Executive Summary

The National eHealth Guidelines and Standards (NeGS) of Sri Lanka is aimed at streamlining the implementation of eHealth solutions in the health sector of Sri Lanka. This document lays down a set of Guidelines and Standards to be adopted when implementing eHealth solutions in the State and Private healthcare institutions in Sri Lanka. The document is drafted within the framework of the "eHealth Policy of Sri Lanka" as this is the overall policy document governing the adoption of ICT in the whole state sector of Sri Lanka.

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

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

2. ICT Governance – This section handles the procurement, deployment, development, maintenance and decommissioning of ICT systems including Hardware and Software.

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

4. 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.

5. 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.

6. Data Communication Standards – This is a set of technical standards (Semantic and Syntactic) to be adopted in the eHealth solutions to ensure seamless data exchange between eHealth solutions.

Some of these guidelines are already in use in the form of informal practice or as internal circulars (Which are attached), but this document also brings all of them together in one place and in a proper sequential manner.

Since Information Communication Technology is ever-evolving, the NeGS too will be reviewed periodically and necessary amendments made if necessary.

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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 has achieved high standards in healthcare when compared to countries with the same level of economic development. This is evident when one compares the traditional health indicators with the Gross National Product (GNP). This can be attributed to the free healthcare policy in the state health sector and the importance successive governments have given to the development of healthcare in the country. But the challenges that the health system is facing are changing. We must adopt the healthcare system in order to face these new challenges.

The National Health Development Plan (NHDP) 2013-2017 is one such initiative undertaken by the Ministry of Health. Healthcare is an information intense field, *relevant*, *accurate* and *timely* information is the key to evidence-based management in healthcare. Even though many aspects of healthcare in Sri Lanka have changed, the information flow has largely remained manual and paper-based in both the curative and preventive sectors. The paper-based record system is inadequate to meet the needs of rapidly evolving present-day health care system especially for the preventive aspect of health. The need to adopt an efficient information management system has been stressed in the National Health Development Plan.

Even though there are no large scale eHealth projects implemented in Sri Lanka so far, some healthcare institutions have piloted or adopted eHealth solutions on their own initiative. It is highly commendable that these institutions have done so on their own initiative. At the same time, it must also be pointed out that these systems have been developed in an ad hoc manner without central coordination.

The *National eHealth Guidelines and Standards for Sri Lanka* aims to achieve uniformity in the eHealth solutions implemented in Sri Lanka while ensuring quality care and rights of the care recipients.

1. Architectural Model of the National Digital Health System

1.1. The Architectural Model

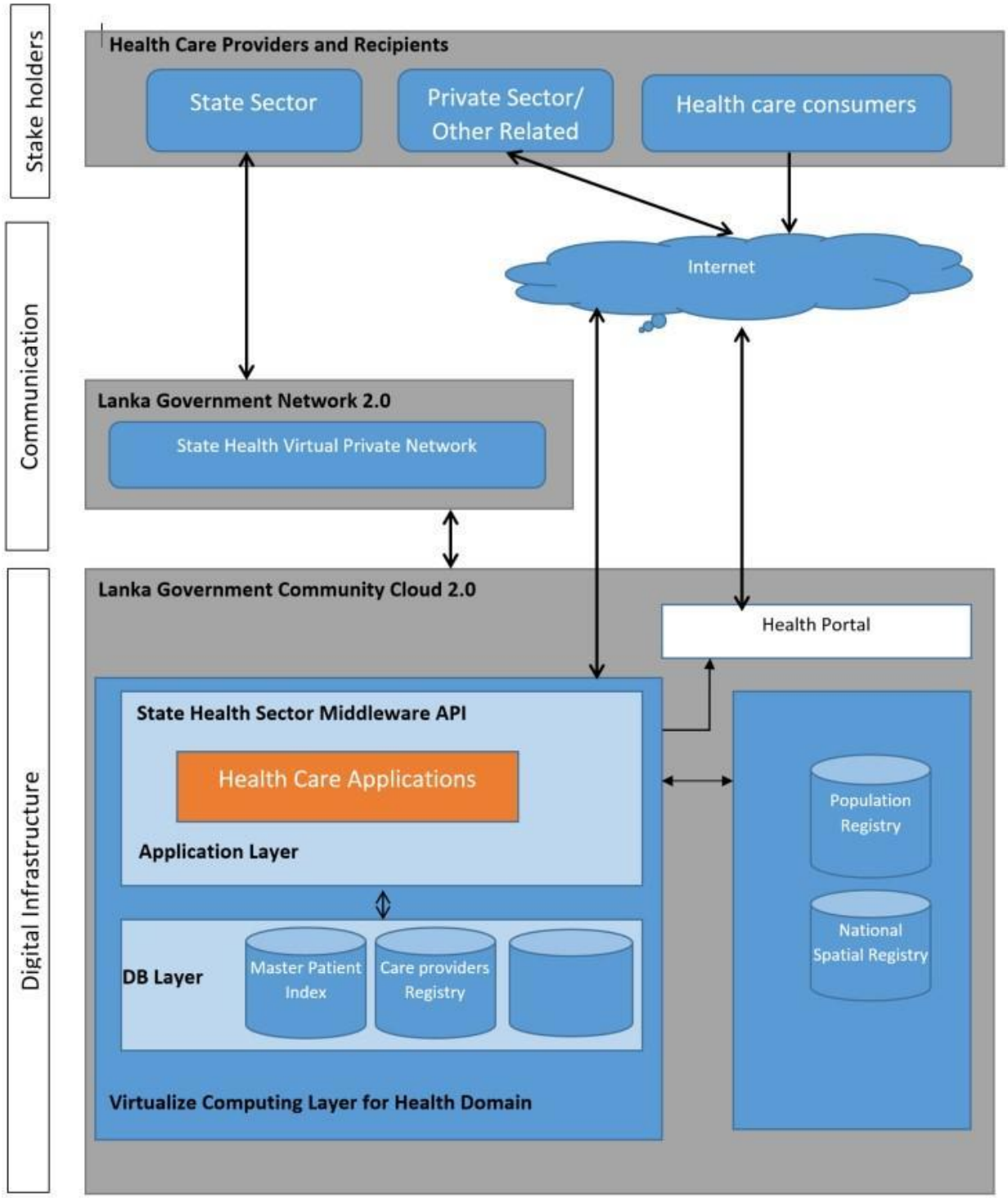

Figure 1: Architectural Model of the National eHealth Information System

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)and the eGovernment Policy should be followed when purchasing computer hardware ["Procurement Guidelines 2019: GOODS, Works, Services and Information Systems"].

2.1.2. Any such procurement procedure should 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 workstation and/or software compatible with the equipment is 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 that is not covered under warranty conditions.

2.1.8. Service agreement/s for maintenance of equipment should be reached as per the relevant guidelines [Procurement Guidelines 2019: GOODS, Works, Services and Information Systems].

2.1.9. Except in extraordinary situations, that is mutually agreed by the Ministry of Health and the ICTA, the Lanka Government Community Cloud 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 eHealth systems that are developed, tested, piloted or implemented in all State Sector Healthcare Institutions should be listed in the eHealth Software List maintained at the Health Information Unit (HIU) of the Ministry of Health as per **Internal Circular No: 02-136/2015**(Annexure I)**.**

3.1.2. State Healthcare Sector Software shall be aligned with Sri Lanka government National Interoperability Standards unless specified in this document (see section 6)

3.1.3. Government healthcare organizations should 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 should clearly define the license.

3.1.4. If donated, vendor locking should be prevented. Cost-benefit should be evaluated by an independent group appointed by the MoH

3.1.5. Acquisition of software including software donated free of charge should 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.

3.1.7. When acquiring software solutions built in-house or as donations, the IPR must be co-owned by the developer and the relevant institution.

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

3.1.9. 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.

3.1.10. Prior to the piloting or implementation of a software solution, a security audit must be performed by the Sri Lanka Computer Emergency Readiness Team Coordination Center (SLCERT).

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 licences.

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

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
- Laboratory module
- Radiology Information system module
- Billing module (for relevant instances)

It is recommended the above modules are loosely coupled and communicate through Application Programming Interfaces (API)

3.2.2. All EMRs shall use the PHN published by the Ministry of Health to uniquely identify patients/ Clients in the system

3.2.3. All EMRs shall use the Health Institution Number published by the Ministry of Health to uniquely identify healthcare institutions in the system

3.2.4. All EMRs should be able to seamlessly communicate (through API) with the eIMMR

3.2.5. EMR should communicate with the relevant systems such as HR, Stock management, etc.

3.2.6. EMR should provide decision support dashboards for the hospital administrators

3.2.7. All EMRs shall comply with the national information security standards as published by SLCERT (Activity log)

3.2.8. All EMRs shall comply with all relevant regulations including, but not limited to the following:

3.2.9. All EMR systems shall communicate with the National/ Cluster MPIs

3.2.10. It is recommended that EMR systems should comply with the HL7 FHIR release 4

3.3. National Electronic Health Record (NEHR)

3.3.1. Ministry of Health should develop and implement National EHR

3.3.2. The NEHR shall provide facilities for all EMRs to communicate with it

3.3.3. NEHR shall comply with the HL7 FHIR release 4

3.4. Personal Health Record (PHR)

3.4.1. All PHRs shall use the PHN published by the Ministry of Health to uniquely identify patients/ clients in the system

3.4.2. All PHRs shall use the Health Institution Number published by the Ministry of Health to uniquely identify patients/ Clients in the system

3.4.3. All PHRs may provide dashboards to support personal health monitoring

3.4.4. All PHRs shall comply with the national information security standards as published by SLCERT

3.4.5. All PHRs shall comply with the relevant sections of the list of relevant documents mentioned in this guideline

3.4.6. All PHRs systems shall communicate with the NEHR

3.4.7. It is recommended that PHR systems should comply with the HL7 FHIR release 4

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, mutually agreed by the Ministry of Health and ICTA, the Sri Lanka Government Network shall be used for networking all institutions in the health domain with VPN.

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 health VPN of the Sri Lanka Government Network.

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 should 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 should 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 must comply with the Guidelines for Development and Maintenance of Websites of Government Organizations set by the ICTA.

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

6.1. Medical Ethics

6.1.1. Ensuring the privacy and confidentiality of care recipient is a fundamental Ethical concept in Medical Practice and should be paramount in all eHealth solutions.

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

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. Further, the institution may use such information for scientific, research or statistical purposes. 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 should 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. It is the duty of Healthcare Institutions to 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 appeal for 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 should 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 SLCERT should be strictly followed.

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

6.3.4. A no-deletion approach should be adopted in relation to clinical data.

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

6.3.6. Institutions should ensure the physical security of all ICT hardware and relevant Documentations.

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

6.3.8. 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 (destroy or deactivate) them appropriately.

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

6.3.10. 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.

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

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

6.3.13. Information systems security audits should be performed annually.

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

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

7. Digital Health Systems Interoperability Standards

7.1. Personal Health Number

7.1.1. Computerized systems in 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 will be issued to the patient upon his 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;

Table 1: Components of the Personal Health Number

Point of Issue number	Serial Number	Check Digit
XXXX (4 digit alpha numeric number)	XXX XXX (6 digit numeric)	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.

7.1.7. Point of Issue (POI) number: The Health Information Unit (HIU) of the Ministry of Health will be the issuing authority to assign a number for the point of issue, which is the "*Point ofIssue*" number. State and private healthcare institutions shall obtain the POI number from the HIU.

7.1.8. Serial Number – will be a 6 digit serially generated number.

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

7.2. Master Patient Index (MPI)

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

7.2.2. Any 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. Such systems shall share the following data of "Persons" with the MPI (Please refer the HL7 FHIR Resource "Person" https://www.hl7.org/fhir/person.html) :

1. Citizen Identification Number/ National Identity Card Number (NIC)/ Sri Lanka Identification Number
2. Personal Health Number (PHN)
3. Surname
4. Initial/ given name
5. Mobile phone number
6. Prefixes (e.g.; Mr., Ms., Dr., Prof., Rev., Ven.)
7. Suffix (e.g.; Thero)
8. Date of Birth

9. Gender
10. Address
11. Person is active or not
12. Person's photo
13. Marital status

7.2.4. Health information systems shall take adequate measures to ensure the accuracy of the data provided

7.2.5. Health information systems may deploy the connection with the MPI actively or passively.

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.

7.4. Healthcare Provider Registry

7.4.1. The Ministry of Health will maintain a Healthcare Provider registry based on the relevant professional registration authorities (e.g. Sri Lanka Medical Council, Sri Lanka Nursing Council).

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 adopt FHIR standards (i.e. the Composition Resource, and DocumentReference resource), as the data standard for clinical documentation and exchange of clinical documents.

7.5.3. For aggregated data exchange - ADX (Aggregated Data Exchange) Standards should be used.

7.5.4. For interchange of Laboratory data it is recommended to use Logical Observation Identifiers Names and Codes (LOINC) developed by Regenstrief InstituteInc.

7.5.5. For transfer and storage of images between software programs in the medical domain Digital Imaging and Communication in Medicine (DICOM)standard of the National Electrical Manufacturers Association, USA and VendorNeutral Archiving (VNA) should be used.

7.6. Standardized Clinical Vocabulary

7.6.1. For the purpose of coding clinical data, 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. For the purpose of statistical reporting of health-related data it is recommended to use ICD 10 (International Classification Disease) or the latest version of the World Health Organisation (WHO).

7.6.3. For the purpose of recording of patient data and clinical activity (such as patient's reason for encounter (RFE), the problems/diagnosis and interventions) in the domains of

General/Family Practice and primary care, it is recommended to use International Classification of Primary Care, Second edition (ICPC-2) ICPC-2

7.6.4.Minimal Data set for electronic health records

Essential components	Minimum functionality	Minimum data set
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	HIN PHN First Name Last Name DOB Gender Clinic/OPD Name Clinic/OPD Number Date and Time of the encounter
OPD	1. Enter patient clinical details 2. View past visit information 3. Refer to different clinic 4. Request Laboratory tests 5. View Laboratory test results 6. Prescribe medicine	Presenting complaint diagnosis Action taken Provider ID If test requested, Name of the test If drugs were prescribed Name of the drug
Laboratory	1. View tests requests 2. Accept samples for testing 3. Enter test results 4. Validate and authorized for release	PHN Encounter ID HIN Lab ID Sample ID Sample type Test Name Test Result Date and time Test authorized Provider ID
Pharmacy	1. View list of medicines requested 2. accept or reject dispatch of medicine	PHN Encounter ID

		HIN Pharmacy ID Prescription ID Name of the drugs Amount issued Date and time Provider ID

Glossary

- Health Information Unit : Unit under the Director – Health Information of the Ministry of Health.

- Ministry of Health : Ministry of Health, Department of Health Services of Sri Lanka which is currently amalgamated merged with each other 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.

List of Related Official Documents

The is a list of legislations, regulations, policy documents and guideline documents of Sri Lanka relevant to 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) · 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)