

# Rapid Acceleration of Diagnostics Technology (RADx® Tech) for Maternal Health Challenge

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## Overview

The National Institutes of Health awarded \$8 million in cash prizes to accelerate development of technologies to improve maternal health outcomes for those who live in areas lacking access to maternity care. The [Rapid Acceleration of Diagnostics Technology \(RADx® Tech\) for Maternal Health Challenge](#) prioritized home-based or point-of-care diagnostic devices, wearables and other remote sensing technologies to improve postpartum healthcare in these regions. The postpartum period is defined as the first year after giving birth or the end of a pregnancy, and it accounts for a large proportion of maternal deaths in the United States.

## Topic Areas

NICHD, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), and the NIH Office of the Director co-sponsored this challenge as part of NIH's [Implementing a Maternal health and PRenancy Outcomes Vision for Everyone \(IMPROVE\) Initiative](#). The initiative supports research to reduce preventable causes of maternal deaths and to improve health for women before, during and after delivery. IMPROVE includes a special emphasis on health disparities and populations disproportionately affected, such as African American/Black women, American Indians/Alaskan Natives, Asian Pacific Islanders, Hispanics/Latinas, very young women, women of advanced maternal age, and people with disabilities.

The challenge prioritized technology solutions that are developed sustainably, at low cost and can be used across societal, economic, and cultural contexts. For example, solutions should be easy to use by individuals in their homes or by health care personnel in local pharmacies, community-based clinics, primary care physician or pediatrician offices, Tribally operated hospitals, or clinics and by emergency medical services. Solutions should also enable continuous health care monitoring during the first year of the postpartum period.

## Winners

### Grand Prize Winners

- [Cardiex](#) , Naperville, Illinois

#### **A continuous, wearable monitor for cardiovascular health**

Cardiex's CONNEQT Pulse delivers central and brachial blood pressure readings along with critical arterial health insights, while its CONNEQT Band continuously tracks arterial health in real time during daily activities, providing data for managing cardiovascular risks during pregnancy. Both devices can integrate with health care providers through cloud-based connectivity.

- [Caretaker Medical](#) , Charlottesville, Virginia

#### **A wireless wrist monitor to evaluate cardiovascular health**

Vitalstream is a wireless wrist monitor that is FDA-cleared to measure heart rate, blood pressure, respiration, cardiac output/stroke volume, left ventricular ejection time, and heart rate variability. Health care providers can monitor patients remotely, directly, or intermittently. The company aims to use the device to monitor postpartum patients for episodes of hypo- or hypertension, as well as detect the onset of hemorrhage and sepsis.

- [HemoSonics](#) , Durham, North Carolina

#### **A rapid, point-of-care diagnostic for postpartum hemorrhage**

The Quantra System is an FDA-cleared, point-of-care diagnostic device designed to help manage acute bleeding in patients. Multi-center studies are underway to expand its clearance to obstetric patients, improving the management of peripartum bleeding.

- [Global Access Diagnostics](#) , New Gloucester, Maine

#### **A rapid home test for urinary tract infections**

Urinary tract infections (UTIs) can be an issue for postpartum individuals, especially if they needed a catheter during or after delivery. The company has developed a rapid immunoassay to diagnose UTIs. The initial version was designed for health care providers. During the challenge, the test was adapted to look and feel like a home pregnancy test. When combined with telemedicine services and/or a call with a doctor, the test may enable treatment to begin earlier and without the need for an in-person appointment.

- [Sanguina](#) , Peachtree Corners, Georgia

#### **A smartphone app to detect anemia in pregnancy and postpartum anemia**

AnemoCheck Mobile is a smartphone app that estimates hemoglobin levels based on an image of a user's nail beds. The company proposes customizing the app by correlating hemoglobin data from routinely scheduled blood draws during pregnancy and before leaving the hospital to improve the accuracy of the app and to enable clinical decision making.

- **Sibel Health, Niles, Illinois**

- **A remote monitoring system for home or point-of-care settings**

- The ANNE® One system is an FDA-cleared remote monitoring system that captures core vital signs and parameters relevant for postpartum monitoring. The system consists of two chest and index finger sensors that wirelessly connect to Android and iOS mobile devices for continuous or point-of-care measurements at home or in other settings.

## **Runners-Up**

- [MyLÚA Health](#) , Albany, New York

- **An AI-powered virtual care platform for maternal mental and social health monitoring**

- MyLÚA is an AI-powered mobile platform that provides support services for mental and social health risk management. The app engages mothers for inclusive data collection, provides virtual peer support groups, health education, an AI chatbot, local resource access, and telemedicine access to promote health literacy and patient-provider communication. MyLÚA aims to improve maternal mental health outcomes, especially for underserved populations facing access barriers, by extending virtual support and facilitating early risk identification.

- [PyrAmes](#) , Cupertino, California

- **A wearable device for continuous, noninvasive blood pressure monitoring**

- Bosimi® is a noninvasive, wearable device that monitors adult blood pressure in real time. It uses neural networks to analyze pulse waveform data to provide continuous determination of systolic, diastolic, and mean blood pressure, and pulse rate. The device is designed to enable better control of blood pressure and timely treatment for postpartum women if adverse events, including preeclampsia and other hypertensive disorders of pregnancy, are detected.

## **Deep Dive Winners**

- [CardieX](#) , Naperville, Illinois

- **A continuous, wearable monitor for cardiovascular health**

CONNEQT Pulse is a blood pressure monitor that provides central and brachial blood pressures, as well as arterial health parameters. The CONNEQT Band is a medical-grade wearable that enables continuous monitoring of arterial health during everyday activities. Together, these devices offer comprehensive monitoring of cardiovascular health. The devices are cloud-based and digitally connected to healthcare providers, improving access to underserved communities.

- [\*\*Caretaker Medical\*\*](#) , **Charlottesville, Virginia**

- **A wireless wrist monitor to evaluate cardiovascular health**

- Vitalstream is a wireless wrist monitor that is FDA-cleared to measure heart rate, blood pressure, respiration, cardiac output/stroke volume, left ventricular ejection time, and heart rate variability. Healthcare providers can monitor patients remotely, directly, or intermittently. The company envisions using the device to monitor postpartum patients for episodes of hypo- or hypertension, as well as detecting the onset of hemorrhage and sepsis.

- [\*\*Dionysus Digital Health\*\*](#) , **San Diego, California**

- **A monitoring system for postpartum depression**

- The Dionysus system helps identify individuals who are at risk for postpartum depression. The technology integrates two types of information—natural language processing of a person's social communication channels and an epigenetic analysis to assess a person's sensitivity to hormonal fluctuations during pregnancy and the postpartum period. The system can proactively communicate risk to postpartum individuals, their care providers, and families, providing actionable health information, including when additional care and interventions should be sought.

- [\*\*HemoSonics\*\*](#) , **Durham, North Carolina**

- **A rapid, point-of-care diagnostic for postpartum hemorrhage**

- The Quantra System is a point-of-care diagnostic device that helps manage bleeding in critical care settings, providing results in 15 minutes or less. It delivers diagnostic information that allows efficient treatment of hemorrhage. For the challenge, the company aims to extend clearance of their current device to the obstetric patient population to improve treatment of peripartum bleeding (before, during, and after delivery). The device can address the needs of underserved regions because it does not require a fully staffed laboratory and its use can optimize scarce resources, such as blood products.

- [Global Access Diagnostics; Mologic](#) , New Gloucester, Maine  
**A rapid home test for urinary tract infections**  
 Urinary tract infections (UTIs) can be an issue for postpartum women, especially if they needed a catheter during or after delivery. The company has developed a rapid immunoassay to diagnose UTIs. The initial version was designed for healthcare providers. However, the test may be adapted into a second version for use at home or in other settings, in a manner similar to home pregnancy tests.
- [MyLÚA Health](#) , Albany, New York  
**A care coordination system for pregnancy and postpartum care management**  
 MyLÚA offers digital maternal care services that predict and manage the risk of maternal complications, specifically maternal depression, preeclampsia, and preterm birth. The mobile app is designed to engage and retain birthing people/mothers for critical, inclusive data collection; promote health literacy, advocacy, and community support; and enhance patient-provider communication. Actionable, data-driven insights are delivered to clinicians via artificial intelligence-driven risk assessments that enhance preventative care management and improve care coordination efficiency.
- [PyrAmes](#) , Cupertino, California  
**A wearable device for continuous, noninvasive blood pressure monitoring**  
 The Bosimi™ is a noninvasive, wearable device that monitors adult blood pressure in real-time. It uses neural networks to analyze pulse waveform data to provide continuous determination of systolic, diastolic, and mean blood pressure, heart rate, and their variabilities. The sensor records waveform data similar to an invasive arterial line (IAL), while avoiding the difficulties and risks of placing and maintaining an IAL. The Bosimi™ device is designed to enable better control of blood pressure and timely treatment if adverse events are detected.
- [Sanguina](#) , Peachtree Corners, Georgia  
**A smartphone app to detect postpartum anemia**  
 AnemoCheck Mobile is a smartphone app that estimates hemoglobin levels based on an image of a user's nailbeds. The company also proposes customizing the app (AnemoCheck MyMobile) by correlating hemoglobin data from routinely scheduled blood draws during pregnancy and before leaving the hospital to improve the accuracy of the app and to enable clinical

decision making. The app does not require any additional equipment and is noninvasive, making it highly accessible and scalable for remote settings.

- **Sibel Health, Niles, Illinois**

- A remote monitoring system for home or point-of-care settings**

- The ANNE<sup>®</sup> One system is an FDA-cleared remote monitoring system that captures core vital signs and parameters relevant for postpartum monitoring. The system consists of two wireless chest and index finger sensors that wirelessly connect to Android and iOS mobile devices for continuous or point-of-care measurements at home or in other settings. The system is compatible with telemedicine, has algorithms designed for critical postpartum conditions, and the sensors are waterproof, reusable, and rechargeable. The sensors have already been tested for maternal monitoring in the United States, India, Ghana, and Zambia.

- **[Washington University](#) , St. Louis, Missouri**

- A remote monitoring system for early detection of postpartum hemorrhage**

- Maternal aRMOR is a remote monitoring system for postpartum hemorrhage that enables earlier diagnosis when inexpensive and broadly accessible interventions (i.e., pharmacologic agents and balloon tamponade) are most effective. Maternal aRMOR consists of a wrist sensor and a mobile app that healthcare teams can use to remotely monitor any laboring or postpartum patient, particularly those at risk for hemorrhage. If early signs are detected, patients and providers are alerted through the mobile app. As a remote monitoring solution, Maternal aRMOR can bridge existing gaps in care for patients living in maternity care deserts.