

A wearable sensor ecosystem is essential to reduce health disparities and maternal mortality.

The Future of Remote Monitoring for Pregnancy

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To maintain access to health care while mitigating the risk of in-person exposure during the covid-19 pandemic, digital and mobile health care expanded as did rapid acceptance by patients, physicians, insurers, and hospital systems (Whitelaw et al. 2020). The pandemic also increased interest in the adjunct role of wearable technologies.

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Wearables—devices integrated in clothing or placed directly on the body—noninvasively capture, wirelessly record, and transmit biomarkers such as heart rate, temperature, and activity. This information may complement virtual medical care by providing comprehensive patient and population-level physiological surveillance (Jeong et al. 2020). The repurposing of wrist-mounted wearables like the Apple Watch or FitBit to detect early markers of covid-19 infection exemplifies how the pandemic expanded the potential value of wearable sensors with machine learning algorithms of longitudinally collected physiological data (Hirten et al. 2021; Jeong et al. 2020; Mishra et al. 2020).

There have also been significant technological advances to more sophisticated, bio-integrated devices strategically positioned directly on the body to provide continuous, clinical-grade monitoring. The US Food and Drug Administration (FDA) has expedited the approval of numerous wearable devices under the Emergency Use Act, signaling a broadly perceived urgency and utility of these and other, emerging diagnostic tools (Whitelaw et al. 2020).¹

Pandemic-Related Disruptions to Maternal Care

Like many aspects of medicine, prenatal care continued but was significantly disrupted during the pandemic. Pregnant patients delayed care because of stay-at-home orders, clinic closures, and fear of presenting to hospitals. Many of the recommended 14 appointments of routine prenatal care were converted to virtual visits or eliminated entirely, and essential components of postpartum care, including depression screening and uptake of long-acting reversible contraception, declined by 50 percent and 70 percent respectively (Fryer et al. 2020; Miller et al. 2021; Sakowicz et al. 2021). At the height of the pandemic, a large New York City obstetrical practice increased video visits by 3200 percent in a single week (Zork et al. 2020).

These rapid changes occurred in the context of an already failing, overburdened maternal-fetal health-care delivery system. In the United States maternal mortality, defined as maternal death either during pregnancy or in the 42 days following delivery, has been stubbornly and soberingly persistent (Rossen et al. 2020). Around the world, more than 800 women

are estimated to die each day as a result of pregnancy or childbirth.²

Furthermore, in the United States for every woman who dies as a result of pregnancy, an additional 50 to 100 women experience severe maternal morbidity (SMM), an unexpected short- or long-term complication, injury, infection, or disability due to pregnancy or delivery (Chen et al. 2021; Grobman et al. 2014). SMM occurs disproportionately in rural, low-income areas of the United States and complicates more than 8 percent of deliveries in low- and middle-income countries (Kozhimannil et al. 2019; Say et al. 2004; Zanardi et al. 2019). Equally concerning is that these life-threatening maternal conditions double rates of adverse perinatal outcomes, such as low Apgar scores and fetal or neonatal death (Zanardi et al. 2019).

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A robust understanding of covid-19's impact on global maternal mortality rates remains incomplete, but studies from Brazil and Peru demonstrated increases of 60 percent and 102 percent, respectively, in the maternal mortality ratio (MMR) in 2020, with only a quarter of these deaths attributed to covid-19 infections (de Carvalho-Sauer et al. 2021; Gianella et al. 2021). The authors of these papers posit that higher MMR likely reflects delayed care, inadequately managed pregnancy-related disorders, and saturated healthcare systems, rather than simply an increased susceptibility to covid-19 among pregnant patients.

Needs and Opportunities for Remote Perinatal Care

Covid-19 exposed both an opportunity and a necessity to accelerate digital medicine, of which the use of

¹ Remote or Wearable Patient Monitoring Devices EUAs, FDA, July 15, 2021, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas>

² United Nations Population Fund: Maternal health (2021), <https://www.unfpa.org/maternal-health>

TABLE 1 Physiological biomarkers that can be derived from pregnant patients and the clinical implications for each vital sign

Source	Vital sign	Clinical implications or disorders
Maternal	Blood pressure	Gestational hypertension Preeclampsia Hemorrhage Infection
	Heart rate	Infection Hemorrhage Amniotic fluid embolism
	Heart rate variability	Stress Autonomic nervous system dysfunction Mood disorders
	Respiratory rate	Infection Sleep disorders Pulmonary embolism
	Sleep quality	Sleep disorders Preterm birth
	SpO2 (blood oxygen level)	Infection Preeclampsia Postpartum cardiomyopathy Amniotic fluid embolism
	Temperature	Infection
	Uterine contraction	Preterm birth Infection Labor dysfunction
	Weight gain	Preeclampsia Gestational diabetes Macrosomia
	Fetus	Fetal ECG
Fetal heart rate		Fetal distress

wearables is likely to be an enduring cornerstone after this pandemic subsides. Wearables may also enable cost-effective, accessible remote monitoring, particularly in resource-constrained settings or healthcare deserts both in the United States and abroad.

Pregnant patients are at a higher risk for more severe disease, hospitalization, and death compared to age-matched, noninfected counterparts (Villar et al. 2021). However, of the six wearable devices that received FDA emergency approval in the first 3 months of the pandemic, none monitored physiology during pregnancy. Furthermore, the numerous longitudinal studies leveraging preexisting consumer wearable devices like the Apple Watch or Fitbit did not explicitly address inclusion or presumptive exclusion of pregnant participants.

A one-size-fits-most approach with wearables agnostic to their underlying population of interest—such as pregnant patients—may lead to inadequate, uninformative,

or, worse, inaccurate surveillance. Even more concerning, many wearables fail to capture the most relevant physiological parameters of pregnancy disorders and diseases such as covid-19.

Pregnancy is a commonplace yet complex and dynamic health state. If wearable devices are to add value in maternal and fetal medicine, the following minimum considerations should drive both function and design:

- the suite and interpretation of measurements required to improve clinical outcomes,
- the spectrum of environments where sensors are used,
- the intended users (lay consumers, experts, or both), and
- an adaptable device form factor (hardware specifications including device material, size, shape, and weight).

In this article we examine the challenges of and minimal necessary criteria for designing wearable devices to monitor

pregnant patients, the state of available technologies, and innovations needed to improve care in this vulnerable population.

Monitoring Digital Biomarkers of Pregnancy

Sensors used in pregnancy must accurately capture core biomarkers such as heart rate (maternal and fetal), blood pressure, pulse oxygenation, and core body temperature. The majority of maternal deaths are caused by hemorrhage, infection, or hypertensive disorders—and most are considered preventable (Berg et al. 2005). Abnormalities in routine vital signs often precede catastrophic complications such as massive hemorrhage (hypotension, tachycardia), eclampsia (hypertension), and sepsis (temperature, hypotension, tachycardia) (table 1). Monitoring of vital signs may identify subtle clinical deterioration earlier, providing time to escalate care and improve the likelihood of preventing morbidity or death.

Interpretation of biomarkers in pregnancy is not as straightforward as for nonpregnant individuals. Data should incorporate not only a patient's baseline but also the corresponding gestational age to correctly identify abnormalities. There is normal expansion of maternal blood volume, changes in cardiac activity, and pulmonary function. Some changes are progressive over 9 months, while others are more acute; for example, cardiac output increases by nearly 80 percent immediately after delivery, but returns to baseline within 1 hour postpartum (Thornburg et al. 2000).

Vital signs during pregnancy (particularly heart rate, blood pressure, and cardiac output) are also uniquely sensitive to body position. When supine, the gravid uterus compresses the inferior vena cava, limiting venous return. Hemodynamic changes are therefore most accurately interpreted if linked to posture. A sufficiently sensitive system able to incorporate posture over a wide range of vitals with high fidelity is essential (Thornburg et al. 2000).

The nascency of rigorous, evidence-based vital sign monitoring throughout pregnancy is exemplified by a recent study providing the first modern, prospective, and gestation-specific vital sign reference ranges for pregnancy based on data rather than expert opinion alone (Green et al. 2020). Previous reference ranges were derived from small cohorts and by equipment not ratified for use in pregnancy (Green et al. 2020; MacGillivray et al. 1969; Morganti et al. 1980). Longitudinal data collection from large cohorts using wearables designed for and validated among pregnant individuals will contribute to a more thorough and scientific establishment of pregnancy-specific reference ranges.

Finally, the ideal remote monitoring system in pregnancy should capture fetal, uterine, and maternal vital signs. Only through the detection of uterine contractions, baseline fetal heart rate, and variability can fetal well-being be established and characterized. Clinical decision making in pregnancy requires balancing the well-being of both the pregnant patient and the fetus.

Monitoring Environments

Prenatal and postpartum care occur in a wide range of high- and low-resource settings both in the United States and abroad, from homes to community clinics, tertiary care facilities, and operating rooms. The potential additive value of wearable devices does not end with delivery of the fetus. On the contrary, the pregnant

patient's health in the immediate postpartum period is too often neglected.

Half of maternal deaths occur after delivery. A pilot study of outpatient postpartum blood pressure monitoring demonstrated that patients requiring readmission had symptoms earlier and outside of the traditionally recommended window for postpartum evaluation of hypertensive disorders (Hoppe et al. 2019, 2020).

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In addition, with the universally rising rate of cesarean deliveries, many postpartum patients are also postoperative. Vital sign monitoring must address the unique needs and higher acuity inherent to postoperative care.

Developing a wearable sensor ecosystem that seamlessly spans the physiology of and physical spaces where care occurs before, during, and after delivery, appropriate for both low- and high-acuity patient recovery, is essential to reduce health disparities and maternal mortality.

Form Factor

Designing low-profile wearable sensors for pregnancy has particular technical challenges. Sensors are ideally small and unobtrusive, and they seamlessly stretch and flex with movement while still accurately capturing physiological data and accommodating the macrobiological changes of pregnancy. Pregnant women often remain fully active until labor begins, so wearables must accommodate daily activities while accounting for anatomical changes including edema and abdominal growth.

The dramatic physiological changes of the uterus shed light on the inherent complexity of maternal and fetal monitoring. A nonpregnant uterus is roughly the size of an adult fist. By the end of the third trimester, the uterine cavity grows more than 500 times its original size—an estimated volumetric change of 10 mL to 5 L—via reversible structural changes (Thornburg et al. 2000). Immediately after delivery of the infant and

placenta, the uterus remodels to prevent bleeding from the placental site and catastrophic maternal hemorrhage; it returns to its nonpregnant size within 4 weeks.

Though the abdomen is the locus of uterine contractions and fetal heart rate, it is not necessarily the ideal location to derive other maternal biomarkers, such as heart rate or pulse oxygenation. If wearables are to meaningfully transform prenatal care, they will require an integrated form capturing physiological data for the pregnant person, fetus, and neonate.

Current State of Wearable Technology in Pregnancy

Surveys of pregnant patients and their healthcare providers demonstrate high acceptability rates of non-invasive monitoring. In one study, nearly half the participants reported amenability to wearing a sensor or having one embedded in maternity clothing and 22 percent reported willingness to wear a theoretical mobile, GPS-enabled sensor to monitor fetal well-being and track environmental exposures for the duration of the pregnancy (Runkle et al. 2019). When participants were asked in what scenarios they would consider using wearables, 76 percent reported pregnancy, compared to 67 percent for personal fitness or dieting. Data security and privacy are consistently identified as potential patient concerns, but more than 90 percent felt comfortable sharing results with physicians (Runkle et al. 2019).

A mobile phone application with curated educational content demonstrated high patient use.

The real-world experience of Babyscripts™, a mobile phone application with curated educational content and linked to a Bluetooth-enabled weight scale and blood pressure cuff, demonstrated high patient use of the application and ancillary devices (sphygmomanometer and scale). Among a cohort of 1058 women with low-risk pregnancies, there were more than 45,000 at-home weight measurements (roughly, a measurement every 3½ days) collected during pregnancy and postpartum (DeNicola et al. 2018).

Patient use of wearables is only the first step toward actionable improvements in maternal and fetal health outcomes. The Pregnancy Remote Monitoring Study II (PREMOM II)³ is an on-going, multicenter randomized controlled trial of Belgian pregnant patients at high risk for hypertensive disorders who will be randomized to (i) conventional care, (ii) remote self-monitoring, and (iii) midwife-assisted remote monitoring. This is one of the first prospective studies to assess the clinical value of remote patient monitoring for pregnancy, with primary endpoints including maternal and neonatal outcomes, compliance, cost effectiveness, and patient-reported outcome measures (Lanssens et al. 2020).

Most applications of wearable remote technologies have adopted a piecemeal approach by targeting a specific timepoint or problem during the pregnancy—such as preterm labor, gestational weight gain, or hypertensive disorders. Piecemeal approaches, though an important stepping stone to fully integrated wearable solutions, have inherent limitations in their ability to address the full scope of maternal-fetal well-being. An integrated solution must advance the hardware of devices specifically designed for pregnancy monitoring.

Existing and Emerging Pregnancy Monitoring Systems

For Remote Use

The only 510(k) FDA-cleared device specifically indicated for remote pregnancy monitoring was developed in 2020. The INVU device created by Nuvo™ consists of a semirigid belt system that wraps around the abdomen. Noninvasive sensors in the belt detect both maternal and fetal heart rate via biopotential signals and acoustic sensors. The FDA approval was awarded based on a feasibility study of 76 pregnant women who demonstrated lay user functionality.⁴ The belt detected fetal heart rate (FHR) in more than 70 percent at gestational age 20–40 weeks and 90 percent among those at 32 weeks or more. In the subsequent pivotal multicenter trial of 149 individuals, accuracy of maternal heart rate (MHR) and FHR measurements was comparable to conventional methods (Mhajna et al. 2020).

In 2021 the FDA approved a supplemental Nuvo application for uterine contraction detection based on

³ ClinicalTrials.gov NCT04031430

⁴ 510(k) Summary Statement, March 26, 2020, https://nuvocares.com/assets/downloads/K191401.510kSummary.Final_Sent001.pdf

extrapolated data from abdominally detected maternal ECG. The INVU belt correctly identified 90 of 96 contractions in the reference dataset from tocometry, yielding a sensitivity of 94 percent, although the false detection rate was 18 percent (Schwartz et al. 2021).

INVU's intended use is home-based monitoring of maternal and fetal heart rate for a maximum of 5 minutes in singleton pregnancies of at least 32 weeks gestational age; it is not indicated for intrapartum use or critical care. The device's rigidity compromises its capacity to monitor maternal vital signs in the absence of a gravid abdomen, precluding seamless extension of its use early in pregnancy or postpartum. Furthermore, neither the pilot nor pivotal study demonstrated a health benefit based on device use.

Clinical utility of devices remains unclear when studies demonstrate only safety, feasibility, or comparability with gold standard measurement techniques. Devices should not simply monitor but demonstrate a measurable patient or population health benefit.

For Clinic-based Use

The Novii Patch of GE Healthcare (previously Monica Health), developed in 2009, is a wireless puck placed on the gravid abdomen, using wireless ECG electrodes to detect MHR, FHR, and uterine contraction frequency. In contrast to INVU, it is marketed for hospital-based use by a healthcare provider in singleton gestations after 36 weeks. Notably, use of the device is discouraged with any maternal or fetal vital sign abnormalities, including maternal tachycardia, hypertension, fever, or abnormal FHR. Six published studies of the device in 487 women present moderate-quality evidence of monitoring equivalence in a narrow population (low-risk hospitalized patients) (e.g., Cohen et al. 2012).

The MERIDIAN M110, developed by MindChild Medical, is similar in form to the Novii Patch. It is a series of connected electrodes adherent to the abdomen that capture maternal and fetal ECG and uterine contractions. The product's intended use is even narrower, designed for inpatient use by healthcare providers among patients in labor at 37 weeks or more.

Bloomlife repurposed an FDA-cleared ECG monitor designed for cardiac arrhythmias and marketed it directly to consumers to assess uterine contractions. But the device essentially provides only a metronome of uterine frequency without quantification of contraction strength. And without concurrent measurement of FHR, the device cannot be used to inform clinical

decision making. The device is not FDA approved for uterine monitoring, but Bloomlife has collected data from over 10,000 pregnant individuals in the United States (totaling more than 500,000 hours). Bloomlife intends to use this large dataset to better understand digital biomarkers of normal labor and preterm labor. The company's efforts also include expansion in fetal ECG monitoring.

Flexible, Bio-Integrated Sensor Networks for Comprehensive Monitoring

Before the covid-19 pandemic, our work in developing advanced sensor systems for pregnancy was driven by a profound unmet clinical need in maternal mortality in low- and middle-income countries, where 99 percent of maternal-related deaths occur (Geller et al. 2018). Our design decisions were based on the need to provide comprehensive, clinical-grade measurements for both maternal and fetal health while also enabling wearability, compatibility with low-cost mobile devices, and ruggedization for low-resource care settings. We recently published our first validation of a bio-integrated, low-profile wireless sensor system in more than 500 pregnant women in an urban US tertiary care hospital and a Zambian hospital (Ryu et al. 2021).

Devices should not simply monitor but demonstrate a measurable patient or population health benefit.

The ANNE (Advanced Neonatal Epidermal Sensor) One system consists of three time-synchronized patches (placed at the suprasternal notch, on the index finger or thumb, and on the abdomen) that capture a comprehensive set of maternal and fetal vital signs (figure 1). The wireless sensors are compatible with Android and iOS mobile devices, enabling rapid scalability without expensive capital equipment. Key components of the ANNE system for pregnancy monitoring are now FDA-cleared as a wireless patient monitor.

The ability to measure core maternal vital signs (HR, respiratory rate [RR], blood oxygenation, and temperature), fetal measurements (FHR via Doppler and fetal ECG sensors), and pregnancy-specific parameters

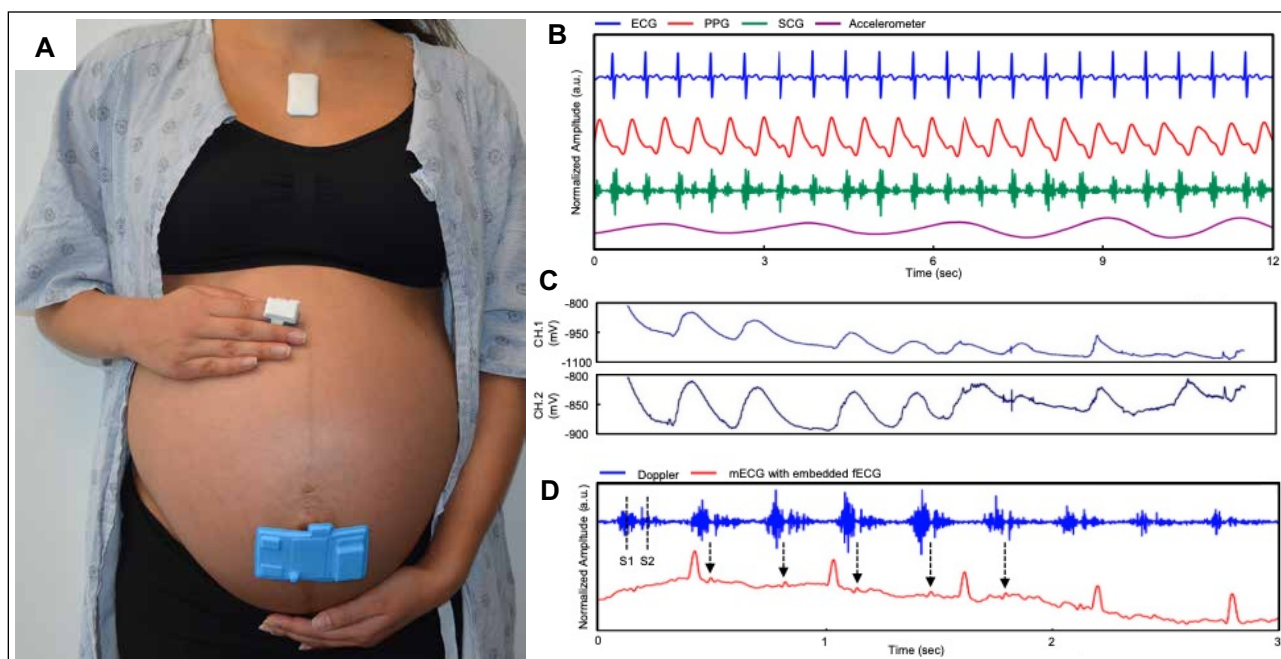


FIGURE 1 (A) Demonstration of ANNE One three-sensor wireless monitoring system for pregnancy. Key outputs from the monitoring system include (B) maternal heart rate (ECG/SCG), respiratory rate (ECG/SCG), SpO₂ (PPG), temperature (not shown), and a surrogate for blood pressure (PPG); (C) uterine contraction; and (D) fetal heart rate via either Doppler or fetal ECG (fECG). mECG = maternal ECG

(uterine contractions) enables comprehensive pregnancy monitoring. Beyond these measurements, the ANNE system detects advanced parameters such as maternal body position—integrated accelerometers provide data on hemodynamic changes linked to posture—and pulse arrival time, a surrogate for continuous blood pressure (Ryu et al. 2021). As noted above, body position is particularly relevant for monitoring maternal vital signs in pregnancy, and the capacity to continuously link it with vital signs increases accurate interpretation (Thornburg et al. 2000). The ANNE system also allows for sleep-related metrics and detection of dysfunctional breathing.

Validation in low-resource settings where maternal mortality and morbidity are highest demonstrates the system's operability even in austere environments. The ANNE One system has been deployed in three low-income countries, at four hospital sites, with an embedded data management infrastructure monitoring more than 6500 pregnant patients, totaling more than 40,000 monitoring hours. Data output streams from the ANNE system are shown in figure 1.

Conclusion

Despite medical progress, the maternal mortality rate in the United States has not improved. This persistence

underscores the need for new monitoring technologies for pregnancy that do more than recapitulate physiological parameters captured in the hospital setting or the home.

The complex physiology of pregnancy requires a monitoring system that captures the full spectrum of both maternal and fetal health. What's needed is a turnkey technological ecosystem that is wireless, continuous when possible, reusable, and appropriate for all levels of care and resource settings, and that incorporates core maternal and fetal biomarkers correctly interpreted based on gestational age or postpartum status and patient posture.

At a minimum, wearables for pregnancy should accurately and continuously measure maternal health parameters (HR, RR, pulse oxygenation, blood pressure, weight gain, uterine contractility, and core body temperature) as well as FHR in a variety of environments—home, clinic, hospital, and operating room, from conception through the acute postpartum period (the 6–12 hours immediately after birth). Data management must be secure and link to existing electronic health records.

New technologies incorporating biomarkers beyond typical clinical convention may help to identify high-

risk patients, yielding opportunities to intervene and potentially improve outcomes. This may be accomplished with future machine learning algorithms that identify signals of impending deterioration earlier than clinical suspicion alone. Additional opportunities include pairing biophysical data with biochemical measurements in blood, urine, and other biofluids to better assess development of major pregnancy-related complications such as preeclampsia and preterm labor.

Finally, to substantially reduce maternal morbidity and mortality, a consortium of stakeholders—physicians, engineers, patients, and policymakers—must work collaboratively to recognize and invest in technology development for pregnancy.

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