Chapter 1

Introduction

1.1. Introduction

All the government hospitals from Tertiary care down to Base hospital level have microbiological laboratories. Most of them provides the service of isolation and culture of bacterial and fungal strains. Specialized centers have the capacity to perform the viral isolation and culture in special live culture media.

When bacterial strain is cultured on a suitable culture medium it is possible to perform an 'Antibiotic Sensitivity Test'(ABST) to identify the antibiotics which can be used to eradicate particular bacterial infection effectively and efficiently. Blind treatment with antibiotics is also possible in case of a bacterial infection. However this may leads to treatment failure as well as emergence of resistant bacterial strains to a particular antibiotic.

Emergence of such resistant bacterial strains to a antimicrobial agent make the drug unusable in the treatment process any longer [7]. Day by day new bacterial strains are discovered having antibiotic resistant genetic composition for various antimicrobial agents [15]. Further to aggravate the severity of the problem, there are no new antibiotics discovered in the last century in the pharmaceutical field.

Timely analysis of ASBT trends will aid prediction of the emerging resistant bacterial strains [17] and hence useful in lay down of therapeutic guidelines to minimize the treatment failure and induction of genetic mutation in bacteria [16].

Based up on the above facts, College of Microbiologists, Sri Lanka plans to develop a free and open as well as uniform laboratory information management software to assists the management of Antibiotic sensitivity data for monitoring and setting standards in the microbiological laboratory operational process of the government hospitals and investigation laboratories.

1.1.1 Background and motivation

There are range of laboratory investigation forms are currently being used by microbiological laboratories of the government sector as well as private sector, depending on the type of microbial specimen and the antibiotic sensitivity test to be performed. The antibiotic sensitivity reporting forms and the information stored will differ from laboratory to laboratory, the investigation performed as well as the micro-organisms being tested. According to the Study Group for the Laboratory Standards of the College of Microbiologists of Sri Lanka, there should be a uniform standard among all the microbiological laboratories in storing and reporting microbiological data. Uniform nature of the microbiological data will be very useful in sharing antibiotic usage related information and predictive analysis of microbial resistant patterns, which is a must in setting up treatment protocols and investigation guidelines.

With above requirements and guidelines, College of Microbiologists decided to involve with designing a web based application for managing microbial sensitivity/resistant data for government microbiology laboratories to make it a uniform process. The main aim of the software is to enable storage and management of antibiotic sensitivity information and on demand analysis of the microbiological sensitivity/resistant patterns to come to conclusion on the variations of the drug resistance.

There are limited numbers of antibiotic sensitivity data analysis systems are being used by few centers in developed countries for the prediction of antibiotic sensitivity information [30, 31]. However such system is not suitable for being used in another part of world, since genetic nature of micro organisms are highly subjected to regional and geographical segregations [21, 28]. Microbiological laboratory information management systems are

mainly the bespoke variety, and commercially developed for individual laboratories. Even in the developed countries, it is still lacking having common standards and protocols for uniform laboratory management frameworks.

The only available Open source solutions for Health Laboratory information management is BIKA Health [37], which is a specialized version of BIKA LIMS (BIKA Laboratory Information Management System). BIKA Health is focused on general lab process management and doesn't possess the ability to generate reports assisting domain specific policy decisions [36].

1.2 Laboratory information handling in government hospitals

Existing system to collect microbiological information is solely depending on manual, paper based processes. When a medical practitioner ordered the microbiological test (e.g. Culture & ABST), hospital contacts the microbiological laboratory to clarify information regarding transportation and culture media. Special containers or on-site culture media will be sent to the ward to collect samples. When the sample is collected, it has to be delivered to the laboratory with due precautions and in timely manner to prevent bacteria being destroyed by environmental factors or specimen being contaminated by commonly found non pathogenic bacterial strains.

In the laboratory a consultant microbiologist will be informed if special attention is necessary for the sample and test procedure. Otherwise, test will be carried out by a medical laboratory technician (MLT) and result is sent for verification by a consultant microbiologist. When test results are verified, the result sheet will be sent to the hospital.

There are no copies of the ABST kept in the laboratory for analysis and even in the hospital; data will not be collected in a long term manner for analysis of bacterial resistant patterns. Due to this reason, there are no data available on the antibiotic sensitivity pattern or bacterial composition of the microbiological specimens.

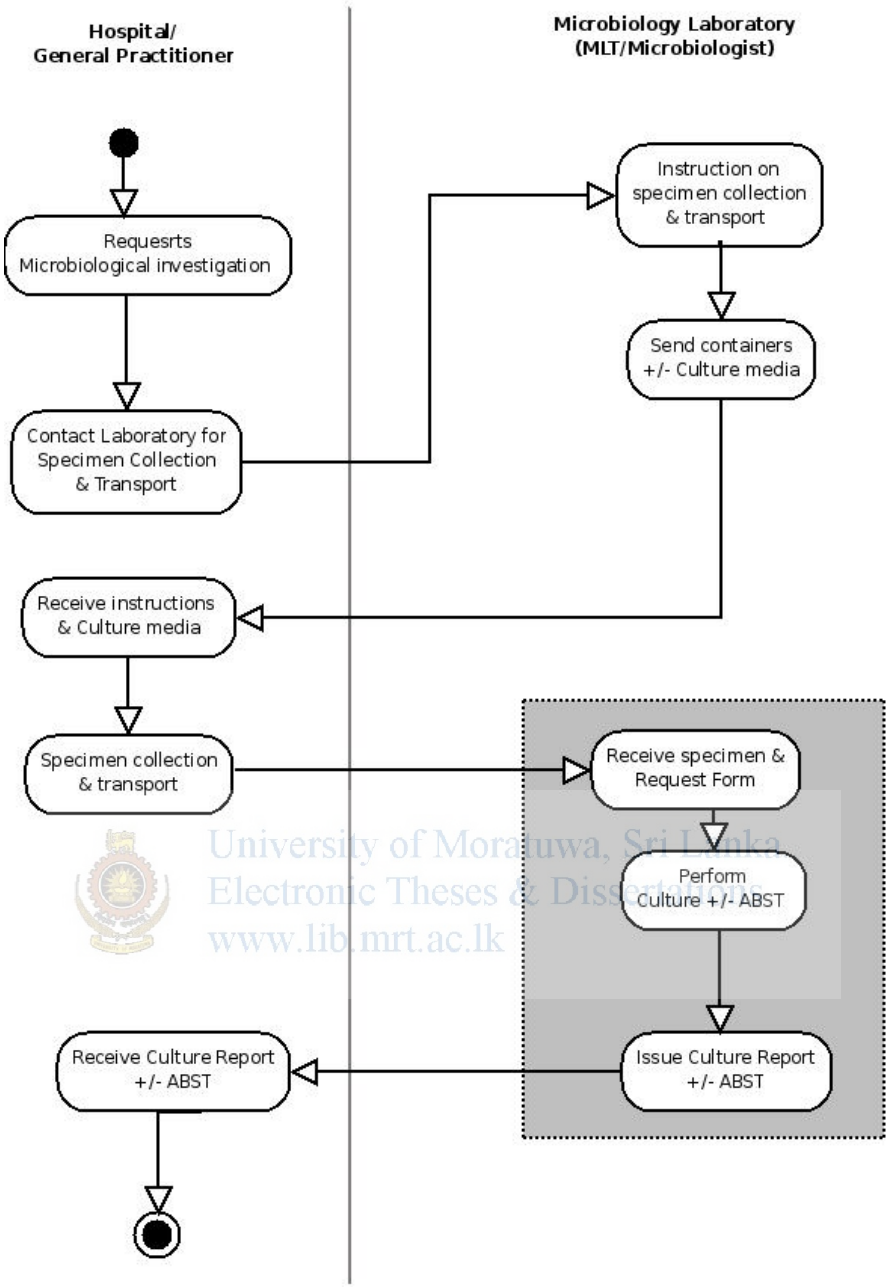

Figure 1: Existing System (System boundary is marked in the gray colored area)

1.1.3 Microbiological investigations

Following is a list of common investigations carried out in a microbiological laboratory with average facilities.

1.1.3.1 Bacterial culture and microscopic examination

Growing of bacteria on culture media (which are consists of living tissues like Agar, Fortified broth etc). Once isolated form the culture medium they can be identified by colony morphology and microscopic features. Depending on the bacterial strain it will take 48 hours to one week to grow the bacteria on the medium. Special staining is used in most of the occasions to aid the identification process (e.g. Ziehl -Neelson, Gram Stain).

1.1.3.2 Fungal culture and microscopic examination

This involves growing of fungus in culture medium. Since the fungi are slow growing compared to bacteria, it will take few weeks to several months to grow the fungus in the medium. When isolated, fungi subjected to microscopic examination for identification.

1.1.3.3 Antibiotic sensitivity test

When bacteria cultured it is possible to detect the response of the bacteria towards a set of anti bacterial agents decided by the medical officer. This will aid in identifying antibiotics which can be successfully used in the therapeutic procedures.

Apart from these investigations, several other investigations including, serological tests (investigations to measure serum antibody levels) and viral isolations and cultures are done in specialized centers with advanced laboratory facilities.

1.1.4 Microbiological sample collection

Basic microbiological specimens accepted by most of the laboratories are listed below.

- Blood
- Urine
- Stool
- Throat Swab
- Nasal Swab
- Other (e.g. Wound swab, Sputum)

There are set of standard precautions which should be taken when collecting a sample for

bacteriological investigations. These procedures will prevent contamination of the sample and ensure the viability of the organisms suspected. Otherwise bacteria in the specimen can be destroyed by the environmental agents like sun light and chemicals or they can be over grown by non pathogenic bacterial strains which are normally found in the human body.

When a specimen is sent to the laboratory, it should be sent with a properly filled microbiological investigation R*equest Form (Health 359)*. Request form contains the identification information of the patient, short history of the illness, differential diagnosis, what antibiotics should be tested for in case of ABST and the information on the ward and medical officer who is responsible for the management of the patient. This will aid microbiologist to decide the set of antibiotics for which ABST should be performed.

1.1.5 ABST

Following is a list of commonly used Antimicrobial agents for ABSTs. This list will vary depending on the institution concerned as well the differential diagnosis of the infective organism suspected.

- Amoxycillin/Ampicillin
- Cefalexin
- Cefepime
- Cefradine
- Cefotaxime
- Ceftazidime
- Ceftriaxone
- Cefuroxime
- Ciprofloxacin
- Cloxacillin
- Co-amoxiclav
- Co-trimoxazole
- Gentamicin
- Imipenem
- Meropenem
- Nalidixic acid
- Netilmicin
- Nitrofurantoin
- Norfloxacin
- Ticarcillin
- Vancomycin
- Amikacin

The list of antibiotics against which the growth of bacteria tested vary according to the available ABST kits to the laboratory and the preferences of the microbiologists who supervise the activity of the laboratory.

1.1.5.1 Level of sensitivity / resistance in ABST

- Resistant (R) - filter paper will have no discernable plaque around it, meaning that the bacteria are growing normally, even in the presence of the antibiotic.
- Intermediate (I) - somewhat cloudy plaque indicates that not all the bacteria in the area around the disk have been killed. This means that there are some members of the bacterial population that are sensitive to this particular antibiotic, but others that are genetically immune to its effects.
- Sensitive (S) - circular "halo" (technically known as a ‘plaque’ or zone of inhibition) will appear around the antibiotic disk, indicating an absence of bacteria.

1.1.6 Reporting in government hospitals and laboratories

1.1.6.1 Employees hierarchy

There are several levels of employees found in a government microbiological laboratory. The document flow is mainly handled by the following four categories of laboratory staff.

1. Clerical staff – Specimen Receive and Report Issue
2. MLT (Medical Laboratory Technician)
3. Consultant Microbiologists

Data entry activities are done by the clerical staffs. Acceptance of specimens and issuing of reports are the main document in-flow and out-flow. In the absence of clerical staff, medical laboratory technicians will do the data entry and report issuing tasks.

Medical Laboratory Technicians (MLTs) are responsible for performing isolation of microorganisms, preparation of culture media and culturing of microorganisms in suitable culture media. They have the authority to decide whether to perform or not to perform a ABST on a particular specimen without consulting a medical officer or consultant microbiologist.

Microbiologists are specialized medical officers who are responsible for higher level decision making on ABSTs and performing microscopic identification of bacteria and fungi. Every investigation results should be verified by consultant microbiologists before issuing to the relevant parties.

Only exception to this is the 'No Growth' bacterial or fungal isolates. Here there will be no bacteria is isolated from the culture.

Overall document/information flow is subjected to the supervision of the consultant microbiologists.

1.1.7 Overall information flow

When a specimen is received to a laboratory, specimen number and receipt will be issued at the specimen counter. Then the container is delivered to the laboratory for the culture and microscopic investigations, with the 'Request form'.

MLT will use a 'lab sheet' to record the details of the specimen, and will perform the Culture of the isolated micro organism. When culture is successful, ABST will be started using the colony of new growth. These bacterial and fungal colonies will be further subjected to microscopic examination to identify the species. If the culture showed no bacterial growth, MLT can issue the report as 'no growth'. No verification needed form a consultant microbiologist in this case. If bacteria grow successfully and ABST is performed, MLT will submit the ABST to consultant microbiologist for report to be verified before it is printed.

Once verified, report will be printed and sent to the report issuing counter to be collected by the client.

Following diagram will represent the overall information flow from acceptance of the request form, to delivery of culture/ABST report.

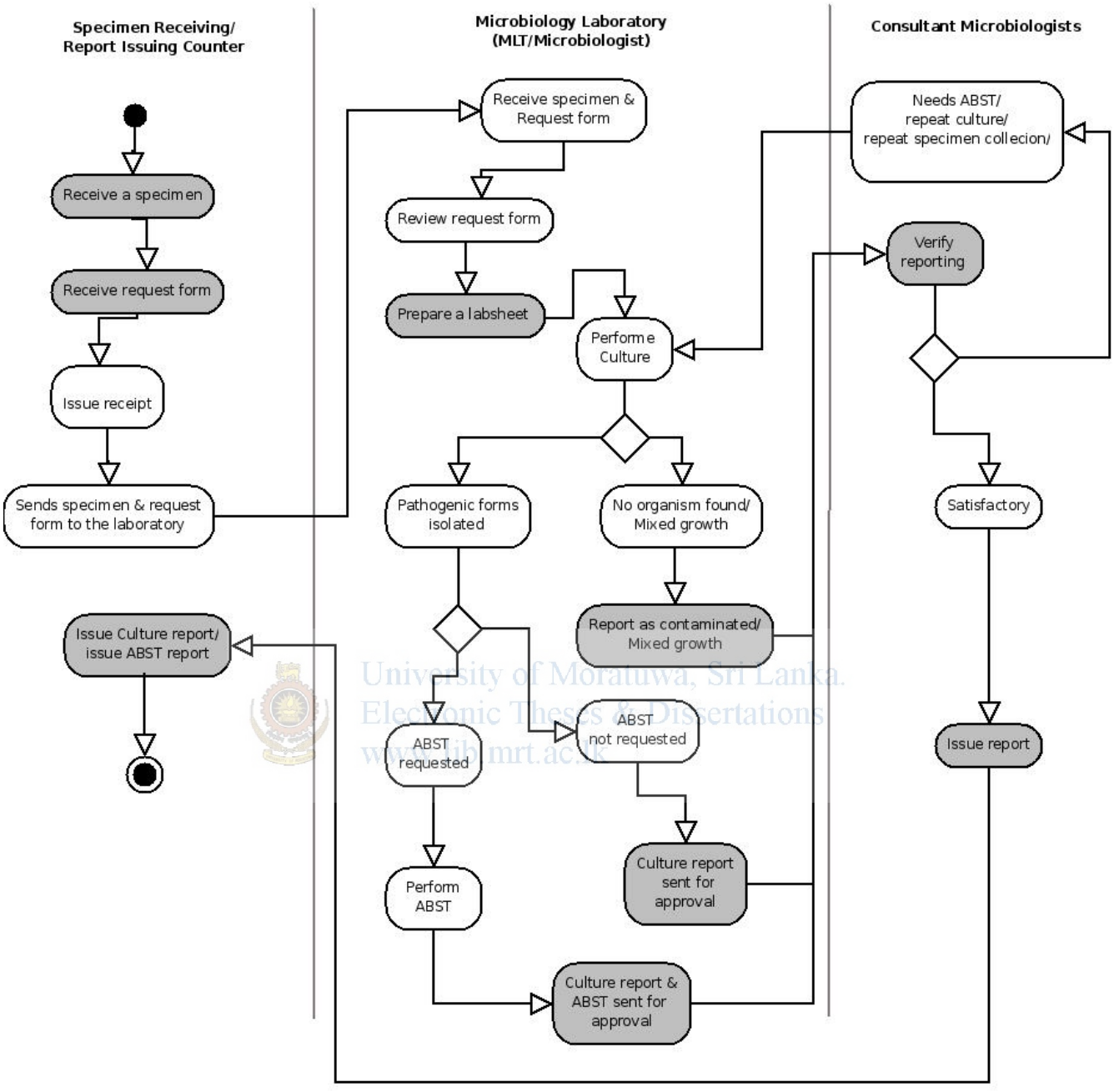

Figure 2: Flow of information and decision making process in existing system

1.2 Problems and weakness of existing system

Not having a uniform reporting frame work, timeliness of manual data entry, no proper storage of ABST data for future analysis and inability to auditing the laboratory process are the main drawbacks of the current paper based system practiced in Sri Lanka.

1.3 Aims & objectives

Aim of this project is to develop a web based open source solution for storage and manage antimicrobial drug, antibiotic sensitivity test data and therapeutically important microbiological information for the laboratory information management.

Objectives of the project includes,

- Developing an open source solution for the information management of the microbiological laboratories, this meets customer requirements.
- Developer expects to explore the open source LAMP stack based system development while completing the project.
- Study of medical data sharing and data analysis, data mining and geographical information system based data visualization.
- To study the use of PHP and MySQL and Java Scripts for data storage, retrieval and analysis.
- To apply and test software development knowledge in a practical environment, to acquiring necessary experience and skills.

1.4 Solutions

Users of the system will be specimen receiving and report issuing clerks, medical laboratory technicians and microbiologists of the government microbiology laboratories. The main input to the system will be the Request Form (Health 359) which is being used to hand over the specimens to the laboratory. Based on the request form, lab work sheet will be generated. Once laboratory process is completed, lab sheet will be updated and these information will be used to generate culture/ABST report.

Open source web technology will be to develop the system, PHP, MySQL and Java Scripts will be the main development languages. System will run on Apache HTTP server using MySQL database engine. Several open source libraries will be used as appropriate.

Features of the system will include data entry portal for request forms, receipt generation, lab sheet generation and data entry portal for lab sheet data and ABST generation. Further to this various data visualizations and searching facilities will be added to the system,

System requires a Linux – Apache – PHP – MySQL (or Windows – Apache – PHP – MySQL) web server environment. It will run on Internet Explorer, Mozilla Fire Fox and Opera web browsers. Uses may need basic computer literacy to work with the system. No software license fee will include since open source technology is used for the development tasks.

Structure of the dissertation

The outline of the dissertation will be as follows. Chapter 2 will explain the Problem domain and chapter 3 will explain the Technology Adapted. Chapter 4 and 5 will describe Approach to the solution and Analysis and Design respectively. Chapter 6 will cover the Implementation and chapter 7 will cover the Evaluation of the deliverables. Finally Chapter 8 will explain the Conclusion & Further works to be done.

Summary

An open source solution for the microbiology laboratory management seems to be an emerging need of the domain considered. The proposed system is designed to address the above mentioned need.

Next chapter will cover more on the problem domain.