SESSION – 7

Proposals on
Electronic Data Standards for the Health Sector of Sri Lanka

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Purpose of the Study
The study aims to understand different data standards that are available. Then each of these standards will be evaluated for their accuracy, efficiency, reliability, usability, dependability, availability and cost. Factors like, how many countries around the world have implemented these standards? What are the countries that have implemented these standards? And the quality of healthcare in these countries which have implemented these standards will be taken into consideration during the evaluation. The study will also identify unique features of Sri Lankan healthcare system compared to other healthcare systems in the world. Taking the above said factors into consideration the study aims to propose the most appropriate data standards that are suitable for eHealth solutions in Sri Lanka.

General Objective
To develop, platform-independent data standards that enable information systems interoperability in the Sri Lankan health sector.

Specific Objectives
1. To identify the need for data standards.
2. To propose data interchange standards for eHealth systems in Sri Lanka.
3. To propose clinical vocabulary standards for eHealth systems in Sri Lanka.
4. To propose a unique healthcare identifier system for Sri Lanka.

Learning Objectives
1. To learn about interoperability.
2. To learn about different Standard Development Organizations (SDO).
3. To study the e-Government policy of Sri Lanka.
4. To study the Lanka Interoperability Framework (LIFe) of Sri Lanka.
5. To Study different data exchange standards that are available.
6. To study different clinical vocabulary standards that are available.
7. To study different patient identifier systems used around the world.
8. To learn about writing a thesis.

Scope of the thesis
The scope of the study will cover data standards regarding electronic data exchange, clinical terminology, and healthcare identifier.

Electronic Data Standards for the Health Sector of Sri Lanka

- Clinical Data Interchange standards
- Standardized Clinical Vocabulary
- Unique Healthcare Identifier

The three main sections addressed in the thesis are all important aspects of electronic data standards to achieve true interoperability within the eHealth solutions.
eHealth solutions reviewed in Sri Lanka

<table>
<thead>
<tr>
<th>eHealth Solution</th>
<th>Institute</th>
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<tr>
<td>Patient information system</td>
<td>Chest clinic Colombo</td>
</tr>
<tr>
<td>eFilm</td>
<td>Chest Clinic Colombo</td>
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<tr>
<td>eMMR</td>
<td>Base Hospital Panadura</td>
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<tr>
<td>Blood bank system</td>
<td>Provincial Hospital Kurunegala</td>
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<tr>
<td>Hospital Management System</td>
<td>Provincial Hospital Kurunegala</td>
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<tr>
<td>Vidusuwa</td>
<td>Base Hospital Maravila</td>
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<td>District Hospital Dankotuwa</td>
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<td>Patient information system</td>
<td>Teaching Hospital Peradeniya</td>
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<tr>
<td>Multi disease surveillance system</td>
<td>District General Hospital Trincomalee</td>
</tr>
<tr>
<td>Hospital management system</td>
<td>Teaching Hospital Anuradhapura</td>
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The study was performed by interviewing the head of the institutions, head of departments and the officers in charge of the eHealth system. The questionnaire for this (Appendix A - Analysis of existing electronic information systems used in curative sector health institutes) was prepared using the WHO’s Basic Operational Framework on eHealth for Healthcare Delivery (BOF-eHCH) (10) as a guide. This was interview driven questionnaire, where the interviewer would explain the question and at most of the time expect —yes‖ or —no‖ answer.

2.3 Arriving to Conclusions
Conclusions were derived on the analysis of data gathered from various sources, using the following as a guide where relevant.

1. Availability of the standard.
2. Friendly nature of the standard.
5. Vendor acceptance of the standard.
7. Popularity of the standard.
8. How long is the standard in use?
9. Is the standard proprietary or is it an open standard?
10. Safety of implementation.
11. Protection of patient privacy.
12. Does the standard comply with e-Government policy?
13. Does the standard comply with LIFe?
14. Is the standard adoptable to the current healthcare system of Sri Lanka?
Clinical Data Interchange Standards / Messaging Standards

Being able to interchange data within the eHealth systems in Sri Lanka is a crucial aspect of interoperability. Many different comprehensive ICT solutions have been introduced to the vast variety of healthcare providing institutions, but the problem has been the exchange of information between them.

There are many definitions for the word interoperability, Integration and Interoperability Steering committee of the Healthcare Information Management System Society (HIMSS) defines interoperability as. "Interoperability means the ability of health information systems to work together with and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities".

There are two main concepts of interoperability,

1. Syntax – provides a format on how the data should be exchanged, it does not care or know about what is being exchanged.
2. Semantics – This ensures that the systems understand the data that is being exchanged.

This chapter of the thesis focuses on the first concept which is the Data Exchange/Messaging Standards.

Literature review
The literature review was focused on understanding the concept of data exchange standard and reviewing some of the widely used data exchange standards.

Need for Data Exchange Standards
If we take a case scenario where in a hospital the Laboratory Information system (LIS) was first installed which was followed by a system for the Intensive Care Unit (ICU) after some years. Now if we want these two different applications to exchange information between them, both of them must have a common understanding of the data that they exchange. This could be achieved by developing an integration/interface engine which will work alongside both the application and tell them what type of data they are receiving or sending. The integration engine on the sending side would add tags to the data regarding the format in which it’s sending it, for example the first set is name of the patient, and second set is the age and so on. This would be understood by the integration engine on the receiving side and translated for the application to understands it.
Different vendors can use different standards or even their own proprietary standards to define these data exchange formats. This becomes even complicated when more and more solutions are introduced. This will lead to different interface engines being developed and they will also be using different data exchange standards.

Having a common data exchange standard in place will prevent this, by letting applications being developed to send and receive data in a uniform format between them. This will allow us to add new systems with ease.
Once the need for a common data exchange standard was realized many Standard Developing Organizations (SDOs) started to develop Data Exchange Standards.

**Commonly Used Data Exchange Standards**
Data exchange/messaging standards mean the format on how data should be transferred from one system to another. This standard does not know what is being transferred, but instead specifies a format on how the data should be transferred between systems. The table below gives a list of such standards developing organizations together with their standards.

**Summary of Key Standards and their Developer Organizations**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Acronym</th>
<th>Description</th>
<th>Developer</th>
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<tbody>
<tr>
<td>Health Level Seven Messaging Standards Version 2 and Version 3</td>
<td>HL7 V2.X and V3</td>
<td>Electronic message formats for clinical, financial and administrative data. V2 is common in commercially available software. V3 was launched in 2005</td>
<td>Health Level Seven</td>
</tr>
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</table>
The remaining part of this chapter briefly describe the above mentioned clinical data exchange standards developing organizations, together with the standards that they produce.

**Health Level 7 (HL7)**

HL7 (14) is a volunteer based SDO with members in more than 55 countries. The organization chooses to have the name HL7 to reflect the seventh layer (application layer) of the Open Systems Interconnect (OSI) model. The organization was initially focused on producing data exchange standards, but now they also produce other standards which are listed below.

Conceptual standards – Reference Information Model (HL7 RIM)
Application Standard – Clinical Context Object Workgroup (HL7 CCOW)
Document standard - Clinical Document Architecture (HL7 CDA)

HL7’s main focus is the administrative and clinical aspects of the healthcare domain. Their data exchange standards are HL7 version 2 and HL7 version 3, these two are the most widely data exchange standards in the world (15). The standard is now in continuous use and development for more than 20 years (15). The first version of the standard was released in 1987, but the real acceptance came with the release of HL7 2.0 in 1988 (7). Version 2.2 released in 1996 was approved by the American National Standards Institute (ANSI) and became the first national health care data interchange standard in the United States of America (USA) (7). Even though the standard document looks very big, its principles are quite easy to grasp (15). Structure of a HL7 V2 message is shown below.
Realising importance of having a standard encoding – decoding software would help increase the interoperability HL7 released their Extensible Markup Language (XML) encoding syntax as the HL7 V2.xml. This made their messages web enabled.

HL7 v2 was widely accepted due to its flexibility, but at the same time it also provided larger optionality. This allowed to perform similar tasks in many different ways, vendors had to spend time figuring out the options used by each systems while designing the interface. To overcome such issues HL7 produced a newer version, which was HL7 Version 3 (HL7 V3). HL7 V3 is designed to be comprehensive in scope, complete in detail, extensible as requirements change, up-to-date and model-based, conformance testable, and technology-independent. The noticeable fact is that they claim it to be comprehensive in scope and technology independent. The version 3 supports object oriented message creation. Different version of the HL7 V2 can be interoperable or adjusted to be interoperable (HL7 V2.4 and V2.5), but in the case of HL7 V3 it cannot be achieved. The HL7 V3 messages are sent using XML tags. Following is a sample HL7 V3 message.
Figure 6 Portion of aHL7 V3 message
Source - Principles of Health Interoperability HL7 and SNOMED by Benson T

**Digital Imaging and Communication in Medicine (DICOM)**

In the recent years more and more hospitals in Sri Lanka have started to use digital imaging, like the Ultra Sound Scan (USS), digital x-rays, Computed Tomography (CT), Magnetic Resonance Imaging (MRI) and Coronary Computed Tomography Angiogram (Coronary CTA). Investigative procedures like Coronary Angiogram and therapeutic procedures such as the laparoscopic appendicectomy are being recorded as digital videos.

There are numerous advantages to both the patients and doctors in using digital images or videos. On the patients’ side, it’s easier for the patient to carry a Compact Disc (CD) or a flash drive, rather than having to large files with x-rays, and CT scans. On the physicians side there are numerous advantages, like the ability to post process the image, which includes changing the contrast, brightness and being able to zoom in to a specific region which cannot be done with a hard copy. The image could be transferred to another physician for a second or specialised opinion, they could be easily stored for educational and research purposes.

Due to a variety in methods used to store and transfer images by different vendors, Our patients still have to carry the hard copy. This is what prompted the American College of Radiologist (ACR) together with the National Electronic Manufactures Association (NEMA) of USA came up with a standard for digital image transferring in healthcare in 1983 (7). Their version 3 of the standard was called DICOM (16). Initially it was a point-to-point transmission standard, but the current standard is in par with the OSI model kept by ISO and the Picture Archiving and Communication Systems (PACS). DICOM is the most commonly used standard for interchanging radiological images, and now the scope of the standard is expanding to non-radiological images too (17). The standard supports transfer of images over point-to-point and network environment (7). The standard has now even adopted to transfer clinical information regarding the image.
Clinical Data Interchange Standards Consortium (CDISC)

Sharing clinical research data prevents persons or organizations from duplication researches. This also allows valuable contents to be reused, and in turn improves innovation. Clinical research data is being acquired and archived in many different formats over various systems. Since this issue was not addressed by other clinical data exchange standards, CDISC was formed to create data exchange standards for this purpose.

CDISC (18) is a non-profit oriented organization, which was formed in 1997. CDISC produces a variety of standards to standardize the process of clinical research, some such standards are Study Data Tabulation Model (SDTM), Clinical Data Acquisition Standards Harmonization (CDASH), Terminology standards, Operational Data Model (ODM), and etc (18).

Their data exchange standard is called the Operational Data Model (ODM) (19). CDISC-ODM is an open standard that is freely available, the standard provides the format for meta data and data exchange in clinical research. The current version of the standard is CDISC-ODM version 1.3.1. This is an XML schema based standard. This standard is mainly used by many biomedical and pharmaceutical companies. The standard is widely used in the field of clinical research in USA, Europe and Japan. Below is portion of a CDISC-ODM message syntax.

![Figure 7: Portion of a CDISC-ODM syntax](source: CDISC-ODM v1.3.1)
**National Council for Prescription Drug Programs (NCPDP)**

This is also a non-profit oriented ANSI accredited SDO, who are involved in developing standards for interchange of data between pharmacy services. NCPDP was formed in 1977, since then they have produced various standards in regard to the pharmaceutical industry in the USA. They have more than 1500 members from various sectors of the pharmaceutical industry. Their Data Exchange Standard is called the SCRIPT. Current version of SCRIPT is version 10. SCRIPT is the messaging standard used for interchange of prescription and related information between doctors, pharmacies and payers in the USA. This is an open standard but not available free of cost. Currently there is a standard correlation project between SCRIPT standard 4.2 and above with HL7 v2.3 till 2.6 to facilitate e-prescribing.

**Accredited Standards Committee X12 (ASC)**

ASC is also an ANSI accredited SDO. Their main focus is to create standards interchange for business purposes in the USA. ASC has been producing standards for this purpose more than 20 years. Their data exchange standard was called X12 often referred to as ASC X12. This standard was a benchmark in e-Commerce. In the health domain X12 is being used widely in USA for the purpose data interchange in transactions in health insurance claims. The X12 standards define commonly used business transactions in a formal, structured manner called the transaction sets. The standards deals with areas such as healthcare eligibility benefit, healthcare claim status request, healthcare services review, etc.

**Discussion**

To achieve syntactic interoperability we need to have a common understanding about the Data Exchange Format among future eHealth solutions in Sri Lanka. The standards described above are different from each other in various aspects. Standards like HL7 V3 and CDISC-ODM are quite broader in scope compared to DICOM, ASC X12 or SCRIPT. eHealth in Sri Lanka is still in its very initial stages and it would better to start off with a standard that is broader in scope.

The purpose these standards serve also are quite different. While HL7 V3 is being used mainly in clinical practice the DICOM standard is used in the Radiological aspect of clinical medicine. CDISC-ODM is being used mainly for the purpose of collecting and interchanging data regarding clinical trials, SCRIPT would be the standard of choice for prescriptions. ASC X12 is more suitable to an insurance based healthcare system, where reimbursement claims are processed. Majority of the inpatient care in Sri Lanka is provided by the state health sector, which provides care free of charge. This has been a reason for the health sector in Sri Lanka not being insurance based, and need therefore a standard like ASC X12 wouldn’t be much of a use in Sri Lanka. The corporation between HL7 and NCPDP to enable ePrescription in HL7 v2.x will allow us to use HL7 for the purpose of ePrescription too, avoiding the need for a separate standard for this. There are not many biomedical and pharmaceutical companies in Sri Lanka doing clinical research, this is mainly carried out by the academic institutions such as the universities. CDISC-ODM can play a role in clinical research in Sri Lanka too. This would increase the efficiency of research done by the universities.
Almost all the standards have been in use for more than 20 years, except CDISC-ODM which is relatively new. The fact that most of these standards have been in use for more than two decades gives us confidence about their maintainability. They have been constantly upgraded to the evolving needs of the healthcare sector. The standards have also kept pace with rapidly changing nature of ICT. The adoption of XML schema in HL7 v2.xml, SCRIPT and CDISC-ODM are examples of this.

HL7 v2 and v3, DICOM stay above the rest of the standards when compared to international acceptance. CDISC-ODM, X12 and SCRIPT are mainly used in the USA and some parts of Europe. The fact that India and Pakistan are also members of HL7 shows the regional awareness about HL7 (14). DICOM has now become such a common standard to the level of being a basic requirement when purchasing imaging systems in healthcare (17). When standards are widely accepted, more and more vendors become familiar with them. This would lead to more applications in the market with these common standards. Sri Lanka should also opt for a standard that is widely used in the world. When going for common standards the choice of vendors becomes more, this would give us a variety of choice in not only choosing the vendor but also the application. At times when we are unable to find local vendors to solve our problem, having widely used standards in place will allow us to go for a foreign vendor with ease. Going for foreign vendors must only be the case when we can’t find a local solution provider. Standards that are widely used also become easier to get trained on. The best example would be the CISCO networking standards which are so widely used that the training is provided in almost all ICT education centers in Sri Lanka.

The fact that all of the above mentioned standards are open standards and not proprietary to a certain commercial organization, gives us the confidence that these standards would not fade off. Very often, proprietary standards have become defunct when the relevant organization closes due to a takeover or bankruptcy. On the other hand since open standards are maintained by many volunteers around the world, these standards would no doubt last longer. Section 010404 of the e-Government policy (9) states that, “It is recommended that government organizations use solutions that meet the characteristics of open standards”. This would also prompt the health sector of Sri Lanka mainly the state healthcare organizations to adopt open standards whenever possible.

The Lanka Interoperability Framework (LIFe) which is the data architecture and data standards document of the e-Government policy stresses that XML format should be used to transfer data between government organizations. The fact that HL7 v2, v3 and CDISC-ODM are using XML for data encoding and decoding gives them an advantage over the other standards to be used in Sri Lanka.
Standardized Clinical Vocabulary

This chapter will focus on the second concept of interoperability mentioned in chapter 3, which is the semantic interoperability.

Literature Review

Need for Vocabulary Standards in Healthcare IT

Chapter 3 emphasized the need for having standard formats on how data should be transferred between systems, this would give them an understanding about the nature of the data they are interchanging, but they wouldn’t know the meaning of the particular data they are interchanging. For example, the a XML tag called `<diagnosis>` will tell the system that the data its transferring is the diagnosis of a patient, but it does not know what that particular diagnosis means. In the field of medicine we often write the same disease in many ways. Consider an example of two different patients with a common cold seen by two different doctors. Doctors may input the diagnosis as common cold or acute coryza, which can be coded in the following ways.

  - `<diagnosis>Common Cold</diagnosis>`
  - `<diagnosis>Acute Coryza</diagnosis>`

In the above example the system will store the data in the database under diagnosis, because it knows that both of them are diagnosis of a disease as specified by the XML tag `<diagnosis>`. What the system does not know is that they are both diagnosis of the same disease. In the future if someone would search the database using the word `Common Cold` the second patient’s detail would be ignored. This emphasizes the need to have a common terminology standard.

This becomes more important where clinical decision support systems are in place, here the systems must understand the data they interchange. When Mr. Mark Horowitz was elected as the chairman of the International Health Terminology Standards Development Organization (IHTSDO), he mentioned the following ‘I recognize the critical role that semantic interoperability plays in improving patient care worldwide. Clinical IT must adopt a standardized nomenclature to facilitate improved data exchange, patient safety, clinical decision support and analytics’ (23).

Terminology standards will bring uniformity our EHRs used in the eHealth systems. This will further prevent developers going through the hassle of having to create sets of terminologies every time they develop software (7) (reinventing the wheel). Imagine a hospital with a centralized database where data comes from many sources, having a unified terminology prevents miscommunication between them (7).

Commonly Used Vocabulary Standards in Healthcare IT

Some of the widely used clinical terminology standards are described in brief.

**International Classification of Disease (ICD)**

This was initially created in the 1850s for the purpose of uniformly identifying the cause of death in healthcare. Initiated and maintained by the International Statistical Institute until 1948, thereafter WHO took over the responsibility of maintaining it from the Sixth
revision. The WHO Nomenclature Regulation adopted by 20th World Health Assembly in 1967, made it mandatory for the member states to use the current version of ICD to report mortality and morbidity statistics (24). WHO sponsored training was given to medical officers and coders on ICD including Sri Lanka. Sri Lanka has also accepted this regulation and uses ICD for reporting morbidity and mortality data. ICD is the most widely used coding terminology standard in the world (7). The current 10th revision (ICD 10) is the one used in Sri Lanka for collecting data regarding morbidity and mortality.

Since ICD mainly serves the purpose of collecting information regarding morbidity and mortality, it focuses mainly on the diagnosis part of a medical record. This is actually a summary of the whole events that took place during the process of giving care to a patient (Abstraction). For instance if a patient was diagnosed and treated for Myocardial Infarction and later discharged after 10 days with further plan. ICD 10 would mainly address the diagnosis part, which is Myocardial Infarction. Other information in medical record like complains during admission, past medical history, the examination findings, investigative findings, treatments given, etc are neglected by the ICD. Therefore ICD only helped in interchanging abstract information of an EHR in a unified manner, and not the whole information.

With the use of EHRs increasing, and ICD only helping us to interchange abstract information, new terminology standards started to emerge. These standards focused on the whole clinical information represented in an EHR (Representation). Some of the widely used such terminology standards are describes in the remaining part of the chapter. It must be noted that the ICD is a freely available open standard.

This terminology standard was created by the American Medical Association (AMA) in 1966. It was primarily meant to code diagnostic and therapeutic procedures, but later this was adopted by the USA government for billing and reimbursement purpose (7). Since USA has an insurance based healthcare system there is a lot of claims to be processed, and there is a need for those claims to be reported in a rather common manner. For example the same procedure cannot be described in two different ways, which will complicate the claim process. The standard is limited in scope and depth (7). This is the most widely used standards in the USA to report physician procedures and services for insurance reimbursement.

**Read Clinical Codes**
This was developed by James Read for coding electronic medical records in general practice. Version 01 of the code was accepted and adopted by the National Health system (NHS) of UK in 1990 (7). Read codes soon became widely used in UK (25), but the hospitals had to report morbidity and mortality data in ICD format. This lead to the release of version 2, which helped cross map data from Read codes to ICD.

With time the 4 digit code became insufficient and a 5 digit code was introduced in version 3, which was called the Clinical Terms Version (CCV3) (25). CCTV3 is claimed to be effective in electronic transaction of data regarding patient records, public health and medical administration (26). The code is widely in use among the primary care providers (26) in UK. This version of the code was taken over by the NHS and now
maintained by them. Vendors who want to use the code have to sign a licensing agreement with the NHS (26).

The next version was a merger with the Systematized Nomenclature of Medicine SNOMED) and the SNOMED-Clinical Terms was founded (SNOMED-CT). Which will be discussed next.

**Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT)**

Systematized Nomenclature of Medicine (SNOMED) was the successor of Standard Nomenclature of Pathology (SNOP) which was widely used to exchange data regarding pathological findings (7). SNOMED was first released in 1974, and released several versions after that. In 1999 College of American Pathologist (CAP) and NHS decided to merge SNOMED and Read Terminology to form the SNOMED CT. This standard is now being maintained by IHTSDO and by the relevant institutions in their countries. The first version of SNOMED CT after the merger was released in 2002 (15). SNOMED CT is declared as a comprehensive and scientifically validated in content (27) by the NHS of UK, which means it covers most areas of clinical information including disease, diagnosis, procedures and treatment. This standard is currently being used in more than 55 countries (27). Singapore is the first Asian country to adopt of SNOMED CT into their EHRs (28), they have made the standard freely available for the vendors to make use of in Singapore.

**Logical Observation, Identifiers, Names and Codes (LOINC)**

This was created to record data regarding laboratory tests and observations, therefore having the name Laboratory Observations, Identifiers, Names and Codes (LOINC) (7). Now the system also includes non laboratory data like vital signs too. The standard is maintained by Regenstrief Institute, Inc. (29) USA. The standard is freely available for developers (29).

**Other Standards**

There are many other terminology standards in the medical domain, which focuses in specific areas of medicine and are therefore not widely used (7), the following are some examples.

- Diagnostic and Statistical Manual of Mental Disorders
- Medical Subject Headings (MeSH) – Terminology for indexing medical literature.

- Drug Codes – WHO Drug Dictionary (7).
Recommendations
The following is the recommended data exchange, clinical vocabulary and healthcare identifier standards for the *eHealth Standards and Guidelines* document of Sri Lanka.

Data interchange/Messaging Standard

- Clinical use - HL 7 version 3
- Radiological Images - DICOM

Vocabulary standard

- Clinical purpose - SNOMED CT
- Statistical purpose - ICD 10

Statistical purpose - ICD 10
The above mentioned standards must be freely available for vendors producing eHealth solutions in Sri Lanka. There must also be legislative support to ensure use of set national eHealth standards.

Healthcare Identifier Number (HIN)
HIN will consist of 14 digit unique identifier. The first 8 digits will be the date the number was issued, and the last 6 digits will be the serial number on that particular issue date. This number is for healthcare purposes only. This number will be issued to the patient upon his first contact with the Sri Lankan health system and can be continued during his/her whole life. The number will not any of his personal details and therefore it cannot be queried using his personal details. The record can be retrieved using the HIN with ease.

If the number is lost past records can be retrieved using an artificial intelligence system, which will ask questions related to patients’ previous healthcare events such as.

- e.g. When was your last admission to hospital?
- Which hospital were you last admitted to?
- What was the cause of last admission?

Limitations of the Study

Standards related to *data ownership, data storage* and *data life cycle* have not been addressed here, as to they do not directly affect the interoperability of eHealth systems.

Comprehensive data architecture for the healthcare sector of Sri Lanka is also necessary. HIN addressed in this thesis is only a part of it. LIFe (37) document addresses this issue quite comprehensively and this document should be reviewed and customized to the need of healthcare domain in Sri Lanka.

Future studies have to be done in regard to the facts mentioned above.