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The CRADLE Vital Signs Alert: an accurate device for use in low-resource settings

By Elodie Lawley, Nicola Vousden, Hannah Nathan, Andrew Shennan

Obstetric haemorrhage, sepsis, and pregnancy-related hypertension kill 830 women every day. About 99 percent of these pregnancy- or childbirth-related deaths occur in low- and middle-income countries, where women in rural communities with limited access to healthcare are at greatest risk. These deaths are preventable, but only if these life-threatening complications are identified early. In many cases, simply monitoring blood pressure (BP) and heart rate (HR) could save lives. However, often women do not have access to working BP devices, leading to delays in identifying those at greatest risk. Even when devices are available, the majority tend to be unsuitable for use in pregnancy.

Professor Andrew Shennan and the CRADLE research team at King's College London developed the CRADLE Microlife Vital Signs Alert (CRADLE VSA). It is a cheap (£12), robust, and easy-to-use device, which accurately detects abnormalities in BP and HR measurements, fulfilling the World Health Organisation criteria for use in low-resource settings. The device can be easily charged through a universal USB port; phone chargers can be used as a convenient charging method.

Extensive validation showed it is accurate in non-pregnant and pregnant women (even in those with pre-eclampsia and low BP). The CRADLE VSA device also features a 'traffic light' early warning system, which acts as a visual alert for healthcare providers who are less familiar with recognising serious conditions like pre-eclampsia or sepsis. For sepsis and obstetric haemorrhage, multi-centre retrospective analysis showed that Shock Index (ratio of HR to systolic BP) is the most reliable predictor of serious maternal adverse outcome. Appropriate thresholds for shock index were

therefore incorporated into the traffic light algorithm, together with universally understood hypertensive thresholds, to trigger the coloured lights. These features make it ideal for those healthcare providers in rural, community settings that have limited training. The VSA is being used by Traditional Birth Attendants in Haiti and community healthcare workers in India.

The CRADLE 3 trial is a stepped-wedge randomized control trial over 20-months, where the device is introduced into a new site every two months until all 10 sites have the device available. The aim is to prospectively evaluate the device's ability to reduce maternal mortality and morbidity by increasing timely referral and management of obstetric haemorrhage, sepsis, and pregnancy-related hypertension. In June 2016, researchers began implementation in 10 low-income countries, including Uganda, Sierra Leone, Ethiopia, and Haiti. Evaluation of training materials commenced in November 2015, with the definitive trial starting in April 1, 2016.

The CRADLE VSA has been recognised as one of the top thirty high impact innovations in global health in a PATH-led award (2015) identifying and showcasing technologies and interventions with great potential toward solving the world's most urgent health issues. Consequently, other areas and industries are showing great interest in the device, such as its potential use in cardiovascular disease and emergency triage in conflict zones. The Science Museum, London is also including the device in their national archives.

Support for the CRADLE Project came from the Bill and Melinda Gates Foundation (BMGF) and the Medical Research Council. For more information on the device and the CRADLE Project, please visit www.cradletrial.com. You can also email Andrew.shennan@kcl.ac.uk for information regarding the device development or use in other settings. The CRADLE VSA is currently available to purchase (\$26 USD) for use in LMICs only from global distributors, Maternova (www.maternova.org).

Andrew Shennan is a Professor of Obstetrics at King's College London, based at St. Thomas' Hospital, UK. He is clinical lead of the Maternal and Fetal Research Unit, and specialises in clinical trials in antenatal and intrapartum care. His research interests include interventions to prevent pre-eclampsia, preterm birth and the use of blood pressure monitoring. He chaired the Department of Health Committee on Blood Pressure Monitoring in clinical practice, and sits on the relevant committees for the International Standardisation Organization (ISO) and the British Hypertension Society (BHS). He also advises the World Health Organisation (WHO) on perinatal

research. Andy was born in Malawi, grew up in Zimbabwe, and worked as an obstetrician in South Africa. His African roots and clinical experience has inspired his passion for improving global women's health, including the development of the CRADLE VSA.

Miss. Elodie Lawley completed her degree in Medical Sciences at Exeter University, achieving a scholarship with Harvard medical school to undertake medical research at Massachusetts Eye and Ear Infirmary, USA, in 2014. Elodie became involved with the CRADLE team following her academic involvement in multi-centre trials at the Women's health Department, St Thomas' Hospital, UK. She is the Research Associate for both CRADLE 2 and 3 trials. She has been actively involved in organising fundraising events for Maternity Worldwide, a charity that is improving healthcare in some of the poorest countries of the world. She will also begin studying Graduate Medicine in September 2017.

Dr. Nicola Vousden is a Clinical Research Fellow in Global Women's Health at King's College London. Nicky's clinical experience in a maternity hospital in Sri Lanka highlighted to her the marked discrepancies in women's health across the world. Keen to pursue a career improving women's health, she undertook an Academic Foundation Programme completing a multi-centre validation study of an obstetric simulator. She then commenced specialist Obstetrics and Gynaecology training as an Academic Clinical Fellow at St. Thomas' Hospital. Nicola is now undertaking her PhD in Global Women's Health at King's College London, whilst working as Trial Coordinator of the CRADLE 3.

Dr. Hannah Nathan is currently an Academic Clinical Fellow in Obstetrics and Gynaecology working at St. Thomas' Hospital, London, UK. As a medical student, she worked with Andy to test the accuracy of the original CRADLE device for use in pregnancy. Following 18 months working clinically in a rural maternity hospital in South Africa she was motivated to make a difference to global women's health. As CRADLE 2 coordinator, Hannah has modified

and evaluated the CRADLE VSA device, whilst working as part of the CRADLE team. This will culminate in the completion of her PhD in Global Women's Health in 2017. Hannah is lead of the Global Health Group in the Women's Health Academic Centre, King's College London.

Ending Eclampsia seeks to expand access to proven, underutilized interventions and commodities for the prevention, early detection, and treatment of pre-eclampsia and eclampsia and to strengthen global partnerships.



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