MINISTRY OF HEALTH

**NATIONAL DIGITAL HEALTH GUIDELINES
AND STANDARDS [NDHGS]**

2.0

Executive Summary

The National eHealth Guidelines & Standards were first published in 2016 with the aim of streamlining the implementation of eHealth solutions in the health sector of Sri Lanka. These Guidelines and Standards were intended to be adopted when implementing eHealth solutions in the state and private healthcare institutions in the country.

The new developments in the digital health ecosystem in the country and innovations in the ICT sector demanded reviewing the existing National eHealth Guidelines & Standards (NeGS). Recognizing this need the National eHealth Steering Committee appointed a Technical Working Group (Technical Working Group: Digital Health Standards & Interoperability (TWG – DHSI)) to review the NeGS and recommend necessary changes. Meanwhile recognizing the importance of digital health in strengthening primary health care services, the Primary Healthcare Services Strengthening Project (PSSP); included updating the e-health guidelines and standards as one of the Disbursement Linked Results (DLR 5.1 Standards to support the robust development of HMIS platforms and use of electronic HMIS at public health service providers, including with unique individual patient records).

Based on the recommendation of the above TWG, current developments in the field were incorporated in the NeGS and changed its name as 'National Digital Health Guidelines and Standards (NDHGS)' while maintaining the major themes and the structure as of the first version. Following are the main changes that were made in this version of the NDHGS document:

1. A new chapter included;
    a. Chapter 3 - Digital health software services
2. New sections and subsections added to the existing chapters
    a. Sec. 3.2. Electronic Medical Record Systems
    b. Sec. 3.3. National Electronic Health Record
    c. Sec. 3.4. Personal Health Record
    d. Sec. 7.2. Master Patient Index
    e. Sec. 7.7. Minimal dataset for National Electronic Health Records (NEHR)
3. Changes were also made to the content of other chapters to improve the relevance and accuracy of the guidelines and the standards, and to address the current needs.

The document lays down standards and guidelines in the following seven areas which are important in adopting ICT in the healthcare sector:

1. Digital Health Architecture – This gives a holistic view of digital health architecture in accordance with the National ICT Architecture and Infrastructure.

2. Hardware for Digital Health – This chapter prescribes guidelines on the management of hardware for digital health services.

3. Digital Health Software Services – The chapter is on the management of digital health software, Electronic Medical Record Systems, National Electronic Health Record, and Personal Health Records.

4. Network and Connectivity – This emphasizes the importance of having a proper network plan for individual healthcare institutions and maintaining them.

5. Communication Interface – The importance of having proper website standards, domain name structure, and official email nomenclature is mentioned in this section. This also emphasizes the proper use of emails as this could be used as an official mode of communication.

6. Privacy, Confidentiality, Security and Medical Ethics – Unlike in many other sectors, the practice of proper ethical standards and patient privacy bears the highest importance in the field of healthcare. The importance of ensuring privacy, confidentiality, and information security during the adoption of ICT in the health sector is mentioned in this section.

7. Digital Health Systems Interoperability – This chapter prescribes guidelines and standards to achieve seamless communication between digital health solutions.

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List of Abbreviations

- ADX   -   Aggregated Data Exchange

- API   -   Application Programming Interfaces

- ATC   -   Anatomical Therapeutic Chemical Code

- DICOM   -   Digital Imaging and Communications in Medicine

- EHR   -   Electronic Health Record

- EIA   -   Electronic Industries Association

- eIMMR   -   Electronic Indoor Morbidity & Mortality Return

- EMR   -   Electronic Medical Record

- FERCSL   -   Forum of Ethical Review Committees of Sri Lanka

- GOSL   -   Government of Sri Lanka

- GP   -   General Practitioner

- HIN   -   Health Institution Number

- HIS   -   Health Information System

- HIU   -   Health Information Unit

- HL7   -   Health Level 7

- HL7-FHIR   -   Health Level 7 – Fast Healthcare Interoperability Resources

- ICD   -   International Classification of Disease

- ICPC-2   -   International Classification of Primary Care – Release 2

- ICT   -   Information Communication Technology

- ICTA   -   Information Communication Technology Agency of Sri Lanka

- ID   -   Identity

- IEEE   -   Institute of Electrical and Electronics Engineers

- IPR - Intellectual Property Rights

- ISO - International Organization for Standardization

- LOINC - Logical Observation Identifiers Names and Codes

- MPI - Master Patient Index

- NEHR - National Electronic Health Record

- NPG - National Procurement Guidelines

- OPD - Outpatient Department

- PHR - Personal Health Record

- P-LAN - Private Local Area Network

- PHN - Personal Health Number

- POI - Point of Issue

- SLCERT - Sri Lanka Computer Emergency Readiness Team

- SLIN - Sri Lanka Identification Number

- SLMC - Sri Lanka Medical Council

- SNOMED - Systematized Nomenclature of Medicine

- SNOMED-CT - Systematized Nomenclature of Medicine--Clinical Terms

- TEC - Technical Evaluation Committee

- TIA - Telecommunications Industries Association

- TWG – DHSI - Technical Working Group: Digital Health Standards & Interoperability

- VPN - Virtual Private Network

- WHO - World Health Organization

Introduction

Sri Lanka with a health system that covers all Sri Lankans, has achieved remarkable progress in most of the health indicators. However, with the country becoming more prosperous and health services reaching more citizens, people live longer lives with changes in their lifestyles. This has accelerated the demographic as well as the epidemiological transition leading to an increase in prevalence and the burden of Non-communicable diseases as the major cause of morbidity and mortality in the country. Meanwhile, the country continues to face the burden of some communicable diseases such as Dengue, Tuberculosis, and influenza.

Fifty percent of outpatient treatment, 95% of hospitalizations, and 99% of the preventive care needs of the country are provided by the state health sector. Therefore, improving the efficiency, effectiveness, and quality of the state healthcare system would benefit most Sri Lankans. Digital Health can play a significant role in improving the efficiency, effectiveness, and quality of state as well as private sector health systems. Identifying the important role of digital health, the Ministry of Health has published the *National eHealth Guidelines and Standards for Sri Lanka in 2016,* to achieve uniformity in the eHealth solutions implemented in Sri Lanka while ensuring quality care and rights of the healthcare recipients.

Further, recent developments and innovations in ICT technologies highlighted the need for revising the currently published National eHealth Guidelines and Standards. Identifying all these requirements, the National eHealth Steering Committee has appointed the Technical Working Group: Digital Health Standards & Interoperability (TWG – DHSI). The Primary Healthcare Services Strengthening Project (PPSSP) of the World Bank has also recognized the importance of the National eHealth Guidelines & Standards in the Disbursement Linked Result 5.1 as follows:

> "DLR 5.1 will support the MoH to update the e-health standards to support the robust development of HMIS platforms and use of electronic HMIS at public health service providers, including with unique individual patient records. The standards may confirm the process for unique identification of patients, minimum functionality, minimum data fields for personal health records, standardized data definitions for minimum data fields, technology standards for the HMIS, and inter-operability standards to report to and read from other systems. It should include the standard for defining the confidentiality of personal health records."

Moreover, the COVID19 pandemic that occurred in early 2020, has clearly shown the value of digital health solutions play in such situations. Digital Health Solutions are expected to transform the post-COVID-19 era health systems.

The Technical Working Group on Digital Health Standards & Interoperability (TWG – DHSI) conducted several discussions, and consultative meetings to review the existing National eHealth Guidelines and Standards. Following several rounds of discussions, the initial draft of the National Digital Health Guidelines and Standards was formulated. This draft was forwarded to the World Bank experts for their review. Parallelly, the draft was also presented to a stakeholder group comprising of academics, government ICT authorities, and the health authorities. Suggestion and comments of the World Bank experts and the stakeholders were accommodated, and a consensus was reached on the guidelines and standards. Following are the main changes that were made in this version of the NDHGS document:

1. A new chapter included;
    a. Chapter 3 - Digital health software services
2. New sections and subsections added to the existing chapters
    a. Sec. 3.2. Electronic Medical Record Systems
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    c. Sec. 3.4. Personal Health Record
    d. Sec. 7.2. Master Patient Index
    e. Sec. 7.7 Minimal dataset for National Electronic Health Records (NEHR)
3. Changes were also made to the content of other chapters to improve the relevance and accuracy of the guidelines and the standards, and to address the current needs.

Currently, the health information unit of the Ministry of Health is revising the National Digital Health Architecture, and the new architecture will be included in the NDHGS once it is formulated and approved.

The National Digital Health Guidelines and Standards are expected to be adhered to by the state and private sector health institutions and Sri Lankan ICT industry on an **opt-in** basis. However, adherence to these guidelines and standards is a mandatory requirement in the software enlisting process of the Ministry of Health.

The National Digital Health Guidelines and Standards is a living document that will be periodically reviewed and updated to be in-line with the current developments in the digital health ecosystem.

*In this document, the word **'shall'** denote a mandatory requirement while words **'should'**, **'may'** and the phrase **'it is recommended'** denote a non-mandatory requirement. These requirements were made non-mandatory, considering the feasibility issues that may be faced by the implementors of digital health solutions. However, in the future versions of the National Digital Health Guidelines and Standards, these non-mandatory requirements would be made mandatory.*

1. Architectural Model of the National Digital Health System

1.1.   The Architectural Model
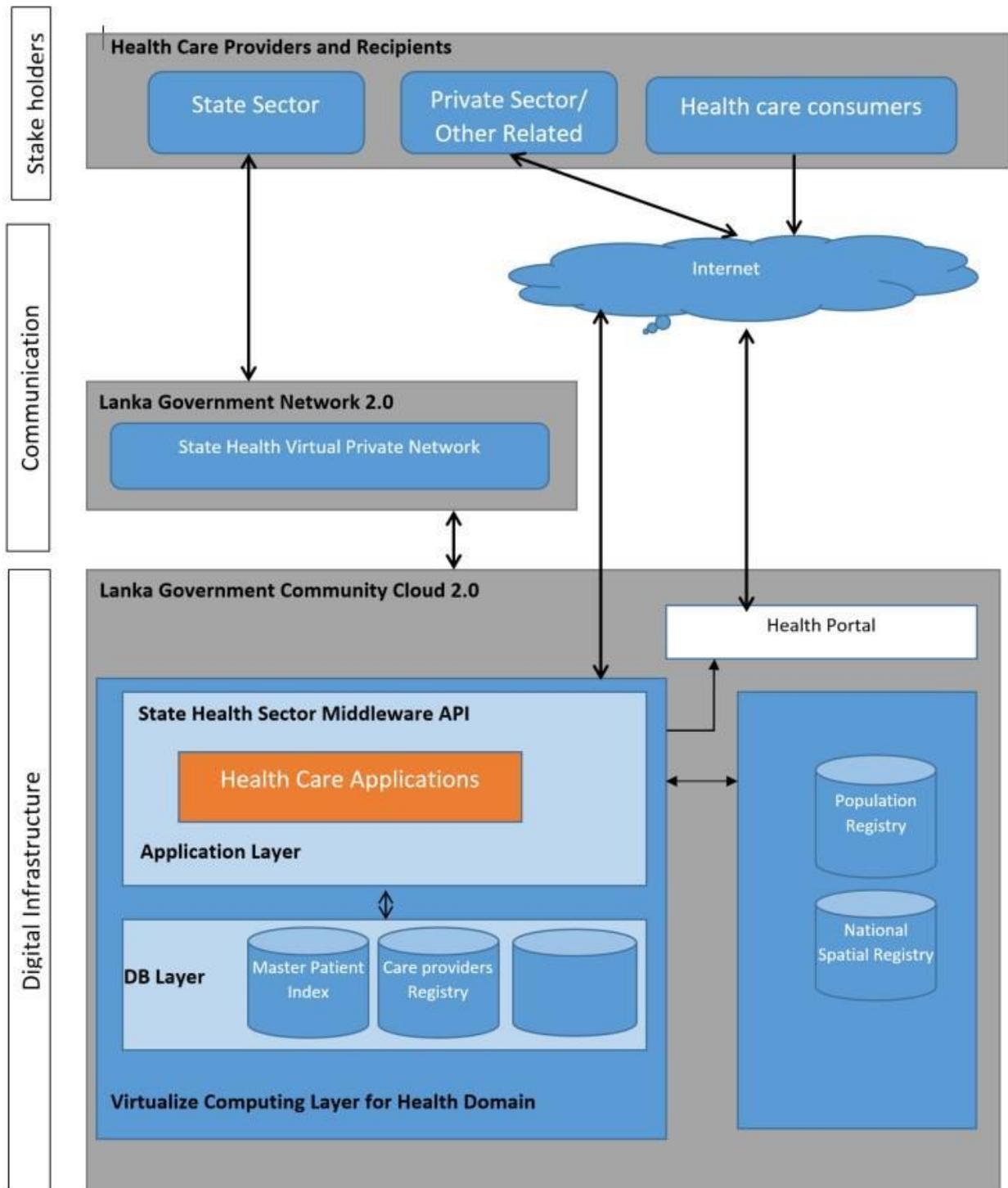
Figure 1: Architectural Model of the National Digital Health Information System

2. Hardware for Digital Health Services

2.1.   Management of Hardware for Digital Health Services

2.1.1. The current applicable National Procurement Guidelines (NPG) shall be followed when purchasing computer hardware.

2.1.2. Any such procurement shall be accompanied by appropriate maintenance and service agreements.

2.1.3. A representative of the Information and Communication Technology Agency (ICTA) and/or an expert on Health Informatics shall be included in Technical Evaluation Committees (TEC) in addition to the minimum requirements on the composition of a TEC specified in NPGs.

2.1.4. When procuring electronic medical equipment, where applicable, it is recommended that the necessary workstations, firmware and/ or software compatible with the equipment are also procured.

2.1.5. When procuring Information and Communication Technology (ICT) hardware, it is recommended that the cost of consumables and maintenance is considered.

2.1.6. A hardware inventory containing detailed specifications of all hardware according to the treasury guidelines must be maintained at the institutional level [Treasury Circular IAI/2002/02].

2.1.7. Service agreement/s shall be reached for maintenance of all equipment, firmware, and software that is not covered under warranty conditions.

2.1.8. Service agreement/s for maintenance of equipment shall be reached as per the currently applicable national procurement guidelines.

2.1.9. Except in extraordinary situations, that is agreed by the Ministry of Health, a hosting facility/ platform maintained by the competent authority of the Government of Sri Lanka or the Ministry of Health shall be used for the purpose of hosting any central database, application, or middleware.

3. Digital Health Software Services

3.1.   Management of Digital Health Software

3.1.1.**State Healthcare Sector Digital Health Software list:** All digital health systems that are developed, tested, piloted, or implemented in all State Sector Healthcare Institutions shall be listed in the Digital Health Software List (previously eHealth Software List) maintained at the Health Information Unit (HIU) of the Ministry of Health. (**Internal Circular No: 02-136/2015 -** Annexure-II)**.**

3.1.2.State Healthcare Sector Software shall be aligned with Sri Lanka government National Digital Architecture & Interoperability Standards unless specified in this document.

3.1.3.Government healthcare organizations shall only use appropriately licensed software. Such licensing is applicable for proprietary as well as free and open-source software. All software developed for, implemented in, or used by the Ministry of Health shall clearly define the license.

3.1.4.If donated, vendor lock-in shall be prevented. Life-cycle cost and the benefit shall be evaluated by an independent group appointed by the Ministry of Health.

3.1.5. Acquisition of software including software donated free of charge shall always be accompanied by contractual agreements with relevant parties for development, customization, and maintenance.

3.1.6.When the Ministry of Health, Provincial Ministries of Health, or Healthcare Institutions award a contract to build software from scratch, the ownership of Intellectual Property Rights (IPR) including the source code of such software lies with the awarding party.

When building software in house Intellectual Property Right (IPR) shall be owned by the Government of Sri Lanka (GOSL).

When accepting software as donations, IPR shall be licensed to GOSL with the necessary rights to modify the source code, except in special circumstances where the donating agency is granted special approval by the National eHealth steering committee.

3.1.7. When acquiring software containing third party components, it is necessary to ensure that appropriate licenses are provided for such components.

3.1.8. Piloting of Software Systems: The decision to implement a software system or component(s) of the software shall be made after piloting and shall be done at selected institutions/units followed by proper evaluation of the pilot project. If the pilot involves a third party, the evaluation shall be done independently of the third party.

3.1.9. It is recommended that the competent authority of the Government of Sri Lanka for conducting information system security audits, is engaged throughout the software life cycle.

3.1.10. Security audits shall be performed by the competent authority prior to the piloting or implementation of a digital health software solution.

3.1.11. Agreements/contracts should cover important issues including the following:

    a. Software Requirement Specifications.

    b. Source code availability.

    c. If the software is a unique solution meant for the healthcare institution

        i. Milestones of the development process and percentage of payments (partial payments) to be made at reaching each milestone.

        ii. Provisions for flexibility in the specifications during the development process.

    d. Software documentation including installation and user manuals.

    e. Provision for modifications and updates to the software.

    f. Declaration of the developer/s stating that the software complies with existing legislation (of the country).

g. Handling of critical and non-critical failures.

h. Clauses handling dispute situations. This should include preventing remotely disabling features.

i. Third-party licenses.

3.1.12. Clauses that are detrimental to the acquiring entity similar to but not limited to the following should not be included in agreements/contracts:

    a. Clauses preventing the smooth transition of the healthcare institution to different software from another vendor in the future (i.e. Vender Lock).

    b. Broad exculpatory clauses that limit or exclude vendor's liability.

    c. Clauses that prevent or limit the inheritance of the software in an event of a change of ownership of the healthcare institution (e.g. taking over a hospital from a Provincial Department of Health by the Ministry of Health).

3.2. Electronic Medical Record (EMR) Systems

EMR systems are computer-based information systems that collect, store and display patient encounter information. EMRs are similar to digital versions of paper-based medical records and they contain personal and clinical information about a patient's clinical encounter/s at a single practice or healthcare institution.

3.2.1. All Electronic Medical Record (EMR) Systems shall have the following basic components (at minimum) :

- Patient registration module
- Admission discharge and transfer module (ADT module)
- Clinical module for outpatient department/ clinics/ wards
- Laboratory module
- Radiology information system module
- Pharmacy module
- Financial module (for relevant instances)

Essential components	Minimum functionality
ADT	Admission/Registration 1. Patient registration 2. Issuing of new PHN 3. Search for patient PHN 4. Edit/Update patient demographic details ODP/Clinic registration 1. Enroll patient to a clinic or OPD consultation
Clinical	1. Enter patient clinical details 2. View past visit information 3. Refer to a different clinic 4. Request Laboratory tests 5. View Laboratory test results 6. Prescribe medicine
Laboratory	1. View tests requests 2. Accept samples for testing 3. Enter test results 4. Validate and authorized for release
Pharmacy	1. View list of medicines requested 2. Accept or reject dispatch of medicine

It is recommended the above modules are "loosely coupled" using a "Microservices Architecture" and communicate through Application Programming Interfaces (API).

3.2.2. All state health sector EMR systems shall use the PHN (prescribed in this document) to uniquely identify patients/ Clients in the system. It is recommended that EMRs implemented in the private sector and other sectors (e.g. Military Forces) use PHN to uniquely identify patients within the system.

3.2.3. All EMR systems shall use the Health Institution Number (HIN) published by the Ministry of Health to uniquely identify sector healthcare institutions in the system.

3.2.4. All state health sector EMR systems shall be able to seamlessly communicate (through API) with the eIMMR system. It is recommended that all other EMR systems also incorporate the functionality to seamlessly communicate with the eIMMR system.

3.2.5. All EMR systems shall communicate with the National Electronic Health Record (NEHR) and submit the prescribed minimal dataset (see section 7.7)

3.2.6. EMR systems should communicate with the relevant support systems such as Human Resources (HR), stock management, etc.

3.2.7. EMR systems should provide clinical decision support, based on the currently accepted clinical guidelines issued by competent authorities

3.2.8. EMR systems should provide decision-support dashboards for the hospital administrators to aid their administrative and operational decisions

3.2.9. All EMR systems shall comply with the national information security standards

3.2.10. All EMR systems shall comply with all relevant regulations published by the government of Sri Lanka

3.2.11. All EMR systems should communicate with the National/ Cluster MPIs

3.2.12. It is recommended that EMR systems should comply with the national HL7 FHIR profiling release 4

3.3.   National Electronic Health Record (NEHR)

Electronic Health Records (EHR) are electronically managed repositories of all personal health information of individuals from their birth to death. EHRs are longitudinal records of healthcare. EHRs contain records of healthcare provided for a particular healthcare recipient by various healthcare providers and professionals. EHRs facilitate information sharing among authorized users including the healthcare recipients irrespective of their geographical location.

Ministry of Health is the owner of the National Electronic Health Record. Ministry of Health is the sole authority for design, develop and maintain the National Electronic Health Record.

3.3.1. The NEHR shall provide API for all EMRs to communicate with it

3.3.2. NEHR shall comply with the National HL7 FHIR profile

3.3.3. Only the EMR systems approved by the Ministry of Health shall have read and write access to NEHR through API

3.3.4. Only the information of care recipients who are positively identified through the National identification system (National Identity card etc.) shall be transmitted to the NEHR.

3.3.5. The care recipient shall have read-only access to NEHR through a patient portal.
Access to the NEHR shall only be granted to care recipients following authentication and authorization at approved healthcare institutions.

3.3.6. Care recipients shall have the functionality to authorize care providers for temporary access to their Electronic Health Record.

3.3.7. PHR systems authorized by care recipients shall have read-only access to that particular recipient information in the NEHR.

3.4. Personal Health Record (PHR)

A personal health record, or PHR, is an electronic application through which patients can maintain and manage their health information (and that of others for whom they are authorized) in a private, secure, and confidential environment.

3.4.1.All PHRs shall use the PHN to access the NEHR

3.4.2.It is recommended that PHRs provide dashboards to support personal health monitoring

3.4.3.All PHRs shall comply with the national information security standards

3.4.4.It is recommended that PHRs systems have the functionality to read the information in the NEHR

3.4.5.It is recommended that PHR systems should comply with the National HL7 FHIR profile

4. Network and Connectivity

4.1.   Network Architecture

4.1.1. It is recommended to follow the latest and/or widely accepted versions on networking (including mobile devices) and cabling standards of the Institute of Electrical and Electronics Engineers (IEEE), International Organization for Standardization (ISO), Electronic Industries Alliance (EIA) and Telecommunications Industry Association (TIA).

4.1.2. Except in extraordinary situations, that is agreed by the Ministry of Health, the official government network of the government of Sri Lanka shall be used for networking of all institutions in the health domain.

4.1.3. All institutions under the Ministry of Health and the provincial departments of health should be able to exchange health-related data through the official network of the Government of Sri Lanka.

4.1.4. Health Institutions are recommended to maintain their own Private Local Area Network (P-LAN) interconnecting all the devices within the institution.

4.1.5. Open network protocols are recommended to ensure freedom of hardware selection.

4.2.   Network Management

4.2.1. Whenever planning new buildings for healthcare institutions, they shall be designed to support network infrastructure.

4.2.2. Physical topology, physical cable layout and upgrades, access methods, protocols, communication devices, operating systems, applications, and configurations shall be adequately documented.

5. Communication Interface

5.1.   Websites of the State Healthcare Sector

5.1.1. Contents should be available in Sinhala, Tamil, and English for documents relevant to the public.

5.1.2. All state sector health-related websites should have a mechanism to handle complaints or concerns on healthcare-related content on the website.

5.1.3. Websites created shall comply with the guidelines and standards for development and maintenance issued by the competent government authority.

5.2.   Domains Names for State Healthcare Sector Institutions

5.2.1. The HIU will issue the official domain names to line Ministry Institutions and Institutions coming under the Provincial Ministries. They should contact the HIU to obtain the official domain names.

5.2.2. The domain names under "healh.gov.lk" and "healthdept.<prov_code>.gov.lk" will be allocated according to "**General Circular Letter No. 02-l87/2012**"(Annexure-II) or a subsequent circular and they will be owned by the Ministry of Health and the relevant Provincial Ministry of Health.

5.2.3. Those wishing to obtain domain names that include health-related generic words from the.lk domain registry should obtain clearance from the HIU. This includes English generic words and Sinhala or Tamil generic words in the native script or transliterated to Latin script.

5.3. Email

5.3.1. Email addresses should be assigned in accordance with the "**General Circular Letter No. 02-l87/2012**"(Annexure-II).

5.3.2. Email accounts on an organization's domain shall be used for official purposes only.

5.3.3. All official electronic communications should only be carried out using the official email address under the organization's domain.

5.3.4. All emails should follow the proper channels of communication as per existing guidelines and norms for paper-based document communication.

5.3.5. Paper-based archiving regulations should also be applied to all email communications.

5.3.6. The relevant officer shall ensure that his/her email account is checked for and responded according to the guidelines applicable to postal mail.

6. Privacy, Confidentiality, Security and Medical Ethics

In this section;

'**anonymize**' means permanent removal of any personal identifiers to render any personal data from being related to an identified or identifiable natural person;

'**consent'** means any freely given, specific, informed and unambiguous indication by way of a written declaration or an affirmative action signifying a **data subject's** agreement to the processing of his/her personal data;

'**data subject'** means an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier including but not limited to a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, psychological, economic, cultural or social identity of that natural person;

'**encryption**' means the act of ciphering or altering data using a mathematical algorithm to make such data unintelligible to unauthorized users;

'**personal data'** means any information whether true or not, relating to a data subject;

'**pseudonymization'** means the processing of personal data in such a manner that the personal data cannot be used to identify a data subject without the use of additional information and such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to a data subject.

In the context of this document, a data subject can be a health care recipient, a parent/guardian of a healthcare recipient, a caretaker of a healthcare recipient, or an individual healthcare provider.

6.1. Medical Ethics

6.1.1. Ensuring the privacy and confidentiality of healthcare recipient is a fundamental ethical concept in Medical Practice and shall be paramount in all digital Health solutions.

6.1.2. Electronic health systems that handle personally identifiable data of patients, clients or the general public for research purposes shall have received ethical approval from an ethics review committee coming under the *Forum for Ethics Review Committees in Sri Lanka* (FERCSL) or approved by Ministry of Health

6.2. Privacy and Confidentiality

6.2.1. Ensure the confidentiality of personally identifiable data and information at all stages of the Health Information Systems (HIS) cycle.

6.2.2. Personally identifiable data and information shall be used only for the specified, explicit, and legitimate purpose for which the data was collected. However, the healthcare institution may process personally identifiable data for archiving, legal, and notification purposes in the public interest. If such data is to be used for any other purpose, a proper de-identification procedure shall be followed.

6.2.3. Unless disclosure is enforced by law, personally identifiable information shall not be disclosed without the written informed consent of the individual concerned for any other purpose than the purpose for which it was collected.

6.2.4. Health care workers' access to healthcare-related information should be strictly on a need to know basis and such access should be revoked immediately when the job role is changed or is terminated.

6.2.5. Role-based access control profiles should be clearly defined and documented.

6.2.6. Healthcare Institutions shall ensure that information of an individual is accessible only to employee/s who have signed an information confidentiality agreement (Non-Disclosure Agreement).

6.2.7. Healthcare institutions shall ensure that employees who leave the organization are bound to maintain the confidentiality of personal information related to patients/clients that they have come to know during the period of employment with the institution unless enforced by the law.

6.2.8. Healthcare institutions shall ensure that third party personnel involved with health information systems including maintenance should sign non- disclosure agreements.

6.2.9. An individual has the right to request for changes and amendments to personal information held in an information system in the event of any discrepancy. The head of the institution or the authorized staff member shall take the decision in-par with the prevailing government regulations and laws.

6.2.10. All personal and health-related data shall be stored and backed up in servers located within the legal jurisdiction of Sri Lanka.

6.3. Security

6.3.1. Electronic documents should be maintained following existing guidelines governing paper-based documents and the prevailing legislation in the country.

6.3.2. The security standards and guidelines defined by the Sri Lanka Government shall be strictly followed.

6.3.3. Digital health systems must ensure that every Creation, Reading, Update and Deletion actions on data should be recorded in an event log with the original data being preserved and visible.

6.3.4. During decommissioning of a system or a data storage device, permanent removal of data shall be ensured using a media sanitation tool or the storage devices shall be removed and physically destroyed.

6.3.5. Institutions shall ensure the physical security of all ICT hardware and relevant Documentations.

6.3.6. Institutions shall maintain access restricted rooms to keep critical computer equipment such as servers and networking equipment. Such access shall be revoked when the job role is changed or the employee is terminated.

6.3.7. Institutions shall ensure employee/s who are leaving the institution/unit have surrendered identification cards, access cards, keys, and other means of access and dispose of (destroy or deactivate) them appropriately.

6.3.8. Maintenance of internal or external data storage devices should be performed on-site whenever possible and should only be done by authorized personnel.

6.3.9. Digital Health systems shall be designed with events (security) log that allows tracing of successful and failed log-in attempts. Personally Identifiable and Login Authentication Credentials must be encrypted using the appropriate algorithm.

6.3.10. Institutions shall ensure that appropriate procedure is followed for secure backup of data following accepted standards.

6.3.11. Institutions shall make sure that the retrievability of backed up data/information is regularly checked to ensure the reliability of the backup process.

6.3.12. Information systems security audits should be performed annually.

6.3.13. Systems should be promoted to enforce the use of strong passwords passphrase or implement two-step verification.

6.3.14. High-level Authentication as System Administration must remain with at least two individuals.

7. Digital Health Systems Interoperability

7.1. Personal Health Number

7.1.1. Digital Health Systems of the Sri Lankan healthcare sector shall use the Personal Health Number (PHN) to connect the healthcare recipients to their appropriate health records.

7.1.2. PHN is a unique number assigned to a healthcare recipient.

7.1.3. The PHN shall be issued to an individual upon his/ her first contact with the healthcare sector and it is strongly advised to continue it for his/her life.

7.1.4. It is recommended that all Healthcare Institution issuing the PHN should not Issue a new PHN for individuals already having a PHN, unless in instances where ensuring the anonymity of the individual is requested.

7.1.5. There are three components to the Personal Health Number which are;

Table 2: Components of the Personal Health Number

Point of Issue ID	Random alphanumeric string	Check Digit
XXXX (4 digit alpha numeric string)	XXX XXX (6-character alpha numeric string)	C

7.1.6. Any segregated unit (functionally or physically) of or within a healthcare institution where PHN is issued shall be referred to as a **Point of Issue (POI)**.

7.1.7. Point of Issue (POI) ID: The Health Information Unit (HIU) of the Ministry of Health will be the issuing authority to assign an identification for the point of issue, which is the

"*Point of Issue*" ID. State and private healthcare institutions shall obtain the POI ID from the HIU.

7.1.8. Only one million PHNs shall be issued under each POI ID. A new POI ID shall be obtained before a particular POI ID reaches its one million upper limit of PHNs.

7.1.9. Random alphanumeric string – shall be a six-character alphanumeric string, generated randomly using a standard random string generation algorithm. All digital health systems issuing PHNs shall have a mechanism to check whether there are duplications in the PHN issued for each POI ID.

7.1.10. It is recommended to use the following characters when generating the PHN:

2346789BCDFGHJKMPQRTVWXY

7.1.11. Check Digit – shall be generated using the modified Luhn Algorithm used by Regenstrief Institute Inc.

7.1.12. PHN shall be validated for transcription errors by the EMR system at each reading of the PHN

7.2.   Master Patient Index (MPI)

7.2.1. A National Master Patient Index shall be maintained by the Ministry of Health.

7.2.2. Any digital health system that needs MPI services shall be pre-registered with the MPI through the Health Information Unit of the Ministry of Health.

7.2.3. MPI services shall be used for the positive identification of healthcare recipients within the health system.

7.2.4. Digital Health systems shall use the following data for positive identification of healthcare recipients within the MPI:

1. Citizen Identification Number/ National Identity Card Number (NIC)/ Sri Lanka Identification Number

2. Personal Health Number (PHN)

3. Legal name

4. Telecommunication details

5. Prefixes (e.g.; Mr., Ms., Dr., Prof., Rev., Ven.)

6. Suffix (e.g.; Thero)

7. Date of Birth

8. Gender

9. Address

10. The person is active or not

11. Person's photo

12. Marital status

7.3.   Healthcare Facility Registry

7.3.1. A registry of Healthcare Institutions is maintained at the HIU and should be referred when necessary.

7.3.2. The registry holds a unique identification number (Health Institution Number (HIN)) for the Institution and other relevant information.

HIN is a 10 character alphanumeric string published by the Health Information Unit of the Ministry of Health.

7.3.3. Following are the recommended data elements of the facility registry:

1. Institution Code

2. Official Name

3. Other names (optional)

4. The abbreviated display name for electronic systems

5. Name of Institution

6. RDHS

7. District

8. Province

9. Category

10. Sub Category

11. Ownership

12. Latitude

13. Longitude

14. Telephone number

15. Address

7.4. Healthcare Provider Registry

7.4.1. The Ministry of Health shall maintain a Healthcare Provider registry of healthcare workers who will have a role in state sector digital health systems.

7.4.2. Following are the recommended data elements of the facility registry:

1. Individual provider identifier

2. National identification number (NIC/ SLIN)

3. Professional registration number

4. Professional registration issuer

5. Legal name

6. Staff category

7. Telecommunication details

8. Active or not

7.5. Data Interchange Standards

7.5.1. For the purpose of data exchange, Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) Release 4 should be used.

7.5.2. It is recommended to use Aggregated Data Exchange (ADX) standard, developed and maintained by the Quality Research and Public Health committee of the IHE (Integrating the HealthCare Enterprise), for exchanging aggregated health data.

7.5.3. For interchange of Laboratory data, it is recommended to use Logical Observation Identifiers Names and Codes (LOINC) developed by Regenstrief InstituteInc. It is recommended that LOINC version 2.67 or later should be used. (https://loinc.org/downloads/)

7.5.4. For the transfer and storage of images between software programs in the medical domain, it is recommended that Digital Imaging and Communication in Medicine (DICOM) version 3 (current version – 3.1) standard of the National Electrical Manufacturers Association, USA. Vendor Neutral Archiving (VNA) should be used. (https://www.dicomstandard.org/current/)

7.6.   Standardized Clinical Vocabulary

7.6.1. For the purpose of coding clinical concepts in clinical settings other than in the out-patient department, it is recommended to use or have provisions to use the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) of the SNOMED International.

7.6.2. International Classification of Diseases (ICD) 10th edition of the World Health Organization (WHO), shall be used to record the final or an intermediate diagnosis of all clinical encounters that occur in in-patient (inward/ indoor).

7.6.3. For the purpose of recording reasons for encounter in the outpatient department (OPD), primary care, and general practice (GP) settings, it is recommended to use International Classification of Primary Care, Second edition (ICPC-2) ICPC-2.

7.6.4. It is recommended that the Anatomical Therapeutic Chemical Code (ATC) of WHO is used to code drugs prescribed and dispensed through digital health systems.

7.7. Minimal Dataset for the National Electronic Health Record (NEHR)

7.7.1. Each EMR System shall submit relevant data elements of following minimal dataset to the NEHR for each healthcare encounter between a healthcare recipient and a healthcare provider where an EMR system is used to record the encounter output:

A Health Care Encounter represents a healthcare recipient care event, which involves a Health Care Provider. The Health Care Encounter is the construct through which all recorded client care activities are identified. Encounters occur to address Health Concerns, and may also address known Health Conditions as well. Health Care Encounter Output represents the results of the event. Currently, NEHR will capture only outputs that are provided by Health Care Providers, such as a diagnosis that identifies a Health Condition, a clinical procedure, a service being provided, or a requisition for a diagnostic procedure, medication, referral, medical device, or health care services. An encounter may occur at a geographic or virtual address and it may also be temporary clinic/service area (e.g. outreach clinic), mobile location (e.g., ambulance, mobile lab), or in the field (e.g. disaster location, accident site).

The following dataset of healthcare recipients' demographic data shall be transmitted to the NEHR when he/she is registered with the healthcare system as a new healthcare recipient or when any of the data elements of the demographic dataset is updated.

Table 3: 'Healthcare recipient demographic data' - complete dataset

The core data Category	Data element
Healthcare recipient demographic data (complete dataset)	Personal Health Number (PHN)
	National Identity type
	National Identity Ex. National Identity card number/ SLIN/ National Digital Identity
	Passport number (For foreigners only)
	Passport issued country (For foreigners only)
	Active
	Reporting name
	Legal Name / Registered Name
	Date of Birth

	Is the date of birth calculated
	Gender
	Address
	(a) Permanent
	(b) Temporary
	Grama Niladhari Division
	Divisional Secretariat
	Contact type ID
	Contact Details

Only following minimal dataset of the Healthcare recipient demographic data, shall be transmitted to the NEHR along with other relevant healthcare encounter data, if the Healthcare recipient demographic data is not updated:

Table 4: 'Healthcare recipient demographic data' - minimal dataset

The core data Category	Data element
Healthcare recipient demographic data (Minimal dataset)	Personal Health Number (PHN)
	National Identity type
	National Identity (Ex. National Identity card number/ SLIN/ National Digital Identity)
	Reporting name
	Legal Name / Registered Name
	Date of Birth
	Is the date of birth calculated
	Gender
	Contact Details

For each healthcare encounter at an outpatient department, special clinic, specialized clinic, public health (preventive health) setting, specialist consultation or a general practitioner's consultation; following minimal dataset shall be transmitted to the NEHR in addition to the Healthcare recipient demographic data:

Table 5: 'Healthcare encounter output' dataset

The core data Category	Data element
Healthcare encounter output	Healthcare Institution Number (HIN)
	Encounter identifier
	Healthcare Institution Name
	Encounter type
	Date and Time of the encounter
	Provider identifier (individual)
	Reason for encounter
	Diagnosis (Current encounter)

For each healthcare encounter at an outpatient department/ special clinic/ specialized clinic/ specialist consultation or a general practitioners consultation, following minimal dataset should be transmitted to the NEHR if relevant to a particular encounter and recorded in the EMR, in addition to the Healthcare recipient demographic data, and Healthcare encounter output data (above):

Table 6: Complimentary dataset for healthcare encounter output

The core data Category	Data element
Allergies & adverse reactions	Allergen name
	Manifestation
Past Medical History	Condition
	Onset
	Clinical Status
Regular Medication	Regular Medication Name
	Regular Medication form
	Regular Medication Dosage
	Regular Medication Route
	Medication Status
Past Surgical History	Procedure name
	Date
Immunizations	Vaccine name
	Date
Obstetric summary	Gravidity

	Mode of Delivery
	Pregnancy outcome
Behavioral Risk factors	Risk factor name
	Risk factor status
	Duration
	Status recorded Date
Health risk assessment	Health risk assessment type
	Risk Assessment Outcome
	Assessment Date
Investigation request	Investigation request identifier
	Name of the investigation
Prescription	Prescription ID
	Medication Name
	Medication form
	Dosage
	Route
	Duration of supply
	Prescription Validity Period
	Prescription ID
Follow-up care plan	Follow-up care plan identifier
	Follow-up care plan author/ institution
	Follow-up care plan category
	Follow-up care plan Description

If laboratory examination results available as a healthcare encounter output, following minimal data should be transmitted to NEHR:

Table 7: 'Laboratory test result' dataset

The core data Category	Data element
Laboratory test result	Date and Time
	HIN - Health Institution Number
	Investigation request identifier
	Personal Health Number (PHN)
	Test Name

	Test Result
	Test authorizing Provider ID

If a radiological imaging examination result/s available as a healthcare encounter output, following minimal data should be transmitted to NEHR:

Table 8: 'Imaging examination results' dataset

The core data Category	Data element
Imaging examination results	Date and Time
	HIN - Health Institution Number
	Investigation request identifier
	Personal Health Number (PHN)
	Radiology test name
	Radiology test Impression
	Radiology Test diagnosis /Conclusion
	Provider ID

If medication, vaccine or other therapeutic/prescribable item administered to a healthcare recipient as a healthcare encounter output, following minimal data should be transmitted to NEHR:

Table 9: ' Medication administration' dataset

The core data Category	Data element
Medication administration	Personal Health Number (PHN)
	Medication Name
	Medication form
	Dosage
	Route
	Number of doses administered

If a diagnostic or a therapeutic procedure is performed on a healthcare recipient as a healthcare encounter output, following minimal data should be transmitted to NEHR:

Table 10: 'Procedure' dataset

The core data Category	Data element
Procedure	Personal Health Number (PHN)
	Provider ID
	Procedure name
	Indication
	Operative note
	Medical device
	Date and Time

For each prescription dispensed, Pharmacy should transmit following minimal data-set to the NEHR:

Table 11: 'Medication dispensing' dataset

The core data Category	Data element
Medication dispensing	Pharmacy ID
	Personal Health Number (PHN)
	Prescription ID
	Prescription issued Healthcare Institution Number (HIN)
	Dispensed Medication Name
	Dispensed Medication form
	Quantity Dispensed
	Date and time

For each inward admission a **discharge summary** consisting of the following minimal data set shall be transmitted to the NEHR on discharge:

Table 12: 'Discharge summary' dataset

The core data Category	Data element
Healthcare recipient demographic data (complete dataset)	See above
Discharge Diagnosis/ Diagnoses	Diagnosis text

	Diagnosis code (ICD10 code)
Allergies and Adverse Reactions	See above
Past Medical History	See above
Past surgical History	See above
Regular Medication	See above
Obstetric summary	See above (only for females if relevant/ and the current reason for admission)
Immunizations	See above (Only if directly related to the current reason for admission)
Behavioral Risk factors	See above (if no risk factors shall indicate that)
Health risk assessment	See above
Physical Examination findings	shall record all significant positive and negative findings directly relevant to the current reason for admission
Laboratory test result	See above (shall record if no laboratory tests were done)
Imaging examination results	See above (shall record if no imaging examinations were done)
Medicine	See above. Details about medication, vaccine or other therapeutic/prescribable items which were administered to the healthcare recipient during this admission
Procedure	Details about therapeutic or diagnostic procedures or operations performed which will be needed for the health care professionals participating in current and future care. See above for more details.
Prescription	See above (shall indicate if a prescription was not issued)

In case the patient was managed at an intensive care unit or a high dependency unit separate discharge summaries should be transmitted to NEHR for each such event.

In case the patient was deceased during the admission, following minimal dataset of the **death declaration** shall be transmitted to the NEHR in addition to the discharge summary (above):

Table 13:'Death declaration' dataset

The core data Category	Data element	Sub-element
Healthcare recipient demographic data (complete dataset)	See above. The race of the deceased also should be recorded.	
Provider ID	Unique identification of the primary performer /performers of the procedure	
Individual healthcare organization Data	Health Institution Name	
	HIN - Health Institution Number	
	Clinic/OPD/ Unit Name	
	Clinic/OPD/ Unit Identifier	
Provider	Provider identifier (individual)	
	Provider Identity type	
	Provider name	
Details of the death	Date of death	
	Age at death (calculate using the date of death & date of birth.)	Years
		Months
		Days
		Hours For neonates less than 24hours of age)
Cause of death	The immediate cause of death	Ia.
	Antecedent causes or underlying causes	Ib. Due to (or as a consequence of)
		Ic. Due to (or as a consequence of)
		Id. Due to (or as a consequence of)
	Contributory causes	II.
	The approximate interval between the onset of each cause and the death	
Date of reporting	Date	

Glossary

- Health Information Unit
  The administrative unit under the Director – Health Information of the Ministry of Health.

- Healthcare recipient:
  A person who is eligible to receive healthcare in Sri Lanka. Maybe a Sri Lanka citizen or a foreign national. Currently, the healthcare recipient is defined as a person presenting to a health care institution or a health care provider seeking healthcare. (A self-care encounters are not recognized)

- Ministry of Health
  Ministry of Health, Department of Health Services of Sri Lanka which is currently amalgamated merged and the Provincial Ministries of Health.

- Middleware
  Computer software that connects software components or people and their applications.

- State healthcare sector
  Any institute, division, or unit in Sri Lanka providing or supporting healthcare and belong to a Ministry, a state department, a provincial department, or a local authority. (This does not include healthcare institutes of state-owned   companies).

- Software
  Is a collection of computer programs and related data that provide the instructions for telling a computer what to do and how to do it.

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Annexure-I: Standardized Definitions of the Minimal Data set

> *** Coding of 'minimum data' with a terminology is preferred. Free text should be used only if there is no appropriate terminology available**
>
> *** * This list may be updated by the healthcare provider during this encounter. If there is no NEHR record, use either the manual records produced by the healthcare recipient or the subjective clinical history reported by the healthcare recipient.**

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology *	Reference to HL 7 FHIR
Individual healthcare organization Data	Organization demographic data	Use in demographic service to collect demographic data about an organization.		Resource organization https://www.hl7.org/fhir/organization.html
Health Institution Name	The name by which an organization is known	Use in demographic services to represent an organization name	Free text	Organization.name
HIN - Health Institution Number	Uniquely identify healthcare institutions in the system	Use to register data about a healthcare institution in the system. Published by the Ministry of Health	String	Organization. identifier
Clinic/OPD/ Unit Name	Identify the administrative category of care provision. Locally maintained dictionary with an identifier	Indicates the name of the administrative category of care provision	Coded data element	

Clinic/OPD/ Unit Identifier	Uniquely identify the administrative category of care provision. Locally maintained dictionary	Use to register the details of the administrative category of care provision.	String	Organization. Identifier

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Provider	A person who is directly or indirectly involved in the provisioning of healthcare.			Resource.practitioner https://www.hl7.org/fhir/practitioner.html
Provider identifier (individual)	An identifier that applies to this person in this role	Use to represent an individual healthcare provider Ex. SLMC Number	String/Integer	Practitioner.identifier
Provider Identity type	The specific type of Provider identification	Use to determine the provider identity type Ex. Identifier issued by SLMC	String	
Provider name	The name(s) that a Practitioner is known by	Use to indicates the health care provider name as it is to be used for display	Text	Practitioner.name

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Healthcare recipient data	Demographic data about a person	Use in demographic service to collect a person's demographic data		Resource Person https://www.hl7.org/fhir/person.html Resource Patient
Personal Health Number (PHN)	Generated by each EMR according to the guidelines & standards published by the Ministry of Health to uniquely identify healthcare recipient	Use to register data about a healthcare recipient	String	Patient.identifier
National Identity type	A specific type of the positive identification Ex. National Identity card / SLIN/ National Digital Identity	Use to determine the type of positive identification. An identification type issued and recognized by the GoSL shall be used	String	
National Identity	Positive identification of subjects of care within and between health care organizations. Ex. National Identity card	Use in the positive identification of subjects of care within and between health care organizations.	String	Person.identifier

Passport issued country (For foreigners only)	The country in which the passport was issued	Use to record the country in which the passport was issued	Coded data element	
Active	Whether this person's record is in active use	Use as the status element which indicates the record should/should not be treated as valid	Boolean	Person.active
Reporting name	Indicates The subject's name as it is to be used for reporting	Use to indicates the subject's name as it is to be used for reporting Not to be used to identify the individuals who can be uniquely referenced from registers of demographic details	Free text	Person.name
Legal Name / Registered Name	Person name details, Name as registered in Registrar General's Department	Use to represent the name registered in the Registrar General's Department. Can be used to identify the individuals who can be uniquely referenced from registers of demographic details	String	Refer HL& FHIR profiles – Sri Lanka
Date of Birth	Date of the Birth of a Person as Registered with the RGD	Use to represent the Date of the Birth of a Person as Registered with the RGD	Date	Person. birth date DDMMYYYY

Is the date of birth calculated	If the date of birth is uncertain, calculated birth of date should be transferred to EHR, flagging that this is a calculated		Boolean	
Gender	Details about the gender of an individual	Use to record details about the individual's gender for administrative purposes.	String	Person. gender

Address
 	
    (a) Permanent
 	
    (b) Temporary
	(a) Used to indicate where a person is Permanently living
	
	(b) a person who usually resides overseas or where the provider of the address is in temporary accommodation due to renovation or treatment etc.
		Use to communicate with, identify service provision requirements and trends, and to provide direct services.	String	Person. address

Grama Niladhari Division	Indicate GN division person's Permanent Address belongs to	Use to communicate with, identify service provision requirements and trends, and to provide direct services.	String	Refer HL& FHIR profiles – Sri Lanka
Divisional Secretariat	Indicate person's GN division belongs to	Use to communicate with, identify service provision requirements and trends, and to provide direct services.	String	Refer HL& FHIR profiles – Sri Lanka

Contact type ID	Refers to the person given contact type	Use to determine "contact" mode Ex. Voice, email, etc	Integer	Refer HL& FHIR profiles – Sri Lanka
Contact Details	Person communication details	Use to record telecommunication details for an individual (including internet-based communication)	String	Person. telecom

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Encounter	Single interaction, contact, or care event between a subject of care and healthcare provider(s).	Used as a generic document-level container for recording details of a single interaction, contact, or care event between a subject of care and healthcare provider(s).		Resource Encounter https://www.hl7.org/fhir/encounter.html
HIN - Health Institution Number	See above			
Encounter identifier	Uniquely identify this encounter in the health institution	Use to register the details of this encounter in the health institution	String	Encounter. identifier
Encounter type	Representation of the administrative category of care provision.	Use to record the administrative category of care provision.	String	Encounter.type

	e.g. Clinic/OPD/ Unit Identifier	e.g. emergency care, pre-operative assessment, routine antenatal visit, or elective admission.		
Date and Time of the encounter	To record the administrative start and end date and time of the encounter	Use to record the administrative start and end date and time of the encounter	DateTime DDMMYYYY	Encounter. period
Provider identifier (individual)	See above			
Reason for encounter	The reason for the initiation of any healthcare encounter or contact by the individual who is the subject of care.	Use to record the chief complaint here as a synonym for 'Presenting complaint' mainly to capture the patient's perceived issues or symptoms which have triggered them to seek healthcare advice	String OPD - ICPC 2 Admission - SNOMED CT	Encounter.reasonCode
Diagnosis (Current encounter)	Details about identified health conditions, injury, disability, or any other issues that impact on the physical, mental, and/or social well-being of an individual.	Use for recording details about identified health problems or diagnosis	String OPD - ICPC 2 Admission -ICD 10	Condition.code Resource condition https://www.hl7.org/fhir/condition.html

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Allergies and Adverse Reactions	Risk of harmful or undesirable physiological response which is unique to an individual and associated with exposure to a substance includes therapeutic substance administered correctly; food; material derived from plant or animal; or venom from insect stings etc	Use to record risk of harmful/ undesirable physiological response which is unique to an individual and associated with exposure to a substance, retrieved from the NEHR.	String SNOMED CT ATC	Resource AllergyIntolerance https://www.hl7.org/fhir/allergyintolerance.html
Allergen Name	Substance, or substance class, that is considered to put the individual at risk of an allergy and adverse reactions.	Identification of the specific substance (or pharmaceutical product) considered to be responsible for the Adverse Reaction event. It may be a specific substance (e.g. a brand medication), a composite product that includes the identified substance or nondrug allergies such as bee stings, foods, pollen	ATC / Free Text *	AllergyIntolerance.reaction. substance
Manifestation	Clinical symptoms and/or signs that are observed or associated with the allergy and adverse reaction.	Use to record clinical symptoms and/or signs that are observed or associated with the allergy and adverse reaction	SNOMED CT	AllergyIntolerance.reaction. manifestation

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Past Medical History	The subjective clinical history of the healthcare recipient reported to the healthcare provider that may influence clinical decision-making and care provision for the individual	Use to record the clinical history of the healthcare recipient as reported to a clinician by the healthcare recipient that may influence clinical decision-making and care provision for the individual, retrieved from the NEHR. * *		Resource condition https://www.hl7.org/fhir/condition.html
Condition	Identification of the condition, problem, or diagnosis	Use to record the condition	String ICD 10	Condition.code
Onset	Estimated or actual date or date-time the condition began, in the opinion of the clinician	Use to record estimated /actual date or date-time the condition began	DateTime DDMMYYYY	Condition.onset[x]
Clinical Status	The clinical status of the condition e.g. active | recurrence | relapse | inactive | remission | resolved	Use to record the clinical status of the condition	Coded data element	Condition.clinicalStatus

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Regular Medication	A persistent and versioned list of medicines for an individual currently in use, retrieved from the NEHR. **	Use to record a persistent and managed list of medicines for an individual, potentially including all prescribed and 'over the counter' medicines, supplements, or natural remedies currently in use		Resource MedicationStatement https://www.hl7.org/fhir/medicationstatement.html
Regular Medication Name	Identifies the medication being administered	Use to record the name of the medication	String ATC	MedicationStatement.medication[x]
Regular Medication form	Describes the form of the item. Powder; tablets; capsules	Use to record the form of the item.	String ATC	Medication.form
Regular Medication Dosage	The combination of a medication amount and administration timing for a single day Ex: '2 tablets at 6	Use to record the combination of a medication amount and administration timing for a single day	String ATC	MedicationStatement.dosage

	pm' or '20mg three times per day			
Regular Medication Route	Specific route or physiological path of administration of a therapeutic agent into or onto the patient. For example, topical, intravenous, etc.	Use to record the specific route or physiological path of administration of a therapeutic agent into or onto the patient	Coded data element	MedicationAdministration.dosage.route
Medication Status	A code representing the patient or other source's judgment about the state of the medication used. e.g. Active Completed Stopped On-hold Not-taken	Use to record patient or other source's judgment about the taking of drug/drugs at the time of recording.	Coded data element	MedicationStatement.status

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Past Surgical History	A list of surgical procedures the client has undergone during the lifetime, retrieved from the NEHR. * *	Use to record the surgical history of the subject of care as recorded directly by the subject, or reported to a clinician by the subject or a care		Resource Procedure https://www.hl7.org/fhir/procedure.html
Procedure name	The name of the specific procedure that is performed	Use to record the name of the specific procedure that is performed	String SNOMED CT	Procedure.code
Date	The date the procedure was done	Use to record the date the procedure was performed	DateTime DDMMYYYY	Procedure.performed[x]

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Immunizations	The record of current and historical administration of vaccines to healthcare recipients across all healthcare disciplines as retrieved from the NEHR. * *	Use to record current and historical administration of vaccines to patients across all healthcare disciplines Mandatory for children and other relevant		Immunization. vaccineCode Resource Immunization https://www.hl7.org/fhir/immunization.html
Vaccine Name	Details about vaccinations that have been administered to the health care recipient	Use to record the list of vaccinations administered that may influence clinical decision-making and care provision for the individual	String Anatomical Therapeutic Chemical	Immunization.vaccineCode
Date	Date vaccine administered	Use to record when immunizations were given. Specific date preferred although partial dates are allowed	DateTime/string	Immunization.occurrence[x]

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Obstetric summary	Summary or persistent information about the numbers of key obstetric events that may influence clinical decision-making and care provision, retrieved from the NEHR. * *	Use to record summary or persistent information about the numbers of key obstetric events that may impact risk assessment or decision support that may influence clinical decision-making and care provision		Resource Condition https://www.hl7.org/fhir/condition.html
Gravidity	The number of times a woman has been pregnant, current, and past, regardless of the pregnancy outcome retrieved from the NEHR. **	Use to record the number of times a woman has been pregnant, current, and past, regardless of the pregnancy outcome	Coded data element/Free Text	
Mode of Delivery	The method by which the baby is delivered * *	Use to record the method by which the baby is delivered	String SNOMED CT	
Pregnancy outcome	The outcome of the pregnancy **	Use to record the outcome of the pregnancy.	Coded data element/Free Text	

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Behavioral Risk factors	Record details relating to relevant lifestyle, e.g. smoking, use of alcohol, physical activity level, etc. The information that may influence clinical decision-making and care provision. Retrieved from the NEHR. * *	Use to record details relating to relevant lifestyle, e.g. smoking, and the use of alcohol. The information that may influence clinical decision-making and care provision	Coded data element	Resource Observation https://www.hl7.org/fhir/observation.html
Behavioral risk factor name	Describe the risk factor that may influence clinical decision-making and care provision, retrieved from the NEHR.	Use to record name/description of the relevant lifestyle e.g. Tobacco smoking	Coded data element	Observation.code
Behavioral risk factor status	Information about behavioral risk factor habits of an individual e.g. – Regarding tobacco smoking Never smoked Current smoker Former smoker	Use to record information about the individual's behavioral risk factor habits	Coded data element	Observation.status
Duration of behavioral risk factor	The time-period the observed value is asserted as being true	Use to record the time-period the individual has been on the current status	DateTime DDMMYYYY	Observation.effective[x]

Status recorded Date	The date and time this version of the observation was made available at NEHR	Use to record the date and time this version of the observation was made available	DateTime DDMMYYYY	Observation.issued
Health risk assessment	Assessment of the potential and likelihood of future adverse health effects as determined by identified risk factors, retrieved from the NEHR.	Use to record known risk factors for an identified disease, condition, or other potentially adverse health issues, and/or evaluation of the likelihood of the individual experiencing it in the future. e.g.WHO CVD-Risk Assessment	String	Resource RiskAssessment https://www.hl7.org/fhir/riskassessment.html
Health risk assessment type	The type of risk assessment performed.	Use to record the name of the risk assessment done	Coded data element	RiskAssessment.code
Risk Assessment Outcome	The outcome of the risk assessment as a whole	Use to record the result of the risk assessment	Coded data element/Fre text	RiskAssessment.prediction.outcome
Assessment Date	The date the risk assessment was performed.	Use to validate the assessment	DateTime DDMMYYYY	RiskAssessment.occurrence[x]

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Physical Examination findings	Findings observed during the examination of a subject of care in the current encounter that may influence clinical decision-making and care provision	Use to record details about findings on examination of the subject of care in the current episode that may influence clinical decision-making and care provision	String LOINC (Logical Observation Identifiers Names and Codes)	Resource Observation https://www.hl7.org/fhir/observation.html
Investigation request	A record of a request for service such as diagnostic investigations	Use to record a request for a procedure or diagnostic or other services to be planned, proposed, or performed on a patient		Resource ServiceRequest https://www.hl7.org/fhir/servicerequest.html
Investigation request identifier	Unique identification of the Investigation request against which the investigations were performed	An identifier assigned to the investigation request by the order institution for its identification	String	ServiceRequest.identifier
Name of the investigation	Identifies a particular investigation/investigation that has been requested	Use to identify a particular investigation/investigation that has been requested	String SNOMEDCT	ServiceRequest.code

The core data Category/ element	Concept Description	Use of the core information	Recommended Data type / Terminology*	Reference to HL 7 FHIR
Laboratory test result	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual or related to that individual that may influence clinical decision-making and care provision	Use to record the result, including findings and the laboratory's interpretation, of an investigation performed on specimens collected from an individual or related to that individual that may influence clinical decision-making and care provision		Resource DiagnosticReport https://www.hl7.org/fhir/diagnosticreport.html
Date and Time	The date and/or time that 'Overall test status' was issued	Use to record the date and/or time that 'Overall test status' was issued	DateTime DDMMYYYY	DiagnosticReport.effective[x]
HIN - Health Institution Number (of the institution which performs the laboratory test)	See above			
Investigation request identifier	A local identifier assigned to the order by the order's health care institution.	Use to identify encounter and encounter occurred health care institution	string	ServiceRequest. identifier
Personal Health Number (PHN)	See above			

Test Name	Name of the laboratory investigation performed	Use to record the name of the laboratory investigation performed	String LONIC	DiagnosticReport.code
Test Result	Results of the test performed	Use to record the results of the test performed	Coded data element	DiagnosticReport.result
Test authorized Provider ID	Individual healthcare provider credentials, who authorized result	Uniquely identify the individual healthcare provider credentials, who authorized result	String	Practitioner. identifier

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology	Reference to HL 7 FHIR
Imaging examination result	Record the findings and interpretation of an imaging examination performed.	Used to record all results related to the diagnostic imaging aspects of any imaging examinations performed.	String SNOMED CT	Resource ImagingStudy https://www.hl7.org/fhir/imagingstudy-definitions.html
Health Institution Number	HIN - See above			
Personal Health Number	PHN - See above			
Investigation request identifier	A local identifier assigned to the order by the order's health care institution.	Use to identify encounter and encounter occurred health care institution	string	ServiceRequest.identifier

Radiology test name	The name of the examination performed. Coding with a terminology, potentially a pre-coordinated term specifying both modality and anatomical location, is desirable where possible.	Use to record The name of the examination performed. Coding with a terminology, potentially a pre-coordinated term specifying both modality and anatomical location, is desirable where possible	String LONIC	ImagingStudy.procedureCode
Radiology test Impression	Narrative concise, clinically relevant interpretation of all imaging findings, and include a comparison with previous studies where appropriate.	Use to record examination result as a whole	Free text	DiagnosticReport.result
Radiology Test diagnosis /Conclusion	Single-word, phrase, or brief description representing the likely condition or diagnosis.	Use to record a single word, phrase, or brief description representing the likely condition or diagnosis.	ICD 10/ Free text	DiagnosticReport.conclusion Code
Provider ID	Individual healthcare provider credentials, who reported the test	Uniquely identify the individual healthcare provider credentials, who reported test	String	Practitioner. identifier

Date and Time	The date and/or time that the result was issued for the recorded 'Examination result status	Use to record the date and/or time that the result was issued for the recorded 'Examination result status	DateTime DDMMYYYY	DiagnosticReport.effective[x]

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology	Reference to HL 7 FHIR
Medication Administration (Current encounter)	Name of the medication, vaccine or other therapeutic/prescribable items which were administered to the client	Use to record the amount of medication, vaccine or other therapeutic item supplied to the patient as part of management during the encounter period	String ATC	Resource MedicationAdministration Resource Medication
Personal Health Number	PHN - See above			
Medication Name	Identifies the medication being administered	Use to record the name of the medication	String ATC	Medication.code
Medication form	Describes the form of the item. powder; tablets capsules.	Use to record the form of the item.	String ATC	Medication.form

Dosage	The combination of a medication amount and administration timing for a single day e.g. '2 tablets at 6 pm' / '20mg three times per day"	Use to record the combination of a medication amount and administration timing for a single day	String ATC	MedicationStatement.dosage
Route	Specific route or physiological path of administration of a therapeutic agent into or onto the patient. e.g. topical, intravenous, etc.	Use to record the specific route or physiological path of administration of a therapeutic agent into or onto the patient	Coded data element	MedicationAdministration.dosage.route
Number of doses administered	Number medication doses administered to the patient	Use to record number medication doses administered to the patient	Integer	

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology *	Reference to HL 7 FHIR
Procedure	Document to communicate information to others about any stand-alone procedure or operation performed which will be needed for the health care professionals participating in current and future care.	Use to record documents to communicate information to others about any stand-alone procedure or operation performed which will be needed for the health care professionals participating in current and future care.	String SNOMED CT	Resource Procedure https://www.hl7.org/fhir/procedure.html
Provider ID	Unique identification of the primary performer /performers of the procedure	Use to uniquely identify the primary performer /performers of the procedure	String	Practitioner. identifie
Procedure name	The name of the specific procedure that is performed	Use to record the name of the specific procedure that is performed	String SNOMED CT	Procedure.code
Indication	Valid reason/ to perform the procedure/operation.	Use to record the reason/ to perform the procedure/operation	ICD 10	Procedure.reasonCode

Operative note	Structured information about the procedure	Use to records detailed, structured information about anatomical location, method & technique, equipment used, devices implanted, results, findings, etc.	Free Text	
Medical device	Medical devices that have been fitted or implanted as part of the procedure	Use to record medical device implanted or removed during the procedure including, but not limited to:e.g. auditory implants; orthotics or artificial limbs; dental implants;	Coded data element	Procedure.usedCode
Date and Time	The date and/or time when the entire procedure was finished.	Use to record the date the procedure was performed	DateTime DDMMYYYY	Procedure.performed[x]

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology *	Reference to HL 7 FHIR
Follow-up care plan	Describe how one or more practitioners intend to deliver care for a particular patient following an encounter	Use to record one or more practitioners intend to deliver care for a particular patient following an encounter		Resource CarePlan https://www.hl7.org/fhir/careplan.html
Follow-up care plan identifier	The identifier assigned to this follow-up care plan	Use for identification of the care plan	string	CarePlan.identifier
Follow-up care plan author/ institution	Indicate the person/team/organization responsible for the care plan	Use to identify who/ where created the follow-up care plan	Code data element/free test	CarePlan.author
Follow-up care plan category	Identifies what "kind" of plan	Use to identifies what "kind" of plan e.g. "disease management", "wellness plan", etc.	Code data element/free test	CarePlan.category
Follow-up care plan Description	Provide a description of the scope of the plan.	Provides more details that may influence clinical decision-making and care provision	Code data element/free test	CarePlan.description

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology	Reference to HL 7 FHIR
Prescription	An order or request for supply and the instructions for administration of medications to a patient by which communicated to the pharmacy	Use to communicate a set of medication order to pharmacy		Resource - MedicationRequest - Content https://www.hl7.org/fhir/medicationrequest.html
Prescription ID	Unique identification of the prescription against which the medications were prescribed	Use to uniquely identify the prescription against which the medications were prescribed	String	MedicationRequest.identifier
Medication Name	Identifies the medication being administered	Use to record the name of the medication	String ATC	MedicationRequest.medication[x]
Medication form	Describes the form of the item. e.g. tablet, Injection	Use to record the form of the item.	String ATC	Medication.form
Dosage	The combination of a medication amount and administration timing for a single day.	Use to record the combination of a medication amount and administration timing for a single day, e.g. '2 tablets at 6 pm	String ATC	MedicationStatement.dosage

Route	Specific route or physiological path of administration of a therapeutic agent into or onto the patient. e.g. topical, intravenous, etc.	Use to record the specific route or physiological path of administration of a therapeutic agent into or onto the patient	Coded data element	MedicationAdministration.dosage.route
Duration of supply	The period for which the medication should be dispensed. e.g. The dispenser is asked to supply sufficient quantities of medication to cover the defined period.	Use to express the amount of medication dispensed as a timing amount	integer	MedicationDispense.daysSupply
Prescription Validity Period	This indicates the validity period of a prescription (stale dating the Prescription)	Use to indicate the prescribers' perspective for the validity of the prescription	DateTime DDMMYYYY	MedicationRequest.dispenseRequest.validityPeriod
Provider ID	Uniquely identify the prescriber	Use to uniquely identify the prescriber	String	Practitioner. identifie

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology	Reference to HL 7 FHIR
Dispensing	Supply of medications to a client responding to a medication order.	Use to record details about dispensing the prescribed medication		Resource MedicationDispense https://www.hl7.org/fhir/medicationdispense.html
Pharmacy ID	Unique identifier for the Pharmacy	Use to uniquely identify the pharmacy which dispenses the medication order/prescription	Integer/ String	Organization. Identifier
PHN- Personal Health Number	See above			
Prescription ID	Unique identification of the prescription against which the medications were prescribed	Use to uniquely identify the prescription against which the medications were prescribed	Integer/ String	MedicationDispense.authorizingPrescription

Prescription issued Healthcare Institution identifier (HIN)	Uniquely identify healthcare institutions which the prescription generated in the system	Use to identify the healthcare institution which the prescription generated. Published by the Ministry of Health HIN - Health Institution Number	String	Organization. Identifier
Dispensed Medication Name	Identifies the medication being administered	Use to record the name of the medication	String ATC	MedicationDispense.medication[x]
Dispensed Medication form	Describes the form of the item. e.g. Powder; tablets; capsules.	Use to record the form of the item.	String ATC	Medication.form
Quantity Dispensed	The amount of medication that has been dispensed. Includes unit of measure.	Use to record the amount of medication that has been dispensed. Includes unit of measure.	Value - Integer Unit - String	MedicationDispense.quantity
Date and time	The time the dispensed product was provided to the patient or their representative	Use to identify the time the dispensed product was provided to the patient or their representative	DateTime DDMMYYYY	MedicationDispense.whenHandedOver

The core data element	Concept Description	Use of the core information	Recommended Data type/ Terminology	Reference to HL 7 FHIR
Death data				
The immediate cause of death	The final disease, injury, or complication directly causing death		ICD 10	
Antecedent causes or underlying causes	The disease or injury that initiated the chain of events that led directly and inevitably to death		ICD 10	
Contributory causes	A significant condition that unfavorably influences the course of the morbid process and thus contributes to the fatal outcome, but which is not related to the disease or condition directly causing death		ICD 10	

Annexure-II: List of Related Official Documents

The is a list of legislations, regulations, policy documents, and guideline documents of Sri Lanka relevant to the use of ICT for Health Information.

Health Sector related

- Medical Ordinance

- Health Services Act, No 12 of 1952

- Declaration on Health, SLMA 1995

- National Health Policy

- Health Master plan 2007-2016

- Declaration on Health, Sri Lanka Medical Association 1995-96

- The National Policy on Health Information 2017

IT-related

- Information And Communication Technology Act, No. 27 of 2003

- Information And Communication Technology (Amendment) Act, No. 33 of 2008

- Electronic Transactions Act, No. 19 of 2006

- Policy and Procedures for ICT Usage in Government (e-Government Policy)

- Lanka Interoperability Framework (LIFe) ⬚ Treasury Circular IAI/2002/02

General (relevant to Health Information)

- National Archives Act, No 48 of 1973

- Intellectual Property Act, No. 36 of 2003

- Companies Act, No. 07 of 2007

- Financial Regulations of the Government of the Democratic Socialist Republic of Sri Lanka 1992

- Provincial Financial regulations

- Guidelines for procurement of pharmaceuticals & medical devices 2006 (National

  Procurement Agency)