A Patient Clinical Record Module for Current Electronic Tuberculosis Information Management System: An Action Research

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August - 2018

Declaration:

I declare that this dissertation does not incorporate, without acknowledgment, any material previously submitted for a Degree or a Diploma in any University and to the best of my knowledge and belief, it does not contain any material previously published or written by another person or myself except where due reference is made in the text. I also hereby give consent for my dissertation, if accepted, to be made available for photocopying and for interlibrary loans, and for the title and summary to be made available to outside organization.

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Abstract

Introduction: Tuberculosis despite being a treatable condition, remains a major public health burden in Sri Lanka. National Tuberculosis Program oversee the curative and preventive services for tuberculosis patients. Care for the tuberculosis patients are provided by the District Chest Clinic. All patient information are recorded in a paper based patient file system at chest clinics. A comprehensive electronic repository of individual patient based data that would also help in clinical management of the patient have been needed for the national program.

Objective: This study is aimed to identify the requirements and perceptions of stakeholders involved in diagnosis and clinical management of tuberculosis patients to design a comprehensive patient clinical record module to capture individual case records and reporting.

Methodology and Data analysis: This research was designed as an Action Research. In-depth interviews with supportive documentary evidences were used for data gathering. It was conducted in two phases. In the first phase major stakeholders in the provision of care to tuberculosis patients were identified and was interviewed to identify the user requirements. In second phase a prototype of the proposed system was developed and was evaluated with the intended users of the system. Evaluation was also carried out in terms of in-depth interviews. Data analysis was done using a modified version of thematic analysis.

Results: Nine major stakeholders from chest clinic and central level participated in the study. Data obtained from the first phase interviews revealed four major themes that described extensively about the work processes involving the stakeholders, Users and their role, challenges and constraints faced in managing patients, and user expectations in the proposed system. A prototype was developed according to user needs and the evaluation with the intended users in overall was a positive feedback with some concerns being expressed in terms of implementation and sustainable use. Many future improvements were suggested by the users.

Conclusions: User centered design approach is beneficial in many aspects in designing an electronic patient clinical record for individual patients that also addresses different information needs of all major stakeholders in following up of patients with chronic illnesses. It would improve the quality of patient care provided through health programs.

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Abbreviations

AIDS; Acquired Immune Deficiency Syndrome
DCC: District Chest Clinic
DHIS 2: District Health Information System 2
DTCO: District Tuberculosis Control Officer
EHR: Electronic Health Record
ePIMS: electronic Patient Information Management System
EPTB- Extra Pulmonary Tuberculosis
FOSS: Free and Open Source Software
GFATM: Global Fund to Fight AIDS,Tuberculosis,and Malaria
HISSL: Health Informatics Society of Sri Lanka
HIV; Human Immunodeficiency Virus
ICT: Information Communication Technology
MDG: Millennium Development Goals
MDR; Multi Drug Resistant
MLT: Medical Laboratory Technician
MOH : Medical Officer of Health
NIC : National Identity Card
NPTCCD: National Programme for Tuberculosis Control and Chest Diseases
NTP: National Tuberculosis Program
PGIM: Post Graduate Institute of Medicine
RDCP: Respiratory Disease Control Program
SDG: Sustainable Development Goals
TB; Tuberculosis
UCD: User Centered Design
UN:United Nations
USD : United States Dollars
WHO; World Health Organization
WRD: WHO approved Rapid Diagnostic Tests

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1. Rationale

TB has remained an urgent public health threat and one of the leading causes of death throughout the world for centuries, especially in lower and middle income countries such as Sri Lanka[1]. It is ranked along with HIV as a leading cause of death by infective causes in the world. TB disease has remained to be such a devastating disease even though the disease is curable unlike HIV/AIDS. Number of global and national efforts at cost of considerable resources have been put to action with the leadership of WHO. Despite these efforts, TB remains to contribute significantly to morbidity and mortality in many parts of the world especially in the most resource limited parts of the world.

The challenges in TB control can be broadly divided in to five categories, which include Inadequacies in patient notification, Inadequacies in patient diagnosis, inadequacies in treatment, Need for expansion of DOTS strategy of WHO in to being more accessible, MDR-TB, and HIV co-infection[2]. The diagnostic methods and treatment traditionally used in TB has been around for many years. With the emergence of smear negative TB, MDR-TB, and HIV Coinfection these diagnostic methods and treatment have proved to be inefficient and newer methods of diagnosis and treatment have been introduced. The outlook of TB management is undergoing changes. Another aspect is that the need for National Tuberculosis Programs (NTP) to work closely with other health agencies and control programs both locally and internationally such as the AIDS & STD control programs, Health Ministries, Other Ministries, Non-governmental organizations, Private sector, and Donor agencies. The need for information exchange is a necessity in carrying out an efficient treatment and control programs for TB and especially in understanding the true public health picture with regard to TB Control and treatment, MDR-TB and HIV coinfection. It is necessary to have accurate and timely data when it comes to program planning, execution, resource allocation, and assessment.

In the Sri Lankan context, provision of diagnosis and treatment is performed by the District Chest Clinics spread across the island. The patient health records and other information is kept in Paper based file format. The reporting to the central level of NTP is by way of paper based registries and returns.

Rapid progresses made in the field of Information Technology in an increasing amount of successful attempts at introducing Information and Communication Technology in Patient clinical record keeping has made the deficiencies of these paper based forms much more apparent. The paper based files containing patient information are usually housed in the DCC and only available at its location, which creates a physical barrier on information and communication. Paper based documents can be illegible and incomplete. Data in these documents can be acquired redundantly. There are variations among individuals and among different clinics in documentation. There is also a high human resource and space requirement for the routing, archiving, and maintenance of paper based patient clinical records. It is evident that the paper based management and poor practices around it leads to poor data quality and poor information communication between the health staff leading to suboptimal care to TB patients. It is safe to say that the conventional paper based recording system maintained by the NPTCCD in its DCC structure is rapidly reaching its limits.

The primary purpose of adopting an electronic patient clinical record for the TB information system is to support efficient, high quality integrated health care, independent of the place and time of TB care. It can culminate in a process of care for TB patients that is safe and sound. It results in efficient communication, better co-ordination, and be more responsive to patient's needs.

Aggregated data such as case findings, sputum conversion, laboratory investigation and treatment outcome, from DCCS are compiled and communicated to the central NPTCCD and the provincial authorities. This is done in form of monthly and quarterly reports. Individual case based data, even though collected at each DCC is not currently communicated to higher levels and aggregated reports are prepared manually using this information.

In 2014, NPTCCD commissions an electronic Patient Information System based on DHIS 2 platform in which all routine aggregated data reporting is automated. It provides a web based open source information system that is stored in the centralized server at NPTCCD. Data entry is carried out by data entry operators at chest clinics using computers connected to the Internet. Validation rules are created for data entry operators and data is entered after the approval of DTCO. There is only a limited amount of information on individual cases reported through the system.

With proper planning and implementation, a comprehensive electronic clinical record of a patient could be integrated in to the ePIMS. An electronic patient clinical record would facilitate to identify important clinical data that would be helpful in identifying disease patterns, trends and facilitate to assess the management and follow guidelines and benefits in many other aspects which have been pointed out earlier.

This study was aimed at to learn and understand the requirements of health care workers who are associated with TB management in such an electronic patient clinical record and how best it would serve the purposes of the NTP.

2. Introduction

2.1. Tuberculosis: Overview

Tuberculosis or TB is an ancient scourge which have plagued humankind throughout the history and claimed many lives earning the name "Captain among these men of death". It has surged in great epidemics especially in European Continent and Northern America in 18th and 19th century [3]. After a while then it had begun to decline. Pathogenesis of Pulmonary and extra-pulmonary tuberculosis was elaborated with the work of The'ophile Laennec, at the beginning of the 19th century [4]. In 1882 Robert Koch successfully isolated the causative agent for tuberculosis and proved the mode of transmission [5].

2.1.1. Causative Agent and Pathology

Tuberculosis is caused by four main mycobacterial species, namely *Mycobacterium tuberculosis*, *Mycobacterium bovis*, *Mycobacterium africanum*, *Mycobacterium microti.* These are non-motile and non-spore forming obligate aerobes and facultative intracellular pathogens usually affecting the mononuclear phagocytes. It is an airborne infection spread via respiratory droplets. Even though inhalation of a minimal number of bacteria need to be inhaled for infection to develop, but fulminant disease is not evident in all whom are infected. The outcome of the exposure is determined upon many factors, with individual's immunity being the most important [6]. In some individuals, M.tuberculosis replicate in alveolar macrophages for several weeks [7]. While continuing multiplication in macrophages it is then carried in to the regional lymph nodes and can spread hematogenously to other sites, such as – Lung apices, vertebrae, liver, spleen, meninges, genitourinary tract and peritoneum. In majority of patients the pathogenesis halts and are said to be 'tuberculosis infected', however some patients progress to tuberculosis disease [8]. Any condition that depresses the cell mediated immunity increases the risk of tuberculosis 'infection' developing in to the 'disease' [9].

Adults whom are otherwise healthy infected with M.tuberculosis have a 5%-10% chance of progressing in to the disease status that being within the first 1- 2 years of infection. Infected and untreated Infants and toddlers have a 40%-50% chance in progression to disease status within 6-9 months from exposure[10].The following figure 2.1 illustrates the possible consequences in an TB infection.

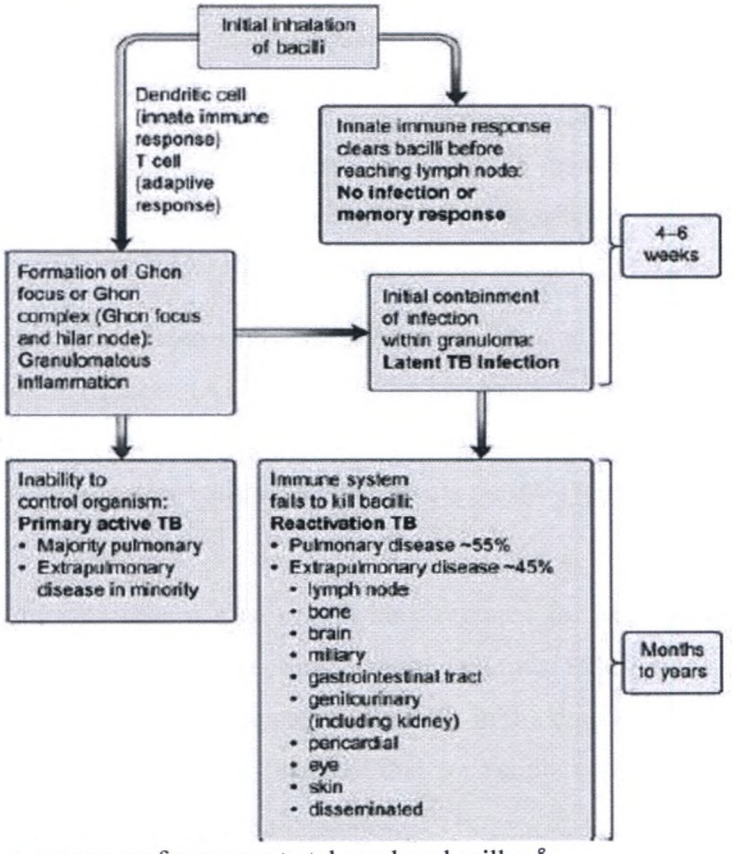

Figure 2-1: The Consequences of exposure to tuberculous bacillus [8]

2.1.2. Diagnosis and Management

Traditionally the diagnosis of tuberculosis is mainly by sputum smear microscopy. The other accepted and important diagnostic investigations for TB are rapid molecular assays and culture based methods. World Health Organization (WHO) in 2010 and again in 2013,

recommends Xpert MTB/ RIF assay (Cepheid, Sunnyvale, CA, USA) for diagnosis of TB disease in adults and children, and also to test resistance to Rifampicin [11].

Xpert MTB/RIF is more accurate relative to Smear microscopy, which can also be conducted safely and accurately, resulting in faster diagnosis, and starting of treatment the same day, making the time between diagnosis and initiation of treatment shorter [12]. Culture based methods are the reference standard in diagnosis of tuberculosis, however it takes a considerable time for the results to be issued by the laboratory.

Radiological investigations such as chest x-rays are one of the main diagnostic methods, mostly as a screening test. Non-molecular technologies such as Interferon- γ assays for latent tuberculosis are also endorsed by WHO for diagnosis of tuberculosis [6].

Uncomplicated TB patients are treated with a globally accepted short course chemotherapy. Anti-tuberculosis treatment regimen (ATT) of four fist line drugs – Isoniazid, Rifampicin, Ethambutol and Pyrazinamide are used for treatment of uncomplicated TB. For people with Rifampicin-resistance and multi drug resistance tuberculosis the drug regimen is much longer and require more potent drugs.

Since of 2016, WHO recommends a nine month long regimen for MDR-TB patients. It consists of seven types of drugs. Drug susceptibility testing is a must for all of the TB patients as it is beneficial in knowing the resistance pattern early on in the diagnosis [13]. WHO also outlines two high risk groups considering treatment that are People with HIV infection and children under age of 5 years with a household contact of TB.

2.2. Global Situation

2.2.1. Tuberculosis burden and Death rates

The burden of tuberculosis is expressed in terms of Incidence, Prevalence, and Mortality. The Incidence can be defined as the number of new and relapsed cases of TB in a given period of time, usually a year, while Prevalence can be defined as the Number of TB cases at any given point and serves as a community snapshot of the epidemic. Mortality is defined as the number of deaths caused by tuberculosis in a period of one year [14].

2.2.2. Tuberculosis Incidence

Incidence of a disease determination involves long term studies involving large cohorts which at times are expensive and difficult to conduct. Therefore notification of TB cases can be taken as a good 'stand-in' for TB incidence in countries with universal health care and unrestricted access to such facilities and with high performance surveillance systems in place [15].

The number of TB incident cases reported in the world in 2016 was 10.4 million (in the range of 8.8million – 12.2 million). The incidence rate is about 140 cases per 100,000 population globally [15]. According to WHO, South East Asian region accounts for 45%, African region for 25%, and the Western Pacific region for 17% of the total number of TB incidence worldwide. The 30 highest burned countries account for 87% of total cases in 2016 while the top five countries- i.e. -India, Indonesia, China, Philippines and Pakistan – account for about 56% of the incident cases. In 2016, it was estimated that the TB incidence was estimated to be about 10% among people living with HIV [15].

Consistent with previous global TB reports, the 2017 report states that the number of TB incident cases are following a decreasing trend. It was reported that in 2016 the rate of decline of TB incident cases were 1.9%, while it was 1.4% for the period of 2000-2016[15].

Deaths among active TB patients whom are HIV negative is defined as TB deaths in the recent version of international classification of Diseases-10(ICD-10), while in case of a Death of a HIV positive patient due to TB, the underlying cause is classified as HIV[16].

2.2.3. Tuberculosis Mortality

TB is the ninth leading cause of death worldwide from 2012-2016, and has also been the leading cause of death from a single infectious agent placing it above HIV/AIDS. An estimated 1.3 million deaths occurred globally attributable to TB (HIV negative) and an additional 374,000 (range, 325000–427000) deaths occurred from TB among the HIV positive individuals. The mortality rate globally is 17 (16-19) per 100,000 of population as per year 2016[17], and 22 when TB deaths in HIV positive people were included. South East Asian region and African region accounted for about 82% of total deaths due to TB in 2016. India

shares about 33% of global TB mortality among HIV negative and 26% of total deaths when the HIV positives are included [15].

Considerable variation in mortality rates are observed around the world. The mortality rates reach to 40 or more per 100,000 population observed in African region and in the five high burdened countries in Asia i.e. Democratic People's Republic of Korea, Bangladesh, Myanmar, Indonesia, and Papua New Guinea.

The TB mortality rate fell about by 3.4% in the period of 2015-2016 and by 37% in the period of 2000-2016.

2.3. Sri Lankan Perspective

Tuberculosis remains a major public health burden in Sri Lanka. In 2016, the estimate for tuberculosis incidence including TB patients with HIV is 13000 (9900-18000) while the expected incidence rate is 65 per 100,000 population. However the situation in Sri Lanka is comparatively better than its South East Asian neighbours i.e. India, Bangladesh and Pakistan being in the top 30 countries with highest TB disease burden. The mortality rate expected (excluding HIV) for 2016 was 6 (4.3-8) for 100,000 population. The expected incidence rate for Multi drug resistant TB (MDR) for 2016 in sri lanka was 0.45 (0-0.95) per 100,000 population.

There have been observed a considerable decrease in the incident rate of 2015, however overall incidence of TB remains static over the years. An increase of relapses was observed over the years while the proportion of relapses in the total number of TB cases detected tends to increase [18]. The total number of TB cases notified for 2016 was 8886 while in comparison to 2015 there is a decrease in all forms of TB. Out of this 93.8% are newly diagnosed cases, 6.2% are previously treated, and 0.04% are cases with unknown treatment history. Out of all new cases 49.1% are bacteriologically confirmed. Among the bacteriologically confirmed TB cases 97.6% are sputum positive Pulmonary TB, 2.3% are sputum negative culture positive TB while a mere 0.05% is WRD positive. In 2016 out of all notified cases of TB 20.6% are clinically diagnosed to be Pulmonary TB and 30.3% are extra pulmonary TB (EPTB) [18].

It is observed that the most of the cases are expected in the age group of 45-65 years of age, while 8700 males and 4700 females in total are expected to have tuberculosis disease by 2016 in Sri Lanka [19]

In 2015 the highest number of newly diagnosed TB cases were in the age group of 45-54, while the lowest is 0-14 year's age group. Therefore TB has an impact on the economically productive age group of 15-55 years in the country

The highest number of cases of tuberculosis was found in Colombo 2156 (24.3%). Gampaha 1083 (12.2%), Kalutara 570 (6.4%), Kandy 566 (6.4%), Ratnapura 510 (5.7%) and Kurunegala 429 (4.8%) [18]. the figure 2.2 summarizes the District distribution of TB cases.

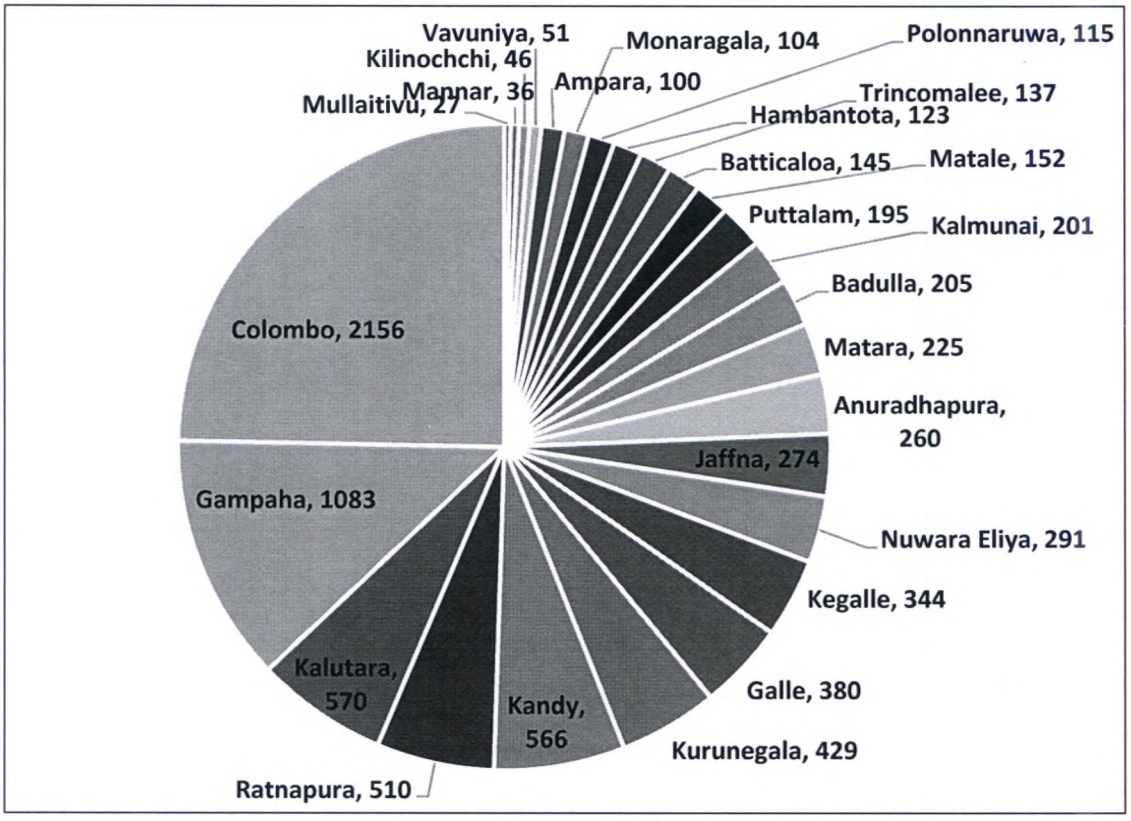

Figure 2-2 Case Detection and notification of TB in Districts 2017. Source: NPTCCD[18]

The WHO General Health Observatory country profile on Sri Lanka regarding TB, states that Sri Lanka had spent an estimated amount of USD 16 million for TB prevention services. Thirty four percent of funding is from domestic sources like the annual health budget and 24% is from International donors. Alarmingly 24% of the required funds remains unfunded. Despite the obvious lack of funds and resources Sri Lanka maintains a healthy TB coverage of 64 % (49-87) with a case fatality ratio of 0.15 in 2016[19].

2.4. TB Control Strategies

In the 1940s, development and use of effective drug treatments and improvement in many socio-economic factors in the population, resulted in rapid declines in TB morbidity and mortality in Western Europe, Japan and North America. However many other less fortunate countries, a significant reduction in TB rates remained a distant dream. The WHO declared TB as a global health emergency in 1993 which is mostly due to the emergence of HIV infection cases in an epic proportion. Despite major progresses in curative and preventive activities it still remains the top cause of death from infective disease, even in the second decade of 21st century. Therefore it is required to intensify Global and national efforts that are needed to reduce TB disease burden and achieve the ambitious global targets and milestones for the period of 2016-2035.

2.5. TB control activities in Sri Lanka

TB control activities in Sri Lanka is conducted under the National TB Control Program (NTP) in Sri Lanka, which is under the purview of the National Program for Tuberculosis and Chest Diseases (NPTCCD).

2.5.1. National Tuberculosis Program of Sri Lanka

The objective of NTP is to reduce morbidity and mortality due to TB disease and thereby reduce the disease burden of TB and contribute to socio-economic development of the state. The program is entrusted with the responsibility of formulating policies, planning activities, and monitoring the disease in Sri Lanka.

The NPTCCD is one of the important institutions that forms the national health system and is responsible for TB and other respiratory disease control activities in the entire country and works in co-ordination with the other aspects of national health services as well as with related governmental and non-governmental agencies.

At present, there are 26 district chest clinics (DCC) functioning in each administrative districts covering the entire country. Apart from the chest clinics, Inward facilities of National Hospital for Respiratory Diseases and in other 13 district hospitals. It also consists of diagnostic services which are carried out through the National Tuberculosis Reference Laboratory (NTRL), Intermediate Tuberculosis Laboratories, DCC Laboratories and Microscopic Centres. Anti-tuberculosis drug distribution is also a vital part of NPTCCD's responsibilities and the Central Drug Stores of the NPTCCD estimates, procures, supplies and distributes anti TB Drugs to chest clinics [18].

2.6. WHO End TB strategy and Millennium Development Goals

National and global efforts were adopted to reduce the burden of TB from 2000-2015 and was focused on achieving targets that are set in accordance with the Millennium Development Goals (MDGs). MDG targets were established by the UN in the year 2000. The MDG target 6C was to stop and reverse tuberculosis incidence (defined as the number of new cases per 100 000 population per year) [20]. DOTS strategy was adopted till 2005 and from the period of 2005-2015 the '*STOP TB strategy*' was adopted [21]. The Stop-TB strategy introduced two other goals in addition to the one set out by MDGs. The two goals introduced are to reduce TB prevalence and mortality by 50% by 2015, in comparison with numbers in 1990[14].

WHO developed a global tuberculosis strategy for the post-2015 era between 2012 and 2014 which is known as the '*End TB Strategy*'. It is for the period of which was for the period 2016-2035.

The basic aim of the '*End TB strategy*' is to bring an end to the global tuberculosis epidemic. This is expressed as the goal of the '*End TB Strategy*', and is part of Target 3.3 in the SDGs, which also includes ending the epidemics of HIV, malaria, and neglected tropical diseases [22].

2.6.1. Digital health for TB

Information and Communication Technology (ICT) presents novel opportunities to support TB efforts in patient care, surveillance, program management, and electronic learning. Such innovative approaches may help in achieving, the *End-TB strategy* objective of ending the worldwide epidemic of TB by year 2035. Electronic health (eHealth) and mobile health (mHealth) are collectively referred to as digital health. The development and effective application of ICT or digital health products at a large scale requires the positive engagement of TB care givers, innovators, funders, policy makers, advocacy groups, and affected communities.

In March 2015, Global Task Force was established by the Global TB program of WHO, to advise for the promotion of ICT for TB prevention, Care and Control aligning with the '*End TB Strategy'* of WHO.

It will advise mainly in the areas of

- Development of digital health products that are helpful in overcoming the challenges posed by TB to health care providers and patients.
- The approach to the review of evidence and best practices in effective use of digital health.
- To support WHO member countries to adopt and scale up ICT solutions in TB care and control.

The global task force in its defined area of work, have identified target product profiles for digital health products relevant to TB care and control. These are introduced with the hope that it will guide system developers and decision makers on the type of products required by end-users to address the challenges posed by TB to health care providers, patients and their families.

The "bold policies and supportive system" of '*End TB Strategy'* defines the "Universal Health coverage policy and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control". In the WHO report for digital health for "*End TB strategy"* states that a digital notification of TB cases to health information system is of paramount importance. It would allow to identify patients with a unique identifier, accommodate additional information needed for the follow up of a patient, facilitate data input through menu driven entry to limit errors and missing information

3. Problem Domain

3.1. History of Tuberculosis Control in Sri Lanka

Many factors such as poor living conditions, limited access to quality health care, limited health care resources and poor preventive strategies made TB disease a major public health problem in Sri Lanka during the early part of 20th century. Sri Lanka which was known as Ceylon back then was governed by the colonial government, who recognised this public health threat. This led to the formation of a Government committee in 1910 to examine its causes and to take necessary steps in order to contain this situation [23].

As a result the government formed the very first specialist service for TB control in the island- Anti-Tuberculosis Institute and Dispensary in Colombo in 1916. Then a respiratory disease hospital in Ragama in 1917 and sanatoriums in kandama and Kankasanthurei by the year 1919[24].

In 1948 Post-Independence Sri Lanka the Director of Medical Services (equivalent of Department of Health services) had considered that TB as the most serious medical and socio-economic problem in Sri Lanka. Few years ago in 1945 Anti-TB Campaign was established as a vertical prevention programme which functioned under a Deputy Director General of Medical Services. The campaign functioned through two chest hospitals, a network of chest wards and nine provincial chest clinics at the time of establishment. It was renamed in 1989 as the Respiratory Disease Control Program (RDCP). The RDCP was re-established as the National Programme for Tuberculosis Control and Chest Diseases (NPTCCD) in 2002 under the Director General of Public health Services[23]. Since then the National TB Control Program (NTP) in Sri Lanka, is under the purview of the NPTCCD.

3.2. National Programme for Tuberculosis Control and Chest Diseases (NPTCCD)

The NPTCCD consists of central or national level, provincial and district level units. The Central or the national level consists of the Central Administrative unit, National Tuberculosis Reference Laboratory (NTRL), Central Drug Stores, Central Chest clinic Colombo, DCC-Gampaha. At the national level the NPTCCD is responsibilities are-

- Formation of policy frameworks, guidelines and standard operating procedures for Tb control activities in the country.
- Planning, organization, implementation, coordination, supervision, monitoring and evaluation of clinical, diagnostic, control and research activities in TB throughout the country.
- Co-ordination within the Ministry of Health and with other national and international stakeholders.
- Maintaining uninterrupted drug supply and other logistics for the programme activities in the country.
- Technical guidance in consultation with concerned specialists.
- Human resource and Infrastructure development.
- Acquiring and utilizing financial resources through domestic and international sources.
- Communication and social mobilization in tuberculosis prevention programs.
- Surveillance and management of information system on TB

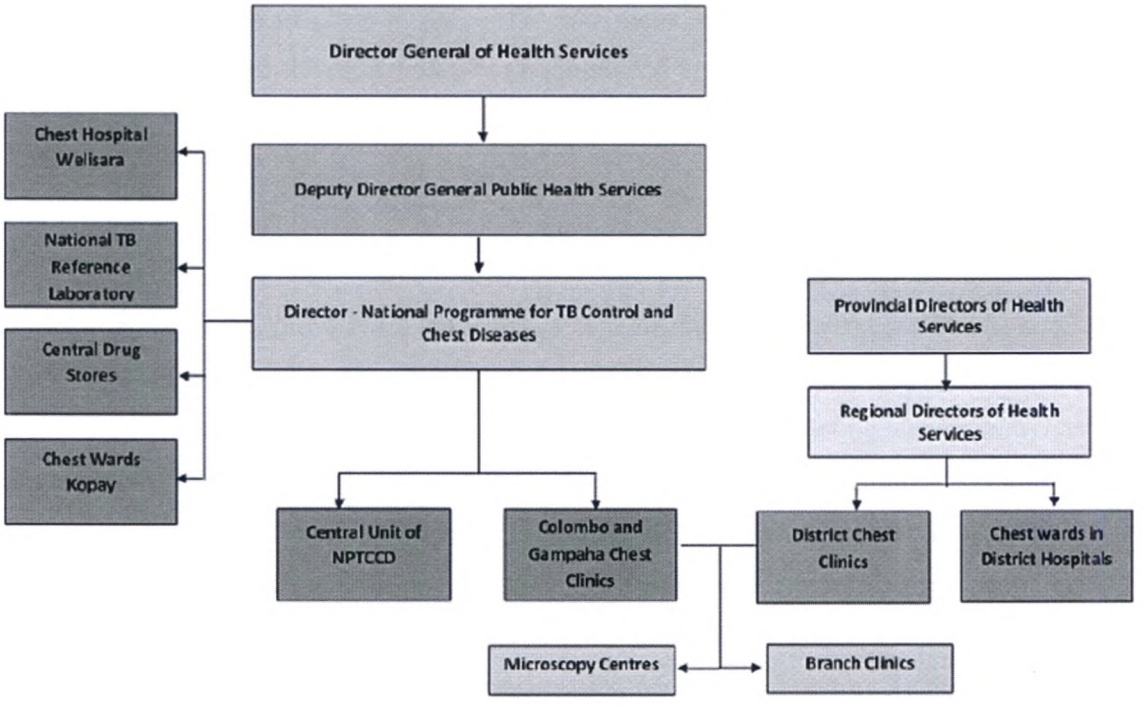

Figure 3-1 Organisational hierarchy of TB control services in Sri Lanka

3.2.1. Collaboration with Provincial Health Services

Sri Lanka consists of nine administrative provinces with each province consisting of two or three administrative districts. There are 26 administrative Districts in Sri Lanka. Each province has its own Health ministry and a Provincial Director of Health services. The 26 administrative districts has a Regional Director of Health Services at each district. The effective management and implementation of public health services including TB control activities are responsibilities of the Provincial Directors of Health Services and Regional Directors of Health Services in their respective districts and provinces. These activities are carried out through a network of DCCs in accordance with the policy and technical guidance provided by the NPTCCD. The DCCs, except Colombo and Gampaha, directly function under the administrative control of provincial health ministries. Responsibilities at provincial level includes mainly Surveillance and management of information system of TB, implementation

and maintenance of TB control activities in the province. Provide guidance and technical support in provision of clinical, diagnostic and management services for the TB patients working in close co-ordination with other regional and provincial health services.

3.2.2. District level

The District Chest Clinic (DCC) is the prime organizational unit of the NPTCCD at district level. It is the focal point of the NPTCCD for all TB related activities and its staff being the first line responders to TB patients. The DCC is the coordinating center and District Tuberculosis Control Officer (DTCO) is the focal point for the tuberculosis and respiratory disease control activities in the district. DTCO, who is the administrative head of DCC, is responsible administratively to the Provincial Director and Regional Director of Health Services and is technically guided by the Director, NPTCCD. Other staff at DCC includes Medical officers, Nursing officers, Radiographers, Medical Laboratory Technicians (MLT), Pharmacist, PHIs, Tuberculosis assistants, Data entry operators and other minor staff.

Consultant Respiratory Physicians are experts with necessary experiences and technical expertise in providing high level care for the TB patients. Every DCC has a visiting Consultant Respiratory Physicians who is attached to a nearby Hospital except in Colombo. Central chest clinic in Colombo has a consultant Respiratory physician attached to the clinic.

The structure of a basic DCC, with regards to provision of TB care, include a TB Registration Desk, Clinical section with the responsibility of attending to the patients, Laboratory, X-ray Department, and Pharmacy.

In each district, one or more branch clinics, will be held at selected public health facilities. Usually this is conducted by the medical staff of DCCs and the number and frequency of such clinics are decided on the patient load and other important factors.

All public health facilities, including the National Hospital, provincial and district general hospitals, base hospitals, district hospitals, Military Hospitals, Police hospitals, Prison hospitals and primary care units must participate in the TB control activities, especially in case detection and case notification.

Public Health officials, namely MOHs and their staff should also play an active role in fighting tuberculosis in their respective regions.

3.3. Recording and Reporting methods used in NTP

Recording and reporting of information is an essential part in any organization. It is vital when it comes to disease control programs with country wide coverage, such as the NTP. Meticulous recording of information helps to monitor the treatment and the progress of each patient. Also, periodic reporting on NTP activities helps to evaluate the performance of the control programs and enables further improvement.

In NTP, registration and notification process consists of a number of paper based registers and notification forms. Aggregated data from DCCs are compiled and communicated through the monthly and quarterly reports. These monthly and quarterly reports to the central unit of NPTCCD are sent within the first two weeks of the next quarter.

They consists of

- Quarterly reports of Case Findings(TB08)
- Quarterly reports on Sputum Conversion(TB09)
- Quarterly report on Treatment Outcome (TB10)
- Quarterly report on Program Management- District Level (TB 12)

Microscopic centres, National Hospital in Respiratory Disease, TB wards and NTRL also maintain registers and send in quarterly reports. Microscopic centres aggregated report is sent to the NPTCCD through DCCs.

- Quarterly report on Microscopy activities and Logistics -district level (TB11)
- Quarterly report TB or non TB wards (TB13)
- Quarterly report on National Hospital Respiratory Disease (TB14)
- Quarterly report – National Tuberculosis Reference laboratory (TB15)

The quarterly reports are compiled at the district level during the first two or three weeks of the next quarter and sends to the central level. It is the responsibility of DTCO to identify

deficiencies in terms of technical and managerial indices and other short-falls. Actions taken and other proposed remedial actions should be communicated to the central unit.

The central unit compiles and analyses reports from all the districts and should provide a feedback to the DTCO within 6 weeks of receipt of the reports. In addition, these data are periodically transmitted locally to provincial authorities and internationally to relevant institutions.

Case based data are recorded at each DCC using Registries and patient files. Presently, this information is not communicated to higher levels and aggregated reports are prepared manually. Additional information that is required by NPTCCD or Provincial Authorities are collected through special requests leading to revisiting these records.

Information regarding laboratory investigations and drug stocks, are also maintained using registries at each place and communicated to the central level through aggregated reports.

In brief, TB aggregated data reporting, TB disease surveillance, TB patient tracking, MDR-TB patient information management, Clinical decision supporting, Laboratory information, Drug management modules and sharing data with national health system are the information needs of NTP. In order to have high quality data with improved communication between stakeholders involved in provision of TB care, and instant and efficient access to patient information and improved data analysis capabilities, the NPTCCD realised the value of commissioning an electronic information system for its operations.

3.4. Electronic Patient Information System (ePIMS) in NTP

A standalone system was developed in 2006, and because of its difficulty to access remotely and maintenance issued it was decommissioned. The present Electronic Patient Information Management System (ePIMS) was developed in 2014 with the network help from PGIM, University of Oslo, GFATM, Health Information Society Sri Lanka, and College of Respiratory Physicians of Sri Lanka. It was developed on a free and open source (FOSS) public health software framework, District Health Information System 2 (DHIS 2) version 2.12, later it was upgraded to version 2.24. In the ePIMS all TB routine aggregated reports are automated[25]. The electronic information management system of the patient was developed with the objective of satisfying the diverse needs of those interested in a platform with advanced analytical capabilities which would overcome paper system problems and increase

sustainability. It is hosted at the NPTCCD server and it is remotely accessed over through the internet. Data entry is done at each of the DCCs and it is done by trained data entry operators. Validation rules have been built in to the system and reports are submitted following approval of DTCO. However the paper based reporting system of aggregated data is still continued. However ePIMS presently electronically transmits aggregated data to the central level but it is not integrated with laboratory investigations and drug stores databases. Individual patient based data is handled in a very limited manner, but supports recording patient location. Individual patient data are recorded in DHIS 2 tracker module program, in which a TB follow up program was created with patient registration with tracked attributes. Patients are enrolled to the system at the point of registration and tracked throughout the program stages under each DCC in the Org unit structure. However most of the clinical data that is being recorded in the patient treatment cards and patient treatment files have not be included in to the ePIMS therefore prompting the DCC to rely mostly on the paper based patient information files when taking a clinical decisions. Use of paper based records for individual patients poses many problems.

4. Literature Review

4.1. Ambulatory Care: Overview

Ambulatory care or out-patient care is basically the medical care provided in terms of outpatient basis rather than requiring the diseased individuals to seek residential or Inpatient care in a hospital. It may include different aspects of medical care such as diagnosis, observation, consultation, treatment, intervention and rehabilitation services. Health conditions that are managed in ambulatory care settings are known as 'Ambulatory care sensitive conditions'. However the term 'Ambulatory Care Sensitive Conditions' has many conceptual interpretations. Billings et al.(1993) defines ambulatory care sensitive conditions as " medical conditions/diagnoses for which timely and effective outpatient care can help to reduce the risks of hospitalization by either preventing the onset of an illness or condition, controlling an acute episodic illness or condition, or managing a chronic disease or condition"[26,27]. Chronic medical conditions such as Tuberculosis, Epilepsy, and Asthma, Chronic obstructive pulmonary disease, Hypertension, Diabetes Mellitus and Iron deficiency Anaemia are some conditions that can be categorized as ambulatory care sensitive conditions. Ambulatory care provision for chronic diseases such as Tuberculosis has its own fundamental characteristics. Success in the provision of ambulatory care is a significant factor to the overall performance of the health care system in a country, especially in a developing country.[28] In the context of treatment of Tuberculosis, ambulatory care is seen as a part of comprehensive continuum of care for tuberculous patient. It embodies holistic patient centered approach taking in to account the individual needs in a background of social and economic vulnerabilities of the individual[29]. Therefore it is evident that the ambulatory patient requires somewhat different care in comparison to a patient receiving inward care, especially when that care is provided by a non-hospital based ambulatory facilities. This can occur in a variety of ambulatory facilities that has no direct association with hospitals such as General Practitioner practices, Outpatient Clinics, Dental Clinics, Community Health centres, Clinics conducted by special programmes for Disease control (Tuberculosis, HIV/AIDS, and Malaria etc.).

The ambulatory care facilities such as clinics for chronic disease management is located more accessible to "high in need communities" and functions as a centre of a network of services focused on the patient[29].It can be described as a facet of care involving Inpatient care, Home care, and outpatient care. Therefore the outpatient clinic or ambulatory facilities are required to maintain a higher degree of communication with its patients, as the patient is seen only for a brief period when compared with inpatient care. The patient is exposed to the environmental 'variables' than a patient in the inward setting, therefore making the management and follow up of such a patient challenging. The patient information that have to be collected at each encounter is critical and it is necessary to monitor adherence to treatment protocol. Therefore it is important for the health care workers to have a system to identify the patients with critical needs that need immediate attention and also to track and enrol – back the "defaulters". The nature of medical services expected of a clinician and his supportive staff may not be of difference than inward setting as it may involve with investigating, diagnosing and treating medical conditions. However it should be noted that it is relatively easy to provide care for the sick in the confines of a ward, and in comparison provision of medical care is quite challenging when the patient is in the outside world. The approaches and strategies for management of such patients obviously have to be different. This distinction is reflective in the nature of record keeping practices in ambulatory facilities. The Clinicians and other health care providers in an ambulatory setting has to face a multiplicity of problems such as physical, mental and social problems of the patient that has to be dealt in a non-clinical setting sometimes. A careful and object oriented approach is necessary to solve these. While a comprehensive and problem oriented medical record would enable the clinicians to approach patient problems systematically[30].

Health care provision has two distinct branches -'Preventive' and 'curative'. Preventive services are often taken in to account with public health programmes. These kind of programs typically involve "Target population" and provide benefits in a collective way. This is in contrast with individual centered care services. However preventive services also has a personal component such as child immunizations and antenatal care for pregnant mothers. This addressing of target population prevents health and most personal preventive services comprise the personal ambulatory health care which has large potential in contributing of health care to improved population health outcomes.[28]

4.1.1. Patient Clinical Record: Paper based and Electronic based

"Verba volant, Scripta manet" –"spoken words fly away, written words remain", As the Roman Emperor Caius Titus (39-81 AD) correctly pointed out in his speech to the Roman Senate, written record keeping has been given utmost importance as long as man walked in to civilization.

New South Wales government of Australia in a Policy directive (PD2012_069) issued in December 2012 in 'Health Care Records - Documentation and Management', defines Patient health care records as a "primary repository of information including medical and therapeutic treatment and intervention for the health and wellbeing of the patient / client during an episode of care and informs care in future episodes"[31]. Record keeping or the written word of a patient's clinical information forms an important part in healthcare delivery.

Patient Clinical records consists of a wide variety of documents generated by or on behalf of the multidisciplinary team of health care personnel involved in patient care. It contains documented accounts of patient's clinical history, health investigations and assessment, diagnosis, treatment, disease progress and health outcome for every health care intervention. It is the duty of the members of the multidisciplinary team to maintain an Accurate, Comprehensive, Objective, Legible and Legitimate clinical record of patients they attend to. A "Good" clinical record, in whatever form-Paper or Electronic- will document the medical history of a patient for the purpose of future referencing. This is of particular importance in ensuring continuity of patient care. Continuity of clinical records is of vital importance in providing continued care to the patient, as in the present day medical practice many different health care professionals are involved with management of a single patient. A properly updated, accurate, and legible clinical notes will make sure that clinical information is effectively shared among all the health care professionals assigned to take care of the patient. This in turn will benefit the patients, as it will enable informed decision making for patient management, risk assessment and root cause analysis. It will also coordinate the treatment process and improve unnecessary repetition of investigations and drug prescriptions, making sure that patient spends less time in health care institutions. Poor clinical record keeping will have the disadvantages of misinforming the health care personnel , increased medicolegal risks, lead to unnecessary repetition of tests or other investigations prolonging hospital stay

and jeopardizing health of the patient[32]. Therefore there have been many attempts at improving patient clinical record documentation throughout the world.

Electronic Patient Clinical Record, Electronic Health Record (EHR), Electronic Medical Record (EMR) and electronic personal health record has been used interchangeably in literature and they have arbitrarily the same definition with much of it overlapping[33,34]. The International Organization for Standardization (ISO) defines a basic EHR as "a repository of information regarding the health status of a subject of care, in computer process able form"[35]. It also defines an EHR as an integrated entity "repository of information regarding the health status of a subject of care, in computer process able form, stored and transmitted securely and accessible by multiple authorized users, having a standardized or commonly agreed logical information model that is independent of EHR systems and whose primary purpose is the support of continuing, efficient and quality integrated health care"[35].

Paul C Tang (2006) defines an EHR as "a repository of electronically maintained information about an individual's lifetime health status and health care, stored such that it can serve multiple legitimate users of the record. The record must integrate elements regarding a patient's health and illness acquired by multiple providers across diverse settings. In addition, the data should be stored such that different views of those data can be presented to serve the many uses"[36].An Electronic Medical Record in short an EMR a synonym for a EHR, is defined in a report by Institute of Medicine in 2003 as "longitudinal collection of electronic health information for and about persons with immediate electronic access to person- and population-level information by authorized users provision of knowledge and decision-support systems that enhance the quality, safety, and efficiency of patient care and support for efficient processes for health care delivery" [37]. An electronic patient record or a Computer based Patient Record (CPR) is also defined as "an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems,& links to medical knowledge, and other aids".

All these definitions accept that an EHR or EMR or Electronic patient record is an electronic version of a "repository" or a collection of an individual's health status and health events he had undergone in his life time stored in electronic and a computer accessible form. It also describes the ability of this electronic record to be accessed by different users and also secure

transmission of information. While the definition for EMR is broadly focus on "medical" information such as Medical charts, ICU flow charts, Surgical summaries, anaesthesia notes, prescribed medication notes [34], an EHR is more of a health care provision details repository including financial and insurance details. However as stated earlier these terms are used interchangeably regardless of subtle differences. However in a more holistic approach, provision of multidisciplinary originated health care, the information needs of the involved personnel be different. Therefore a much more comprehensive term to use would be an electronic patient record as its definition also allows recording of information that cannot be termed outright 'clinical'[38]

The concept of an electronic version of a patient record comprising of a wide range of information systems from files of information from a single department of an institution to a longitudinal records shared between different departments, in order to meet the information needs of its users. These can be employed in different settings such as in-patient care and outpatient care as well as curative and preventive arms of health care. However because of the uniqueness of these areas of health care provision not many papers define or outline a common structure for a EHR[39]. It can be observed the patient records that is currently maintained in health care institutions are different from each other and this difference stems up from a variety of affecting factors such as information needs of users, the type of care provided, and type of patients or individual it caters to [36].

Ngyuen et al. (2014) in a systematic review on electronic health records impact confirms that electronic patient clinical records aid in patient care and better patient outcome. For example, it reports that the implementation of this technological solution has a positive impact in the clinical documentation improvement, increased administration efficiency, and better, safe and coordinated care for the patient. However they also report in negative outcomes such as changes to workflow and work disruption[40].

4.1.2. Patient Clinical Record keeping in Ambulatory Care

Ambulatory facilities has to have expanded services such as infection control, community education, social support and outreach to individuals and populations of high risk. Therefore

it needs to be integrated with other medical and non-medical services. An Outpatient clinic worker may have to work with other services like HIV/AIDS campaigns, hospitals and clinicians of other specialities, as well as non-medical services like social services, law enforcement, education and religious entities. The information exchange between these entities are quite unique and therefore it is the responsibility of the health care providers to maintain an adequate record keeping practices.

The ambulatory care setting is subjected to problems and errors that includes medication errors, adverse drug reactions, delayed or missed diagnosis, delay of proper treatment and preventive measures, ineffective communication and information flow. A better understanding of quality, safety and systems problems clinicians face in providing outpatient care will come through prompt availability of information at hand[41]. Especially ineffective communication and information flow would occur between the patient and clinical staff, ambulatory care to hospital care, missing reports from laboratories, imaging and other important clinical documentation. However The Joint Commission: 2008 Ambulatory National Patient Safety Goals published by the Veteran affairs national centre for patient safety in United states has emphasized on accurate patient identifying information, effective communication practices with proper documentation practices and active involvement of patients and family in ambulatory care to minimize errors and negligence in provision of outpatient care[42].

It is evident as shown above that provision of ambulatory care poses challenges to the clinicians and their supportive staff which at times are similar to and at times different to challenges faced in inward setting. In providing patient centered care and at the same time associating with community care seem to be a hallmark of ambulatory care. This unique nature in ambulatory or outpatient care for diseases such as tuberculosis, demand that the nature of information collected from patients and exchanged between different groups of health care workers, also be unique. This has to be appreciated in the medical records and other clinical documentations maintained at such facilities. The mobile nature of some chronic disease clinics and screening programs requires a more versatile, accessible and comprehensive form of recording, updating and retrieval of information.

4.1.3. Quality of Clinical documentation practices in ambulatory care and Clinical documentation Improvement

When inquiring about the quality of clinical documentation in outpatient care authors commonly cite attributes such as accuracy, legibility, correctness, readability, appropriateness and accuracy and some draws attention to components such as structure of the clinical record and the content of the note[43,44]. From many years medical education has emphasised the importance of using a structured format for clinical documentation. The Subjective, Objective, Assessment, and Plan (SOAP) has been widely used as a format in clinical documentation for the last 40 years. This has been common in both Inpatient and Outpatient care[30]. There are other systemic approaches designed to improve clinical documentation such as TITRS (Title, Introduction, Text, Recommendation, and Signature) and FARM (Findings, Assessment, Recommendations or Resolutions, Management). However it is a common observation that unstructured and semi structured clinical notes and documentation are widely used.

In a study conducted to evaluate the quality of clinical documentation of pregnant mothers in confinement in Madhya Pradesh India, between 2012-2013 claims that, of the 1273 records evaluated there was significant variation in the recorded elements. Only 13.8% had recorded the blood pressure of the mother, 35.3% had fetal heart rate and about 1.5% had not recorded the admission date[45].

In 2014, a study conducted in a university medical college in Nepal in 2010, reports high omission rates in terms of final diagnosis, results, duration of hospital stay and diagnosis summary[46].

Therefore it is clear that clinical documentation in ambulatory care needs to be improved in order for the betterment of the patient. This need has been identified as Clinical Documentation Improvement in Ambulatory care (Ambulatory CDI). Ambulatory CDI can be defined as improvement in the quality of clinical documentation in an ambulatory setting, to ensure complete accurate, and compliant clinical documentation, coding and billing resulting in an accurate reflection of patient severity, quality of services provided, quality of care delivered and at times reimbursement[47].

Ambulatory setting in terms of clinical documentation has key differences from inpatient care. In ambulatory setting, as in chronic disease management clinics, the volume patient encounters are high. Time allotment for episodes of care is significantly shorter. Because of the multidisciplinary nature in chronic disease management there is a significant amount of non-physician documentations. Multiple different codes, Guidelines, and forms exists in the ambulatory setting requiring different levels of information. CDI though has a financial component and goal in it, it forms an important aspect in the future of health care provision. A successful program of CDI would strengthen documentation infrastructure for point of care capture, and will support care delivery and continued process improvement through enhanced data quality[48]. It can be argued that with the benefits of adopting an electronic patient clinical record over the existing paper based system is in fact an approach in to improvement of clinical documentation. Studies have shown that electronic patient records have allowed documentation of comprehensive clinical problems of patients, medication lists, identifying patient related factors in the outcome of diseases in much efficient way than the traditional paper based system[49]

4.1.4. How adoption of Electronic Patient Record had helped in Ambulatory care

Throughout the world, ambulatory care programs have slowly but steadily adopted electronic information systems with electronic management of patient level data. Literature has shown that adoption of electronic patient records have impacted these programs in efficiency and quality of services they provide. Some of these studies and the inferences they have made on ambulatory care services are described in the table 4.1 below.

Table 4.1 Studies and their inferences on the impact of electronic patient record in Ambulatory care

Study	Study Design and methodology	Results and Inferences	Conclusions
Garrido et al[50]	Retrospective, serial, cross sectional study conducted in Colorado and Northwest regions of Kaiser Permanente, a US integrated healthcare delivery system in Colorado and North west region. In the aim of evaluate the effect of an integrated electronic patient record in its work processes.	Regular follow up visits have been reduced by 9%. Age adjusted primary care visits have reduced by 11% than the average which are significant. Members requiring more than 3 primary care visits per year, decreased by 10%.	Comprehensive, integrated clinical information reduced use of ambulatory care while maintaining quality and allowed doctors to replace some office visits with telephone contacts
Herrin et al[51].	A naturalistic experiment in which the objective was to assess the impact of implementation of EHR on primary care in diabetes mellitus patients the study conducted in 34 primary care centres with 14000 diabetes patients	Patients exposed to EHR were significantly more likely to have optimal care.an estimated difference of 9.2% was observed in comparison to unexposed patients. Patient care indicators	Implementation of an EHR in a primary care setting may improve patient outcome among patients with

		were optimal in patients enrolled in the EHR	diabetes mellitus.
Moody et al[52].	A descriptive study among 100 nurses in a large 'Magnet' Hospital in South-west Florida, to assess needs and perception associated with EHR methods.	The majority (64%) preferred the paper based bed head ticket and not the EHR as it didn't allow bed side charting. However an overall of 75% of the nurses believed that the EHR had improved quality of documentation and 76% believed that it would result in improved patient safety.	EHR results in improved clinical documentation. But it also mentions that the design of the electronic system should actually cater to the user's needs in order to achieve higher acceptance.
Bates et al[53]	Have developed a computerised clinical record for outpatient care employed at General physician practices and have performed a series of pilot evaluations.	Evaluations have revealed improvement with clinical personnel communication, in prescription writing, user and patient satisfaction.	In overall electronic ambulatory medical records have substantial benefits over a paper based system.
DesRoches et al[54].	National survey of 2758 physicians were conducted to find out proportion of physicians using EHR and associated characteristics of their use.	Four percent had a high quality system and 13% had a basic system. Physicians reported positive effects in several aspects.	EHR use improves clinical outcome considerably despite it being a relatively new among physicians

4.2. User Centered Design

User centered design in its fundamental level can be describes as a philosophy that emphasizes on the involvement of Users early in the design and continue to employ them in to the evaluation process. The concept outlines a number of phases in the design and development life cycle and while gaining a deep insight in to its end users.

The term User centered design (UCD) is a broad term giving rise to the concept of involving a product's end users influence on the design and development process of the product in concern. The broadness of the concept gives rise to a spectrum of ways in which a user can be involved in influencing the final outcome of a product. The product here is an Electronic patient record or a software solution. While in one end of the spectrum the end users can be intermittently involved in the design and development of the software especially in the requirements engineering process and Usability testing. While on the other end of the spectrum is that the end users involve themselves in a much more deeper level with a deep impact on the outcome of the product by being involved as partners with the designers throughout the design and development process[55].

User centered design was first conceptualized by Donald Norman in 1980s in his co-authored book "User-Centered System Design: New Perspectives on Human-Computer Interaction (Norman & Draper)"[56].

Donald Norman offers four basic suggestions on how a design should be – they are

- Should make it easy to decide and determine what actions are possible at any moment.
- Should make things plain visible with the inclusion of its conceptual model, alternate actions, and the results of the actions.
- Should make it easy to evaluate the present status.
- Follow natural mapping in between the desired intentions and the required actions, between action and the effect, and between the information that is visible and the interpretation of system state.

Norman's four basic suggestions place the end user at the centre of the design, and it is the role of the designer to make sure that user is able to make use of the designed product in its optimal level of use with minimal effort to learn it.

UCD has basic phases which is modified and used according to the needs and developers in a system. But the fundamentals steps can be describes in four steps[57].

- The Context of Use
- User requirements
- Creation of Design Solutions
- Evaluation of design

Even though these steps have been mentioned in a step wise manner, it is actually a cyclical process in which both the User and Designer are involved until the 'perfect' solution is reached. This process is summarized in the figure 4.1 below.

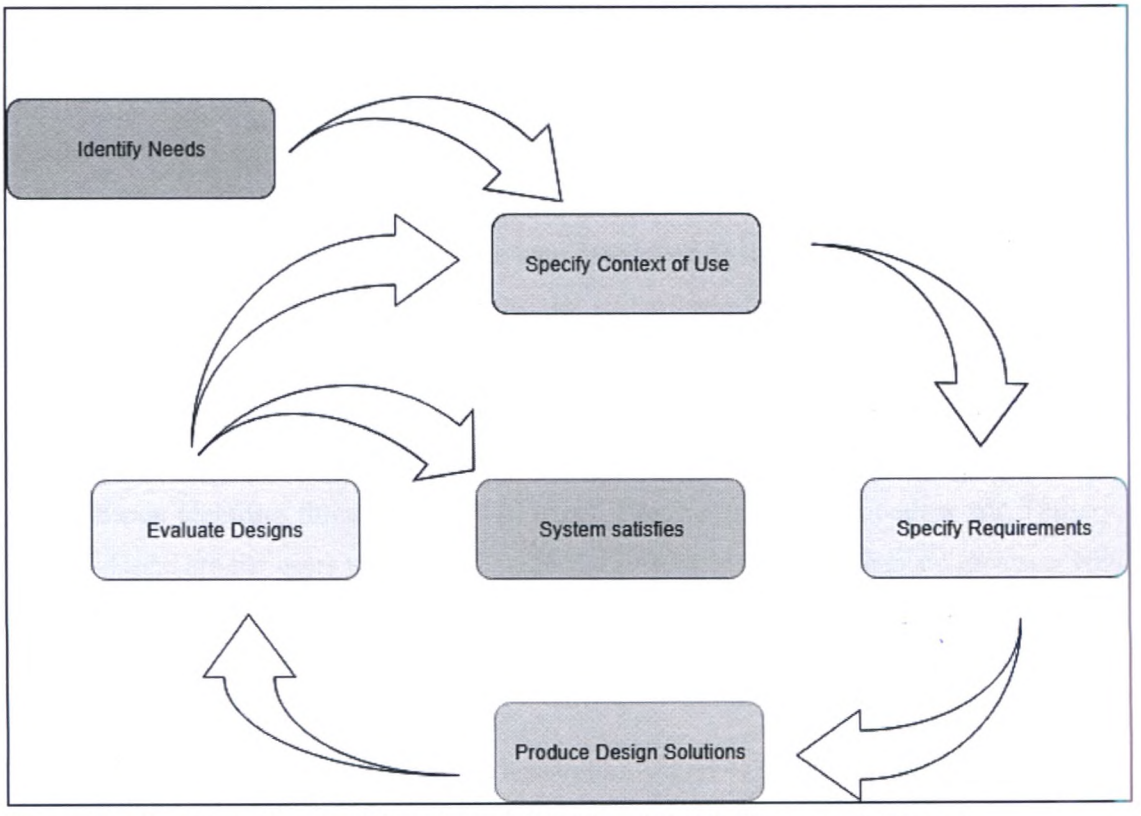

Figure 4-1 Fundamental steps of User Centered Design approach, Source-usability.gov

There is special interest among the 'human-computer interaction' enthusiast to "Study the User" which signifies the understanding between the system designers and the end users. The need to study the user arises not only to understand about how the end users think and behave but also to understand peoples need for variety and challenge in the tasks that they

perform. For an example in building an 'Idiot-proof system', a concept with much greater impact, refers to the design of human-computer interfaces that are easy to use. Even though the term is quite misleading, it embodies the conceptual framework of designing a system that is proof against the workings of the people who wreak havoc of the system[56].

4.2.1. How to involve Users in Design Process

It is important to identify who a user is before the commencement of the involvement of the users in the designing of the program.

Legal information Institute of US in Code 8541- definitions defines the term 'End user' as "The term "end-user", with respect to a good, service, or technology, means the person that receives and ultimately uses the good, service, or technology"[58]. However this is a much broader term encompassing in to goods, services and technology. But when it comes to software development the end users can simply be identified as "The person who uses a computer application, as opposed to those who developed or support it"[59]. According to this definition the end users stand in contrast to system administrators, system developers, database administrators, software professionals and computer experts. Which means that the end users lack the technical expertise that the designers have and this is an aspect that is often let out in the dark and leads to customer dissatisfaction and render developed software useless.

Eason identifies three categories of users. They're Primary, Secondary and Tertiary. Primary Users are the users who actually uses the system, secondary users are the users who will intermittently use the system who would act as an intermediary and tertiary users are the ones who will be affected by the use of the system or make administrative and financial decisions in the organization[60].

Therefore it is necessary that the successful design of a product must involve a wide range of stakeholders. Even though all of them are not in consultation with the design team their presence and influence in the successfulness of the project must be considered.

Once the stakeholders have been identified and their expectations and needs are thoroughly investigated, the designers can come up with design solutions to be evaluated by the users. Iterative cycles of designing solutions, evaluating and redesigning will clear the view of the designer of the stakeholders needs. As the design cycle progresses, prototypes can

be produced and user tested. The table below produce a summary of methods in which the users can be involved in this design process.

Table 4.2 Summary of User involvement methods in designing in User centered approach

Technique	**Purpose**	**Stage of the design cycle**
Sequence of work interviews and questionnaires	Collection of data of the sequences of work and processes to be performed in the system	Early in the design cycle
Focus groups	Inclusion of a group or groups of a wide range of stakeholders to discuss issues and requirements	Early in the design cycle
On-site observation	Collection of information by observing the users in the said environment in which the system will be placed	Early in the design cycle
Background interviews and questionnaires	Collection of information related to the requirements of users; evaluation of alternatives to the design, prototypes and the final output	At the beginning of the design cycle
Role playing and simulations	Evaluation of alternative designs and gaining additional information about user needs and expectations; prototype evaluation	Early and midpoint

Usability testing	Collecting quantitative data related to measurable usability criteria	Final stage of the design cycle
Interviews and questionnaires	Collecting qualitative data related to user satisfaction with the artefact	Final stage of the design cycle

4.2.2. User centered approach in developing ambulatory care information systems

Literature regarding successful application of UCD principles in ambulatory care domain are available globally.

DeVoe et al (2014) describes a study to develop customized health information technology tools to federal health centres to have children with insurance in the US. The study conducted in eight clinics with very high number of children without health insurance, collected qualitative data (observational and interview with stakeholders) to identify the requirements and work flow processes and additional requirements for the EHR in use in terms of insurance needs. These additional requirements are in nature of patient portals, automatic messages and reminders. However they conclude by stating that they were able to employ UCD design methods to better align the health information tools with the user needs successfully[61].

Johnson et al (2004) in a methodological review on User centered approach in redesigning healthcare interfaces describes a case study in which a family history tracking and pedigree drawing program employed at a genetic testing facility at a teaching hospital in Houston, US with poor functionality and usability problems was transformed with UCD techniques in to a system with higher task success and user satisfaction.

4.3. Action Research

The term Action Research has a working definition in which it is defined as a "participatory, democratic process that together with developing practical knowing in the pursuit of worthwhile human purposes, grounded in a participatory worldview"[62]. It means that action research aims to contribute both to the practical concerns of people in a problematic situation and to further the knowledge of science simultaneously, in simple "producing knowledge by action" and aims to link theory with practice [63]. What differs the action research methodology from daily problem solving is its contribution to scientific knowledge.

There is a broad agreement in the scientific community that the information systems research should respond to dual mission, that it should contribute to practice as well as to academia. It has been criticized for its lack of influence on practice. An approach for being more relevant means conducting research using appropriate research methods that balance interests to both the researcher and the practitioner [64].

The core of Information Systems research is the ICT artefact or the product. It consists of the designers building and the organizational stakeholders shaping of it as a single entity. Therefore the designing of an Information Systems for an organization involves dimensions that exceeds the technology and include the interaction of design efforts and contextual factors throughout the design process. The current Design research approaches has more emphasis on the abstraction and inventions. They consider organizational intervention to be secondary. Therefore in order to go beyond, a design approach that the researcher deemed to be necessary and has organizational intervention at its very heart should be employed, namely the Action Research method.

Action research can be summarised in the following manner in the figure 4.2 below.

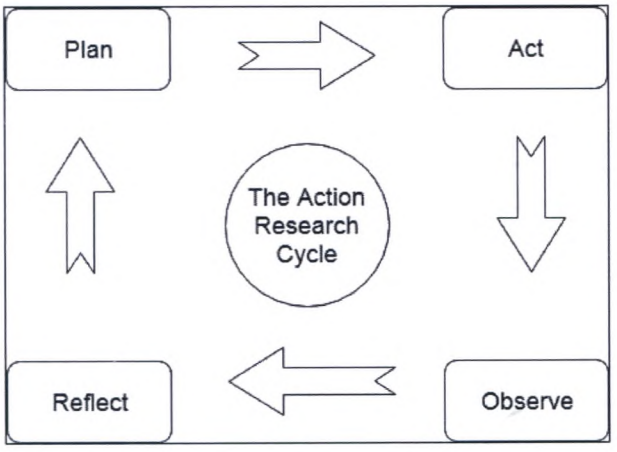

Figure 4-2 Action research cycle

5. Materials and Methods

5.1. Objectives

5.1.1. General Objective

To identify the requirements and perceptions of stakeholders involved in diagnosis and clinical management of Tuberculosis patients to design a comprehensive patient clinical record module to capture individual case records and reporting.

5.1.2. Specific Objectives

1. To identify the critical stakeholders regarding the diagnosis and management of tuberculosis as well as the key decision makers and their role in information management.
2. To study the data elements, indicators, reports captured and generated in the recording and reporting system of National TB program.
3. To determine detailed user requirements of different stakeholders with regards to a case based data as a clinical records module.
4. To design and develop the additional requirements to the system used at the NPTCCD with regards to case based data as a clinical records module.

5.2. Study Design and Materials

This research was designed as a comprehensive and in-depth inquiry in to stakeholder's requirements and subsequent system design. In-depth open ended interviews and supportive document evidence were used for data gathering. Qualitative data analysis was performed.

5.2.1. Study Setting

The research project was carried out at National Programme for Tuberculosis Control and Chest Diseases Narahenpita, District Chest Clinic Colombo and District Chest Clinic Galle.

5.2.2. Procedures and Protocol

The research was carried out in two phases.

First phase

The major stakeholders in management of TB patients were identified strategically by going through documents pertaining to treatment of Tuberculosis patients in Sri Lanka and preliminary observations made at chest clinics in Colombo and Galle district. They are the ones who are expected to influence or be influenced by adoption of an electronic patient record in this disease program.

Stakeholders who had important and vital contributions in provision of TB care were included in the study.

The participants identified, worked at either the peripheral chest clinic level, majorly concerning themselves with Patient management and preventive services or at the Central level. Important stakeholders were also identified in the central level of NPTCCD, whom associate themselves with monitoring and evaluation of services provided through the peripheral chest clinics.

In depth interviews was carried out by the researcher with the identified stakeholders in order to identify user requirements. Interviewees were given the chance to talk freely about their perceptions of the existing system, with their expectations and requirements. Minimal prompting was done with open ended questions. Interviews were audio recorded and transcribed after each interview word to word. Interviews that was not in Sinhala was translated in to English for the ease of analysis. The interviews were analysed to systematically identify user perceptions and user requirements.

Second Phase

A prototype of the user interface of the proposed system was designed to give the "look and feel" of the system that the users would be using to record patient level data. The prototype was developed using PHP, HTML and CSS languages with the functionalities the participants wished to see in the new system. The prototype consists of a number of graphical User Interfaces that would directly interact with the users for the data capturing purposes and data visualizations.

The users were introduced to the prototype and evaluated user satisfaction in meeting with their requirements. Evaluations were done with open ended interviews similar to what was done in Phase One. Interviews were audio recorded and transcribed after each interview.
Post evaluations was analysed using thematic analysis to suggest modifications and suggestions for wider implementations.

5.3. Methods of Data Analysis

5.3.1. Thematic Analysis

Thematic analysis is one of the most common methods of qualitative analysis used in research. It can be defined as the process of identifying patterns or themes within qualitative data[65].It emphasizes in identifying, pinpointing and observing patterns within a qualitative data set or among data sets. This method draws the focus on to description of the organization and context of the dataset. It encompasses beyond just reduction and summarizing of data to identifying and observing implicit and explicit data within a dataset. The 'Dataset' entails a vivid variety from just phrases of textual data to as something complex as that of a text with thousand pages. However it is better to perceive thematic analysis as an umbrella term, with varied approaches to data analysis. However in this research, thematic analysis as described by Virgina Braun and Victoria Clarke had described – using the "Six phases of thematic analysis"[66] was used as the basis. Even though the phases are listed out here, it should not be taken as a linear process but rather a recursive process.

Six phases of thematic analysis (Braun & Clarke, 2006)

1. Familiarization with the data
    - Is seen in all most all forms of qualitative analysis. It involves the investigators or researches getting immersed and familiarised with the qualitative data collected (ex- interview excerpts, audio recordings and etc.) by going through them thoroughly and in multiple frequencies.
2. Coding
    - It is an analytic process where the data is categorised in to 'codes' deemed relevant to the research question. It is not simply a method of data reduction

or summarization, but a method of harnessing the conceptual and semantic reading of data. The codes can range from single words to phrases that best captures its analytic value.

3. Searching for Themes
    - A Theme is a lucid and meaningful pattern in the data in the context of the research question. Searching for themes is an active iterative process that requires actively identifying codes that represent a pattern of meaningfulness and categorizing them together. This stage is ended by collating all codes in to themes.

4. Reviewing Themes
    - In this stage the themes are reviewed in the context of research question and whether they are representative of the body of data analysed. The constructed should be reflected upon to look whether the themes tell a convincing and compelling story about the data, and begin to define the nature of each individual theme, and the relationship of themes.
5. Defining and Naming Themes
    - In this stage it is required to write a comprehensive analysis that identifies the 'essence' of each theme and constructing a concise name for each theme.
6. Writing up
    - In thematic analysis, writing is a very important process. It involves putting the elements of the analytic narrative and data extracts in order that would tell a rational narrative about the data and contextualising it in relation to existing related concepts.

Braun & Clarke defines two levels of thematic analysis, which is Semantic and Latent. Semantic is that the analysis is only on the explicit or the surface meaning of the data and shall

not be looking anything beyond what the participants have provided. Latent level of analysis is to look beyond the data to understand the underlying ideas, assumptions, and conceptualizations[66].

5.3.2. Steps in analysis of gathered data

Data analysis will be approached in an Inductive approach. In inductive approach, in contrast to deductive approach identifies themes are strongly linked to the dataset, rather than trying to fit in to a preconceived model. The level at which the themes analyzed in this research is rather Latent than Semantic. Therefore much interpretation was done while focusing specific areas of interest across the majority of the dataset.

The analysis of data in this research endeavor was based on the six phases as described by Braun & Clarke[66–68]. The 'searching for themes' 'Reviewing themes', 'defining themes' and 'writing up' stages in the original Braun & Clarke model were combined and regrouped in this research endeavor in to 'Identification and of Organizing themes and major themes' and

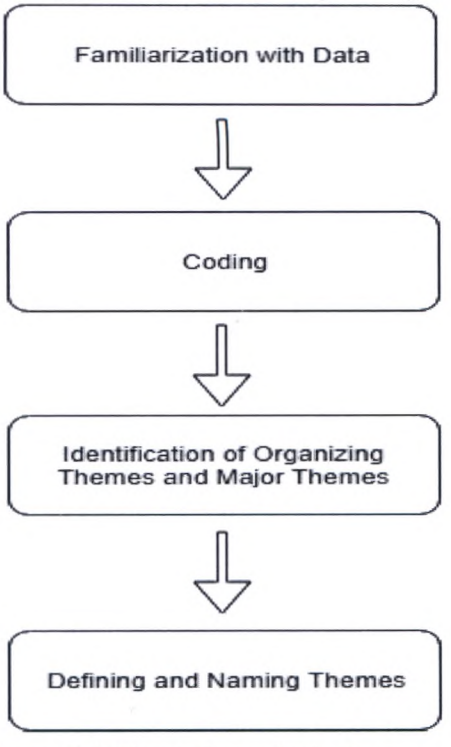

Figure 5-1 Thematic analysis steps followed in data analysis of the participant interviews

'Defining and naming Themes'. Even though the stages were grouped and rearranged the basic steps of analysis remained the same. Therefore the figure 6-2 summarizes the data analysis steps followed in this research.

Familiarization of Data

The audio recordings of In-depth interviews with major stakeholders were transcribed in to word documents and were read and re-read to get familiarized with data and to identify preliminary analytic patterns.

Coding

After getting familiar with the interview data. The transcriptions were 'coded'. Brief labels of single worded to phrases were generated for important features and data in the interviews that is in relevance with research objectives of this study. These initial codes were then grouped together on similarity in to code categories. Since each interview was coded separately there were codes with similarity repeating within each set of codes. However the same code appearing within a set of codes were taken as a single code and codes which gave the same interpretation were combined as 'Code categories'.

Identification of Major themes and Organizing themes

As it was mentioned earlier a Major Theme is identified as a coherent pattern of data relevant to the research question of the study. Major themes were constructed in a way to understand the true essence of what the in-depth interviews stated.

Organizing themes were defined with a collating similar codes and code categories. Number of organizing themes would consist a Major theme.

Defining and naming themes

The constructed major themes and its consisting organizing themes are reviewed in order to find out whether they tell a compelling and a convincing story about the collected data. Then a suitable name for the major theme, a definition or a comprehensive description of the theme was constructed.

5.4. Ethical Considerations

Data collection was started after receiving ethical clearance from the Ethics review committee of Post Graduate Institute of Medicine (Annexure 1). All interviews were conducted following informed consent of participants (Annexure 1). They were assured of anonymity and personally identifiable data was not collected. All interviews were audio recorded with the consent of the study participants. The audio recordings and interview transcribes are kept secured under lock and key with the principal investigator. Data analysis was done by using the designation of the participants only.

6. Results

6.1. Participants

The total number of participants who took part in In-depth interviews was Fourteen. They all had worked in the NTP for more than a year and was confident about their knowledge on the work processes of NTP.

All the participants were confident about their computer literacy up to a level in which they are comfortable in day to day use, such as internet browsing, use of online search engines, working with word processing software and email. Some of the participants had used computerized patient records for varying degrees either in previous work places or abroad.

The following participants were identified as important stakeholders in developing an electronic patient clinical record for TB patients at the level of chest clinics as indicated by the table 6.1.

Table 6.1 Participants from the Chest Clinic Staff

Designation of Participant	**Number of participants**
Consultant Respiratory Physician	2
Medical Officer/ Chest Clinic	2
Medical officer /OPD-Chest Clinic	2
District Tuberculosis Control Officer (DTCO)	2
Public Health Inspector	1
Nursing Officer	1
Data entry operator of present ePIMS (DEO)	1

At Central NPTCCD level the following was identified as important stakeholders. They oversee monitoring and evaluation of patient care services conducted through the chest clinics. Medical officer/health informatics based in the central unit of NPTCCD monitors the present ePIMS. These important stakeholders are listed out in the following table 6.2.

Table 6.2 Participants from the Central level

Designation of Participants	Number of participants
Consultant Community Physician (Monitoring and Evaluation)	1
Consultant Microbiologist (NTRL)	1
MO/ Health Informatics	1

The identified stakeholders who participated in the in-depth interviews play a crucial role in providing optimal care to the diagnosed TB patients both at the central and peripheral levels. Therefore it is important to identify the role they play, their functions and responsibilities within the NTP. The health staff in DCCs who were participants of the study are summarized in the table 6.3 below together with their functions and responsibilities.

Table 6.3 Functions and Responsibilities of Stakeholders identified at DCC

Designation	Function and Responsibilities
Consultant Respiratory Physician Experts with necessary technical expertise and experience in providing higher level of care to TB patients.	• Provide guidance and expert opinion on diagnosis and treatment of TB patients to his subordinate medical staff. • Management of New, clinically diagnosed and retreatment cases involving taking complex medical decisions. • Management of comorbidities, complications and adverse drug reactions to Anti-TB drugs. • Initiation of diagnosis and management of drug resistant cases and severe complications of TB during hospitalisations. • Coordinate with relevant experts in managing comorbidities and special situations. Ex- Pregnancy with TB, HIV/AIDS patient with TB.

	• Provide Insight and advice in formulating policy decisions on TB patient care and preventive services at district, regional and national level. • Facilitate training activities to other health staff when required.
Medical Officer/ DCC Medical officer with basic MBBS qualifications and sometimes with a postgraduate diploma in respiratory medicine, entrusted with implementation of all aspects of TB patient management under guidance of a consultant respiratory physician.	• Manage patients with TB and other respiratory diseases and provide follow up care. • Provide counselling to patients and family members of patients. • Undertake clinical work delegated by the Consultant Respiratory Physician and collaborate in patient care. • Coordinate with other supportive health staff in the DCC to provide optimal care to the TB patients. • Coordinate with NTRL, radiological services and Central pharmacy in management of TB patients. • Carry out administrative, managerial and financial work delegated by the District Tuberculosis Control Officer(DTCO)
Medical Officer/OPD Medical Officer with basic MBBS qualifications who provide care in the Outpatient Department of the DCC.	• Provide outpatient diagnostic and treatment services in the outpatient department of the DCC. • Screen and detect of patients whom are suspected of having TB (Presumptive TB) and make necessary arrangements for definitive diagnosis. • Refer clinically diagnosed and patients with complex conditions to the Consultant Respiratory Physician.
District Tuberculosis Control Officer (DTCO)	• To oversee the case screening and diagnostic activities are in agreement with the national guidelines

Medical Officer with basic MBBS qualifications whom acts as a liaisons officer between the NPTCCD, regional administrative services, and his respective DCC.	• To ensure that all TB patients are receiving treatment and care at optimal level and in accordance to the guidelines from the DCC • To make sure that DOTS centres, microscopy centres and Branch clinics function properly and successful implementation of patient centered '*Direct Observation Treatment*'. • Responsible for proper maintenance of records and reports by the DCC • Coordinate with NPTCCD and regional level in carrying out administrative, financial and technical management of DCC.
Public Health Inspector-DCC With basic qualification of PHI diploma awarded by the National Institute of Health Sciences, who is entrusted with upholding public health standards within the program's mandate.	• Prepare quarterly reports, update treatment cards and maintain the District TB register and ePIMS • Oversee the TB case notification process between Health institutions, NPTCCD and relevant MOH areas • Carry out contact tracing and management of treatment defaulters in close collaboration with DOTS providers. • Assist DTCO in disease surveillance and TB control activities
Nursing Officers With basic qualification of Diploma from Nurses training schools under Ministry of health, trained	• Undertake enrolment of TB patients in to TB program • Maintenance of District TB register and Patient treatment files • Assist the medical officers in providing patient care

in providing patient clinical services.	
Data entry operator Person with a non-medical background entrusted with data entry and update to the ePIMS from each DCC.	• Entering of Patient level data and aggregated data from DCC to the ePIMS. • Assist DTCO and other medical staff by generating reports from the ePIMS at their request

Apart from the health care workers in a DCC who engage with TB patients as 'first line responders' would be the end users of an electronic Patient clinical record implemented at the chest clinic. At the central level in NPTCCD some of the stakeholder may not directly be "users" of the electronic system, but have major influence on the design and development of such a system. The presence of individual data of TB patients in an electronic format will change the tasks and work processes that these central level stakeholders are expected to perform.

Consultant Community Physician (Monitoring and Evaluation) based in NPTCCD central level is responsible in providing technical expertise in monitoring and evaluation of TB treatment and preventive services provided through the DCC network. Objective analysis of aggregated data from chest clinics, monitoring the TB indices in the country and in regions, identification of problems in the program and actively pursuing remedial actions are some of other responsibilities assigned to the designation.

Consultant Microbiologist is mainly based in the NTRL in Ragama and looks over the quality and efficiency of Laboratory services of the NTP. The Consultant Microbiologist provide high level technical expertise in bacteriological and drug resistant laboratory investigations for TB patient diagnosis and follow up.

The present ePIMS and its related activities are supervised by the Medical Officer in Health Informatics based at the central level in NPTCCD. The smooth functioning of the system, troubleshooting of problems in the system, coordinating with IT field experts on developing further modification to the ePIMS and other Information technology related activities in NTP are some of the functions of Medical Officer in Health informatics.

6.2. Thematic analysis of Interview data in Phase one

In phase one, thematic data analysis of all interview transcribes revealed 257 codes initially. These codes were then categorized in to 'Code categories'. They collectively gave rise to 17 Organisational Themes and 4 Major Themes.

In phase one data analysis the following Major themes were identified.

1. Primary Work Processes or Tasks
2. Users of the System and their Characteristics
3. Challenges and Constraints faced by the health staff faced in execution of their work
4. Expectations of the Users

6.2.1. Major Themes identified in Phase one

6.2.1.1. Primary Work Processes or Tasks

The major theme "Primary Work Processes or Tasks" consists of 9 organisational themes. This major theme consists of a collection of related, structured activities in a specific sequence in order to achieve a specific objective or a set of objectives in provision of care to TB patients from diagnosis to treatment completion.

The participants described their tasks in relation to providing care to TB patients and explained how the tasks of each of them are aligned in a work process so that the patient receives optimal care.

The Nine organisational themes are 'Registration of new patients', 'Patient Clerking', 'Disease Classifying', 'Investigating', 'Follow-up/Review', 'DOTS treatment', 'Treatment' , 'Transfer of Patients', 'Documentation' and 'Preparation of aggregate reports'. The code categories, organisational themes are elaborated in the following table 6.4.

Table 6.4 Organisational themes, Code categories of the Major theme- 'Primary Work Processes and Tasks'

Major Theme	Organisational Theme	Code Categories
Primary Work processes or Tasks	Registration of New Patients	Patient identification process, Unique patient identifiers, Patient contact details, Existing patient identifiers, demographic details, Next of kin information, Guardian details, MOH area.
	Patient Clerking	TB patient-case definition, Common symptoms(respiratory, constitutional, site specific, other), first visit meeting, Time Gap between diagnosis and treatment, Past history of TB, high risk patient categories, Patient hospitalization, past medical history, Comorbidities, Referral information,
	Disease Classifying	Importance of classification, Adherence to guidelines, Anatomical site, previous TB treatment, HIV status, Drug resistance
	Investigating	Diagnostic Investigations, preliminary investigations, second level investigations(GeneXpert, Line Probe assay), diagnostic investigations for special

		situations(Tissue Biopsy),supplementary diagnostic investigations(ESR, Mantoux), Radiological Investigations, Routine supportive Investigations, Special Supportive Investigations, investigation report properties, report interpretation,
	Treatment	Anti-Tuberculous drugs, Intensive phase, Continuous Phase, Treatment category, Treatment durations, adjuvant Steroid treatment, FDC tablets, Treatment dosages, Treatment interruptions, Treatment outcomes.
Primary Work processes or Tasks	DOTS Arrangement	DOTS Providers, DOTS centre, Providers role, Arrangement, assessment, Patient support, Patient Education.
	Transfer Patients	Transfer before commencing treatment, Transfer following treatment, Patient transfer documents, Transfer procedure.
	Documentation	Patient file, Patient registers, standard treatment documents. Investigation forms.
	Preparation of aggregated reports	Patient level data, aggregated data requirement, aggregated data reports

Lot of emphasis was made on work processes and user tasks during the participant interviews. They expected the proposed system encapsulate the important work processes and tasks that each user was entrusted when it came to management and follow-up of TB patients. The organisational themes are briefly described with excerpts from interviews here.

6.2.1.1.1. Registration of New patients

The point of commencement of diagnosed TB patients is to register them at the 'Registration desk'. This is mainly the responsibility of DTCO but it has been delegated to the nursing officers at many chest clinics. This is the first and foremost point of contact of a newly diagnosed TB patient. Information regarding Patient identification, demographic details and other relevant information is recorded in to the District TB register by the Nursing officer. The Nursing officer checks for the relevant referral documents or evidence for a clinical decision of enrolling the patient in to the TB program. The patient is assigned a new District TB number and a patient file is opened for each patient at the first visit. Then the patient proceeds for "Patient Clerking" with the medical doctor, mostly the MO/Chest clinic. The following are some interview excerpts detailing about registration process.

> *"Once the patient is diagnosed by way of three sputum samples and so, the patient get registered. The standard card issued at the OPD states the patient's disease classification information such as pulmonary/extra pulmonary, new or relapse, smear positive/negative etc."(Medical officer/OPD)*
>
> *"During the first meeting at registration in to the TB program, it is important to record the patient's address and other relevant contact details (e.g. partner or spouse, parents, work place, place of study, family physician) so that we can trace the patient. Recording mobile phone numbers of the patient and family has been very helpful in many settings."(Nursing officer)*

Unique patient identification is an important issue in registration and participant expressed some of their experiences in this process.

> *"NIC (National Identity card) number is required to be registered in the System. Most of the time the NIC number is missing, because patients don't accompany the NIC when they come to the clinic. When this piece of information is missed at the registration, most of the time it is not recorded*

at all. Address and telephone number is used to filter and search patients in the system"(DEO)

"The patients MOH area should be correctly identified at the registration. Sometimes the difference between two houses on either side of a street means two different MOH areas. This has happened so many times now."(Public Health Inspector)

Some important facts were also brought up such as inclusion of 'Next of kin information' and 'Guardian details when it comes to minors of age less than 18 years. This information is important in tracing the patient and this would be the only point where it is possible to collect this particular data.

"It is good to include next of kin information of patients in the record. It is vital to keep a close eye on the patient, especially during the DOTS period. So a next of kin information would help in keeping contact with the patient. When it comes to children, it's a must to have a guardian contact detail. Because it is impossible to trace out a child in a community without the parent details. It is always good to have as much as info at hand."(DTCO)

6.2.1.1.2. Patient Clerking

Once the patient is enrolled in to the program either as a new patient or a previously treated patient, he or she then proceeds to the 'Patient Clerking' stage. This is usually done by a Medical officer. It involves a Patient Interview and an examination. In the patient interview the medical officer inquires in to the patient's medical history especially regarding TB specific history, Comorbidities, significant past medical history, Drug and Food allergies, and Social history. Information gathered at Patient Clerking is recorded in the Patient file by the medical officer.

"Once a diagnosed patient is registered a file is opened for him. The patient is then clerked by the MO in the CC. We collect data such as medical and personal information of the patient. About civil status, residence and contact details, whether living with family guardian details and etc. are also included at the time of first meeting"(Medical Officer/Chest Clinic)

Participants elaborated on the information that they would associate at patient clerking and what they would like to see in the electronic patient record.

> *"The symptomatology and information like past medical history and other associated comorbidities should be in the patient file, respiratory symptoms such as Cough - usually more than two weeks, Shortness of breath, Chest pain, Haemoptysis. However in immunosuppressed and in the presence of any other risk factor, cough of any duration should lead to screening for TB. Also symptoms related to the affected system such as the neurological symptoms"(Medical Officer/Chest clinic)*
>
> *"It is very important to maintain a record of patient's weight as the patient drug dosage is measured according to weight. Weight is measured at each clinic visit. "(Medical officer/Chest clinic)*
>
> *"High risk details should also include in the system such as prison inmates, HIV patients. Risk behaviours such as smoking and alcoholism should be included. Whether the patient is a health worker is also important."(DTCO)*

Some of the participants stressed on the fact that the diagnosis to treatment gap in a TB patient and pointed out that this particular information should be included in the proposed electronic system, as it carries a prognostic value in the disease outcome.

> *"Also it is important to record the time of TB diagnosis and the time of starting TB treatment. Because there have been several studies indicating the positive prognosis when the duration is lesser. I think it is quite important. Then we can assess in which stations this is prolonged and cross check it with patient outcome."(Consultant Respiratory Physician)*
>
> *"It's good if you could find out the delay in diagnosis in this system. Time it took from onset of symptoms to diagnosis. It is a prognostic factor."(Consultant Microbiologist)*

6.2.1.1.3. Disease Classifying

It is important to classify the TB patient in terms of Anatomical site, Bacteriological diagnosis, Drug resistance and history of previous treatment as it decides the treatment modality for the patient. The process of classifying starts when the patient presents with symptoms and follows through till the patient receives treatment. Many participants expressed inclusion of a comprehensive account of the disease classification in individual patient's clinical record and a separate section that would provide the user this information at a glance.

> *"The TB patient is classified according to the anatomical site of disease like pulmonary and extra pulmonary. The patient can be classified on whether he has been treated for TB previously or not, his HIV status, and drug resistance features. These are important clinical information that must be in the system. It's better if the patient's disease classification is visible at a glance, than rather looking for it throughout the record."(Medical officer/Chest clinic)*

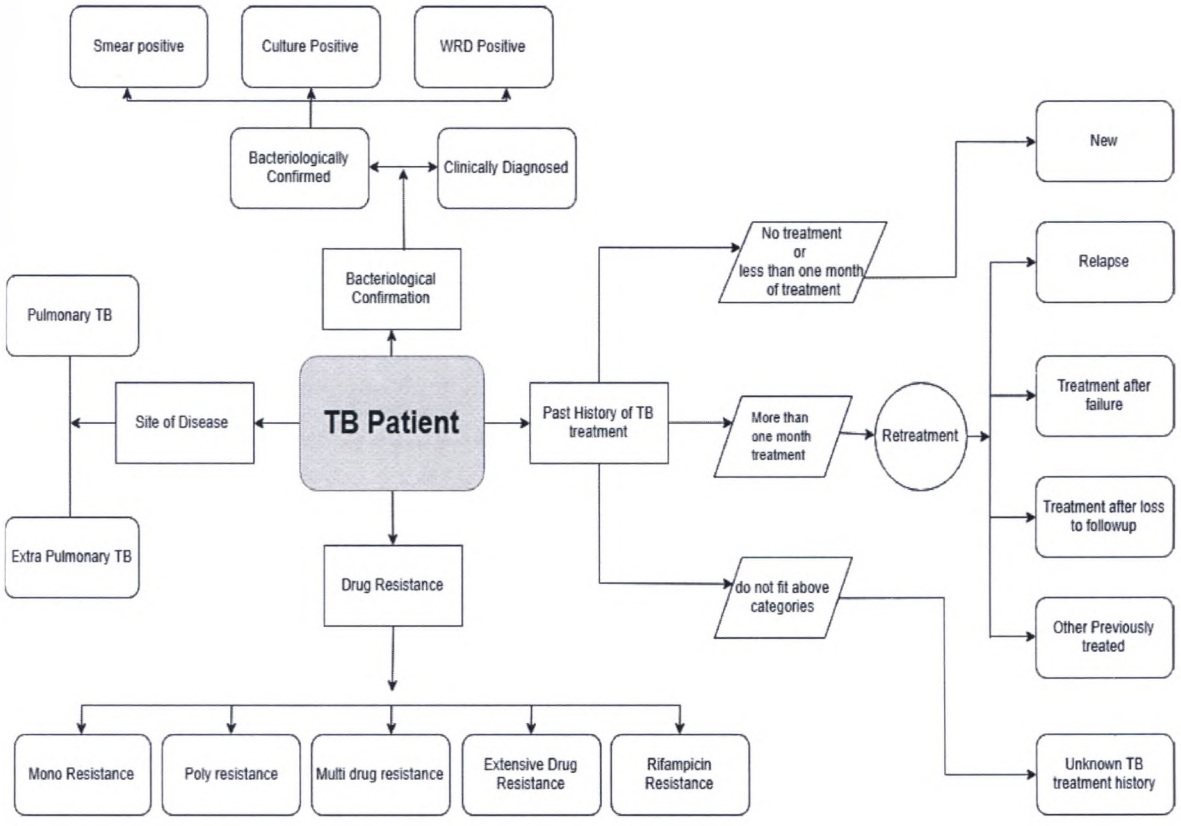

Figure 6.1 Disease Classification of Tuberculosis Patient

During the Interviews the participants stressed the fact that disease classification should adhere to the TB treatment guidelines.

> *"I think patient's disease classification is very important. You know it should follow the guidelines by the NPTCCD. That would do lot of good when treating the patient."(DTCO)*
>
> *"It will allow us sort of filter the patients also. Like we could have pulmonary TB patients in the morning and EPTB patients afterwards. When the information is easily available it opens up lot of avenues. So I think you should better go through the guideline to collect what are the disease classification."(DTCO)*

6.2.1.1.4. Investigating

Investigations are an important part of TB patient care. Diagnostic Investigations would start even before the patient is enrolled in the TB program. However participant revealed that it is necessary that the individual patient record should contain all the information about Diagnostic investigations done on the patient, indications and their results.

> *"When taking the patient record in to account, I think there should be a separate section on lab investigations."(DTCO)*
> *"It would be better if it could be according to the chronological order. Like if we are displaying results of each investigations the latest results should come first. But this may differ with each physician's preference. Some would like to view in ascending order of information and some would like to view in descending order. If you can provide the functionality of choosing between these two it would be good."(Consultant Microbiologist)*
> *"Diagnostic investigations like sputum examination, the date of collection, date of report, and serial numbers should be recorded so that later we can trace it back to them."(DTCO)*
> *"There are tests such as Xpert MTB/RI which is this WHO recommended test for early detection of TB and resistance to rifampicin, which is one of the most important drugs used in the first line regimen for treating TB. This is also done in some limited manner but this will be the future. So it's better to include these tests in your system too."(Consultant Microbiologist)*

Some participant expressed about the importance of having the radiological investigation details and Culture investigations in the system.

> *"Then there are also the radiological investigations with chest x-ray. And sometimes EPTB cases may require CT scans and culture from other types of samples. Like CSF for AFB and culture. Including x-ray information is necessary."(Medical officer/Chest Clinic)*

During the patient clerking the patient undergoes several other supportive or baseline investigations. These include investigations like Full Blood Count, Liver functions, Fasting Blood Sugar, and Renal function tests

> *"Once registered supportive investigations are done for HIV screening, FBC, FBS, Liver function (bilirubin, protein, ALT AST) serum creatinine, pre chest x-ray. These investigations are only done once and not repeated unless the patient's condition demands."(Medical officer/Chest clinic)*

6.2.1.1.5. Treatment

Treatment is mainly with short-course chemotherapy with Anti-tuberculous drugs. The treatment modality is determined on the disease type of the patient. Treatment plan is drawn up after patient clerking by the medical officer. In some complex cases the technical expertise of a consultant respiratory physician is taken. The medical officer works under the clinical supervision of the consultant. Treatment also entails adjuvant therapy with steroids in some cases, desensitization regimens and other supportive aspects such as nutrition status. Patient treatment algorithms are produced in Annexure 2 for reference.

In interviews with participants, information about treatment of TB patients were discussed especially regarding treatment phases, categories, fixed drug doses, treatment durations and treatment interruptions.

> *"Next important thing is the follow-up of treatment. Short course chemotherapy is recommended for the treatment of pulmonary TB, as well as all forms of extra-pulmonary TB in all new cases."(Consultant Respiratory Physician)*
>
> *"A TB treatment regimen consists of two phases, the intensive phase and the continuation phase. The number before a phase is the duration of that phase in month's anti-TB drugs namely isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin. There is a standard code for*

TB treatment regimens and each anti-tuberculosis drug has an abbreviation.

H R Z E S - Isoniazid - Rifampicin - Pyrazinamide - Ethambutol – Streptomycin"

"The recommended treatment regimen depends on the treatment category of each patient. There are two treatment categories, new and retreatment, and two standardized treatment regimens in Sri Lanka, CAT1 and CAT2."(DTCO)

6.2.1.1.6. DOTS Arrangement

DOTS or Direct Observation Therapy – Short course is a unique aspect in TB patient treatment. In which the Patient undergoing treatment is required to take his medicine under direct observation of a person appointed by the NTP. Most of the time the relevant DCC acts as the DOTS centre but depending on the convenience of the patient, this is subjected to change. The DOTS providers can be other health care workers and sometimes it can be a person of no medical background such as a religious leader or a community leader.

Important information regarding DOTS arrangement were discussed by the participants during the interviews.

"A separate card is issued for TB DOTS treatment where the patient is followed up for strict adherence in TB treatment by the PHI."(Public Health Inspector)

"..If the sputum is found to be positive, patient is started on treatment accordingly. He is assigned to a DOTS centre. The medicine pack for the duration of 2 months or whatever the time duration decided is prepared at the chest clinic to be sent to the DOTS provider..."(Nursing officer)

"The first two months of treatment-Initiation Phase is by the DOTS centre. The patient does not come to the chest clinic, unless he/she develops a drug side effect. The patient is followed up at TB DOTs centres for the first two months." (DTCO)

"...It should record about the details of DOTS arrangement. Details of DOTS provider, contact details. It should record how the follow up is going. Whether it is defaulted or completed. DOTS centre is allocated upon patient's preference...."(DTCO)

"The DOTS provider can be a medical or a non-medical person, they have to observe the patient while swallowing drugs daily during the intensive phase of treatment and mark the Treatment Card accordingly. Refer the

patients at correct intervals for follow up sputum examination. If the patient develops any side-effects to the drugs, or any other complication he must refer the patient to a Medical Officer in the particular DCC."(Public Health Inspector)

"The Dots providers can be from Healthcare workers in state healthcare facilities, Field healthcare workers ,General practitioners , Healthcare workers in private health facilities ,Trained community volunteers Community leaders or any person in community who can be trained and is ready to take the necessary responsibility."(DTCO)

6.2.1.1.7. Transfer of Patients

Due to various patient related factors, a patient may present to a DCC that is not the chest clinic closest to his permanent residence. In such occasions following diagnosis, the patient prefers to be transferred to a DCC that is situated in his district of residence. The transfer of patients is an important process. Participants expressed details regarding patient transfers during the interviews

"If the patient is not living in this district we call the relevant district the patient is living in and get down a number. Therefore our register and their register both have that number."(Nursing Officer)

"Ok now we have a few Patient transfers between the chest clinics from time to time, what we do in cases of patient whom have already started on treatment, we fill this form called Referral/transfer form in three copies. One is given to the patient to be taken to the chest clinic he is transferred to, one we send through post to that chest clinic. The remaining one is kept by us. Once the patient has completed treatment, the treatment outcome is informed to us through the form we sent them."(Nursing officer)

6.2.1.1.8. Documentation

Documentation is an important task that the health care workers of the DCC has to perform, especially the clinical documentation. The clinical documents expect to serve as the primary repository of information on the TB patient. In the present system as mentioned earlier the patient information are recorded in the paper based patient file. Documents regarding patient management are produced in Annexure 3.

There are number of standard formats of documents such as treatment cards and patient registers used to record TB patient information. The patient file is stored in the relevant DCC and while some documents such as the 'Follow Up card is kept with the patient. The follow

up card is the only document that the patient will have about his diagnosis and treatment details. If this card is lost then it is very difficult to locate the patient file. However since the ePIMS is employed, this task has been made a little easier, but still ePIMS does not provide the facility to search by the District TB number. The participant expressed about the aspects of documentation in the interviews.

> *"There are several documents we use for treatment of TB patient, Diagnosed TB patients records are kept in paper files maintained at each chest clinic."(Medical officer/Chest clinic)*
> *"A number of standard cards are used for TB treatment such as the 'Treatment card','The follow-up card'. Information should be taken from these cards in to relevant registers at the chest clinic, because these are important for program indicators."(Public Health Inspector)*
> *"A tuberculosis treatment card. the follow up card is kept with the patient and serves as a patients summary of information. it contains all the information that is in patients file in a summarized form. once the treatment is completed it serves as a Diagnosis card."(DTCO)*
> *"Tuberculosis Treatment Card is issued in duplicate if the DOTS provision is arranged away from the chest clinic. The original card is retained in the clinic and the duplicate is sent to the treatment centre where patient is provided with DOTS."(Public Health Inspector)*
> *"It is the responsibility of DTCO, but other staff helps him in this task"(DTCO)*

6.2.1.1.9. Preparation of aggregated reports

Aggregated reports such as the quarterly returns asses the programs impact on TB curative and preventive services it provides throughout the country. As it was mentioned in chapter 3.3 the NTP produces a number of aggregated data reports on case detection, sputum conversion, and treatment outcome and district level project management. Since the NPTCCD is the central authority and co-ordinator in providing TB Patient care and preventive services, it is required to provide these information to number other Governmental and Non-governmental agencies.

Most of the aggregated reports are prepared from the information derived from patient registries and patient files, compiled at the DCCs under the supervision of DTCO. Therefore it is evident the primary source of information is from the Patient encounters with the health care workers of the DCC. Some participants stressed on the importance of considering patient

encounters at point of care as important occasions of data collection and this importance should be reflected in the newly proposed system.

> *"It is important that the patient encounters be considered as opportunities of data collection. Therefore it is important that the individual patient record design help with data requirements at the reporting level. Therefore it is important that the aggregated data reports such as quarterly returns"*
> *"...The system should be able to generate aggregated data requirements with the data collection at point of care..."*
> *"And also when it comes to investigations we need information like number of sputum examinations what their results were, and what were the HIV screening like,. So the system should record these. then all these collected data can be funnelled down in to collective information which we can use in the reporting. And should appear as in quarterly reports"(Consultant Community Physician)*

6.2.1.2. Users of the System and their characteristics

The major theme "Users of the System and their characteristics" can be described as individuals and their associated characteristics of whom are key persons in provision of care to TB patients that are responsible in keeping a complete record of the patient's information. They are responsible in eliciting information from the patient, compiling it in a meaningful pattern with timely updates, communicating with each other and with the patient and preserving the information for future reference. Individual Patient records are kept in each DCC in form of Patient files under a unique District TB number. At the moment the files are maintained with medical information and demographic information of the patient. It is the duty of the health staff at DCC to keep these files in order.

This major theme comprises of two organisational themes and they are 'User groups' and 'User privileges'.

Participant interview shed light on the Users and their functions with regards to an electronic patient record. Table 6.5 below summarizes the interview data in this major theme

Table 6.5 Organisational themes and Code categories of Major theme-'Users of the System and their Characteristics'

6.2.1.2.1. User groups

User groups are categorisation of end users who will be using the electronic patient clinical record to create a new patient, view and update information of an existing patient. The users can be categorised according to the work and tasks they carry in

Major theme	Organisational theme	Code Categories
Users of the System and their characteristics	User groups	External Users ,Internal Users Registration desk, Clinical staff, Supportive staff, laboratory, administrative, interrelations,
	User privileges	User access levels, User accounts, Unique User ID, User profiles, electronic signature.

the management of TB patients. These can be clinical staff such as Consultant Respiratory physicians, medical doctors, and Nurses, who associate themselves directly with diagnosis and management of the patient. Then there are other categories such's PHIs, DOTS providers, pharmacist who aid in the management of a TB patient.

> *"I think the all those who associate themselves in patient files should be the end users. The registration desk will take all the necessary details about the patient's demographics, so whom ever there should be able to do the same once the electronic system comes. Obviously much emphasis has to be on the medical notes and lab investigation results. We have to decide who will be doing the entering of data"(Medical officer/Health Informatics)*

During the interviews there was a difference of opinions of who should be entering the medical data, especially information gathered at the patient clerking. While some argued that the doctor seeing the patient should enter the details in to the system while clerking and some expected a data entry operator to enter the details while looking at doctors notes on patient treatment documents.

> *"The medical data has to be entered by the medical officer in concern during patient clerking, After all that's what you do with the paper based file. I mean this is how you practice medicine, taking down notes is a part of clinical practice. It is not fair to delegate that to another person."(Consultant community physician)*
>
> *"On some days the medical officers has to go through many patients and I don't think it's practical for them to stare in to a computer screen with the patient in front of you. Since we already have the paper file, I think it's best for the data entry operator to fill out the relevant information from the file. If the medical jargon is the problem we can have a pre intern doctor to do the data entry"(Medical officer/OPD).*

Participants expressed that not all stakeholders involved with TB patient care needs to use the system, but they agreed that it's good to take everybody's requirement in designing and development of the system. End users would be the people who would be directly interact with the granular data level of the module.

> *"There are many people, whom are key players in taking care of TB patients. Their requirement of information is different. The clinical staff needs information of individual level, the patient level information. So they should be the users of this electronic patient clinic record. Because everything else is derived from the information collected from the patient"(Consultant Community Physician)*

6.2.1.2.2. User Privileges

User privileges is a collection of characteristics and functions assigned to a particular user role. Interviews revealed special emphasis in having user accounts with different user access levels.

"Now it's better if each user would have something like a user profile. Which can be password protected. The user can be identified by a user name and username should include the designation. Its good if users contact details are included in this" (DTCO).

"I think the central level should be responsible to create the user profiles and assign user roles to them. Maybe a system administrator can do that job. Each user will be defined with how much of information he can see. Now this is quite important. Patient information must be secure. I have seen even in other countries this patient information security is a serious issue." (Medical officer/Health Informatics)

Even though most participants expressed the need for User access some participants didn't view it to be of much importance. While they agreed doctor patient relationship has confidentiality, clinical documentation is still visible to any health care worker who has access to them.

"I do not think there should be a difference in what each user can view and cannot view. After all if you take a patient file today anybody can look up anything.so far it had not been a problem. There's no need to create problems. patient confidentiality is kept whatever the documents we use." (Nursing officer)

6.2.1.3. Challenges and Constraints faced by the health staff in execution of their work

This major theme encapsulates the problems and limitations that have an inefficient and a negative impact on TB management services provided. The participants felt the need that these challenges and constraints should be brought in to light and solutions were expected. This major theme consists of three organisational themes. They are 'Inefficient Work Processes', 'Documentation Issues', and 'Tracing Issues'. The interview data relating to this major theme is summarized in the table 6.6 below.

Table 6.6 Organisational themes and Code categories of Major theme - 'Challenges and Constraints faced by the health staff in execution of their work'

Major Theme	**Organisational Theme**	**Code categories**
Challenges and Constraints faced by the health staff faced in execution of their work	Inefficient Work Processes	Ad-Hoc methods, Non-compliance with guidelines, Overburdening of work, Time consuming work processes.
	Documentation Issues	Manual recording, Paper based systems, Storage of records, vulnerability of records, Communication issues, Quality of recorded data, Lack of structure, Privacy and security of Information.
	Tracing Issues	Patient Contact detail discrepancies, MOH division detail errors, contact tracing issues

6.2.1.3.1. Inefficient Work Processes

Inefficient work processes describes the work flows that have been adopted by health care workers in chest clinics that does not provide a positive outcome. Participants felt that these ad-hoc methods that have been adopted felt far from the treatment guidelines and sometimes may have an impact on the TB program indicators. They also emphasised the need to follow the national guidelines

> *"The indications and the treatment algorithms should be taken from the TB treatment guidelines. It is very important in sticking to these. Sure sometimes you have to move away depending on the patient. But a structured format would not cause any aspect to go missing. Now for an example sometimes instead of three sputum samples, some are happy with two samples. That is not right."(Consultant Community Physician)*

Participants highlighted some of the workflow errors in the interviews.

> *"Sometimes the contact screening is not carried out properly. Instead of getting down the close contacts for screening, the patient is asked whether anybody at home had cough. If not that's the end of contact screening."(DTCO)*

6.2.1.3.2. Documentation Issues

Documentation issues is about the problems and limitations faced by the staff at DCC's when maintaining documentations. Some of the problems highlighted was lack of a standard format in documenting patient information, Information failed to record, communication problems, Storage and vulnerability problems of paper based records. The participants also felt that the ePIMS helps in aggregated data reporting but not when it comes to individual patient records.

> *"In most places the quality of recorded information is abysmal. In some places when inward patients are registered, and the information in BHT is not even recorded in the patient file. In order to prevent this a format of data should be common to all the places".(Consultant Respiratory Physician)*
>
> *"There are lot of information that is not recorded electronically at the moment like patients education level and occupation details."*

"What the present file system does not contain will make the MO to miss those information. Comorbidities such as DM, CKD, CLCD, Leukaemia, lymphoma history of immunosuppressive. If these information are missed in the first visit then it's possible that information may never be recorded in subsequent visits. These information are missed most of the time."(Consultant Community Physician)

"Most of the results of lab investigations arrive late and some investigation reports have to be traced. There's a lot of reports with me of whom the patient cannot be identified. It may take a day or two. Sometimes investigations like culture is sent from the OPD using the standard card number or the OPD number. Problem with this is that sometimes the patients name is written differently in these forms, so it is difficult to trace patients with the name only,"(DEO)

6.2.1.3.3. Tracing Issues

One of the characteristic features about NTP is that the TB patients are very closely followed up and are observed in the field. They are required to regularly attend clinics with strict adherence to drug regimen. However due to many constraints the tracing of patients and their close contacts is problematic. Participants pointed out that some of these constraints were posed due to lack of information or poor organization of information.

"Tracing of patients who do not start treatment and interrupt treatment is necessary. Therefore necessary information like an address, telephone number, a close relatives contact details are quite important. Then action is taken to counsel and support these patients in meeting with the treatment. The patients MOH area should be correctly identified at the registration. Sometimes the difference between two houses on either side of a street means two different MOH areas. This has happened so many times now. So it's better if the information on MOH area is a must fill information in the new system. If it's not entered in the first meeting with patient there should be a method where the system will give notification in reminding that."(DTCO)

"There are problems with paper based documentation. There are missing details and sometimes the patients go missing. Requiring the Public Health Inspector (PHI) to trace back to patients."(DTCO)

"Patient MOH area is important as the local MOH office plays a part in the tracing of contacts. Sometimes the patients don't know their local MOH office then we have to find out."(Public health inspector)

6.2.1.4. Expectation of the Users

This major themes encapsulates the details or elements that the users would expect or anticipate to see in the electronic patient clinical information module. Especially clinical information that in the scope of their job description.

The major theme 'Expectation of the users' consists of three organisational themes which are elaborated in the following table 7.7. .

Table 6.7 Organisational themes and Code categories of the Major theme - 'Expectation of the Users'

Major Themes	**Organisational Themes**	**Code categories**
Expectation of the Users	Adherence to Guideline	National guidelines, Diagnostic algorithms, Treatment algorithms, Physician's authority, Clinical decisions, workarounds, special cases.
Expectation of the Users	Improved data collection, documentation and management	Improved data accuracy, data quality, simplified processes, treatment monitoring. Easy patient

	tracing. Improved structure of documentation, supplement existing work culture,
Efficient patient management Processes	Clinic scheduling, Improved follow up, Easy contact tracing, new information , Easy contact tracing, overdue and defaulted events,

6.2.1.4.1. Adherence to Guidelines

Participant expressed the need to enhance the adherence to treatment guidelines and algorithms in managing a TB patient. They pointed out that adoption of an electronic recording system of patient level data could be used to increase adherence to the guidelines

> *"It is good that the system be built according to the treatment guidelines and diagnostic algorithms because we have a problem in adhering to the guidelines."(Consultant Respiratory Physician)*
>
> *"Drug information such as drug combinations, dosages, should also be included. It is better when the drug is selected the dosage is automatically calculated and appear in the field. But the thing is the MO/doctor should have the power to change the drug dose according to his wishes. We can have a comments section there to include the reasons for deviation from the drug dose."(DTCO)*

However some of the participants expressed the system should allow the clinicians some space in making clinical judgements of their own.

> *"The guidelines are there to follow, but the burden of the clinical decision lies with the physician. So if your system requires strict adherence to*

guidelines then it will not be accepted. You will have a great system but nobody will use it."(Consultant Community Physician)

6.2.1.4.2. Improved Data collection, Documentation and Management

This organisational theme includes user's expectation and need of improving data collection at the point of care from the patient and improved documentation and ultimately better provision of care to the patient. The participants felt the need to have better information management to provide better service to the patient.

"It is necessary that this system you propose meets the expectation of the users. Like the doctors would expect their work to be easier and to be carried out efficiently. If the patient details are readily available they will use it. If you take other staff in chest clinic it is the same. For an example the PHI has difficult time in tracing patients. Therefore if this could help him in his day to day work. There will be no problem. Otherwise they will not use the system"(DTCO).

"Personal identification details and search ability through the district TB number is important. Apart from that OPD number should also include. When it comes to children, the guardian details should be available, because it is difficult to the PHI to trace the patients with the child's name. At the moment it is not possible in the existing system"(Medical officer/OPD)

"Sometimes the patients don't know their local MOH office then we have to find out. That takes time. If that could be automatically available it would be good."(Nursing officer)

"How patient presented to the chest clinic, was it a self-referral or referred by another institutions. This information is quite important."(DTCO)

"An electronic patient record would be welcomed among the doctors. It's better if there is less amount of typing to do and more like check boxes and menu driven. For an example most TB patients come with the same symptomatology for the most times. So it could be better if there was a way to select them rather than type."(Medical officer/Chest clinic)

6.2.1.4.3. Efficient Patient Management Process

The participants also expressed their requirement in making patient management tasks and processes efficient by adopting an electronic patient clinical information module. Mostly with easy retrievability of relevant clinical information in order to make a sound clinical judgement. They focused mainly on having a user friendly design.

"The software should be easy to operate, for an example most TB patients come with the same symptomatology for the most times. So it could be better if there was a way to select them rather than type"(Medical officer OPD)

"The diagnosis should also include the workup to exclude other differential diagnosis. Because sometimes the patients turn out to be diagnosed of a malignancy at the time of end of treatment. So it's better to mention that malignancy has been excluded. However workflow for that should be deduced."(DTCO)

Providing the ease of clinic scheduling and rescheduling was also requested by a participant during the Interviews

"Therefore the clinic schedule may differ from patient to patient. So the system should have the functionality to schedule the clinic. Like an electronic clinic scheduling for patients. I think then that would even provide a view of the number of patients expected at clinic each day."(Nursing officer)

Participant also expressed their expectation of streamlining the processes in the chest clinic accordingly with an electronic system in place

"I believe that an electronic system should streamline the activities of a chest clinic. I have lot of positivity towards such intervention. However it

should be according to the working culture of the chest clinic. Otherwise I don't think people will be interested in using such a system."(Consultant Respiratory Physician)

One participant pointed out that the individual patient level data accumulates in to aggregated data that would fulfil the overall programs data requirements. Therefore aggregated data requirements must also be taken in to account when designing the granular level data reporting modules.

"It is important that the patient encounters be considered as opportunities of data collection. Therefore it is important that the individual patient record design help with data requirements at the reporting level. Therefore it is important that the aggregated data reports such as quarterly returns. The system should be able to generate aggregated data requirements with the data collection at point of care"(Consultant Community Physician).

6.2.2. Synopsis of data analysis in Phase one

Information requirements of the stakeholders varies according to the tasks they perform within the tuberculosis program in the scope of their designation and the level of the NTP they work with. e.g. - central level, district chest clinic level.

While the information requirement of the central level stakeholders were aggregated reports the clinical staff at chest clinic were more concerned of the patient level data. However stakeholders such as DTCO and PHI had equal interest in having patient level and aggregated data in an electronic system.

Even though only a few had working experience with electronic patient record system, participant had a general understanding about the usefulness of such a system and the lapses of the current system.

In the interviews with participants described the tasks and work processes and occasions of deviations from the standard flow in managing a TB patient, the challenges and constraints, and what they expect the new systems to do.

The interview data gave rise to 4 major themes, they are 'Primary work processes or Tasks', 'Users of the system and their characteristics', 'Challenges and constraints faced by health staff' and 'Expectation of the users'.

Participants whom operate at the chest clinic level came up with many new data elements to be included in the patient record.

Participants also stated that although the data collected from the patients is important to all stakeholders, not all of them have to be end users of this module.

However there were disagreements between various participants about the user roles and access levels,

6.3. Translation of Interview Data to User Requirements

Information gathered from in depth interviews conducted with participants, workflow observation and study of relevant documentation, were translated in to user requirements in the table below by enriching the conceptual level statements made by the participants in to implicit and relatively detailed requirements with implications on the design of the electronic patient clinical record. These translated user requirements are summarized in the table 6.8 below.

Table 6.8 Summary of User requirements

Themes or Organisational theme concepts from which the requirements were derived from	**Elements\ feature\ functionality**
Registration of new patients	Capture patient registration information Demographic details- Name (full name, Last name with Initials),Sex, Age/Date of Birth, Nationality Contact information- Permanent address, Telephone number (Mobile/fixed), Next of Kin information/ guardian details in case of a child.

	Provision to register using the NIC number/ Personal health number Assign Unique patient identifiers District TB number, OPD standard card number Register MOH area of the patient Search whether the new patient is already in the system, if already existing show patient list to allow update of patient information. If not in system move to the program stages.
Patient Clerking	With standardized data fields for capturing and where possible with probes or reminders to capture or ask about Automatically appear the clerking MOs name in the patient record with date and time of clerking. Clinical history including presenting complaints (common respiratory symptoms/ constitutional symptoms/ and systemic symptoms.) Physical examination details Past medical history/comorbidities(Diabetes Mellitus, COPD, BA, HIV, Others, specify) Allergic history Drug reaction history Height, Weight and Body Mass Index Disease classification parameters (Anatomical site, bacteriological, previous treatment history) Date of presentation, Date of definitive diagnosis.

	High risk categories Patient HIV status whether on ART or CPT
Investigations	<u>Diagnostic investigations</u> Date of Collection, Sample collected, date of results, Serial number, results, and interpretation should be captured. Sputum smear microscopy, sputum culture, WRD (Gene Xpert, Line probe assay) <u>Supportive Investigations</u> Chest X-ray, Fasting blood sugar, Full blood count, Serum Creatinine, Liver profile(S. protein, AST,ALT) HIV screening details. Integration of laboratory information Upload images of chest X-ray
Treatment	Chosen regimen, treatment phase and duration Date of commencement of treatment Number of Fixed Dose Tablets and dosage of Streptomycin
DOTS treatment	DOTS provider name, category contact details, treatment progress, drug side effect details.
Follow-up	Scheduling of clinic visits for follow up with date suggestions according to guidelines.

	Patient complaints, details of drug reactions, treatment interruptions should be captured System should assist by suggesting tasks(repeat investigations)
Contact screening	Capture information regarding screening of close contacts Number of contacts screened, outcome
Sputum Conversion	Capture details of sputum conversion, plan of treatment.
Treatment Outcome	Details of treatment outcome according to TB guidelines

6.4. Prototype and its user interfaces

The interview data analysis of the first phase revealed the user requirements of the stakeholders in the NTP concerned with diagnosis, treatment and Follow up of TB patients. The design was done using HTML, PHP and CSS programming languages. The end users of the system at chest clinic level who are capturing data at the chest clinic using this module are Consultant Respiratory Physicians, Medical officers, DTCOs, Nurses and PHIs, User roles are defined for each User group with different access levels. Some sensitive information like HIV screening reports and personally compromising data remains hidden from unauthorized persons. All users are required to have a specific username and password for log-in to the system. User roles and functions are illustrated in the following figure.

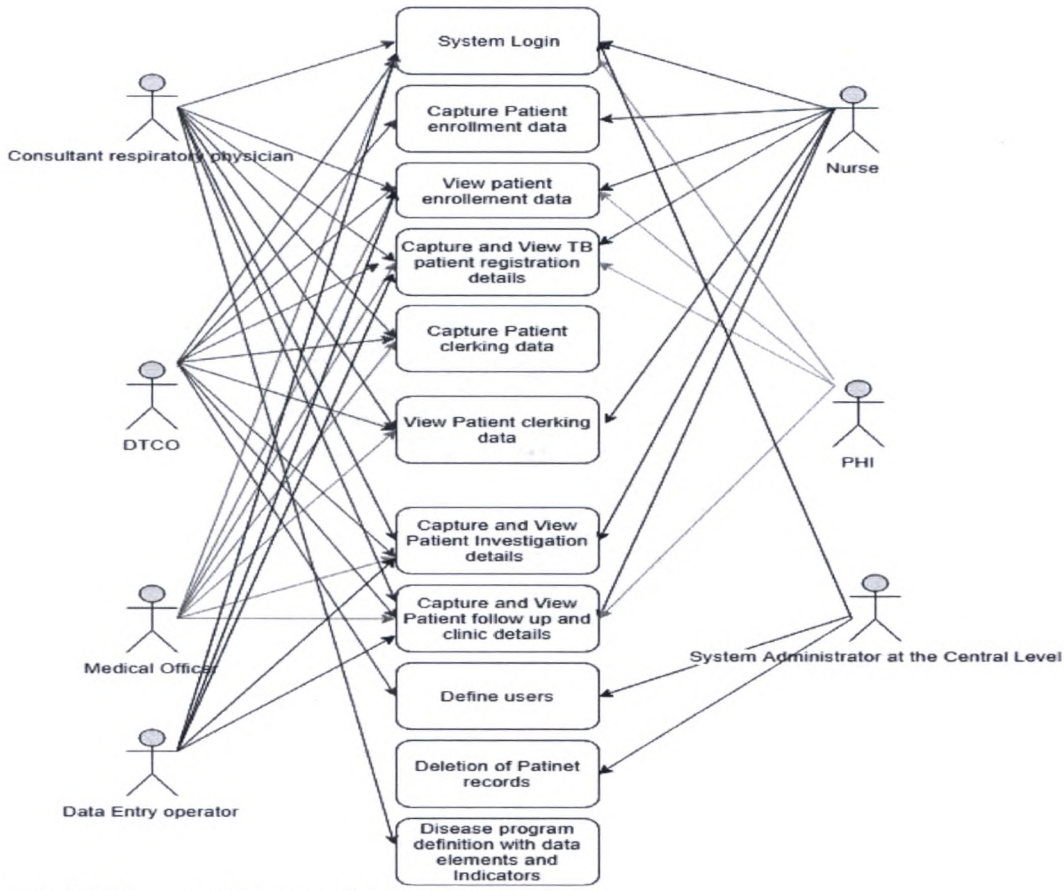

Figure 6.2 Use case diagram of the prototype

The screen shots of the login screen and the user dashboard is produced here in figure and some more are produced in Annexure 4.

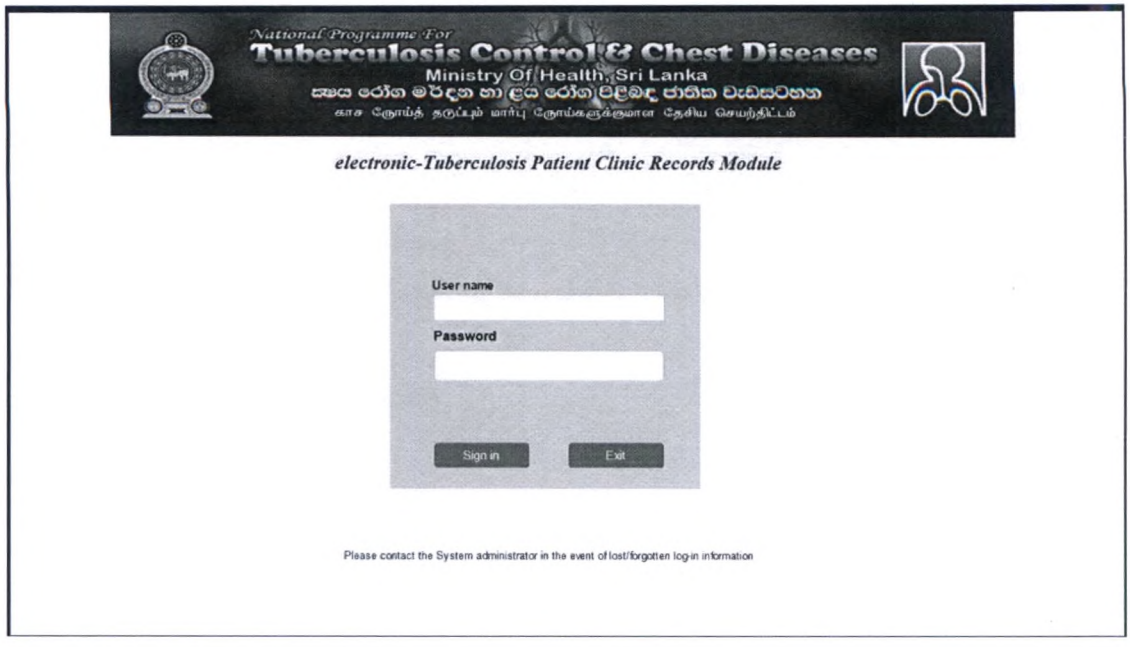

Figure 6.3 Log-in screen of the prototype

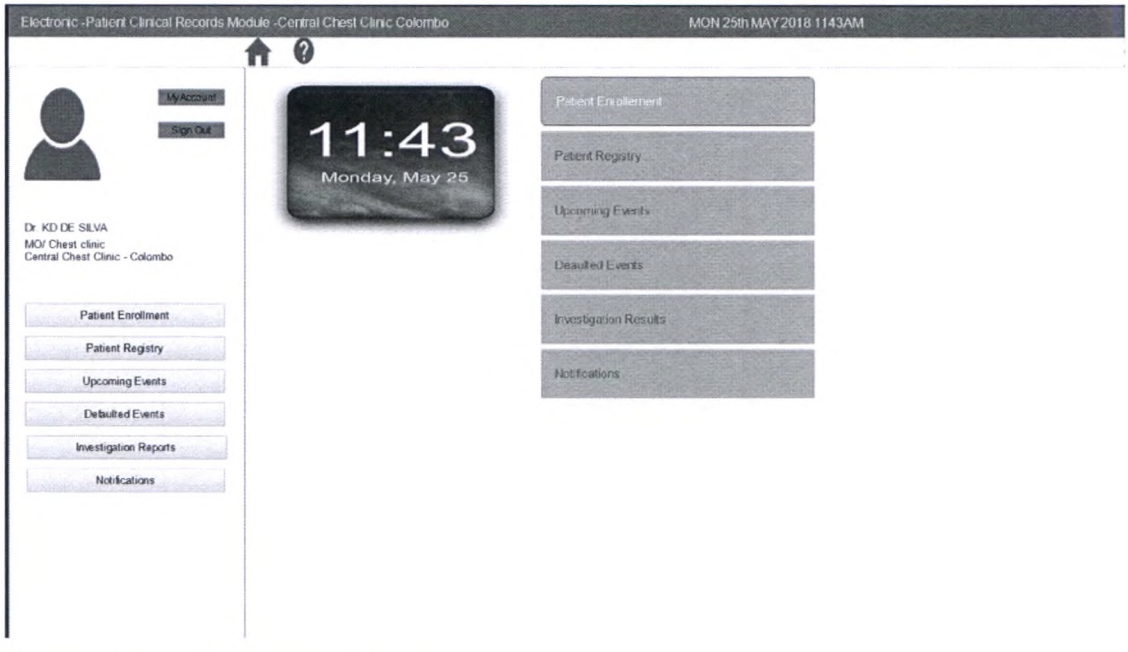

Figure 6.4User dashboard of the prototype

6.5. Thematic Analysis of Interview data Phase two

In phase two, following the introduction of the prototype to the participants, thematic data analysis of all interview transcribes revealed 121 codes initially. These codes were then categorized in to 'Code categories'. They collectively gave rise to 10 Organisational Themes and 3 Major Themes. Post evaluation

In phase two data analysis the following Major themes were identified.

1. Feed back
2. Concerns in Implementation
3. Further Improvements

6.5.1. Major themes identified in Phase two

6.5.1.1. Feed Back

The Participants who were given the opportunity to go through the prototype gave their feedback regarding the solution. While most were positive about the endeavour in general but did not give specific feedback on the system. However some participant expressed some negative aspects also. The organisational themes and code categories are briefed in the following table.

Table 6.9 Organisational themes and Code categories of Major theme 'Feed Back'

Major Theme	**Organisational Themes**	**Code Categories**
Feedback	Positive Feedback	Standard structure, good layout, improvement, good start, easily understood, data elements of aggregated reports.
	Negative Feedback	Time to get used to, lack of personalisation, not comfortable, missed data elements, too much to type.

	Less doctor patient interaction
Neutral Feedback	Test against real situation, variability in success, clinical orientation, implement an already tested system,

"I think its difficult to just label something good or bad just by looking at this prototype. I mean we wouldn't know how it would actually work in the real situation. But by the looks of it, it seems complete. I do appreciate that this will provide some form of standard to patient information recording. the amount of data to be recorded can be changed along the way. i have a good feeling about this."(DTCO)

However some were eager about adoption of an electronic system.

"I have heard about systems like this in other countries. It's good that we are starting to move that way. Afterall sooner or later we must be having this kind of electronic information. I like the fact that you have taken the important information like disease classification, treatment details and allergy details to the top. i believe it would be complete it would be better if we could have the durations up there too."(Medical Officer/chest clinic)

Participants were also concerned with fulfilment of their information requirement. So they particularly based their feedback on the fact whether those have been included or not.

" have you included all the data fields in the quaterly report in to this system. Like I have told you before this the point of contact with the opatient and it's a must that we have the minimum of reporting data collected. Theres no use of this system if the aggregation is not happening. personally

i believe this should start from the presumtive TB patient."(Consultant CommunityPhyician)

"As for the registration purposes I believe all information have been included. I think this will take off the load of work from our shoulders. It's really cumbersome when you have to give through all the patient files just to look up a minor detail or attach a lab report. Sometimes when you can't find a file people just give up looking for it. This looks good to me. The patient investigations are presented in a good manner. It gives a good way how the patient was diagnosed."(Consultant Respiratory Physician)

Some participants gave negative feedback on the solution, however most of it were not related to the prototype but a generalized feedback on the endeavour.

6.5.1.2. Concerns in Implementation

Concerns in implementation majorly describes about the issues and concerns that the participants expressed that are related to the successful implementation and adoption of the electronic patient clinical record to the existing work culture in the NTP. Many expressed that in order to see this endeavour become successful there need to be changes implemented prior to the implementation of the electronic system. They expressed that it is necessary to have the relevant hardware requirement and infrastructure in place. These ranged from supply of Computers and networking equipment to having a continuous supply of electricity. The table 6.10 below summarizes this major theme and its organisational themes.

Table 6.10 Organisational themes and Code categories in Major theme – "Concerns in Implementation".

Major Theme	**Organisational Themes**	**Code Categories**
Concerns in Implementation	Management and Leadership	Clinical champion, Better Coordination, prompt response, leadership, Authority, adaptability, Planning for crisis, Plan for further improvements.
Concerns in Implementation	Facilitating Conditions	Hardware Concerns, Technical Staff, breakdowns, System failures, Accidental erasure, Electricity, net connectivity, Training.
	Change management	Duplication of work, Appropriate transition time, guidelines and documents, Defined User roles

The participants pointed out that it is necessary to have a senior person in each chest clinic to provide leadership insight in the implementation process. They had lot of concern regarding the implementation of the system and how the impending transition from paper based to electronic can be smoothened.

"We have a sort of job hierarchy in this place, just like in a ward at a hospital. If you can get a consultant chest physician or some other senior person to direct the implementation in the chest clinic, then it will succeed. Then everybody will have to use the system. If it gets rejected at the top it's bound to fail."(Consultant Respiratory Physician)

"I think some technical person should be around during the first few months. If we know that the problems we get can be sorted quickly then it will be helpful in using this system or at least there should be some kind of a hotline to call. Our experience with health ministry hotlines is that they don't work"(Medical Officer/health Informatics)

"You have to come up with a plan to identify the challenges ahead and how to tackle them. Just because the system is nice, it's never going to be accepted. For that you have to manage these people and their concerns. For that you have to have a plan. The problem is will this ever happen."(Consultant Respiratory Physician)

Lot of emphasis was made on management of the "change' in work processes and work culture that will happen once the system is implemented.

"So we will have to work with both the paper based file and the new system at the same time for some months. This will over burden the staff and there will be lot of resistance. And maybe how they work will also have to be changed. So somebody has to step in and guide them. The central level will have to come up with support to the chest clinic staff."(Nursing officer)

"Not all these people work here have the ability to work with a computer. So they might need some kind of a training program on the use of computers. Anyway you will have to train them on the new system."(Public Health Inspector)

6.5.1.3. Further Improvements

Participants also expressed views about what further additions that are necessary for the electronic patient clinical record to be a comprehensive one. The organisational themes and code categories are illustrated in the table 6.11.

Table 6.11 Organisational themes and Code categories of the major Themes - "Further Improvements"

Major Theme	**Organisational Themes**	**Code Categories**
Further Improvements	Integration with Health Information Network	National health Information backbone, integration with Hospital Information systems, Data sharing, Integrate with other disease programs.
	Prototype improvements	Notification process, Access to MOH, presumptive TB patients, Link up with TB patient details with Lab and drug stores, patient information portal, training portal,
	Interface design revisions	Help information, Personal preference, Links to guidelines, inclusion of e-signature, acceptability, usability.

Additional Modules	Other Respiratory disease included, TB notification process, Contact tracing field level data capture. Clinical decision support.

The participants also elaborated on further improvements that can be incorporated in to the design.

Analysis of interview data revealed that participants wanted the proposed system to be interoperable with the National Health Information System.

> *"....Now in Ragama National Hospital for Respiratory Diseases has a functional Hospital information system, I believe our system should be able to share information with that one and vice versa. In the large picture the patient data we have, should be merged with the National health information backbone in future. I maybe talking about the distant future but we should have it built in to our system."(DTCO)*

Improvements to the functionalities of the prototype was also mentioned by the participants during the interviews.

> *"It is good if we can have this notification process incorporated. We need this as it is necessary track down patients in their MOH areas. This will help us to work in better coordination with the MOH and his staff." (DEO)*

> *"I think the patient lab investigation details and x-rays should incorporate automatically in to the patient record. This is of course after the Medical officer has validated it"(Medical Officer/Chest clinic)*

Therefore it is evident that the users expect much functionality that would solve in their challenges and constraints of day to day work.

The participants also mentioned that it would be better if the information would exchange between disease programs with similar interests such as the NTP and HIV/AIDS prevention program.

> *"It would (be) nice if we could collaborate at information level with other programs like the HIV/AIDS control program"(Public Health Inspector)*

7. Discussion

7.1. Stakeholders and their Influence on Information Requirements

Management of TB patients within the NTP is unique in that the patient is closely monitored while the treatment process is underway. The program has to co-ordinate with multiple players in provision of care and these players can be of with a medical background or not. Therefore it is important that proper communication is maintained between the stakeholders. It is also necessary that processes such as 'Contact Screening' be carried out with collaboration between the local MOH and PHI. In the central level the stakeholders have an interest over aggregated data and hence Performance indicators of the TB program. Therefore it is evident that provision of TB related services in both curative and preventive arms, are highly 'information- driven' process.

The information requirements within the stakeholders in the clinical staff in the chest clinic was observed to vary with the designation or Job description. The medical officers and the consultant chest physicians were interested in capturing patient clinical data in to a user friendly information structure. They expressed that they need the patient level information to be easily retrievable with all the important clinical data to be presented in a clinically friendly manner enabling the clinicians to make an informed decision. The PHI has the responsibility in tracing the patients and their close associates for screening purposes. Therefore the PHI's information needs are regarding tracing of the patient's whereabouts. The stakeholders in the central level at NPTCCD are more concerned with aggregated data reporting, which consists of information like TB indices, prevalence and incidence rates.

The stakeholders had a common consensus that each patient encounter can be considered as an opportunity to collect data. So it was necessary that the electronic patient clinical record module be designed to cater the information needs of all stakeholders in TB program. Aggregated data such as case detection rates, and Treatment outcomes should be derived from the case based data. It is necessary that in design and development of the electronic patient clinical record, this information requirement is acknowledged.

DTCO plays an important role in the NTP. He is the liaisons officer who co-ordinates between the central NPTCCD, Provincial and District health services, Hospital network in the district

and the DCC. Apart from the administrative, and supervisory functions of the DTCO, he is also expected to function in a clinical role in patient management. DTCO needs to have patient level data including clinical information and other demographic data. He also requires aggregated data pertaining to his district in order to assess the performance of the relevant DCC. The DTCO is also responsible for preparing the quarterly reports to the central level. Therefore the DTCO is the point at which the individual patient data gathered at the DCC is aggregated. It is necessary to identify the central role a DTCO has to play in terms of designing, development and implementation of an electronic patient information repository.

7.2. Patient level clinical data recording and reporting: present situation and Users expectations of the new system

As it was mentioned earlier the primary source of Patient level data recording is in a Paper based file system. Each registered patient has a patient file identified by a unique identification number- "District TB number".

Interview data and observations made at the DCCs revealed many deficiencies in the present paper based system. The NTP uses a standard set of documents when it comes to recording of clinical data such as the Tuberculosis treatment card. Unstructured recording of information, illegibility, inadequate data recording, lack of validation of information, difficulty in retrieving information, storage and other logistics problems, are some of the more generic inadequacies identified in the NTP. However these are common in place where paper based recording system is used for information management.

Participants also pointed out that there are some specific issues pertaining to the recording and reporting in the NTP. The commonest confirmation of diagnosis of TB is by Sputum smear microscopy in which three samples are observed for acid fast bacilli. Patients whom are very suggestive of TB clinically are investigated at the Out Patent Department of DCC and samples for investigations such as Sputum culture, WRD are sent prior to diagnosis. These investigations takes time for the results to be issued. Tracing the investigation reports to the relevant patient files have been a painstaking process and leads to many errors.

Information that are important in tracking down patients are quite often not recorded in the system. Such as the next of kin information, a second phone number, the NIC number.

A lack of structure leads to loss of important pieces of clinical information as well. Occupational and risk behaviour history is not recorded most of the time.

The ePIMS employed at the NPTCCD is expected to generate aggregated data that is required in the form of quarterly reports. However the system that is employed is actually a hybrid system, where the electronic system is used in addition to the paper based reporting formats. This parallel use of electronic and paper based reporting formats have actually created inconsistencies between the two systems. The inconsistencies may vary from slight change in a number to entire documents be missing. This leads to overburdening of work and confusion among the stakeholders. Because of this issue the paper based quarterly returns and registers remain to be the main source for information management.

7.3. User Centered Design approach and Action Research methodology

Involving the end users and other stakeholders who are able to influence the system or be influenced by the system, from the earliest possible time in the design and development is beneficial. This is the fundamental feature of User centered approach in design.

The adoption of a new system in any organization entails 'change' in the working culture and work tasks of its workers. It is the same in health care institutes. Interviews with the study participants revealed that adoption of a new system might actually create some challenges and constraints in terms of implementation and successful adoption of the new electronic module. These issues were regarding the change in interaction with the patients, the need to acquire new skills, the concerns regarding clinical outcome and friction among workers. However UCD approach provides avenues to incorporate the stakeholders from the early stages of the design and development process of the module. Thereby it gives the stakeholders a sense of 'ownership' of the outcome, rather than considering the endeavour as an outside influence. The hierarchical nature among the stakeholders in NPTCCD, which is commonly seen in health care institutes in Sri Lanka poses some challenges in adopting a UCD approach. The central level stakeholders influence power and interests in the electronic module for patient based data varies with that of the stakeholders at DCC. This has a significant impact on the design outcome of the proposed system. Therefore proper mediation between all stakeholders is necessary at every step of the iterative cycles of UCD approach. However participant interview data analysis shows that the end users requirements should receive priority and

precedence in the design process in order for the electronic patient clinical record module of the ePIMS to be successful.

It is evident that the UCD approach adopted in designing an electronic patient clinical record module for the NTP enabled to understand the organisational, user behavioural, and sociological factors that would affect the successful implementation and adoption. Thereby improve the overall quality of patient care and its documentation.

Action research methods were briefly explained in 6.1.1 and it is necessary to appreciate that the aim of Action research is to build scientific knowledge while attempting to find practical solutions to problematic situations. It is an iterative process of planning to solve problems, coming up with solutions, learning from the implemented solutions and outcomes and reflection upon the existing knowledge with the new information. This cyclical process enables better understanding of the problem and solution. It is useful in considering complex programs such as the NTP with its multiple stakeholders with different information demands and outputs. It was discussed earlier about the complex nature of NTP in terms of its functions and interactions with local and international agencies. Action research provided a good method to understand the intricacies and complexities involving the adoption of an electronic system to manage patient level data in day to day clinical practice. UCD also follows a cycle of planning, designing, and evaluating of design until the optimal design is reached. It also involves fa firm grasping of user requirements, designing to meet those requirements and testing in terms of usability and acceptability to the end users. The study also infers that the iterative nature of UCD process and action research compliments each other and provides better understanding about the problem domain and different variables at play.

7.4. Users evaluation of the Prototype and Integration with existing ePIMS

In-depth interviews was used to evaluate the participant's perceptions about the designed prototype. The in-depth interviews allowed the participants to freely express their opinions regarding the solution that was presented them. All of them appreciated the fact that it provided a structured format for information gathering and presentation, which was one of the major concerns regarding the practices at chest clinics. This provision of structured format enables more accuracy in data collection. It would result in all the important pieces of information to be gathered and not be missed in the process of information gathering.

But some clinicians pointed out that a strict enforcement of a structured model for information gathering may be a hindrance. Patient presentation and the course of the disease of a patient is does not always follow a strict pattern. There is considerable variability on how disease would progress in patients. While it is possible to observe a common disease pattern in most individuals, there may be Patients with rare presentations, rare complications and disease progressions. It is important that this variability be observed in designing an electronic patient clinical record for any speciality in medicine. Some participants expressed concern that in an event where the paper based documentation had ceased to exist, and the electronic format is the only form of clinical documentation, strict enforcement of a structured format would affect the management of a patient with rare forms of TB disease. Therefore it was clear that the design of the module would need to incorporate the fact that there can be altered pathways of disease course. Some of the strategies that can be employed is to allow the users to record additional information by way of text input fields. The clinic follow-up may be longer and more frequent of these patients. Therefore by allowing the users to override the system suggested dates for clinic follow-ups can accommodate tailored clinic schedule to the patient. Usage of Data capture aids such as 'Favourite lists' can also be employed to harness the disease progression variability in the electronic module.

The participants expressed that this electronic module would improve adherence to the TB Treatment Algorithms and Guidelines as expected by the NPTCCD. It was expected that improved adherence to guidelines results in improved patient outcome. However it is important to recognise that treatment algorithms and guidelines are subjected to change from time to time. Newer investigation techniques and treatment modalities are expected to come in to play with revision of guidelines. Therefore it is important that timely revision of the electronic module is also necessary when it comes to revision of guidelines. It is necessary to appreciate the fact while the core functionalities such as history taking, examination, and disease classification would unlike to be subjected to change, some other aspects of the design of the electronic module would need to be modified.

It is evident that an adoption of an electronic patient clinical record module or an EHR would enable a health care program such as NTP to collect lot of data from patient encounters. Even though most of the data may not be directly required to manage the patient or to fulfil

aggregated reporting needs, but might serve an academic and research interests. A comprehensive data repository of TB patient data may provide important insights in to aspects of TB patient's adherence to treatment and advices given, treatment protocols, follow-up arrangements, and efficiency of the NTP's workforce. A design with overcrowded data elements in the module would result in the users to spend more time on data capturing rather than attending to their work. This would actually decrease the usability of the system and leads to user dissatisfaction. Therefore it is necessary to prioritise the data in to required and optional during the design process with technical expertise from the relevant stakeholders.

Evaluation of the prototype prompted the participants to express needs in terms of improvements in the design. Their suggestions on the design of the prototype varied from finer details of font sizes and colour selections to inclusion of clinical decision support systems. For an example, the users wished to see that once the investigations are ordered through the system, the results to appear in the individual patient record rather than a separate report. This sort of requirement would fall within the realm of a Laboratory information management module. Though this level of functionalities would actually lessen the burden of work on the staff, it is beyond the scope of this study. Therefore suggestions of this nature were considered and note to be future work and improvements.

A system's graphical user interface design quality affect implementation outcomes. Participants expressed concerns about the challenges in implementing the electronic module in to the existing work culture at the chest clinics. While much emphasis can be taken to design the module to align with the existing work processes and preferences of the end users, it is inevitable that its adoption would result in some 'change'. While most were enthusiastic about the endeavour, they expressed that some users may feel otherwise. Positive user perception is necessary for the successful implementation and adoption. It is necessary that the users requirements are met in the design of the system while fulfilling the organization's needs. Revisiting the design process several times to get the user requirements correctly even during implementation would result in a better outcome. Piloting the electronic module in a carefully selected chest clinics before country wide adoption would give opportunity to revisit the design process with a better understanding of how the users work with the new module. An

optimization strategy needs to be identified and adopted. However this may be hindered by time and financial constraints.

As mentioned earlier, the existing ePIMS in the NPTCCD based on the DHIS 2 platform concerns mainly on the aggregated data reporting conforming to the quarterly reports of the NPTCCD. It also has a tracker module developed to capture patient level data that is necessary to fulfil the data requirements of the aggregated reporting. There is a limited amount of data pertaining to clinical management of patients. Even though there was a potential to use the existing tracker module of ePIMS to develop in to a comprehensive clinical record, the user's expectations are beyond its capabilities. For an example, the users expected to search for patient details across all patient registry databases to find out whether the patient had been registered earlier. This functionality is difficult to achieve in the present ePIMS. The replication of complexities in work processes and task carried out in the chest clinics in clinical management of TB patients in the DHIS 2 (version 2.29) tracker module in its present state would have been quite challenging. But use of Free and Open Source software are beneficial in the resource limited setting NPTCCD, Sri Lanka. It enables easy configuration of data elements, indicators and reports which is best suited for aggregated information management. It enables validation of information at data capture, reporting in a pre-defined structure, presentation of Data in graphs, maps, and tabulations in user defined dashboards. Analysis of information according to the wishes of the user. In order to achieve the user requirements, I as the investigator perceived that the best approach would be due to design an external web application. The proposed user interfaces for a web application designed enabled me to thoroughly asses' user's requirements.

However for the purpose of translation of granular data to aggregated data, DHIS 2 platform would be a good option since it is already employed in the NTP. There are literature in which such an approach had been adopted in health programs for longitudinal care of chronic disease patients. The Ministry of Health of Bangladesh had employed a DHIS 2 based health information system since 2011 and Bangladesh's NTP had employed a web based patient management tool -'eTB Manager'. Interoperability between these two systems was achieved by way of a web application programming interface using hypertext transfer protocol ensuring

flow of data from one to another[69]. However it is only the summarized data that is being exchanged here.

The same model could be adopted to achieve interoperability between the electronic patient clinical record module and the ePIMS. The fact that DHIS 2 embraces to be a platform that can aggregate information from contrasting systems[70], enables linking up the electronic module with the ePIMS. The basic outline is illustrated by the figure 8.1 below. This proposed architecture would allow high level interoperability that will guide the NPTCCD to have efficient, accountable and transparent data flow which will lead to improved quality of clinical data.

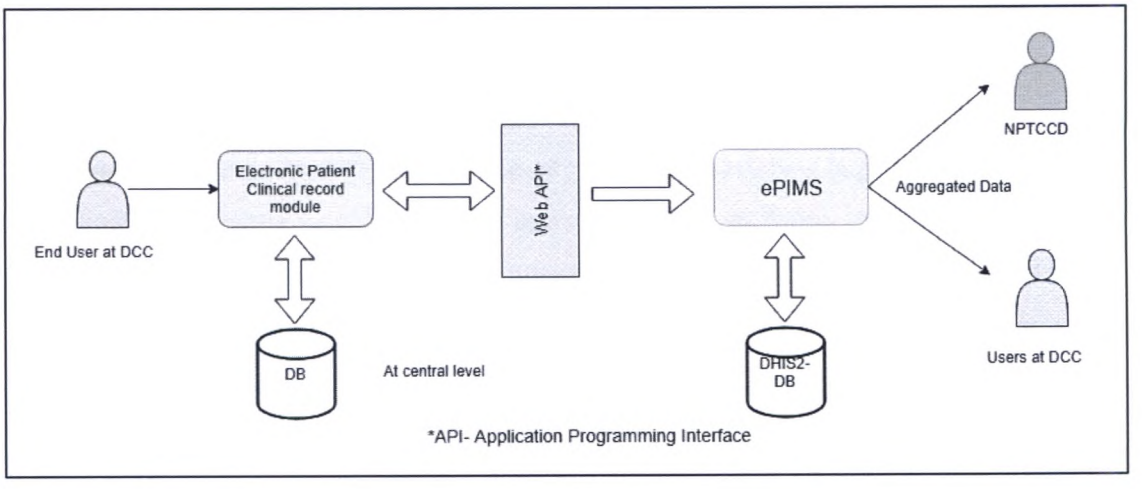

Figure 7-1 Proposed architecture to link up the electronic patient clinical record and ePIMS

8. Conclusion

Adoption of an electronic patient clinical record linked with the existing ePIMS at NPTCCD for diagnosed TB patient's clinical information is an important and a beneficial improvement in provision of quality care to the patients. The aim of this study was to design an electronic patient clinical record module to the ePIMS by identifying key stakeholders who would influence or be influenced by such a module and to identify their expectations in such a system.

The study revealed about the different critical stakeholders, their influence and the role they would play in terms of patient management. It was revealed that each stakeholder's requirements and expectations in information management was different and dependant largely upon the role they played in the NTP. It was revealed that not all stakeholders would be end users of the system. Those who directly involve themselves in providing patient care and preventive services would be the end users of the system. A user centered approach was adopted to understand the information requirement complexities that are associated with the services they provide.

Data gathered from In-depth interviews in the first phase of the study in order to identify the user requirements revealed that participants focused on four main themes. They were 'work processes and tasks', 'users and their role in the system', 'challenges and constraints in their work' and 'user expectations'. With the user requirements gathered a prototype of the proposed module was designed and evaluated for user satisfaction. Users perceived that the designed prototype was a useful tool for day to day use. However they were concerned about the proper change management required to make the endeavour a success. It was also noted that proper integration with the present ePIMS would result in improved quality of data in terms of accountability, efficiency and transparency of information flow.

The study can be concluded by saying that a user centered approach from early in the design process would enable better understanding of the organisational, behavioural and sociological factors surrounding an ambulatory care program for chronic disease. It would enable the users to work closely with the designers in designing and developing a more usable and a satisfying electronic patient clinical record module for vertical programs of ambulatory care.

9. Limitations, Recommendations and Future work

9.1. Limitations

Limitations were observed in terms of the study design and the scope of the project.

In this study data was collected from central chest clinic and DCC-Galle. It is possible that the DCC staff in other districts have additional requirements. Especially in the under-developed districts of the country. These were not included in the study due to time constraints.

Some participant expressed to have some functionalities that would be better come under other modules like Drug stock management and laboratory information management systems. Some participants required the TB patient notification system to be included where all the MOHs would have access to the system in patient and contact tracing. However this was beyond the scope of this project. Identified limitations were excluded from the design phase of the project and recorded to be used in future implementations.

9.2. Future Work

The application proper has to be developed and properly implemented in the NTP

The electronic patient clinical record would benefit from supplement modules such as Laboratory Information Management System and a Drug Stock Management System. Introduction of such modules would contribute in streamlining and automating Patient investigative processes and drug prescription.

A clinical decision support system would help the clinicians to determine best course of management for the individual patient.

9.3. Recommendations

The study provided evidence that stakeholders of provision of TB care to the patients, have unique requirements that stems from the intrinsic complexities of the National TB control program. Therefore a tailor made solution was required to cater to their demands. It was revealed that user centered approach adopted early in the design process was beneficial in identifying their complex user requirements and to come up with the most suitable design for the electronic patient clinical record module.

Despite the fact that the stakeholders were much enthusiastic about the module, some expressed concerns in adopting it in daily practice. However most of these concerns would not have been raised if they were allowed to use the prototype for a considerable length of time. This was not possible due to time constraints of the research project.

The study also revealed important information about implementation process. It was evident that once the prototype is developed, it should be piloted in a suitable clinic setting for testing purposes. This will reveal information about the usability and further improvements.

This study revealed important findings about designing an electronic patient record in an ambulatory care setting such as involvement of end users early in design process, identifying the complexities of the tasks and processes, the work culture of the organization and the challenges they face in provision of care . Improvement in ambulatory care allows the patient to receive treatment in an environment where he is comfortable and convenient to him. It reduces the burden on hospital resources in providing in ward care. Further research in this area is recommended.

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12.Annexures

Annexure 1- Ethical review documents, Consent and Information sheets

Ethics Review Committee- Post graduate Institute of Medicine Permission Letter

ETHICS REVIEW COMMITTEE
POSTGRADUATE INSTITUTE OF MEDICINE
UNIVERSITY OF COLOMBO, SRI LANKA

29.01.2018 *Ref No: ERC/PGIM/2018/15*

Dr. Akhila Rakshitha Wimalasundera
47B, Hirimbura Lane,
Galle.

Application Number: ERC-PGIM-2018-15

Title: A Patient Clinical Record Module for Current Electronic Tuberculosis Information Management System: An action research

Investigator – Dr. Akhila Rakshitha Wimalasundera, Trainee (MSc Biomedical Informatics)
Supervisor – Dr. Roshan Hewapathirana (MBBS, MSc (IT), SCJP, SCMAD, MIEEE) & Dr. Kanthi Ariyarathne (MBBS, MSc, MD)

The ERC/PGIM has reviewed the following documents submitted by you.

Document	Version No.	Date of Submission
Information sheet & Consent form-English	1.0	02.01.2018
Information sheet & Consent form-Sinhala	1.0	02.01.2018
Information sheet & Consent form-Tamil	1.0	02.01.2018
Study Instrument-English	1.0	02.01.2018
Project protocol	1.0	02.01.2018

The ERC/PGIM at its meeting held on 15.01.2018 has reviewed your protocol and decided to exempt it from review for the following reason.

1. Not collecting personally identifiable data

Please note that this exception is pertaining to the submitted protocol and any alteration or deviation should be notified to the ERC.

Dr Achala Jayatilleke
Secretary-ERC/PGIM

Information and consent documents produced here.

Information sheet

Research Project

A Patient Clinical Record Module for Current Electronic Tuberculosis Information Management System: An action research

Introduction

I (Dr.AR Wimalasundera, Trainee MSc in Biomedical Informatics, attached to Postgraduate Institute of Medicine, University of Colombo) would like to invite you to participate in this project, which is concerned with identifying your requirements for the development of ***A Patient Clinical Record Module for Current Electronic Tuberculosis Information Management System*** at National Programme for Tuberculosis Control and Chest Diseases (NPTCCD)

Why am I doing the project?

The project is part of my final year for the completion of MSc in Biomedical Informatics at Postgraduate Institute of Medicine, University of Colombo. It is hoped that the final output of the project would define the functionalities of a patient clinical record module that would contain clinical data of tuberculosis patients and would be helpful in implementing a secure comprehensive and with high quality of database of TB patients in near future.

Choice of participants:

Identified current users (direct and indirect) of the "Electronic TB Patient Information Management System"

What will you have to do if you agree to take part?

A convenient time for you will be arranged at your working place

There will be two interviews, one for the identification of your requirements and the second one will be carried out after the development of a prototype of the clinical records module to get your feedback for further developments and modifications

The interviews will be carried out in the form of in depth interviews, where you will be provided with a brief introduction and given the chance to talk freely about your requirements. Interview will conclude once you have come up with all your requirements and other concerns. The interview will be recorded in the form of voice recording to be transcribed later.

Will your participation in the project remain confidential?

If you agree to take part, your name will not be recorded at any point of the process, the transcript of the interview will be analysed by your job title or designation with full anonymity.

The access to the interview transcript will be limited to me (Dr AR Wimalasundera) and academic colleagues and my supervisors with whom I might collaborate as part of the research process.

You can be assured that the Information provided will be used for the purpose of this project only. Any summary interview content, or direct quotations from the interview, that are made available through academic publication or other academic outlets will be anonymized so that you cannot be identified, and care will be taken to ensure that other information in the interview that could identify yourself is not revealed.

The actual recording will be kept until the end of this project and will be destroyed later

What are the advantages of taking part?

The interviews will provide you with the opportunity of expressing your concerns and requirements for the development of ***A Patient Clinical Record Module for Current Electronic Tuberculosis Information Management System***. Once the project is completed it will facilitate identification of important clinical data that maybe helpful in identifying disease patterns, trends and facilitate to assess the management and follow up guidelines in practice. It would enable the policy

makers and the clinicians to make appropriate steps to optimize the current practice in a timely manner and improve quality and efficiency of healthcare services provided as well as support personalized care. It would also produce data and information for strengthening in further research in to the disease status in Sri Lanka. Reduced duplication of diagnostic testing, imaging and history taking and increased adoption of screening programs and preventive health measures are another long-term benefit.

Researcher:
Dr AR Wimalasundera

Trainee Msc in Biomedical Informatics

Postgraduate Institute of Medicine,

University of Colombo

Consent Form for Interviews

Thank you for reading the information sheet about the research project. If you are happy to participate, please read and sign the consent from to confirm that you agree with each statement.

By signing this form I agree that

I have read and understood the information sheet provided to me and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.

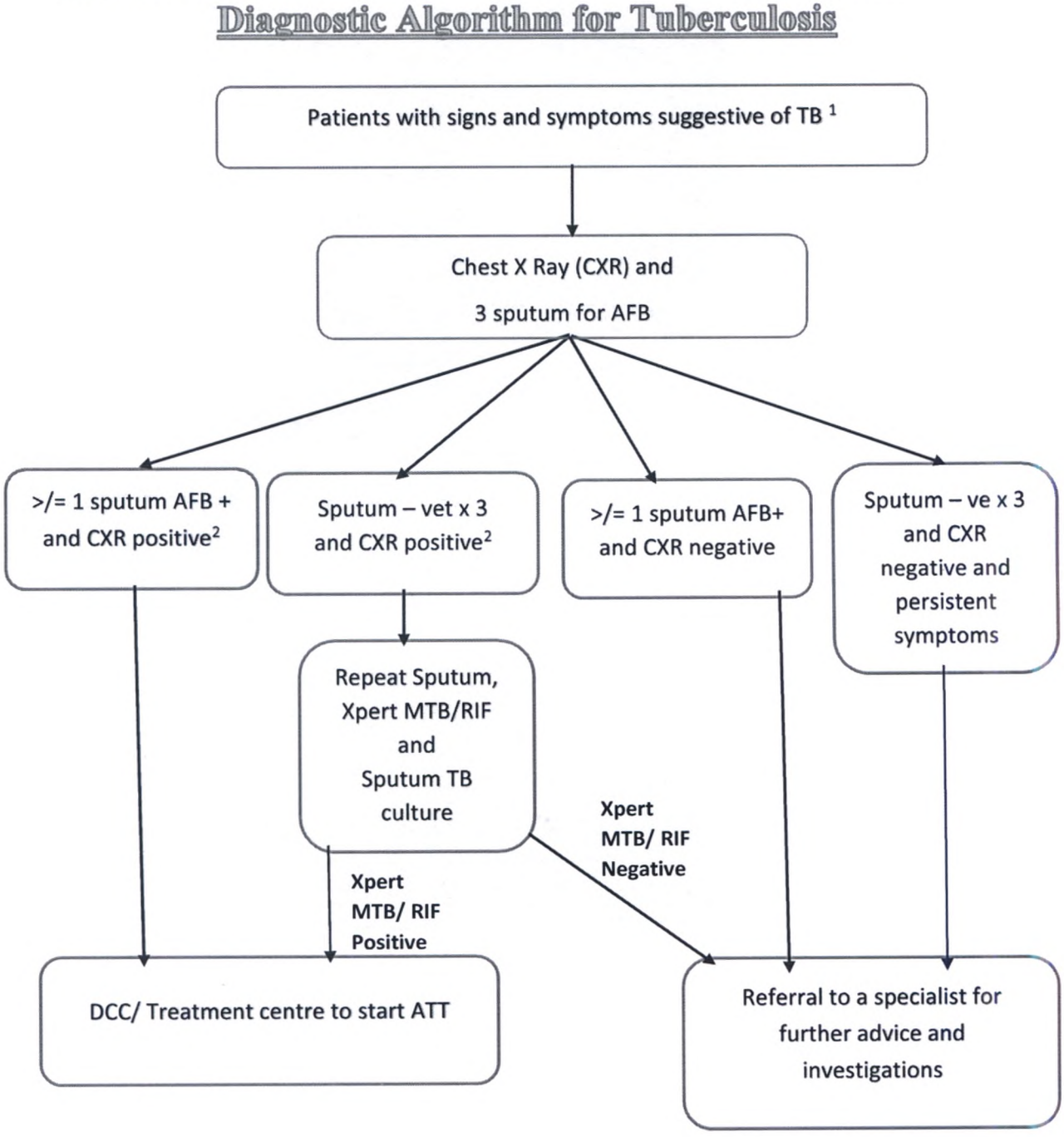
I understand that my responses will be kept strictly confidential. I understand that my job title will be linked with the information I provide. My name will not be linked with the research materials, and will not be identified or identifiable in the report or reports that result from the research.

I agree for this interview to be tape-recorded. I understand that the audio recording made of this interview will be used only for analysis and that extracts from the interview, from which I would not be personally identified, may be used in any conference presentation, report or journal article developed as a result of the research.

I understand that no other use will be made of the recording without my written permission, and that no one outside the research team will be allowed access to the original recording.

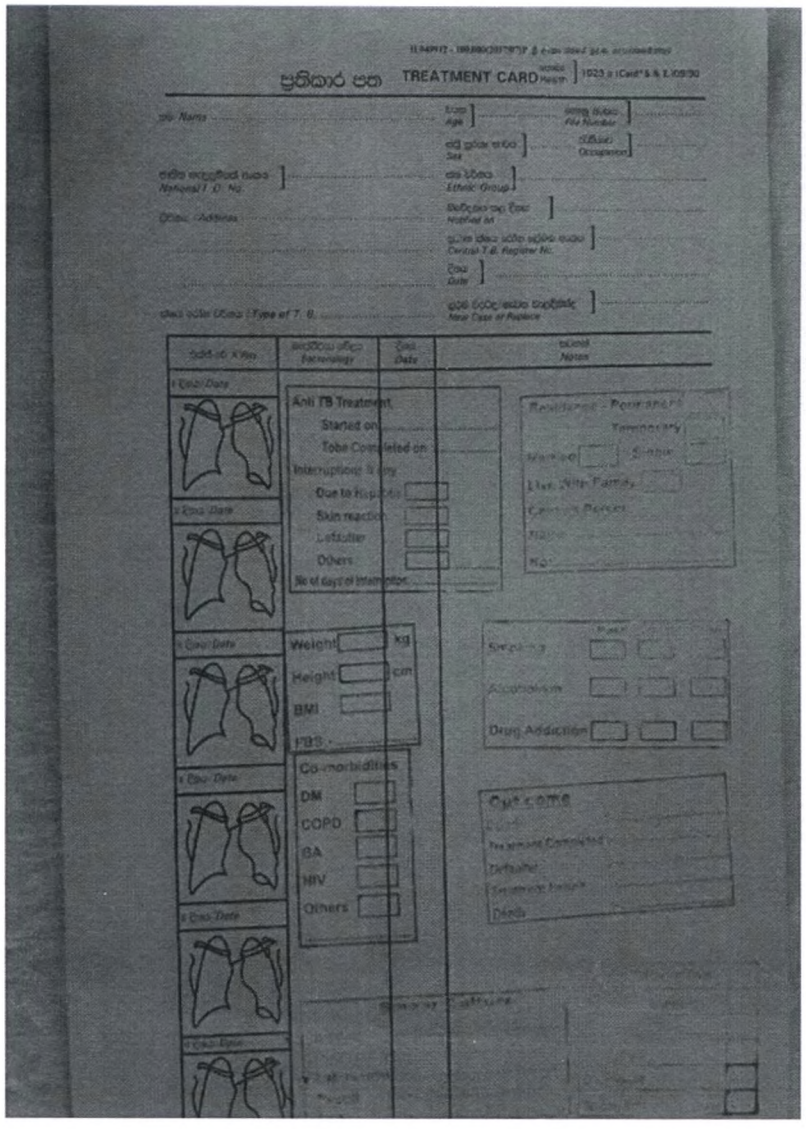
Name of participant	Date	Signature
Principal Investigator	Date	Signature

Annexure 2- Diagnostic and Treatment algorithms of TB patient management

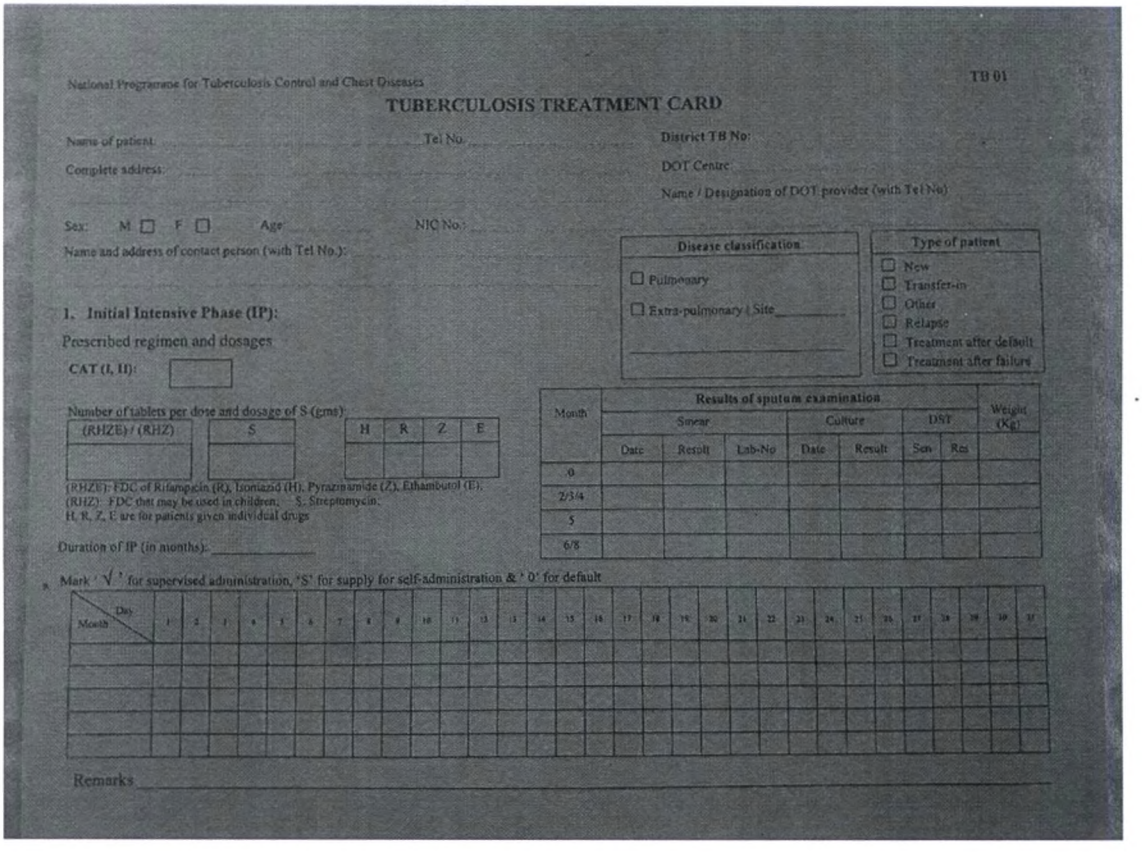


Annexure 3- Document formats used in treating TB patients at the DCCs

TB Treatment Card



Tuberculosis Treatment Card issued to DOTS provider



National Programme for Tuberculosis Control and Chest Diseases

TB 01

TUBERCULOSIS TREATMENT CARD

Name of patient: Tel No.: District TB No:

Complete address: DOT Centre:

Name / Designation of DOT provider (with Tel No)

Sex: M ☐ F ☐ Age: NIC No.:

Name and address of contact person (with Tel No.):

Disease classification	Type of patient
☐ Pulmonary	☐ New
☐ Extra-pulmonary (Site_____	☐ Transfer-in
	☐ Other
	☐ Relapse
	☐ Treatment after default
	☐ Treatment after failure

1. Initial Intensive Phase (IP):

Prescribed regimen and dosages

CAT (I, II):

Number of tablets per dose and dosage of S (gms):

(RHZE) / (RHZ)	S	H	R	Z	E

(RHZE): FDC of Rifampicin (R), Isoniazid (H), Pyrazinamide (Z), Ethambutol (E).
(RHZ): FDC that may be used in children; S: Streptomycin.
H, R, Z, E are for patients given individual drugs

Duration of IP (in months): _____

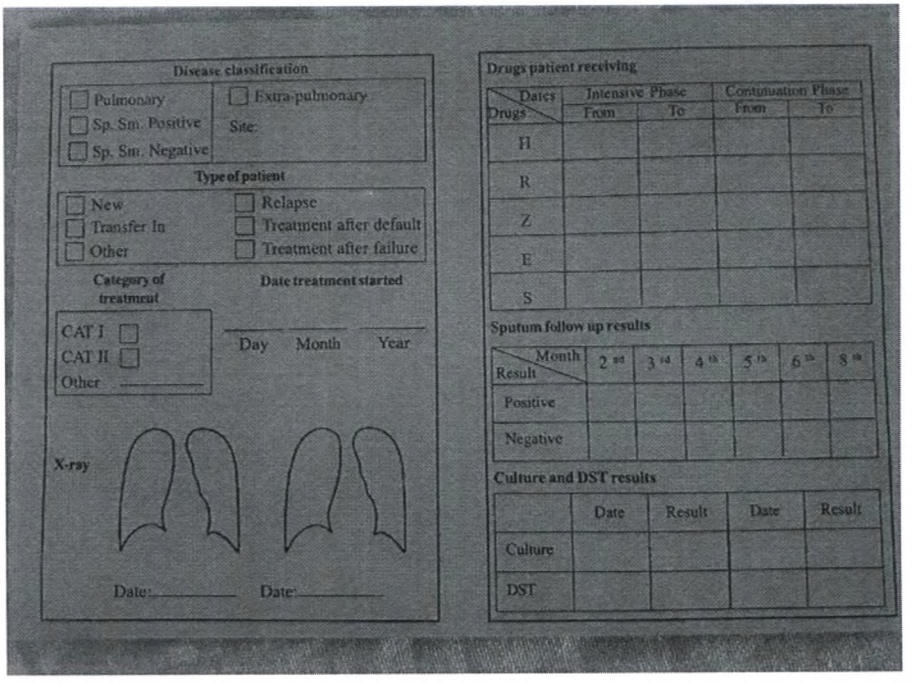
Month	Results of sputum examination							Weight (Kg)
	Smear			Culture		DST		
	Date	Result	Lab-No	Date	Result	Sen	Res	
0								
2/3/4								
5								
6/8								

Mark '√' for supervised administration, 'S' for supply for self-administration & 'O' for default

Month \ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Remarks _____

TB diagnosis card that remains with the patient



Disease classification

- ☐ Pulmonary
- ☐ Sp. Sm. Positive
- ☐ Sp. Sm. Negative
- ☐ Extra-pulmonary

Site:

Type of patient

- ☐ New
- ☐ Transfer In
- ☐ Other
- ☐ Relapse
- ☐ Treatment after default
- ☐ Treatment after failure

Category of treatment

- CAT I ☐
- CAT II ☐
- Other _____

Date treatment started

_____ _____ _____

Day Month Year

X-ray

Date:_____ Date:_____

Drugs patient receiving

Drugs \ Dates	Intensive Phase From	Intensive Phase To	Continuation Phase From	Continuation Phase To
H				
R				
Z				
E				
S				

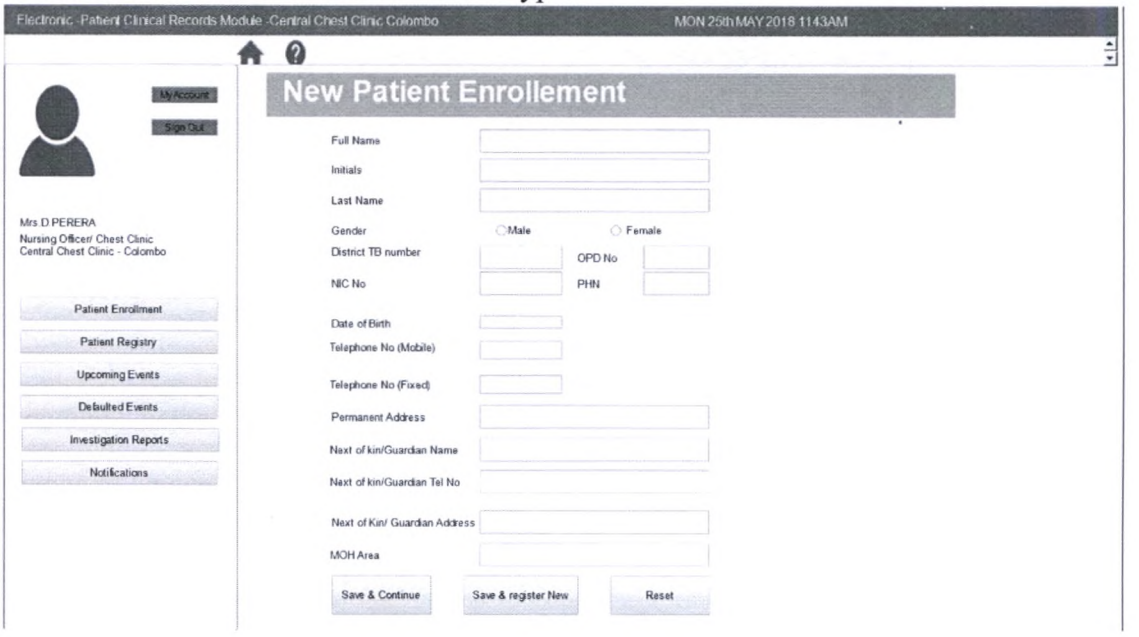
Sputum follow up results

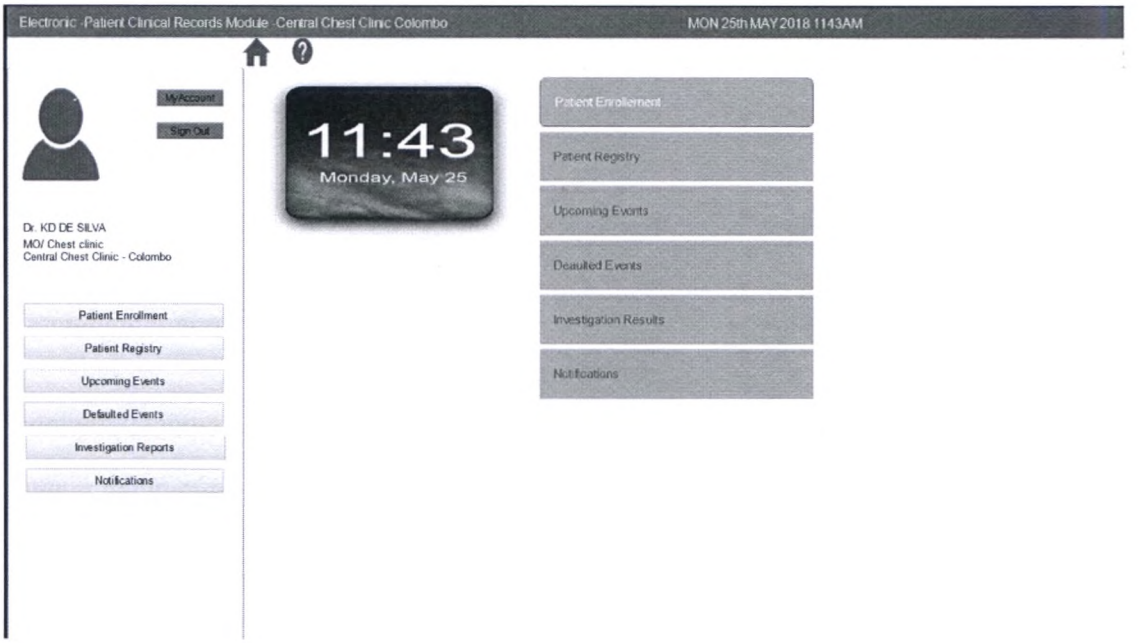
Result \ Month	2nd	3rd	4th	5th	6th	8th
Positive						
Negative						

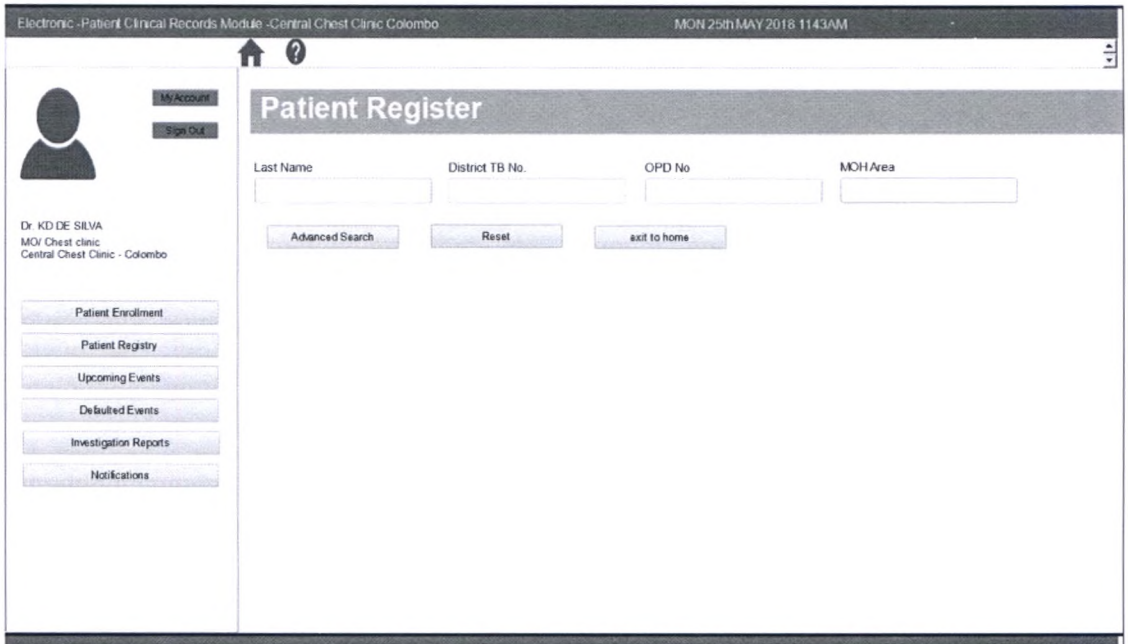
Culture and DST results

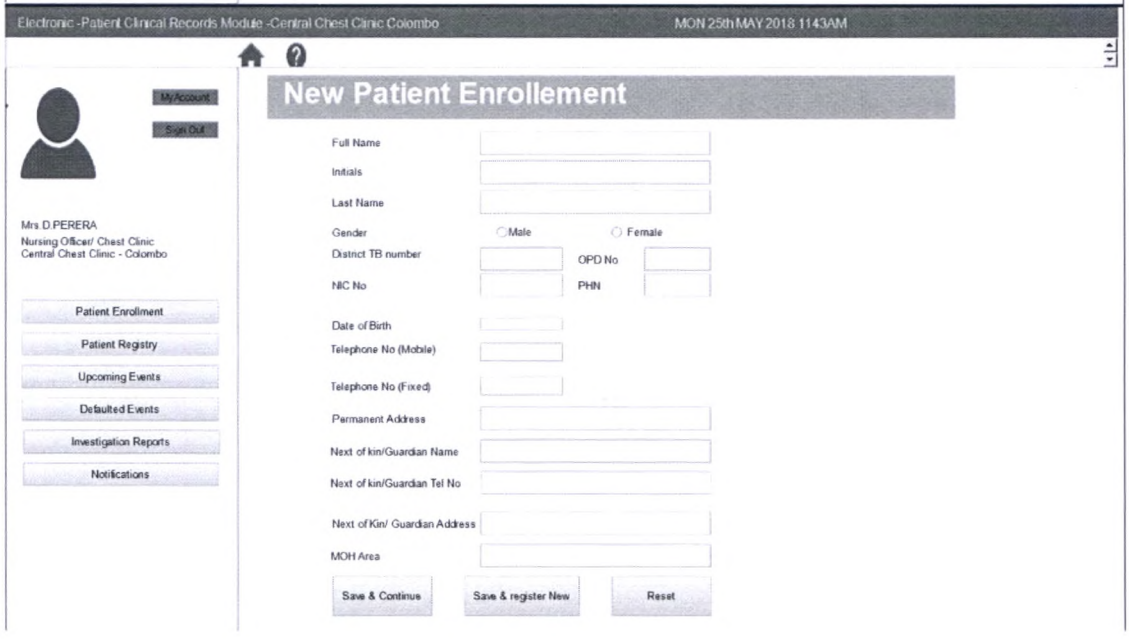
	Date	Result	Date	Result
Culture				
DST				

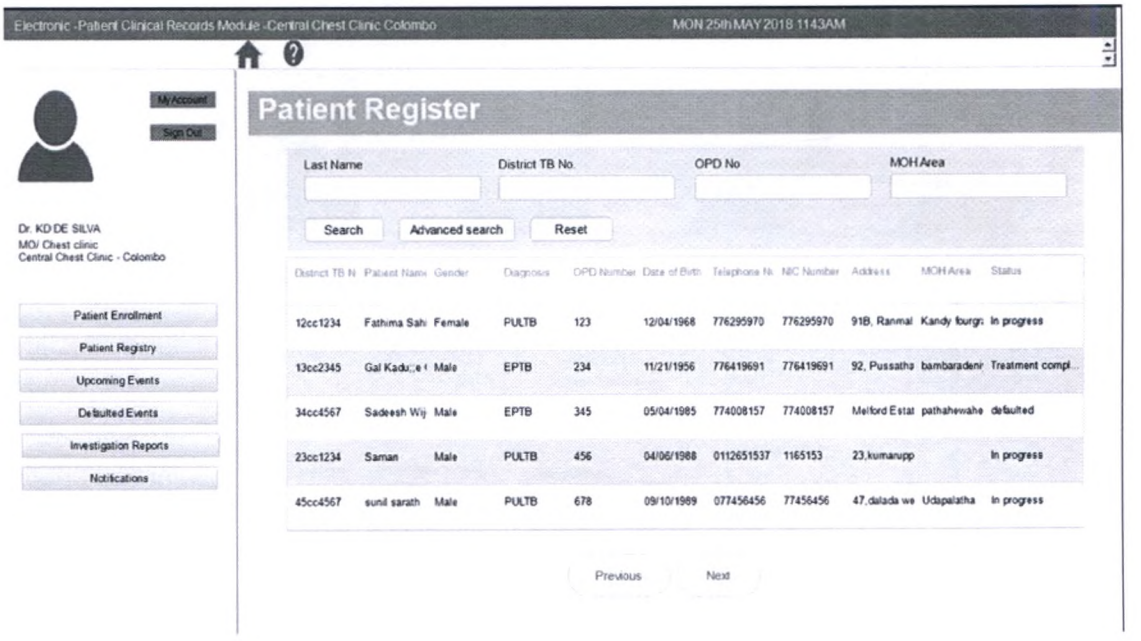
Annexure 4 - Screen shots of the Prototype






Electronic -Patient Clinical Records Module -Central Chest Clinic Colombo
MON 25th MAY 2018 1143AM
My Account
Sign Out
Patient Register
Last Name
District TB No.
OPD No
MOH Area
Advanced Search
Reset
exit to home
Dr. KD DE SILVA
MO/ Chest clinic
Central Chest Clinic - Colombo
Patient Enrollment
Patient Registry
Upcoming Events
Defaulted Events
Investigation Reports
Notifications


Electronic -Patient Clinical Records Module -Central Chest Clinic Colombo
MON 25th MAY 2018 1143AM
My Account
Sign Out
New Patient Enrollement
Full Name
Initials
Last Name
Gender
Male
Female
District TB number
OPD No
NIC No
PHN
Date of Birth
Telephone No (Mobile)
Telephone No (Fixed)
Permanent Address
Next of kin/Guardian Name
Next of kin/Guardian Tel No
Next of Kin/ Guardian Address
MOH Area
Save & Continue
Save & register New
Reset
Mrs.D.PERERA
Nursing Officer/ Chest Clinic
Central Chest Clinic - Colombo
Patient Enrollment
Patient Registry
Upcoming Events
Defaulted Events
Investigation Reports
Notifications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Patient Registry
Upcoming Events
Defaulted Events
Investigation Reports
Notifications
Patient Register
Last Name
District TB No.
OPD No
MOH Area
Search
Advanced search
Reset
District TB N
Patient Name
Gender
Diagnosis
OPD Number
Date of Birth
Telephone N
NIC Number
Address
MOH Area
Status
12cc1234 Fathima Sahi Female PULTB 123 12/04/1968 776295970 776295970 91B, Ranmal Kandy fourgr In progress
13cc2345 Gal Kadu;e (Male EPTB 234 11/21/1956 776419691 776419691 92, Pussatha bambaradeni Treatment compl...
34cc4567 Sadeesh Wij Male EPTB 345 05/04/1985 774008157 774008157 Melford Estat pathahewahe defaulted
23cc1234 Saman Male PULTB 456 04/06/1988 0112651537 1165153 23,kumarupp In progress
45cc4567 sunil sarath Male PULTB 678 09/10/1989 077456456 77456456 47,dalada we Udapalatha In progress
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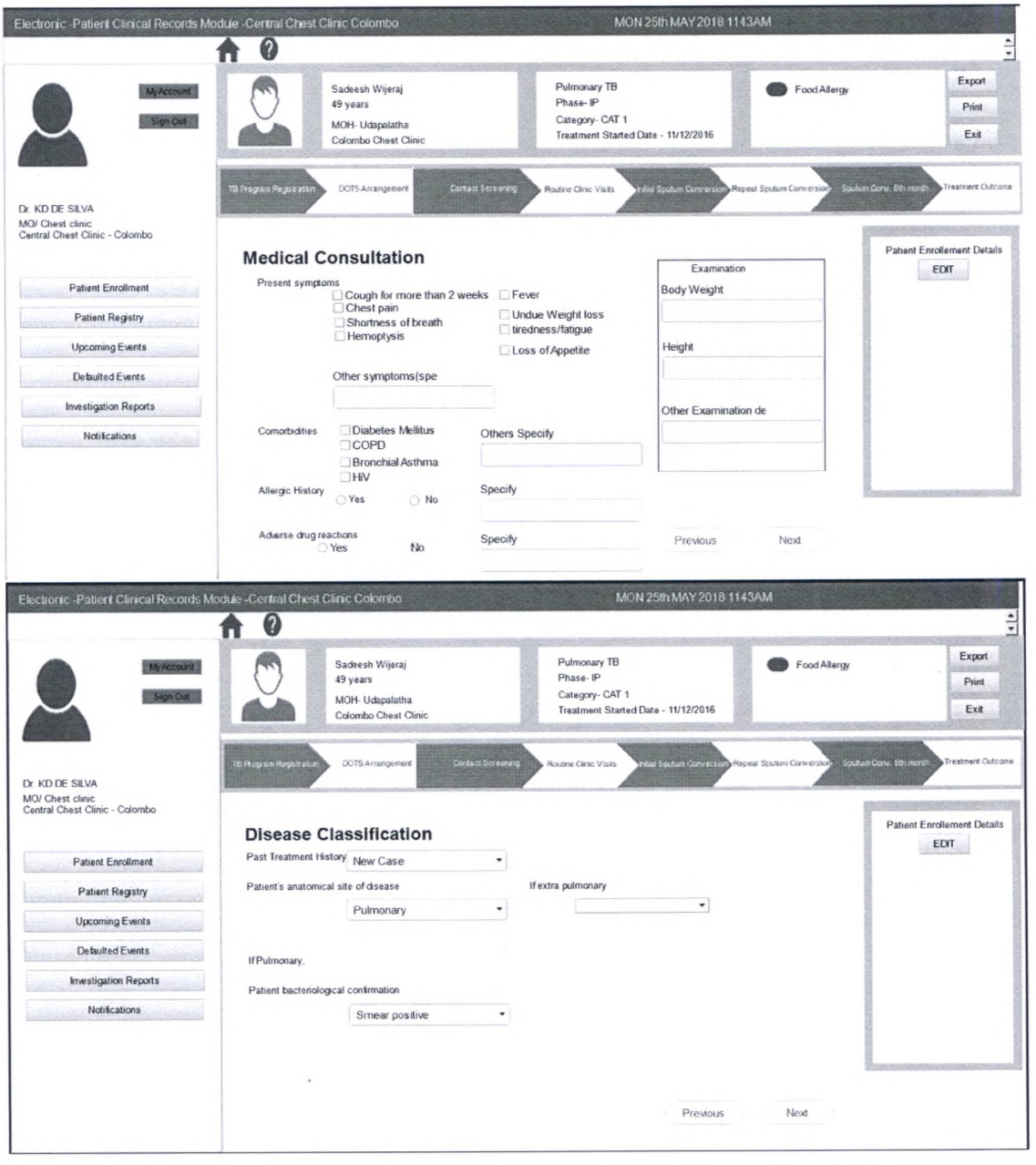
Next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Sadeesh Wijeraj
49 years
MOH- Udapalatha
Colombo Chest Clinic
Pulmonary TB
Phase- IP
Category- CAT 1
Treatment Started Date - 11/12/2016
Food Allergy
Export
Print
Exit
TB Program Registration
DOTS Arrangement
Contact Screening
Routine Clinic Visits
Initial Sputum Conversion
Repeat Sputum Conversion
Sputum Conv. 6th month
Treatment Outcome
Medical Consultation
Present symptoms
Cough for more than 2 weeks
Fever
Chest pain
Undue Weight loss
Shortness of breath
tiredness/fatigue
Hemoptysis
Loss of Appetite
Other symptoms(spe
Examination
Body Weight
Height
Other Examination de
Comorbidities
Diabetes Mellitus
COPD
Bronchial Asthma
HIV
Others Specify
Allergic History
Yes
No
Specify
Adverse drug reactions
Yes
No
Specify
Previous
Next
Patient Enrollement Details
EDIT
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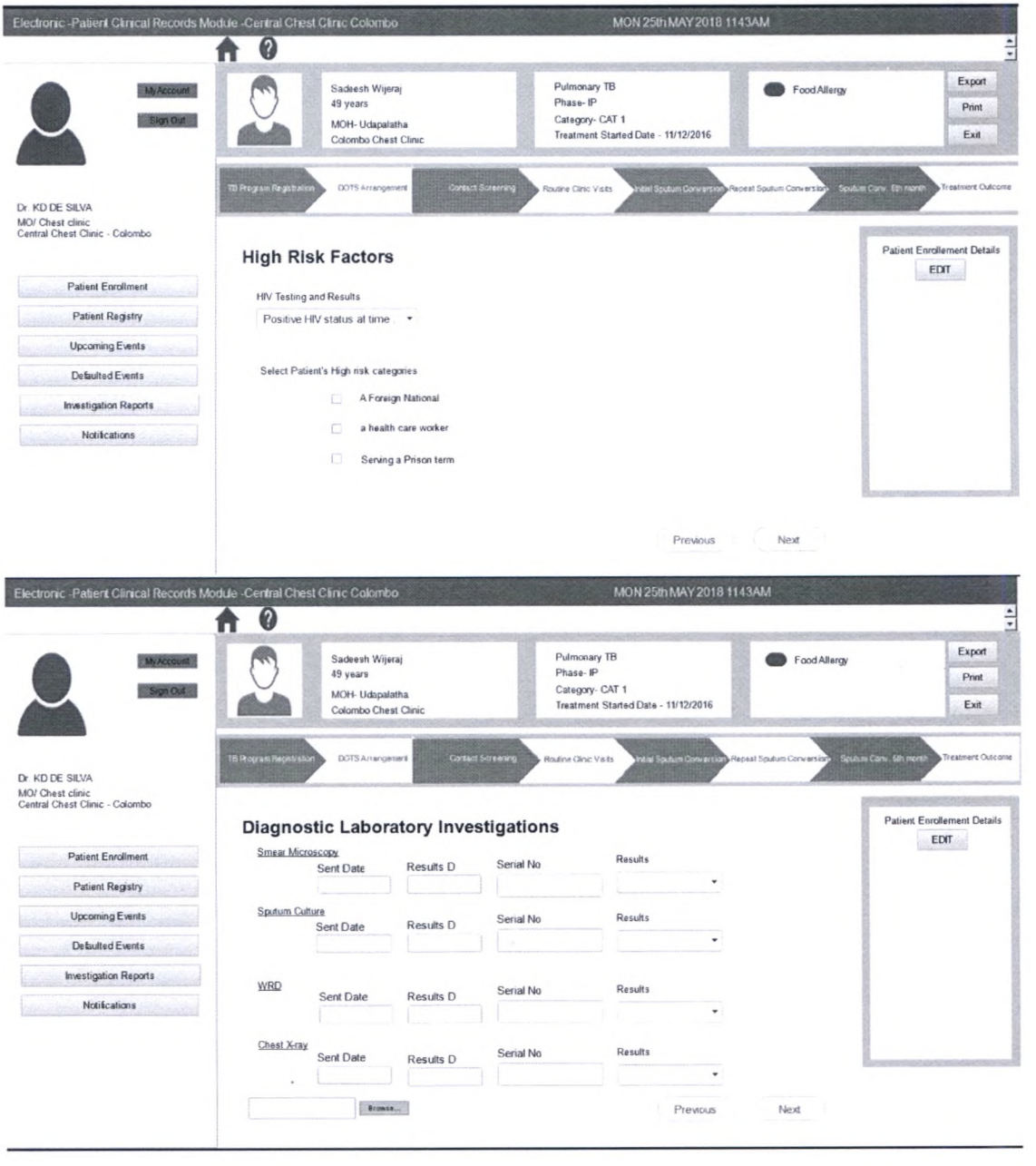
Sputum Conv. 6th month
Treatment Outcome
Disease Classification
Past Treatment History
New Case
Patient's anatomical site of disease
Pulmonary
If extra pulmonary
If Pulmonary,
Patient bacteriological confirmation
Smear positive
Previous
Next
Patient Enrollement Details
EDIT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Repeat Sputum Conversion
Sputum Conv. 5th month
Treatment Outcome
High Risk Factors
HIV Testing and Results
Positive HIV status at time
Select Patient's High risk categories
A Foreign National
a health care worker
Serving a Prison term
Patient Enrollement Details
EDIT
Previous
Next
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TB Program Registration
DOTS Arrangement
Contact Screening
Routine Clinic Visits
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Repeat Sputum Conversion
Sputum Conv. 5th month
Treatment Outcome
Diagnostic Laboratory Investigations
Smear Microscopy
Sent Date
Results D
Serial No
Results
Sputum Culture
Sent Date
Results D
Serial No
Results
WRD
Sent Date
Results D
Serial No
Results
Chest X-ray
Sent Date
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Serial No
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Browse...
Patient Enrollement Details
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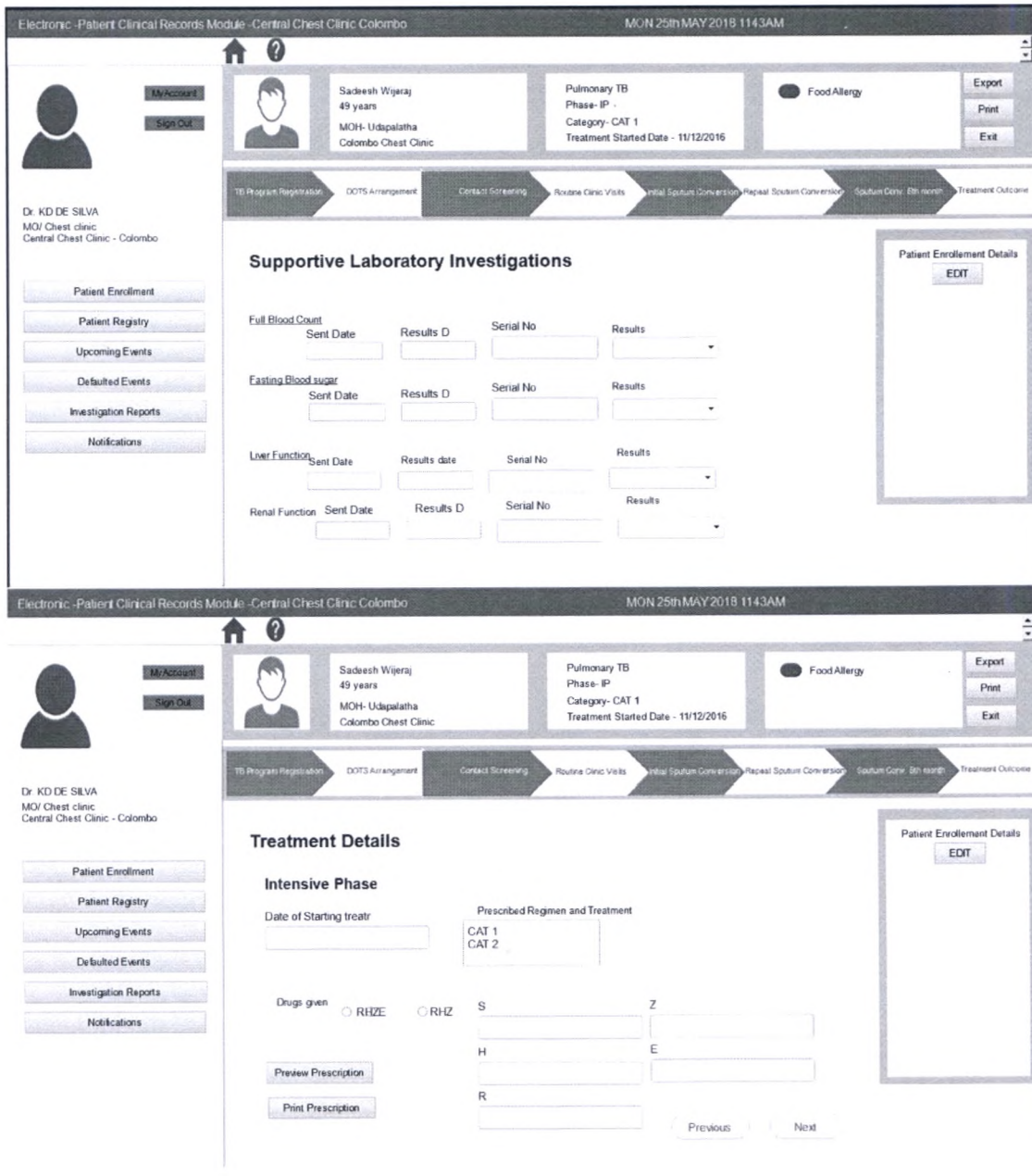
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Treatment Outcome
Supportive Laboratory Investigations
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Full Blood Count
Sent Date
Results D
Serial No
Results
Fasting Blood sugar
Sent Date
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Results
Liver Function
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Serial No
Results
Renal Function
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Treatment Outcome
Treatment Details
Patient Enrollement Details
EDIT
Intensive Phase
Date of Starting treatr
Prescribed Regimen and Treatment
CAT 1
CAT 2
Drugs given
RHZE
RHZ
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Print Prescription
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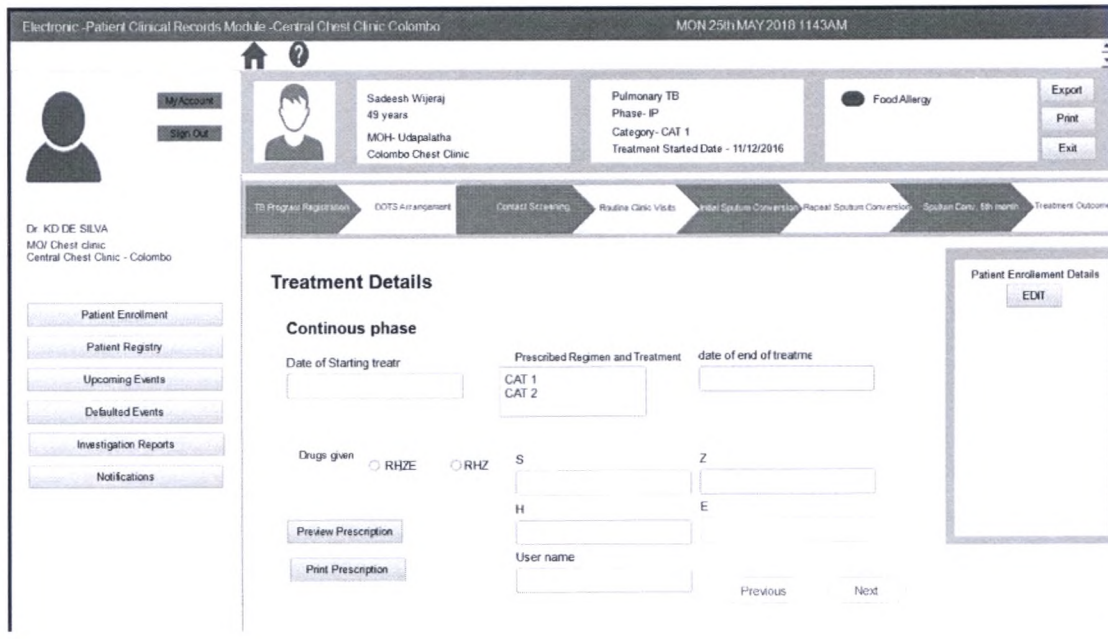
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CAT 2
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