Original Research

Wireless Vital Sign Monitoring in Pregnant Women: A Functionality and Acceptability Study

Adeline Adwoa Boatin, MD, MPH,[1] Blair Johnson Wylie, MD,[2] Ilona Goldfarb, MD,[2] Robin Azevedo, RN-C,[3] Elena Pittel, BS, RN, MSc,[3] Courtney Ng, BA,[4] and Jessica Elizabeth Haberer, MD, MS[5]

[1]Department of Obstetrics and Gynecology, [2]Division of Maternal Fetal Medicine, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts.
[3]Department of Nursing, Massachusetts General Hospital, Boston, Massachusetts.
[4]Harvard School of Public Health, Boston, Massachusetts,
[5]Massachusetts General Hospital Center for Global Health, Harvard Medical School, Boston, Massachusetts.

Abstract

Objective: *To test the functionality and acceptability of a wireless vital sign monitor in an inpatient obstetric unit.* ***Materials and Methods:*** *Pregnant women at a U.S. tertiary-care hospital wore a wireless vital sign sensor that captures heart rate, respiratory rate, and temperature. Measurements were compared with vital signs obtained by standard devices. We defined continuous capture of vital signs for 30 min with wireless data transfer to a central monitor as functional success. Acceptability was assessed per the pregnant women and nurses observing the device. Bland–Altman plots were constructed to assess agreement between the wireless sensor and standard measurements.* ***Results:*** *Thirty of 32 enrolled pregnant women had successful monitoring; 2 cases were stopped early for non–study-related reasons. Comparing wireless sensor and standard measurements, the mean difference (limits of agreement) values at the 25th and 75th percentiles were 1.6 (±13.2) and 4.2 (±18.6) heartbeats/min, 4.2 (±6.1) and 0.7 (±5.4) respirations/min, and 0.02°C (±1.5) and 0.5°C (±1.8), respectively. Most pregnant women found the device comfortable, likeable, and useful (78%, 81%, and 97%, respectively); 80% of nurses found the monitor easy to use, and 84% would recommend it to a patient.* ***Conclusions:*** *We successfully obtained maternal vital signs using a simple wireless monitor with high acceptability. Well-validated monitors of this nature could significantly alleviate the human resource burden of monitoring during labor and confer greatly desired mobility to laboring pregnant women, although incorporation of blood pressure monitoring will be critical.*

Key words: *wireless monitoring, vital sign, wireless device, pregnant women, maternal care, obstetrics*

Introduction

With 4 million admissions per year, childbirth is the most common reason for inpatient monitoring in hospitals within the United States.[1] During this type of admission, monitoring is typically intense. Vital signs, including heart rate (HR), blood pressure (BP), and temperature, can be monitored every 30 min during active labor and every 15 min in the immediate 1–2 h following delivery. Maintaining this level of monitoring requires a significant dedication of human resources. Current obstetric nursing standards in the United States call for a 2:1 nursing to patient ratio for pregnant women in the active phase labor and a 1:1 ratio for those in the second stage of labor (from full cervical dilation until delivery).[2] Achieving such coverage is costly and unattainable in settings with health provider shortages.

Advances in technology have allowed for continuous monitoring of vital signs. For example, automated monitors are commonly used to continuously record HR, oxygen saturation, and temperature and can intermittently record BP. These devices are wired, are often bulky, and restrict patient mobility. In the last decade there has been increasing attention to wireless monitoring in various healthcare settings.[3] Most research efforts have used such technology to extend vital sign monitoring beyond the borders of the traditional health facility such as in disaster situations or monitoring of recently discharged patients.[4,5] These studies have shown wireless technology to be safe, cost-effective, feasible, and acceptable to patients.[4–6]

Investigating wireless technology for vital sign monitoring in an inpatient obstetric population represents a novel application of this technology. In this particular setting, patients are for the most part healthy and can potentially labor as an inpatient for 24 h or longer. Mobility therefore is greatly desired. Monitoring, however, still remains important because complications like sepsis, hemorrhage, or embolism may occur. In such cases, vital sign abnormalities may signal catastrophic events that require expedient management.[7–9]

Wireless monitoring of maternal vital signs therefore lends a triple advantage: the potential to significantly reduce the human resource burden required for intensive monitoring, while maintaining a high level of surveillance, with the added benefit of allowing more flexibility and mobility for patients. In this study we tested the functionality and assessed the acceptability of a wireless maternal vital sign monitoring system in a tertiary-care inpatient obstetric ward in the United States.

Materials and Methods

STUDY DESIGN AND PARTICIPANTS

We performed a cross-sectional, mixed-methods study to test the functionality and acceptability of a wireless vital sign monitoring system in an inpatient obstetric ward in a tertiary-care hospital in the United States. Two groups of participants were studied: (1) healthy, full-term pregnant women 18 years of age and older, carrying singleton gestations and who presented to the Labor and Delivery Triage Unit at the Massachusetts General Hospital prior to the onset of active labor and (2) non–study nurses who observed monitoring of these pregnant women. Pregnant women were recruited to wear the wireless sensor and comment on its acceptability after non–research providers evaluated them and deemed them to be clinically stable without evidence of active labor. Non–study nurses were recruited to assess clinician acceptability of the device. Both groups of participants were enrolled as a convenience sample until sufficient data were obtained to assess the study goals (i.e., additional data did not change data interpretation).

WIRELESS VITAL SIGN MONITORING SYSTEM

We used the BioPatch™ (Zephyr Technology, Annapolis, MD), a physiologic monitoring sensor that captures and transmits HR based on the R-R interval of a single-lead electrocardiogram, respiratory rate (RR) via impedance, estimated core temperature based on HR variability, and the position of the wearer via an accelerometer.[10] This sensor was chosen for its ease of use, compactness, and range of monitoring capabilities. In this study the sensor was used to assess HR, RR, and temperature. The sensor is housed in a holder attached to the chest wall via two standard adhesive electrodes (*Fig. 1a*). Data are transmitted to a central monitor over a wireless network where vital signs are on display for the clinician (*Fig. 1b* and *c*). The central monitor (ZephyrLIFE™ HOSPITAL™) is a fully functional central processing unit with a USB-attached wireless receiver and with software enabling reception, display of received vital sign data, and customizable on-screen and audible alerts. Repeaters were used to extend the range and ensure transmission throughout the labor and delivery unit. The BioPatch is approved for use by the Food and Drug Administration for the measurement of HR and RR but for not temperature.[10]

STUDY PROCEDURES

Pregnant women were asked to wear the wireless sensor for 30 min. We chose this time frame to allow participants sufficient time to interact with the device and to obtain reasonable collection of vital sign data within the constraints of a feasibility study. Obstetric nurses (henceforth called "study nurses") trained in the use of the study devices were responsible for applying sensors to women and measuring vital signs using standard devices. During the study time, routine clinical care continued without interruption (including patient monitoring performed by non–study nurses). The sensor was applied, and a study nurse confirmed data transmission to the central monitor. Study nurses were also responsible for entering participant data into the central monitor to allow tracking of vital signs. They then obtained HR, RR, temperature, and BP using standard labor and delivery devices. Specifically, HR and BP were measured with a wired pulse oximeter and BP cuff. RR was counted manually. Temperature was measured using an infrared scanner that measures temperature at the temporal artery. Standard vital sign assessments including HR, RR,

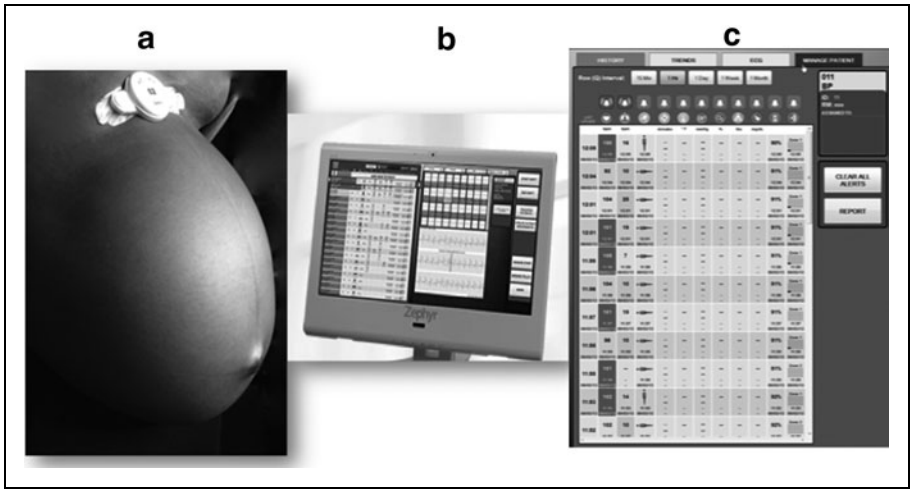

Fig. 1. The different components of the wireless monitoring system: **(a)** wireless sensor attached to the sternum via adhesive electrodes, **(b)** ZephyrLIFE central monitor, and **(c)** close-up screenshot of vital sign display from a central monitor.

temperature, and BP were performed at 0 (baseline), 15, and 30 min of monitoring. As part of monitoring, the pregnant women also wore a wireless fetal HR monitor, the results of which are reported elsewhere.[11]

Following monitoring, participants completed a closed-ended questionnaire assessing their acceptability of the monitor. Using a 5-point scale, the questionnaire investigated perceptions of comfort, usefulness, and overall likeability of the device. Five participants completed a longer interview with open-ended questions on likes and dislikes of the test device compared with standard vital sign monitoring. These participants were chosen based on their level of interest and availability of time. Non–study nurse participants completed similar closed and open-ended questionnaires on acceptability.

DATA ANALYSIS

We defined a successful monitoring session as the continuous capture of maternal HR, RR, and temperature for at least 30 min and transfer of these data to the central monitor. To assess functionality, we determined the number of successful vital sign monitoring sessions out of the total attempted, as well as the comparability of the measurements obtained through the wireless sensor and through the standard devices.

Bland–Altman plots were used to assess agreement between vital sign measurements taken by standard devices and corresponding values measured by the wireless sensor.[12] Vital sign data from the wireless sensor were averaged across the minute corresponding to time recorded for standard baseline measurements. A trend between the mean difference and average of the measurements was supported by graphical and Spearman rank correlation analysis. This trend was not remediated through log-transformation, and hence the line of mean difference and lines of agreement were calculated through a regression adjustment. This method accounts first for the dependence of the mean difference on the magnitude of the measure through linear regression of the mean difference on the average. Second, it accounts for heteroskedasticity of the mean difference through a regression of the absolute residuals from the first model on the average. Together these regressions yield equations for the line of mean difference and limits of agreement. The slope of the line of mean difference reflects the dependence of the mean difference on the magnitude of the measure, and the slope on the line for limits of agreement reflects heteroscedasticity.[13] For clinical interpretability we calculated mean difference and limits of agreement from each regression equation using the 25th and 75th percentile average measurements (wireless and standard) for each vital sign, respectively.

Table 1. Characteristics of Study Participants

PARTICIPANT CHARACTERISTIC	VALUE
Maternal age (years) at enrollment	33.1 ± 9.7
>18–34	19 (59.4%)
≥35	13 (40.6%)
Race or ethnic group[a]	
Black	1 (3.12%)
White (non-Hispanic)	22 (68.8%)
White (Hispanic)	3 (9.3%)
Asian	3 (9.3%)
Other or unknown	3 (9.3%)
Parity	
0	17 (53.1%)
1	7 (21.9%)
2	8 (25%)
Gestational age (weeks)	39.2 ± 1
Body mass index (kg/m^2) at enrollment	25 ± 6.6
Education level[a]	
Some high school	2 (6.25%)
High school diploma	3 (9.38%)
Some college	4 (12.5%)
College graduate	9 (28.1%)
Graduate school	13 (40.6%)
Income level[a]	
<$50,000	8 (25.0%)
$50,000–$100,000	7 (21.9%)
>$100,000	13 (40.6%)
Unknown/missing	4 (12.5%)
Clinician age (years) at enrollment	33.5 ± 11
>18–34 years	3 (50%)
≥35 years	3 (50%)
Years in clinical practice at enrollment	9.5 ± 13
Sex	
Female	6 (100%)
Male	0 (0%)
Time spent interacting with devices	
1–15 min	1 (16.7%)
16–30 min	5 (83.3%)

Data are number (%) or median ± interquartile range unless otherwise specified.
[a]Race or ethnic group, education level, and income level were self-reported.

To determine device acceptability, quantitative questionnaire data were summarized descriptively. Open-ended responses were reviewed for common themes and summarized.

ETHICS STATEMENT

The Partners Healthcare/Massachusetts General Hospital Institutional Review Board approved this study, and all participants provided written, informed consent. All study devices were inspected and approved by the Biomedical Engineering Department at Massachusetts General Hospital.

Results

PARTICIPANT CHARACTERISTICS

In total, 38 participants were enrolled; 32 pregnant women wore the sensor, and six non–study nurses observed the monitoring sessions. Baseline and demographic characteristics of participants are presented in *Table 1*.

FUNCTIONALITY

Thirty of the 32 pregnant women completed the 30-min monitoring sessions using the wireless monitoring system. Monitoring was stopped earlier than 30 min in two pregnant women whose planned cesarean deliveries were moved ahead of schedule. Our study nurses had no difficulty entering patient data to the central monitor system or applying the device to the patients. *Table 2* shows median values (interquartile range) for HR, RR, and temperature taken at baseline, 15 min, and 30 min. All recorded values were within normal clinical ranges.

Bland–Altman plots and regression equations showing mean difference and limits of agreement are displayed in *Figure 2*. Comparing wireless sensor and standard measurements, the mean difference at the 25th and 75th percentiles were 1.6 and 4.2 heartbeats/min (bpm), 4.2 and 0.7 respirations/min (rpm), and 0.02°C and 0.5°C for HR, RR and temperature, respectively. Corresponding limits of agreement were ±13.2 and ±18.6 bpm, ±6.1 and ±5.4 rpm, and ±1.5°C and ±1.8°C for HR, RR, and temperature, respectively (*Table 3*).

ACCEPTABILITY OF DEVICES

Participant ratings of the monitoring system are presented in *Table 4*. The majority of pregnant women found it comfortable or very comfortable (78%), although many were neutral. Most pregnant women and clinicians found the sensor likeable or very likeable (81% and 84%, respectively) and useful or very useful (97% and 67%, respectively). Most would either wear the sensor again or have another patient wear them (78% and 83%, respectively). All assessments were either positive or neutral.

PARTICIPANT REFLECTIONS

Participants were generally positive and identified several benefits of the wireless monitor. Representative quotations are presented from both pregnant women and clinicians below.

Benefits of wireless compared with standard monitoring. Most pregnant women reported that increased mobility was a desirable feature of wireless fetal monitoring and a reason for recommending the technology:

> That's small and really convenient … it's wireless, so I don't have to drag anything with me.
> I didn't even know I was wearing it. I mean, yeah, I forgot about it, so that was very comfortable.

Pregnant women in general found the shape, material, and size of the device acceptable; however, some did express some discomfort:

> It was all around fine, a bit noticeable, but nothing big.
> I mean, it didn't even irritate.

Table 2. Heart Rate, Respiratory Rate, and Temperature in Our Study Population

	MEDIAN VALUE AT TIME								
	MEDIAN HEART RATE (BPM)			TEMPERATURE (°C)			RESPIRATORY RATE (RPM)		
	BASELINE	15 MIN	30 MIN	BASELINE	15 MIN	30 MIN	BASELINE	15 MIN	30 MIN
Standard devices	78 (20)	75 (18)	75 (19)	36.4 (0.7)	36.2 (0.4)	36.2 (0.4)	18 (2)	18 (2)	18 (2)
Wireless monitor	65 (6)	75 (23)	77 (18)	36.9 (1.0)	37.5 (1.0)	37.5 (0.8)	9 (10)	12 (6.7)	15 (3)

Data are median values (interquartile range).
bpm, heartbeats per minute; rpm, respirations per minute.

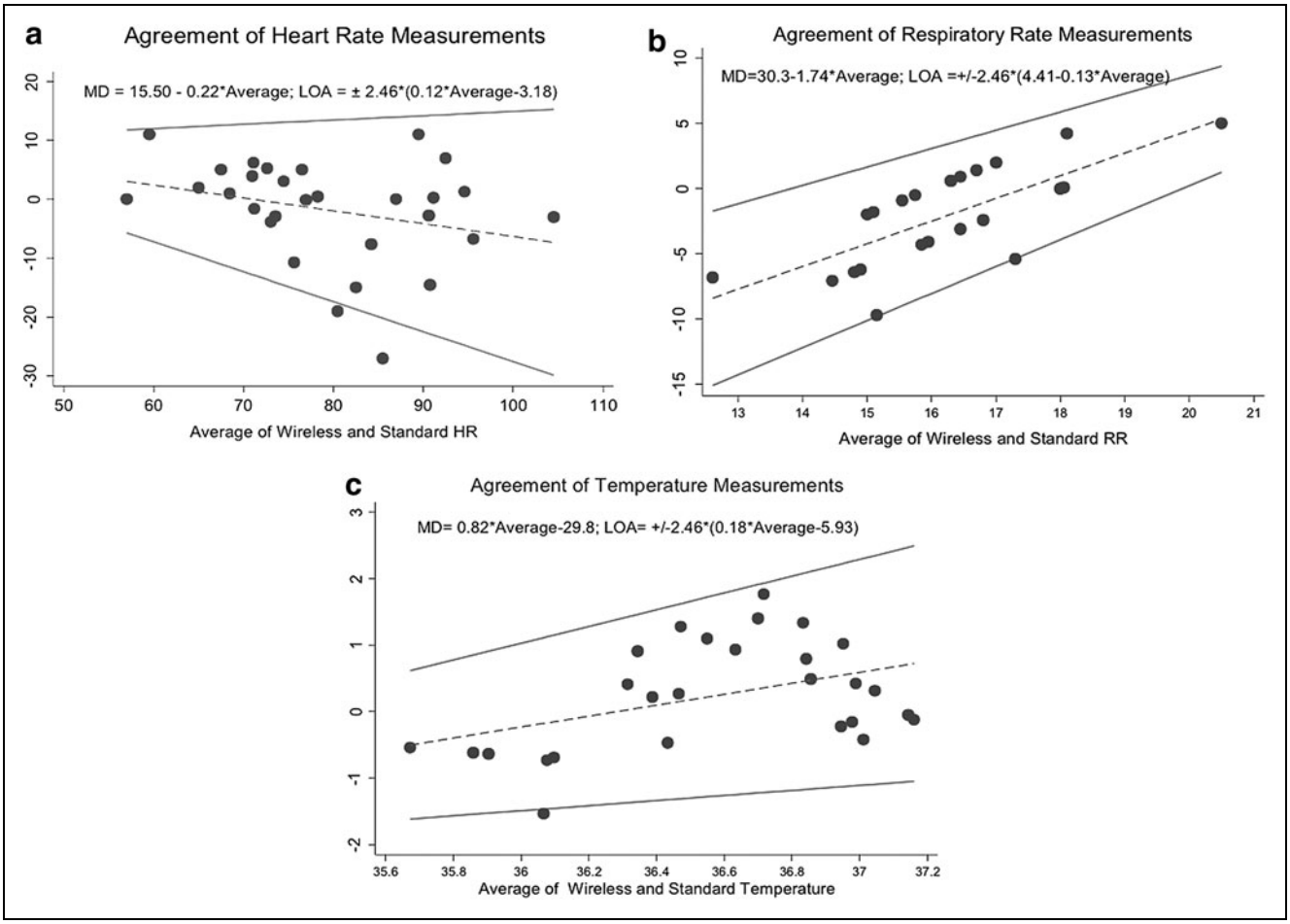

Fig. 2. Bland–Altman plots of measurement comparisons: **(a)** heart rate (HR), **(b)** respiratory rate (RR), and **(c)** temperature. In each plot the center dotted line indicates the mean difference (MD) between measurements. Solid lines indicate the 95% limits of agreement (LOA).

> Around the arm could be a little better, but I like on the chest, rather than a strap around the chest.

Pregnant women also expressed some added comfort in knowing the device could extend the amount of monitoring done:

> I can be monitored literally for *x* amount of time you want … most of the time I don't know if you really monitor that.
>
> For someone who's required [to have monitoring] or beneficial for them to keep track of their heartbeat and all the things, it could be beneficial.

Table 3. Calculated Mean Difference and Limits of Agreement at the 25th and 75th Percentiles of Average Wireless and Standard Measurements

	HEART RATE (BPM)		RESPIRATORY RATE (RPM)		TEMPERATURE (°C)	
	25TH PERCENTILE	75TH PERCENTILE	25TH PERCENTILE	75TH PERCENTILE	25TH PERCENTILE	75TH PERCENTILE
Average	71.0	90.0	15.0	17.0	36.3	37.0
Mean difference	1.6	4.2	4.2	0.7	0.02	0.5
Limits of agreement	±13.2	±18.6	±6.1	±5.4	±1.5	±1.8

bpm, heartbeats per minute; rpm, respirations per minute.

Table 4. Acceptability of the Wireless Vital Sign Monitor

	PREGNANT WOMEN	NURSES
How comfortable did you find wearing the device?		
Very comfortable	13 (41%)	NA
Comfortable	12 (38%)	NA
Neutral/ok	7 (22%)	NA
Somewhat bothersome	0 (0%)	NA
Very bothersome	0 (0%)	NA
How useful did you find the device?		
Very useful	10 (32%)	1 (17%)
Useful	20 (65%)	3 (50%)
Somewhat useful	1 (3%)	2 (33%)
Not at all useful	0 (0%)	0 (0%)
How did you find the device?		
I really like it	10 (31%)	1 (17%)
I like it	16 (50%)	4 (67%)
Neutral/OK	6 (19%)	1 (17%)
I do not like it	0 (0%)	0 (0%)
I really do not like it	0 (0%)	0 (0%)
Would you wear the device or have another patient wear it?		
I definitely would	25 (78%)	5 (83%)
I wouldn't care one way or the other	7 (22%)	1 (17%)
I definitely would not	0 (0%)	0 (0%)
Compared with standard devices how easy did you find using the device?		
Very easy	NA	2 (40%)
Easy	NA	2 (40%)
Neutral/ok	NA	1 (20%)

Data are *n* (%).
NA, not applicable.

Non–study nurse participants similarly appreciated the increased mobility the device offered, felt the device fit within and was perhaps more accommodating of clinical duties, and offered the patients less interruptions:

> Continuous vital sign data will be useful, for documentation, very convenient.
> It does not interfere with other clinical duties.
> It is nice to get vital signs without having to bother the patient, especially if she was resting or sleeping.

Concerns. Neither patients nor clinicians had any safety concerns regarding the device. Most appreciated the size of the device, and comments about discomfort were minimal:

> The only thing is it's kind of sticky—not sure how that would feel if I would have to wear it for a longer time.

Discussion

In this study we evaluated the functionality and acceptability of a wireless vital sign monitor in an inpatient obstetric setting. We found implementation to be simple and effectively carried out by obstetric nurses after minimal training. The majority of pregnant women and clinicians found the technology acceptable and desirable with no concerns raised on safety of the device.

The primary advantage offered by this device, being wire free, did not appear to present any challenge to information collected. Data transmission from the sensor to the central monitor occurred without any delays, interruptions, or interference with hospital networks. Although overall mean differences between our devices were small (less than 5 bpm for HR, 5 rpm for RR, and 0.5°C), fairly wide limits of agreement for HR and temperature (±18.2 bpm and ±1.8°C, respectively) suggest clinically important differences between the standard and wireless devices that may preclude interchangeability in this patient population.

Higher agreement was seen with the RR assessment; limits of agreement differed by only ±6 rpm. In most clinical scenarios this difference is unlikely to be clinically meaningful. This finding is encouraging, as manual RR measurement has been shown to have poor accuracy and limited inter-rater agreement.[14–16] In one study of RR measurement, 94% of RRs recorded in inpatient charts were between 18 and 22 rpm, although reference ranges for "normal adult respiration" have shown normal ranges as wide as 12–32 rpm.[17] These findings purport the potential clinical and nursing benefit of a well-validated automated measure for RR.

Our study findings come with severable caveats. First, desirable levels of agreement are not absolute and may vary with clinical scenario and clinical judgment; others might choose more stringent or lenient acceptable levels of difference.

Second, our small sample size, restricted to nonlaboring women over a short period of time, limits our ability to draw firm conclusions on the validity of vital sign measurement by the wireless sensor. Our ranges of values for both RR and temperature are relatively narrow, and it is possible that agreement would differ in a larger sample and among more actively laboring women, where movement, perspiration, and wider ranges might occur. Future studies that test this system

in pregnant women over longer periods of time and throughout the duration of monitored labor are needed to further test agreement.

Third, although the studied device has received U.S. Food and Drug Administration clearance for use in the general population, the new test population of pregnant women may account for study findings.[18] It is possible that a gravid abdomen may alter chest wall movement, affecting signaling and accuracy of assessment.

Fourth, the referent or "standard" measurements do not represent a proven gold standard. As mentioned above, manual RR has demonstrated inadequacies. Similarly, there is conflicting evidence on the agreement of infrared temporal artery measurement with the current gold standard, pulmonary artery temperature.[19]

Our closed and open-ended questions reveal a positive attitude to the device from both pregnant woman and non–study nurses with size, shape, and the benefit of mobility noted as key desirable features. Few inpatient studies have directly assessed patient or clinician acceptability of wireless technology for vital sign monitoring, and to our knowledge none has examined these perspective in the obstetric inpatient setting.[20] It is interesting that concerns of self-efficacy, computer anxiety, technology apprehension, and cost, as raised by other studies, were not reported by our study population.[21,22] This difference may be related to the following: the type of device in our study, which required minimal patient interaction; the inpatient study setting; the study population, which was mostly white, upper-middle class women in an urban setting; or a combination of these factors. Caution should be taken in generalizing our findings to diverse populations in different health settings.

Our study provides preliminary evidence toward the high functionality and acceptability of this wireless monitor. This provides the basis for future studies to assess the potential for wireless devices to extend human resources in caring for pregnant women. In different settings this technology may play different roles. In resource-rich environments where one-to-one nursing is currently standard, this technology is unlikely to replace nursing assessment; however, it might provide a useful adjunct, facilitating monitoring while limiting interruptions to the pregnant woman and freeing up time for the nurse to attend to other needs. Additionally, it may provide the opportunity to extend monitoring outside the labor unit in healthy term pregnancies, particularly in the earlier stages of labor, or to allow remote supervision of labor and delivery units without access to specialized staff. In resource-poor settings where severe shortages in human resources exist, particularly at higher levels of specialization, such technology may provide a way to extend monitoring to women who currently labor, deliver, and recover with little to no vital sign monitoring. Newer design models for this wireless system that allow vital sign transmission to smartphones may be even more conducive to use in this environment, where technological infrastructure is limited. In both these settings, further research would be needed to assess the actual impact on clinical outcomes, cost feasibility, and optimal case-use for maximal benefit.

A notable limitation of the studied device is the lack of BP assessment, which in an obstetric population bears heavily on clinical management. Incorporating wireless BP, however, is limited by the current available technology, which is currently in the infancy of development. Most available "wireless" systems rely on a BP cuff and bladder attached via tubing to a small but separate manometer equipped with either Bluetooth® (Bluetooth SIG, Kirkland, WA) or Wi-Fi capability.[23–27] Some products exist that rely on a wrist or upper arm cuff with a manometer placed directly on the cuff, eliminating the need for a separate monitor.[28,29] As wireless vital sign technology continues to advance, the ability to incorporate truly wireless BP will be key in making monitoring complete.

In conclusion, we found that the studied wireless monitor has potential for use in an obstetric inpatient population. We found the monitor to be well received by pregnant women and nurses and found no difficulties in the relay of vital sign wirelessly. Further study is needed to ensure that vital sign assessment by the wireless sensor is valid and accurate in pregnant women, and at all stages of labor, with careful attention paid to the accuracy and validity of the referent standard measurement. Additionally, further study on the comparative cost and potential impact on clinical outcomes will be helpful in assessing the potential added value of this technology.

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Disclosure Statement

No competing financial interests exist.

The sponsor had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Address correspondence to:
Adeline Adwoa Boatin, MD, MPH
Department of Obstetrics and Gynecology
Massachusetts General Hospital
Harvard Medical School
55 Fruit Street, Founders 5
Boston, MA 02114

E-mail: aboatin@partners.org

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