

Evaluation Guideline

Real-Time Biosurveillance Program

Version 0.4



November 30, 2009

Authors:

Nuwan Waidyanatha¹, Gordon Gow², Suma Prashat³, Ganesan Muthiah³, Artur Dubrawski⁴, Mahesh Sabhnani⁴,

¹LIRNEasia, Sri Lanka, email: nuwan@lirneasia.net

²University of Alberta, Canada, email: ggow@ualberta.ca

³Rural Technology and Business Incubator, IIT-Madras, India, email:
{suma, ganesan} @tenet.res.in

⁴Carnegie Mellon University's Auton Lab, email: {awd, sabhnani}
@cs.cmu.edu

Table of Contents

| | | |
|-------|---|----|
| 1 | Introduction..... | 5 |
| 1.1 | Purpose of this document..... | 5 |
| 1.2 | About the RTBP pilot study..... | 6 |
| 1.3 | Goals of the Pilot..... | 7 |
| 1.4 | Background on Evaluation Methods..... | 7 |
| 2 | Proposed Research Matrix..... | 14 |
| 2.1 | Who is involved in Evaluation and why?..... | 16 |
| 2.2 | Formulation of the Mock-drills..... | 16 |
| 3 | Hypothesis..... | 18 |
| 4 | Data collection (upstream communication)..... | 19 |
| 4.1 | Social Layer – Research Questions and methodology..... | 19 |
| 4.2 | Content Layer – Research Questions and methodology..... | 22 |
| 4.3 | Application Layer – Research Questions and methodology..... | 23 |
| 4.4 | Technology Layer – Research Questions and methodology..... | 25 |
| 4.5 | Data Reliability..... | 26 |
| 4.6 | Certification Exercise..... | 27 |
| 5 | Event detection (data processing)..... | 29 |
| 5.1 | Social Layer – Research Questions and methodology..... | 29 |
| 5.2 | Content Layer – Research Questions and methodology..... | 30 |
| 5.3 | Application Layer – Research Questions and methodology..... | 31 |
| 5.4 | Technology Layer – Research Questions and methodology..... | 32 |
| 5.5 | Economic Aspects..... | 33 |
| 5.6 | Utilization, Outcome, and Usability assessment..... | 35 |
| 5.7 | Replication study..... | 37 |
| 5.8 | Measure RECALL, ROC, and AMOC..... | 38 |
| 6 | Alerting / Reporting (downstream communication)..... | 41 |
| 6.1 | Social Layer – Research Questions and methodology..... | 41 |
| 6.1.1 | Methodology..... | 41 |
| 6.2 | Content Layer – Research Questions and methodology..... | 41 |
| 6.2.1 | Methodology..... | 42 |
| 6.3 | Application Layer – Research Questions and methodology..... | 42 |
| 6.3.1 | Methodology..... | 43 |
| 6.4 | Technology Layer – Research Questions and methodology..... | 43 |
| 6.4.1 | Methodology..... | 43 |
| 7 | Millennium Development Goals..... | 44 |

| | |
|--|----|
| 7.1 MDG 4: Reduce Child Mortality..... | 44 |
| 7.2 MGD 5: Improve Maternal Health..... | 44 |
| 7.3 MDG 6: Combat HIV/Aids, Malaria, and other diseases..... | 44 |
| 7.4 Methodology..... | 45 |
| 7.4.1 Objective study..... | 45 |
| 7.4.2 Subjective study..... | 45 |
| 8 References..... | 46 |
| 9 APPENDIX A – QUESTIONNAIRES..... | 47 |
| 9.1 Health Worker - Data collection simulation survey..... | 47 |
| 9.2 Observer - Data collection simulation survey..... | 47 |
| 9.3 Health Official - Event detection simulation survey..... | 47 |
| 9.4 Observer - Event detection simulation survey..... | 47 |
| 9.5 Health Official - Health alerts simulation survey..... | 47 |
| 9.6 Health Worker - Alert simulation survey..... | 47 |

Index of Tables

| | |
|--|----|
| Table 1: Main evaluation methods of the components in relation to Figure 1 (may need to rework)..... | 7 |
| Table 2: Multiple approach to RTBP evaluation..... | 8 |
| Table 3: Measurable attributes of Biosurveillance Systems..... | 12 |
| Table 4 Matrix with Divisions, Community-Healthcare-Workers, and Communities..... | 14 |
| Table 5 proposed participation with respect to the research matrix (confirm)..... | 15 |
| Table 6 Health administration levels and respective health workers and officials..... | 16 |
| Table 7 three components of the RTBP with the pilot solutions and the present solutions..... | 16 |
| Table 8 Mandatory and optional data collection social layer research questions..... | 19 |
| Table 9 Mandatory and optional data collection content layer research questions..... | 22 |
| Table 10 Mandatory and optional data collection application layer research questions..... | 23 |
| Table 11 Mandatory and optional data collection technology layer research questions..... | 25 |
| Table 12 Mandatory and optional data processing social layer research questions..... | 29 |
| Table 13 Mandatory and optional data processing content layer research questions..... | 30 |
| Table 14 Mandatory and optional data processing application layer research questions..... | 31 |
| Table 15: Utilization questions..... | 35 |
| Table 16: Outcome questions..... | 36 |
| Table 17: Usability questions..... | 36 |

| | |
|--|----|
| Table 18: listing of detected events though the present and introduced system..... | 38 |
| Table 19: Example of a list of bi-weekly alerts produced to health officials..... | 39 |
| Table 20: Two by two contingency table..... | 39 |
| Table 21 Mandatory and optional notification social layer research questions..... | 41 |
| Table 22 Mandatory and optional notification content layer research questions..... | 41 |
| Table 23 Mandatory and optional notification application layer research questions..... | 42 |
| Table 24 Mandatory and optional notification technology layer research questions..... | 43 |

1 Introduction

1.1 Purpose of this document

The objective of this document is to outline the evaluation methodology for assessing the upstream communication: data collection, data processing: event detection, and downstream communication: alerting/reporting stages (verticals in Figure 1) on the aspects of social, content, application, and technology (horizontals in Figure 1) of a Real-Time Biosurveillance Program (RTBP). The blue arrows across the verticals and the horizontals indicate the interoperability between elements.

Purpose of the content in this document is to share the research questions and methodology with Investigators (or Researchers) with respect to evaluating a RTBP. First the document gives an overview of of evaluation methods applicable to the RTBP based on a literature survey. Then introduces the **RTBP pilot study proposed research matrix** (the way it is setup and applied to the two case studies in Tamil Nadu and Sri Lanka) and discusses the hypothesis these two case studies are investigating. Thereafter, the sections are divided in to the data collection, event detection, and alerting/reporting communication verticals. In each of the verticals the relevant questions and evaluation methodology is discussed in the context of social, content, application, and technology elements as well as the cross communication between the verticals and horizontals.

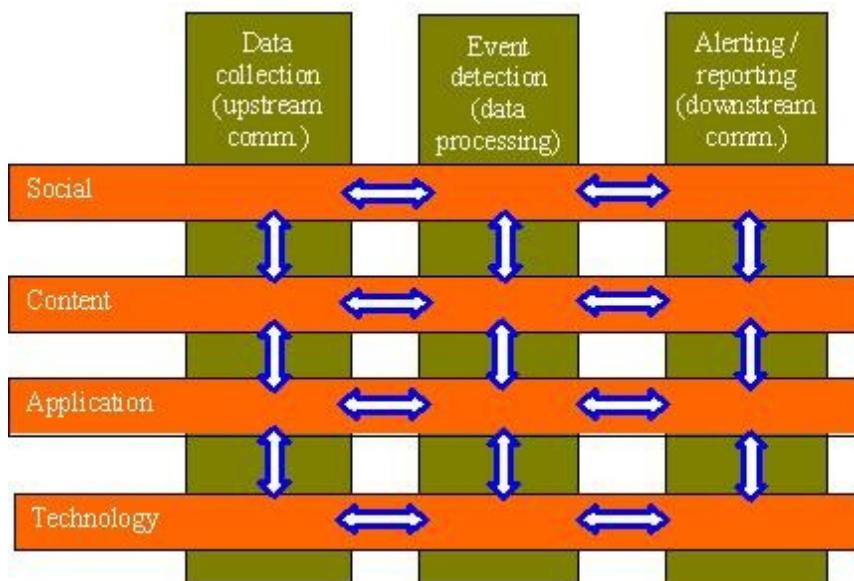


Figure 1 Vertical and Horizontal components of the evaluation process

The set of questions are divided in to two sections: mandatory and optional; where the mandatory questions must be answered during this pilot phase; while the optional questions are more forward looking questions that the project will attempt to answer at the end of the RTBP evaluation cycle.

1.2 About the RTBP pilot study

RTBP, at this stage, is a pilot aiming to prove the concept of using mobile phone applications for data collection, data mining statistical analysis software for health event detection, and Common Alerting Protocol based messaging for disseminating health situational reports.

The RTBP is being field tested in the state of Tamil Nadu's Sivaganaga District in India and North Western Province's Kurunegala District in Sri Lanka. There are twenty four Village Health Nurses (VHNs) administering Health Sub Centers (HSCs) in the four Primary Health Center (PHC) divisions: Thirukostiyur, Nerkuppai, Keelasevalpatty, and Sevenipatti of Sivaganga District along with the PHC staff and Sector Health Nurses (SHNs) are responsible for submitting data. They are also responsible for assisting the Medical Officers and Health Inspectors with responding to disease outbreaks. The Indian Institute of Technology – Madras's Rural Technology and Business Incubator and the National Center Biological Sciences in India are facilitating the field level work with the Government of Tamil Nadu's Health Department.

Sarvodaya, Sri Lanka's largest community embedded NGO, has established Comprehensive Community Healthcare Programs in all districts in Sri Lanka. The community health centers providing primary healthcare are called Suwadana Centers. These centers are managed by local village volunteers who have been trained in primary healthcare. Sixteen of the Suwadana Center Volunteers (abbreviated as Suwacevo), from four Medical Officer of Health (MOH) divisions: Wariyapola, Kuliapitiya, Pannala, and Udubeddewa in Kurunegala District have been selected to assist in the RTBP. These volunteers will be collecting patient data from the nearby health facilities: hospitals, clinics, general practitioners, etc as well as records of patients visiting the Suwadana Centers. Sarvodaya has sought approval and consent of the Regional Director of Kurunegala District to field test the RTBP in the aforementioned MOH divisions,

The RTBP is using a mobile application: m-HealthSurvey, a web application with database: Sahana Biosurveillance Module (BSM), a web accessible analytical tool: T-cube Web Interface (TCWI), set of auto detection algorithms, and a situational awareness reporting web interface: Sahana Alerting/Messaging Module (SAMM). These application will be field tested for the purpose of proving the concept of automating disease surveillance and notification.

The RTBP is made possible through a research grant from the International Development Research Center of Canada. Parts of the grant has funded the development of the m-HealthSurvey, Sahana BSM, and Sahana SAMM; as well as the adoption of a customized

version of the TCWI. Another part of the fund is facilitating the implementation and evaluation phases of the RTBP.

1.3 Goals of the Pilot

The main research question of the RTBP pilot is “*whether software programs that detect events in health symbolic and categorical data sets and mobile phones that collect health data and receive health alerts are able to predict and prevent disease outbreaks in near-real-time*”. The evaluation will mainly focus on proving the concept, which is the Application horizontal layer but also evaluate the supporting layers or the layers it inter-operates with. This document will identify all the evaluations nodes but the researchers should determine a priority subset to evaluate that is achievable.

Another focus of this exercise is to identify and evaluate elements that may lead to recommendations that can be leveraged for additional research or leading to another phase of the RTBP. For example, evaluating the content standards such as incorporating the global Health Level 7 (HL7) standard may not be feasible at this point but can surely be regarded as future work. While this stage of the project will accomplish the task of developing and proving the workability of the technology components, it is important that the program is made operational for an extensive period (2 – 3 years) to assess the impact of the system.

Some of the questions and methodology addresses in each of the sections below may be repetitious and even bleed in to other vertical or horizontal components (Figure 1). A general question and applied methodology may be applicable to a series of the components. These cases should be identified to minimize the project evaluation workload as well as minimize the burden imposed on the participants.

Table 1: Main evaluation methods of the components in relation to Figure 1 (may need to rework)

| | Data collection | Event detection | Alerting/Reporting |
|-------------|--|-----------------|--------------------|
| Social | interviews and usability questionnaire | interview | interviews |
| Content | | training | |
| Application | | performance | performance |
| Transport | cost and access factors | | |

1.4 Background on Evaluation Methods

Table 2 elaborates how the multiple approaches to evaluation [Friedman and Wyatt] are applied to the RTBP.

Table 2: Multiple approach to RTBP evaluation

| Evaluation approach | Notes with respect to RTBP study |
|--|--|
| Approach rooted in objective assumptions | |
| Comparison-based [employees experiments and quasi-experiments; the resource under study is compared to a controlled condition] | <p>It was envisioned that a sample space can be designed based on geography (health divisions) and health worker participation (see Table 4 – research matrix). In this setup the comparison will take place between the present practices that can be used as a basis to assess the introduced system (i.e. group exposed to the system and group not exposed to the system).</p> <p>Data Collection</p> <p>A problem associated with disease surveillance data is that two subjects will not submit the same type and volume of data. In other words, a fever case reported at health facility A will not be reported at health facility B. If facility A uses the introduced system and facility B uses the present system, comparing facility A with facility B is inappropriate because in reality facility A volume and nature of patients will differ from facility B.</p> <p>However, a comparison can be done with facility A using both the introduced and present system. Given that disease surveillance systems already in place are government implemented systems with in-place policies and protocols. A pilot study cannot ask the subjects to suddenly switch to the introduced system; not until such time the introduced system is fully accepted with policies are implemented and the system mandated as a substitute.</p> <p>Event detection</p> <p>Present surveillance incorporates a set of paper forms such as the “S” and “P” forms in India and the “H-544” and “H-399” forms in Sri Lanka for communicating a set of notifiable disease by the health workers (e.g. Medical Officers and Nurses) to central health departments (e.g. DDHS or MOH offices). The RTBP introduced computer statistical analysis tool (resource) involves the TCWI with accompanying processes.</p> <p>The comparison is two fold. One is using past data to identify events such as high counts of fever cases, dengue outbreaks, or leptospirosis outbreaks that occurred and checking whether TCWI is capable of identifying the same events (also termed as a “replication” study).</p> |

| Evaluation approach | Notes with respect to RTBP study |
|---|--|
| | <p>Second involves the parallel study with surveillance information are submitted via paper and a richer data set submitted via the m-HealthSurvey. For example, one can scrutinize the timeliness as to when TCWI was able to identify certain high fever cases versus when the health departments actually received the “S”, “P”, “H-544”, or “H-399” forms and processed them.</p> <p>It is questionable whether the comparison is fare because the RTBP works on a richer data set versus the paper system working on a handful of fixed diseases. Also depends on the frequency the health departments use TCWI.</p> <p><u>Alerting/Reporting</u></p> <p>When an infectious disease like dengue or malaria is diagnosed by a Medical Officer, the case is immediately notified to the the MOF or DDHS office by phone. In reality this may happen at the end of the day. Thereafter, a response unit (team comprising - Health Inspectors, Medical Officers, Nurses, etc) is deployed to examine the case, which includes visiting the house. These personnel are presently alerted via voice calls, if it is an urgent priority. The equivalent would be the RTBP introduced Sahana SMS/Email CAP messaging module; where health departments can issue alerts to the response units. The comparison would be on the ability to issue the same or a complete set of information to effectively and efficiently communicate the message to the response units.</p> |
| <i>Objective-based</i> [seek to determine whether the resource under study meets the design requirements] | <p><u>Data collection</u></p> <p>The expectation of the m-HealtSurvey is to receive real-time data from the field</p> <p><u>Event detection</u></p> <p><u>Alerting/Reporting</u></p> |
| <i>Decision facilitation</i> [seeks to resolve issues important to developers] | <p><u>Data collection</u></p> |

| Evaluation approach | Notes with respect to RTBP study |
|--|--|
| and administrators for individuals to make decisions about the future of the resource] | <u>Event detection</u> <u>Alerting/Reporting</u> |
| <i>Goal-free</i> [blinding the intended effects of the resource and gather all evidence to identify all effects of the resource] | <u>Data collection</u> <u>Event detection</u> <u>Alerting/Reporting</u> |
| Approach rooted in subjective assumptions | |
| <i>Quasi-legal</i> [establishes a mock drill or other formal adversary proceeding to judge the resource] | <u>Data collection</u> m-HealthSurvey Certification exercise <u>Event detection</u> <u>Alerting/Reporting</u> |
| <i>Art Criticism</i> [relies on an experienced and reputed critic to highlight the benefits and shortcomings of the resource, not necessarily a domain expert on the resource being evaluated, but has a great deal of experience with evaluating resources] | <u>Data collection</u> <u>Event detection</u> Arrange for a set of e-Health drive T-Cube (Panacea) <u>Alerting/Reporting</u> Arrange for a set of none RTBP related health officials and e-health experts, to review SAM to criticism. |

| Evaluation approach | Notes with respect to RTBP study |
|--|---|
| Professional review [“site-visit” approach, employees panels of peers to spend time with the resource in the field] | <u>Data collection</u> <u>Event detection</u> <u>Alerting/Reporting</u> |
| Responsive/Illuminative [seeks to represent the view points of those who are users of the resource; i.e. not be judgmental but be illuminated] | Health workers and health officials (epidemiological) are the key users of the RTBP. The goal is to be illuminated by understanding their view points. The research assistants working in the field will spend time with the health workers and health officials or immerse themselves in the environment where the RTBP is operational. <u>Data collection</u> <u>Event detection</u> <u>Alerting/Reporting</u> |

Develop a comparison table to measure the price, reliability, sensitivity, false alarm rates, timeliness.

Estimate the cost and benefits as a social utility and estimate the value it provides the population.

QUESTIONS NOT ADDRESSED BY BENCH TESTING OF DATA AND ALGORITHMS

Do epidemiologists use the system?

How often do the components of the system fail and result in degradation of the system or complete failure of the system?

What is the quality of the data under field conditions?

What are the time latencies inherent in the various processing steps of a system?

What is the actual detection and characterization performance in the field?

What are the benefits of a system?

How long does it take to deploy or build a system?

What are the costs and level of effort required to build and maintain a system?

Are the correct decisions and actions taken in response to surveillance data?

How well does the system interoperate with other systems?

The range of uses, data, and users of a fielded Biosurveillance system are, typically, quite large. The uses may include, in addition to prevention and control of disease, policy making, needs assessments, and accountability.

Professional evaluators use the concepts of *formative study* and *summative study* to help them achieve clarity about their goals in designing and conducting a study. Formative study will study the goal of the RTBP improving the disease surveillance and notification in Tamil Nadu and Sri Lanka with respect to the analysis of error or failures and determine how the RTBP can be improved. Summative study will evaluate the value of the system with respect to the present disease surveillance and notification systems in Tamil Nadu and Sri Lanka as well as evaluate with respect to other ICT based systems.

Table 3: Measurable attributes of Biosurveillance Systems

| Attribute | Examples of What Can Be Measured |
|---|---|
| Data quality | Completeness and accuracy of data |
| Sampling bias (Representativeness) | Reporting by zip code, socio-demographic group |
| Disease coverage | Number of diseases in system database |
| Reliability (Stability) | Number of errors by people or computers |
| Sensitivity, specificity, timeliness of case/outbreak detection (Sensitivity, PPV, and timeliness) | Sensitivity, specificity, timeliness of case and outbreak detection |
| Diagnostic precision for case and outbreak detection support for outbreak characterization (Alluded to) | Sensitivity specificity and timeliness at different levels of diagnostic precision |
| Support of outbreak characterization | Relevant data collected by the system, collects usage during outbreak investigations |
| Time latencies (Timeliness) | Delays between collection and receipt of surveillance data |
| Meets functional requirements | The difference between pre-specified requirements and actual functions |
| Acceptability of system or components | Subject or agency participation rates, interview completion rates and question refusal rates; log-ins |
| Compliance with standards | Results of conformance testing of user interface, data |

| | |
|--|---|
| | format, data coding |
| Portability | Cost to install in a different location |
| Privacy and Confidentiality | Compliance with local and state regulations; ability to reidentify individuals |
| Security | System vulnerabilities or security failures as identified by security audits |
| Benefits (morbidity and mortality reduction) | Expected reductions in mortality and morbidity through earlier detection |
| Other Benefits (Usefulness, simplicity, representativeness) | Expected reduction in operational costs owing to policy improvements or workflow efficiency |
| Cost to build or acquire (Flexibility, comparable hardware and software, simplicity) | Actual cost to build or purchase and install |
| Cost to operate | Salaries and overhead; hardware and licenses |
| Cost to add functionality | Actual cost |
| Cost to integrate with other systems | Actual cost |
| Cost of false alarms | Staff time, costs of treatments or other measures taken in response to a false alarm |

Focus group interview

Model the flow of information for the internal processes of the m-HealthSurvey and Sahana BSM-CM as well as the interoperability information flows between the vertical layer – data processing (event detection) and the horizontal layers – application and social. This method is also termed as the “Leapfrog” methodology. Each piece of information should be assigned a ranking from 0 to 5 to identify its level of importance for the internal processing as well as interoperability.

The basic question we need to ask is – “Did the m-HealthSurvey work better than the procedures it may replace?” This question will be answered with a series of indicators that will be measured through statistical calculations, focus group interviews, and observations. In most cases the observations will be through a series of simulations.

Typical economic aspects

Calculate the following

- Percentage of GDP directed towards national health care over the past 3 years to obtain an average. Most countries spend approximately 5% to 11%.
- What percentage of the GDP or Health Care budget is allocated for disease surveillance and notification

- Choices facing a decision maker; i.e. streams of costs and outcomes for both the introduced resource (innovation) and the present system (status quo). The highlight the tension between the costs and outcomes
- Measurement of cost and measurement of outcome for the following -
 - Cost minimization: assume the outcomes are equivalent (measure of cost=monitory value, measure of outcome=none)
 - Cost consequence: list the costs and outcomes, even if multiple end points are used, fore each option (measure of cost=monitory value, measure of outcome=variables)
 - Cost-effectiveness: measure outcomes in clinical terms – lives, life expectancy, number of infections averted (measure of cost=monitory value, measure of outcome=clinical outcome)
 - Cost utility: measure the outcome in utilities, measure of the outcome state (measure of outcome=QALY)
 - Cost benefits: requires that outcomes (lives, quality of life) be given a monitory value (measure of cost=monitory value, measure of outcome=monitory value)

2 Proposed Research Matrix

Kurunegala: 32 villages have been uniformly selected in four MOH divisions: Wariyapola, Udubedewa, Pannala, and Kuliyapitiya, belonging to the Kurunegala health administrative district with each division having 8 villages; where 16 have an operational Sarvodaya Suwadana Primary Healthcare Center. The villages with a Suwadana Primary Healthcare Centers are regarded as organized villages while the remaining 16 villages are regarded as less-organized villages

Sivaganga: 32 villages have been selected in four PHC divisions: Nerkuppai (Block PHC), Sevani Patti (Additional PHC), Keelaseval Pattu (Additional HC), Thirukostiyur (Additional PHC). The village that the Health Sub Center (HSC) is situated and also the resident village of the Village Health Nurse (VHN), will be regarded as the organize villages while the neighboring village without an HSC is regarded as a less organized village.

Table 4 Matrix with Divisions, Community-Healthcare-Workers, and Communities

| Exposed to RTBP | | | | | Unexposed to RTBP | | | | |
|-----------------|-----|-----|------------|-----|-------------------|-----|------------|-----|--|
| Division 1 | | | Division 2 | | Division 3 | | Division 4 | | |
| + | C01 | C05 | C09 | C13 | C17 | C21 | C25 | C29 | |
| | H01 | H03 | H05 | H07 | H09 | H11 | H13 | H15 | |
| - | C02 | C06 | C10 | C14 | C18 | C22 | C26 | C30 | |
| | | | | | | | | | |
| + | C03 | C07 | C11 | C15 | C19 | C23 | C27 | C31 | |
| | H02 | H04 | H06 | H08 | H10 | H12 | H14 | H16 | |
| - | C04 | C08 | C12 | C16 | C20 | C24 | C28 | C32 | |

Note 1 In Table 1, H – denotes Community-Healthcare-Worker and C denotes Community. The cells with “magenta” background are the Organized Communities with the presence of a Community-based Healthcare facility (+) and the cells with “orange” background are the Communities that do not have a formal Community-based Healthcare facility (-). Basically each Community-Healthcare-Worker (“yellow” cells) will cover an Organized Community and a Less Organized Community.

Table 5 proposed participation with respect to the research matrix (confirm)

| <u>Terminology</u> | <u>Sivaganga</u> | <u>Kurunegala</u> |
|----------------------------|---|---|
| Unexposed to RTBP | Villages (or Block) in Sivaganaga district not cover by RTBP | Sarvodaya villages not covered by RTBP |
| Exposed to RTBP | Selected villages in Nerkuppai, sevani Patti, Keelaseval Patti, and Thirukostiyur PHCs. | Villages selected in Kuliyapitiya, Wariyapola, Udubedewa, and Pannala MOH divisions |
| Division | PHC | MOH division |
| Organized Community | Village with Gov HSC | Village with Sarvodaya Suwadana Center |
| Less Organized Communities | Villages that have no HSC | Villages that have no Sarvodaya Suwadana Center |

Note 2 – Given the way the villages are selected, at the time of conducting the mock drills and other assessments, the villages will be selected or deselected and segregated in to each parts of the research matrix to answer the hypothesis

2.1 Who is involved in Evaluation and why?

Table 6 Health administration levels and respective health workers and officials

| <u>Administrative level</u> | <u>Sivaganga</u> | <u>Kurunegala</u> |
|-----------------------------|---|---|
| Province/State | State Public Health Service | Northwestern Province Director of Health Services office |
| District | Sivaganga district Deputy Director of Health Services | Kurunegala district Director of Health Services |
| Division | Thirupathur Block Public Health Center – Block Medical Officer, Medical Officer, Health Inspector, and Sector Health Nurse, IT assistant, and other staff | Wariyapola, Udubedewa, Pannala, and Kuliyanpitiya Medical Officer of Health – Medical Officer of Health |
| Area | Thirupathur Block Health Sub Centers - Twenty five Village Health Nurses | Wariyapola, Udubedewa, Pannala, and Kuliyanpitiya Medical Officer of Health – Public Health Inspectors |

2.2 Formulation of the Mock-drills

The research matrix is mostly applied during the mock drills, which aims to evaluate the RTBP at three different vertical components (Figure 1), described in Table 1. Each of these stages will be further partitioned into the four horizontal layers: social, content, application, and technology.

Table 7 three components of the RTBP with the pilot solutions and the present solutions

| <u>Vertical</u> | <u>Groups</u> | <u>Method</u> | <u>Kurunegala</u> | <u>Sivaganga</u> |
|---|---------------|----------------------------|------------------------------|--|
| Data collection and transmission (upstream comm..) | RTBP: | Mobile phone with software | m-HealthSurvey | m-HealthSurvey |
| | Control: | Present paper forms & ICT | H-544, H-399, telephone, fax | Morbidity form, Communicable disease form, telephone |

| | RTBP: | Computer with software reports | T-Cube | T-Cube |
|--|----------|--|--|---|
| Event detection (data processing) | Control: | Present semi electronic manual process | H-399 consolidated report and Epidemiology Unit aggregated reports | Morbidity report and National Health Information System |
| Reporting and notification (downstream comm..) | RTBP: | RTBP EDXL/CAP situational reports | Sahana Alerting Module | Sahana Alerting Module |
| | Control | Present paper and electronic reports | Weekly Epidemiological Reports and phone, fax | DDHS office mailed reports and phone, fax |

The Group RTBP means the health workers and villages exposed to the RTBP processes and Control means the health workers and villages that are not exposed to the RTBP processes but practice the present processes. The processes of the Control groups will vary between Kurunegala district (Sri Lanka) and Sivaganga district (Tamil Nadu) but the RTBP processes in both countries will be the same.

http://www.eduyu.com/bm_index.asp

3 Hypothesis

The six hypothesis were taken from the proposal “Evaluating a Real-Tim Biosurveillance Program: A Pilot Project¹”

- 1. Healthcare Workers in Divisions 1 & 2 exposed to the RTBP will respond more effectively to communicating disease to the respective Epidemiology Center than the Healthcare Workers in the Control Divisions 3 & 4 unexposed to the RTBP.*
- 2. Epidemiology Units in Divisions 1 & 2 exposed to the RTBP will detect disease outbreaks accurately and contain the outbreak efficiently than Epidemiology Units in Control Divisions 3 & 4 unexposed to the RTBP.*
- 3. Healthcare Workers and Epidemiology Units in Divisions1 & 2 exposed to the RTBP will show interest and recognize the benefits in adopting e-Health programs opposed to the Healthcare Workers and Epidemiology Units in the Control Divisions 3 & 4 unexposed to the RTBP.*
- 4. Communities in Divisions 1 & 2 exposed to the RTBP will have confidence in the National Disease Surveillance and Notification programs more than the Communities in the Control Divisions 3 & 4 unexposed to the RTBP.*
- 5. Healthcare Workers and Epidemiology Units in Divisions 1 & 2 exposed to the RTBP in addition to their RTBP function will leverage ICTs in other areas to enrich their daily activities more than the Healthcare Workers and Epidemiology Units in the Control Divisions 3 & 4 unexposed to the RTBP.*
- 6. Communities that have non governmental Community-based Healthcare Organizations will perform better in monitoring, communicating, and containing disease outbreaks than communities that do not have a formal non governmental Community-based Healthcare Organization.*

¹A copy of RTBP proposal is store on line here - <http://lirneasia.net/wp-content/uploads/2008/07/evaluating-a-rtbp-proposal-v6.pdf>

4 Data collection (upstream communication)

This vertical will evaluate the health workers submitting patient case records from house visits or health care facilities using the m-HealthSurvey mobile phone application and in some cases the Biosurveillance Module Case Management (BSM-CM) web application (e.g. by Public Health Clinic staff).

4.1 Social Layer – Research Questions and methodology

Table 8 Mandatory and optional data collection social layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|--|---|--|
| <u>Mandatory question for pilot phase</u> | | | |
| 4.1.1 How well were the health-workers trained to use the m-HealthSurvey? | Reliable: records sent / total patient counts Accurate: number of errors? Fast: Time to enter record | Health workers Were the health workers submitting all patient data? | Certification Exercise: Is data entry reliable? Is data entry accurate? Is data entry fast? [Method] |
| 4.1.2 Identify, if any, reasons for health workers to reject the m-HealthSurvey (Acceptability of system or components)? | Subject or agency participation rates, interview completion rates and question refusal rates; log-ins | Health workers Apply TAM Gurujaran Perceived usefulness, Perceived ease of use Is there a real need for it? | Certification Exercise / simulations |
| 4.1.3 What is the reliability of health | Number of errors by people, MTTF (what | | Certification Exercise / |

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|---|---|--|----------------|
| workers using the m-HealthSurvey? | was recoded by physician vs m-HS) = case error; other is failed to add a field (mandatory) | NA | simulations |
| 4.1.4 What are the m-HealthSurvey operational costs and benefits compared to present system? | Salaries and overhead; hardware and licenses | NA | NA |
| 4.1.5 What are the costs associated with necessary content development and benefits compared to present system? | Salaries, content development, Implementing cost | Health workers Health officials What are the benefits of using the RTBP developed content over present system available content? | NA |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 4.1.6 Support of outbreak characterization: How is the mobile being used in other ways to support health communication? | NA | Health workers What relevant data is collected through the m-HealthSurvey? What other data is communicated through the mobile phone? | NA |
| 4.1.7 What is the feasibility of deploying the workable components of the m-HealthSurvey nation | Calculate the cost factor | Health workers Health officials | NA |

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|--|---|----------------|
| wide? | | | |
| 4.1.8 How can the Government health system financially sustain the data collection component of the RTBP? | Salaries, hardware, software, indirect costs | Health officials What are the benefits of amalgamating or replacing present system with RTBP? | NA |
| 4.1.9 Will the m-HealthSurvey have an impact on control in the organization? | NA | Health workers Health officials | NA |
| 4.1.10 Does the m-HealthSurvey complement the ongoing initiatives of data collection for curative and preventive programs? | NA | Health workers Health officials | NA |
| 4.1.11 What are other health system outcomes such as better disbursement of public health funds or medicine? | NA | Health workers Health officials | NA |
| 4.1.12 What are the impacts of the m-HS on the health system at large? | NA | Health workers Health officials impact of the m-HS: Do health workers use it? Do health workers like it? Does it improve health workers efficiencies? Does it influence | NA |

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|------------------|---|----------------|
| | | <p>the collection of data?</p> <p>Does it influence health workers decisions?</p> <p>Does it influence the health worker knowledge or skills?</p> <p>Does it help patients?</p> <p>What might ensure from widespread use?</p> | |

Data Quality

Methodology in this section will answer questions 4.1, 4.2, 4.3

4.2 Content Layer – Research Questions and methodology

Table 9 Mandatory and optional data collection content layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|--|--|----------------|
| <u>Mandatory question for pilot phase</u> | | | |
| 4.2.1 What is the minimum data required for reliable outbreak detection? | Number of m-HealthSurvey and DB attributes relative to the present system's attributes | Health workers Health officials What additional content is required by the health department that are part of the SOP? Number of diseases | NA |

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|------------------|--|--|
| | | the m-HealthSurvey hold in internal memory (% of disease w.r.t WHO DB)? Does the m-HS collect enough data to produce desired results? What are the gaps in the m-HS? | |
| 4.2.2 What are the m-HealthSurvey privacy and confidentiality issues? | NA | Compliance with local and state regulations; ability to re identify individuals? Ask from random sample of patients? | NA |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 4.2.3 Can the m-HS be upgraded to comply with available standards? | NA | RTBI Auton Lab | Results of conformance testing of user interface, data format, data coding |
| 4.2.4 What information not being captured could be a good data source? | NA | Health Workers Health officials Auton Lab RTBI | Literature review |

4.3 Application Layer – Research Questions and methodology

Table 10 Mandatory and optional data collection application layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|---|--|--|---|
| <u>Mandatory question for pilot phase</u> | | | |
| 4.3.1 Did the m-HealthSurvey work technically as designed (i.e. meet the functional requirements)? | Fast: Transmission time relative to paper report? Reliable: Data entry time relative to paper record? | Health workers Usability: Is it user friendly? How can it be improved? What were the problems? Did the applet work with the phones? Where their any technical issues? Which parts caused the effects? What were the problems or difficulties application developers and system developers encountered? Is it reliable? Is it accurate? | Certification Exercise / The difference between user/software requirement specifications and actual functions |
| 4.3.2 What is the cost associated with developing and maintaining the m-HealthSurvey? | Salaries, hardware, software, licenses for design, develop, and integrate | NA | NA |
| 4.3.3 What are the costs associated with adding functionality to the m-HealthSurvey? (build in standards and improve) | Actual costs to improve existing functionality, building in standards, adding security to minimize vulnerabilities | NA | NA |
| 4.3.4 What are the costs associated with | Actual costs of transferring from | NA | NA |

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|--|---|----------------|
| integrating the m-HealthSurvey with Sahana BSM Module database? | RTBI db to SHN db | | |
| 4.3.5 What is the cost of installing the m-HealthSurvey in a different location (portability)? | Actual hardware, software, customization, and training costs | NA | NA |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 4.3.6 How can data entry times be reduced? | | Health workers RTBI Auton Lab What means are available to reduce data entry times? Can training be improved? Can other systems such as bar codes be used? | |

4.4 Technology Layer – Research Questions and methodology

Table 11 Mandatory and optional data collection technology layer research questions

| | <u>Calculate</u> | <u>Interview / Questionnaire</u> | <u>Observe</u> |
|---|----------------------|----------------------------------|----------------|
| <u>Mandatory question for pilot phase</u> | | | |
| 4.4.1 Is there any latency in | Average and variance | | Simulations |

| | | | |
|--|--|----------------|-------------|
| m-HealthSurvey delivering data? | between mobile and server date-time | | |
| 4.4.2 Is there any latency in BSM-CM delivering data? | Average and variance between mobile and server date-time | | Simulations |
| 4.4.3 Was the GPRS connectivity available at all times you wanted to transmit m-HealthSurvey data (certainly)? | Count outliers w.r.t average latency | Health workers | Simulations |
| 4.4.4 Was the internet connectivity available at all time you wanted to transmit Sahana BSM-CM information? | Count outliers w.r.t average latency | Health workers | Simulations |
| 4.4.5 Was the data received through the mobile phone and GPRS complete and accurate (data quality)? | | Health workers | Simulations |
| 4.4.6 Was the data received through the personal computer and ADSL complete and accurate (data quality)? | | Health workers | Simulations |
| 4.4.7 What is the cost associated with transmitting data over GPRS? | Fixed+ variable cost per record | | |
| 4.4.8 Any issues around maintain batteries and power supply? Malfunction or theft of device? | | | |

4.5 Data Reliability

Number of records submitted per week, what is the trend

Number of correct vs. error data sent per week, what is the trend
Measure the number of records that needed be cleaned up
Frequency of cleanup

4.6 Certification Exercise

Certification exercise should be conducted after the user has had two months experience of using the m-HealthSurvey application. The objective to judge the competency of the user's ability to setup the application (Part I), operate the application (Part II), and have knowledge of the standard operating procedures (Part III). The exercise should be explained to the participants. The entire exercise should be conducted under 60 minutes.

Part I – Application initialization (exercise time 12 minutes)

- Download and install application - if already in system then delete current installation and reinstall; if completed under 2 minutes 3 points, under 5 minutes 2 points, under 10 minutes 1 point; else 0 points.
- Configure application – download list, register profile, and retrieve locations; if completed under 3 minutes 3 points, under 7 minutes 2 points, under 10 minutes 1 point; else 0 points.
- Objective of this exercise should be given in writing; i.e. proof of users ability to fully restore application in the field
- instruction guide or user manual should be provided

Part II – Data Entry (exercise time 20minutes)

- Determine a set of, environment (i.e. country or state) specific, patient complaints and diseases
- Generate a set of case records (i.e. patient complaints) with random assignment of date, gender, and age based on distributions observed from previous data
- Construction exercise
 - Three different entry methods: 1) “unknown” disease with symptoms and signs only
 - select disease but edit symptoms, and signs
 - 3) disease not in list (i.e. “other”) with disease, symptoms and signs
- Vary the gender: male, female, and unknown in each of the records
- Vary the age-group in each of the records
- Vary the location for each record, duplication in acceptable

- Construct a set of story problems for the 6 different records
- Have the health workers enter and submit the data
 - objective of the exercise should be stated, in writing
 - written instructions on data entry (user guide or manual) must be provided
 - The data entry process of the 6 records should take no more than 15 minutes (estimate 2.5 min to serve a single patient including data entry of 15 seconds, which would be equivalent of reading the story problem and entering the data)
 - Run the exercises in small groups, PHC or MOH division wise; i.e. 4 separate exercises in each country
 - Run all group exercises at the same time (i.e. morning or evening) to eliminate any nuisance factors
- Evaluating individual health worker
 - Count the number of records submitted by each health worker, benchmark all 6, deduct a point for each missed entry
 - Average the time taken to enter 5 of 6 records; deduct a point for each additional minute over 15 minutes; add point if all 6 were sent under 15 minutes.
 - After evaluation is complete and using live database, simply deactivate those records from the exercise
 - extraneous factors impacting the exercise 1) time and day the exercise is conducted for each group 2) order the story problems are listed (can eliminate by randomizing the order but may vary with each person as well) 3)

Part III – Standard operating procedures (exercise time 8 minutes)

- Have health workers realized the standard operating procedures
- The objective is to evaluate the competency in the standard operating procedures
- A set of multiple choice questions should be made use in this participants and the questions should address the criteria of assessing the competency in
 - What the user should do if the required content such as the disease, symptom, or signs are not in the application
 - What the user should do if there are technical problems with the software and hardware
 - What actions should be taken by the users ensure the constant workability and upkeep of the hardware

Sample certification exercised used in RTBP

m-HealthSurvey Certification Exercise

Real-Time Biosurveillance Program

This form is intended for the Real-Time Biosurveillance Program (RTBP) to assess and certify the health workers operating the m-HealthSurvey mobile phone software used for digitizing and submitting patient case data. The information gathered through this exercise is for the purpose of the RTBP project and is not to be distributed without the consent of the RTBP's Principal Investigators.

Each participating Healthcare Worker should complete this exercise to the best of their ability. If any of the instructions are unclear, please inquire from the RTBP staff member conducting this exercise. The RTBP staff member will explain the process to you before starting Parts I, II, and III of the exercise.

| | | |
|--|--------------------------------|--|
| Health Worker Personal Information: | Today's Date: | |
| Full Name : | Employee ID: | |
| Division Name: (PHC/MOH) | Center Name: (HSC/Suwadana) | |

Exercise instructions

- 1 You may refer the user manual during this exercise at anytime
- 2 You may not consult any of the RTBP staff or any of the colleagues for answers
- 3 Begin and end the exercise when you are instructed by the RTBP staff member

Part I – Install and configure m-HealthSurvey

(Exercise time: 12 minutes)

| | | | | | |
|-----------------------------|--|---------------------------|--|---------|--|
| Start Time: (e.g. 13:15) | | End Time: (e.g. 13:27) | | Points: | |
|-----------------------------|--|---------------------------|--|---------|--|

Purpose of this part of the exercise is to judge your ability to install and configure the m-HealthSurvey application on your own. If the m-HealthSurvey was to stop working and required re-installation and configuration while in the field, you should be able to complete this task by yourself.

- 1 If the application is already installed on your mobile handset then delete the application.
- 2 Use the mobile phone's WAP application to enter the url: [INSERT URL HERE, remove this comment] to download and install the application
- 3 Configure the application by applying the steps: download list, register profile, and retrieve locations

Part II – Data entry and submission

(Exercise time: 20 minutes)

| | | | | | |
|------------------------------|--|----------------------------|--|---------|--|
| Start Time: (e.g. 1:15pm) | | End Time: (e.g. 1:27pm) | | Points: | |
|------------------------------|--|----------------------------|--|---------|--|

Enter and submit the patient records A – F, through m-HealthSurvey, to the best of your ability. In this exercise you are not required to submit patient names, notes, or status. You are required to submit the mandatory fields: case date/time, location (village name), symptoms, gender, and age-group. In some cases you are required to submit the disease and signs as well as determine using “unknown” or “other” options for the disease.

| Record | Date | Time | Gender | Age | Symptoms | Signs | Disease |
|--------|----------|-------|--------|-----|--|---------------------|----------------|
| A | 15/08/09 | 14:30 | M | 46 | headache, nausea, | fever | |
| B | 15/08/09 | 14:34 | M | 13 | sneezing, nasal itching | runny nose, red eye | Hay Fever |
| C | 15/08/09 | 14:39 | F | 5 | scratchy feeling | Swollen eye lid | Conjunctivitis |
| D | 15/08/09 | 14:45 | M | 8 | fever, nausea | kidney failure | Leptospirosis |
| E | 15/08/09 | 14:48 | F | 33 | Fever, headache, sore throat | running nose | |
| F | 15/08/09 | 14:52 | F | 61 | burning, inflammation on skin, irritation on skin, itching | redness | Insect sting |

Part III – Standard Operating Procedures

(Exercise time: 08 minutes)

Check (□) any of the answers that best fits each of the scenarios 1) – 3)
“other suggestions” that you mention will be bonus points, if valid.

Points:

1) If the disease name is not in the m-HealthSurvey what should you do?

- Report problem to RTBP
- Write on paper but do not submit record though mobile
- Use “other” and type the disease name
- type disease name in symptom or signs field
- Try download-list first to check if disease was updated
- Do nothing

Other suggestions:

2) If you have problems or encounter any faults with the m-HealthSurvey, what should you do?

- Inform the DDHS office
- Note records on paper until problem is fixed, then submit via m-HealthSurvey
- Call the mobile service provider
- Contact an RTBP staff member
- Do nothing

Other suggestions:

3) What should you do to maintain the m-HealthSurvey and mobile phone

- Delete and reinstall software once a month
- Charge phone battery every day
- download-list once a week or when required
- Do nothing

Other suggestions:

Marking Scheme

DO NOT translate or include this section in the actual exercise. This section is purely for RTBP staff for scoring the health worker completed certification exercises.

Part I - Install and configure m-HealthSurvey (Total 20 points)

- | | |
|-----------------------------|--------|
| 1) Delete m-HealthSurvey | 04 pts |
| 2) Install m-HealthSurvey | 04 pts |
| 3) Configure m-HealthSurvey | |
| download list | 04 pts |
| register profile | 04 pts |
| retrieve location | 04 pts |

Bonus points – for each minute (round up) under 12 minutes is worth 1 point.
Example, if completed in 8 minutes ,then $12 - 8 = 4$ minutes is worth 4 bonus points

Part II - Data entry and submission (Total 50 points)

Deduct 1 point from each record if incorrect date, gender, or age; i.e. deduct maximum 1 point..

| Record s | Availeble points | Point deduction scheme |
|-----------------|-------------------------|---|
| A) & E) | 10 pts | Select disease = “unknown” or compatible disease matching exact symptoms & signs - Deduct 2 point, if improper disease name is given not matching symptoms and signs |

| | | |
|---------|--------|--|
| | | <ul style="list-style-type: none"> - Deduct 2 point if any of the listed symptoms are missing; i.e. should type all symptoms - Deduct 2 point if any of the listed signs are missing; i.e. should type all signs |
| B) & D) | 10 pts | <p>Set disease = "other" and type the given disease name</p> <ul style="list-style-type: none"> - Deduct 2 point, if improper disease name is given - Deduct 2 point if any of the symptoms are missing; i.e. should type all symptoms - Deduct 2 point if any of the signs are missing; i.e. should type all signs |
| C) & F) | 05 pts | <p>Search and select disease name from list, then edit the symptom and signs lists</p> <ul style="list-style-type: none"> - Deduct 1 points if symptoms are not edited - Deduct 1 points if signs are not edited |

Bonus points - for each minute (round up) under 20 minutes is worth 1 point.

Example, if completed in 16 minutes ,then $20 - 16 = 4$ minutes is worth 4 bonus points

Part III - Standard operating procedures (Total 30 points)

Add 05 points for each correct answer listed below and **deducted 02 points for each incorrect answer**

1) Correct answers:

- use "other" and type the disease name
- try download list first to check if disease was updated

2) Correct answers:

- Contact RTBP staff member
- Note records on paper until problem is fixed, then submit via m-Healthsurvey

3) Correct answers:

- download list once a week or when required
- Charge phone battery every day

Bonus points - give an additional **02 points** for "other suggestions" that are correct and applicable to question 1) - 3).

Certification criteria

- A health worker scoring above 70 points is a certified m-HealthSurvey user.
- A health worker scoring above 95 points is a potential m-HealthSurvey trainer.

5 Event detection (data processing)

5.1 Social Layer – Research Questions and methodology

Table 12 Mandatory and optional data processing social layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|---|---|--|----------------|
| <u>Mandatory question for pilot phase</u> | | | |
| 5.1.1 What are the cost benefits of using the TCWI and detection algorithms? | Hardware, software, support costs relative to baseline: over conventional aggregation reports | Health officials | NA |
| 5.1.2 Do the health officials find the TCWI an additional burden to the present workload? | Percentage of time spent on TCWI w.r.t total workingtime | Health officials | NA |
| 5.1.3 Were there losses in data? | # records in T-Cube / # records in DB | Health officials Were the health officials seeing all data submitted? If not what were the causes for loss of data? | Simulations |
| 5.1.4 How well were the health-officials trained to use TCWI? | Receiver operating characteristic | Health officials | Simulations |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 5.1.5 Will the TCWI have an impact on the control in the organization? | NA | Health officials | NA |

| | | | |
|---|----|------------------|----|
| 5.1.6 What are the layers of the health administrative system in public health that the TCWI be made available? | NA | Health officials | NA |
| 5.1.7 What are the impacts on the health system at large? | NA | Health officials | NA |

5.2 Content Layer – Research Questions and methodology

Table 13 Mandatory and optional data processing content layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|--|----------------------------------|--|--------------------------------|
| <u>Mandatory question for pilot phase</u> | | | |
| 5.2.1 What is the minimum set of data elements required for detecting disease outbreaks? | NA | Auton Lab | Literature survey |
| 5.2.2 Were the time series and spatial scan information presented well for epidemiologist to detect outbreaks? | NA | Health officials | NA |
| 5.2.3 Was the pivot table helpful in filtering the data to your needs? | Usage logs | Health officials | NA |
| 5.2.4 Where the algorithm detected event alert meaningful and easy to comprehend? | NA | Health officials | NA |

| <u>Questions to ask at the end (forward looking questions)</u> | | | |
|--|----|---|----|
| 5.2.5 What is the level of granularity the analyst would like to perform the analysis? | NA | Health officials Location, disease, symptoms, time | NA |
| 5.2.6 What additional information would you like the TCWI to offer? | NA | Health officials | NA |

5.3 Application Layer – Research Questions and methodology

Table 14 Mandatory and optional data processing application layer research questions

| | <u>Calculate</u> | <u>Interviews / Questionnaires</u> | <u>Observe</u> |
|---|---|---|---|
| <u>Mandatory question for pilot phase</u> | | | |
| 5.3.1 Did the TCWI and algorithms work technically as designed? | Error rates, login frequencies, usage times | Health workers Meet the functional requirements? Were all the data available at the time you initiated the analysis cycle? Did they produce the desired results? Was the TCWI used as anticipated? Did they work better than the present system? Were they easy to understand and use? Were the controls provided adequate | Simulations actual deliverable vs. proposed requirements |

| | | | |
|--|---|--|-------------|
| | | <p>to conduct the analysis?</p> <p>Were the display of information and controls acceptable or appropriate?</p> <p>Were the introduction of the TCWI and algorithms useful?</p> | |
| 5.3.2 Did he TCWI out perform the present analytical methods? | Timed to detect, false alarm rates, hit rates, miss rates, correct rejection rates, ROC, AMOC | Health officials | Simulations |
| 5.3.3 What were the problems or difficulties application developers and system developers encountered? | Time spent relative to previous implementations | RTBI, Auton Lab Was it easy to interface with data collection layer? What were the challenges of customizing to the fit the environment? | NA |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 5.3.4 What additional features are required for a full scale deployment? | NA | Auton Lab Health workers | NA |

5.4 Technology Layer – Research Questions and methodology

Table 15: Mandatory and optional data processing technology layer research questions

| | <u>Calculate</u> | <u>Interview</u> | <u>Observe</u> |
|---|------------------------------|------------------|----------------|
| <u>Mandatory question for pilot phase</u> | | | |
| 5.4.1 Was the hardware (server) specifications adequate for TCWI to perform at its fullest? | Processing times (latencies) | NA | Simulations |
| <u>Questions to ask at the end (forward looking questions)</u> | | | |
| 5.4.2 | | | |

5.5 Economic Aspects

Calculate the following

- Choices facing a decision maker; i.e. streams of costs and outcomes for both the event detection analytical tools and the present system analytical methods (i.e. IDSP in India and WER in Sri Lanka). The highlight the tension between the costs and outcomes.
Measurement of cost and measurement of outcome for the following -
 - Cost minimization: assume the outcomes are equivalent (measure of cost=monitory value, measure of outcome=none) – cost of reentry of data at IDSP or EPID; cost of algorithms detecting event vs. human analyst going through spreadsheet to find anomalies, analysis of all case records vs analysis of all records by IDSP or EPID
 - Cost consequence: list the costs and outcomes, even if multiple end points are used, fore each option (measure of cost=monitory value, measure of outcome=variables). Cost of generating a trend graph using T-Cube vs IDSP or WER systems outcome is the time to obtain the results on demand.
 - Cost-effectiveness: measure outcomes in the number of infections averted. Use the replication and parallel study to determine the number of cases detected using conventional method vs. the T-Cube by looking at the time differences and the number of new cases reported between the time lag.
 - Cost benefits: requires that outcomes (lives, quality of life) be given a monitory value (measure of cost=monitory value, measure of outcome=monitory value)

The costs calculated for implementing and operating the introduced resource: T-Cube and present system is for a single governance district for a three year operational cycle.

T-Cube TCO

Implementation

Software Development

3 software engineers x 200 days
development tools

Static data collection

1 GPS units
1 persons x 50days
transport cost

Customization

User Training (EPID Unit)

Data Center

Server

Intel high end Personal Computer
Uninterrupted Power Service

Operating system

3rd Party Software
Firewall
Anti virus guard

Internet

512kbps connection

Office space

10M3 space
Computer table
Utilities
Environment control (AC)

System Administrators

1 person x 50 days

Present system

Development

Training MOH

Training PHI

Training MO

Training EPID Unit

5.6 Utilization, Outcome, and Usability assessment

If your application does not have the capability to monitor the login and utilization; else you want to verify the subjective response to the utilization logs that you have obtained through your system, then apply this assessment. Users are expected to submit the assessment each week. If it is done each month then users may forget the actual answers. Moreover, the assessment forces them to use TCWI more often.

Table 16: Utilization questions

| Question | Answers | Purpose |
|--|---|--|
| 1) Where were you accessing TCWI from? | List the set of health department locations in a drop down list e.g. PDHS office Kurunegala, DDHS office Sivagangai, PHC – Thirukostiyur, MOH - Kuliyapitiya | Identify the locations that most utilize the application |
| 2) How many days did you use TCWI during the week? | List a range of days also giving zero as an answer e.g. Never (zero), 1-2, 2-4, over 5 | Identify the frequency of use during a week to understand as to how often T-Cube should refresh the data |
| 3) On average, how many hours do you spend on TCWI each time it is used? | List a range of hours to select from. If question 2) answer is “never” then user may skip this answer and it is intuitive that 0 hour e.g. Less than 1 hour, 1 – 2 hours, 2 – 4 hours, more than 5 hours | Identify the number of hours a user spends on disease surveillance using TCWI |

| | | |
|------------------------------------|--|--|
| 4) What are the features you used? | List all the available main features for user to select a subset of them; also give “other” as an option to write in a feature that is not listed in the list e.g. Query analyzer, Massive scan, Spatial scan, Pivot tables, Other | Identify the most popular analytical methods |
|------------------------------------|--|--|

Table 17: Outcome questions

| Question | Answers | Purpose |
|--|--|--|
| 5) How many of the Massive Screening alerts generated by TCWI were of any significance? | List intervals of numbers in a drop down list e.g. None (Zero), 1 – 5 per week, 5 – 10 per week, over 10 per week | Identify the effectiveness of the Massive Screening function |
| 6) How many "Spatial Scan" scores over 0.9500, generated during the week, were of any significance? | List intervals of numbers in a drop down list e.g. None (Zero), 1 – 5 per week, 5 – 10 per week, over 10 per week | Identify the effectiveness of the Spatial Scan function |
| 7) If you detected any potential out breaks of significant event list each case in the text box below? | Provide space for user to write the disease, locations, and counts e.g. 1) disease=dengue, location=Nerikkupai, Sevanipatti, count=3; e.g 2) symptoms=high fever, skin rash, vomitting, location=Naramala, Udubeddewa, Wairiyapola, count=12 | Identify the list of most significant events that were of importance to the health officials |

Table 18: Usability questions

| Question | Answers | Purpose |
|--|--|---|
| 8) How often did TCWI fail or not work properly during the week? * | List a set of intervals in a drop down list e.g. Never – always worked perfectly, Failed 1-5 time a week, Failed 6-10 times a week, Failed over 10 times a week | Identify the frequency of dysfunctional |

| | | |
|--|---|--|
| 9) What are some of the common problems you encountered during the week? | <p>Provide a set of options with check boxes to select all the applicable answers</p> <p>e.g. Internet connection was down, Could not access TCWI but my Internet was working, In the "Time Series" panel the data did not load properly, In the "Map" panel the map and data did not load, In the "Time Series" panel "Query analyzer" did not work properly, In the "Time Series" panel the "Massive Scan" function did not work properly</p> <p>In the "Map" panel Spatial Scan did not work properly, Pivot tables did not work properly, Pivot table did not load the Time Series and Pi-Charts properly, Other:</p> | Identify the some of the key problems that usually occur |
|--|---|--|

5.7 Replication study

In the replication study the main research criteria is evaluating the speed of detections and the ability to detect all significant events.

- Identify a period in the past with a significantly high count of one or more diseases (e.g. dengue outbreak, Sri Lanka, Jan – May 2009)
- Obtain the reported disease counts with locations and time periods from the Epidemiology Units for that period; e.g. weekly epidemiological reports published by the Epidemiology Unit of Sri Lanka that give weekly counts of selected diseases.
- Use those sparse data (i.e. distributed weekly data) of disease counts to generate a set of synthetic data. The data should be distributed to obtain daily counts; e.g. take the weekly count X of a disease for a particular location (district) distribute it over the seven days: S, M,T, W,T,F,S in a week with probability distribution p_1,p_2,\dots,p_7 , where p_i represents the percentage of patients that report a case on day i . The can be further split based on gender and age groups. Use a similar strategy as splitting the weekly data over days; e.g. using national consensus data to determine the male/female ration and infant/child/teen/adult/elder ratios.

- Load the synthetic data directly into the database. If the replication study is to be performed over an extensive period then the data can be loaded in stages to emulate the gradual receiving of data over a period; e.g. the detection algorithms can be run in four occasions on four weekends. The six months of data can be partitioned into four chunks of data with each six weeks of data in each chunk.
- The team that is executing the algorithms to detect events in the datasets should not be the same as the team producing the synthetic data and injecting it into the database. Otherwise, the team running the algorithms will know exactly what parameters to tweak in order to ensure the algorithms accurately detect the past known events
- The algorithm detected events and the time of the alert should be recorded. This list will be compared against the list generated by the health officials based on their experience of past events. **Table 18** shows an example of the list that would be generated through the consultative process based on information of present system and through the introduced process.

Table 19: listing of detected events though the present and introduced system

| Present detection system / Introduced detection system (T-Cube) | | | | |
|---|---------------|-------------|-----------|--------|
| Disease | Detected date | Location(s) | Gender(s) | Age(s) |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

speed of detection

retrospective analysis

5.8 Measure RECALL, ROC, and AMOC

Objective is to evaluate the T-Cube biosurveillance detection algorithms by measuring its accuracy (sensitivity and false alarm rates) and time to detection (i.e. time of infection of an individual case to the time algorithm detected the outbreak).

With respect to RTBP this measure will be applied to the TCWI. Health Officials (DDHS, PDHS, and MOH) will be presented with a set of alerts generated on a bi-weekly basis (or twice each month). These alerts would be a combination of both actual alerts produced by TCWI as

well some pretentious alerts injected in to the list to judge the mood of the respondent. Then they will be asked to mark them as true or false based on their knowledge of the state of health affairs.

The top 10 weekly list of alerts will be generated by a person who is not a health official but is competent and familiar with operating TCWI as well as can make up some fake alerts. The alerts will be copied in to an excel file and emailed to the respective staff in the DDHS, PHC, PDHS, and MOH offices.

Table 18, shows and example of a list of alerts produce to the health departments. The health officials will be asked to indicate the date, they first came to know of the disease. If the date is left unpopulated (i.e. empty) that is an indication that the alert is false or is not known to the health departments.

Table 20: Example of a list of bi-weekly alerts produced to health officials

| Disease | Location | Count | Score | 30. Dec. 1899 | Health Dept Identified date |
|-----------|----------|-------|-------|---------------|-----------------------------|
| Fever | Naramala | 3 | 0.98 | 13. Aug. 2009 | |
| Malaria | Naramala | 1 | 0.93 | 13. Aug. 2009 | |
| | | | | | |
| Diarrhoea | Amalgama | 10 | 0.97 | 22. Aug. 2009 | |

Table 21: Two by two contingency table

| Prediction Rate | <i>Actual value</i> | |
|-----------------|--|--|
| | True Positive A TCWI generated alert that corresponds to an actual out break or event identified by the officials | False Positive A TCWI generated alert that was rejected by the health official indicating it was not a significant event or was not brought to their attention |
| | False Negative Any significant events that were identified by the health officials but was not presented in the list of alerts | True Negative Any of the randomly generated fake data that were correctly rejected as an insignificant event that the health officials have no record of or are not aware of |

Next few paragraphs define the calculations of ROC, AMOC, and RECALL.

Recall, commonly known as *sensitivity*, is a measure specifically referred to in detection analysis, which measures the proportion of actual positives which are correctly identified.

$$Sensitivity = \frac{\text{number of True Positives}}{\text{number of True Positives} + \text{number of False Negatives}}$$

ROC, is an abbreviation for Receiver Operating Characteristic. The ROC curve is a plot of the sensitivity vs. 1-specificity. Another way to plot the ROC curve is to graph the True Positive Rates (TPR) vs the False Positive Rates (FPR), also known as the relative operating characteristic curve. This computation is used in the RTBP because ROC analysis is related in a direct and natural way to cost/benefit analysis of diagnostic decision making.

AMOC - Activity Monitoring Operating Characteristic is a measure that evaluates the relationship between the false alarm rates and the time-lines. The AMOC curve is obtained by plotting the false alarm rates against the time-lines (Fawcett and Provost, 1999).

Replicated data do we get quicker detection, we don't need mobile phones

simulations study look at current system, added benefits

6 Alerting / Reporting (downstream communication)

6.1 Social Layer – Research Questions and methodology

Table 22 Mandatory and optional notification social layer research questions

| <u>Mandatory</u> | <u>Calculate</u> | <u>Interview</u> | <u>Observe</u> |
|--|------------------|------------------|----------------|
| 1) What are the costs and benefits of the alerting component? | X | | |
| 2) How well were the health-officials trained to use the SAM? | | X | X |
| 3) How well were the health-workers trained to interpret the SAM disseminated health alerts? | | X | X |
| <u>Optional</u> | | | |
| 4) Will the SAM have an impact on control in the organization? | | | |
| 5) Do the recipients (subscribers) perceive SMS/Email/Web/Voice alerts as a nuisance? | | X | |
| 6) How, when, where, whom should alert be issued? | | X | |
| 7) Who should issue the alerts and what policies should be in place? | | X | |
| 8) What are the impacts on the health system at large? | | X | |

6.1.1 Methodology

6.2 Content Layer – Research Questions and methodology

Table 23 Mandatory and optional notification content layer research questions

| <u>Mandatory</u> | <u>Calculate</u> | <u>Interview</u> | <u>Observer</u> |
|---|------------------|------------------|-----------------|
| 1) Were the health officials and health workers receiving all information? If not what were the causes for the loss of information? | X | X | X |
| 2) | | | |

6.2.1 Methodology

6.3 Application Layer – Research Questions and methodology

Table 24 Mandatory and optional notification application layer research questions

| <u>Mandatory</u> | <u>Calculate</u> | <u>Interview</u> | <u>Observe</u> |
|---|------------------|------------------|----------------|
| 1) Did the SAM work technically as designed? | | X | X |
| 2) Was the SAM used as anticipated? | | X | |
| 3) Did the SAM produce the desired results? | | X | X |
| 4) Did the SAM work better than the procedures it has replaced? | | X | |
| 5) Was the display of the form, attributes, and content of the SAM acceptable or appropriate? | | X | X |
| 6) Was the display of alert message content over, SMS, email, and web acceptable and appropriate? | | X | X |
| 7) What were the problems or difficulties application developers and system developers encountered? | | X | |
| 8) Was the introduction of the SAM useful? | | X | |

6.3.1 Methodology

Compare result 1)

6.4 Technology Layer – Research Questions and methodology

Table 25 Mandatory and optional notification technology layer research questions

| <u>Mandatory</u> | <u>Calculate</u> | <u>Interview</u> | <u>Observe</u> |
|---|------------------|------------------|----------------|
| 1) Were the health officials able to publish the alert at the desired time? | | X | X |
| 2) Did the health workers receive the alert on time? | X | X | X |

6.4.1 Methodology

7 Millennium Development Goals

It is proposed that the impact of the RTBP on the MDGs² is taken in to consideration. The sections below have listed relevant MDGs agreeing with the RTBP objectives. The items crossed off may or may not be relevant to the RTBP and should be discussed.

7.1 MDG 4: Reduce Child Mortality

4a: Reduce by two thirds the mortality rate among children under five

- 4.1 Under-five mortality rate
- 4.2 Infant mortality rate
- ~~4.3 Proportion of 1 year old children immunized against measles~~

7.2 MGD 5: Improve Maternal Health

Target 5a: Reduce by three quarters the maternal mortality ratio

- 5.1 Maternal mortality ratio
- ~~5.2 Proportion of births attended by skilled health personnel~~

Target 5b: Achieve, by 2015, universal access to reproductive health

- ~~5.3 Contraceptive prevalence rate~~
- ~~5.4 Adolescent birth rate~~
- ~~5.5 Antenatal care coverage (at least one visit and at least four visits)~~
- ~~5.6 Unmet need for family planning~~

7.3 MDG 6: Combat HIV/Aids, Malaria, and other diseases

Target 6a: Halt and begin to reverse the spread of HIV/AIDS

- 6.1 HIV prevalence among population aged 15-24 years
- ~~6.2 Condom use at last high-risk sex~~
- ~~6.3 Proportion of population aged 15-24 years with comprehensive correct knowledge of HIV/AIDS~~
- ~~6.4 Ratio of school attendance of orphans to school attendance of non-orphans aged 10-14 years~~

² MDGs list on UNDP website - <http://www.undp.org/mdg/>

Target 6b: Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it

6.5 Proportion of population with advanced HIV infection with access to antiretroviral drugs

Target 6c: Halt and begin to reverse the incidence of malaria and other major diseases

6.6 Incidence and death rates associated with malaria

6.7 Proportion of children under 5 sleeping under insecticide-treated bednets

6.8 Proportion of children under 5 with fever who are treated with appropriate anti-malarial drugs

6.9 Incidence, prevalence and death rates associated with tuberculosis

6.10 Proportion of tuberculosis cases detected and cured under directly observed treatment short course

7.4 Methodology

7.4.1 Objective study

For each of the applicable criteria MDG 5 – 6:

- 1) Identify MDG initiatives in RTBP conducted areas
- 2) Understand their strategies and impact to date
- 3) Obtain the past 2 – 3 years of data with respect to the MDGs
- 4) Study the impact trends, and compare with the RTBP data.

7.4.2 Subjective study

Interview random samples of villagers and local health workers in the areas RTBP is being tested to collect their opinion pertaining to the identified MDGs:

- 1) Are they aware of the MDGs?
- 2) Do the MDG apply to their village or area?
- 3) Are they aware of the MDG programs in affect in their area?
- 4) What is their opinion on the outcomes of those programs? (how, when and why?)
- 5) Are they aware of the RTBP?
- 6) What is their opinion on the outcome of the RTBP?
- 7) Do they think that the RTBP can help achieve the MDGs? (how, when and why?)
- 8) What are other health related issues they would like see resolved? (how, when and why?)

8 References

Friedman, C. and Wyatt, J. (2006) Evaluation methods in biomedical informatics, second edition, health informatics series, Springer.

9 APPENDIX A – QUESTIONNAIRES

9.1 Health Worker - Data collection simulation survey

9.2 Observer - Data collection simulation survey

9.3 Health Official - Event detection simulation survey

9.4 Observer - Event detection simulation survey

9.5 Health Official - Health alerts simulation survey

9.6 Health Worker - Alert simulation survey