

MINISTRY OF HEALTH

NATIOAL DIGITAL HEALTH GUIDLEINES AND STANDARDS [NDHGS]



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 Sri Lanka.

The new developments in the digital health ecosystem in the country and innovations in the ICT sector warranted reviewing the existing National eHealth Guidelines & Standards (NeGS). Recognizing this need the National eHealth Steering Committee appointed a Technical Working Group to review the NeGS (Technical working group on). 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 into their Disbursement Linked Results (DLR 5.1 Standards to support the robust development HMIS platforms and use of electronic HMIS at public health service providers, including with unique individual patient records.)

The revised National Digital Health Guidelines Standards maintains the major themes and the structure of the first version of the document. Following are the main changes done in this version of the NDHGS document:

- 1. Included new chapters on;
 - a. Chapter 3 Digital health software services
 - b. Chapter 8 Telemedicine
- 2. Added new sections and subsections 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. 7.6.4 Minimal data set for electronic health records
- 3. Changes were also done to the content of the other chapters based on the relevance, accuracy, and currency of the guidelines and the standards.

The document lays down standards and guidelines in the following seven areas which are important in the adoption of ICT.

- 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...
- Digital Health Software Services The chapter is on Management of digital health software, Electronic Medical Record Systems, National Electronic Health Record, and Personal Health Records
- 4. Network and Connectivity This emphasize the importance of having a proper network plan for individual healthcare institutions and maintaining them.
- 5. Communication Interface The emphasis on 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 office mode of communication.
- 6. Security, Confidentiality, and Privacy 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 this being ensured even during the adoption of ICT in the health sector is mentioned in this section.
- 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
- DICOM Digital Imaging and Communications in Medicine
- EIA Electronic Industries Association
- FERCSL Forum of Ethical Review Committee of Sri Lanka
- HIU Health Information Unit
- HL7 Health Level 7
- HL7-CDA Health Level 7 Clinical Document Architecture
- ICT Information Communication Technology
- ICTA Information Communication Technology Agency of Sri Lanka
- ICD International Classification of Disease
- ICPC-2
 International Classification of Primary Care Release 2
- IEEE Institute of Electrical and Electronics Engineers
- IPR Intellectual Property Rights
- ISO International Organisation of Standardization
- IHTSDO International Health Terminology Standards Development
 Organization
- LOINC Logical Observation Identifiers Names and Codes
- NPG National Procurement Guidelines

- P-LAN Private Local Area Network
- PHN Personal Health Number
- SNOMED-CT Systematized Nomenclature of Medicine--Clinical Terms
- SLCERT Sri Lanka Computer Emergency Readiness Team
- TEC Technical Evaluation Committee
- TIA Telecommunications Industries Association
- 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 care recipients.

Further, recent developments and innovations in ICT technologies also, and innovations 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 recognized the importance of the National eHealth Guidelines & Standards in the Disbursement Linked Result 5.1. "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."

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Following several discussions, and consultative meetings the initial draft of the National Digital Health Guidelines and Standards and forwarded to the World Bank experts to review it. Parallelly, the draft was also presented to a stakeholder group including academics, government ICT authorities, and the health authorities.

Finally, 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 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. Adherence to these guidelines and standards is a mandatory requirement in the software enlisting process of the Ministry of Health.

1. Architectural Model of the National Digital Health System



1.1. The Architectural Model

Figure 1: Architectural Model of the National eHealth 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.It is recommended that service agreement/s should 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 should 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, the Lanka Government Cloud or a facility maintained by 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 eHealth Software List maintained at the Health Information Unit (HIU) of the Ministry of Health. (Internal Circular No: 02-136/2015 Annexure I).
- 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 should 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 Health Care 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.

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 should 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
 - Milestones of the development process and percentage of payments (partial payments) to be made at reaching each milestone.
 - 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
 - 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 	
OPD	 Enter patient clinical details View past visit information Refer to a different clinic Request Laboratory tests View Laboratory test results Prescribe medicine 	
Laboratory	 View tests requests Accept samples for testing Enter test results Validate and authorized for release 	
Pharmacy	 View list of medicines requested 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 data set (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 on NEHR
- 3.4.5.It is recommended that PHR systems should comply with the National HL7 FHIR profile

4. Networking 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 the extraordinary situation the Sri Lanka Government Network (LGN) shall be used for networking 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 LGN
- 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-I87/2012**" (Annexure-II) 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-I87/2012" (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

'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.

6.1. Medical Ethics

6.1.1.Ensuring the privacy and confidentiality of care 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.eHealth 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 particular individual.
- 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 number which are;

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

Table 1: Components of t	e Personal Health Number
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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**.

- 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
- 7.1.9.Random alphanumeric string shall be a six-character alphanumeric string, generated randomly using a standard random string generation algorithm.
- 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 reding 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 positive identification of care recipients within the health system
- 7.2.4.Digital Health systems shall use the following data for positive identification of care 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
- 5. Telecommunication details
- 6. Prefixes (e.g.; Mr., Ms., Dr., Prof., Rev., Ven.)
- 7. Suffix (e.g.; Thero)
- 8. Date of Birth
- 9. Gender
- 10. Address
- 11. The person is active or not
- 12. Person's photo
- 13. 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 Data set for the Nationa Electronic Health Record (NEHR)

7.7.1.Each EMR System shall submit relevant data elements of following minimal data set to the NEHR for each clinical encounter between the client/ patient with the EMR system

	Concept description
Person data	Demographic data about a person such as birth data
Active	Whether this person's record is in active use
National Identity	National Identity card number/ SLIN/ National Digital Identity
PHN	Personal Health Number to identify healthcare recipients uniquely
Reporting name	Indicates The subject's name as it is to be used for reporting
DOB	The date of birth of a person/Date of the Birth of a Person as Registered
	with the RGD
Age	Details about the age of an individual (If DOB is uncertain)
Gender (The gender of an individual used for administrative purposes.)	Details about the gender of an individual
Address (a) Residential (b) Temporary accommodation	(a) Used to indicate where a person is living (b) such as for a person who usually resides overseas or where the provider of the address is in temporary accommodation due to renovation or treatment etc.
Grama Niladhari (GN)	Used to indicate GN division person belongs to where a person has
Division	voting rights
Divisional Secretariat	Used to indicate a person's GN division belongs to
Communication	Person communication details (Telephone number/ Mobile number/
Details	email address)

For each clinical encounter at an outpatient department/ specialist consultation and general practitioners consultation, following minimal data-set should be transmitted to the NEHR:

	Concept description
	Summary of the clinical details that occurred during a particular
Encounter details	encounter by the care recipient with a health institution/ healthcare
	provider
Encounter ID	Uniquely identify this encounter in the system
Health institution	Name of the health institution as per the health institution registry
HIN	HIN based on the provider registry published by the Ministry of Health
OPD/ Clinic	HIN extension of the OPD or the clinic
Clinic Name	Commonly used name of the clinic
Date and Time of encounter	To record the administrative Date and Time of the encounter
	The reason for the initiation of any healthcare encounter or contact by
Reason for encounter	the individual who is the subject of care. This should be coded using
	ICPC2 or SNOMED CT
Working Diagnosis/	Final discharge diagnosis or probable diagnosis. Multiple diagnoses
Diagnoses	should be allowed. Shall be coded usingICPC2 or SNOMED CT
Past Medical History	Names of the diagnosed diseases in the past, coded using SNOMED CT
	and the duration of each illness should be recorded
Past surgical History	Names of the surgical procedures performed in the past. Coded using
	SNOMED CT with the date of the procedure
Immunization	Details of immunization received. Only for children
Allorgios	Known allergies as reported by the patient (substance, reaction,
Allergies	severity, and status should be recorded)
Adverse events	Any adverse events occluded during the encounter (Date & time,
Auverse events	adverse event and outcome should be recorded)
Examination findings	Positive significant physical examination findings of this encounter
Risk factors	Details about smoking status, use of alcohol, use of narcotics, and
	tobacco, etc.
CVD Risk category	CVD risk category as determined using WHO criteria.

Provider ID	Uniquely identify the Consultant in-charge of the ward/ unit (Refer
FIONICELID	provider registry)
Laboratory Tests	Details about laboratory tests performed during this admission
Date and time	To record the Date and Time relevant to laboratory test
	Uniquely identify the laboratory which received the request and has
Lab ID	overall responsibility to manage reporting of the test, even if other labs
	perform specific aspects.
Test Name	Name of the laboratory investigation performed on the specimen(s).
rest name	This should be coded using LOINC codes
Tost Posult	The result, including findings and the laboratory's interpretation, of an
Test Result	investigation, performed on specimens collected from an individual
Test authorized	Uniquely identify the person performing the test authorization
Provider ID	oniquely identity the person performing the test autionzation
Radiology	Details about the radiological investigations/ procedures performed
Radiology department	Name of the particular radiology department/ unit. This may be
name	"institution name.radiology unit"
HIN	Extension of the HIN identifying this radiology unit/ department
Test ID	Unique ID of the test performed
Radiology test	Name of the radiology test that was performed. LOINC codes should be
performed	used to code this
Result	Interpretation/ report of the test
Provider ID	Healthcare worker performing/ reporting the test
Date and Time	Date and Time of the test
Procedures	Details about procedures performed
Provider ID	Unique identification of the provider performing the procedure
Procedure name	Name of the procedure coded using SNOMED CT
Operative note	Detailed operative note
Outcome	The outcome of the procedure
Date and Time	Date and the time of the procedure
Details of treatment	Details of drugs administered during admission
Drug administered	Name, code, dose, frequency, route of administration and the duration
	administered
Prescription	Details about drugs prescribed on discharge
Prescription ID	Unique identification generated for this prescription

Drug	Name, dose and the form of the drug e.g. Azithromycin 250 MG Oral Capsule
Duration	The time duration for which the drug is prescribed
Date and time	Record the time and the date when the medication item was intended to be administered
Provider ID	Uniquely identify the person formally authorized to issue from the pharmacy
Dispensing	Details about dispensing the prescribed medication
Pharmacy ID	Unique identifier for the Pharmacy
Prescription ID	Unique identification of the prescription against which the medications were prescribed
Date and time	Date and time of dispensing

For each admission following minimal data set should be transmitted to the NEHR on discharge:

	Concept description
Discharge Summary	Summary of the clinical details that occurred during a particular
Discharge Summary	admission to a particular health institution
Encounter ID	Uniquely identify this encounter in the system
Health institution	Name of the health institution as per the health institution registry
HIN	HIN based on the provider registry published by the Ministry of Health
Admission ward ID	HIN extension of the ward
Admission ward name	Commonly used name of the ward
Date and Time of	To record the administrative Date and Time of the encounter
admission	
	The reason for the initiation of any healthcare encounter or contact by
Reason for admission	the individual who is the subject of care. This should be coded using
	SNOMED CT
Discharge Diagnosis/	Final discharge diagnosis or probable diagnosis. Multiple diagnoses
Diagnoses	should be allowed. Shall be coded using the ICD-10 classification
Past Medical History	Names of the diagnosed diseases in the past, coded using SNOMED CT
	and the duration of each illness should be recorded

Dact curraical History	Names of the surgical procedures performed in the past. Coded using
Past surgical history	SNOMED CT with the date of the procedure
Immunization	Details of immunization received. Only for children
Allorgios	Known allergies as reported by the patient (substance, reaction,
Allergies	severity, and status should be recorded)
Adverse events	Any adverse events occluded during the admission (Date & time,
Auverse events	adverse event and outcome should be recorded)
Examination findings	Positive significant physical examination findings of this admission
Risk factors	Details about smoking status, use of alcohol, use of narcotics, and
Misk factors	tobacco, etc.
CVD Risk category	CVD risk category as determined using WHO criteria.
Provider ID	Uniquely identify the Consultant in-charge of the ward/ unit (Refer
	provider registry)
Laboratory Tests	Details about laboratory tests performed during this admission
Date and time	To record the Date and Time relevant to laboratory test
	Uniquely identify the laboratory which received the request and has
Lab ID	overall responsibility to manage reporting of the test, even if other labs
	perform specific aspects.
Test Name	Name of the laboratory investigation performed on the specimen(s).
rest Name	This should be coded using LOINC codes
Test Result	The result, including findings and the laboratory's interpretation, of an
Test Result	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual
Test Result Test authorized	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual
Test Result Test authorized Provider ID	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization
Test Result Test authorized Provider ID Radiology	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed
Test Result Test authorized Provider ID Radiology Radiology department	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be
Test Result Test authorized Provider ID Radiology Radiology department name	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit"
Test Result Test authorized Provider U Radiology CRadiology Cepartment name HIN	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department
Test Result Test authorized Provider I Radiology Radiology department name HIN Test ID	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department Unique ID of the test performed
Test Result Test Result authorized Provider ID Radiology Radiology Iname HIN Test ID Radiology test Radiology test	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department Unique ID of the test performed Name of the radiology test that was performed. LOINC codes should be
Test Result Test authorized Provider Radiology Radiology HIN Test ID Radiology test performed	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department Unique ID of the test performed Name of the radiology test that was performed. LOINC codes should be used to code this
Test ResultTest authorizedProvider IDRadiologyRadiologyRadiologyHINTest IDRadiologytest IDRadiologytest IDRadiologyRadiologyRadiologyRadiologyResult	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department Unique ID of the test performed Name of the radiology test that was performed. LOINC codes should be used to code this Interpretation/ report of the test
Test ResultTest authorizedProvider IDRadiologyRadiologyRadiologyHINTest IDRadiologyRadiologytest IDRadiologyResultProvider ID	The result, including findings and the laboratory's interpretation, of an investigation, performed on specimens collected from an individual Uniquely identify the person performing the test authorization Details about the radiological investigations/ procedures performed Name of the particular radiology department/ unit. This may be "institution name.radiology unit" Extension of the HIN identifying this radiology unit/ department Unique ID of the test performed Name of the radiology test that was performed. LOINC codes should be used to code this Interpretation/ report of the test Healthcare worker performing/ reporting the test

Procedures	Details about procedures performed
Provider ID	Unique identification of the provider performing the procedure
Procedure name	Name of the procedure coded using SNOMED CT
Operative note	Detailed operative note
Outcome	The outcome of the procedure
Date and Time	Date and the time of the procedure
Details of treatment	Details of drugs administered during admission
Drug administered	Name, code, dose, frequency, route of administration and the duration
	administered
Prescription	Details about drugs prescribed on discharge
Prescription ID	Unique identification generated for this prescription
Drug	Name, dose and the form of the drug
	e.g. Azithromycin 250 MG Oral Capsule
Duration	The time duration for which the drug is prescribed
Date and time	Record the time and the date when the medication item was intended
	to be administered
Provider ID	Uniquely identify the person formally authorized to issue from the
	pharmacy
Dispensing	Details about dispensing the prescribed medication
Pharmacy ID	Unique identifier for the Pharmacy
Prescription ID	Unique identification of the prescription against which the medications
	were prescribed
Date and time	Date and time of dispensing

Mh

Glossary

- Health Information Unit under the Director Health Information of the Ministry of Unit Health
- Care recipient: A person presenting to a health care institution or a health care provider seeking healthcare
- Ministry of Ministry of Health, Department of Health Services of Sri Health
 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 Any institute, division, or unit in Sri Lanka providing or sector 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 thatprovide the instructions for telling a computer what to do and how to do it.

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

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) 2 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)