

# Lessons learned from implementing a rapid test of a technology device for monitoring patients' vital parameters in a tertiary hospital in Uganda, a resource limited setting.

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## **Abstract**

Many African hospitals participate in technology research trials that take many months or years. Fewer sites have experience with rapid studies, conducted over a period of weeks. We conducted a rapid validation study of consumer temperature and pulse technology in a National Referral Hospital in Uganda. In doing so, we captured valuable lessons about how to conduct a rapid study that will be useful to future researchers conducting similar fast-paced studies. In under two months, we secured ethical approval, developed research tools, hired and trained staff, oriented hospital leaders, implemented the study and compiled the final data set. While we faced a number of typical implementation challenges, a team management approach allowed us to quickly overcome the challenges within the short study period. The study was conducted through a partnership between a Ugandan university faculty member as principal investigator (PI), a Ugandan health company and a US technical consulting firm.

## **Introduction**

Technology evolves quickly. On the consumer market, technology firms release new products and updated versions of existing products at a fast pace. Wearable fitness devices are increasingly marketed to consumers as a way to track their steps, measure calories burned, and report on their sleep. A rapid study in a health care setting can help determine whether a commercial fitness product has potential for health-related use. If early data validation in a health setting shows potential and is usable by health workers, then the product could go forward through standard medical technology sensitivity and specificity testing for approval as a diagnostic and monitoring instrument.

To introduce a fitness device into the consumer market requires no independent review or certification of the validity of its readings. There is increasing interest in validating consumer fitness devices [1] for possible use to provide data for patients and providers in outpatient health care settings for such purposes as monitoring activity after hospital discharge [2], assessing gait and fall risk [3,4], and monitoring sleep in patients with sleep disorders [5]. Hospital-based applications are under review as well [6]. While there are data that demonstrate accuracy of these measurements in healthy, mobile populations, there are a paucity of data to confirm the accuracy of such devices for detecting ill health such as fever and abnormal heart rate in patients. We found no literature of such devices being tested in resource-limited settings in Africa.

Wearable technology such as fitness devices have potential interest to the developing world health delivery sector. For example, the Red Cross recently conducted a series of stakeholder interviews and focus group discussions in which wearable devices were highly prioritized for their potential value in assisting first responders in locating and diagnosing persons in emergency settings and assisting in preventing disease transmission if healthcare professionals can access the patient's

information remotely [7]. Wearable devices have shown promise in monitoring changes in vital signs of patients with infectious disease in the context of epidemics [8].

Some of the most basic but very critical routine monitoring indicators for patients in a hospital setting are the vital signs such as temperature and pulse. The purpose of this study was to compare vital signs taken using standard clinical methods with those taken by a consumer fitness device to determine associations with blood pressure, respiration and oxygen saturation. In addition the study was intended to provide formative information about how such studies might be conducted in the future.

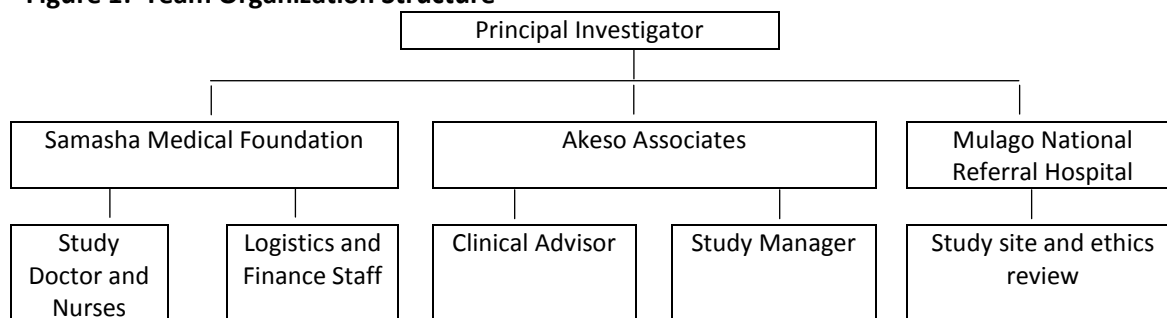
## **Methods**

We conducted a descriptive study of a convenience sample of 57 patients on the medical ward at Mulago National Referral and Teaching Hospital in Kampala, Uganda. Patients who volunteered to participate wore a fitness wrist-band device during a portion of their hospital stay. During this period, study staff collected vital signs using standard approaches. The data were recorded and compared with the readings from the fitness wrist-band device. The study took place over 21 days. Due to the proprietary nature of the data from the device, the results of the comparison are not presented here. We present lessons learned during implementation of this study.

## **Study Team**

The study was conducted by a partnership brought together by Akeso Associates, a global health consulting firm, Makerere University College of Health Sciences and Samasha Medical Foundation, a locally registered health company. The team structure is portrayed in Figure 1.

**Figure 1: Team Organization Structure**



### Ethical considerations

The study was approved by Mulago Hospital Research and Ethics Committee [9] (MREC 664), and Uganda National Council for Science and Technology [10] (HS 1728). All study participants provided written informed consent prior to enrollment.

### Study site and procedures

The study was conducted on the medical ward of Mulago National Referral and Teaching Hospital. Prior to study start, a study team was constituted including six nurses, two doctors, a study assistant, study manager and a clinical advisor. The team received protocol training and training on study procedures.

The head nurses on the ward where the study took place received orientation and training and assisted with implementation components as necessary. The hospital provided a small room to serve as the study office.

### Site selection

Akeso Associates conducted a rapid assessment of potential sites by contacting members of its network in South Africa, Swaziland, Malawi and Uganda. The three criteria were an appropriate patient profile, a qualified and ready PI, and the likelihood a site could complete the study on a rapid

schedule. The desired patient profile would include an inpatient setting with at least 50 persons with high fever, ideally whose conditions fluctuate during their stay.

### Staff composition and training

The study assistant managed schedules, documents, equipment inventory and patient reimbursements. The study doctors screened hospital patients for eligibility and enrolment and provided clinical oversight where needed. The six study nurses worked in pairs across three shifts to provide 24 hour presence in the hospital. The nurses enrolled patients, took vital signs, and removed and replaced the wrist-bands for daily cleaning, recharging, and data downloading.

The fast paced implementation timeline required staff training to largely be on the job. Study staff participated in one day of orientation and training before the data collection began. Training involved practical testing of the vital sign-taking process. The clinical advisor provided ongoing support supervision to the study doctor and nurses during the study.

### Screening and enrollment

The sample was a convenience sample and not representative of all febrile patients at Mulago. Patients were enrolled if they were age 18 years or older and had fever  $>38.5^{\circ}\text{C}$ . Pregnant women and patients who were moribund with predicted survival less than 3 days were excluded. Patients were withdrawn from the study when they left the ward, requested to be withdrawn, died, or had been stable for several days with limited likelihood of further change.

The study nurses provided the patient with a fitness wrist-band on one arm and a pink identification band on the other arm. The identification bands were similar to the type used in US hospitals. The identification band was marked with a unique number identical to the unique number on the fitness band. The study protocol emphasized a one-patient-one-band approach. No band was to touch two

patients as an infection control precaution. The band was removed by the study nurse once in a 24-hour period to download the data and recharge the battery. At removal each band was disinfected with an alcohol wipe and stored in separate bag to avoid contact with other bands. A new band was applied to a new patient and retrieved when that patient withdrew. Bands were not reused. Enrolled patients received a small amount of money during the study period sufficient to purchase meals available at the hospital.

Vital signs measured included

- ear and oral temperature using digital thermometers
- blood pressure using a digital or manual sphygmomanometer
- pulse and pulse oximetry using a finger oximeter
- respiration rate using visual observation

These were provided to the attending clinicians and nurses for use in patient management.

## **Results and Discussion**

57 patients were correctly enrolled over a 10 day period. An additional two patients completed the enrollment process but were subsequently identified as ineligible and are not included in the study data set.

One patient requested to discontinue study participation due to worries from the patient's family that the fitness band may be contributing to the patient's decline in health. Five patients transferred to other parts of the hospital (four to the Tuberculosis ward and one to the cancer center). The study participant's status at the end of the study is described in Table 1.

**Table 1: Study participants' end of follow-up criteria**

Discharged from Hospital (possible indicator of improvement)	10
Died	8
Withdrew Consent	1
Transferred to another ward	5
Limited likelihood of further change (stable vital signs for two days)	23
Study period ended while on follow-up	<u>10</u>
Total number of patients enrolled	57

Participants' mean age (standard deviation) was 35.6 (15) years, 31(54%) were males. The mean duration of observation was 4.3±1.6 days.

### Successes

**Rapid implementation through partnership:** The project was completed on time. Due to the teamwork between the parties in coordinating the time line and due to the efficient operational infrastructure of Samasha Medical Foundation as a host-country facilitator, the project was implemented extremely quickly. The work of the PI to secure approvals was essential to the rapid implementation. A good partnership has been created between the PI, Makerere University College of Health Sciences, Mulago National Referral Hospital, Samasha Medical Foundation, and Akeso Associates to serve as a base for further studies.

Lesson: Effective leadership and teamwork by local experts can assure success.

**Expedited ethics board approval and communication:** The Mulago Hospital Research and Ethics Committee agreed to perform an expedited review which was completed in unprecedented time (just over one week).

Lesson: A PI with an excellent reputation to the ethics committee is essential to a rapid study.

**Benefit to the hospital and patients:** Patients in the study and other patients in the ward benefitted from the presence of study nurses on the ward. Study nurses assisted with general patient care as time allowed, supplementing the regular staffing in the ward, which was quite limited. The study

patients' care was assisted by having their vital signs taken more regularly and providing information for the hospital doctors. The hospital was provided with study supplies such as thermometers and sphygmomanometers at the end of the study period. There were very few nurses to serve the number of patients on the ward. Our study added two nurses to each shift which sometimes more than doubled the presence of nurses on the ward. Our study nurses were often called up to help with other procedures for patients and resolve problems raised by family members. During the study, the regular nurses (not the study nurses) went on strike for one day. As the nursing shortage was already significant and notable, we did not observe whether the strike caused an even greater shortage in staffing.

Lesson: Assuring the study design is beneficial to patients and the institution aids rapid approval and adds benefit to the patients and institution.

#### Challenges and how they were overcome

**Study population profile addressed:** The study population had different clinical characteristics than we expected. The rapid implementation of the project sacrificed careful scoping of the patient profile on the ward. Ideally we would have spent time conducting chart reviews to describe the patient population before deciding to go ahead with the site. Instead we conducted interviews with key informants knowledgeable about the patients. We expected more patients with malaria and with conditions where the patient's health would fluctuate while they were hospitalized. Instead, many of the patients were in a chronically ill and unchanging situation.

Lesson: Conduct detailed scoping in advance.

**Band arrival challenges addressed:** The fitness bands were ready for use one day later than anticipated due to complications upon arrival with the Uganda Customs Office. We had arranged customs clearance through DHL. DHL reported that the government payment system for receiving the duties was off line one day so the government could not clear the fitness bands.

Lesson: Allow extra time for goods arrival.

**Enrollment challenges addressed:** Enrollment was slow at first, leading to a push at the end to achieve the target. Reasons for the slow start up included the research training and skills of the original study doctor (then replaced), and our learning about the timing and flow of new patient entry onto the ward

Lesson: Quickly pivot the approach as needed, consistent with the protocol.

**Data quality and completeness challenges addressed:** After approximately 10 days of the study we experienced several data quality issues and protocol deviations. We implemented corrective actions immediately. The primary data quality concerns were possibly due to nurse fatigue. When we had access to secondary data, we followed up with the study nurses to make corrections. Examples of common data quality issues:

- oral temperature readings were skipped in several cases
- fields were left blank on the vital sign data sheets
- patient ages were recorded incorrectly
- the ambient temperature was not listed due to a missing thermometer

An additional challenge was that some nurses were not familiar with the 24-hour military time designation, requiring careful attention by the study manager to assure times were designated accurately by the end of each nursing shift.

Lesson: Conduct data quality review at the end of each shift.

**Supply challenges addressed:** Maintaining proper supplies was a challenge across the six nurses on the team. Each nurse required the following supplies for her shift: ear thermometer and sheaths, oral thermometer and sheaths, pulse oximeter, sphygmomanometer (electronic and manual), pen, flashlight, hand sanitizer, sanitizing wipes, air temperature thermometer, face mask, and gloves.

Supplies were sometimes borrowed by the regular hospital staff, who often had no supplies otherwise. Nurses sometimes were not available for a full handover to the next shift so supplies were not fully accounted for at shift change. During each shift nurses sometimes left their supplies on a common table in the ward (the only table available) which was shared by staff not involved in the study. Extra supplies were kept in a room that was locked in the evening and at night so supplies could not be replenished after hours. The cause of missing equipment was believed to be accidental. At the end of the study, only two pulse oximeters and two oral thermometers could not be accounted for.

Lesson: Conduct a supplies inventory at the end of each shift.

**Staff training challenges addressed:** The team management approach between the PI, the study manager, and the director of the logistics organization allowed for quick decisions to resolve challenges to staffing. The staffing needs were greater than originally planned, so overnight three additional nurses were hired. The skills of the first study doctor were not a suitable match for the revised approach to client intakes, so he was reassigned to other study responsibilities. Of the six study nurses recruited for this project, three did not have a research background and did not bring sufficient expertise to the position to adhere to the protocol rigorously. Two of the nurses were relieved of duty toward the end of the study after it appeared their attention to detail was slipping. Most of the six nurses had other jobs at the same time, which meant they sometimes were quite tired while working on this project. The rapid scale up of the project meant that we did not have the option of recruiting highly experienced and also fully available full-time nurses.

Lesson: Make rapid decisions about hiring and discontinuing study staff.

**Patient location challenges addressed:** One of the most significant challenges in the study was that the hospital beds are not identified by number and do not remain in a consistent location. The ward was designed for 52 beds but housed over 100 beds. Beds would be moved from one part of the

ward to another to make room for more patients or to locate a particular patient near the equipment he or she required, such as the sole oxygen tank on the ward. Beds would be rolled into the hallway or into the narrow space between other beds to meet the needs of newly arrived patients. The movement of beds was especially challenging during the final two days of data collection when the Makerere University College of Health Sciences practical exams took place on the ward. To make room for a team of medical students, a dozen or more beds would be rolled to another area for a day and then rolled back to a different location at the end of the day. A system for tracking and locating patients and beds would have aided the study tremendously. As it was, nurses identified patients by the summary sheets taped to the foot of the bed. At night, when lights were dimmed on the ward, nurses used flashlights to try to find enrolled patients. The presence of at least one family member or caregiver per patient added to the crowding. Family members slept in the hospital near the patients they were connected with, sometimes on the floor in the only walking space available and sometimes underneath the patients' beds. Several vital sign readings were skipped while patients could not be located but no patients were lost altogether. To address the challenge, the study manager asked the nurses at each nursing shift handover to identify the location of the study patients for the incoming staff.

Lesson: Implement a patient location protocol at the start of the study.

**Long study staff break challenge addressed:** In the beginning, we were challenged by the nurses walking out of the hospital during shifts to have breakfast or lunch. Sometimes they took longer than expected to return which led to taking readings later than the required time. This was later solved when we organized for delivery of tea and snacks in the study room which was much closer to the ward. The nurses took turns in taking time off for lunch so there was always a nurse available at the ward to take the readings on time.

Lesson: Ensure availability of all study staff necessities in the study room

## **Conclusion**

A rapid technology test can be successful at a hospital in a resource limited setting.

African health care settings will increasingly want to participate in rapid technology studies. Such studies can be beneficial to the institution and its patients in the short term and in the long term can help prepare the institutions for adopting new technology. Technology studies are conducted in a different manner than standard health research projects and require rapid scale up and quick results. The lessons learned from Mulago National Referral Hospital's work on this project can benefit future studies of this type in similar settings.

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