Swasthya Slate Device testing Summary

Introduction
Swasthya Slate as a device aims to provide integrative services for diagnostics and care delivery. It aimed to provide multiparameter as well as programmatic support and hence it was important to evaluate the system using a multistage evaluation framework. Our evaluation framework is captured in Figure 1.

![Evaluation Framework](image)

**Figure 1. Evaluation Framework**

Hardware and Software evaluation
In the first stage of testing we focused on hardware evaluation. We followed standards based approach to hardware testing. Each component and submodule was tested individually for repeatability, consistency and durability. We developed a detailed requirement specification following which a checklist was developed to look at individual submodules. This checklist was important in linking product capabilities desired to hardware specification required and was a major tool in reducing the price of the entire system. We aimed from the beginning to provide a requirement specifications based approach. In our system each module was designed to fulfil at least 95% of the requirement specifications with the hardware. Our testing procedure verified that over 1000 uses the system met the 95% requirement. Then integration testing was performed. Integration testing allowed testing of the complete system including the firmware. The integration testing was specifically designed to optimize on dataflow across hardware and also to meet power requirement. An interesting case was in using Bluetooth module. The Bluetooth module consumes a portion of the power and conventional design tends to give more power to the Bluetooth unit which is evident in battery drain of mobile phones when Bluetooth is turned on.

We developed custom hardware that sources power to the Bluetooth unit only when data collection from the diagnostics is completed locally on the system. This allows us to maximize power and we have now obtained a power backup on our system of 6-7 days with this system. Our integration testing was hence designed to provide a comprehensive approach. Firmware testing of our system was carried as per a set protocol that looked at accuracy of output given an input, firmwares capacity to handle multiple commands, the ability of firmware to queue certain functions and optimize them, signal processing capabilities and the ability to be remotely updated. A checklist was developed to cover all aspects of firmware functionality and its stability. A key strategy in firmware testing was regression testing - ensuring that fixed bugs remain fixed when other changes are applied. We used Polyspace Bug Finder™ that identifies run-time errors, data flow problems, and other defects in C and C++ embedded software. Using static analysis, Polyspace Bug Finder helped analyze software control and interprocedural behavior. We were able to test and develop the system with predictable efficacy. We also employed the Polyspace Code Prover™ that evaluated the absence of overflow, divide-by-
zero, out-of-bounds array access, and certain other run-time errors in C and C++ source code. The
system employs formal methods-based abstract interpretation to prove code correctness. These tools
were extremely essential in us completing the firmware testing and the hardware integration testing.
All our systems met the established criteria of meeting the checklists with 95% or more score.

From the industrial design side, we had to evaluate the quality of construction, physical design and
accessibility. Our system was designed to meet IEC 60601-1 IEC 60601-2 and other related standards.
This meant we had to use certain materials from the beginning. Our testing of the system was to
ensure that it meets the standards. We developed a detailed Risk Control, Validation of Effectiveness,
Residual Risk Evaluation worksheet. This worksheet developed in collaboration with our certification
consultants looked at the device, hardware, software and construction holistically and provided us
with risks in our design and how we needed to address them. The risk file looked at

1) **Function:** These set of criterion were developed to address incorrect or inappropriate output
or functionality. Examples of this included dirty LED lights indicators which may make user
misdiagnose the system functionality and cause errors or even erroneous data transfer.
2) **Use errors.** These set of risks included human errors caused primarily by improper design like
attention failure, memory failure. We developed a protocol to ensure that these errors are
minimized.
3) **Electromagnetic energy management:** These sets of risk pertained to voltage management
of our system and leaking currents and also in the case of ECG on use of defibrillator along
with Swasthya Slate.
4) **Mechanical Energy:** The casing and system was evaluated of the risks due to gravity falls,
vibration, stored energy, moving parts and moving and positioning of patient and operator.
5) **Radiation Energy:** We evaluated if the systems met with radition norms of CE/FDA approval
6) **Thermal Energy:** We looked at the systems tolerance to high and low temperature, NIBP
motor compliance with IEC 60601-1 and temperature rise for LED light for Pulse oximeter.
7) **Biological/Chemical/Environmental:** The system was evaluated for risks of biological entities
to its performance like bacterial, viral and other agents. We also evaluated the systems risk to
rain, dust, general uncleanliness etc.
8) **Biocompatibility.** The system was evaluated againsts risks of allergenicity, irritancy
pyogenicity to ensure that operator and patient are safe in using the device.
9) **Labeling.** The systems labelling was evaluated in details to meet the standards and avoid risks.
We evaluated the labelling for completeness, warning/prohibition/mandatory symbols being
there and being obvious and adequacy of descriptions, specifications, disclosure of limitations,
instructions on unpacking and leakage of batteries.
10) **Operating instructions.** The given operating instructions were evaluated in details to make
sure they are easy to understand and read.
11) **Warning/Errors:** All known errors were properly documented and displayed on screen. Error
descriptions were tested for completion. Unknown error logs were produced and uploaded.
Alarms were introduced and tested into the system to inform the user on avoidable
malfunction and misuse.
12) **Software version update mechanism.** We tested the system for its ability to update itself,
withstand updates of base software i.e. Android, protection against local and online dataloss,
datafile corruption,
13) **Base Software capabilities.** interference from other Android applications and memory
overrun or full errors.
14) **Device booting.** We evaluated the risk of device booting, switch problems, connection to
mobile device.
For each of these risk categories we evaluated

1) Foreseeable sequence of events/effects
2) Hazardous situations
3) Involved actors which could be patient, operator, bystander, service engineer, property or environment
4) Cause of risk which could be
   a. Incomplete requirements
   b. Manufacturing processes
   c. Transport and storage
   d. Environmental factors
   e. Cleaning, disinfection, sterilization
   f. Disposal and scrapping
   g. Formulation
   h. Human factors / Usability
   i. Failure modes except software
   j. Software
5) Harm possible
6) Severity of the harm
7) Probability of the harm
8) Risk factor which was multiple of severity and probability
9) Risk Acceptance which was set to be at risk factor of less than 0.05

Using this framework the entire hardware and software was evaluated. We set risk acceptance to be low so as to allow for the system to work in trying conditions. The system evaluation was completed and overall we achieved a score of 99.2% in functionality of submodules, 99.58% in firmware completion and 96.57% in our risk mitigation strategies and integration testing. Our data upload score was 98.3% and data local storage score was 100%. Batch upload function and delayed upload function scored 99.78% and 99.89%. All risks were below 5%. These tests and evaluations were performed independently in our certification consultant labs and in our labs. Both the scores were within 2.5% of each other and both met the CE/FDA criteria.

**Simulator Testing**

For many of the 33 tests, we were able to identify simulators that helped in testing the clinical outputs of the tests before going to patient testing stage. This helps in testing the system and its bounds and also helps in testing whether the system can handle rare cases and rare readings. The evaluation against simulators are exact and dependable and the testing protocols is as follows. The tester sets the simulator to deliver an exact intended signal. We then measure the signal using the Swasthya Slate. If the reading comes to be same or within reasonable error bounds which in our case was plus or minus 2.5% then the reading was marked accurate else inaccurate. We calculated the correlation coefficient and accuracy scores of the readings. The following table gives the scores of the simulator testing with minimum of 1000 tests per system except for troponin for which we could get 780 samples only. Calibrated samples were arranged from partner laboratories and manufacturers.

The simulator testing provided a comprehensive base for further testing and evaluating the system. It is important to note that 15% of the samples in our simulator/lab testing represented rare readings and results. This is an important aspect of the multistage testing. It allows us to not only focus on gathered results from patients which tend to centre around normative readings but also around rare and complex cases. The scores for rare and complex cases were in line with the ones shown in the
Table 1 which again points to the robustness of the system in dealing with the variations one may see in the field.

Our next step after the simulator/lab testing was to focus on usability testing. Usability is an important and often ignored part of medical device design. However, in the case of our system, meant for use by auxiliary nurse midwives, usability assumes highest importance. We developed the system for multiple languages. The usability testing was conducted in Hindi.

<table>
<thead>
<tr>
<th>Table 1. Simulator/Lab Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter</td>
</tr>
<tr>
<td>Blood Pressure</td>
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<tr>
<td>Blood Sugar</td>
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<tr>
<td>ECG</td>
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<td></td>
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<tr>
<td>Water Quality</td>
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<tr>
<td>Blood Hemoglobin</td>
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<td>Urobilinogen</td>
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<td>Urine Protein</td>
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<td>Urine Nitrile</td>
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<td>Urine Glucose</td>
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<td>Urine pH</td>
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<td>Urine Specific Gravity</td>
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<tr>
<td>Urine Leucocytes</td>
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<tr>
<td>Urine Ketone</td>
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<tr>
<td>OnSite Typhoid IgG/IgM Rapid Test</td>
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<tr>
<td>Malaria Check</td>
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<tr>
<td>Rapid Immunochromatography test for HIV-1 and HIV-2</td>
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<tr>
<td>Tira hCG One step Pregnancy Test</td>
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<tr>
<td>Troponin I Whole Blood/Serum Test</td>
</tr>
<tr>
<td>Hepatitis &amp; Virus (HBV) &quot;detection of (HBsAg in Plasma&quot;</td>
</tr>
<tr>
<td>ImmunoDost Test Kit (HCV)</td>
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<tr>
<td>Slide test for Anti Streptolysin-o</td>
</tr>
<tr>
<td>Slide test for Rheumatoid Factors</td>
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<tr>
<td>Slide test for C- Reactive Protein</td>
</tr>
<tr>
<td>Routine Blood Grouping and typing</td>
</tr>
<tr>
<td>Widal Antigens for Slide and tube tests</td>
</tr>
<tr>
<td>Pulse Oximetry</td>
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<tr>
<td></td>
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<tr>
<td>Syphilis</td>
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<tr>
<td>Body Temperature</td>
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<tr>
<td>Fetal Doppler</td>
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<tr>
<td>Stethoscope</td>
</tr>
</tbody>
</table>

Usability Testing

Multi-billion dollar investments in health IT infrastructure have been made recently to transform health care delivery systems in several countries. Recent policy initiatives in India have also emphasized the use of health IT as a foundation to improve quality and access of health care. However, IT-related initiatives have experienced greater than expected challenges to implementation. Although successful transformations have occurred in a few pioneering healthcare
organizations globally\textsuperscript{iii,iv}, the vast majority of organizations are still in the process of implementing their IT systems and modifying their work processes\textsuperscript{v,vi}. Moreover, there are increasing reports of unintended consequences of health IT adoption, including new safety problems and reduced provider efficiency\textsuperscript{vii,vi,ix,x}. In order to ensure that IT fulfills its promise of enhancing health care quality, the health care system in India needs to successfully transform itself into what we define as a safe and effective “health IT-enabled clinical work system.”\textsuperscript{xii} Successful health care reform in India is dependent on a safe and effective IT-enabled clinical work system, especially when over one billion patients’ lives are at stake.

In response to difficulties clinicians and organizations have encountered with IT implementation, we have developed an 8-dimension, socio-technical model of safe and effective IT use\textsuperscript{xii}. This model (see Figure 2) provides a comprehensive framework for studying all aspects of health IT design, development, implementation, use and evaluation within complex, adaptive health care systems. We propose to use this model as a guide to evaluate health IT systems. This system was developed by Dr Hardeep Singh, Dr Dean Sittig and Dr Kanav Kahol and published in MEDINFO 2013 (Dean F. Sittig, Kanav Kahol, Hardeep Singh: Sociotechnical Evaluation of the Safety and Effectiveness of Point-of-Care Mobile Computing Devices: A Case Study Conducted in India. Proceedings of MEDINFO 2013 held in Copenhagen Denmark 515-519).

![Diagram of 8-dimension socio-technical model](image)

**Figure 2. 8-dimension socio-technical model used to identify and categorize the items in the guide.**

**Development of a “Sociotechnical” Assessment Guide**

First, we developed an itemized assessment guide to identify potential risks or challenges to safe and effective use of the tablet under realistic clinical practice conditions. Item content was derived from several sources: 1) an extensive review of the literature, 2) interviews with experts in clinical care and health IT implementation, 3) surveys of challenges and opportunities to user acceptance of these types of devices, and 4) field observations of primary care workers with various levels of clinical and computing expertise working with these and similar devices.

1) **Literature reviews:** We reviewed the literature relevant to each of the eight dimensions of our model to identify items that were applicable to safe and effective use of IT, particularly those which were directly applicable to tablet devices.

2) **Interviews:** We conducted interviews in both the US and India with experts in public health, medicine, and health IT. We focused to a large degree on frontline health workers, who bear the
burden of delivering most clinical care in rural India. Interviews with health workers were important to identify potential improvements to the system in terms of usability (user interface), training requirements, compliance with local, regional and national laws and reporting requirements for specific clinical conditions (e.g. pregnancy), workflow and communication, and supervision and monitoring by physicians. We interviewed administrators to further understand legal, monitoring, and workflow issues which could pose as barriers and facilitators to implementation of such a device. Finally, we interviewed physicians regarding issues of clinical content (knowledge, rules and logic embedded into the device) and whether the communication and reporting channels under development and supervision mechanisms of front-line personnel collecting data would be aligned with their expectations.

3) Documenting/observing user acceptance: We administered the IsoMetrics Usability Inventory to frontline healthcare workers to document usability in the following 7 domains:
   1) suitability for the task;
   2) self-descriptiveness of the system (e.g. functions of the system are self-explanatory);
   3) controllability of the system;
   4) conformity with user expectations;
   5) error tolerance;
   6) suitability for individualization; and
   7) suitability for learning.

We also administered a custom developed questionnaire to evaluate how well the system fulfilled the reporting requirements of selected conditions such as pregnancy.

4) Field observations: Field observations were used to examine the effectiveness of training of trainers and evaluate the durability of the tablet. It also helped us study how environmental factors (e.g., temperature, rain, direct sunlight) affect the usability of the system.

Mobile Computing Device Evaluation Guide

An initial set of evaluation items from each of the eight sociotechnical dimensions was created from the results of the literature search and interviews. The items were then refined based on additional expert opinion, user acceptance testing, and observations. The following items (under each dimension) were determined to be most relevant to the safety and effectiveness of the device and were included in the final draft of the guide.

Hardware and software

Reliable hardware and software is essential for any mobile POC mobile device. The following items were found to be most relevant for safety and effectiveness of POC devices.

- The tablet will run the required software applications for at least 18 hours on battery power.
- The device has a protective case to reduce breakage or damage and prevent entry of dust into the system.
- The device is water-resistant; the screen can be cleaned with liquid disinfectant.
- The device has up-to-date virus protection software.
- The device’s hardware interfaces have been tested with all external, ancillary devices (i.e., thermometer, water quality gauge, blood glucose monitor, etc.).
- The device is password protected.
- The device’s hard drive is encrypted and can be erased by remote command in the event the device is lost or stolen.
- The device can connect to the Internet through a variety of means (e.g., either a wireless LAN or 3G/4G connection) and has a way to store data locally and then upload it at a later time in the event that Internet connections are not available.
**Clinical content**

Up-to-date clinical content (i.e., data, information, and knowledge) is required to encode the user entered information as well as provide clinicians with reference information at the point of care.

- Required clinical content has been loaded on the device.
- Clinical content can be updated remotely.
- Clinical guidelines and CDS content are up to date.
- Clinical content is available in one of the native languages of the user. (An example of the system in Hindi appears in Figure 3 below.)

**Human-computer user interface**

The user interface enables users to interact with the data, information, and knowledge required to understand the patient’s physiologic state and document their findings and intended actions.

- Users can see the information on the screen in sunlight.
- The fonts are large enough for middle-aged and older health care workers to read without difficulty.
- The touch screen is properly registered (i.e., when the user touches an item on the screen, the device recognizes that object has been touched).
- The device cannot be used with gloves on.
- The required software applications can be used with a finger or a stylus.

*Figure 1. Health maintenance reminders for maternal and child health are installed and working.*

- The application allows both freehand and keyboard-based data entry.
- The device and key software applications provide multi-language support.
- Using the applications on the device requires limited text interface with audio support.
- The applications are easy to learn and text-based, audio, or video support is readily available.
- The software does not create tasks that are superfluous to the user’s normal daily routine.
- The software adds value to the user’s daily life.
- The software automatically produces reports and letters of discharge and referrals to minimize administrative work.
Personnel
People are required to design, develop, implement, use, and manage all aspects of the IT-enabled healthcare system.

- All health care workers have had at least 2 hours of training on how to use the tablet in their native language.
- Centralized IT support personnel are accessible via cellphone or Voice-over-IP to health care workers.
- Health care workers are able to answer healthcare questions that are frequently asked by patients in rural areas who are unfamiliar with similar types of data collection instruments.

Workflow and communication
Modern healthcare requires extensive collaboration between disparate members of the healthcare team. Meeting the needs of various healthcare workers continues to be a challenge.

- Workflow observations are conducted and recorded prior to local implementation of the tablet.
- Indications for referral are clearly specified and sent to the referring provider either via paper, fax, email, etc.

Organizational policy, procedure, culture, & environment
Organizations that are involved with implementing and using the mobile device, policies and procedures and the culture and physical environment should empower workers and not burden them with constraints. Items that address this include:

- Standard operating procedure documents specify the scope and indications for use of the tablet.
- Procedures for maintenance and technical problem-solving are clearly delineated.

External rules and regulations
Local, regional and federal rules and regulations (i.e. those that originate outside of the organization) also have a significant impact on the safe and efficient functioning of the organization. This was addressed by the following items:

- Laws and provisions created by the government are adequate to protect the use of the tablet for its intended purposes and to prevent fraud and theft.
- Regulations create mechanisms to strictly reinforce the delivery of expedited clinical care and referrals for patients who are found to need urgent medical attention. We found the system to be supportive of this referral initiative in particular and with the 108 service it was made efficacious by the government.

Measurement and monitoring
The key to improving the safety and efficiency of the IT-enabled healthcare system is to measure and monitor important details. This was addressed by the following items:

- The demographics interface is able to validate patient identity through a legitimate source such as user identification (UID), ration card, etc.
- Calibration of all physiologic or chemical sensors is performed every 3 months.
- 5% of data collected are validated for accuracy (e.g., 5% of automated EKG interpretations should be verified by a clinician).
- Outcome assessments are conducted using random samples of 5% of patients should be conducted to ensure that the tablet is serving its intended purpose (e.g., a positive diabetes screening should consistently prompt a referral or treatment).

Results of Sociotechnical and Usability Evaluations.

Use of the guide for evaluation of the Swasthya Slate system resulted in several product enhancements and considerations of how the device fit within the larger social context of the health system. For instance, the tablet case was redesigned in response to feedback generated from these items. The initial design emphasized the technology focus, but the final design aims to provide a more robust look with better protection against environmental factors.

**Figure 4. Usability Evaluation**

Software reliability was significantly improved as well. The user interface was also improved by focusing on both affect (i.e., making it look more “sophisticated”) and functionality. We utilized Microsoft’s new “metro interface” design language emphasizing typography and large text on large buttons to catch the user’s eye. This allowed users with limited education to use the tablet easily. We developed the reporting system to be in line with the reporting requirements of the government. For example, one of the requirements was that health workers complete a register with a list of mothers. We interfaced the Slate with a label printer to automatically generate stickers for applicable cases, which the health worker could in turn simply stick on the register to save time and reduce omission or transcription errors. Following the ethnographic observations, the workflow was modified so that the upfront diagnostics were performed before the checkup which fit the user’s workflow better as well as minimizing the time the kit needed to be turned on, maximizing the battery life. To comply with legal directives (external rules and regulations), our decision support system (content) was designed to limit interventions by frontline health workers to those that are non-pharmacological, i.e. so they didn’t receive specific CDS interventions about prescribing medications beyond their expertise. We also identified skill sets of the types of personnel that would be using the device.
Quantitative data were also collected and analyzed with a specific focus on improving the usability of the tablet. To date, we have surveyed 100 community health workers, 50 nurse midwives, and 50 equivalent health workers in the private sector for our usability study. A composite scoring system was developed for each of the 7 usability domains. The mean usability rating across all of the domains was 8.9/10 (SD = 0.6). The lowest domain score was for user customization (mean 7.8/10, SD 1.1), although this was not unexpected because, by design, customization was limited to avoid potential interference with best practices. The highest domain score was suitability for the task (mean 9.2/10, SD 0.6).

Average learning time to first correct execution of the software was 10 minutes, and by 45 minutes users were able to use the apps with less than 1% “slip” errors (e.g., accidental pressing of buttons, etc.). Our training, which lasts 1 day, has been very successful in ensuring the full use of the system.

As the device is implemented more widely, we will continue to conduct additional iterative evaluation to inform device use as well as add additional items to the guide if needed for its subsequent use in other types of settings.

**Discussion**

We developed a “sociotechnical” assessment guide for safe and effective use of a mobile computing health care device in India. A sociotechnical assessment can be used to help prevent unintended consequences of using mobile IT and for helping proactively detect, mitigate, and ameliorate unintended consequences and potential failures associated with the use of such devices. Our evaluation was grounded in a multifaceted socio-technical model of health IT implementation and use. Based upon the work we conducted, others planning to collect and interpret data at the point of care in rural settings could consider similar evaluation methods to ensure successful design, development, implementation and use of these devices.

Health information technology is changing the way we deliver health care and can be used in reforming health care and improving health care access especially in developing countries. In India, there is a large deficit of physicians in rural settings, and thus point of care mobile devices can be used by trained non-physician health care workers to collect data and assist with primary health care needs. However, there might be little benefit of data collection and point of care devices unless the data is used successfully to improve clinical care in terms of improving quality, safety and efficiency. Thus, these devices must be integrated within the social context of the health system where they are implemented and used. We envision that stakeholders planning to use such devices would assemble multidisciplinary assessment teams to conduct such a comprehensive evaluation which will ensure that the device fits within the broader context of health care delivery and improvement.

**Clinical Testing**

Clinical testing was performed in District Bhatinda Punjab in 10 laboratories and in Delhi’s 2 laboratories. Additionally we also had labs in Peru and Timor Leste which tested the system but those results are not included in the presented analysis to maintain consistency with the Indian application of the system.

We tested minimum of 1000 patients per test using our system in the lab. A list of confirmatory tests for each of the tests was developed the accuracy of the system against these confirmatory tests was
measured. Additionally we also measured the software’s ability to show the readings same as the readings gathered. We also tested the uploads and local storage.

We found that in the field condition we were able to gain specificities and specificities for the tests which are in line with expected norms. The tests were performed by ASHAs or ASHA equivalent in NGO sector. These tests and their results show the robustness of the system and the usability in clinical lab settings.

In one site, we had an issue of tablet running out of local storage space due to which 7 records could not be uploaded. This was due to the fact that the tablet had excessive software. To avoid this in the field, our software now allocates 80% of memory for use by the Swasthya Slate software. Also we have notifications to warn users of space running out on which some of the old records can be deleted after checks are made on their online presence.

In this manner, we have tested the system extensively. However the final testing in the field has been most important and we now have presence in multiple locations across the world on field evaluations. We will summarize some of those results in the next section.

Table 2. Clinical Evaluation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>People Tested</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Match on Software Readings</th>
<th>Local Storage</th>
<th>Online Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (Hypertensive &gt;140&gt;90)</td>
<td>1000</td>
<td>0.9</td>
<td>0.95</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Blood Sugar (Fasting BG&gt;100)</td>
<td>1000</td>
<td>0.921908</td>
<td>0.966443</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>LEC (leukocytes)</td>
<td>1000</td>
<td>0.979313</td>
<td>0.990332</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Water Quality (TDS&gt;150)</td>
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<td>0.888089</td>
<td>0.961831</td>
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<td>100%</td>
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<tr>
<td>Blood Hemooglobin (&gt;10 mg/DL)</td>
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<td>0.916993</td>
<td>0.931801</td>
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<td>Urine Blood &gt;10</td>
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<td>100%</td>
<td>100%</td>
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<td>Urine Bilirubin &gt;10</td>
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<td>0.923667</td>
<td>0.972715</td>
<td>100%</td>
<td>100%</td>
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<td>Urine Protein &gt;100</td>
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<td>0.974214</td>
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<td>100%</td>
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<td>0.981701</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<td>Urine Glucose &gt;100</td>
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<td>0.264039</td>
<td>0.982314</td>
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<td>100%</td>
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<tr>
<td>Urine PH &gt;6.5</td>
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<td>0.940197</td>
<td>0.980657</td>
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<td>100%</td>
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<tr>
<td>Urine Specific Gravity&gt;1.010</td>
<td>1000</td>
<td>0.918361</td>
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<td>Urine Leucocytes&gt;10</td>
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<td>0.977851</td>
<td>100%</td>
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<tr>
<td>Urine Ketone &gt;10</td>
<td>1000</td>
<td>0.929944</td>
<td>0.971357</td>
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<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Heart Rate &gt;100</td>
<td>1000</td>
<td>0.884837</td>
<td>0.960806</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>OnSite Typhoid (IgG/IgM) Rapid Test -positive</td>
<td>1000</td>
<td>0.882671</td>
<td>0.974624</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Malaria Check-positive</td>
<td>1000</td>
<td>0.915027</td>
<td>0.993838</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Rapid Immunochromatography test for HIV-1 and HIV-2-positive</td>
<td>1000</td>
<td>0.960909</td>
<td>0.988854</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Tita HCG One step Pregnancy Test-positive</td>
<td>1000</td>
<td>0.970198</td>
<td>0.998843</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Treponema Whole Blood/ Serum Test-positive</td>
<td>1000</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Hepatitis B Virus (HBV) “detection of HBsAg in Plasma”-positive</td>
<td>1000</td>
<td>0.863036</td>
<td>0.997909</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>ImmunoTest Kit (HCV)</td>
<td>1000</td>
<td>0.951142</td>
<td>0.995698</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Slide test for Anti Streptolysin-O</td>
<td>1000</td>
<td>0.952361</td>
<td>0.957065</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Slide test for Rheumatoid Factor</td>
<td>1000</td>
<td>0.987106</td>
<td>0.995942</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Slide test for C-Reactive Protein</td>
<td>1000</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Routine Blood Grouping and typing-definitive diagnosis</td>
<td>1000</td>
<td>1</td>
<td>1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Widal Antigens for Slide and tube tests</td>
<td>1000</td>
<td>1</td>
<td>1</td>
<td>99.3%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Pulse Oximetry&gt;90</td>
<td>1000</td>
<td>0.95</td>
<td>0.93</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Sphygm</td>
<td>1000</td>
<td>0.9275</td>
<td>0.995969</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Body Temperature&gt;99</td>
<td>1000</td>
<td>0.901478</td>
<td>0.997843</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Fetal Doppler Beyond 10 Range for 20 weeks pregnant</td>
<td>1000</td>
<td>0.943662</td>
<td>0.997847</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Stethoscope (increased respiratory rate&gt;40 Infant)</td>
<td>1000</td>
<td>0.877193</td>
<td>0.989385</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Field Evaluations

Figure 5 shows our global deployments in the past 9 months. These evaluations have helped us look at the system comprehensively and inform learnings.

A few samples of the learnings are as follows.

1) The value of integration. We performed a simple experiment in two sites in Punjab. In the first site, we gave maternal and child health workers the complete kit and in another we gave them the tablet. Each was asked to perform 100 ANC visits. We measured the completion of ANC, the reported test results and compliance with training. We found that both groups reported complete ANC coverage of 100%. However, the group with the tablet only completed 5 of the 10 diagnostics and on followup it was noticed that the readings were not reliable only with the tablet. On the other hand, the group with the tablet on an average completed 9 of the 10 tests and completed all questions of ANC. Follow up interviews showed greater compliance with the whole system and a tablet only was not seen as a complete medical device. This limited its acceptance in the field.

2) Patients tend to value the whole kit as a medical device and this increases their compliance. Number of telemedicine consults with the whole kit was 130% more than with the tablet alone. This was again a result of doctors trusting the systems readings more than manual entry.

3) The complete kit actually produces more ownership by the ANMS and better care. An analysis of the ANMS care of the tablet was performed and it was seen that they tend to be more protective of the kit (40% more) than only the tablet. This analysis was revealed in Peru and in West Bengal.

4) The increased access to diagnostics increases patient compliance. In our database of 25000 patients, roughly 49.5% of people did not know of a pre-existing condition and 90% of them said they got the tests done due to its ease and accessibility. 89% of the patients followed up
with referrals. This is a high rate of compliance and needs to be sustained with continuous monitoring of diagnostics.

5) Empowering all levels of the chain produces best results. We found that in areas where FHWs, FRU and SRUs were all linked with the tablet (roughly 20 out of our 80 locations worldwide), the rate of screenings, referrals is 27.6% more than other units. This clearly shows the benefit of looking at a ground level empowerment. In Uttar Pradesh where ground level workers do not have a tablet and complete system but only materials the screening rates are 30% lower. With only tablet, the screening rates improve only marginally to 26%. Complete kits with complete delivery is 30% better in terms of screening.

References.


