical section should be separately published and kept up to date by the digital health governing entity. This document is the policy foundation for conformance-testing.
- A conformance-testing platform should be set up that will be employed by the MOH to "certify" digital health solutions. The open source test platform employed by the European eHDSI initiative, IHE Gazelle, should be considered as a risk-mitigating option.
- A policy should be enacted that requires "conformance certification" against Kosovo's published norms and standards as a pre-requisite for a solution's authorization to access the national HIE.
- As previously recommended by a WB report, MOH should establish a centre of excellence (COE) related to the domestic development of national clinical practice guidelines (CPGs) to address key "top-10" diseases. In line with the role the present digital investments are expected to play, the scope of this COE should include the publishing of these CPGs as conformance-testable computable care guidelines (CCGs).

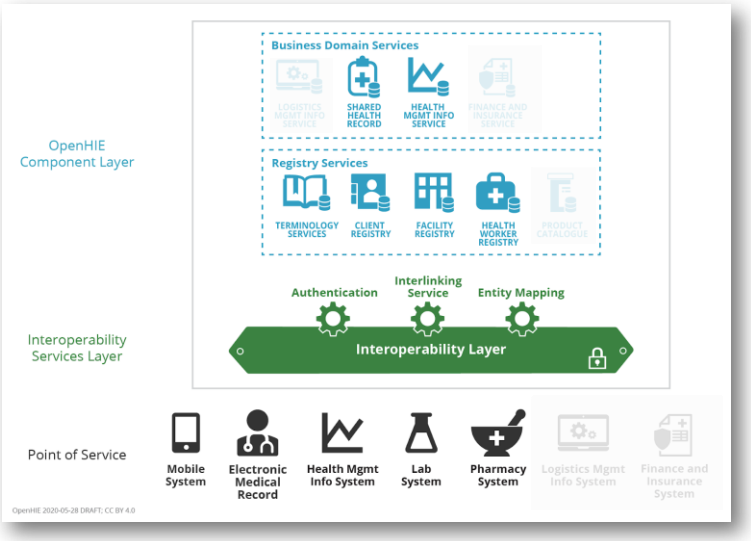


Figure 11 - OpenHIE Blueprint (health-related actors)

The buildable blueprint design leverages an existing, "off the shelf", set of digital health **architectural** specifications as generally defined in the OpenHIE[7] framework. The OpenHIE Architecture diagram is shown in Figure 11. To bring the blueprint to life, its care delivery workflows are mapped to a set of implementable, standards-based, interoperability specifications as defined by the IHE Mobile Health Document Sharing (**MHDS**) Profile[8]. A set of architectural "actors" relevant to an OpenHIE-conformant HIE are listed in Table 1. An engineering diagram depicting how an OpenHIE-based architecture could be operationalized in a cloud-hosted infrastructure is illustrated in Figure 12.

- **TS***: a terminology server that supports ontology mapping and code list publishing
- **CR***: a standalone client registry that supports patient record matching and de-duplication
- **CR* POS**: a client application that supports the "ceremony" of adding a new demographic record to the HIE (e.g. ID card printing, etc.)
- **POS Solution**: point of service digital health application (e.g. Electronic Medical Records (EMR), Lab Information System (LIS), Community Health Worker app, etc.)
- **CCG Engine**: computable care guidelines processor
- **CR**: runtime client registry service
- **ILR/TS:** runtime terminology service, including interlinked health service codes
- **ILR-HWR:** runtime interlinked health worker registry
- **ILR-FR:** runtime interlinked facility registry
- **ILR-ORG**: runtime interlinked organization registry
- **SHR**: shared health record repository
- **HMIS**: health management information system, including a data analytics engine
- **HWD**: federation of health worker directories
- **FD**: federation of facility directories

[7] https://guides.ohie.org/arch-spec/architecture-specification/overview-of-the-architecture
[8] https://wiki.ihe.net/index.php/Mobile_Health_Document_Sharing_(MHDS)

• **Interoperability Layer**: enterprise shared service bus	• **ORG**: federation of organization directories • **ATNA**: audit trail and node authentication services

Table 1 - Digital health infrastructure actors

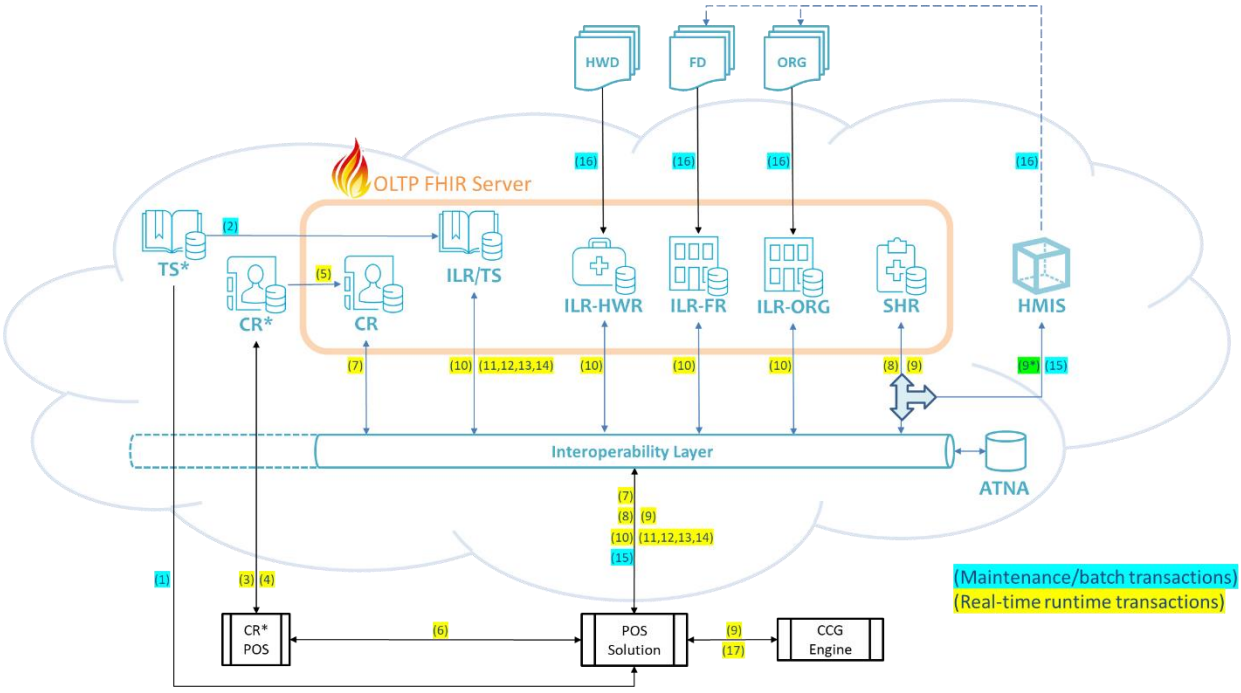


Figure 12- Functional Capability of a Cloud-hosted OpenHIE-based architecture

As may be noted from the diagram, it is anticipated that the national HIE will be cloud hosted[9]. To defend online transaction processing (OLTP) performance, computationally "expensive" services such as terminology mapping and publishing, client record creation and management (e.g. de-duplication), and analytic processing (e.g. HMIS) will be architecturally separated from the OLTP-optimized FHIR Services. It is also expected that the interlinked registry (ILR) of health workers, facilities, organizations, and health services will be refreshed from an underlying federation of directories as part of a regular maintenance cycle. As an example, extracts from the membership databases of the College of Nurses, College of Physicians, College of Pharmacists, etc. will be regularly updated to the OLTP FHIR Server's interlinked registries as part of a managed batch update process.

[9] It is noted in the Digital Health Strategy and in the Feasibility Study that digital health infrastructure, including the HIE, will leverage the Government Gateway (GG) and will be hosted on Kosovo's national datacentre (ASHI). Notwithstanding this, there were mixed results from the TWG workshop (Apr-24 2024) regarding the relative risks vs rewards of a hosted approach and regarding the success of existing government-hosting initiatives. The TWG survey results are documented in the Workshop-2 materials, available as supporting documentation to this blueprint.

The following list outlines the HIE's transactional functionality as depicted in Figure 12. Transactions supporting maintenance processes are identified in blue; real-time processes are shown as yellow.

a) **Terminology Publishing**. A terminology server (TS*) will be employed to curate and cross reference the national lists of normative codes. As part of a regular refresh process, the MOH will publish updated code lists and make these available so that digital health POS solutions can update their code lists. This is illustrated by transaction (1). As shown by transaction (2), these published terminologies will also update the runtime code lists maintained in the OLTP-optimized FHIR Server. NOTE: it is common for such publishing processes to employ Excel and/or PDF files as the means of distributing code lists. Each POS solution will be required to be able to ingest the published format. The interactions with the TS* *may* be managed via the Interoperability Layer.

b) **Manage Client Registry Records.** It is expected that there may be a *ceremony* associated with managing Client Registry records. A barcoded unique ID card may be issued, as an example, that will associate the client's demographic information with their unique health identifier. As part of maintenance, duplicate client records that have been created in error will need to be de-duplicated (and the underlying IDs merged). These processes may be operationalized by every POS, or there may be a specialized solution (CR* POS) that is dedicated to efficiently and correctly executing client record ID-management, including the "new client ID" ceremony. The CR* POS will need to support both adding and updating client demographic records, as illustrated by real-time transactions (3) and (4). The CR* server will need to be able to sync new or updated client demographic records to the HIE's OLTP-optimized FHIR Server, as shown in transaction (5). If there is a separate CR* POS, and if an *offline* mode must be supported, there may be a sync transaction between a POS Solution and the dedicated CR* POS application. This is shown as transaction (6). NOTE: the CR* POS' interactions with the CR* *may* be managed via the Interoperability Layer.

c) **Query for a Client Demographic Record.** As part of its normative behavior, a digital health POS will need to be able to query the HIE for a client demographic record. The HIE's FHIR Server, playing the role of a Client Registry, will need to be able to respond with the relevant record(s). This is shown as transaction (7).

d) **Query for a Client's Patient Summary.** As part of its normative behavior, at the beginning of an encounter, a digital health POS will need to be able to query for and ingest/parse a client's (IPS) patient summary document. The HIE's FHIR Server, playing the role of a Shared Health Record repository, will need to be able to respond to a POS request by returning a well-formed IPS. This is shown as transaction (8).

e) **Submit a Client's Patient Summary.** As part of its normative behavior, at the end of an encounter, a POS must be able to submit a well-formed IPS to the HIE that includes the details of the encounter including any forward-looking orders or follow-up. The HIE's FHIR Server, playing the role of a Shared Health Record repository, must ingest/parse the inbound IPS and persist it. This is shown as transaction (9).

f) **Execute Computable Care Guideline (CCG) Processing.** Transaction (9) is employed, during an encounter, to launch the processing of one or more CCGs. A POS solution

provides a CCG Engine actor with the client's current IPS using transaction (9) and invokes a *$apply* operation using transaction (17). Relevant guideline-based care recommendations are returned from the CCG Engine actor and processed by the POS solution. Actions that operationalize the CCG-based recommendations (e.g. measure and record blood pressure, order medications, etc.) are reflected in the client's real-time IPS. Over the course of the encounter, the transaction 9-17 pattern is repeated until no further recommendations are returned from the CCG Engine.

g) **Query for Interlinked Registry Content**. As part of routine processes, a POS may need to query the HIE for information related to facilities, organizations, health workers, available services, and/or the relationships between these. The HIE's FHIR Server, playing the role of an Interlinked Registry (ILR), will respond to the query and return the relevant content. Such a query against the interlinked registry is shown as transaction (10).

h) **Query for Codes**. As part of routine processes, a POS may need to look up a code, validate a code, query for a concept map, or query for a translation from one code system to another. The HIE's FHIR Server will need to be able to respond to such requests. These are shown as transaction (11), (12), (13) and (14), respectively.

i) **Submit Reportable Indicators**. There may be MOH mandates for POS solutions to regularly submit reportable indicators (e.g. number of new HIV patients started on antiretroviral medications, number of babies receiving their DPT-3 immunization, etc.). Such a submission, shown as transaction (15), will be directed to the HIE's Health Management Information System (HMIS). As an alternative, an MOH could opt to leverage a "t-connector" in its data processing pipeline that could de-identify inbound patient summary submissions as part of a separate workflow that does not impede the transaction processing of the HIE's OLTP-optimized FHIR Server. These de-identified, person-centric data could be persisted to the HMIS to support advanced analyses not possible with aggregated data, alone. Such a pipeline, which could operate either in near real time or as a batch, is shown as transaction (9*).

j) **Refresh and Update Interlinked Registries**. The HIE FHIR Server's data regarding facilities, organizations, and health workers will need to be regularly refreshed and the cross-referencing between these data will need to be governed and managed. The sources of these data are expected to be a *federation* of underlying health worker directories (HWD), facility directories (FD) and organization (ORG) directories. Some HMIS solutions, such as DHIS2 as an example, can also play the role of a facility directory or an organization directory. The refresh transaction is shown as transaction (16).

k) **Privacy, Security, and Auditing**. The Interoperability Layer is used to manage the HIE's transactional traffic. This includes enforcing key mandates related to authentication, authorization, privacy / consent, consistent time, and auditing. These are *pervasive* requirements that apply to all traffic that traverses the HIE.

To be good "HIE citizens", POS solutions will need to follow a set of normative behaviors. These behaviors are described, using the business process modelling notation (BPMN), in Figure 13. This generic and re-usable care encounter pattern may be leveraged to support care delivery use cases across a wide range of healthcare scenarios. The care encounter pattern is mapped to the

transactions (as described in **Error! Reference source not found.**). The conformance testable IHE Profile transactions are also indicated (in red).

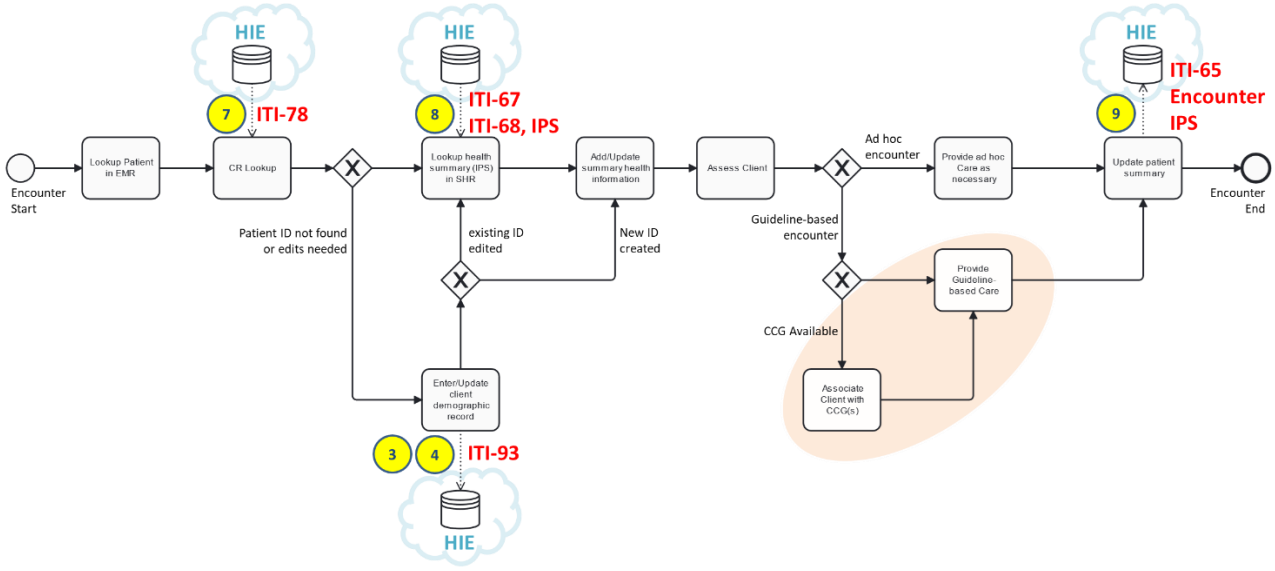


Figure 13 -Generic care encounter pattern

Following the flow of the diagram:

- A person-centric care encounter starts.
- The client's patient demographic record is looked up in the local electronic medical records (EMR) database.
- The client's "enterprise" demographic record is looked up in the HIE's client registry (CR); this is transaction (7) and maps to IHE conformance testable transaction ITI-78.
- If the record is not found in the CR, or if the CR's record needs to be updated with new information, new content is captured using the CR* POS transactions (3) or (4) and this is saved to the HIE's CR using IHE transaction ITI-93.
- If the client's record was found in the CR, the patient summary (IPS) is retrieved from the HIE's shared health record (SHR) repository. This is transaction (8) in Figure 12 and leverages IHE transactions ITI-67 and ITI-68 and the IPS data specification.
- The client's IPS is updated with relevant information. In cases where no previous client record existed, the patient summary is created as a brand-new record.
- The client is assessed.
- If it is an ad hoc encounter and guidelines do not apply, care is provided as necessary.
- If one or more care guidelines are applicable, guideline-based care is provided. In cases where relevant CCGs are available, the POS solution may transact with a CCG Engine leveraging transactions 9-17-18 in a repeating pattern. This latter scenario would occur in the orange-shaded area of Figure 13.
- The patient summary is updated to reflect the activities of the encounter. The encounter details (e.g. client ID, health worker ID, facility ID, timestamp, etc.) plus the client's updated health summary are persisted to the HIE's SHR. This is transaction (9) and uses IHE transaction ITI-65 along with the FHIR Encounter and IPS data models.

It is expected that POS solutions will maintain their own (local) copies of health data and that the HIE will be leveraged to share data between and across POS solutions. As a best practice, the originators of new data (e.g. blood pressure reading, lab order, etc.) should be the ones to assign the unique FHIR resource ID and this resource.id should be a standards-based globally unique ID (GUID). As a corollary to this best practice – when a POS solution retrieves content from the HIE, the resource IDs of the retrieved content should be faithfully persisted to the POS' local database. Adopting this engineering discipline across the care delivery network will allow data management and de-duplication processes to successfully execute at all points of care.

To support high quality, patient-safe, continuity of care – a re-usable data model is leveraged to exchange patient-centric health information within the care delivery network. Following the "off the shelf" risk-mitigation and cost-reduction strategy, the blueprint design leverages the standards-based, conformance-testable data model defined in the International Patient Summary (IPS) specification.[10]

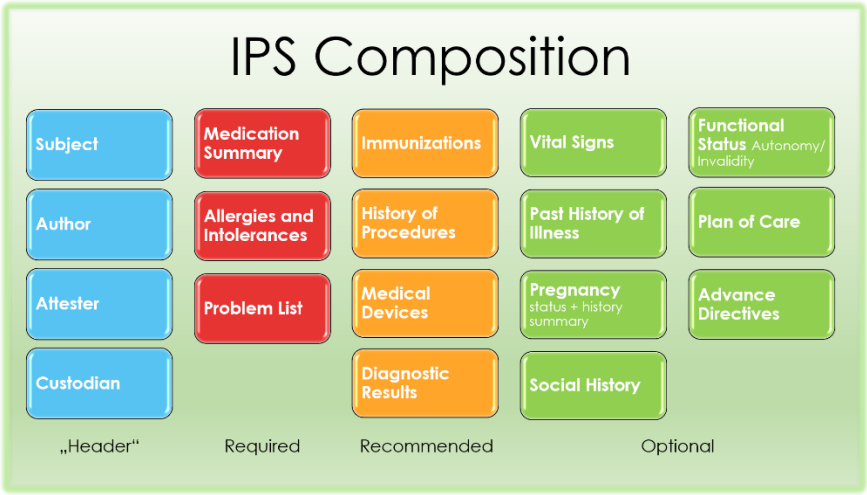


Figure 14 - IPS Data Model

The component data elements of an IPS "document" are listed below along with links to the underlying FHIR data model specifications (those noted with an (R) are mandatory; all others are "required if known"[11]):

- Medication Summary (R) [Medication Statement (IPS) | Medication Request (IPS) | Medication (IPS)]
- Allergies and Intolerances (R) [Allergy Intolerance (IPS)]
- Problem List (R) [Condition (IPS)]
- Immunizations (S) [Immunization (IPS)]

[10] http://hl7.org/fhir/uv/ips/

[11] Mandatory data (R) must be included in the IPS document. Required "if known" (S) data *may* be blank, but if it **is available**, it must be included in the IPS document.

- History of Procedures (S) [Procedure (IPS) | Organization (IPS) | Device (performer, observer)]
- Medical Devices (S) [Device Use Statement (IPS) | Device (IPS)]
- Diagnostic Results (S) [Observation (Results) | DiagnosticReport (IPS) | Organization (IPS)]
    - Laboratory results [Observation (Results: laboratory) | Specimen (IPS) | Media observation (Results: laboratory, media)]
    - Radiology results [Observation (Results: radiology) | Device (performer, observer) | Imaging Study (IPS) | Practitioner (IPS)]
    - Pathology results [Observation (Results: pathology) | Specimen (IPS) | Media observation (Results: laboratory, media)]
- Vital Signs [Vital Signs]
- Past history of illnesses [Condition (IPS)]
- Pregnancy (status and history summary) [Observation (Pregnancy: EDD) | Observation (Pregnancy: outcome) | Observation (Pregnancy: status)]
- Social History [Observation (SH: alcohol use) | Observation (SH: tobacco use)]
- Functional Status (Autonomy / Invalidity) [Condition (IPS) | Clinical Impression]
- Plan of care [Care Plan]
- Advance Directives [Consent]

To ensure semantic interoperability, different data elements in the IPS are *required* to be coded. For Kosovo, the following codes will be mandated in service of the relevant care activities:

- WHO Anatomical Therapeutic Chemical (**ATC**) classification system[12] will be leveraged to support workflows based on generic INN (International Non-proprietary Names) **prescribing**, which is mandated.
- **Dispense** transactions will leverage GS1's **GTIN**[13] (Global Trade Identification Number) codes to record the *actual* medicinal product given to the patient.
- For **laboratory** orders and results, the LOINC[14] code system will be used.
- The Ministry has identified WHO's **ICD-11**[15] code set as the normative terminology for **diagnoses** and WHO's **ICHI**[16] (International Classification of Health Interventions) as the code set for **procedures**. These will be leveraged *instead* of SNOMED IPS.
- To record and track **patient outcomes**, the WHO's **ICF**[17] (International Classification for Functioning, Disability & Health) will be used.

[12] https://www.whocc.no/atc_ddd_index/
[13] https://www.gs1.org/standards/id-keys/gtin
[14] https://loinc.org/
[15] https://icd.who.int/en
[16] https://www.who.int/standards/classifications/international-classification-of-health-interventions
[17] https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health#

The IPS has undergone high level evaluation regarding its applicability against key care use cases. It is anticipated that the IPS data model, **unmodified**, will support the guideline-adherent care workflows related to Kosovo's top-10 burden of disease.

Conformance-testable Building Blocks

NOTE: The following sections contain normative content intended for a technical audience.
The balance of the technical specification is laid out in eight main sections:

- Terminology Service (TS*/TS)
- Client Registry (CR*/CR)
- Facility Registry (ILR-FR)
- Health Worker Registry (ILR-HWR)
- Shared Health Record repository (SHR)
- Interoperability Layer
- Health Management Information System (HMIS)
- Point of Service Application (POS)

As a tactical matter, the underlying digital health standards are based on **HL7 FHIR R4** and the **IHE Profiles** that operationalize these. The specific IHE Profiles are:

- International Patient Summary (IPS) – which is a data content standard that also references underlying code system specifications:
  - SNOMED International Patient Summary (IPS)[18]
  - WHO Anatomical Therapeutic Chemical (ATC) classification system[19]
  - LOINC[20]
- Mobile Health Document Sharing (MHDS) – which is an umbrella specification that encapsulates underlying IHE Profiles:
  - Patient Master Identity Registry (PMIR)
  - Mobile Care Services Discovery (mCSD)
  - Mobile access to Health Documents (MHD)
  - Sharing Value Sets, Codes and Maps (SVCM)
  - Internet User Authorization (IUA)
  - Audit Trail and Node Authentication (ATNA)
  - Consistent Time (CT)
  - Aggregate Data Exchange (ADX) and Mobile Aggregate Data Exchange (mADX)

This strategy of referencing "off the shelf" specifications leverages the conformance tests that IHE has already defined for each of the Profiles named above.

The full text of the IHE Profiles, and their associated conformance tests (defined using IHE's open-source testing platform: Gazelle), are not replicated in this document. Rather, links to the applicable artefacts are included in the relevant subsections. Each subsection, however, *will*

[18] https://www.snomed.org/international-patient-summary-terminology
[19] https://www.whocc.no/atc_ddd_index/
[20] https://loinc.org/

stipulate configuration and code system requirements. These requirements apply **in addition to** the base IHE specifications. The complete set – the base IHE Profiles ***plus*** these additional terminology specifications – constitutes the **National HIE Reference Architecture**.

Terminology Service (TS)

This spec will leverage a FHIR-capable data store as its Terminology Service (TS* in Figure 12). The TS* will be populated with value sets, code systems and concept maps and will operate as per the behaviors defined in the IHE SVCM Profile[21]. The TS* actor will be leveraged by the MOH to manage and map terminologies and to regularly publish relevant code lists. These published code lists will be leveraged to regularly update POS solutions and to update the content exposed by the TS actor in the HIE's OLTP-optimized FHIR Service. The TS actor will operationalize runtime access to codes in response to POS solutions' real-time queries.

For the purposes of conformance to this spec, a TS* actor shall be able to:

1. Play the role of a **Terminology Repository** and execute a query value set **ITI-95** transaction, a query code system **ITI-96** transaction, expand value set **ITI-97** transaction, lookup code **ITI-98** transaction, validate code **ITI-99** transaction, query concept map **ITI-100** transaction and translate code **ITI-101** transaction.
2. Persist and retrieve **ICD-10** codes, **ICD-11** codes, **SNOMED IPS** codes, **LOINC** codes, **WHO ATC** codes or other terminological artefacts that an MOH may determine.
3. Generate code lists and value set extracts, as defined by the MOH, and publish these in a format that may be ingested by conformant POS solutions and by the HIE's FHIR service. The format(s) of these published extracts will be determined by the MOH (e.g. Excel spreadsheet, PDF, xml or json file, etc.). The method of dissemination of these published artefacts will be determined by the MOH (e.g. GDRIVE, web portal, etc.).

For the purposes of conformance to this spec, a TS actor shall be able to:

1. Play the role of a real-time **Terminology Repository** and execute and return values from a: lookup code **ITI-98** transaction; validate code **ITI-99** transaction; query concept map **ITI-100** transaction; and translate code **ITI-101** transaction.

Client Registry (CR)

The HIE infrastructure will include both a CR* actor and a CR actor. The CR* actor will be responsible for client demographic data management and de-duplication (e.g. merging). These are separate from the OLTP-optimized HIE services in order to defend performance requirements. The CR actor will be operationalized as part of the HIE's OLTP-optimized FHIR Service and will support highly performant responses to patient demographic content queries and correct cross-referencing to relevant SHR data. NOTE: the CR* actor will need to be able to execute real-time synchronization updates to the CR actor as part of its transaction processing.

For the purposes of conformance to this spec, it is mandated that the CR* actor be able to:

[21] https://profiles.ihe.net/ITI/SVCM/index.html

1. Play the role of a **Patient Identity Registry** and support patient identity feed transaction **ITI-93** as both an *initiator* and a *responder*, patient identifier cross-reference query transaction **ITI-83** as a responder, patient demographic query transaction **ITI-78** as a responder, and patient update subscription transaction **ITI-94** as a responder. The detailed conformance requirements are defined by IHE's PMIR Profile[22].
2. Support the demographic content data model defined by the HL7 FHIR International Patient Summary Implementation Guide (**IPS IG**).[23]
3. As part of a single transaction where it is acting as a Patient Identity Registry ***responder***, persist new or updated content to the CR actor via an **ITI-93** transaction (as an ***initiator***).
4. As part of a single transaction where it is acting as a Patient Identity Registry ***responder***, and where the ITI-93 transaction creates a **merge**, update relevant records in the SHR (playing the role of an **MHDS Document Registry** actor) to effect linking of the deprecated patient.id to the surviving patient.id as per the normative behaviors defined IHE MHDS Profile[24].

For the purposes of conformance to this spec, it is mandated that the CR actor be able to:

1. Play the role of a **Patient Identity Registry** and support a patient identity feed transaction **ITI-93** (initiated from CR*, *only*) as *responder*, and patient demographic query transaction **ITI-78** as a responder. The detailed conformance requirements are defined by IHE's PMIR Profile.
2. Support the demographic content data model defined by the HL7 FHIR International Patient Summary Implementation Guide (**IPS IG**).

For conformance to this specification, the following demographic data are to be persisted, and these data are *required if known*:

- Patient's full legal name, date of birth, and sex at birth (stored in the gender element)
- Existing ID numbers (e.g. CRVS-assigned ID number, driving license number, locally assigned clinic ID number(s), etc., where available). In all cases, both the issuing authority ID# and the ID# itself are stored, as a coded pair.
- Patient's phone number
- A link to the Patient's mother's RelatedPerson record will be maintained in the patient.link.other data element with a patient.link.type = seealso. The mother's RelatedPerson.identifier will be set to her patient.id, if she has a patient record in the CR*, and the RelatedPerson.patient will be set to point to the patient.id. The mother's full name will be persisted in the mother's RelatedPerson.name field and the RelatedPerson.relationship field will denote MTH (mother). This information about the mother will be **required if known**, whether she be alive or dead, in order to support demographic lookup of the patient's demographic record.

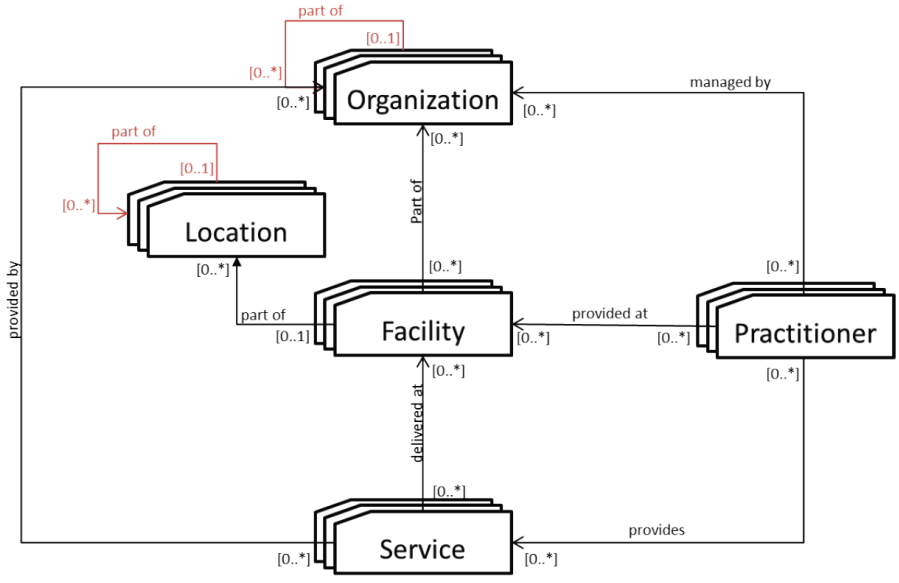
[22] https://profiles.ihe.net/ITI/PMIR/index.html
[23] http://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-Patient-uv-ips.html
[24] https://profiles.ihe.net/ITI/MHDS/volume-1.html#1501-mhds-actors-transactions-and-content-modules

As a mandatory CR* (and CR) behavior, the patient.id shall be a globally unique ID (GUID). The "wallet ID" (Health ID in the case of Kosovo) will be created for the client on initial registration, the patient.identifier shall contain the unique identifier that appears on this artefact and the MOH shall be denoted as the issuing authority of the identifier.

In cases where a unique ID is established for an individual, but **no health ID card or other artefact is issued** at the time of establishing the unique ID, the patient.id (the GUID) shall be persisted as the patient.identifier with the MOH denoted as the issuing authority. This *temporary* patient.identifier will act as a placeholder until a wallet ID can be created and provided to the client. This temporary placeholder shall be overwritten by the MOH-issued unique ID at the time a card is issued to the individual. This behavior is intended to support situations where persons need to be set up with a unique ID but where it is not possible to issue them a card at the time their demographic record is created. This may happen, for example, due to an equipment malfunction at the registration site, or other similar situations.

The CR shall also maintain and persist any and all locally assigned IDs (e.g. a locally unique medical records number created by a care facility) in the patient.identifier element. In the case of locally assigned ID's, the assigning authority shall be identified using the MOH-assigned care delivery organization's org ID, or in the case of the National ID, the org ID shall be that of the Ministry of Internal Affairs. These org IDs shall match valid organization.id records (see the ILR-FR section, below).

Facility Registry (ILR-FR)



N

Figure 15 - The Logical Model of an Interlinked Registry (based on IHE's mCSD Profile)

This specification expects to leverage a FHIR-capable data store[25] as its Interlinked Registry (ILR). It is expected that the ILR will behave as if part of a *single logical* HIE FHIR Service. The ILR will

[25] An example could be the HAPI FHIR server: https://hapifhir.io/

act as the Facility Registry (ILR-FR) and will be populated by two underlying facility directories (FD) as defined by the IHE mCSD Profile[26]. As an example, a FD could be a directory of public care facilities or a directory of private sector facilities or a directory of faith-based facilities. As a practical matter, it is often possible to leverage the HMIS as at least one of the FDs to populate the ILR-FR.

For the purposes of conformance to this specification, an ILR-FR shall be able to:

1. Play the role of a **Care Services Selective Supplier** and support queries for Facilities (Location resources), Health Services, Organizations, and PractitionerRole resources via the **ITI-90** transaction, as a responder.
2. Play the role of a **Care Services Update Consumer** and support requests for care services updates via transaction **ITI-91**, as an initiator.
3. As a **Care Services Selective Supplier**, support the **Location Distance Option**.

For the purposes of conformance to this specification, a FD shall be able to:

1. Play the role of a **Care Services Update Supplier** and support **Facility** (and, optionally, **Organization**, **PractitionerRole** and **HealthcareService** resource) refresh queries using the **ITI-91** transaction.

As a mandatory functional capability, the ILR-FR shall be able to be updated to establish relationships between facilities, organizations and health services via the creation or updating of **PractitionerRole** resources. For each unique combination of organization and facility (location), a PractitionerRole resource shall be created that references all the applicable HealthcareService resources for the facility. Where these relationships have been established, they shall be persisted and be updated based on the results of subsequent ITI-91 transactions.

It is expected that the ILR-FR will be refreshed on a regular basis from the underlying directories using the ITI-91 transaction (which can run as part of a scheduled batch operation). To ensure ongoing data reliability, it is also expected that the ILR will be updated to reflect annual assessments leveraging, for example, the WHO's Harmonized Health Facility Assessment[27] tool.

Facility type codes

Kosovo's existing system of facility type codes ideally needs to be expanded to include aspects like managing authority and service offerings. It is recommended to use the WHO's Harmonized Health Facility Assessment Tool (HHFA) as the code system. Such an approach is described below.

[26] https://profiles.ihe.net/ITI/mCSD/
[27] https://www.who.int/publications/i/item/harmonized-health-facility-assessment-(hhfa)

Harmonized health facility assessment (HHFA) – Combined questionnaire: Availability and readiness (core)

Mod/Ind	No.	Question	Response	Skip
		12. PAGE TO MAIN MENU, HIGHLIGHT "WAYPOINT LIST" AND PRESS "ENTER" 13. HIGHLIGHT YOUR WAYPOINT 14. COPY INFORMATION FROM WAYPOINT LIST PAGE ON THE FORM BELOW. BE SURE TO COPY THE WAYPOINT NAME FROM THE WAYPOINT LIST PAGE TO VERIFY THAT YOU ARE ENTERING THE CORRECT WAYPOINT INFORMATION ON THE DATA FORM		
ALL	110	Waypoint name (facility number)	_ _ _ _ _ _ _	
ALL	111	Elevation (m)	_ _ _ _	
ALL	112	Latitude	N/S.....(a) — DEGREES.....(b) _ _ DECIMAL.....(c) _ _ _ _ _	
ALL	113	Longitude	E/W.....(a) — DEGREES.....(b) _ _ DECIMAL.....(c) _ _ _ _ _	
ALL	114	Consent given by facility contact?	YES.....1 NO.....2	→ END
		1.2. FACILITY CHARACTERISTICS		
ALL	115	Type of facility [COUNTRY ADAPT LIST AND CATEGORIES PRIOR TO IMPLEMENTATION]	NATIONAL REFERRAL HOSPITAL.....01 REGIONAL (PROVINCIAL) REFERRAL HOSPITAL.....02 DISTRICT HOSPITAL.....03 OTHER GENERAL HOSPITAL.....04 SPECIALTY HOSPITAL.....05 COMPREHENSIVE HEALTH CENTRE/POLY CLINIC.....06 HEALTH CENTRE.....07 CLINIC/DISPENSARY.....08 HEALTH POST.....09 MATERNAL/CHILD HEALTH CLINIC.....10 OTHER_____.....96 (SPECIFY)	
ALL	116	Which of the responses best describes the managing authority for this facility? That is, the authority that makes policy decisions and provides supervision for the facility. [COUNTRY ADAPT LIST AND CATEGORIES PRIOR TO IMPLEMENTATION]	GOVERNMENT/PUBLIC.....1 NGO/PRIVATE NOT-FOR-PROFIT.....2 PRIVATE-FOR-PROFIT.....3 MISSION/FAITH-BASED.....4 PARASTATAL (MILITARY/POLICE/NATIONAL GUARD).....5 UNIVERSITY.....6 OTHER_____.....7 (SPECIFY)	
ALL	117	Service levels available	OUTPATIENT ONLY.....1 INPATIENT ONLY.....2 BOTH OUT AND INPATIENT.....3	

Figure 16 - WHO's HFFA Questionnaire

The HHFA question number (column 2 in **Error! Reference source not found.**) may be concatenated with the response ID number (column 4) to create a unique identifier. As an example, this heuristic could be leveraged to generate code 115.01 to denote National Referral Hospital. The question's scope (column 3) – in this case "Type of Facility" – denotes the *type* of the code or the code's relevant *concept*.

Following this approach, three relevant code *types* may be denoted:

- 115 facility type
- 116 facility managing authority
- 117 available service levels

Within these code types, the set of codes may be generated, as per the example above, by concatenating the question ID# with the response number. The concept for each code would be the text of the response. To illustrate, the full list for available service levels would be:

- HHFA.117.1 outpatient only
- HHFA.117.2 inpatient only
- HHFA.117.3 both outpatient and inpatient

Health service type codes

Similar to Facility Type codes, the WHO's HHFA questionnaire numbers are recommended, as illustrated in the previous section. The health services shall be identified by FHIR HealthcareService resources; the HealthcareService.identifier for each unique service shall be by concatenating 'HHFA.' plus the HHFA question heading number (e.g. HHFA.14, COMMUNICABLE DISEASE SERVICES; HHFA.15, NONCOMMUNICABLE DISEASES (NCDs), etc.). For each HealthcareService, the description shall be persisted in the HealthcareService.category element. If a greater degree of precision is desired, the HHFA subcategory question codes may be employed (e.g. HHFA.14.1, MALARIA, HHFA.14.2, NEGLECTED TROPICAL DISEASES (NTDs), etc.).

Health Worker Registry (ILR-HWR)

This spec leverages a FHIR-capable data store as its Interlinked Registry (ILR). It is expected that the ILR will behave as if part of a *single logical* HIE FHIR Service. The ILR acts as the Health Worker Registry (ILR-HWR) and will be populated by one or more underlying health worker directories (HWD) as defined by the IHE mCSD Profile[28]. It is expected that an mCSD-capable health worker database (such as, for example, iHRIS[29]) will act as at least one of the HWDs to populate the ILR-HWR. Generally, it is expected in this design that the membership directories of each clinical association (e.g. physicians, nurses, lab technicians, pharmacists, etc.) will be leveraged to populate and regularly update the ILR-HWR.

For the purposes of conformance to this spec, an ILR-HWR shall be able to:

1. Play the role of a **Care Services Selective Supplier** and support queries for Practitioners, Facilities (Location resources), Health Services, Organizations, and PractitionerRole resources via the **ITI-90** transaction, as a responder.
2. Play the role of a **Care Services Update Consumer** and support requests for care services updates via transaction **ITI-91**, as an initiator.
3. As a **Care Services Selective Supplier**, support the **Location Distance Option**.

For the purposes of conformance to this spec, an HWD shall be able to:

1. Play the role of a **Care Services Update Supplier** and support **Practitioner** (and, optionally, **Organization**, **PractitionerRole** and **HealthcareService** resource) refresh queries using the **ITI-91** transaction.

As a mandatory functional capability, the ILR-HWR shall be able to be updated to establish relationships between practitioners, facilities, organizations and health services via the creation or updating of **PractitionerRole** resources. For each unique combination of organization, facility and practitioner, a PractitionerRole resource shall be created that references all the applicable HealthcareService resources provided by the practitioner at the facility under the auspices of the

[28] https://profiles.ihe.net/ITI/mCSD/index.html
[29] https://www.ihris.org/

organization. Where these relationships have been established, they shall be persisted and be updated based on the results of subsequent ITI-91 transactions.

Health worker type codes

Health workers shall be defined using FHIR **practitioner** resources; there will be one practitioner resource for each distinct health worker. The health worker's type shall be persisted in the practitioner.qualification.code element using Kosovo's existing codes for health worker types

Shared Health Record Repository (SHR)

This specification leverages a FHIR-capable data store as its longitudinal Shared Health Record repository (SHR). The SHR will persist person-centric health information as an International Patient Summary "document" (IPS) associated with a uniquely identified patient, including metadata related to the document. The SHR will also parse and separately persist the individual resources in a submitted IPS, de-duplicating (as necessary) to ensure the integrity of longitudinal, person-centric data. The SHR will generate an IPS[30] and return it when a query is made for an individual's health summary. The reference server for such operational capabilities can be found at the ips.health[31] website maintained by the Global Digital Health Partnership (GDHP)[32].

The SHR will play the roles of an **MHD Document Recipient** and an **MHD Document Responder** as defined by the IHE Mobile Health Document Sharing (MHDS) Profile[33].

For the purposes of conformance to this specification, and SHR shall be able to:

1. Play the role of an **MHD Document Recipient** and execute an **ITI-65** transaction when a document bundle is provided, including support for the Uncontained Reference Option as defined in the MHDS Profile.
2. Persist an **Encounter** resource. Where the ITI-65 transaction is conveying an **Encounter** resource, the encounter.identifier shall be a GUID, the encounter.subject shall reference the unique patient ID, the encounter.status shall be either in-progress or finished, the encounter.participant.individual shall reference the unique health worker ID, the encounter.period.start and encounter.period.end shall indicate the start date and time and end date and time of the encounter (respectively), and the encounter.location.location shall reference the facility ID.
3. Persist the contents of an **IPS document**. Where the ITI-65 transaction is conveying an **IPS** document, the data elements of the IPS will be persisted to the SHR as individual resources such that any new content is inserted, and any edited content is updated and any unchanged content is not duplicated. The IPS's composition.subject shall reference the unique patient ID, the composition.encounter shall reference the applicable encounter.identifier, the composition.date shall coincide with the applicable

[30] https://build.fhir.org/ig/HL7/fhir-ips/OperationDefinition-summary.html
[31] https://ips.health/
[32] https://gdhp.health/
[33] The IHE MHDS profile describes the overall operations of the HIE, including the support for health document exchange. The SHR's behaviours are described within this overall context, here: https://wiki.ihe.net/index.php/Mobile_Health_Document_Sharing_(MHDS)

encounter.period.end, the composition.author will reference the practitioner identified in the encounter.participant.individual element.

4. Persist a **bundle** containing both an Encounter and an IPS. Where the ITI-65 transaction is conveying both an Encounter resource and an IPS document, the Encounter resource shall be persisted to the SHR before the IPS document.
5. Play the role of an **MHD Document Responder** and execute an **ITI-66** find document manifests transaction, an **ITI-67** find document references transaction, or an **ITI-68** retrieve document transaction as defined in the MHDS profile.

It should be noted that, in an HIE implementation where there is *no* requirement to support IHE cross-enterprise document sharing (XDS), the lighter IHE-based CA:FeX profile[34] may be favored over IHE MHD. Given that CA:FeX is a pure-FHIR document exchange format based on IHE MHD, but where the requirements related to XDS support have been relaxed, this lighter specification is very relevant for Kosovo. The conformance-testable CA:FeX specification[35] is published by Canada's national digital health agency and will be soon submitted to IHE for global ballot.

Interoperability Layer (IL)

In this specification, an Interoperability Layer (IL) acts as the shared services bus for the national HIE. The IL enforces the HIE behaviors defined in the IHE MHDS Profile[36] and supports non-functional requirements related to scalability, maintainability and extensibility.

For purposes of conformance to this specification, the IL shall be able to:

1. Play the roles of a **Document Registry** and **HIE Central Infrastructure** as defined by the MHDS profile and enforce all the conditions and behaviors defined for these actors including, where necessary, the enforcement, coordination and orchestration of transactions between different HIE actors.
2. Support the behaviors of the **Authorization** option, **Consent Manager** option, and **UnContained Reference** option, as defined in the MHDS Profile.
3. Support **non-functional requirements** as may be defined by an MOH related to response time, load balancing and scalability, maintainability, performance monitoring, etc.

Health Management Information System (HMIS)

Kosovo does not currently have a central HMIS system and needs to set one up. Because of its wide adoption in LMICs, a "reference" HMIS will be assumed to be functionally comparable to the open source DHIS2 platform supported by the University of Oslo (UiO).[37] Information about DHIS2's functionality can be found at the product website.

[34] https://infoscribe.infoway-inforoute.ca/display/PCI/CA%3AFeX+Release+Information
[35] https://simplifier.net/guide/CA-FeX/Home?version=current
[36] https://profiles.ihe.net/ITI/MHDS/
[37] https://www.dhis2.org/

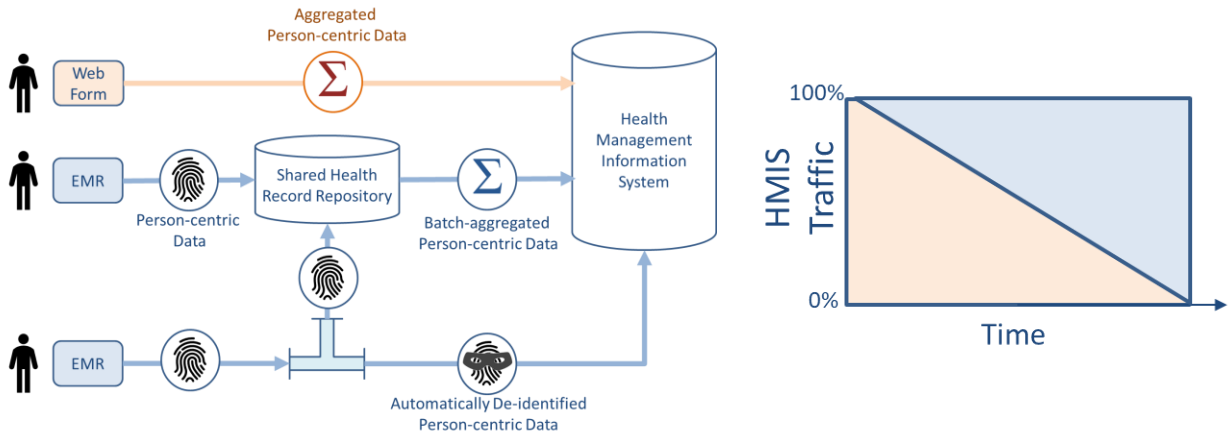


Figure 17 - Anticipated Evolution of HMIS Traffic, over time

There is expected to be an evolution, over time, in how content is fed to the HMIS. As there is broader adoption of person-centric digital health solutions, more and more of the content in the HMIS will come from regular extracts on SHR data and less and less will be uploaded (by hand) to the HMIS' web forms. This evolution has advantages, not least of which will be the liberation of health worker time and effort that is, today, spent on tally sheet data entry.

There are also opportunities to leverage increasing person-centric traffic on the HIE to generate large, de-identified, person-centric data sets in the HMIS. Such data sets support innovative opportunities for advanced analytics, including machine learning and other AI techniques. Such an option is suggested by the "T-junction" shown in Figure 17.

Implications for Cross-domain Integration

The health transaction workflows illustrated by Figure 12 do not include other companion domains, such as supply chain or health financing. It is anticipated that the HMIS and its analytic capabilities will be leveraged to loosely couple the HIE to enterprise systems that support these cross-domain workflows. An example, follows, related to how HIE transactions can support the automatic development of supply chain transactions that may be uploaded to logistics management information systems (LMIS) at regular intervals (e.g. in a nightly batch, or monthly report, etc.). A medication stock management workflow is used to illustrate. This is relevant for integration with the current Pharmacy and Stock Management system in use in Kosovo

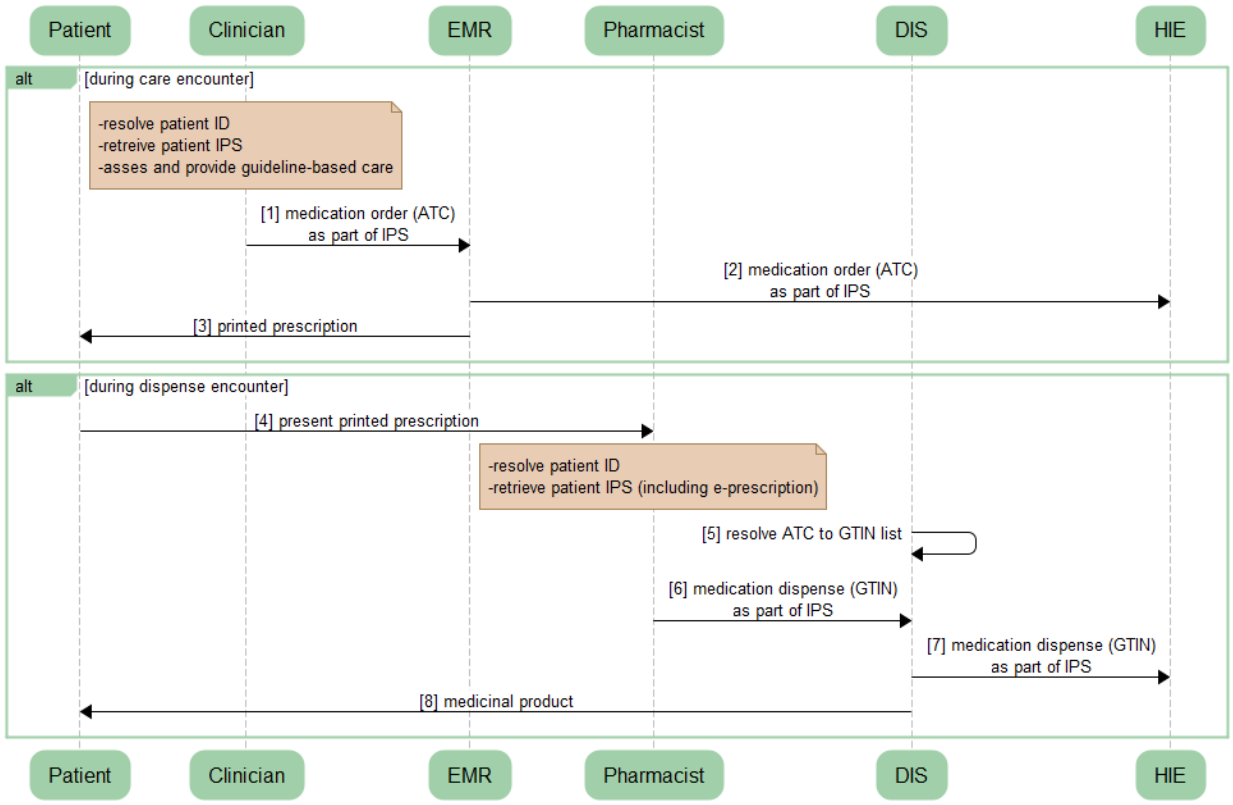


Figure 18 - Medication Order / Dispense Transactions

A generic mediation order / dispense workflow is illustrated in Figure 18. Following the transaction flow:

- During a care encounter, a clinician may order medications for a patient. The medication order is recorded in the EMR and communicated to the HIE as an update to the patient's IPS-based health summary document (transactions [1] and [2]). A printed prescription is provided to the patient (transaction [3]). Importantly, the electronic medication order is coded using WHO's Anatomical Therapeutic Chemical (ATC) classification code list. At the time of the order, the **drug** is indicated – but not its brand name or its packaging configuration.
- When a patient presents his or her prescription to a pharmacist (transaction [4]), the pharmacist uses Pharmacy and Stock Management System to resolve the patient's unique ID and retrieve the patient's IPS-based health summary, including their electronic medication order, from the HIE.
- The Pharmacy and Stock Management System uses a mapped database to cross reference WHO ATC codes to GS1 Global Trade Item Number (GTIN) codes (transaction [5]). GTINs are globally assigned and managed codes used by *all* drug manufacturers; they are the identifiers barcoded on the packaging of medications.
- From the list of candidate **medicinal products**, the pharmacist chooses which to dispense to the patient based on the MOH's formulary, on stock availability, and on the insurance coverage (and perhaps personal choice) of the patient (transactions [6], [7], and [8]).

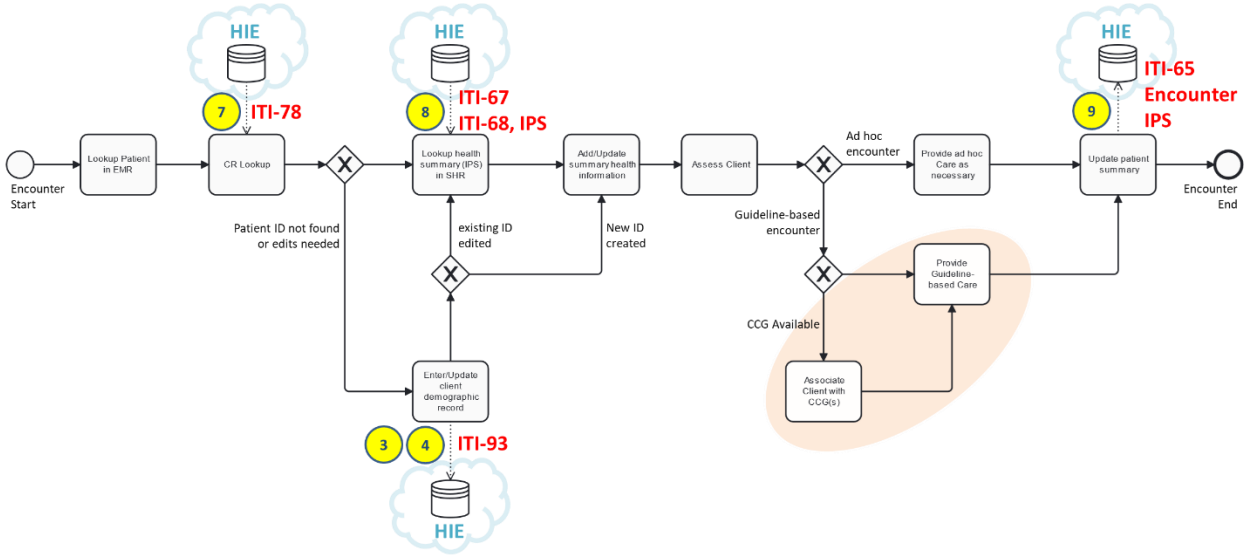
The importance of the ATC-to-GTIN mapping database cannot be overstated. Prescription transactions are coded using **drug** codes (ATC); dispense transactions are coded using **product** (GTIN) codes. Computable care guidelines, and important patient safety routines such as drug-to-drug interaction algorithms, are expressed using ATC codes. For its part, the dispense transactions' GTIN contains manufacturer and lot number information that is important for post-market surveillance (regarding reactions, for example) and is essential in supporting medication recall workflows, if necessary.

The GTIN-based transactions also provide essential information needed by the LMIS to support usage analytics that underpin stock replenishment and management decision-making. A similar mapping of clinical activities to supply chain consumption may be done for HIE transactions related to immunizations, lab tests, surgical procedures, etc.

This same cross-domain pattern can be employed in Kosovo, to support integrations to other systems like the HFIS

Point of Service application (POS)

Point of service (POS) applications shall adhere to a pattern of processing that enables them to be "well behaved" digital health participants in the HIE. This pattern was illustrated in Figure 13 (replicated below, for ease of reference).



As predecessor steps **prior** to the beginning of the care encounter workflow (not shown in the figure), the application shall enable the health worker to login and to establish the context of care delivery. It is mandatory that digital health applications are secure and that they protect access to personal health information (PHI) by requiring authentication of health workers via, at a minimum, unique user login credentials. It is also mandatory that an application can cache the health worker ID and the location ID once the login is accomplished; these data are needed to support transaction processing with the HIE for every patient encounter.

Referencing the Figure 13, the care encounter workflow steps may be described as follows:

1. The patient is looked up in the local digital health application (e.g. the EMR).
2. The same patient lookup is executed against the CR as an **ITI-78** transaction.
3. If the patient demographic content from the CR needs to be updated, or if the patient is not found and needs to be entered into the CR (and locally), the workflow progresses to the Enter/Update Patient data step. At this step, the updated or new patient data is persisted to the CR via an **ITI-93** transaction. NOTE: the patient.id GUID will be assigned by the CR* POS solution actor and will be faithfully persisted by the CR. If a health card or other "wallet ID" cannot be issued at the time a new demographic record is being created, this GUID is also persisted as the MOH-assigned identifier (patient.identifier). If the POS solution is **not** playing the role of the CR* POS actor, then following this step in the encounter (which will accomplished using the CR* POS), the POS solution will **return to step 2** of this process.
4. If the patient update is completed, or if it was not needed in the first place, the patient's health summary "id" is queried from the HIE using an **ITI-67** transaction and retrieved from the HIE via an **ITI-68** transaction, which returns an **IPS** document as the query response.
5. The IPS content is reconciled with the local data, and both are updated as appropriate. If no IPS was returned by the HIE, then the appropriate background and health history information is captured, in its entirety, during this workflow step.
6. The patient is assessed to determine the presenting issues and to ascertain whether the encounter's care pathway will be to provide ad hoc[38] care or whether the patient's encounter should follow a guideline-based care plan.
7. If the encounter should follow a guideline-based care plan, and if a computable care guideline (CCG) is supported, then the appropriate CCG is leveraged. NOTE: this specification is silent on how the CCGs are made available to the POS solutions. There *may* be circumstances where the CCG is retrieved from the HIE via an ITI-68 transaction, which returns the CCG bundle – but it is not expected that these would be runtime transactions during the encounter.
8. The patient receives either guideline-based care or ad hoc care, as appropriate. The care encounter context is logged, and the care activities are faithfully updated to the POS' database. An **encounter** resource is created which is uniquely identified by a GUID, and which cross-references the provider ID, facility ID, client ID, and care encounter timestamp. This encounter resource plus a new **IPS** document (updated to contain the results of the present encounter) are together submitted to the HIE, in a single bundle, using the **ITI-65** transaction.

For purposes of conformance to this spec, a POS shall be able to:

1. Authenticate a health worker and establish both the health worker's unique ID and the unique ID of the care facility. For authentication, the application *may* have to play the role of an **IUA Authorization Client** and execute **ITI-71** (or implement some functionally

[38] Ad hoc care is care that is **not** following a pre-defined guideline. This ***may*** be emergency care; however, this is not true in all cases that emergency care is ad hoc. Sometimes, emergency care may also be guideline-driven (head trauma, for example).

equivalent authentication mechanism, such as public key infrastructure (PKI)). To fulfill these mandatory requirements, a POS solution *may* be required to play the role of a **Care Services Selective Consumer** and execute an **ITI-90** transaction as defined by the mCSD profile. It is mandatory that the application will also need to be able to play the role of a **CT Time Client** and execute **ITI-1** and play the role of an **ATNA Secure Node/App** and be able to execute transactions **ITI-19** and **ITI-20** as defined in the IHE ITI Technical Framework.

2. Play the role **Patient Demographics Consumer** and execute transaction **ITI-78** and as defined in the PMIR profile.
3. If supporting the **CR* POS** role[39], play the role of a **Patient Identity Source** and execute transaction **ITI-93** as defined in the PMIR profile.
4. Play the role of an **MHD Document Consumer** and execute transactions **ITI-67** and **ITI-68** as defined in the MHD profile. A received **PCC-IPS** health summary document must be ingested, parsed, and persisted to the application's local data store.
5. Play the role of an **MHD Document Source** and execute transaction **ITI-65** as defined in the MHD profile. The **IPS** health data content profile must be generated from the content in the local data store as normatively defined in the IPS profile. NOTE: it is essential that resource.id values are properly managed by the POS solution. Resource id's contained in IPS documents returned by HIE queries must be faithfully persisted to the local data store and faithfully returned in any updated IPS document. For *new* IPS content reflective of the activities of the encounter, the POS solution must generate GUIDs for all relevant resource.id values.
6. On a periodic basis, the POS solution *may* be required to play the role of a **Content Creator** and submit indicator reports to the HMIS via the **QRPH-53** transaction as defined in the ADX profile. Such report schema will be defined by the MOH and POS solutions will be conformance-tested to confirm their ability to correctly generate reports adherent to these schemata.

For a **dedicated** CR* POS solution that is **only** used for onboarding new client demographic records, only requirements 1, 2 and 3 (listed above) must be met.

[39] It is not expected, necessarily, that all POS solutions will be employed to onboard new client demographic records to the national CR. This may be a centralized administrative process that includes generating a unique ID card, for example. Or there may be a dedicated CR* POS app that all care sites are required to use, external to the digital health solution.

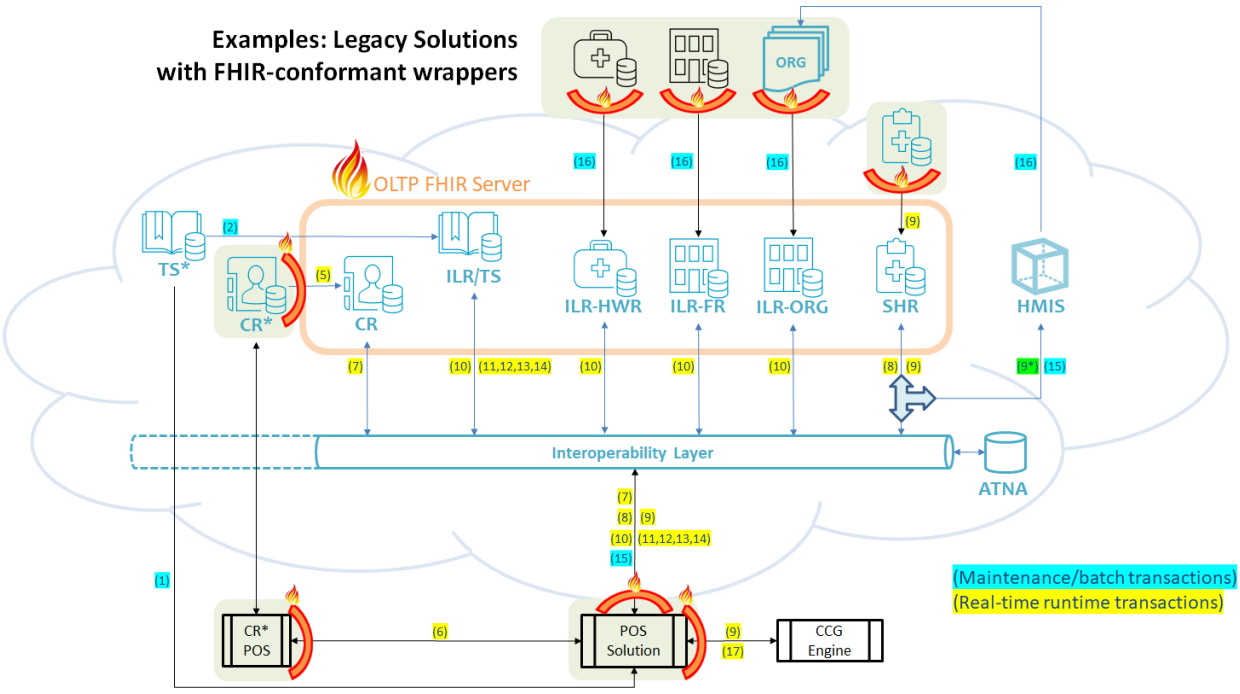
Digital Health Landscape and Quick-win Opportunities

KEY MESSAGES: Existing digital health investments can be strategically leveraged to both accelerate and not impede the national-scale implementation.

- There are strong opportunities to leverage existing content to "seed" the HIE registries and repositories. An example is BHIS, which has demographic information regarding 1.6M Kosovars.
- All existing MOH-funded software solutions were designed to be point of service (POS) applications, and not as HIE architectural elements. None are (presently) able to play a role in this "infrastructure". Today, none are conformant to the new digital health norms and standards.
- The workflows operationalized by some of the existing MOH-funded POS software solutions are ripe for being re-engineered. Kosovo will benefit greatly from adopting international best-practices related to patient "flow" and workflow management techniques.

RECOMMENDATIONS: The existing set of MOH-funded POS solutions should be rationalized and re-purposed, in line with the enterprise architecture and the new digital health norms and standards.

- No long-term software development (or support) contracts should be executed for existing MOH-funded solutions until their future role in the overall architecture is established. The assessment of each POS solution should be completed by no later than year-end 2024.
- MOH should leverage its new norms and standards, plus international best-practices in clinical care workflows, to establish target requirements for each of the core solutions needed for the care delivery network (e.g. hospital systems, ambulatory care EMRs, lab systems, pharmacy systems, diagnostic imaging, etc.). The functionality of credible open source options can be leveraged to set the "floor" (e.g. no expensive custom solution should be considered if it is less functional than the free option).
- An independent assessor should compare each MOH-funded solution to the relevant "floor" solution's functionality and report on the gap analysis. These analyses should be leveraged to drive forward-looking investment decisions for the national infrastructure initiative – including the identification of any existing solutions for software façade development



This section lists key digital health solutions, their use cases, where they are deployed, who is supporting them, and germane technical attributes (where known). These are mapped to the architecture described in 12 and implications and quick-win options are discussed.

High-level overview of broadly deployed digital health solutions

System	How broadly adopted?	Potential HIE role	Deployment model	Interoperability standards	Product source code model	Local support organization	Annual support code (USD) for national implementation
BHIS	5000 users 1.6M patients	CR* POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Euro 360,000
e-presecription	1000 users	POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Unknown
Surveillance and Early Warning System	251 users	POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file	Closed source	MOH	Euro 226,560

				format import / export			
Pharmceutical Stock Management System	1700 users	POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Unknown
Licensing Module for Private Health Institutions	2000 users	FD/POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Unknown
Health Worker Module	50 users	HWD/POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Unknown
Health Fund Information System	50-100 users	POS	Web Application, Hosted Solution	Proprietary application programming interface (API), CSV file import / export, Proprietary file format import / export	Closed source	MOH	Unknown

Table 2 – TWG Responses to the role(s) that existing systems can play in the HIE

Mapping existing solutions to HIE actors

The existing systems in Kosovo (listed above) including those in the private sector, are all Point of Service (POS) applications and so are not good candidates as HIE architectural elements. In some cases, however, these solutions contain data that can be uploaded to relevant registries/HIE components in order to provide a running start.

The elements of the HIE infrastructure may be generally grouped as follows:

HIE Roles residing in the "OLTP FHIR Server":

- Client Registry
- Facility Registry
- Health Worker Registry
- Shared Health Record
- Terminology Service
- Organizational Registry

Other HIE Roles:

- Client Registry*
- Terminology Service*
- HMIS
- Interoperability Layer

Registry "Feeder" systems external to the HIE:

- CR* Point of Service solution
- Health Worker Directory
- Facility Directory
- Organizational Directory

Based on the above, the key procurements for operationalizing the hosted HIE infrastructure will be:

1. High-performance OLTP FHIR Server
2. Client Registry*
3. FHIR-capable Terminology Service*
4. Data Analytics Engine (HMIS) plus T-junction
5. Interoperability Layer, including orchestration, authentication and auditing services

All of these will be expected to operate as managed services on Kosovo's eGovernment datacentre. The Interoperability Layer will act as the sole gateway for transactions destined for the OLTP FHIR Server and the HMIS. This will centralize the health-related authentication and auditing functions for healthcare related transactional traffic from POS solutions.

Registry "feeds" will generally not operate as OLTP actors and so will not need to traverse the Interoperability Layer. Each feeder system will operate as a trusted application with direct, secure access to the underlying Registry via a managed, conformance-testable interface.

An exception to this pattern is the Client Registry* POS. This application *may* need to establish a new client demographic record in real time. The Basic Health Information System (BHIS) was originally intended to be a Patient Registration system. In this role, it can be potentially utilized as the CR* POS – a point of service application for patient registration that, in turn, feeds data to the Client Registry* and then onward to the OLTP FHIR Server. Given that BHIS already has data for 1.6 million citizens of Kosovo, as a running start, this data can be uploaded to the new Client Registry* (and to the OLTP FHIR Server). In order for BHIS to function as a standards-based CR* POS, however, it must be adapted to perform the minimum functions and address the minimum dataset required as per the profile of the CR* POS. This would require both adaptation and refactoring of the BHIS system as well the development of a façade.

The Licensing Module and the Health Worker Module solutions will both be expected to play "feeder" roles as a Facility Directory / Organization Directory and as a Health Worker Directory, respectively. Each solution will require a facade to meet the conformance-testable requirements defined in the relevant technical sections.

The Stock Management solution and the Health Fund Information System are expected to operate as "companion" systems. These solutions will not participate in the HIE's healthcare-focused OLTP processes, but rather are expected to operate in near-real-time based on transactions routed via the T-junction. Healthcare transactions may have stock and/or financial implications. Where they do, the healthcare transactions will feed these companion systems via the T-junction plus necessary downstream processes (for example, to map from healthcare codes to supply chain or financial codes).

It is expected the Surveillance solution will also operate as a companion system fed by the T-junction. Reportable data that have been collected by POS solutions during the course of patient care will be "routed" to the surveillance system.

The Lab Information System is a possible POS application that could be connected to the HIE. To accomplish this, it would need a facade that operationalizes the relevant FHIR standards.

There was a clear preference expressed by the TWG to ***not*** have a proliferation of POS solutions during care encounters. For this reason, an argument can be made for refactoring the ePrescription solution as a companion or facade for "platform" electronic medical records (EMR) solutions. This will have to be considered in the context of the national care guidelines strategy and its potential use of CCGs to operationalize evidence-based, patient-safe prescribing practices.

A proposed HIE structure for Kosovo is shown below:

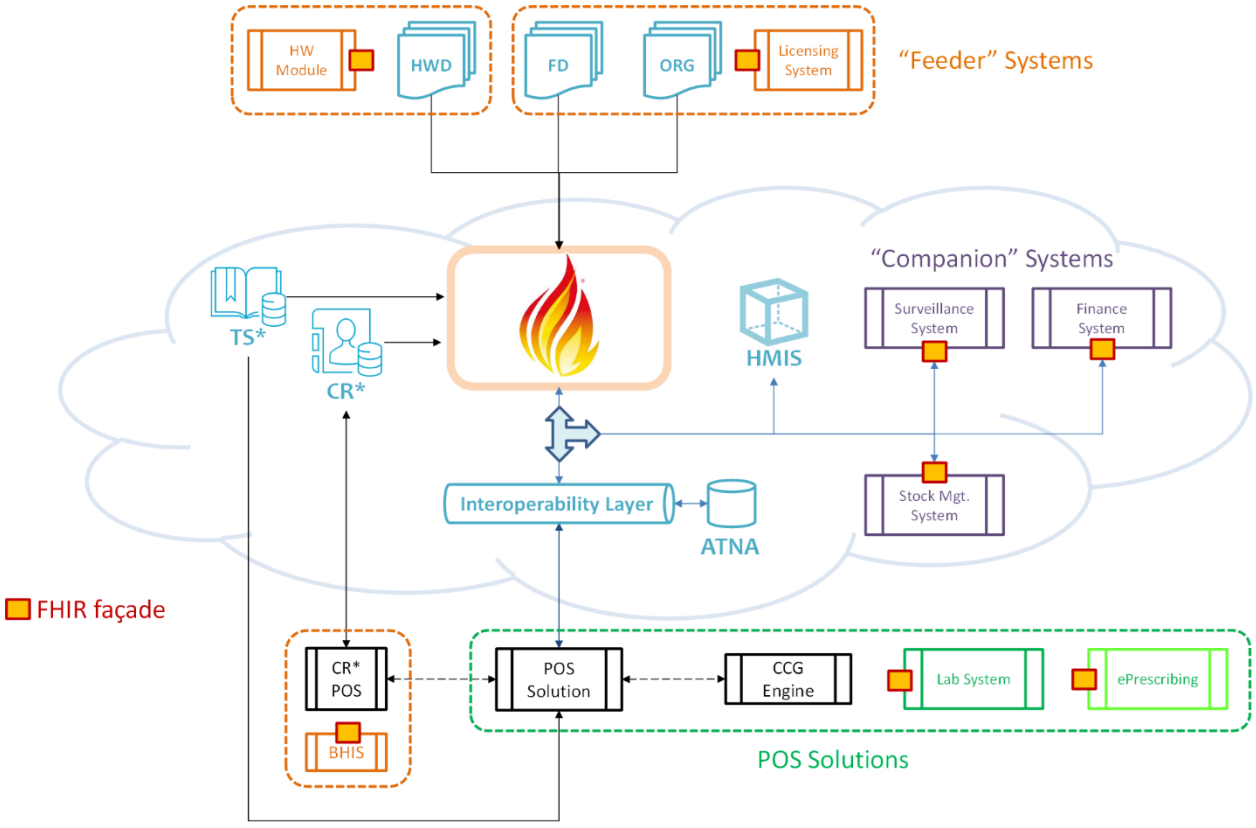


Figure 19 - Proposed HIE Structure for Kosovo

It is important to note that the Feeder Systems, Companion Systems and POS Solutions shown in the graphic do ***not*** represent closed sets. Other directories will be needed, for example, to provide source health worker information for the care providers ***not*** in the HW Module's database. Likewise, more Facility and Organization directories will also be connected to the HIE as feeders, other Companion Systems will be fed from the T-junction, and more POS solutions will be connected to the HIE's Interoperability Layer (e.g. EMRs, dentistry solutions, pharmacy and lab systems, diagnostic imaging, etc.).

Of particular interest is the notion of connecting the eKosova platform to the HIE as a patient-facing app that could give citizens access to their health data. Many in the TWG felt this should be saved for later in the project. However, there is a strong opportunity for such an app to significantly accelerate adoption within the private sector, and for this reason it should be considered a prime candidate for ***early*** rollout.

Given all of the above, it is not advisable for the Ministry of Health to sign off on any new long-term contracts for development and/or maintenance of existing systems prior to establishing their role in the future HIE. This determination should ideally be completed by the end of 2024 so that there is no delay in moving forward. Further it would be advisable for the Ministry of Health to consider existing free and open-source software as a baseline by which to judge whether or not investments in custom-solutions are worthwhile. A new custom solution should be developed only when that solution will be demonstrably superior to existing free and open-source options. An independent assessor can support the Ministry of Health on this exercise both for existing and for planned investments in digital health.

Governing the National HIE

KEY MESSAGES: Legislation, policy, governance, and executive-level choices related to "implementation science" will have a huge impact on the risk, time, and cost of the national digital health project.

- In preparation for joining the EU, Kosovo should ensure its legal basis for national-scale health data sharing is in line with the European Health Data Space (EHDS) regulation. EHDS speaks to areas of patient rights related to their data and to patient-safe continuity of care, provider access to standards-based health data in support of care (including across borders), solution providers' requirements to adhere to the EEHRxF, and the requirements for data in support of "secondary use" (to support system management, research, etc.).
- To ensure coordination across all relevant digital health initiatives, a cohesive programme management approach is needed. Every initiative must adhere to the new norms and standards and fit into the national health enterprise architecture.
- Implementation choices should be, to the extent possible, informed by an econometric model of QALYs gained per invested EURO.

RECOMMENDATIONS: Kosovo can and should embrace existing models and exemplars related to digital health regulations and implementation best practices.

- As an immediate action, MOH should establish the interim programme governance structure discussed and agreed upon earlier this year. The programme management office (PMO) operationalized by this governance structure should be empowered by the MOH to exert governance across all relevant projects.
- As an immediate action, key MOH teammates should be enrolled in appropriate capacity-building courses to increase the health informatics "bench strength" that will be needed in the coming months. As a medium term action – capacity-building across the entirety of the health workforce should be planned for, and at least one health informatics academic programme should be established at a domestic university.
- As a medium term action, the MOH should begin drafting legislation in line with EHDS to be adopted by the parliament, once ready.
- Wherever possible, MOH policy should be drafted to "pre-adopt" the core elements of this EDHS-aligned legislation and bring it to immediate effect. This approach can be leveraged, for example, to address challenges related to the use of digital documents as the legal "document of record" for health purposes, instead of paper.
- Implementation decisions related to unique IDs for health, financial support for private sector digital health updates, etc. should be informed by the blueprint's investment case tool. These what-if analyses will provide an objective basis for forward-looking decisions.

This section describes policy options which could be leveraged ensure the necessary legal basis is in place for nation-wide sharing of person-centric, protected health data. A digital health

governance framework is proposed which would coordinate efforts across all national projects and programmes.

A conceptual policy framework for national scale health data sharing

This section describes a policy structure that supports national scale health data exchange across both private and public sector care providers.

Two key digital health related policy recommendations are anticipated to be especially impactful and foundational in support of the national HIE:

- Health Data Governance Policy
- Health Data Sharing Policy

Health Data Governance

To support the large-scale implementation of digital health care delivery solutions, it is essential that the applicable rules of person-centric health data management and governance are defined and enforced for all parties, both in the public sector and the private sector. To provide a legal basis for a national HIE, regulations must define the parties over whom governance will be exercised. The three relevant parties are: health data *owners*; health data *custodians*; and health information *network providers*.

It is an international best practice that data about the care subject is *owned by the care subject*. Care provider organizations are *health data custodians*. The MOH, or related agencies or departments, become *health data custodians* when they maintain person-centric data holdings in shared health record (SHR) repositories or other related registries that form components of the national HIE. Parties that process health data, but **do not retain** it, are not custodians but are considered *network providers*.

Different regulations apply to health data *owners*, health data *custodians*, and health information *network providers*. Typically, as the owner of data about himself or herself, a subject of care should have a right to access their own data and may share their personal health data with whomever they choose. This right applies to digital data in the same way as it would apply to paper copies of personal health data. Health data custodians are generally required to safeguard data holdings, ensure they are available when they need to be, and ensure they are only used by authorized persons for authorized purposes. All healthcare providers are health data custodians. Network providers are typically required to ensure the integrity of the content they convey and to ensure that their operational processes do not inadvertently create data holdings that would cause them to become a custodian. These actors are depicted in Figure 20

	 	
Health Data Owner It is a best practice that patients are the legal ***owners*** of health data about themselves.	**Health Data Custodian** Care providers, including independent clinicians, care provider organizations, or the MOH, will be ***custodians*** of personal health data.	**Health Data Network Provider** Network operators ***convey*** personal health data but do not become ***custodians*** of it.

Figure 20 - Conceptual Health Data Governance Actors

Kosovo will need a separated Health Data Governance Policy and Masterplan as a stakeholders' agreement on a single vision of data domain in health, including consolidation and coordination of current systems and projects already underway. The Policy and Masterplan shall also define institutional arrangements on improved health data governance and responsibilities, including sources of investments and sustainable systems' development and maintenance.

On a national level, the Ministry of Health and National Institute of Public Health (NIPH) will share responsibility for health data governance layers[40]:

- **Health Data Policies**. The MoH shall continuously develop and update the policies and strategic plans for the health data governance to ensure strategic relevance in data management and utilization. This will also include defining roles and responsibilities in health data governance such as data standardization, collection, management, and publishing.

- The data stewardship role coordinates the use of sectoral data assets to achieve business objectives. They are concerned with the fitness of data assets to purpose of healthcare system. They are caretakers of data assets, responsible for data content as well as the business rules of data utilization. They are also designers and guardians of data analytics processes that allow dynamic data analytics to reflect the ever-changing needs of data consumers. They maintain accountability for data analytics and a coordinated system of data quality assurance.
- The data custodian is responsible for technical data storage, and technical implementation of data analytics based on agreed business rules. This role is responsible for providing the technical environment for data storage, processing, and exchange, including an assurance of authorized access to analytical data sets, indicators, and reports. The data custodianship role shall coordinate closely with the data stewardship role to ensure data quality, accuracy, security, and accessibility.
- **Health Data Standardization.** The MoH will maintain health data standardization by procedures and guidelines within the health data governance model but will also inherit

[40] Please, note that on national level, the role of custodian shall be separated into two roles - stewardship and custodianship. On some other levels, for example, within a healthcare facility that is not necessary. The Health Data Governance Policy and Masterplan shall clearly define such roles on national level.

general health sector data standardization. The health data governance will follow general health sector and national digital data rules and standards for data definitions, creation, storage, exchange, and use, including the assurance of data privacy and security.

Appendix 3 provides more inputs for national level health data governance roles.

Health Data Sharing

To operationalize the national HIE, Health Data Sharing legislation may be needed to provide a legal basis for its operation. There are two key aspects to be addressed by such a policy framework:

1. Patient consent management; and
2. Patient rights related to safety and quality of care.

As a best practice, patient consent regarding health data sharing should be based on an **implied consent** or *opt-out* model. In plain terms, this means a patient's data will be shared within the care delivery network, for the purpose of delivering care to that patient, unless the patient explicitly decides they wish to *withdraw* their consent for such sharing. This option is preferred over explicit opt-in consent because of its fundamentally easier implementability and scalability. That said, it is important that citizens *must* have the right to withdraw their consent to share their data. This right is foundational to the notion of health data ownership referred to in the previous section.

As a useful example of what is the scale of consent withdrawals that can be expected, of the 5.1 million patients with records in the National Electronic Health Record (NEHR) system in Singapore, approximately 0.01% have opted out of data sharing.[41] Even though these numbers are low – without the option to withdraw consent there is no actual right of privacy on the part of the citizenry. It is a must-have.

Typically, a patient can withdraw their consent to data *sharing*, but cannot withdraw their consent to have their data *collected*. This distinction is important. Patient-level health data *collection* is necessary to support key business processes. Care provider organizations need these data for managing provider payments processes, meeting medico-legal requirements, and satisfying regulations related to mandatory notifiable public health reporting. Usefully, such a collect-but-not-share policy approach means that content that was collected during the period when consent had been *withdrawn* can again be shared if the patient reconsiders their decision and later reinstates their consent for data sharing. The collect-always and share-by-default approach is illustrated in Figure 21

[41] https://www.ihis.com.sg/nehr/faqs

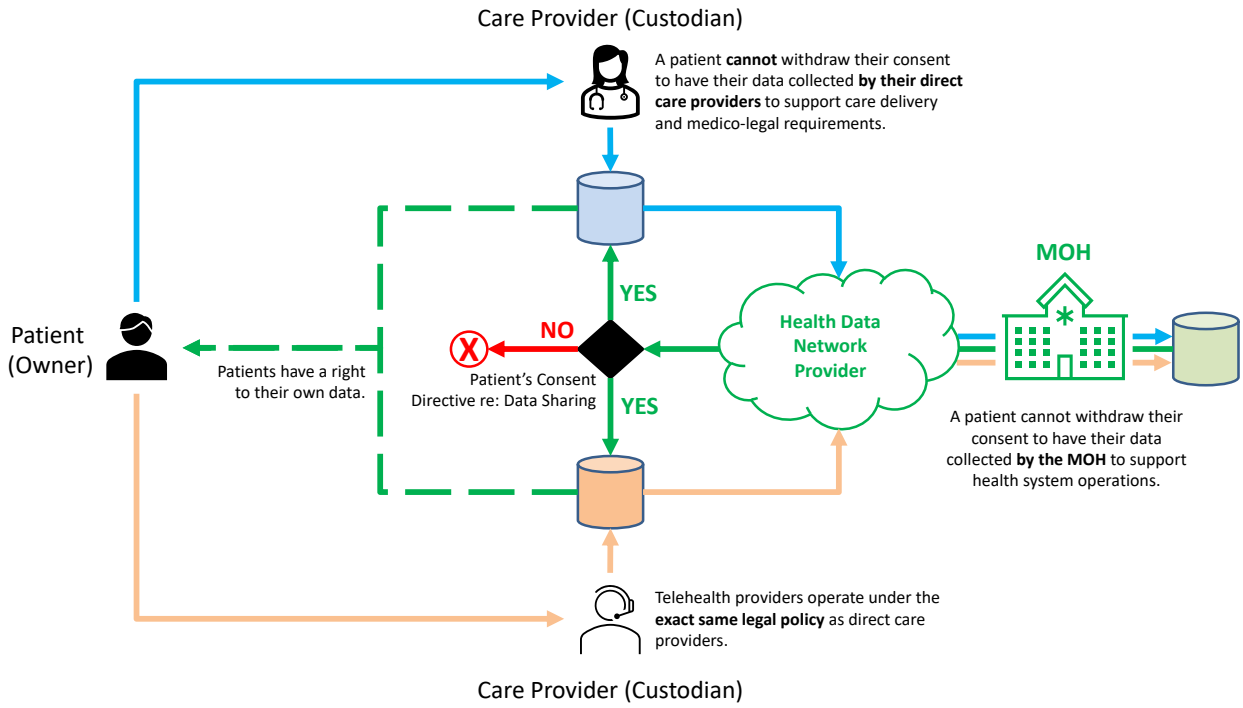


Figure 21 - Conceptual Data Sharing Consent Model

As a matter of implementability, it is useful to adopt as a default policy that *all* health data will be shared with *all* care providers unless consent to do so has been revoked. Although it is *theoretically* possible to articulate fine-grained data sharing rules that can describe consents to share *some* content with *some* care providers and other content with other providers – the practicalities of such approaches are daunting.

For these reasons – as a starting point – a simple consent policy is recommended that affords the patient the right to choose to be either *all-in* or *all-out*. This *all-in* default behaviour is illustrated in Figure 21**Error! Reference source not found.**. The patient's consent directive decision gate (black diamond) will share data across the care delivery network (data flows shown in green) *unless* the patient's consent rule is explicitly set to **NO**.

There have been, in some jurisdictions, challenges in having private sector actors share patient data (which they may regard as *customer* data). To combat issues related to health data blocking or hoarding, health data sharing policy should be framed as a patient *rights* issue. The premise for such an approach is that each patient is entitled to safe, high-quality healthcare. The delivery of safe, high-quality care relies on good care continuity and this, in turn, relies on health data sharing across the care delivery network (including *both* public and private sector providers).

This premise is also illustrated in Figure 21 where it may be noted that data flows on a mandatory basis from Direct Care Providers to patients (as owners) and to the MOH (who, alongside the Direct Care Provider, is also a custodian). These MOH data holdings are operationalized by the secure data sharing infrastructure of the HIE. In situations where private sector players have been

reticent to share health data about their patients, framing the data sharing as a *patient rights issue* establishes a legal basis for prohibiting *data blocking* or *hoarding*[42] by care providers.

All of the above are in line with the Data Governance Act[43] and the Data Act[44] of the European Health Data Space (EHDS), adherence to which is required for countries joining the European Union. Kosovo would be well served to adopt legislation that aligns with the EHDS since this also aligns well with international best practices.

TWG Recommendations

Based on TWG feedback, the following are recommended as policy action items that should run in parallel to the HIE's technical deployment efforts:

- Align Data Governance legislation with the European Health Data Space
- There is presently a policy gap related to an explicit definition of data **owner**. It is recommended this be clarified.
- With the anticipation of **AI training data sets** as being important to progressing this technology in Kosovo, a clear policy on the use of person-centric health data for this purpose of use should be defined, with appropriate **guardrails** to ensure the public good is served.
- Although it is not explicitly defined by the existing legislation, the present default policy regarding data sharing appears to be "opt-in/no-BTG/individual-carer/any-purpose". In the interests of **implementability**, the TWG recommends MOH to consider adopting an explicit healthcare policy related to data sharing that would favour a **default** where health data is shared unless consent is withdrawn (**opt-out**), with no "break the glass" (**no-BTG**) capability for care providers to circumvent a person's consent directive, and that *all* of a person's health data will be shared with *all* members of the care delivery network (**whole-network**) for the purposes of care delivery (**care-purpose**). A person would have the right to withdraw their consent to data sharing (but not to data *collection*).
- MOH clearly articulate its health data sharing policy scope to include private sector care providers.

Exerting MOH governance over disparate digital health projects

To operationalize the national HIE, it will be important to coordinate and govern the activities of multiple stakeholders and their projects.

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42 https://www.researchgate.net/publication/332530889_Digital_Health_Data_and_Information_Sharing_A_New_Frontier_for_Health_Care_Competition

43 https://eur-lex.europa.eu/eli/reg/2022/868/oj

44 https://eur-lex.europa.eu/eli/reg/2023/2854/oj

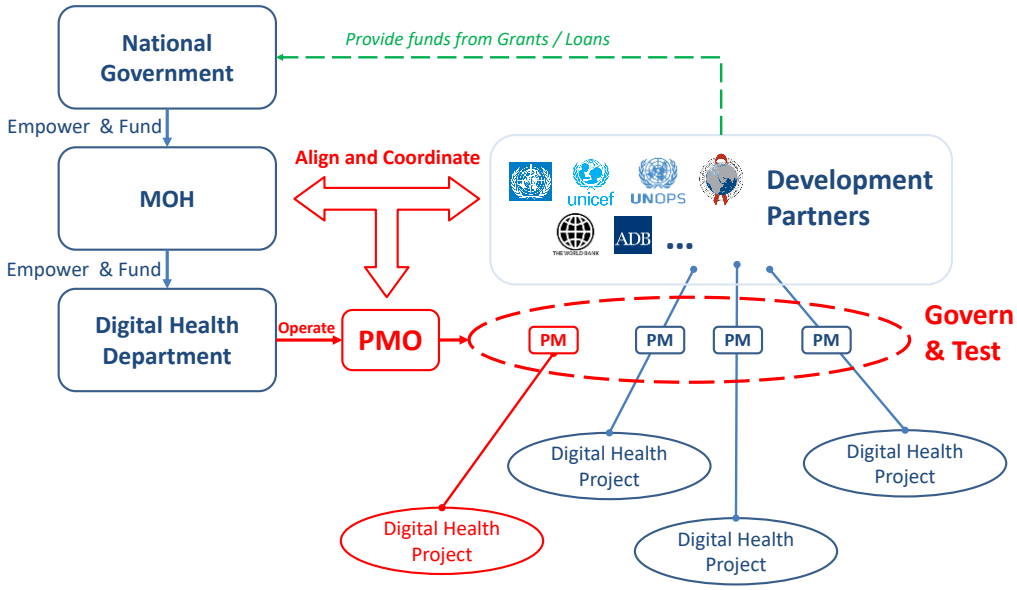

Figure 22 - Conceptual DH Governance Structure

Figure 22 illustrates a conceptual digital health governance structure informed by country examples that were generally adherent to the Paris Declaration.[45] Such a governance structure may be leveraged to coordinate digital health activities. Its operation may be described, at a high level, as follows:

- The Government may benefit from grants and/or loans from Development Partners. Some funds may directly be targeted to health-related initiatives or to digital health, specifically; others may be more general.
- The Government empowers and funds the Ministry of Health (MOH) to execute activities within its national mandate. Successful execution of this mandate relies on digital health, which will receive project funding for new initiatives and sustaining funding for ongoing operations.
- MOH and its relevant departments and agencies will engage with Development Partners to coordinate activities and to ensure projects and programmes are aligned to MOH's strategies, priorities, timelines, and the norms and standards documented in its digital health blueprint.
- MOH will empower and fund a Digital Health Department (or Agency) to be the body that exercises the specific mandate related to executing the national digital health strategy. This department will operate a Programme Management Office (PMO) that exerts governance over **all** digital health projects in the country. All Project Managers (PMs) will coordinate their efforts under the auspices of the PMO regardless of whether they are overseeing MOH-funded or Development Partner-funded projects.
- As an instrument of this governance, the Digital Health Department will conduct the conformance testing of implemented solutions to ensure they are adherent to the national norms and standards for digital health. All digital health solutions, whether implemented

[45] https://www.oecd.org/dac/effectiveness/45827300.pdf

by public or private sector entities, will be subject to successful conformance testing before they can participate in the national HIE.

The Digital Health Department will also have a role in addressing digital health skills gap. Capacity-building, generally, will focus on requirements related to ongoing HIE operation. To address short-term requirements, external capacity will be leveraged to support one-time tasks related to implementation. All external contractors will operate under the governance of the PMO. Specific train-the-trainer capacity-building will be used to close gaps in frontline workers' abilities to leverage digital health at the point of service, and to close gaps related to IT technical support within the care delivery network.

Specifically related to pandemic and epidemic preparedness and response, the Digital Health Department may explore opportunities to collaborate with Mobile Network Operators (MNOs) through the GSMA's M4D initiative.[46] Such collaboration may help address challenges related to big data analytic capacity shortfalls that can be important in addressing public health emergencies.

In summary, it is expected that the activities of the Digital Health Department will include:

1. Operating the Programme Management Office that exerts governance over all digital health projects and programmes (including projects executed by the MOH and those of development partners).
2. Operating the national digital health conformance-testing platform. This platform should include both a 24x7x365 prototyping and self-testing service (also known as a sandbox) that may be employed by innovators to experiment against a reference implementation plus an assessment test rig that could be employed to certify digital health solutions against the norms, standards and mandatory behaviors delineated in the Digital Health Blueprint.
3. Providing a Center of Excellence in digital health that can provide thought leadership to inform decision makers and policy makers at MOH and in the Government as well as develop and disseminate educational materials to be leveraged by participants throughout the digital ecosystem (e.g. academia, private sector start-ups, and care delivery participants at all levels of the network).

TWG Recommendations

Based on TWG feedback, the following are recommended as governance structures and activities in support of the national HIE deployment efforts.

The conceptual framework for digital health governance envisages important principle of separating layers of governance. Concentration of layers in one organizational form leads to

[46] https://www.gsma.com/mobilefordevelopment/resources/webinar-on-demand-digital-health-a-tool-for-building-resilient-health-systems-in-a-covid-19-world/

concentration of decision-making power, low representation of stakeholders, and potential conflict-of-interest situations. Typical digital health governance layers are[47]:

- **Business processes:** The management of daily operations of clinical and basic administrative systems that support business processes is done by public or private health care providers or local communities. It should be mainly contracted to the ICT industry. Software solution providers help users to use systems properly, provide training and helpdesks, and fix potential system malfunctions.

- **Implementation support:** The government or health care facilities will systematically provide implementation support. For public sector, the government will provide and maintain general infrastructure and shared services for software providers. Providers can have their own teams for direct users support and basic maintenance of systems and infrastructure. Different arrangements are possible and agreements about who does what should be contracted for each specific software solution.

- **Implementation Management**: To ensure better coordination and quality of solutions, the government shall manage the overall process of implementing software solutions. It needs to provide guidance and technical support to help providers and other institutions to steer clear of process mistakes and contracting low quality solutions. This layer is usually delegated to a dedicated main digital health implementation body. Depending on the implementation strategy, that body shall provide support through overall coordination, through implementation of quality assurance mechanisms (such as the software certification process mentioned earlier), but also through specific and practical technical work on managing central registries and databases, implementing central services, such as e-prescription and e-referrals, assuring data quality, and even directly supporting operations by maintaining common infrastructure. It can cooperate with providers and even contract some solutions for them. For example, in a relatively small country, one implementation strategy can be that hospitals directly contract their own software solutions, while a central digital health implementation body contracts one solution to be used by all primary health care facilities.

- **Data governance and management**: It is advisable to treat data governance and management separately from operational systems use because health data should be treated as a strategic national resource. One of the objectives of this layer is to change the focus from simply gathering data to data use, reuse, and repurposing. Inconsistent data management practices can lead to siloed data systems where value of data remains unrealized. Data governance can facilitate consistent data management decisions at every stage of a data life cycle. This enables fit-for-purpose flows of different data types across all stakeholders to realize value from data use. This layer of governance also takes care of health data analytics framework that includes health statistics and other forms of health data use for policy- and decision-making. These frameworks have the potential to create

[47] Digital-in-Health: Unlocking the Value for Everyone. World Bank. (2023). Washington DC. License: Creative Commons Attribution CC BY 4.0

innovations in repurposing and combining diverse data sources (public intent and private intent data) that opens doors to development impacts previously unimaginable.

- **Policy making and regulation:** Finally, to stay coordinated and deliver value through synergy, all of these layers should use consistent policies and a common regulatory and standardization framework. The government, typically the MoH, or even other ministries (for instance, digital development) should provide the overall vision, strategic plans, standards, and basic regulations to facilitate more efficient and effective implementation on other layers. Institutional and organizational separation of these levels is critical. Countries that have followed similar national multi-stakeholder, and governance-focused approaches often support a national coordinating body, such as a technical working group or a steering committee, led by the ministries of health or public health delivery agencies, with the necessary representation and authority to perform the desired functions. The functions may include the adoption of standards, compliance, the definition of requirements, certification, and testing.

We need to create structures and capacity to separate at least policy and implementation management to improve accountability and "allow health people to govern digital health".

Given that the HIS department of the MOH does not currently have the capacity to function as a full-blown digital health department or agency (described above), the following structure is proposed as an interim step with the HIS department serving as a *de facto* PMO but coordinating very closely with other departments.

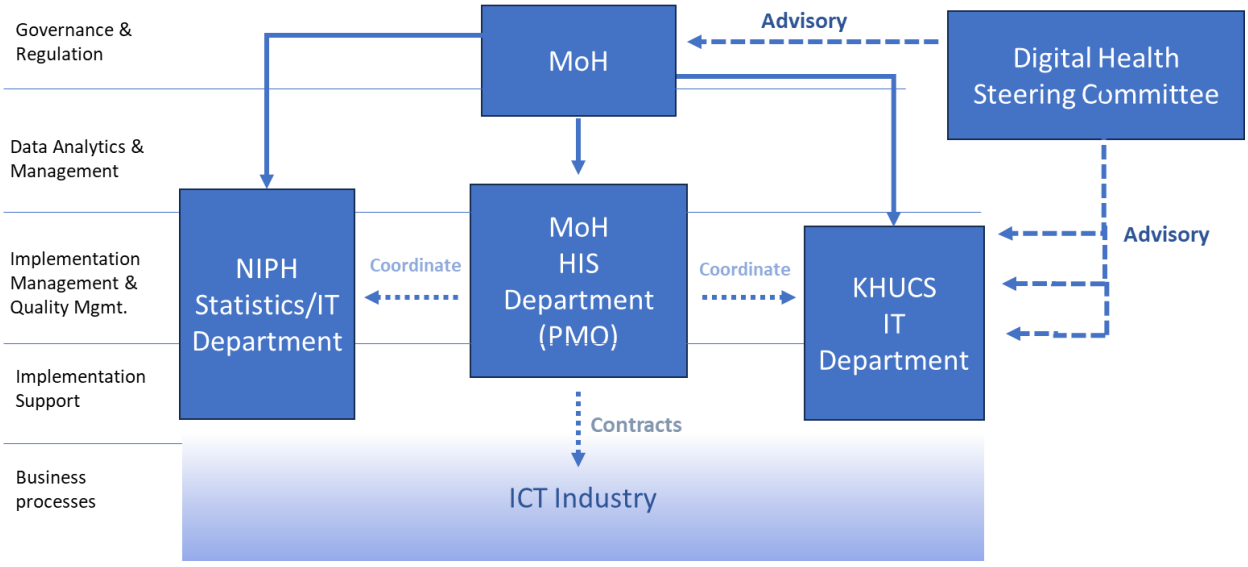

Figure 23 - Proposed Interim DH Governance Structure

The model envisages the following:

- Policy level is under full control of the MoH. The MoH issues binding policy mandates (or enact new legislation) through the office of the Minister, office of the General Secretary and under chiefs of departments (depending on the type of the policy/decision).
- The MoH is informed by the Steering Committee. The SC is oversight and advisory body, it will not be an operating entity. The SC is not permanent structure, but allows involvement of all key health sector decision makers (MoH chiefs of departments, CUKS, NIPH, hospitals, municipalities…), stakeholders (PM office of digitalization, other ministries, ..) and academic/expert communities. The SC drafts policies, decisions and recommendations for the MoH. Current Technical Working Group (TWG) will be gradually transformed into SC.
- The MoH HIS Department coordinates implementation and acts as a Project Management Office (PMO), including strong alignment with Kosovo Digital Public Infrastructure (DPI).
- Implementation is distributed between: (i) MoH HIS Department, (ii) CUKS IT Department, and (iii) NIPH IT Department. These three teams play the role of the eHealth Body envisaged by the Feasibility Study. There is a clear delineation of responsibilities.
- In initial stage, until the CUKS IT Department and NIPH IT Department build capacity, the MoH HIS Department will be the only contractual authority.
- Daily operations are managed by the same three units, but partly also by healthcare facilities (hospitals, PHC centers, pharmacies, drugs agency, private facilities, …). Hosting of systems and services is managed by the central DPI structures (PM digitalization office and data center of the Ministry of Public Administration.
- Systems/services development and maintenance is mainly given to the ICT industry. In-house software development is limited and considered exceptional.
- Health data governance is under MoH, but strong institutional responsibilities on that governance layer are placed to the NIPH.

At a later time, after efforts to build the capacity of the HIS department, the TWG envisions the structure below:

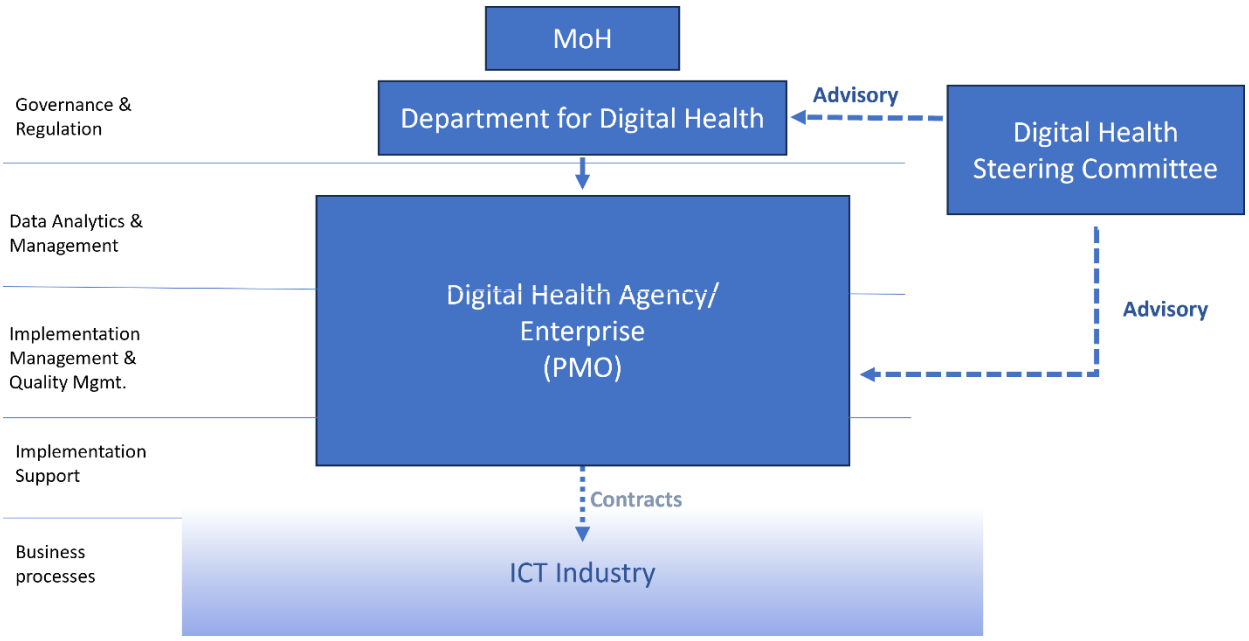

Figure 24 - Proposed long term DH Governance Structure

The transformation will lead to the following institutional set up:

- The MoH still keeps full decision-making control on policy, regulations and standardization, but through new Digital Health Department that reports directly to the GS/Minister. It is relatively small department, focused on strategic planning, policy making, regulations and implementation monitoring, not technical implementation. Non-technical part of the existing MoH HIS Department is transformed to new Digital Health Department.
- The Steering Committee is still engaged as the advisory body for the Digital Health Department.
- Implementation management is concentrated into new Digital Health agency/unit/public enterprise (similar to vision of eHealth body presented in the Feasibility Study). The implementation/technical arms of the MoH HIS Department, the CUKS and NIPH IT Departments are merged into new structure. Exact form is to be decided later, there are several options - for example, agency, public enterprise, unit within the Prime Minister's Digitalization Office (or some other central eGovernment structure).

Implementation Capacity

Implementation of the overall Kosovo digital health ecosystem envisaged in Strategy and Action Plan, and elaborated more in this Blueprint is a long-term endeavor. That requires stable

governance structures, as described above, but also capacity of staff engaged in these structures. At this moment, that shall be considered as most important critical success factor.

The MoH HIS Department, the CUKS and NIPH IT Departments need to be strengthened to be able to acquire the following competencies:

- Apply a systems approach to improve digital health services.
- Develop digital health business/economic models.
- Evaluate and select digital health solutions.
- Design and implement digital solutions.
- Create interoperability of tools and workflows.
- Assess project viability.
- Use human-centered design.
- Apply the software development lifecycle.
- Implement new products and solutions.
- Evaluate software performance.
- Evaluate effectiveness of digital health solutions.
- Identify strategic digital health infrastructure needs.
- Design and plan the enterprise architecture.
- Align individual projects with the enterprise architecture.
- Design and implement systems integration.
- Support application interoperability to enable data sharing and use.

In addition, the government should invest into improving the following competencies of top MoH decision makers (top management and chiefs of departments) and Steering Committee member:

- Develop Policies, Governance Structure, and Processes.
- Develop Regulations.
- Disseminate, implement and reinforce Policies, Governance Structures, Processes and Regulations.
- Develop clear vision and well-informed strategies.
- Implement digital health strategies.
- Facilitate institutionalization of DH strategies.
- Monitor and evaluate DH strategy.
- Promote organizational change management processes.
- Lead digital transformation.
- Coach and mentor individuals and teams.
- Promote innovation.
- Follow regulations and governance structures and processes.
- Monitor and evaluate regulations and Governance Structures and processes.
- Stewards implementation of Regulations and Governance structures and processes.
- Develop costed plan.
- Develop investment/funding strategy.

- Execute the investment/funding strategy.

Based on Health Data Governance Policy and Masterplan to be developed, the following competencies shall be developed for national level health data custodians:

- Use data coding and interoperability standards.
- Develop data coding and interoperability standards.
- Develop data security policies.
- Follow data security policies.
- Develop and use data analysis methods and tools.
- Apply data collection methods.
- Demonstrate effective donor communications.
- Demonstrate effective government directed communications.
- Demonstrate effective academic and research communications.
- Demonstrate effective general population centered communication.
- Demand and use information to derive insights.
- Implement evidence-based recommendations and policies.
- Apply the principles of evidence-informed practice (from WHO-UHC).

Conclusion

Given the above discussion it can be concluded that Kosovo is placed very well to build a standards-based conformance-testable national HIE, that this initiative is cost-effective and, if done well, will improve health outcomes and provide a significant return on investment, and that existing investments can play a role in this effort.

The critical areas to focus on to ensure this success are:

1) Adherence to international standards wherever possible and relevant
2) Embracing an Adopt/Adapt/Build prioritization when it comes to procurement of software applications
3) Bringing the private sector's solutions into conformance with the norms and standards for Kosovo and connecting them to the national HIE
4) Improving digital health governance and data governance to bring it into line with the EHDS
5) Building local digital health capacity

Next Steps

As mentioned in the Introduction section, the target audience of the present document is the MOH. The role of this document is to inform the publication, by the MOH, of a set of national Digital Health Blueprint artefacts. These will be reference artefacts; they should be published in the country's official language. The overall "Blueprint" should be released in two complementary parts, each part focused on a defined audience.

Developing the Blueprint Artefacts

National Digital Health Blueprint

This Blueprint document should target non-technical health system stakeholders who have an interest in the digital health agenda and will participate in the national implementation, whether actively or as supporters. This document should "make the case" for the national plan.

To establish **context**, it can summarize content from the *National Burden of* Disease, ***Error! Reference source not found.***, and ***Error! Reference source not found.*** sections. To indicate the MOH's chosen technology-related **direction**, summary information and graphics from the ***Error! Reference source not found.*** and ***Error! Reference source not found.*** subsections of the ***Error! Reference source not found.*** section can be leveraged. Technical details of the implementable specifications should not be included; rather the Blueprint document should refer to the companion document: the National Norms & Standards for Digital Health (see below)

The **concluding** section of this Blueprint should describe the Ministry's planned governance structure and note relevant legislative changes that will be enacted to support the project. Optionally, references can be made to the Investment Case and the budget, timeframe, and health impact (ROI) targets that it establishes.

National Norms and Standards for Digital Health

This technical specification should be targeted to health informatics professionals who will be involved in the design and deployment of conformant digital health infrastructure and point of service solutions. It need not replicate the contextual information included in the Blueprint, but rather should refer to it.

High level conclusions from the Blueprint's context-setting chapter can be summarized in a short **introduction**. The ***Error! Reference source not found.*** section can be leveraged, in its entirety, as the normative description of the national norms and standards. Where decisions have been made to incorporate existing legacy solutions (as described in the *Digital Health Landscape and Quick-win Opportunities* section), these should be described, and illustrative architecture diagrams should be included.

The **concluding** section of this Norms and Standards specification should describe the MOH's planned approach for conformance-testing as well as any supportive (prototyping environments) that will be provided to assist technical teams in meeting the national requirements. Citations should be provided, that reference relevant legislation regarding the normative requirements for digital health solutions.

Publication and Dissemination

The national Blueprint artefacts should be translated into Albanian and officially published and noted in the government's Gazette. The National Norms and Standards for Digital Health should be officially adopted by enacting a Policy of the Ministry of Health that references this national specification and establishes an enforceable requirement that digital health solutions in the

nation's ecosystem shall operationalize these specifications and shall connect to the national HIE within the specified timeframe.

The governance structure of the MOH should adopt ownership of both the Blueprint and the Norms and Standards. Both documents will be refreshed on a regular timeframe established by the Policy. Maintenance of the Norms and Standards will be taken on as an ongoing responsibility of the relevant Digital Health Department or Agency.

Appendix 1: Example Use Case – Diabetes

This section outlines an example workflow for guideline-adherent diabetes care. It includes the mandatory behaviors necessary for good HIE "citizenship", such as establishing a unique client ID, obtaining a patient summary from a shared repository, providing guideline-based care during an encounter, and updating the shared health record repository with the encounter's details. It will describe the NCD workflows in terms of the blueprint's transactions and illustrate the conformance-tests that could be applied to a digital health solution to demonstrate that it is adherent to the blueprint. This set of scenarios could be used for demonstration purposes (e.g. at a conference or an AeHIN Convergence meeting) or for testing purposes at an official MOH "Projectathon" event.

Archetypal Transaction Patterns

This example use case is expressed using a simplified set of archetypal transaction patterns operating within a digital health architecture that includes the key actors identified in Figure 12. For these archetypal patterns, the relevant participants are:

- patient – the subject of the care encounter
- HW – the health worker that is the provider of care during the encounter
- app – the digital health solution used by the health worker
- IL – the interoperability layer actor that supports security, authentication, and transaction orchestration between the app and the other actors in the digital health shared infrastructure
- CR – the client registry actor that supports resolution of the patient's unique ID
- ILR – the interlinked registry actor that supports resolution of unique facility, organization, health worker, and health service IDs and codes
- SHR – the shared health record repository that contains health summary documents based on the International Patient Summary (IPS) specification as well as encounter records and, if applicable, computable care guideline records (CCGs)

At a top level, the transaction pattern may be described as follows:

> A HW logs into their app and their credentials are established, including their access rights to the HIE. An HIE transaction (TX-A) establishes their care context. An access token is obtained, the HW ID, facility ID and organization ID are resolved, and the app is ready to begin recording care encounters.
>
> FOR EACH CARE ENCOUNTER…
>
> > The patient's unique ID is established (TX-B)
> >
> > The patient's health summary is retrieved from the national HIE (TX-C)
> >
> > Guideline-based care is provided, leveraging one or more CCGs (TX-D)
> >
> > A record of the Encounter, including the updated health summary, is posted to the national HIE (TX-E)

At the end of the work session, the HW logs out of their app

This top-level transaction pattern is illustrated in Figure 255. The details of each transaction are described in the following subsections.

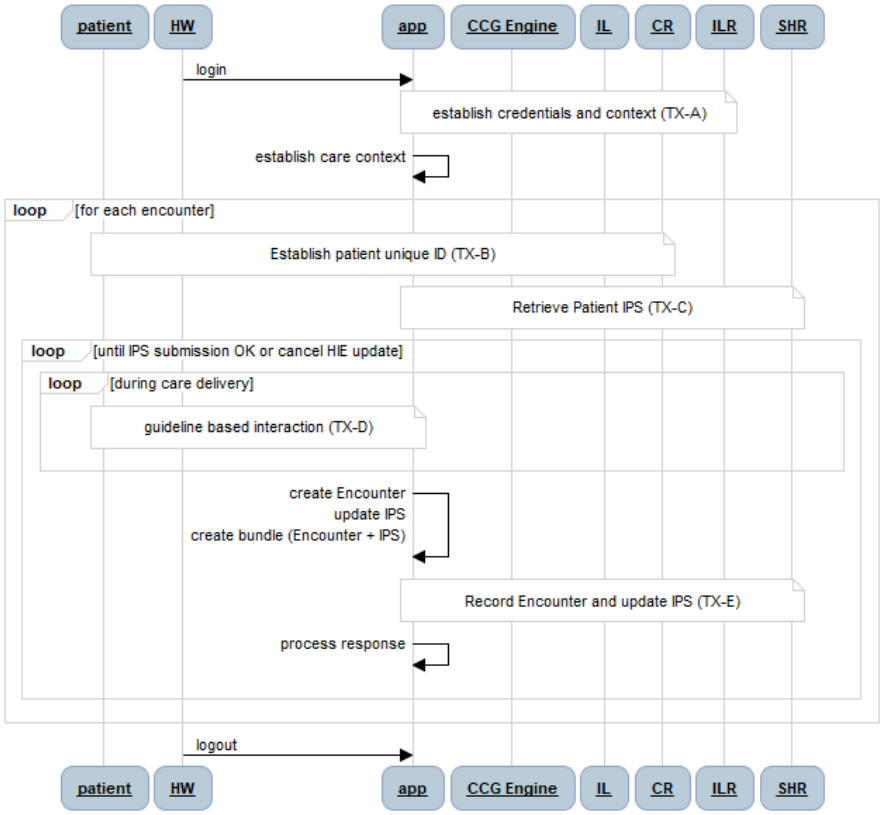

Figure 25 - Top level Transaction Diagram

NOTE: it is assumed that ***all*** HIE transactions traverse the interoperability layer (IL), and that this enterprise service bus authenticates and authorizes HIE access. For brevity, it is not illustrated on the sequence diagrams that follow, but **all** HIE transaction will need to be coupled with an OAuth token (a companion ITI-72 transaction). As shown in the diagrams, **all** HIE transactions are audited using the IHE audit trail and node authentication, ATNA, transaction). Where necessary to meet the criteria outlined in the IHE MHDS specification, the IL will orchestrate transactions and enforce data consistency rules. These internal IL processes are not shown in the diagrams.

TX-A: Establish HW credentials and care context

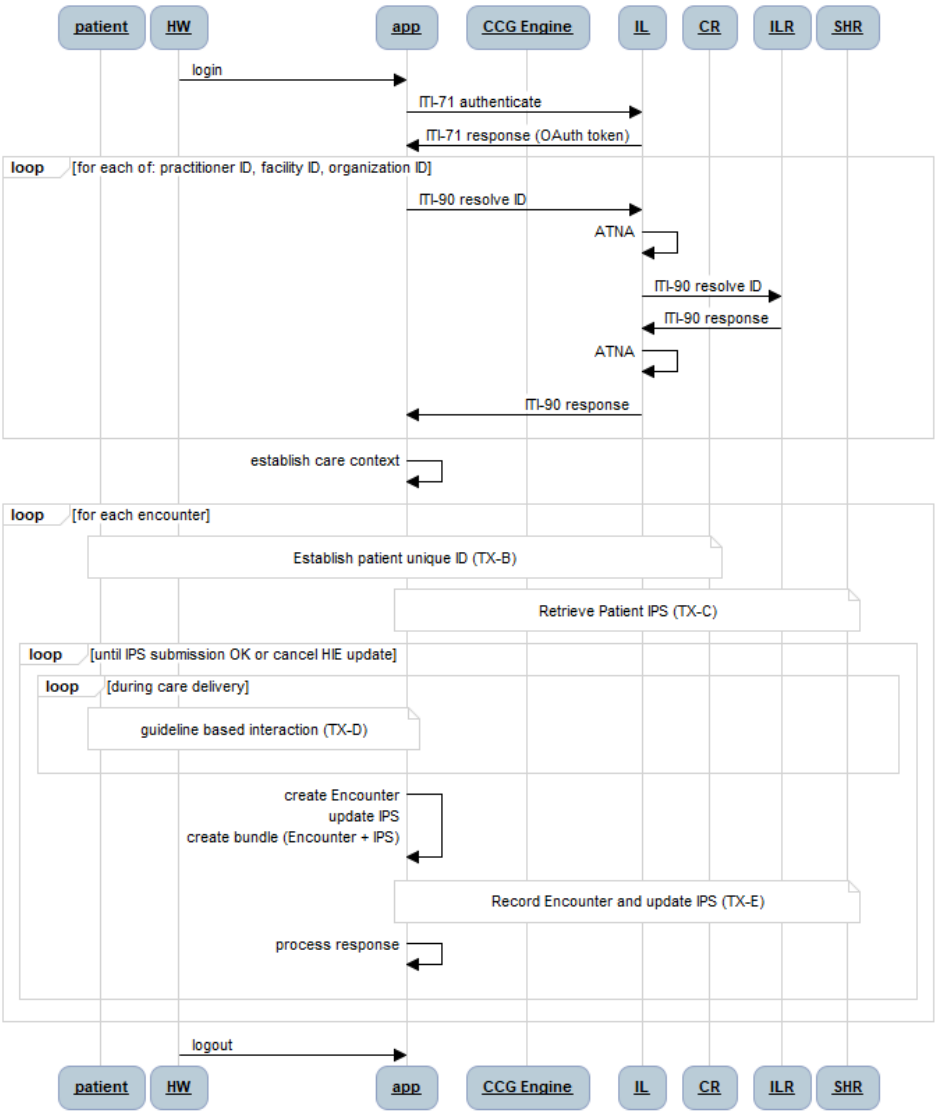

Figure 26 - TX-A: Establish Authorization and Care Context

=

The authentication, authorization, and care context transaction set (TX-A) is described in the sequence diagram in Figure 26. The health worker logs into his or her digital health solution (app) and the login credentials are leveraged to establish authorized access to the HIE and its shared data holdings. To enforce data governance and interoperability, the interlinked registry is used by the app to obtain and cache the unique national IDs that must be logged as reference data on each care encounter record (HW ID, facility ID and organization ID).

TX-B: Establish Unique Patient ID – TX-B

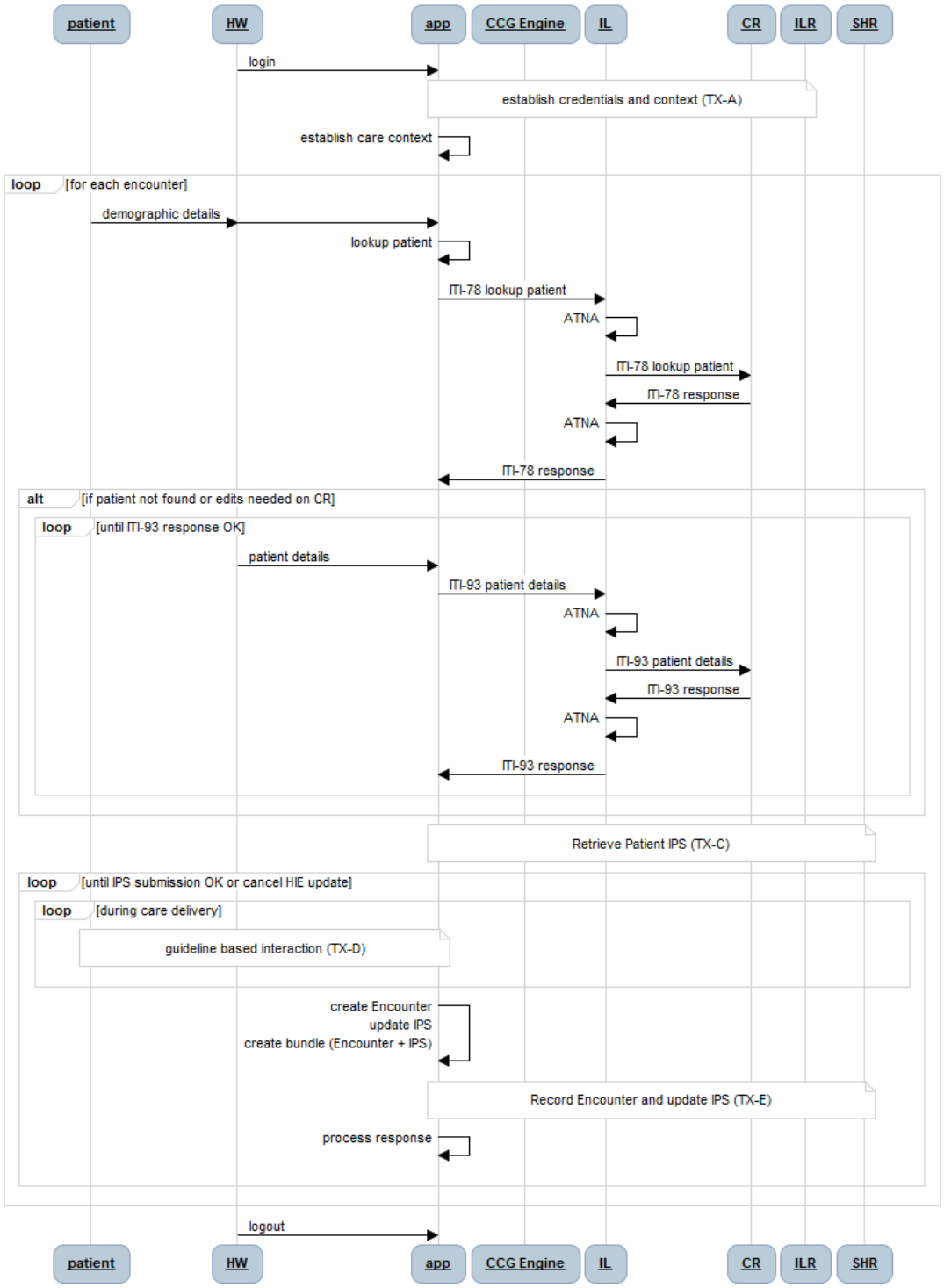

Figure 27 - TX-B: Establish Unique Patient ID

The patient ID resolution transaction (TX-B) is described by the sequence diagram in Figure 27. As illustrated by the diagram, patient demographic information is collected by the health worker (HW) and keyed into the app to execute a local lookup. The demographic information is then used to execute a lookup against the HIE's client registry (CR). If the patient is not found, or if the local patient data is more up to date than the HIE's demographic data, the app's local demographic content is persisted to the CR.

TX-C: Retrieve Patient IPS

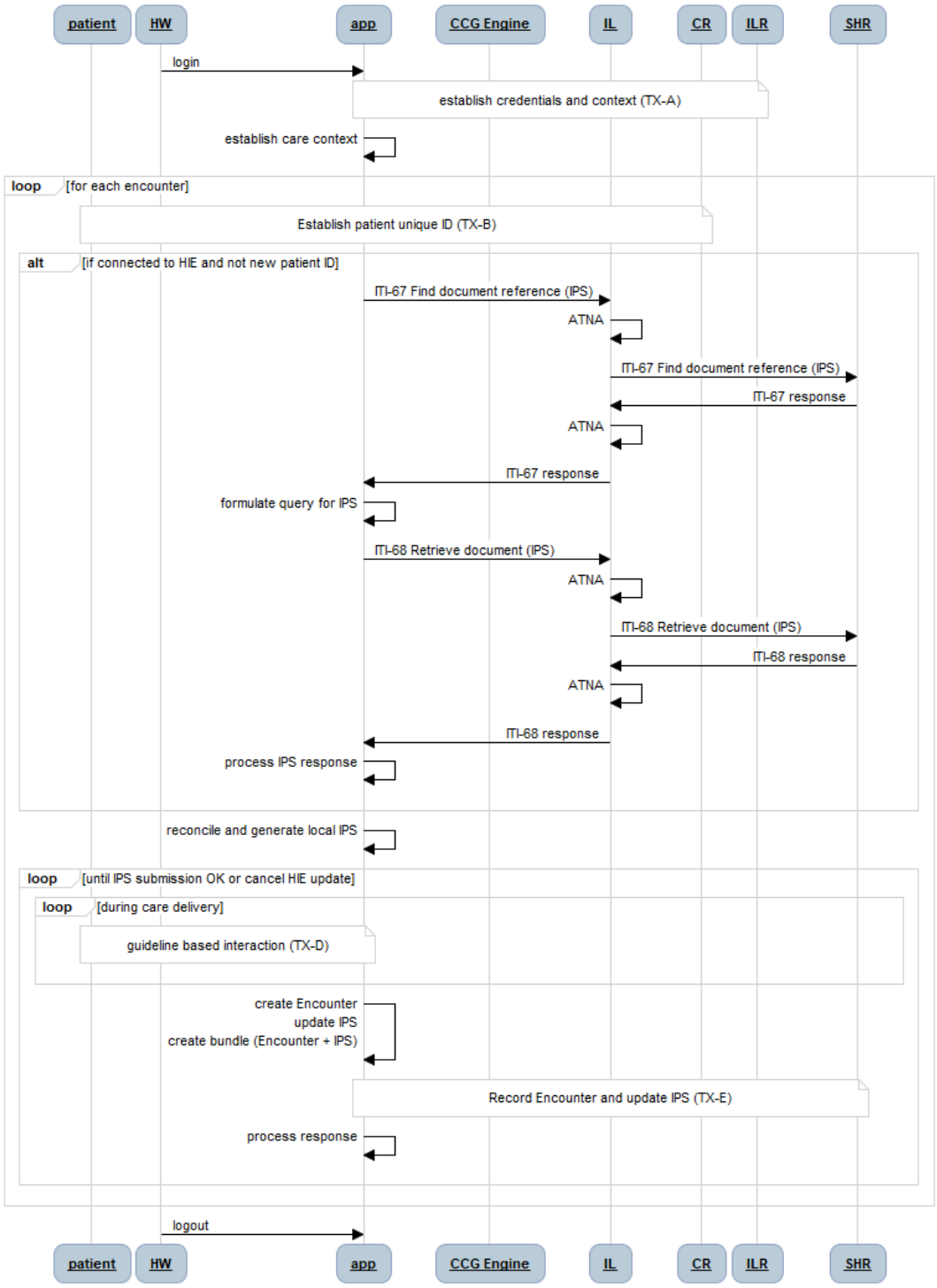

Figure 28 - TX-C: Retrieve Patient IPS

The patient health summary retrieval transaction (TX-C) is described by the sequence diagram in Figure 28. As illustrated by the diagram, following the successful execution of TX-B, a query is made against the app's local database to retrieve the patient's health summary. Using the

patient's unique ID, a query is made against the HIE's shared health record (SHR) repository to find the patient's most up-to-date International Patient Summary (IPS) document. The document ID for this IPS document is used to retrieve it from the SHR. This IPS is processed by the app, which reconciles it with the local health summary. If the IPS contains information not in the local summary, the local database is updated. If the app's summary data is a superset of the IPS, then the local copy of the HIE's IPS document is updated to reflect the more up-to-date content.

TX-D: Guideline-based care delivery

For the purposes of this demonstration, it is assumed that a computable care guideline (CCG) is developed that reflects national diabetes care guidelines. Notionally, a CCG can be metaphorically thought of as a "folder" full of "cards". The guideline-based diabetes care recommendations would be contained in a Diabetes folder. Following the analogy, guideline-based antenatal care recommendations would be contained in an ANC folder. Depending on the diagnoses reflected in a patient's health summary document (their IPS), one or more CCG folders may be applicable to them. Following the present example, a pregnant woman who is under care for diabetes would have both an ANC folder and a Diabetes folder associated with her IPS.

Each guideline-based recommendation for diabetes care can be thought of as being represented by a "card" in the Diabetes "folder". Every card has three key elements (the **C-A-R**):

1. A "**C**ondition statement" that defines when this card is applicable;
2. A care "**A**ction" instruction that defines what is recommended when the card's condition statement is evaluated to be TRUE; and
3. An action "**R**esult" that defines what will be documented in the patient's IPS after the action is taken.

An example illustrates this metaphor. An example country's Clinical Practice Guidelines for Type 2 Diabetes describes the first-line use of Metformin and second-line use of Sulfonylureas to reduce high glucose levels. Both medications are on the essential drugs list.

Drugs	Daily dose	Mode of action	Efficacy	Advantages	Disadvantage
Biguanide*					
Metformine	500-2000mg daily in 2-3 times with/after meals	Reduce hepatic glucose output	Reduce A1c 1% - 2%	No weight gain, may reduce triglycerides	GIT symptoms. Avoid in renal impairment (Cr>1.5 in males or >1.4mg/dL in females or CrCl < 60-70), age>80 years, chronic heart failure and in those with hepatic disease or heavy alcohol intake,
Sulfonylureas (SFUs, second generation)**					
Glibenclamide (glyburide)	2.5 – 20mg 1-2 with meals	Stimulate insulin Release by receptor mediated, glucose independent mechanism	Reduce A1c 1% - 2%	Well tolerated	Hypoglycemia, weight, gain, allergy. Use with precaution in elderly or in patients with liver or renal insufficiency.
Gliclazide	40-320mg 1-2 with meals				
Glimepiride (amaryl)	2-8mg once daily				

Figure 29 - The country's Type 2 Diabetes Guideline re: Glucose Lowering Agents

A Diabetes folder would contain a card for every recommendation in the National guideline, including routine initial, follow-up and annual visits. An example card for Metformin (the C-A-R) can be narratively described as follows:

Metformin

- Conditions for applying the card (all must be TRUE):
  - HbA1C > 9% or fasting BSL > 180 or postprandial > 360
  - (Cr < 1.5mg/dL and Sex=Male) OR (Cr < 1.4mg/dL and Sex=Female)
  - Age < 80 years
  - Number diagnosis of heart failure = 0
  - Number diagnosis of hepatic disease = 0
  - Number current findings of high alcohol intake = 0
  - Number existing orders for Metformin = 0
  - The card has not already been "applied" during the present encounter
- Actions to recommend if all Conditions are TRUE:
  - Order Metformin 500mg 2 time daily with meals
- Result of the recommended action having been taken (one of the 2 options):
  - Medication order for Metformin (ATC code A10BA02) dose = 500mg, route = by mouth, timing = 2 times per day (with meals) for 4 weeks, status = active
  - Medication order for Metformin (ATC code A10BA02) dose = 500mg, route = by mouth, timing = 2 times per day (with meals) for 4 weeks, status = cancelled, reasonCode = {select code from list in Figure 30}

Code	Display	Definition
altchoice	Try another treatment first	This therapy has been ordered as a backup to a preferred therapy. This order will be released when and if the preferred therapy is unsuccessful.
clarif	Prescription requires clarification	Clarification is required before the order can be acted upon.
drughigh	Drug level too high	The current level of the medication in the patient's system is too high. The medication is suspended to allow the level to subside to a safer level.
hospadm	Admission to hospital	The patient has been admitted to a care facility and their community medications are suspended until hospital discharge.
labint	Lab interference issues	The therapy would interfere with a planned lab test and the therapy is being withdrawn until the test is completed.
non-avail	Patient not available	Patient not available for a period of time due to a scheduled therapy, leave of absence or other reason.
preg	Parent is pregnant/breast feeding	The patient is pregnant or breast feeding. The therapy will be resumed when the pregnancy is complete and the patient is no longer breastfeeding.
salg	Allergy	The patient is believed to be allergic to a substance that is part of the therapy and the therapy is being temporarily withdrawn to confirm.
sddi	Drug interacts with another drug	The drug interacts with a short-term treatment that is more urgently required. This order will be resumed when the short-term treatment is complete.
sdupther	Duplicate therapy	The drug interacts with a short-term treatment that is more urgently required. This order will be resumed when the short-term treatment is complete.
sintol	Suspected intolerance	The drug interacts with a short-term treatment that is more urgently required. This order will be resumed when the short-term treatment is complete.
surg	Patient scheduled for surgery.	The drug is contraindicated for patients receiving surgery and the patient is scheduled to be admitted for surgery in the near future. The drug will be resumed when the patient has sufficiently recovered from the surgery.
washout	Waiting for old drug to wash out	The patient was previously receiving a medication contraindicated with the current medication. The current medication will remain on hold until the prior medication has been cleansed from their system.

Figure 30 - Normative list of Medication Status Reason Codes

As may be noted from the Metformin example – the logic rules expressed by the C-A-R operationalize the country care guideline. If the Conditions are met, a clinician will be presented with the recommended Action to begin Metformin for their patient. The Result written to the patient's health summary document will either be an active prescription for Metformin, or a cancelled prescription for Metformin with a reason code indicating why the clinician has foregone the guideline-based recommendation. It should be noted that, if a clinician has foregone the

Metformin option, the alternate Sulfonylureas option will be next proposed (defined by a separate card). For patients who are already on Metformin, there will be cards defined that would gradually increase their dosage levels, per the guidelines, until such point as the second line option should be tried (if blood glucose levels were not brought back to target levels).

There are card "types" defined for the tasks that occur during a care encounter. These include medication order cards (as illustrated by the previous example), stop medication cards, cards to record observations (e.g. height, weight, blood pressure, heartrate, etc.), cards to order lab tests (e.g. HbA1C, CBC, x-rays, etc.) or procedures (foot exam, eye exam, etc.), cards to schedule follow-up visits, and cards to augment or escalate care by creating a patient referral. There are also cards to record the actioning of any order (e.g. dispense medications, report lab test results, report procedure results, etc.).

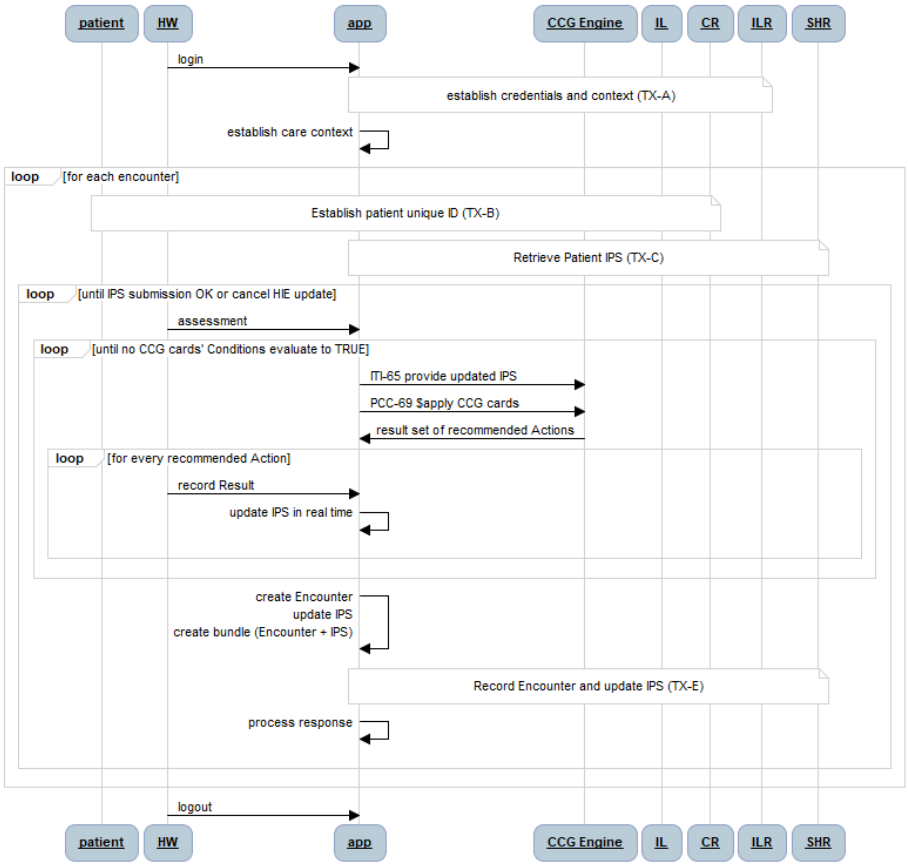

Figure 31 - TX-D: CCG Execution

The patient-safe card processing algorithm (shown in Figure 31) may be described as follows:

- The patient's health summary is retrieved along with applicable CCG folders in TX-C; if a clinician so chooses, one or more new CCG folders may be associated to the patient during the assessment phase of the encounter
- Iteratively LOOP…

- The updated patient summary (IPS) is submitted to the CCG engine
- All the cards from all applicable folders are evaluated based on the current content in the health summary (invoked via a $apply operation submitted to the CCG engine)
- For every card whose **C**onditions evaluated to TRUE
  - The clinician is shown the recommended **A**ction
  - The clinician has either accepted the recommendation or indicated why it will be followed – and the appropriate **R**esult has been written to the health summary

- …UNTIL no cards evaluate true

TX-E: Post Encounter details and updated Patient IPS to HIE

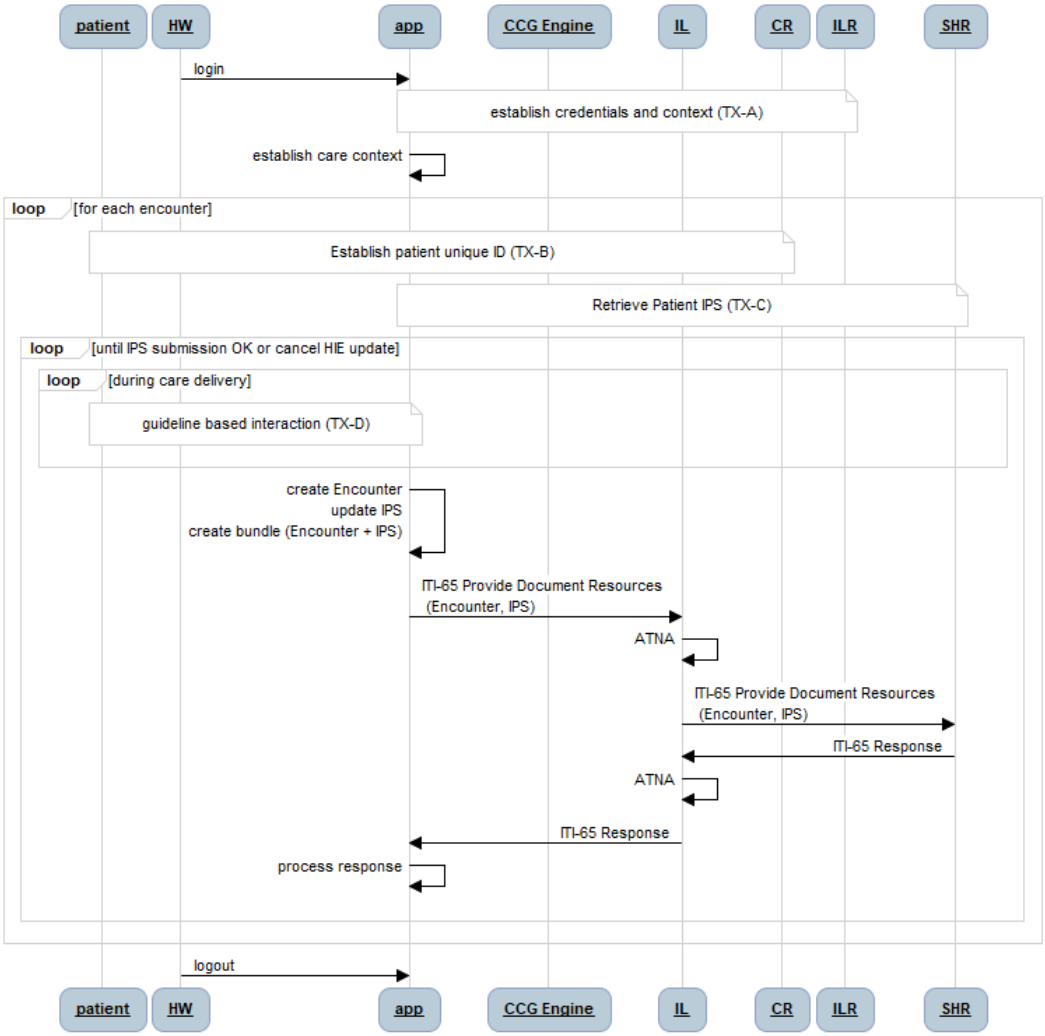

Figure 32 - TX-E: Post Encounter details and updated IPS to HIE

The patient encounter update transaction (TX-E) is illustrated by the sequence diagram in Figure 32. As illustrated by the diagram, following the successful execution of TX-B and TX-C, guideline-based care delivery activities are undertaken as per TX-D. The outcomes of these activities are reflected in an Encounter resource (which faithfully captures the context of the care encounter) plus an updated patient IPS document. The app creates a bundle including the Encounter and the updated patient IPS and persists this bundle to the SHR.

Demonstrating CCG-based Diabetes Care

A critical slice "demonstration" implementation of diabetes care, adherent to the country's Clinical Practice Guidelines for Type 2 Diabetes, would require the architectural actors as described in the previous section. This means a simple HIE will need to be operationalized (perhaps leveraging a generic FHIR server plus a SanteMPI instance).

To successfully model the operationalization of CCG-based care workflows, including care escalation, at least two point of service EMR instances are needed. If at least a rudimentary CCG is created, including at least one care escalation "card" (e.g. referral to ophthalmologist), then the managed movement of a patient through the care network can be modeled.

To model care continuity, over time, and across multiple care sites, the following simple scenario may be leveraged:

1. At a primary care facility, onboard a new diabetic patient not found in the CR. Leverage the history, examination, and blood tests outline for an **Initial Visit**. Execute TX-A to TX-E to establish baseline information about the patient, which is saved to the patient's IPS on the HIE.
2. Subsequently, at the same facility, execute a **Follow-up Visit** for the same patient. Execute TX-A to TX-E. Confirm details from step 1 are available in the patient's IPS. Update the patient's phone number. Record readings which establish that blood glucose levels warrant the first-line initiation of Metformin. Order and dispense the Metformin from the facility. Record encounter details in the IPS.
3. Subsequently, at the same facility, execute an **Annual Visit** for the same patient. Confirm the details from visits 1 & 2 are available in the patient's IPS. Execute TX-A to TX-E. Record results which establish that Metformin has successfully reduced blood glucose levels to within target. Establish a referral to an **ophthalmic specialist** for the annual eye examination.
4. Subsequently, at the ophthalmic specialist's facility, execute a **Referral Visit**. Confirm the patient's IPS details reflect steps 1, 2 & 3. Execute the eye examination and record favourable results to the patient IPS.
5. Subsequently, at the primary care facility, execute a **Follow-up Visit**. Confirm the results of the referral are found in the IPS. Execute TX-A to TX-E to record unremarkable results.

This simple scenario:

- Creates a new patient in the CR
- Finds, retrieves, and updates an existing patient's CR record
- Creates a new patient IPS and saves it to the SHR

- Retrieves a patient's most recent IPS from the SHR
- Saves an updated IPS to the SHR
- Triggers CCG-based recommendations based on data collected during an encounter
    - Orders and dispenses meds
    - Refers a patient to another care provider

Appendix 2: 10-year HIE Investment Rationale

This section will describe the assumptions behind a 10-year investment case model and report the results of leveraging these assumptions in a digital health investment case spreadsheet tool evolved from the one used at the 2017 AeHIN General Meeting in Myanmar.

Assumptions

Demographics

As per World Bank statistics the population of Kosovo is estimated to be 1.6 million with an anticipated growth rate over the coming 10 years of -1.4% (to a total of 1.39 million).

It will be assumed, for purposes of the model, that the total population of health workers is 16,600[48] and that this population will grow at 1%

Facilities

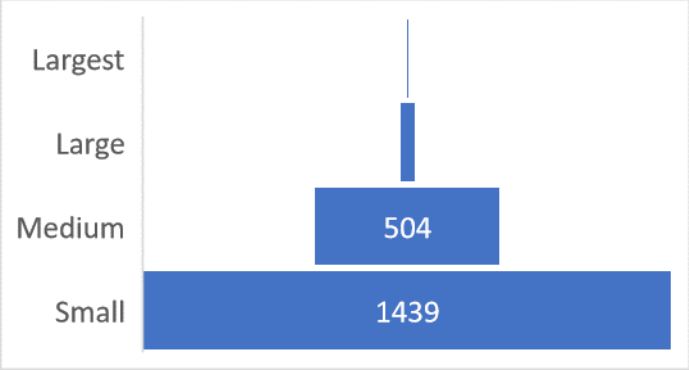

Figure 33 - Facilities as per TWG - April 2024

It is assumed that digital health will be deployed at all facilities in the Kosovo care delivery network. To drive the costing model, three different cost categories are assumed:

1. Large-scale digital health implementations with a one-time cost of €250,000 and digital system operating costs of €444000 per year (e.g. implement a cloud hosted solution; provide hardware and training for dozens of digital solution users; sustain hardware maintenance, network access, and local help desk support). For the model, it is assumed that the University Clinical Center of Kosovo is in this cost category. (i.e. 1 facility)

[48] As per TWG estimates across public and private sectors

2. Medium-scale implementations with a one-time cost of € 50,000 and operating costs of 10,000 per year (e.g. implement a cloud hosted solution; provide hardware and training for ~10 users; sustain hardware maintenance, network access, and remote help desk support). (est. 38 facilities). The municipality level hospitals are assumed to be in this category
3. Small-scale implementations with a one-time cost of €10,000 and annual operating costs of €2,000 (e.g. implement a cloud hosted solution; provide hardware and training for ~5 users; sustain hardware maintenance, network access, and remote help desk support). Health centers are assumed to be in this category. (est. 169 facilities)
4. The smallest-scale implementations with a one-time cost of €5000 and annual operating costs of €500 (e.g. implement a cloud hosted solution; provide hardware and training for ~2 users; sustain hardware maintenance, network access, and remote help desk support). Health centers are assumed to be in this category. (est. 197 facilities)

Economics

Based on historical trends, an average annual inflation rate of 2.6%[49] was assumed. This rate drives the year over year cost escalation over the course of the 10-year model horizon.

The per capita total health expenditure (THE) for Kosovo in 2020 was €256[50]

According to World Bank, Kosovo's GDP per capita was €5,078 (2022).

Theoretical DALYs

Data from Kosovo's neighboring countries was accessed via IHME and used to estimate the potential DALYs averted by the target interventions of this model

[49] https://data.worldbank.org/country/kosovo

[50] Calculated from https://msh.rks-gov.net/Documents/DownloadDocument?fileName=ENG%20%E2%80%93%20Raporti%20NHA%20202053574044.8295.pdf

DALYs Cause	DALYs total across peers	Estimated DALYs (Kosovo)
Ischemic heart disease	721,312	107,152
Stroke	706,750	104,989
Low back pain	272,658	40,504
Tracheal, bronchus, and lung cancer	230,330	34,216
Diabetes mellitus	230,147	34,189
Chronic obstructive pulmonary disease	109,650	16,289
Colon and rectum cancer	101,645	15,100
Age-related and other hearing loss	99,439	14,772
Headache disorders	94,516	14,040
Hypertensive heart disease	91,850	13,644
Falls	87,360	12,977
Breast cancer	80,169	11,909
Cardiomyopathy and myocarditis	75,101	11,156
Neonatal disorders	70,934	10,537
Self-harm	61,922	9,199
Road injuries	52,762	7,838

Table 3 - DALYs by Cause

The disability-adjusted life-years (DALYs) associated with significant causes of death and disability are shown in Table 3. On a theoretical basis, it can be proposed that if 100% of the burden of disease could be alleviated by the application of digital health solutions for Ischemic Heart (#1 in the list), then 107 thousand "life-years" of lost health could be averted.

It is not possible to drive the disease burden to zero using digital health. Even so – sensitivity analysis can be leveraged to answer the question: "how much reduction in disease burden is reasonable to expect from the implementation of digital health – and what are the health impacts, expressed in economic terms, of such a reduction?"

Evaluating the economic value of health impacts is controversial. The long-standing rule of thumb from WHO is that an averted DALY that costs less than 3 annual GDP per capita is a "good buy" and an averted DALY that costs less than 1 annual GDP per capita is a "great buy". Although this is a much-debated topic – the 1-GDP-per-capita-per-DALY is a simple and widely used heuristic and therefore is leveraged in this model.

Investment Rationale Model (example)

This section describes the values entered into the investment case model to develop a first-draft 10-year projection. These values are starting point examples. The relevant fields for each worksheet tab in the spreadsheet are noted in the following sections. NOTE: in the model – the **green** fields are filled in… all others are calculated.

Summary

The fields data-entered in the Summary tab are shown below.

Year-over-year cost escalation (%)	**2.6**
Annual facility growth rate	**1%**
Population size	**1,800,000**
Annual population growth rate	**-1.4%**

# Health Workers	16,800
HW population growth rate	-1.4%

	TYPE 1	TYPE 2	TYPE 3	TYPE 4
	0.1%	2.1%	25.4%	72.5%
1,986	1	42	504	1,439

These numbers reflect the assumptions listed in the previous section.

Governance

The fields data-entered in the Governance tab are shown below.

	#	Units	Cost per Unit	Extended Cost
Digital Health Strategy				
Lump sum cost				€ 292,000.00
Digital Health Blueprint				
Lump sum cost				€ 146,000.00
eHealth Norms and Standards				
Subtotal				€ 70,000.00
Health Data Sharing Policy				
Subject Matter Experts	50	days	€ 700	€ 35,000
Local Expert	3	months	€ 2,000	€ 6,000
Subtotal				€ 41,000
Digital Health Governance			**Annual cost/unit**	**Annual costs**
Departments	1	department	€ 270,000	€ 270,000
Regular meetings	12	meetings	€ 750	€ 9,000
National meetings	1	meetings	€ 30,000	€ 30,000
Subtotal				€ 309,000

The assumptions regarding the strategy, blueprint, standards, and policy activities are the following:

- Digital Health Strategy and Digital Health Blueprints will be revised every five years
- eHealth Norms and Standards will be kept to up to date on an ongoing basis by a dedicated staff member. In the first two years, this individual will be supported by international experts and by Year 3, they are expected to be self-sufficient and to manage the process on their own
- Health Data Sharing Policy will be revised every five years, with a local expert supported by international experts

The last cost category, Governance, is assumed to be ongoing through every year of the 10-year plan with appropriate accommodation for inflation. This is the sustaining cost for operating a secretariat within a Digital Health Department plus the costs of the PMO and conformance testing services that this group will be responsible for.

Datacentre

These costs reflect the setup and operation of the national HIE. The costs are broken down as 1-time fees (license fees, installation fees, and virtual machine fees, where those might be applicable). Separately, the monthly operating costs are determined. These will be driven by prorated software maintenance fees and by VM costs and IT team size.

Software maintenance fee (% of license fee)	**15%**

It is industry practice to pay an annual maintenance fee (often 15% of the original license fee) for enterprise class software. This supports the costs of upgrades and bug fixes and tech support. Even though there are many open-source options that SL should consider – it should not expect to be a "free rider" on these open-source communities even where the license fee is zero. For this reason, a notional license fee was assumed for each software element, and this was used to drive "maintenance fees" that would be expected to sustain the ongoing costs of either commercial or open source products.

	Software fee (€)
Datacentre Installation (1-time costs)	
Client Registry (CR)	**€100,000**
Health Worker Registry (ILR-HWR)	**€100,000**
Facility Registry (ILR-FR)	**€100,000**
Terminology Server (TS)	**€100,000**
Shared Health Record Repository (SHR)	**€100,000**
Health Management Information System (HMIS)	**€100,000**
Interoperability Layer (IL)	**€100,000**

The MOH currently contributes €30,000 per month for the running of the national data center. The figure of €75,000 per month below reflects the projected increase in services and applications and the accompanying spike in network traffic that the digitalization of health service will result in.

	Software fee (€)
Datacentre Operation (monthly costs)	**€75,000**

CR (client registry)

The National ID (assigned at birth) will be used as the Health ID for all citizens. There is therefore no implementation, ID generation, or ID replacement cost to be considered for the Client Registry implementation since this is done outside of the ambit of the Ministry of Health. There are therefore no specific costs for this that are specific to health.

ILR-FR (Interlinked Facility Registry)

The costs for the ILR-FR are driven by the number of underlying data sources, the cost to connect each data source to the ILR (and to maintain this interface) and by the number of interactions (i.e. phone calls) the MoH will need to have with **each facility, each year** to ensure the data is kept current and correct. An average cost of €3 per "check" is assumed.

Facility databases (#)	**2**
Cost per database application interface (€)	**€23,000**
API maintenance cost per year (%)	**15%**
MoHS interactions per facility per year (#)	**2**
Cost per interaction (€)	**€3**

ILR-HWR (Interlinked Health Worker Registry)

The cost drivers for the ILR-HWR are identical to the ones for the ILR-FR, with the exception that MoHS interactions to ensure data correctness involve data checks with health workers vs with facility operators. The idea is that a phone call solution could be made to confirm details with each health worker at least once every six months. The estimated cost reflects connecting 10 underlying databases.

Health Worker Cadre databases (#)	**10**
Cost per database application interface (€)	**€23,000**
API maintenance cost per year (%)	**15%**
MoHS interactions per HW per year (#)	**2**
Cost per interaction (€)	**€3**

SHR (Shared Health Record repository)

The cost drivers for the SHR are not as much related to the central server as they are related to the point of service (POS) applications that must be implemented at facilities and connected to the HIE. Here, the assumptions (denoted in the previous section) for implementation costs for each of the 4 different facility types drive the model. Also, it is assumed that each different POS application will need to be interfaced to the SHR and the costs of these interfaces will need to be maintained.

Unique health ICT applications (#)	10
Cost per application interface (€)	€25,000
API maintenance cost per year (%)	15%

For the deployments to facilities, an estimate is made of the implementation cost plus the annual operating costs. To model the timing, an estimate is made of the number of facilities that already have solutions implemented. There is an expected requirement that MoHS interact with each facility to audit conformance or to refresh software or other tasks – and these costs are estimated by annual number of interactions and cost per interaction.

Facilities (from Summary sheet) (#)	**1,986**	**TYPE 1**	**TYPE 2**	**TYPE 3**	**TYPE 4**
Facilities of this TYPE (%)		**0.1%**	**2.1%**	**25.4%**	**72.5%**
Facilities of this TYPE (#)		**1**	**42**	**504**	**1,439**
Facilities for which MOH pays (%)		100%	90%	34%	14%
MOH-supported facilities (#)		**1**	**38**	**169**	**197**
1-time ICT implementation cost for TYPE (€)		€ 250,000	€ 50,000	€ 10,000	€ 5,000
Annual ICT operating cost for TYPE (€)		€ 444,0000	€ 10,000	€ 2,000	€ 500
Current ICT adoption by this TYPE (%)		0%	50%	30%	10%
Current ICT-capable by this TYPE (#)		**-**	**19**	**51**	**20**
ICT rollout period (yrs)		0.5	1	1	1
MOH interactions per year (#)		1	1	1	1
MOH cost per interaction (€)		€ 200	€ 100	€ 50	€ 10

TS (Terminology Service)

The costs for the terminology service are driven by the number of underlying code lists that have to be licensed plus the annual maintenance fees per year for these licenses. For SL, it is expected

that open standards will be leveraged so these costs are omitted. The other cost driver is the number of times the code lists must be refreshed by the POS applications and the cost of each refresh.

Total cost of codelist databases (€)	-
Codelist maintenance cost per year (%)	15%
MoHS interactions per app per year (#)	4
Cost per interaction (€)	€ 2000

HMIS (Health Management Information System)

The HMIS costs are driven by the number of data warehouses, the cost for an SHR-HMIS data interface, and the annual maintenance costs for each interface. Operational costs are also driven by the number of data collections per year and by the cost of each of these data reporting workflows.

HMIS databases (#)	1
Cost per SHR-HMIS interface (€)	€ 25,000
API maintenance cost per year (%)	15%
HMIS data collections per facility per year (#)	12
Cost per interaction (€)	€ 1

CUA (Cost Utility Analysis)

The CUA is a cost-effectiveness analysis. For this reason, the calculated 10-year costs based on the preceding assumptions are compared against the 10-year health benefits that can be expected to accrue from broadly deploying digital health in support of guideline-based care and care continuity.

Target cost/QALY (CET)	€ 5,078

As described in the previous section, a cost-effectiveness threshold (CET) is determined to be 1 annual GDP per capita (a "great buy", based on the simple WHO heuristic). Also leveraging the section on Theoretical DALYs, the following 4 targeted diseases are identified as those amenable to being impacted by improvements in guideline adherence and care continuity.

Interventions	Ischemic Heart D.	Stroke	Lower Back Pain	Lung Cancer	Diabetes
Potential Health Impact (QALYs)	107,152	104,989	40,504	34,216	34,189
Lead time (years before benefit)	3	3	3	3	3
Benefit realization (%)	2%	2%	2%	2%	2%

For each target, the total health impact is identified, expressed as QALYs (which for this analysis are assumed to be equal to averted DALYs). The time to benefit, in years, is indicated for each. This is noting that benefits may not be realized until, for example, all of the health facilities have

completed their digital health implementations. To support sensitivity analysis, a benefit realization value (expressed as a percent) is used to calculate how much of the total disease burden can be ameliorated through the digital health intervention. It is an underlying assumption that the impact of digital health will be to operationalize guideline-based care – and in this way, the health impacts could be dramatic. Even so, conservative benefit values of 1%, 2% and 5% were used to determine the cost effectiveness curves over the 10-year model horizon.

Results

Based on the assumptions in the model, the following results may be reported.

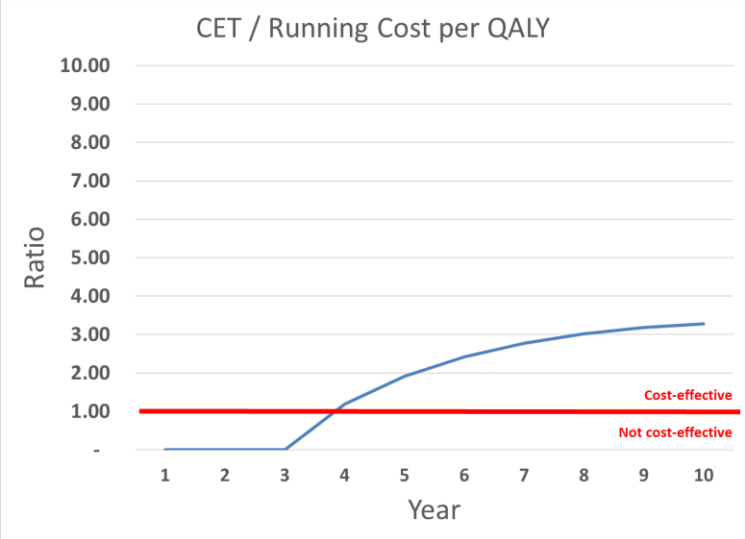

Figure 34 - Cost-effectiveness over 10-year Horizon (2% health benefits Impact)

Year	1	2	3	4	5	6	7	8	9	10	10-yr Total
Governance	€ 420,000	€ 388,854	€ 348,962	€ 358,035	€ 898,137	€ 376,895	€ 386,694	€ 396,748	€ 407,064	€ 1,021,126	**€ 5,002,515**
Datacentre infrastructure	€ 1,600,000	€ 923,400	€ 947,408	€ 972,041	€ 997,314	€ 1,023,244	€ 1,049,849	€ 1,077,145	€ 1,105,150	€ 1,133,884	**€ 10,829,436**
Client Registry	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	**€ -**
Facility Registry	€ 57,916	€ 19,427	€ 20,059	€ 20,712	€ 21,387	€ 22,084	€ 22,804	€ 23,548	€ 24,317	€ 25,112	**€ 257,367**
Health Worker Registry	€ 329,600	€ 139,119	€ 144,333	€ 149,748	€ 155,372	€ 161,215	€ 167,284	€ 173,589	€ 180,138	€ 186,942	**€ 1,787,340**
Shared Health Record	€ 4,787,400	€ 1,406,932	€ 1,457,553	€ 1,509,999	€ 1,564,336	€ 1,620,632	€ 1,678,959	€ 1,739,389	€ 1,801,999	€ 1,866,867	**€ 19,434,065**
Terminology Services	€ 80,000	€ 82,080	€ 84,214	€ 86,404	€ 88,650	€ 90,955	€ 93,320	€ 95,746	€ 98,236	€ 100,790	**€ 900,394**
HMIS	€ 48,832	€ 28,544	€ 29,539	€ 30,570	€ 31,637	€ 32,741	€ 33,885	€ 35,068	€ 36,294	€ 37,563	**€ 344,672**
HHR Capacity-building	€ 1,242,000	€ 390,885	€ 403,748	€ 417,057	€ 430,829	€ 445,079	€ 459,827	€ 475,089	€ 490,885	€ 507,234	**€ 5,262,634**
Total Annual Cost	**€ 8,565,748**	**€ 3,379,242**	**€ 3,435,817**	**€ 3,544,565**	**€ 4,187,661**	**€ 3,772,846**	**€ 3,892,621**	**€ 4,016,322**	**€ 4,144,083**	**€ 4,879,517**	**€ 43,818,423**
Running total cost	**€ 8,565,748**	**€ 11,944,990**	**€ 15,380,807**	**€ 18,925,373**	**€ 23,113,034**	**€ 26,885,880**	**€ 30,778,500**	**€ 34,794,823**	**€ 38,938,905**	**€ 43,818,423**	

Figure 35 - 10-year Investment Model (Summary)

Year	1	2	3	4	5	6	7	8	9	10
Total QALYs	-	-	-	6,155	6,069	5,984	5,900	5,818	5,736	5,656
Running total QALYs	-	-	-	6,155	12,224	18,208	24,108	29,926	35,662	41,317
Total costs (€)	€ 8,565,748	€ 3,379,242	€ 3,435,817	€ 3,544,565	€ 4,187,661	€ 3,772,846	€ 3,892,621	€ 4,016,322	€ 4,144,083	€ 4,879,517
Running total costs (€)	€ 8,565,748	€ 11,944,990	€ 15,380,807	€ 18,925,373	€ 23,113,034	€ 26,885,880	€ 30,778,500	€ 34,794,823	€ 38,938,905	€ 43,818,423
Cost per QALY	**€ 8,565,748**	**€ 3,379,242**	**€ 3,435,817**	**€ 576**	**€ 690**	**€ 630**	**€ 660**	**€ 690**	**€ 722**	**€ 863**
Running cost per QALY	**€ 8,565,748**	**€ 11,944,990**	**€ 15,380,807**	**€ 3,075**	**€ 1,891**	**€ 1,477**	**€ 1,277**	**€ 1,163**	**€ 1,092**	**€ 1,061**
CET / Cost per QALY	0.00	0.00	0.00	8.82	7.36	8.05	7.70	7.36	7.03	5.89
Cost per QALY / CET	1,686.72	665.42	676.56	0.11	0.14	0.12	0.13	0.14	0.14	0.17
CET / Running Cost per QALY	0.00	0.00	0.00	1.65	2.69	3.44	3.98	4.37	4.65	4.79
Running Cost per QALY / CET	1,686.72	2,352.14	3,028.71	0.61	0.37	0.29	0.25	0.23	0.22	0.21

Figure 36 - 10-year Benefits Model (2% benefits realization)

Discussion

The investment rationale spreadsheet tool is expected to be leveraged to support top-level planning. It may be leveraged to develop and evaluate scenarios and their impacts. The model results reported here are sensitive to the underlying assumptions, including a key assumption that digital health will impact health outcomes by improving adherence to care guidelines and care continuity and, hence, care quality.

The following may be noted from this model analysis:

- Over a 10-year model period, the assumed investment and operating plan would require an average annual digital health budget of **approximately €4.4 million** (starting at €8.6 million accounting for upfront investments and setup costs and then going down to €4.9 by year 10 as the bulk of investments move to maintenance, upkeep and ongoing governance). Such an annual budget represents **less than 1% of total health expenditure**.
- The model conservatively assumes that digital health investments are "starting from zero". This is not actually the case and the actual time to realize benefits may be accelerated.
- A platform approach is recommended that could be employed to operationalize guideline-based care for **any** disease. This is in contrast with siloed investment in treating particular diseases or in providing services only for particular groups of patients.
- Using the burden of disease across only 5 conditions, and assuming guideline-based care operationalized through digital health would have an only **2% impact** on this burdsen, and further assuming a 3-year implementation period during which zero benefits will accrue, the modeled investment plan is **cost-effective by year 4**. This scenario assumes all the cumulative costs, from inception, are "recovered" by the health benefits realization by year 5.
- Were the digital health enabled care quality improvements to make a **5% impact** on the burden of disease, the HIE investments are still cost-effective in year 4 but, more notably, under this 5% impact scenario, the investment's **ROI** represents a **14:1 economic benefit** from year 9 onwards.

Appendix 3: Inputs for National Level Health Data Governance Roles

Health Data Policy

This is the **role of health data governance steering and policy making**. The core mandate is to discuss and approve the policies that can be enforced and promoted on both national and subnational levels.

This role is responsible for health data analytics policies, strategic planning, monitoring, and evaluation. The role shall have the representation of all key stakeholders. It has the power not only to make decisions for their domains but also political and other forms of influence to make progress in the implementation of approved policies, decisions, and agreements.

Typical responsibilities:

- Approves policies and strategic plans for the health data governance to ensure continued strategic relevance in data management and utilization, including a regular update of the National Masterplan for Health Data Governance;
- Gives mandates for the development of procedures and guidelines for health data standardization, collection, management, and publishing;
- Provides general policies on data access rules;
- Sets strategic goals for data analytics based on stakeholders' business needs;
- Approves catalogs of analytical data sets, indicators, and reports;
- Evaluates the achievement of goals and makes correctional decisions;
- Organizes the health data use ethics committee;
- Makes strategic decisions on investments in technical data analytics systems and tools;
- Promotes an evidence-based decision-making culture; and
- Pursues public communication and awareness related to the use of the health data analytics.

Health Data Stewardship

This role is responsible for the design and maintenance of data collection, management, and publishing processes, including the development of health data analytics policies, taxonomies, catalogs, general rules, procedures, and guidelines for data analytics and so on. Typical responsibilities include:

- Maintains a coordinated system and transparent governance processes both for data quality assurance and for accountability for data management and use;

- Helps stakeholders to embed data analytics processes into their resource allocations, budgets planning, project pipelines, and so on;
- Develops and maintains catalogs of analytical data sets, indicators, and reports (on content and methodology) based on continual assessments and communication with stakeholders (both data consumers and providers);
- Utilizes the analytical data sets, indicators, and reports to provide health data analytics to stakeholders;
- Utilizes the analytical data sets to provide advanced analytics based on business intelligence, AI, and machine learning methods and tools;
- Develops analytics use cases, and advises the stakeholders on architectural and technical implementation of use cases;
- Sets the principles and rules for use of analytical data sets, indicators, and reports for data consumers, including the rules for avoiding the misuse of information;
- Employs business-oriented data stewards (such as those trained as physicians, nurses, administrative clerks and managers, billing and coding experts, researchers, health data scientists, and so on) to ensure the relevance of data analytics to business needs;
- Helps data consumers to perform data analyses themselves or conducts analyses for them;
- Develops survey-based analytical use cases and advises stakeholders on the execution of surveys;
- Designs, creates, and publishes regular and ad hoc health analytics reports;
- Designs, develops, and maintains the content of the portal for online access of analytical data sets, indicators, and reports;
- Develops cases for health data standardization through collaborative processes with data providers and consumers;
- Provides a second opinion benchmark for data quality assurance to perform inspections of data providers, re-capture (manually) the analytical data ("golden standards"), and link analytical data with other available data sets (quality registries) for quality benchmarking;
- Develops the content certification system for compliance with health data analytics rules, methodologies, and standards:
    - Certifies data providers; the content certification will ensure that the content of data sets provided by data providers comply with data quality requirements (standardized and timely provision of data, completeness of data sets, and so on);
    - Certifies data consumers/processors; the content certification will ensure that data sets, indicators, and reports provided to data consumers are used and potentially further processed in accordance to agreed rules, methodologies, and standards;
- Proactively works to improve not only its own but also overall Kosovo health data analytical capabilities;

- Identifies health data analytics subject matter experts and maintains an expert roster;
- Promotes evidence-based decision-making culture; and
- Pursues public communication and awareness related to the use of the health data analytics.

Health Data Custodianship

This role provides tools and services for data collection, storage, quality assurance, access, and processing, including the collection and maintenance of health analytics data sets, indicators, and reports. Typical responsibilities include;

- Designing/specifying, acquiring, and maintaining the technical services of health data management;
- Manages technical systems, tools, and services for analytical data set collection and storage and also for indicator and report generation;
- Makes sure the analytical data sets, indicators, and reports are in accordance the stakeholders' needs, data catalogs, and data analytics use cases;
- Makes sure the data sets are consistent with the standardized data models;
- Ensures that the access to data is authorized and controlled and maintains data integrity;
- Implements the systems for access to analytical data sets, indicators, and reports for data consumers and hosting a portal for online access to analytical data sets, indicators, and reports; managing additional data access services and dashboards, and providing external business intelligence tools with access to data sets, and so forth;
- Manages analytical data sets and ensures that the quality of the data and data services comply with the applicable standards and regulations;
- Complies with the overall national digital data analytics procedures and guidelines in its activities;
- Proposes updates and participates in defining health analytics metadata, catalogs, data analytics procedures and guidelines, and data standards;
- Designs and executes survey-based data collections;
- Provides tools and services (web portals and similar tools) for survey-based data collection;
- Provides Analytics as a Service (AaaS) for some data consumers;
- Implements data systems and processes for computing and delivering analytical indicators, which are specified by metadata or are requested ad hoc;
- Implements data systems and processes for compiling and delivering analytical reports, which are specified by metadata or are requested on an ad hoc basis;

- Provides online services for publishing analytical indicators, catalogs, and reports according to the data access regulations and agreements;
- Provides online services for publishing health data procedures and guidelines;
- Provides online web services for automatic access to data sets, based on access rights and other standards and regulations;
- Supports real-time clinical decision support systems to use available data sets.
- Develops and implements advanced machine learning and AI-based systems for data analytics;
- Provides access to analytical data sets to data consumers' advanced analytics based on business intelligence, AI, and machine learning methods and tools;
- Develops a technical certification system for compliance with health data analytics standards, including data exchange, interoperability, and security standards;
    - Certifies data providers; the technical certification will ensure that data providers' systems comply with data description, data exchange, interoperability, and security requirements;
    - Certifies data consumers/processors; the technical certification will ensure that data consumers' systems (including systems for further analytical data processing) comply with data description, data exchange, interoperability, and security requirements;
- Implements, as required, data protection and access control within the organizational and technical solutions of external data providers and consumers;
- Prepares and executes annual maintenance plans for data assets to manage exponential growth of data volumes and complexity; and
- Manages data quality by measuring data quality and performing corrective actions, managing quality issues resolution; informing primary data source systems about cases of corrupt and inconsistent data, automating data quality monitoring, and so on;

Health Data Standardization

This role shall provide the standards of terminology, naming, and definitions used in all health information systems and methods of collection. It will also coordinate the development, setting, promotion, adoption, maintenance, and enforcement of these standards. Typical responsibilities are:

- Collects requirements and expectations of health care sectors and national level consumers;
- Adopts an international coding system for diseases, supervises its implementation in all health authorities, and works to adopt this coding system into the Kosovo context on a regular basis;

- Coordinates the definition and acceptance of security and privacy principles governing the design and implementation of the data services;
- Standardizes the e-identification and registration of people, organizations, and devices for better integrity, analytics, and future use of data;
- Introduces catalogs of analytical data sets (including establishing the minimal content of data sets), indicators, and reports through standards;
- Develops and maintains a National Health Data Reference Model that includes a Health Data Dictionary and definitions of process actors and events, data content, and terminology;
- Coordinates enforcement of the standards by collaborating with standards-setting and standards-enforcement organizations;
- Develops and maintains data exchange standards that enable sharing of data and coordination of work between systems of the domain;
- Develops and maintains health care information technology standards and a database of architecture and solution building blocks including service management and data protection standards; and
- Promotes the adoption of standards via public communication, awareness building, and support services.