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Evaluation of blood pressure measurement software that is integrated with a digital pregnancy record and decision-support system to improve high blood pressure detection and pregnancy outcomes in Indonesia

Submission date	**Recruitment status**	[X] Prospectively registered
22/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/03/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/03/2024	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypertensive disorder of pregnancy (HDP) is a group of high blood pressure disorders that include preeclampsia. It is one of the leading causes of maternal illness and death. Death and other adverse outcomes caused by HDP can be prevented through timely detection and effective management of high blood pressure (BP). Therefore, BP measurement is an essential part of antenatal care (ANC). Early detection and effective management of HDP is still a challenge, especially in low- and middle-income countries (LMICs), as it relies on the ability of healthcare providers to measure BP, recognize elevation, and provide a referral when needed. In Indonesia, BP assessment in pregnancy remains inconsistent in both coverage and quality, leading to preventable pregnancy complications. Cuffless BP measurement software (OptiBP) within a validated digital pregnancy registry and decision support system (OpenSRP) for use by frontline health workers (FHWs) can be used to ensure pregnant women are routinely and accurately assessed at each ANC contact point, with consequent correct action. OptiBP transforms optical pulse waves on the fingertip captured by smartphone cameras into accurate BP readings. The results will be integrated into the WHO's Open Smart Register Platform (OpenSRP), which is a patient record and decision-support software system for frontline health workers. This integrated software package is aimed to ensure: (1) BP is taken accurately using a reliable and easy-to-calibrate method; (2) the measurement is automatically recorded in the women's medical history; (3) decision support and follow-up recommendations from the clinic to the community are prompted to facilitate appropriate treatment. The aims of this study are: (1) to develop a WHO-ANC and OptiBP integrated system that is appropriate for Indonesia, as well as to develop the training curriculum needed by frontline health workers and community health workers (i.e. trained laypersons or kader) to implement the system effectively; (2) to determine the effect of the WHO-ANC and OptiBP integrated system on the innovation process and research output, as well as the economic and societal benefits.

Who can participate?
This study will involve front line health workers and community health workers as ANC providers and pregnant women as the clients. All health workers or trained laypersons in the catchment area who provide antenatal care (ANC) services can be included in this study. Pregnant women of any gestational age are eligible to enrol upon their first visit to a midwife or doctor at the integrated health post, village health clinic, or community health center in the catchment areas.

What does the study involve?
Two primary care level facilities (Puskesmas) and its networking village maternity clinics (Polindes) will be selected in East Lombok with similar characteristics in terms of the number of providers, the number of women seeking ANC, and the catchment areas. ANC providers from the intervention group facility will receive training to use the system effectively before deployment. Consenting women will do their routine ANC visits in the data collection period as usual. They will be divided into two groups. The intervention group will get their ANC data collected in the WHO-ANC and OptiBP integrated system while the control group will get their ANC data measured and saved conventionally (manual blood pressure measurement and a paper-based registry).

What are the possible benefits and risks of participating?
There is no direct benefit of participating in this study. However, if the researchers find that a participant's blood pressure is not in the normal range, they will provide the necessary treatment that is integrated with antenatal care. The SUMMIT Institute for Development has been closely collaborating with local partners to improve care for mothers and babies in the context of primary health care. They acknowledge that blood pressure assessment alone may not contribute to the reduction of preeclampsia or hypertensive disorders of pregnancy. This innovation aims to not only expand access to accurate blood pressure assessment but also increase opportunities for the early management of hypertensive disorders of pregnancy including preeclampsia by linking together the pathway from measurement to appropriate management. There are no side effects or risks of participating in this study.

Where is the study run from?
Summit Institute for Development (Indonesia)

When is the study starting and how long is it expected to run for?
November 2021 to February 2024

Who is funding the study?
Grand Challenges Canada (Canada)

Who is the main contact?
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Additional identifiers

Protocol serial number
303/UN18.F7/ETIK/2021

Study information

Scientific Title
Cuffless optical blood pressure measurement integrated with antenatal decision-support and client tracking to improve health provider performance to detect hypertension and improve pregnancy outcomes

Study objectives
OptiBP is cuffless blood pressure measurement software that can transforms optical pulse waves on the fingertip captured by smartphone cameras into accurate blood pressure (BP) readings. The results will be integrated into WHO's Open Smart Register Platform (OpenSRP), which is a mature longitudinal patient record and decision-support software system for front-line health workers. This integrated software package is aimed to ensure:
1. BP is taken accurately using a reliable and easy-to-calibrate mechanism
2. The measurement is automatically recorded in the women's history
3. Decision support and follow-up recommendations from clinic to community are prompted to facilitate appropriate treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/11/2021, Ethical Committee for Medical Research Universitas Mataram (Pendidikan Street No. 37, Mataram City, West Nusa Tenggara, Postal Code 83125, Indonesia; +62 (0) 370640874; no email address), ref: 303/UN18.F7/ETIK/2021

Study design
Single-center quasi-experimental randomized study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Hypertensive disorders in pregnancy

Interventions
A quasi-experimental design will be employed comparing the innovation to the standard practice (paper data collection and manual/digital sphygmomanometer). The researchers will perform cluster random sampling. Two primary care level facilities (Puskesmas) and its networking village maternity clinics (Polindes), with similar characteristics in terms of the number of providers, the number of women seeking antenatal care (ANC), and the catchment areas, will be randomized from a total of 35 Puskesmas and villages in East Lombok using a computer-generated system. Pregnant women undergoing ANC in one working site of Puskesmas will be the intervention group while pregnant women undergoing ANC in the other working site of Puskesmas will be the control group. The researchers are anticipating 32-38 doctors and midwives (6-7 health workers from Puskesmas and 24-28 health workers from Polindes) in each facility. ANC providers from the intervention group facility will receive training

to use the system effectively before deployment. The sample size, i.e. the number of clients to be assessed, was calculated based on the proportion of hypertensive disorder in pregnancy (HDP) cases detected and managed correctly, which is 2.9% in Lombok. The anticipated loss to follow-up was 10% with a 15% allowance for abortions. With a power of 80% and a two-sided significance level of 5%, enrolment and follow-up of 5,584 pregnant women would be needed to detect at least a 30% change in WHO-ANC and OptiBP integration system group relative to the paper-based group.

Consenting women will do their routine ANC visits in the data collection period as usual. The intervention group will get their ANC data collected in the WHO-ANC and OptiBP integrated system while the control group will get their ANC data saved in the paper-based registry. Pregnant women who refuse to participate in this study will still get their ANC services from health workers as usual.

The intervention will be 6 months during the data collection period. In the first month, pregnant women of any gestational age are eligible to enroll upon their first visit to a midwife or doctor at the integrated health post, village health clinic, or community health center in the catchment areas. Consenting women will do their routine ANC visits in the following months as usual while their data is being recorded in WHO-ANC and OptiBP integrated systems or in the paper-based registry. If the number of samples does not fulfill the study quota in the first month, pregnant women of any gestational age coming in the second and third months can also participate.

Intervention Type
Other

Primary outcome(s)
The rate of ‘correct’ action measured using WHO’s guidance on appropriate management of elevated blood pressure in pregnancy as the comparison at the end of data collection period (6 months)

Key secondary outcome(s))
1. The proportion of ANC contacts in which BP is captured consistently, measured by dividing all ANC visits with overall enrollment over 6 months of data collection
2. The proportion of pregnant women detected by OptiBP receiving counseling, measured by dividing counseling attendance with all pathological cases that require counseling over 6 months of data collection
3. The proportion of pregnant women receiving referrals (treatment and/or proteinuria lab test), measured by dividing numbers of referrals with all pathological cases that require referral over 6 months of data collection

Completion date
29/02/2024

Eligibility

Key inclusion criteria
Health workers and trained laypersons:
1. Age 18-55 years
2. Health workers or trained laypersons in the catchment area who provide antenatal care services
3. Informed consent

Pregnant women:
1. Pregnant women of any gestational age
2. Informed consent

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
Health workers and trained laypersons:
1. Health workers or trained laypersons who cannot operate Android-based applications

Pregnant women:
1. Does not meet the inclusion criteria

Date of first enrolment
01/05/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
Indonesia

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Sponsor information

Organisation
SUMMIT Institute for Development

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
IPD will be stored in non-publicly available repository. The repository will be managed by the independent company ONA. The type of data that will be shared are videos and case report forms (CRFs). Data will be transferred/uploaded twice a week during the data collection. The data will be supervised by the Project Investigator. Biopectal and the Swiss Center for Electronics and Microtechnology (CSEM) will have access to the data for the purpose of data validation. The data analysis will be done independently by WHO researchers. ID numbers will be used to match the data from OptiBP and CRFs.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes