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ORIGINAL RESEARCH

Lessons Learned from Implementing a Rapid Test of a Technology Device in a Tertiary Hospital in Uganda

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Abstract

BACKGROUND Many African hospitals participate in technology research studies that take many months or years. Fewer sites have experience with rapid studies, conducted over a period of weeks. Such studies can benefit the institution and its patients in the short term, and in the long term can help prepare the institution for adopting the new technology.

OBJECTIVES We conducted a rapid validation study of consumer fitness device at Mulago National Referral and Teaching Hospital in Kampala, 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.

METHODS We conducted a descriptive study of a convenience sample of 57 patients. Patients who volunteered wore a fitness wristband device. Study staff collected vital signs using standard approaches.

FINDINGS Our findings were as follows: (1) effective partnership by local experts can ensure success; (2) a PI with experience working with the hospital ethics committee is essential to a rapid study; (3) reassurance that the study design benefits patients and the institution can help speed approval; (4) conduct detailed assessment of patient population in advance; (5) allow sufficient time for logistics arrangements; (6) quickly pivot the approach as needed, consistent with the protocol; (7) conduct data quality review on every shift; (8) conduct a supplies inventory at the end of each shift; (9) make rapid decisions about hiring and discontinuing study staff; (10) implement a patient location protocol at the start of the study; and (11) ensure availability of study staff refreshments in the study room.

CONCLUSION A rapid study of innovative technology can be successful at a hospital in a resource-limited setting.

KEY WORDS Mulago Hospital, Uganda, vital signs

INTRODUCTION

Technology evolves quickly. On the consumer market, technology firms release new electronic 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 consumer fitness product has potential for health-related use. If early data validation in a health setting indicates accuracy and shows that it

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could be usable by for health monitoring, 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. However, 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] Although data 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 hospital settings in Africa.

Wearable technology items such as consumer fitness devices have potential interest to the developing world's health delivery sector. For example, the International Federation of Red Cross and Red Crescent Societies recently conducted a series of stakeholder interviews and focus group discussions in which wearable devices were prioritized as an emerging technology with potential humanitarian use to assist first responders in locating and diagnosing persons in emergency settings.[7] Wearable devices have shown promise in monitoring changes in vital signs of patients with infectious disease in epidemics.[8]

Basic but critical routine monitoring indicators for patients in a hospital setting are the measurements of vital signs such as temperature, respiratory rate, and pulse rate. 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 correlation of measurements. 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 wristband 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 wristband device. The study took place over 21 days. The measures taken by the nurses during the study are reported elsewhere. [Byakika-Kibwika P, Watts R, Muwonge M, Watts W. Vital signs and clinical characteristics of patients in a national referral hospital in Uganda: a descriptive profile. Unpublished. Contact the authors care of raleigh.watts@akesoassociates.com.]. 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

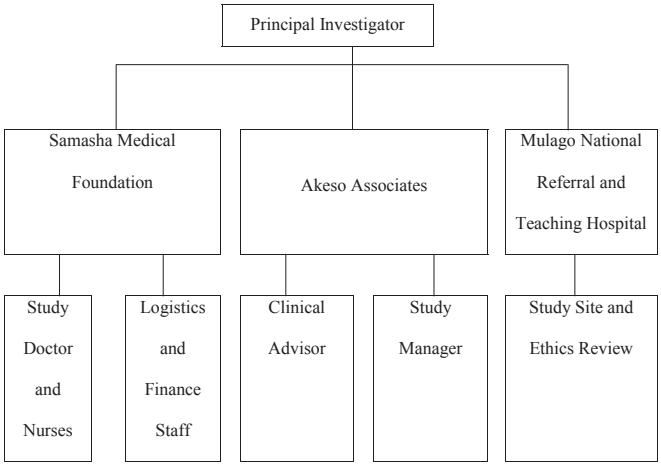

Figure 1. Team Organization Structure.

of Health Sciences; and Samasha Medical Foundation, a health company registered in Uganda. The team structure is portrayed in Figure 1.

Ethical Considerations. The study protocol 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 before enrollment.

Study Site and Procedures. The study was conducted on the medical ward of Mulago National Referral and Teaching Hospital. Before beginning the study, a study team was created including 6 nurses, 2 doctors, a study assistant, a study manager, and a clinical advisor. The team received orientation to the protocol and training on study procedures.

The head nurses on the ward where the study took place received orientation to the study protocol. 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 3 criteria were an appropriate patient profile, a qualified principal investigator (PI), and the likelihood a site could complete the study on a rapid schedule. The desired patient profile would include an inpatient setting that could provide access to at least 50 persons with high fever over a short period, ideally patients whose conditions fluctuated during their stay.

Staff Composition and Training. The study manager was responsible for staff schedules, documents, equipment inventory, and patient reimbursements. The study doctors screened hospital patients for eligibility and enrolment and provided clinical oversight where needed. The 6 study nurses worked in pairs across 3 shifts to provide 24-hour presence in the hospital. The nurses enrolled patients, took vital signs, and removed and replaced the wristbands for daily cleaning, recharging, and data downloading.

The fast-paced implementation timeline limited the amount of training time available before data collection began. Study staff participated in 1 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 may not have been representative of all febrile patients at Mulago National Referral and Teaching Hospital. Patients were enrolled if they were age 18 years or older and had fever >38.5°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 in vital signs.

The study nurses provided the patient with a fitness wristband on one wrist and a pink identification band on the other wrist. The identification bands, which were similar to the type used in US hospitals, were marked with a study number corresponding to the number on the fitness band. The study protocol emphasized a 1-patient, 1-band approach as an infection control precaution. The band was removed by the study nurse 1 time for approximately 2 hours in a 24-hour period to download the data and recharge the battery and then reapplied to the same patient. At removal each band was disinfected with an alcohol wipe and carried 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 payment each day sufficient to purchase meals available at the hospital.

Vital signs measured included the following:

- Ear and oral temperature using digital thermometers
- Blood pressure using a sphygmomanometer
- Pulse rate and pulse oximetry using a finger oximeter
- Respiration rate using visual observation

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

RESULTS AND DISCUSSION

Fifty-seven patients completed the protocol. They were enrolled over a 10-day period. An additional 2 patients completed the enrollment process but

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 (possible indicator of stabilization)	5
Limited likelihood of further change (stable vital signs for 2 days)	23
Study period ended while on follow-up	10
Total number of patients enrolled	57

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were subsequently identified as ineligible and are not included in the study data set.

Of the enrolled patients, 1 requested to discontinue study participation because of worries from the patient's family that the fitness band might be contributing to the patient's decline in health. Five patients transferred to other parts of the hospital (4 to the tuberculosis ward and 1 to the cancer center). The study participants' status at the end of the study is described in Table 1.

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

Successes. ***Rapid implementation through partnership.*** As a result of the teamwork between the parties in coordinating the timeline and because of the efficient operational infrastructure of Samasha Medical Foundation as a host-country facilitator, the project was implemented extremely quickly and was completed on time. The PI's research experience within the hospital was essential to the rapid implementation. A good partnership has been created between the PI, Makerere University College of Health Sciences, Mulago National Referral and Teaching Hospital, Samasha Medical Foundation, and Akeso Associates to serve as a base for further studies.

> Lesson: Effective partnership by local experts can ensure success.

Expedited ethics board approval and communication. The Mulago Hospital Research and Ethics Committee agreed to perform an expedited review that was completed in unprecedented time (just more than 1 week).

> Lesson: A PI with experience working with the hospital ethics committee is essential to a rapid study.

Benefit to the hospital and patients. Both study patients and other patients in the ward benefitted from the presence of study nurses on the ward. The study patients' care was assisted by having their vital signs taken more regularly and providing information for the hospital doctors. During and at the end of the study, the hospital was provided with study supplies such as thermometers and sphygmomanometers. There were very few nurses to serve the number of patients on the ward. Our study added 2 nurses to each shift, which sometimes more than doubled the presence of nurses on the ward. Our study nurses were often called upon 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 1 day. Because the nursing shortage was already significant and notable, we did not observe whether the strike caused an even greater shortage in staffing.

> Lesson: Reassurance that the study design benefits patients and the institution can help speed approval.

Overcoming Challenges. ***Study population profile.*** The eventual study population had different clinical characteristics than we expected. The rapid implementation of the project sacrificed careful assessment of the patient profile on the ward. Ideally we would have spent time conducting chart reviews to assess the patient population before deciding to proceed with the site. Instead we conducted interviews with key informants knowledgeable about the patients. We expected more patients with malaria and with other acute 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 assessment of patient population in advance.

Band arrival challenges addressed. The fitness bands were ready for use 1 day later than anticipated because of customs complications on arrival. 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 sufficient time for logistics arrangements.

Enrollment challenges addressed. Enrollment was slow at first, leading to accelerated enrollment 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) not being an ideal fit for the project 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. About 10 days into the study, when we realized that we were experiencing several data quality and protocol deviation issues, we implemented corrective actions immediately. The primary data quality concerns may have been due to nurse fatigue. We initiated a procedure to review all data collected by the nurses at least once during the shift so corrected readings could be taken if needed. Examples of common data quality issues included the following:

- Oral temperature readings were skipped 12% of the time.
- Data fields were left blank on the vital sign data sheets.
- Patient ages were recorded inconsistently from one day to the next.
- The ambient temperature was not listed because of 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 ensure times were designated correctly by the end of each nursing shift.

Lesson: Conduct data quality review on every shift.

Supply challenges addressed. Maintaining proper supplies for the 6 study nurses was a challenge. Each nurse required the following supplies for her shift: ear thermometer and sheaths, oral thermometer and sheaths, pulse oximeter, sphygmomanometer, pen, flashlight, hand sanitizer, sanitizing wipes, air temperature thermometer, face mask, and gloves. 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. Supplies were sometimes borrowed by the regular hospital staff, who often had no supplies otherwise. Despite inventory challenges, at the end of the study, only 2 pulse oximeters and 2 oral thermometers could not be accounted for. Extra study supplies were kept in a room that was locked in the evening and at night so supplies could not be replenished after hours. The study manager carried a few extra supplies in his briefcase in order to replenish the nurses' supplies at the end of an evening shift when the supply room was locked.

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 staffing challenges. 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. The staffing needs were greater than originally planned, so 3 additional nurses were quickly 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 6 study nurses recruited for this project, 3 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 eventually relieved of duty after it appeared their attention to detail was slipping. Most of the 6 nurses had other jobs at the same time, which meant they sometimes were quite tired while working on this project.

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 were not numbered and did not remain in a consistent location. The ward was designed for 52 beds but housed more than 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 2 days of data collection, when the Makerere University College of Health Sciences practical exams took place on the ward. (For example, 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

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of at least 1 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 delayed when 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 leaving the hospital during shifts to have breakfast or lunch. Sometimes they took longer than expected to return, which led to readings being taken later than the required time. This challenge 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 time off for lunch so there was always at least 1 nurse available at the ward to take the readings on time.

Lesson: Ensure availability of study staff refreshments in the study room.

CONCLUSIONS

A rapid study of innovative technology 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 benefit 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 require rapid scale-up and quick results. The lessons learned from Mulago National Referral and Teaching Hospital's work on this project can benefit future studies of this type in similar settings.

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