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# A Functionality and Acceptability Study of Wireless Maternal Vital Sign Monitor in a Tertiary University Teaching Hospital in Rural Uganda

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## Abstract

**Background:** The emergence of wireless technologies and advancements in on-body sensor design can provide continuous physiological data with the potential to reduce the need for human resources.

**Objective:** To test the functionality and acceptability of a wireless maternal vital sign monitor in southwestern Uganda.

**Methods:** Healthy, full-term pregnant women were recruited to wear a wireless vital signs monitor that captures heart rate (HR), respiratory rate (RR), and temperature (T). Measurements were compared with standard of care vital signs.Successful functionality was defined as continuous capture of vital signs for 30 minutes with wireless transfer to a central monitor. We evaluated agreement between wireless and standard measurements using Bland–Altman plots. Acceptability by pregnant women and clinicians was assessed by questionnaires.

**Results:** Fifty pregnant women were enrolled and observed by 10 clinicians. Successful capture and transmission by the wireless monitor occurred for 83% of the vital signs. The 95% limits of agreement at 50th percentile between wireless and standard of care measurements were ±10.9 beats/minute for heart rate, ±8.4 respirations/minute for respiratory rate ±-0.1° Celsius for temperature. Mostpregnant women (90%) found the monitor very comfortable, 80% would recommend it for future use and 100% of clinicians found it very useful.

**Conclusions:** We found reasonable functionality and a high acceptability level for the use of this wireless vital sign monitor among pregnant women in a resource-limited setting. Further study is needed to establish potential impact on clinical outcomes and cost-effectiveness.

**Keywords:** Wireless device; Wireless monitoring; Uganda; Mbarara University; Vital signs; Pregnant women; Obstetrics

**Abbreviations:** MUST-Mbarara University of Science and Technology; LOA-Limits of agreement; HR-heart rate; RR- respiratory rate; T-temperature; MMR-maternal mortality ratios; MRRH-Mbarara Regional Referral Hospital; WHO-World Health Organization

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## Background

Despite encouraging reductions in global maternal mortality ratios (MMR), there are still an estimated 289 000 maternal deaths per year worldwide. Sub-Saharan Africa carries a disproportionate number of these deaths with a lifetime risk of maternal death of 1 in 38 compared to 1 in 3700 in developed countries[1]. Most direct causes of maternal deaths occur in the first 24 to 72 hours after delivery. The most common obstetric complications leading to maternal death are postpartumhemorrhage, sepsis, eclampsia, prolonged or obstructed labour, and complications of abortion; most of these conditions can be readily addressed if skilled health personnel and key medical technology and drugs are available [18].

Abnormalities in maternal vital signs–heart rate, temperature, blood pressure, respiratory rate, oxygen saturation and urine output- may be the first indication of maternal compromise.Identification of critically ill patients through vital sign monitoring can lead to active management that can prevent clinical deterioration and more serious adverse patient outcomes [2,3,17]; however, routine vital sign monitoring of pregnant women in resource-limited settings often does not occur due to shortages in clinical staff, as well as an inadequate supply of easy-to-use monitoring equipment [4].

The emergence of wireless technologies and advancements in on-body sensor design can provide continuous physiological data with potential to reduce human resourcesby allowing simultaneous monitoring coupled with automated alerts to the clinical care team [5]. Studies assessing such wireless technology in a non-pregnant population have shown initial success with good acceptability by patients [6,7]. Pilot work testing wireless technology in pregnant woman in resource-rich settings has also shown promising results [8]. To our knowledge, however, there is no such research into the feasibility and acceptability of using wireless technology for vital sign monitoring in resource-limited settings. In this study, we tested the functionality and acceptability of a wireless maternal vital sign monitoring device in a rural sub-Saharan African setting. We describe the technical function of the monitor, compare vital sign measurements using wireless versus current standard of care approaches, and report on the maternal and clinician views of the monitor.

## Methods

### Study setting

The Mbarara Regional Referral Hospital (MRRH) is a teaching hospital located in southwestern Uganda and serving a population of 3 million people. Approximately 12,000 deliveries occur per year in this facility with a MMR of 400 per 100,000 live births and a caesarean delivery rate of 39%. The physician to patient ratio ranges from 1:8 during the day to 1:14 during the night. The nursing/midwife to patient ratios are approximately1:25 during the day and 1:50 at night. The facility includes two open wards in a concrete building.

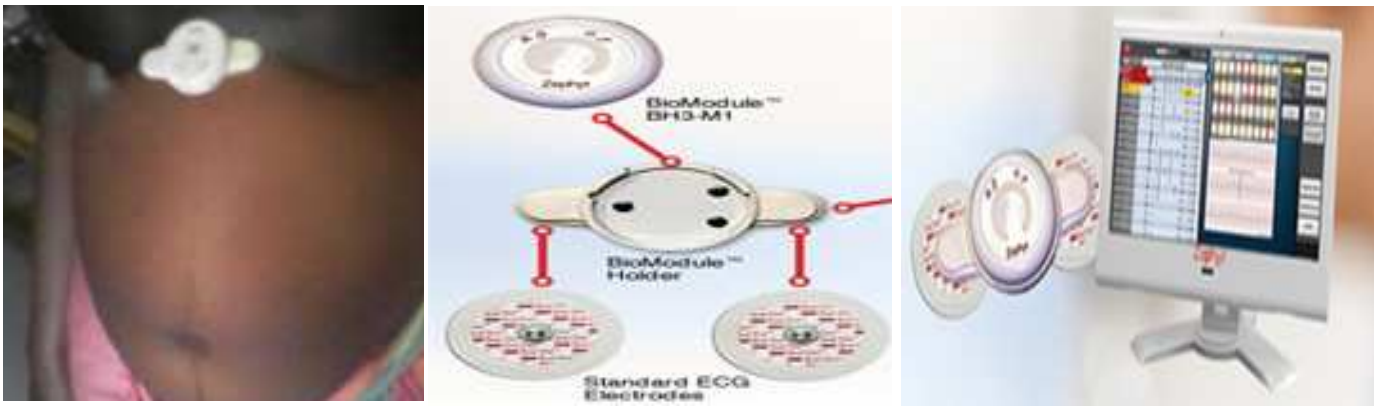
### Study methods

We conducted a cross-sectional study involving two groups of participants. The first group included healthy, full-term pregnant women aged 18 and older, with a singleton gestation, in early labor admitted to the MRRH maternity wardafter a standard evaluation by non-study clinical staff on duty. The pregnant women were recruited to wear the wireless vital sign monitor for 30 minutes and then comment on its acceptability. Pregnant women were excluded if they were in active labor, unwilling to wear devices or participate in questionnairesor had a known infectious disease diagnosis including but not limited to viral hepatitis, tuberculosis, or HIV. The second group of participants were non-study, clinical staffon the MRRH maternity ward, including midwives and both faculty and trainee obstetricians/gynecologists. Clinical staffs were asked to observe the use of and interact with the monitoring system and then provide their views on its usefulness and acceptability. Visiting staff or trainees were excluded. Written consent for the study was obtained for all participants prior to monitoring.

### Wireless vital sign monitor

Pregnant participants wore the Zephyr BioPatch ™, which is a physiologic monitoring sensor that enables the capture and transmission of heart rate based on the R-R interval of a two-lead electrocardiogram; respiratory rate via impedance; temperature; and position of the wearer via an accelerometer. There is no capacity for blood pressure assessment currently with this device. In this study, the sensor was used to assess heart rate, respiratory rate and temperature. The monitoring system consists of a sensor housed in a holder that is attached to the patient's chest wall via two standard adhesive electrodes (Figure 1). Data captured is then transmitted to a central monitor over an internal wireless network to a central monitoring station (Zephyr LIFE™). This central monitor is a fully functional central processing unit with a universal serial bus attached to a wireless receiver with software enabling reception and display of received vital sign data. Several repeaters were used to amplify the wireless signal and ensure transmission throughout the labor and delivery unit, which is housed in a building constructed with cement blocks. United States FDA approval is available for general use of this device for all measurements other than temperature.

**Figure 1:** The wireless vital sign monitoring system applied onto a mother




### Study procedures

All study procedures were conducted by obstetric midwives or physicians who received training on the use of the wireless monitor and study protocol prior to study initiation. Socio-demographic characteristics of both pregnant women and staff and the obstetrical history were collected at enrollment through an interviewer-administered questionnaire and additional data extracted from medical records. Study staff then applied the wireless monitor on the pregnant women, entered the pregnant women's data into a central monitor to allow tracking of vital signs, and confirmed data transmission to the central monitoring station. Women were then asked to wear the monitor for 30 minutes. Heart rate, respiratory rate and temperature were also measured during this same monitoring period at 0, 15 and 30 minutes by radial pulse palpation, manual count of chest movements, and an axillary thermometer, respectively. These techniques for vital sign measurement are the current standard of care for the MRRH maternity ward and were made available to the clinical care team (the wireless monitor readings were not used for clinical care).

After the monitoring session, the pregnant women participants were asked to complete a brief questionnaire on acceptability assessing how comfortable the monitor was when worn; whether they thought it was useful, whether they liked interacting with the monitor and whether they would be willing to wear it again in the future. Clinicians similarly completed a questionnaire regarding their impressions on the wireless monitor. Choice of questions was guided by the Technology Acceptance Model [9].

### Analysis

We used descriptive statistics to summarize participant characteristics, vital signs, and monitor functionality, including percentage of expected data successfully obtained and technical challenges encountered. Monitor functionality was deemed successful if there was continuous capture of the maternal heart rate, respiratory rate, and temperature for 30 minutes and transfer of that captured data to the central monitor for review.The wireless monitoring device values corresponding to the 0, 15 and 30-minute standard of care measurement time points were computed as the mean of the 60 values obtained in the minute following the standard of care reading. For instance if temperature on the standard method was measured at 11:00:00, the corresponding wireless temperature was the meanwireless temperature between 11:00:00 and 11:00:59.

We assessed agreement of the wireless monitor and standard methods for heart rate, respiratory rate, and temperature using Bland Altman plots [10]. We assessed Bland-Altman plots for trend using Spearman rank correlation. For any comparisons where a trend was observed, a log transformation of measurements was attempted. If the trend persisted, we fit a regression of the absolute residuals on the average of methods to model the trend in the limits of agreement and computed the limits of agreement by combining the two regression equations. For ease of interpretation, we computed the mean difference and corresponding limits of agreement at the 25th, 50th and 75th percentiles of compared vital sign measurements.

## Results

### Participant characteristics

Fifty pregnant women and 10 clinicians were enrolled; participant characteristics are described in Tables 1 and 2. Most pregnant women participants were between 20 and 30 years old, married and multiparous; the average gestational age was 39.7 weeks. Seven midwives and three obstetricians observed the monitoring system; 80% had been in practice for more than 5 years and their median age was 38.5 years.

### Functionality

Successful transmission of vital signs at 30 minutes of monitoring occurred 82%, 84% and 84% of the time for heart rate, respiratory rate, and temperature, respectively. Therefore the rate for the entire 30 minutes across all the vitals was 83%. Median values of vital signs measured are described in Table 3. Bland-Altman plots [10] comparing vital signs measured at the 15-minute mark are shown in Figure 2. The 15-minutes time-point was chosen to compare vital signs as it contained more complete monitoring information than the 0-minute and 30-minute time-points.

**Table 1:** Participant characteristics (Pregnant women and Clinicians)

| Characteristic | N (%) or median (IQR) |
|---|---|
| Age of pregnant women | 38.5 (31.3-51.8) |
| Pregnant women's characteristics | |
| Age categories | |
| 18-19 | 7 (14) |
| 20-24 | 2 (40) |
| 25-29 | 16 (32) |
| 30-34 | 6 (12) |
| >34 | 1 (2) |
| Education level attended | |
| Primary | 27 (54) |
| Secondary | 15 (30) |
| Tertiary | 8 (16) |
| Religion | |
| Protestant | 24 (48) |
| Catholic | 14 (28) |
| Muslim | 7 (14) |
| Other | 5 (10) |
| Occupation | |
| Unemployed | 13 (26) |
| Self-employed | 14 (28) |
| Unskilled labor | 17 (34) |
| Professional | 6 (12) |
| Marital Status | |
| Married | 46 (92) |
| Never Married | 2 (4) |
| Other | 2 (4) |
| Parity | |
| 0 | 18 (36) |
| 1 | 9 (18) |
| 2 or more | 23 (46) |
| Gestational age | 39.7 (38.4-40.6) |
| Clinician characteristics | |
| Clinician type | |
| Obstetrician | 3 (30) |
| Midwife | 7 (70) |
| Years of clinical practice | |
| 5 or less | 2 (20) |
| >5-10 | 3 (30) |
| >10 | 5 (50) |

**For the marital status, the category of other included women who were not sure of their marital status.

**Table 2:** Summary of vital sign measurements

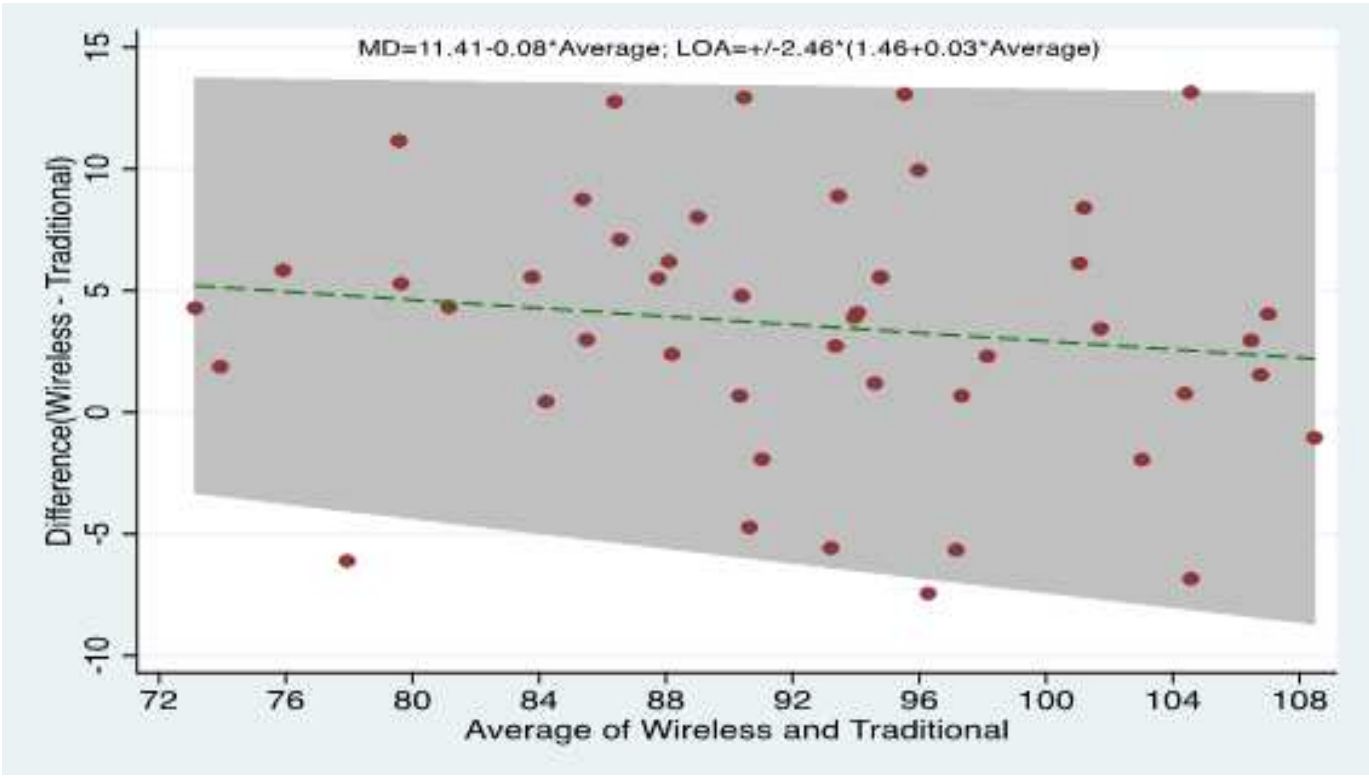
| Vital sign | Time | Wireless-monitoring device | Standard Monitors | | |
|---|---|---|---|---|---|
| Functionality | | N | Median (IQR) | N | Median (IQR) |
| Heart rate | 0 | 36 | 91 (87-101) | 50 | 93 (83-98) |
| | 15 | 47 | 94 (89-101) | 50 | 92 (84-98) |
| | 30 | 41 | 94 (91-99) | 50 | 95 (83-101) |
| Respiratory rate | 0 | 36 | 18 (14-20) | 50 | 20 (18-24) |
| | 15 | 47 | 18 (16-20) | 50 | 20 (18-24) |
| | 30 | 42 | 18 (15-19) | 50 | 20 (19-24) |
| Temperature | 0 | 36 | 37.2 (37.1-37.3) | 50 | 36.4 (36.1-36.8) |
| | 15 | 47 | 37.5 (37.5-37.6) | 50 | 36.5 (35.9-36.8) |
| | 30 | 42 | 37.6 (37.5-37.6) | 50 | 36.4 (36.1-36.8) |

**Table 3:** Mean difference and LOA

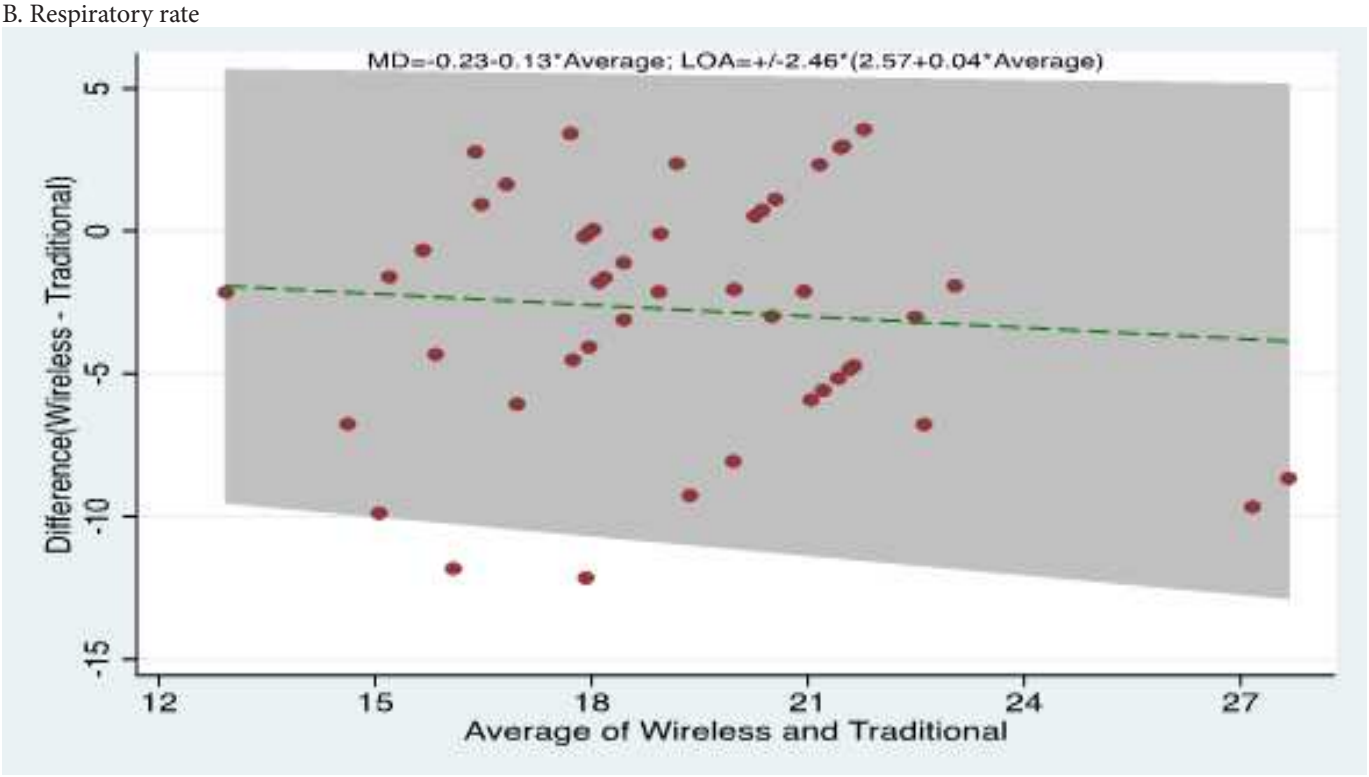
| | Heart Rate | Respiratory Rate | Temperature |
|---|---|---|---|
| Percentile | 25th 50th 75th | 25th 50th 75th | 25th 50th 75th |
| Average | 86.4 93.4 98.2 | 17.7 19.1 21.4 | 36.7 37 37.2 |
| Mean difference | 4.5 3.9 3.6 | -2.5 -2.7 -3 | 0.4 0.1 -0.1 |
| Limits of Agreement (LOA) (±) | 10 10.5 10.9 | 8.1 8.2 8.4 | 0.4 0.1 -0.1 |

**Figure 2:** Bland Altman plots comparing agreement between wireless and standard vital sign monitoring (A: Heart Rate, B: Respiratory Rate, C: Temperature). Limits of agreement are shown in the shaded region.

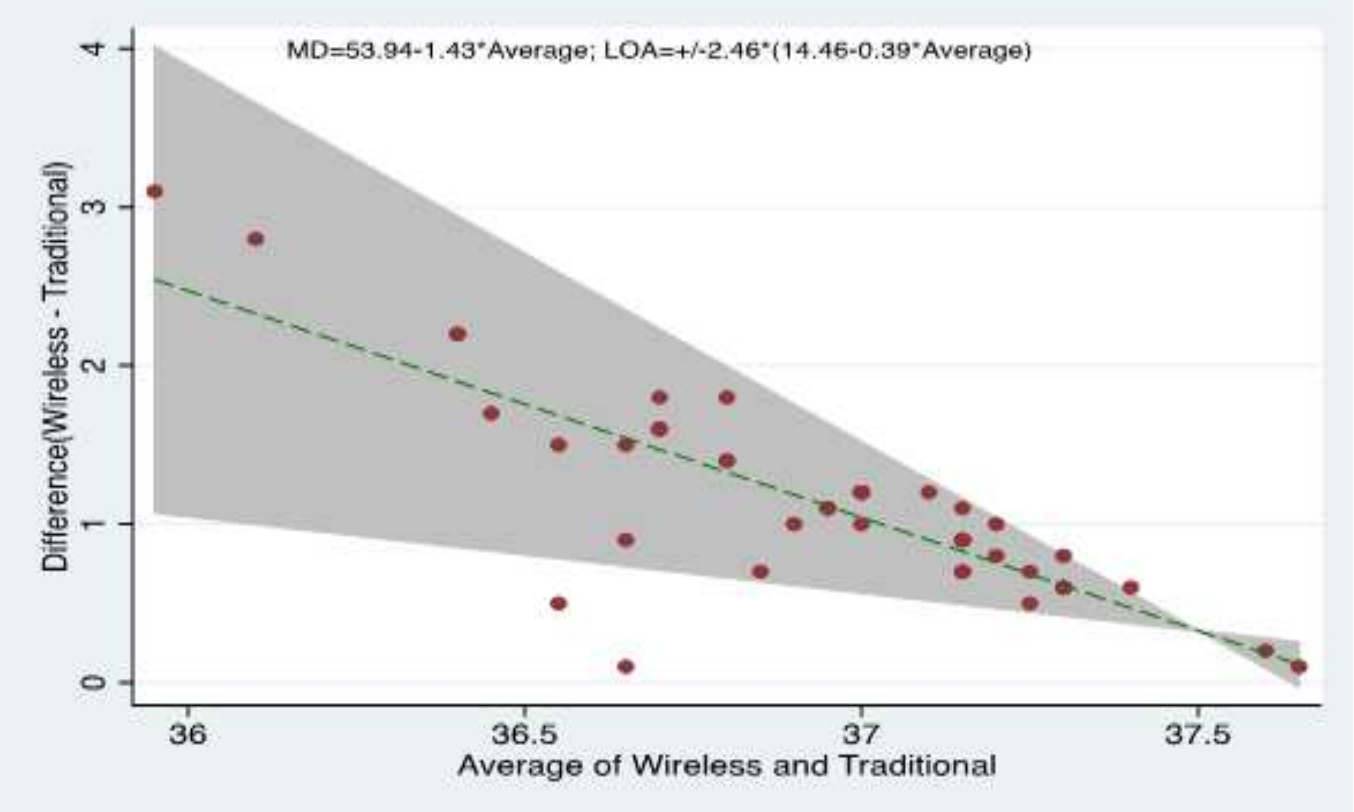
A. Heart rate




B. Respiratory rate



C. Temperature




For all three vital signs considered, atrend was observed between the mean difference and the average of the measurement (spearman rank coefficients -0.21, -0.03, -0.72 for heart rate, respiratory rate, and temperature, respectively). These trends were not remediated by log transformation and therefore the lines of mean difference and limits of agreement were calculated using a regression adjustment. As shown in Table 4, the mean difference and limits of agreement for the 25th and 75th percentile of average measurements (wireless and standard) were 4.5 (LOA ±10) and 3.6 (LOA ±10.9) beats per minutes (bpm) for heart rate, -2.5 (LOA ±8.1) and -3 (LOA ±8.4) respirations per minute (rpm) for respiratory rate, and 1.5 (LOA ±0.4) and 0.7 (LOA ±-0.1) °Celsius (C) for temperature. Compared to the standard of care measurements, the wireless monitor measurements were generally higher for heart rate and temperature, but lower for respiratory rate. The LOA were consistent across heart rate and respiratory rate, yet were broader at lower compared to higher temperatures.

### Acceptability

As shown in Table 2, most pregnant women found the wireless monitor to be "very comfortable" (90%) and "very useful" (86%). All "liked it" or "really liked it", and all but one participant would opt to wear it again in the future. All of the clinicians also found the wireless monitor "easy" or "very easy" and "very useful". All also "liked" or "very much liked it" and "would recommend having it worn by their patients". All clinicians found the monitor very useful and would definitely recommend its use again in the future. The results from the monitor could be assessed immediately after the monitoring sessions within a period of less than 5 minutes.

## Discussion

To our knowledge, this study is the first of its kind a pilot assessment of the functionality and acceptability of wireless vital sign monitoring in a resource limited setting. We found that the wireless maternal vital sign monitor demonstrated reasonable functionality and was highly acceptable to both pregnant women and clinicians in southwestern Uganda. These results are encouraging in this resource-limited setting where the available number of clinicians is inadequate and monitoring gaps may contribute to preventable morbidity and mortality.

Successful transmission of data from the wireless monitor at 30 minuteswas 83% on average. Limits to transmission may stem from the physical infrastructure of the maternity ward where multiple concrete walls could potentially prevent wireless transmission of data. Additionally the integrity of the electrode adherence to the pregnant chest wall might have been affected by the gravid abdomen and/or increased perspiration or chest wall movements that are common, even in early labor. Electrode adherence may differ in pregnant women in a non-temperature regulated environment as compared to prior populations and settings where this wireless monitor has been tested [8]. A little more in-depth study in non-pregnant populations such as postpartum women and also longer term monitoring say 3 days rather than 30 minutes will be required to measure clinical outcomes.

**Table 4:** Acceptability of the wireless monitor

| | Pregnant women | Clinicians |
|---|---|---|
| How comfortable did you find wearing the monitor? | | |
| Very comfortable | 45 (90%) | n/a |
| Comfortable | 3 (6%) | n/a |
| Neutral/ok | 1 (2%) | n/a |
| Somewhat bothersome | 1 (2%) | n/a |
| Very bothersome | 0 (0%) | n/a |
| How useful did you find the monitor? | | |
| Very Useful | 43 (86%) | 10(100) |
| Useful | 7 (14%) | 0(0%) |
| Somewhat useful | 0 (0%) | 0(0%) |
| Not at all useful | 0 (0%) | 0(0%) |
| What do you think of the monitor? | | |
| I really like it | 43 (86%) | 8 (80%) |
| I like it | 7 (14%) | 2 (20%) |
| Neutral/OK | 0 (0%) | 0 (0%) |
| I do not like it | 0 (0%) | 0 (0%) |
| I really do not like it | 0 (0%) | 0 (0%) |
| How likely would you be to wear the monitor again or recommend its use to another patient? | | |
| I definitely would | 49 (98%) | 10 (83%) |
| I wouldn't care one way or the other | 0 (0%) | 2 (17%) |
| I definitely would not | 1 (2%) | 0 (0) |
| Compared to standard of care monitoring, how easy did you find using the wireless vital sign monitor? | | |
| Very Easy | n/a | 10 (100) |
| Easy | n/a | 0 (0%) |
| Neutral/ok | n/a | 0 (0%) |
| Difficult | n/a | 0 (0) |
| Very difficult | n/a | 0 (0) |

Comparability of vital signs between the wireless monitor and standard methods of measurement was generally reasonable. Differences between the measurement settings are difficult to interpret as the standard of care methods used in this study may or may not have been accurate. Both heart rate and respiratory rate relied on manual assessment, which are both subject to human error [11,12]. Similarly, axillary temperature assessment has been shown to have poor accuracy [13]. In this context, limits of agreement for heart rate, respiratory rate, and temperature that are within ±11 bpm, ±8.1rpm and ±0.4°C respectively, are reasonable enough to warrant larger feasibility and outcome studies for this wireless vital sign monitor.

Prior studies of wireless vital sign monitoring devices conducted in resource-rich settings,where technology is more pervasive, have reported technology anxiety/apprehension as barriers to provider technology adoption [14,15]. In contrast, we found high acceptance of the wireless monitor by both participants and clinicians. We had anticipated that the pregnant women participants would have a number of concerns in using the monitor (such as harm to the fetus), given limited prior exposure to technology. For instance, data from a national Ugandan survey indicated that only about half of the rural population own a mobile phone and less than a third of the population uses the internet [16]. We found, however, high acceptance and desirability for this monitor. Similarly, local midwives with minimal technology experience were readily trained as study staff and were able to correctly apply the wireless monitor, input patient information, and track the vital sign output. Clinician participants generally felt the device would be simple to use.

The study has limitations. First, it involved a small number of participants in one setting with a short monitoring period. Additional studies in other resource-limitedsettings with longer periods of monitoringand follow-up are needed to obtain a more complete understanding of the broader acceptability and functionality of the technology. Secondly, we did not assess cost, which may be an important limitation to introducing this technology to developing settings [5]. Third, the chosen wireless monitor does not incorporate blood pressure assessment, which is integral to the monitoring and management of many of the complications associated with pregnancy and childbirth.

Based on our findings of reasonable functionality and high acceptability for wireless vital sign monitoring among pregnant women in early labor in a resource-limited setting, further study on the comparative cost and impact on clinical outcomes is warranted and needed to help assess the added value of wireless monitoring technology. This work could have a significant impact on human resource constraints in a population with an unnecessarily high rate of morbidity and mortality.This technology may contribute to reduction in poor outcomes especially when the derangements in the vital signs are detected early to allow for early and timely interventions.

## Ethics approval and Consent statement:

The protocol was presented to the MRRH Department of Obstetrics/Gynecology and approved by the Mbarara University of Science and Technology Research Ethical Committee (reference number was 05/02-13), and the Uganda National Council of Science and Technology (reference number was IS 99). Informed consent was obtained from the participants.

## Funding

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## Authors' Contributions

JN, JEH, BJW were involved in the initial study design and planning. JN, GM were involved in the conduct of the study. JN, JEH, BJW, AB, GM were involved in the data analysis and writing up of the manuscript. All authors read and approved the final manuscript.

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