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| Ministry of Health |
| National eHealth Guidelines and Standards |
| [NeGS] |
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# 1. The Architectural Model of the National eHealth information System

## 1.1 Architectural model

1. The National eHealth Information System architecture consist of

Stakeholders connected through a communication network to the eHealth services

1. Categories of stakeholders identified in the national eHealth information

system are as follows (Figure 02).

* + - Health service providers (State and Private)
    - Health service consumers
    - Allied Services (e.g registrar General Dept)

1. Communication layer will consist of a dedicated State Health Network,

Internet and the Mobile.

1. All eHealth services handling Personally Identifiable Data should only be

connected through the State Health Network (SHN). It is recommended to connect through a secure VPN until such time a State Health Network is established.

1. eHealth services will closely follow the Health Service domain categories

listed below

* + - Curative Health Services (CHS)
    - Public Health Services(PHS)
    - Health Supportive Services (HSS)
    - Administrative Services (AS)

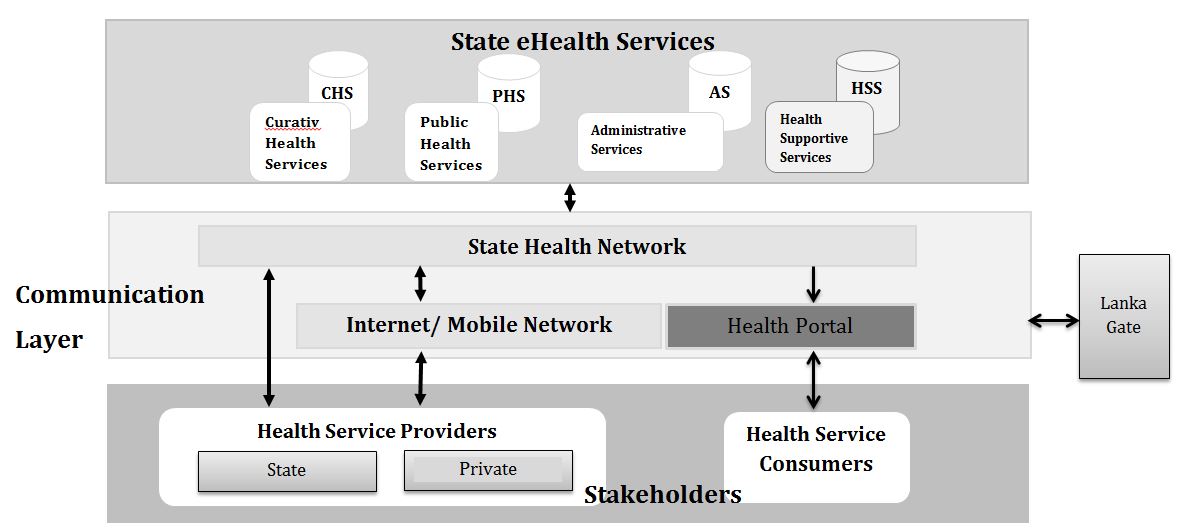


Figure 1.The detail architectural model of the National Electronic Health Information System

# 2. Management of Computer Hardware and software for eHealth Services

## 2.1. Computer Hardware

1. The current applicable National Procurement Guidelines should be followed

when purchasing computer hardware. “*Procurement Guidelines of 2006 for*

*Goods and Work by National Procurement Agency*”

1. Any such procurement procedure should essentially be accompanied with

appropriate maintenance and service agreements.

1. While ensuring the minimum requirement of the composition of a TEC, an

expert on Health Informatics shall be included whenever possible.

Procurement of electronic medical equipment should be accompanied by a

compatible necessary workstation and / or software, where applicable

1. When procuring ICT hardware, it is recommended that the cost of

consumables and maintenance are considered.

1. A hardware inventory must be maintained at institutional level with detailed

specifications of any hardware following the treasury guidelines of Sri Lanka.

“Treasury Circular IAI/2002/02”

1. It is recommended that service agreement/s should be reached for

maintenance of equipment that are not covered under warranty conditions.

1. Service agreement/s for maintenance of equipment should be reached as a

service following relevant guidelines. “Procurement Guidelines of 2006 for

Goods and Work by National Procurement Agency

## 2.2. Software

1. **State Healthcare Sector eHealth Software list:**All eHealth systems that are

developed, tested, piloted or implemented in all State sector Healthcare

Institutions should be enlisted in the eHealth software List maintained at the

HIU of MoH.

1. **Piloting of software systems:**Decision to implement a software system or

component(s) of software shall be done after a piloting, and shall be done at

selected institutions/units followed by a proper evaluation. If pilot involves a

third party, the evaluation may be done independent of the third party.

1. ***Acquisition of software*** Government healthcare organizations should only

use appropriate licensed software. Such licensing is applicable for both

proprietary as well as free and open source software.

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

always be accompanied by contractual agreements with relevant parties for

developing, customizing or piloting of software.

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

always be accompanied by an appropriate software maintenance agreement

1. When a software is Built From Scratch, the total ownership of the intellectual

property rights of such software should be transferred to the healthcare

organization/ Ministry of Health.

1. When accruing Built from Scratch or Customized software solutions where

third party components have been used, appropriate licenses for such

components should also be provided along with the software

1. Agreements/contracts should cover important issues including the

following:

* + - Software Requirement Specifications
    - Source code availability
    - If the software is a unique solution meant for the healthcare institution
      * Milestones of 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
    - Software documentation including installation and user manual
    - Provision for modifications and updates to the software
    - Declaration of the developer/s stating that the software complies with existing legislations (of the country).
    - Handling of critical and non-critical failures.
    - Clauses handling dispute situations. This should include preventing remotely disabling features.
    - Third party licences

1. Clauses which are detrimental to the acquiring entity similar to but not

limited to the following should not be included in the agreement/ contracts:

* + - Clauses preventing smooth transition of the healthcare institution to a different software from another vendor in future (i.e. Vender Lock)
    - Broad exculpatory clauses which limits or exclude vendor’s liability
    - 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 PDoHS to MoH)

# 3. Network and Connectivity

## 3.1. Network Architecture

1. It is recommended to follow the latest and/or widely accepted versions on networking (including mobile devices) and cabling standards by IEEE (Institute of Electrical and Electronics Engineers), ISO (International Organization for Standardization), EIA (Electronic Industries Alliance) and TIA (Telecommunications Industry Association)
2. All institutions under the Ministry of Health and the provincial departments of health should be able to exchange health related data through a dedicated State Health Network when available.
3. Health Institutions are recommended to maintain their own Private Local Area Network (P-LAN) interconnecting all the devices within the institution.
4. Open network protocols are recommended to ensure freedom of hardware selection.
5. Wired communication is preferred over wireless communication.

## 3.2. Network Management

1. Whenever planning new buildings for healthcare institutions, it should be designed to support the network infrastructure.
2. Physical topology, physical cable layout and upgrades, access methods, protocols, communication devices, operating systems, applications, and configurations should be adequately documented.

# 4. Communication Interface

## 4.1. Websites of the state healthcare sector

1. Contents to be available in Sinhala, Tamil and English for documents relevant

to the public.

1. Any complaints or concerns on healthcare related content in a web site may

be submitted to Health Information Unit of the Ministry of Health.

1. Websites created must comply with the “Guidelines for Development of

Websites for Government Organizations Guidelines for Development and

maintenance of Websites of Government Organizations” set by the ICTA

## 4.2. Domains names for State Healthcare Sector Institutions

1. Line Ministry Institutions and Institutions under the Provincial Department

should contact the HIU of the MoH with regard to obtaining the official

domain address.

1. The domain names under “healh.gov.lk” and

“healthdept.<prov\_code>.gov.lk” will be allocated according to “**General**

**Circular Letter No. 02-lB7/2012**” and owned by the Ministry of Health

and the relevant Provincial Ministry of Health.

1. Domain names that include health related generic words under the .lk

domain should obtain a clearance from the Ministry of Health. This includes

English generic words and Sinhala or Tamil Generic words in native script or

transliterated to Latin script.

## 4.3 Email

1. Email addresses should be assigned in accordance with the “**General**

**Circular Letter No. 02-lB7/2012**”

1. Email accounts on the organization’s domain shall be used for official

purposes only.

1. All official electronic communications should only be carried out using the

official Email address under the organization’s domain.

1. All email should follow the proper channel of communication as per existing

guidelines and norms of paper based document communication.

1. Paper based archiving regulations should also be applied to all email

communications.

1. The relevant officer shall ensure that his/her email account is checked for and

responded according to the guidelines applicable to postal mail.

# 5. Privacy, Confidentiality, Security and Medical Ethics

## 5.1 Medical Ethics

1. Ensuring privacy and confidentiality of care recipient is a fundamental Ethical

concept in Medical Practice and should be considered in eHealth solutions.

1. eHealth systems that handle personally identifiable data of patients, clients

or general public for research purposes should get ethical approval from an

accepted ethics review committee coming under the *Forum for Ethics Review*

*Committees in Sri Lanka* (FERCSL).

## 5.2 Privacy and Confidentiality

1. Ensure confidentiality of personally identifiable data and information at all

stages of HIS cycle

1. Personally identifiable data and information shall be used only for the

intended purpose of collecting the data. If such data is to be used for any

other purpose, a proper de-identification procedure shall be followed.

Annexure - Manjula

1. Unless the disclosure is enforced by law, personally identifiable information

should not be disclosed without informed written consent of the individual

concerned for other than the intended purpose.

1. Employees’ access to healthcare related information should be strictly on a

*need to know* basis and such access should be revoked when the job role

changes or terminates.

1. Role based access control profiles should be clearly defined and documented.
2. It is the duty of the Healthcare institutions to ensure information of an

individual is accessible only by employee/s who have signed an information

confidentiality agreement (Non-Disclosure Agreement).

1. Healthcare institutions shall ensure that employees who left the organization

are bound to maintain the confidentiality of information which belongs to

the institution.

1. Healthcare institutions shall ensure that third party personnel involved with

health information systems including maintenance should sign non-

disclosure agreement.

1. An individual has the right to appeal for amendments of personal

information in an event of any discrepancy.

## 5.3. Security

1. Electronic documents should be maintained following the existing guidelines

governing the paper based document and the prevailing legislation in the

country.

1. eHealth 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.

1. A No-Deletion approach should be adopted in relation to Clinical Data.
2. During decommissioning of a system removal of data should be done using

media sanitation tools. ????? Or the Storage devices should be removed and

physically destroyed.

1. Institutions should ensure security of all ICT hardware and relevant

documentations.

1. 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 changes or terminates.

1. 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.

1. Maintenance of internal or external data storage devices should be

performed on-site whenever possible and it should only be done by

authorized personnel.

1. Computerised eHealth systems shall be designed with an events (security) log

that allows tracing of successful and failed Log-in attempts.

1. Personally Identifiable and Login Data must be encrypted using the

appropriate algorithm.

1. Institutions shall ensure an appropriate procedure is followed for secure

backup of data.

1. Institutions should make sure that the retrievability of backed up

data/information is regularly checked to ensure reliability of the backup

process.

1. Information systems security audit must be performed at least twice a year.
2. Systems should be promoted to enforce the usage of strong passwords [A

strong password should contain at least 8 characters, consisting of at least

one uppercase character, one numeric character and one special character]

or implement a two-step verification.

# 6. eHealth Systems Interoperability standards

## 6.1 Personal Health Number

1. Computerised systems in the State healthcare sector shall use the Personal

Health Number (PHN) and healthcare recipients are linked to their

appropriate health record.

1. PHN is a unique number assigned to a particular individual.
2. 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.

1. 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 anonymity of the individual is requested.

1. There are three components to the number which are;

|  |  |  |
| --- | --- | --- |
| Point of Issue number | Serial Number | Check Digit |
| XXXX  (4 digit alpha numeric number) | XXX XXX   1. digit numeric ) | C |

1. 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.

1. “Point of Issue” number – Health Information Unit (HIU) of the Ministry of

Health will be issuing authority to assign a number for the point of issue,

which is the “*Point of Issue*” number.

1. Serial Number – will be a 6 digit serially generated number
2. Check Digit – shall be generated using the modified Luhn Algorithm used by

Regenstrief Institute Inc.

## 6.2 Healthcare Institution Registry

1. A registry of the healthcare institutions is maintained at the Health

Information Unit of the Ministry of Health and should be referred when

necessary.

1. The registry will hold a unique identification number for the Institution and

another relevant attributes.

## 6.3 Healthcare Provider Registry

1. The Sri Lanka Medical Council maintains a registry of the medical

practitioners (Category code to be decided)

## 6.4 Data Interchange Standards

1. It is recommended to adopt Version 3.0 of the Health Level Standard (HL 7,

Version 3.0) by *Health Level Seven International* as the data exchange

standard in the healthcare domain.

1. For the purpose of clinical Document Recording it is recommended to use

HL7-CDA release 2.

1. For interchange of Laboratory data it is recommended to use Logical

Observation Identifiers Names and codes (LOINC) by Regenstrief Institute

Inc.

1. For transferring images between software programs in the medical domain

DICOM (Digital Imaging and Communication in Medicine) standard by

*National Electrical Manufacturers Association, USA* shall be used.

## 6.5 Standardized Clinical Vocabulary

1. For the purpose of coding clinical data, it is recommended to use SNOMED CT

(Systematized Nomenclature of Medicine – Clinical Terms) by *International*

*Health Terminology Standards Development Organisation* (IHTSDO).

1. For the purpose of statistical reporting of health related data it is

recommended to use ICD 10 (International Classification Disease) by WHO.

1. Applications that record data in SNOMED CT should be able to cross map

their data into ICD 10 for the purpose of reporting