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Exploring digital health interventions for pregnant women at high risk for pre-eclampsia and eclampsia in low-income and-middle-income countries: a scoping review

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ABSTRACT

Objective To explore digital health interventions that have been used to support pregnant women at high risk for pre-eclampsia/eclampsia (HRPE/E) in low-income and middle-income countries (LMICs).

Design Scoping review.

Data source EMBASE, MEDLINE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and CINAHL were searched between 1 January 2000 and 20 October 2020.

Eligibility criteria The review included original research studies that were published in English, involved pregnant women at HRPE/E and implemented digital health interventions for PE/E in LMICs.

Data extraction and synthesis Two reviewers independently completed the data extraction for each of the 19 final articles. An inductive approach was used to thematically organise and summarise the results from the included articles.

Results A total of 19 publications describing 7 unique studies and 9 different digital health interventions were included. Most studies were conducted in South Asia and sub-Saharan Africa (n=16). Of nine unique digital health interventions, two served the purpose of predicting risk for adverse maternal health outcomes while seven focused on monitoring high-risk pregnant women for PE/E. Both of these purposes used mobile phone applications as interface to facilitate data collection, decision making, and communication between health workers and pregnant women. The review identified key functions of interventions including data collection, prediction of adverse maternal outcomes, integrated diagnostic and clinical decision support, and personal health tracking. The review reported three major outcomes: maternal health outcomes including maternal and neonatal morbidity and mortality (n=4); usability and acceptability including ease-of-use, and perceived usefulness, (n=5); and intervention feasibility and fidelity including accuracy of device, and intervention implementation (n=7).

Conclusion Although the current evidence base shows some potential for the use of digital health interventions for PE/E, more prospective experimental and longitudinal studies are needed prior to recommending the use of digital health interventions for PE/E.

Strengths and limitations of this study

- ► First scoping review to explore the use of digital health interventions (DHIs) in low-income and middle-income countries (LMICs) to support pregnant women at high risk for pre-eclampsia/eclampsia (PE/E).
- ► This scoping review has identified several gaps in the area of DHIs use for PE/E in LMICs which can be explored through future research.
- ► The high heterogeneity of the DHIs and study outcomes limited the interpretation of the studies through quantitative analysis.
- ► This review only included peer-reviewed articles and papers published in the English language.
- ► The review did not include information that may have been found in other databases and sources (abstracts, reviews, conference proceedings, opinion papers, books).

INTRODUCTION

Approximately 16% of all maternal deaths in low-income and middle-income countries (LMICs) are attributable to pre-eclampsia/eclampsia (PE/E).[1] High maternal mortality from PE/E results from: (1) lack of early identification and treatment of pregnant women, (2) difficulties in reaching treatment centres and (3) poor health-seeking behaviours linked with low patient education.[2] To meet the United Nations Sustainable Developmental Goal target 3.1 of reducing the maternal mortality ratio to less than 70/100 000 live births by 2030, innovations are required to decrease PE/E-related mortality.[3]

The most effective strategies to ensure early diagnosis and management of PE/E include self-monitoring of blood pressure, use of magnesium sulfate therapy, proteinuria determinations and timely delivery.[1]

International guidelines including the European Society of Hypertension, American Heart Association, National Institute for Health and Care Excellence (NICE), and American Society of Hypertension guidelines, recommend self-monitoring for PE symptoms and recording of blood pressure for pregnant women at high risk for PE/E (HRPE/E) because of their potential benefits such as effective control of blood pressure, early risk identification, and treatment, and cost savings due to fewer hospital visits.[4–6] Self-monitoring also has a role in preventing conditions like white coat hypertension and masked hypertension in pregnant women at HRPE/E. WHO suggests home blood pressure monitoring for pregnant women at HRPE/E to detect changes in blood pressure between antenatal visits and to ensure care continuity.[7]

Digital health interventions (DHIs) are increasingly being used to support pregnant women at HRPE/E for remote monitoring of blood pressure and symptoms. To date, four reviews explored the use of digital tools for remote monitoring of pregnant women at HRPE/E. Aquino *et al* reported 16 unique, feasible and cost-effective telemonitoring interventions to support pregnant women with hypertensive disorder of pregnancy.[6] However, the review mainly focused on telemonitoring interventions for remote blood pressure monitoring of pregnant women. The review also primarily identified studies from high-income countries like the UK, USA and Belgium.[6] Lanssens *et al* reported 14 studies from 1988 to 2010 that used telemonitoring interventions for pregnant women during the prenatal period.[8] This review, however, used a narrow time range and focused on telemonitoring solutions implemented in high-income countries for pregnant women at high risk for gestational diabetes and preterm labour. In addition, the included studies had a high methodological risk of bias. When only studies with low risk of bias were considered, the added value of telemonitoring became less pronounced.[8] Rivera-Romero *et al* captured only 11 studies conducted in high-income countries, on mHealth interventions for the hypertensive disorder of pregnancy.[9] The included studies showed positive results in the improvement of maternal health and acceptability of solutions, although most of the studies involved a small number of participants, and none were complete clinical studies.[9] van den Heuvel *et al* reported 12 studies on the use of telemonitoring and teleconsulting interventions to improve pregnancy care generally.[10] The review did not focus on the use of eHealth for the hypertensive disorder of pregnancy and generally included all aspects of perinatal care.

These four reviews provided foundational information on the use of telemonitoring to support high-risk pregnant women in antepartum and postpartum period. However, quality evidence on the appropriate use of DHIs to support pregnant women at HRPE/E in LMIC is scarce. None of the reviews extensively documented the use of DHIs in LMICs for the early diagnosis and management of pregnant women at HRPE/E. This gap highlights the need to explore the potential role of DHIs to support pregnant women at HRPE/E in LMICs. This review aims to systematically explore the available literature on the use of DHIs to support early detection and management of PE/E in LMICs.

METHODS

The 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews' (PRISMA-ScR) checklist was used to guide the design and reporting of this scoping review.[11] . The review was registered in the Open Science Framework-Center for Open Science on 19 October 2020 (Registration link: https://osf.io/gncvj). The review was guided by the methodological framework by Levac *et al*[12] and Arksey *et al*[13] to examine articles describing the use of digital health solutions to support early detection and management of PE/E in LMICs.

Identifying research question

The main research question for this scoping review is: What is known in the literature about DHIs that have been used to support pregnant women at HRPE/E in LMICs?

Our study has used the broad population, concept and context (PCC) framework recommended by the Joanna Briggs Institute for Scoping Reviews. The operationalisation of PCC framework for our scoping review include: population (pregnant women at HRPE/E), concept (DHIs) and context (LMICs).

Eligibility criteria

The review included studies that involved pregnant women at HRPE/E and implemented the digital health solutions to support early detection and management of PE/E in LMICs. For this scoping review, the DHIs included wearable devices, predictive models operationalised through clinical applications, health information technologies, health management systems, and other innovations related to mobile health, telehealth and telemedicine that can guide diagnosis, monitoring and treatment.[14] The review included only English-language studies, which were conducted in LMICs. The World Bank's 2020 country classification list was used to select LMICs with a Gross National Income per capita between US$1036 and US$4045.[15] The review primarily aimed to include original and primary research studies, including experimental studies (eg, randomised controlled trials (RCTs), quasi-experimental studies), observational studies (eg, cohort, case–control, cross-sectional, qualitative studies) and study protocols. All types of reviews, meta-analyses, letters to editors, commentaries, viewpoints, news articles, abstracts and books were excluded. Articles published between 1 January 2000 and 20 October 2020, were included, given that DHIs prior to 2000 would likely have little applicability for current implementation (online supplemental file 1: eligibility criteria).

Information sources and search strategy

Five main electronic databases were searched including Excerpta Medica Database (EMBASE), Medical Literature

Analysis and Retrieval System Online (MEDLINE), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Cumulated Index to Nursing and Allied Health Literature (CINAHL). A supplementary search was conducted using the first seven pages of Google Scholar to capture peer-reviewed literature on the use of DHIs to support pregnant women at HRPE. The reference lists of relevant systematic reviews and final included articles were also handsearched to find pertinent studies. The search strategy was developed with the assistance of an expert librarian specialising in health services research. It included four main concepts of interest: target population (pregnant women), health condition (PE), intervention (digital health tools) and settings (LMICs). The search strategy included both keywords and subject headings such as MeSH, and Emtree (online supplemental file 2: search strategy).

Selection procedure

Records from all the electronic databases were exported to Endnote software for screening purposes. The primary reviewer (ASF) developed a predefined screening form, and pilot testing was carried out using 10 randomly selected articles to ensure appropriate screening reliability among the two reviewers (ASF and NA), which was found to be 90%. All articles were independently screened by the two reviewers to exclude those that did not fulfil the inclusion criteria. Two reviewers then met to review any discrepancies which were discussed until a consensus was reached.

The initial search found a total of 4078 articles. After deduplication, 3389 titles and abstracts were screened by the two reviewers (ASF and NA) to evaluate whether they met the eligibility criteria. Of these, 72 records were found to be eligible for full-text screening by the two reviewers. Finally, 19 articles were identified after the full-text screening that met the inclusion criteria for this review.[16–34] Fifty-three articles were excluded for the following reasons: (1) the study was not reported in the English language; (2) the publication did not talk about pregnant women at HRPE; (3) the research did not include any of the DHIs; (4) the publication was a conference abstract, review, editorial, commentary or (5) the study implemented the DHIs for pregnant women at HRPE in high-income countries. The study selection procedure was recorded according to the PRISMA-ScR flow diagram (figure 1).

Data extraction

A data abstraction form was designed collectively by the research team to determine appropriate variables such as study characteristics, type of DHIs, intervention description and study outcomes (online supplemental file 3: data abstraction form). To ensure consistency in the data extraction process, the form was pilot tested using three randomly selected articles, which resulted in consistent data being abstracted by both reviewers. Both reviewers (ASF and NA) independently completed the data extraction sheet for each of the 19 final articles. The data abstraction sheets of both the reviewers were compared with confirm that all major results were included in the scoping review. In the case of inconsistencies between the data extraction sheets from the two reviewers, a third reviewer would have been invited to make a final decision, but no inconsistencies were found.

Data analysis

An inductive approach was used to thematically organise and summarise the results from the included articles to explore our research question. The extracted results from each article were read several times to identify frequent patterns, similarities and differences on the use of DHIs to support pregnant women at HRPE in LMICs. The identified emerging patterns were organised into five thematic groupings including study characteristics, overview and appraisal of included studies, purpose of DHIs, users of DHIs, and types of outcomes examined by the included studies. The first, and last author discussed the results and agreed on the final groupings of the results.

Patient and public involvement

No patients or members of the public were involved in the protocol design and conduct of the scoping review.

RESULTS

Study characteristics

A total of 19 publications describing 7 unique studies were included in this review. The included articles were published between 2009 and 2020. Of these 19 articles, a total of 16 articles described studies that were conducted in South Asia and sub-Saharan Africa, one article described a study conducted in Africa, Southern Asia and the Middle East, and the remaining two articles described studies conducted in unspecified resource-poor settings (LMICs) (online supplemental file 4: overview of the included articles).

The 19 articles were classified into three types of articles: observational studies (n=12), experimental studies (n=4 including two RCTs) and protocol papers (n=3). All included articles reported the use of DHIs for antepartum women. The articles reported varying eligibility criteria for selecting high-risk pregnant women for different DHIs. Some articles selected high-risk pregnant women based on the NICE guidelines,[20] specific age groups such as pregnant women aged 15–49 years,[22] while a few articles selected pregnant women based on their residential area such as women living in study catchment area,[23] permanent resident of the particular area, or non-resident who delivered in the study area.[18] Most DHIs collected blood pressure, heart rate and pulse oximetry, with some innovations collecting data on additional indicators such as demographic data, haemoglobin, urine dipstick test to detect proteinuria and glucose, other urinary markers and PE symptoms. Only one article reported the use of international guideline (NICE clinical guideline 107) to

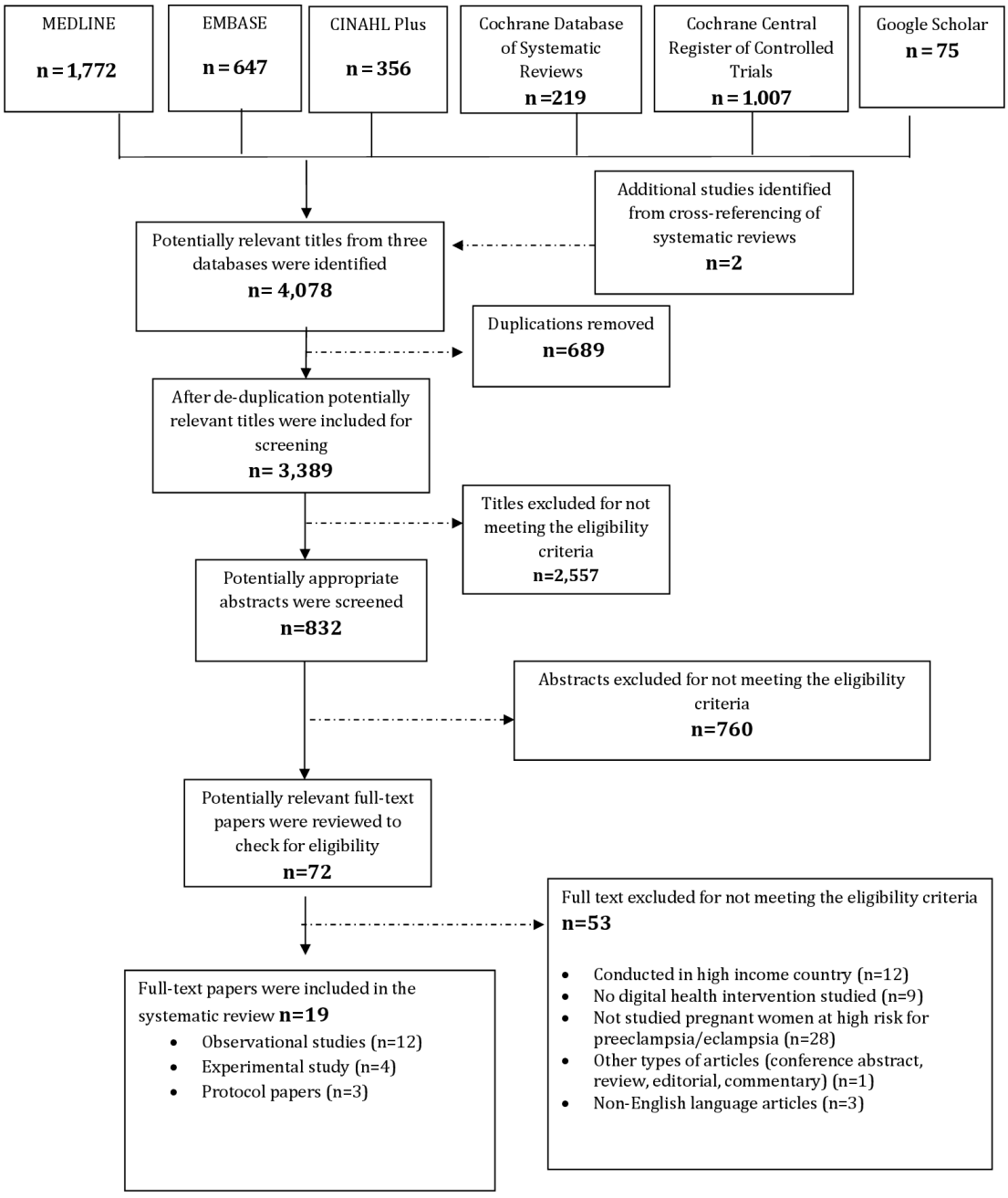

Figure 1 PRISMA-ScR flow diagram for database search of studies. PRISMA-ScR, Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

determine blood pressure thresholds[28] (online supplemental file 5: DHIs characteristics).

Seven articles described the application of theoretical frameworks to guide the implementation and evaluation of digital health tools, including the technology acceptance model,[25] diffusion of innovation model,[26 31] three delay model,[26 29] normalisation process theory,[23] medical research council framework,[34] logic models,[31 34] realist evaluation theories[31] and cost-effectiveness models.[22] Two articles described the use of the LambdaNative framework for the development of the 'Pre-eclampsia Integrated Estimate of RiSk (PIERS) on the Move (POTM)' mHealth application.[19 24] The remaining 10 articles did not mention the use of theory or frameworks for the implementation of DHIs.

Overview of the appraisal of included studies

A total of 10 publications in this review reported research work of the monitoring component of PRE-EMPT (PE/E Monitoring, Prevention & Treatment) project by Von Dadelszen *et al*, University of British Columbia.[17–19 22–24 29–31 33] The elements of the monitoring component include predictive models, Community Level Interventions for PE (CLIP) and integrated mHealth applications. The PRE-EMPT initiative involved the work of the following research groups: CLIP Pakistan working

group, CLIP India working group, CLIP trial collaborative group and MiniPIERS and FullPIERS study working group. The PRE-EMPT project was funded through the Bill & Melinda Gates Foundation (US$25.9 million).

A total of four articles reported research work of CRADLE vital sign alert (VSA) trial led by Nathan *et al*, which aimed to evaluate the ability of the device to accurately detect abnormalities in women's vital signs during pregnancy.[26–28 34] The remaining five publications reported five unique DHIs to support pregnant women at HRPE including the Congo Red Dot test,[21] a hypothetical telemonitoring programme,[20] a new hypertension detector,[32] an integrated diagnostic and clinical decision support system named 'Bliss4Midwives' (B4M),[16] and a smart wristwatch (called the F1 smart wristwatch) for blood pressure monitoring of expectant mother.[25]

Following PRISMA-ScR guidelines, each of the above-mentioned included article was reviewed to identify emerging themes related to the use of DHIs to support pregnant women at HRPE in LMICs. The key themes that emerged from the observational and experimental studies and protocol papers are as follows: (1) purpose of DHIs including risk prediction and monitoring of high-risk pregnant women; (2) users of DHIs including healthcare providers (HCPs), caregivers and pregnant women; (3) types of outcomes examined in included studies including maternal and neonatal health outcomes, usability and acceptability and intervention feasibility.

Purpose of DHIs

This review reports nine unique DHIs from 19 included articles to support pregnant women at HRPE/E in LMICs. These unique interventions are clustered into two main groups based on their purpose: predicting risk of adverse maternal health outcomes (n=2) and monitoring high-risk pregnant women to manage PE/E (n=7). Most articles (n=7) described the use of more than one unique DHI (figure 2).

Predicting risk of adverse maternal health outcomes

Five observational studies and two RCTs described the use of two unique clinical predictive models named fullPIERS[19] and miniPIERS[17–19 24 29–31] to facilitate the prediction of adverse maternal outcomes occurring as a result of PE based on demographics, symptoms, clinical signs (including SpO2) and laboratory tests. In order to implement these predictive models, the mobile application 'POTM' was developed as an interface to enable healthcare workers to easily determine the risk of adverse maternal health outcomes. One article reported the use of both the miniPIERS and fullPIERS predictive models,[19] while six articles only reported the use of the miniPIERS model to predict adverse health outcomes among

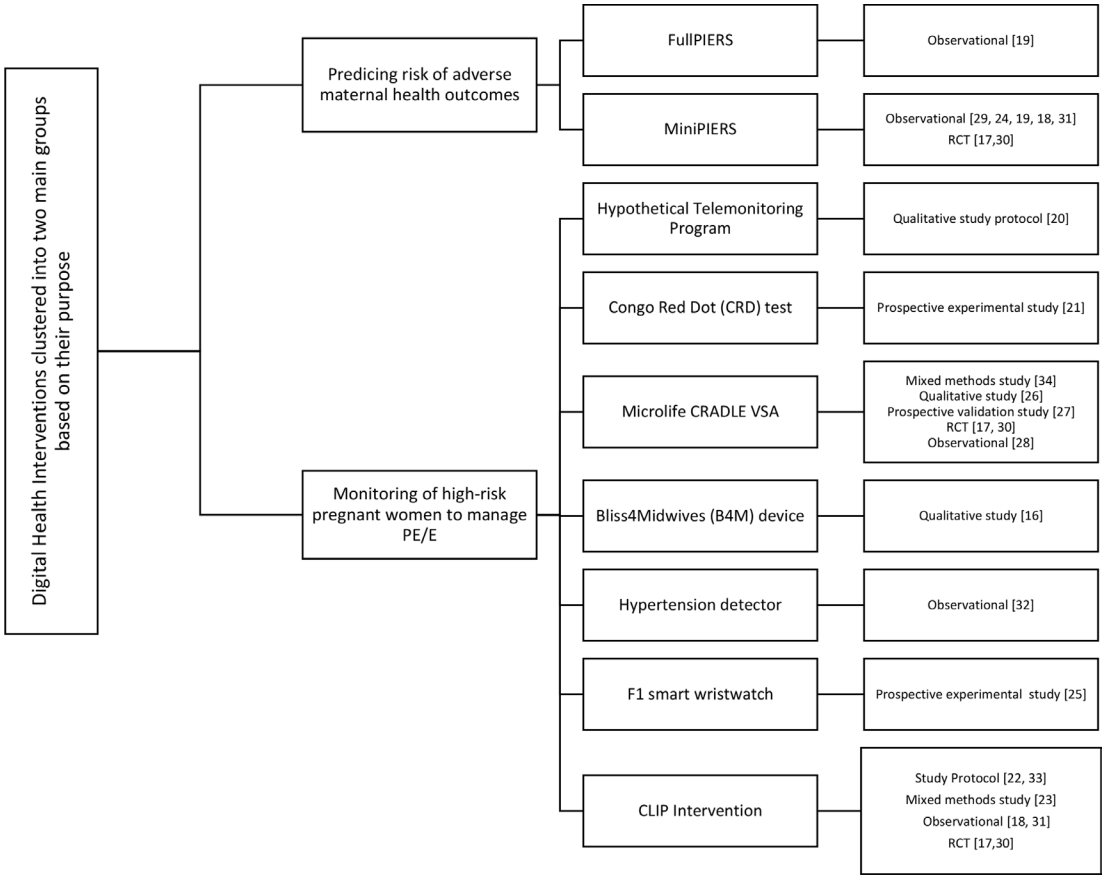

Figure 2 Classification of the included studies based on the purpose of digital health interventions. CLIP, community-level interventions for PE; PE/E, pre-eclampsia/eclampsia; RCTs, randomised controlled trials.

pregnant women with PE/E in LMICs.[17 18 24 29–31] Payne *et al* described the development process of the miniP-IERS model to identify pregnant women at HRPE/E in five LMICs using simple-to-measure indicators: personal demographics (gestational age); clinical signs (blood pressure readings and proteinuria); and PE symptoms (headache, visual disturbances, chest pain, dyspnoea, vaginal bleeding and abdominal pain).[29] The fullPIERS model included additional predictors such as SpO2 and laboratory tests, to calculate a risk score for pregnant women.

Monitoring high-risk pregnant women for managing PE/E conditions

The review identified seven unique DHIs for continuous monitoring high-risk pregnant women for managing PE/E including one diagnostic test named Congo Red Dot for monitoring misfolded protein in the pre-eclamptic urine,[21] CLIP intervention for monitoring blood pressure among high-risk women through community health workers,[17 18 22 23 30 31 33] as well as five unique devices for monitoring blood pressure.[16 20 25 27 28 32 34] The five unique devices for measuring blood pressure among high-risk pregnant women include the Microlife CRADLE VSA device,[27 28 34] the B4M' device,[16] a new hypertension detector device,[32] hypothetical telemonitoring programme[20] and the F1 smart wristwatch.[25]

The Congo Red Dot test was evaluated in a prospective experimental study design. The Congo Red Dot test requires minimal specialised equipment and enables minimally trained personnel to diagnose PE in resource-limited healthcare settings. The test was developed in 2016, based on the ability of constituents in pre-eclamptic urine to bind the amyloidophilc dye Congo Red. At the core of the test is the discovery that pre-eclamptic women eliminate misfolded proteins in their urine, a molecular feature that is proportional to disease severity.[21]

The CLIP intervention was implemented in Mozambique, Pakistan, India, and Nigeria as part of cluster RCTs (cRCTs).[17 18 22 23 30 31] The implementation of CLIP intervention involved scaling-up of existing community health workforce to provide community engagement and community health worker-led app-guided monitoring for high-risk pregnant women for hypertension. Community health workers were able to undertake all aspects of the app-guided visits, and approximately 10% of pregnant women were found to be hypertensive.

As a first example of blood pressure measurement device, Nathan *et al* assessed the accuracy of the Microlife 3AS1-2 blood pressure device in 2014 for use in pregnancy and PE in a low-resource setting.[27] The study recruited a total of 45 pregnant women, of whom 15 had PE, from Kimberley Hospital in South Africa. The study concluded that the device can be recommended for use in pregnancy, including PE as it fulfils the requirements stipulated by the WHO for an automated blood pressure device suitable for use in antenatal clinics and primary healthcare facilities of LMICs. The device has been extensively validated for accuracy, usability, and acceptability in low-resource settings.[27] The device calculates the pregnant woman's risk of hypovolaemic or septic shock and alerts frontline healthcare workers about vital sign abnormalities through a traffic light early warning system display. In 2018, a 3-month mixed-methodology feasibility study was conducted to incorporate the CRADLE VSA device into routine maternity care in 10 low-income sites.[34] Primary, secondary and tertiary facilities were allocated devices and training packages consisting of a short-animated film, interactive sessions, booklet, and posters.

As a second example, a study conducted in Ghana used the B4M device which included infrared sensors to measure haemoglobin, a self-inflating cuff for blood pressure measurement, and an automated reader for urinary protein and glucose through dipsticks. The device facilitated non-invasive screening of PE and served as an integrated diagnostic and clinical decision support device for PE.[16] The third example of a device for blood pressure monitoring was a new hypertension detector, developed by Thakor *et al*, which was compared in an observational study with other traditional devices for use in developing countries to support pregnant women at HRPE/E.[32] The new device was found to be more accurate and easy-to-use than CRADLE VSA and other devices, due to the reduced number of steps required for use.[32] As a fourth example of a device for blood pressure monitoring was a hypothetical telemonitoring programme,[20] which was described in a qualitative study protocol. The study intended to explore the perspectives, needs, and preferences of a telemonitoring programme for pregnant women at HRPE in a tertiary health facility of Karachi, to inform future implementation.

Finally, one prospective experimental study used a wearable device called the F1 smart wristwatch that included an integrated chip for sensing blood pressure readings and displaying real-time data on the screen. The smartwatch on the expectant mother's wrist takes blood pressure readings and transfers them by Bluetooth to their phone at regular intervals to facilitate personal health tracking. The caregiver can access the expectant mother's records, as well as receive alerts on blood pressure readings.[25]

Both of these purposes used mobile phone applications as an interface to facilitate data collection, decision making and communication between health workers and pregnant women. The majority of these studies used the POTM application[17–24 30 31 33] to facilitate the collection of relevant clinical data during antenatal visits. The application was used by community health workers in India, Pakistan, Nigeria, and Mozambique, as part of a CLIP cluster RCT.[17 30] The POTM platform combined two interventions, which were the miniPIERS model and a Phone Oximeter to accurately predict the risk score for pregnant women at HRPE/E in LMICs. The application generated a risk estimate which enabled community health workers and other HCPs to stratify high-risk pregnant women, escalate care and make referrals to

the facility. In addition, Jonas *et al*'s study used a mobile application for administrating CRD test for monitoring misfolded protein in the pre-eclamptic urine.[21] Finally, the Feroz *et al*'s study protocol described a hypothetical mobile-based telemonitoring programme which would serve as a communication aid between nurses and high-risk pregnant women.[20]

Users of DHIs

Most articles involved HCPs (n=17) as the targeted primary users of the DHIs, while only two articles had pregnant women and caregivers as the primary users of the DHI.[20 25] The articles described various healthcare workers as the users of the DHIs, including mid-level HCPs, community-based HCPs, female health supervisors, semi-literate volunteers, community health nurses, female health workers, midwives and accredited social health activists. Sixteen articles included information on the training of patients and HCPs on how to use the DHI, interpret physiological metrics, and take actionable measures for critical results.[16 18 19 21–24 26–34] The HCPs received advanced training to enhance their assessment skills and ability to facilitate the overall management of pregnant women at HRPE/E. Three articles did not specify the training component for either HCPs or patients.[17 20 25]

Type of outcomes examined

The included articles (n=19) reported on three major outcomes: (1) maternal and neonatal health outcomes (n=4), (2) usability and acceptability (n=5) and (3) intervention feasibility (n=7) (online supplemental file 6: outcomes of DHIs).

Maternal and neonatal health outcomes

Four articles examining maternal and neonatal health outcomes were observational studies (n=2) and RCTs (n=2).[17 18 28 30] Maternal health outcomes included magnesium sulfate use, hospital admissions, critical care unit (CCU) admissions, birth preparedness, complication readiness, facility delivery attended by skilled birth attendants, and adverse maternal outcomes such as an increase in kidney injury, maternal morbidity, and mortality. For example, Nathan *et al*'s observational study evaluated the association between blood pressure measurements and adverse outcomes in women with PE using CRADLE VSA traffic light early warning system. The study demonstrated that the risk of maternal death, eclampsia and perinatal death was similar across the women who triggered a yellow or red light on the CRADLE VSA. However, the risk of kidney injury, maternal use of magnesium sulfate, maternal CCU admission and preterm delivery, was greater for those who triggered a red light, compared with a yellow light.[28] The two RCTs reported non-significant findings regarding maternal morbidity and mortality for participants in the DHI arm.[17 30] Neonatal health outcomes included stillbirths, fetal and neonatal morbidity, and mortality. Only one of the two RCTs reported a reduction in stillbirths (0.89 (95% CI 0.81 to 0.99); p=0·03) in the DHI group; however, no impact on neonatal morbidity or mortality was reported for participants in the DHI group.[30]

Usability and acceptability

Five articles reported on the usability and acceptability of DHIs in LMICs.[19 24–26 32] The articles mentioned pregnant women, caregivers and HCPs' experience of use of DHIs in LMICs. Usability outcomes included: trust in technology, ease of use, content richness, perceived usefulness and user satisfaction. For instance, Musyoka *et al*'s study found that a 24-hour ambulatory blood pressure monitoring system has a great potential for actual adoption in healthcare systems in low-income and middle-income countries, given its simplicity and affordability.[25] The study found that content richness had a slightly positive linear effect on perceived ease of use, while there is a slightly negative relationship between content richness and perceived usefulness.[25] Lim *et al* used the computer systems usability questionnaire to assess the usability of the POTM mHealth application.[24] Nurses and midwives who participated in the study rated the usability high for the integration of these technologies and thought it would help their fieldwork. The study found that usability issues were often related to navigation of the app and phone features such as scroll wheels, touch screen use, etc. In a study by Nathan *et al*, most HCWs perceived the CRADLE device to be easy to use; however, some described manual inflation as tiring, particularly when measuring vital signs in obese and hypertensive women.[26] Dunsmuir *et al*'s study reported on the usability of CLIP POTM application; the CLIP trial received requests from different countries for modifications in POTM to consider different user needs and cultural differences leading to modified application versions for each country.[19]

Intervention feasibility and fidelity

Most articles (n=7) reported on the feasibility and fidelity of DHIs for pregnant women at HRPE/E in LMICs in order to provide evidence on the evaluation of DHIs for replication and scale-up of successful DHIs.[16 21 23 27 29 31 34] Study outcomes included: fidelity and accuracy of the CRADLE VSA device, MiniPIERS model development and validation, understanding of enabling and impeding factors for CLIP trial implementation, experiences of pregnant women with B4M intervention and cost-effectiveness of the Congo Red Dot test. For example, Payne *et al*'s study informed that miniPIERS model has a reasonable ability to identify women at increased risk of adverse maternal outcomes associated with the hypertensive disorders of pregnancy.[29] Nathan *et al*'s another study assessed the accuracy of Microlife 3AS1-2 blood pressure device for accuracy for use in pregnancy in LMICs. The authors concluded that the device can be recommended for use in pregnancy, including PE as it meets the standards stipulated by the WHO for automated blood pressure devices suitable for low-resource settings.[27] One mixed-methods

study reported high fidelity of the implementation of the CRADLE VSA device, with improved HCPs ability to make clinical decisions, escalate care, and make immediate referrals in case of emergency.[34] The study by Khowaja *et al* reported factors associated with the feasibility of the CLIP trial implementation including community mobilisation, institutional support, system integration, knowledge gaps, lack of trained personnel, cultural myths and misconceptions, poor health service quality and high cost of care.[23]

DISCUSSION

Principal findings

This review summarises evidence on the existing DHIs to support pregnant women at HRPE/E in LMICs. Given that most articles (11 out of 19) were published between 2015 and 2020, the novelty of DHIs use to support pregnant women with HRPE/E was indicated. Only nine unique DHIs were identified in this review from 19 included articles, reflecting the limited understanding and use of DHIs to support pregnant women in LMICs. Most included articles used observational and exploratory research methods to study DHIs. This suggested the need for concerted efforts to learn from small innovation projects and deployments as outlined in WHO guide on monitoring and evaluation of DHIs.[35] Most articles in this review did not report information on the blood pressure thresholds, which limited our understanding of standardised blood pressure thresholds used in LMICs. The explicit reporting of standardised blood pressure thresholds could help in designing effective clinical decision support systems for monitoring pregnant women in LMICs.[36]

Implementation barriers and strategies for DHIs

The Microlife CRADLE VSA blood pressure monitoring device has been extensively validated for use in LMICs for pregnant women.[27 28 34] However, HCPs faced several barriers during the implementation of CRADLE VSA device including lack of supportive supervision for device use, high staff turnover and poor availability of the device, poor battery life of device, misleading displays, broken hand pump, tubing and broken charging ports.[34] Nathan *et al* and Vousden *et al* suggested a range of implementation strategies to address known barriers, prior to scale-up, including recognising designated device champions who can provide in-depth local training and support for device use, emphasising the importance of a device training package (short animated film, interactive sessions, booklet and posters), updating training materials to explain the traffic light alert system, providing chargers in addition to the USB cable, and ensuring an adequate supply of VSA devices.[28 34] Lim *et al*'s study mentioned that the general unfamiliarness of using touch screen smart phones was reported as the major barrier faced during the implementation of POTM application.[24] Abejirinde *et al*'s study trained users on the technical and operational functions of the device to address technical and procedural issues including software freezes, slow response time and low user dexterity with operating the device.[16]

Research gaps and suggestions for future research

Enabling the use of DHIs by pregnant women as end-users instead of HCPs as end-users

Most articles in this review targeted DHIs at HCPs who have less formal training and education, as opposed to studies conducted in high-income countries where DHIs have been targeted at family physicians and clinicians who have specialised medical training.[6] This review identified only one study that targeted DHI at pregnant women for personal health tracking[25]; however, DHIs implemented in high-income countries are often targeted for use by pregnant women to improve maternal health behaviours and maternal–fetal health outcomes.[37] Given the increasing cell phone penetration in LMICs,[38] there is an opportunity to use mobile phone technology to target DHIs at the patient level (pregnant women) to encourage personal health tracking. Yet, health informatics researchers should consider issues of technological literacy, user characteristics (age, gender, computer skills, experience), cultural factors and socioeconomic status when designing and implementing DHIs in the LMIC context.[39] None of the studies delivered targeted client instructions via a digital platform, in response to abnormal blood pressure readings or signs and symptoms of PE. In high-income countries, some digital health platforms have delivered manual or automated targeted instructions to the pregnant women to provide information about medications, referrals and diet.[40] LMICs can learn from the experiences of high-income countries for developing context-specific digital platforms that can facilitate targeted client communication between providers and pregnant women. Evidence suggests that the targeted client communication for transmission of health information, health event alerts and reminders, and diagnostic results have shown positive impacts on health behaviours and health outcomes in high-income countries.[41]

Using multidisciplinary team approach for designing DHIs

None of the DHIs used a multidisciplinary team approach for monitoring of pregnant women for PE/E. Blandford *et al* suggest that DHIs should involve collaboration between different cadres of HCPs across all levels of the health system, to achieve the full potential of digital intervention.[42] For instance, a nurse or midwife at a primary level could communicate about a pregnant women's health condition to a clinician at a secondary institution to seek recommendations for managing pregnant women at HRPE/E. Murray *et al* suggest that high-quality research in the digital health field requires fertile multidisciplinary collaborations that draw on insights and experience from multiple fields, including clinical medicine, health services research, behavioural science, education, engineering and computer science.[43] Thus, research

aimed at designing and evaluating DHIs to support pregnant women at HRPE/E should draw insights from collaborators belonging to diverse disciplines including obstetricians and gynaecologists, telemedicine experts, knowledge users, HCPs (nurses, doctors), public health specialists, maternal health specialists, health services researchers, as well as patient partners.

Exploring telemedicine use to enable remote consultation between pregnant women and HCPs

Most articles used DHIs for the prediction of adverse maternal outcomes, data collection and decision aid, diagnostic and clinical decision support, and personal health tracking. There is a lack of evidence on using DHIs for referral coordination, teleconsultation between pregnant women and HCPs, communication between the HCP and their supervisor, and HCPs' training. Telemedicine has been extensively used in high-income countries for providing a range of obstetrical services such as using videoconference to replace in-person visits, implementing at-home monitoring, enabling consultation with remote specialists, earlier postpartum follow-up visits and access to lactation consultants.[44] This evidence shows the potential of using telemedicine for pregnant women at HRPE/E in LMICs to enable remote monitoring and remote consultation between pregnant women and providers.

Monitoring and evaluating the implementation and effectiveness of DHIs

Most articles reported on intervention feasibility, usability and acceptability outcomes. Two RCTs reported non-significant findings for maternal morbidity, mortality and neonatal deaths[17 30] with only one RCT that reported a significant difference in stillbirth rate in DHIs group.[30] This suggests the need of conducting more experimental studies such as RCTs to evaluate the efficacy and effectiveness of diverse DHIs to improve maternal and child health outcomes. In the review, only one study protocol described the methodology to conduct an economic evaluation of the CLIP package in South Asian and African countries.[22] This shows the paucity of evidence on the economic impact of DHIs to support pregnant women with PE/E. Ramsey *et al* recommend that future clinical trials should incorporate cost-analysis of DHIs as there is mounting evidence on embedding economic evaluations within clinical trials to build a robust cost-effectiveness model that has high internal validity and timeliness.[45] The articles included in this review did not extensively identify facilitators and challenges encountered during the implementation of DHIs for pregnant women with PE/E in LMICs, unlike many studies conducted in high-income countries.[6] This review identified only a few facilitators: easy to use technology, trust in technology, and availability of diagnostic service at the point of care. This indicates the need to examine and report on enablers and barriers faced when employing DHIs for pregnant women at HRPE/E across the stages of design, development, implementation and evaluation.

In summary, this scoping review suggests four recommendations for future research: (1) enable the use of DHIs by pregnant women as end-users to encourage personal health tracking including individualised patient instructions; (2) consider a multidisciplinary team approach when designing DHIs for pregnant women at HRPE/E; (3) explore the potential of using telemedicine in LMICs to enable remote consultation between pregnant women and health providers; (4) conduct further studies including prospective longitudinal and experimental studies to establish the implementation effectiveness and efficacy of DHIs to support pregnant women at HRPE; exploratory studies to identify barriers and enablers associated with the development, implementation and evaluation of DHIs; and economic evaluations of DHIs within large clinical trials to identify cost-effective DHIs.

CONCLUSION

The current evidence base is sparse but shows some potential for the use of different DHIs to support pregnant women in early diagnosis of PE/E through predicting the risk for adverse maternal health outcomes and monitoring high-risk pregnant women for PE/E through devices and other DHIs. Limited evidence exists on types, benefits, cost-effectiveness and outcomes of DHIs. The weak evidence may impede the adoption of these promising technologies in community and healthcare settings to support pregnant women at HRPE/E in LMICs. Future research work should target DHIs at the pregnant women level to promote personal health tracking with targeted instructions for pregnant women, consider a multidisciplinary team approach for designing DHIs, explore the role of telemedicine to enable remote consultation between pregnant women and HCPs, and evaluate the implementation and effectiveness of DHIs.

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Supplementary File 1 - Eligibility Criteria

Question 1: Does this study include humans?

a) If yes, **INCLUDE**
b) **EXCLUDE** animal studies/models, non-humans or vertebrae studies

Question 2: Is the primary language of the study English?

Is the primary language of the study English?

a) If yes, **INCLUDE**
b) **EXCLUDE** if study is listed as described in a non-English language

Question 3: Is the article classified as one of the following?

a) **INCLUDE** all types of study designs including, observational studies, experimental studies, qualitative studies, study protocols, grey literature.
b) **EXCLUDE:** systematic reviews, meta-analysis, letter to editors, scoping reviews, commentaries, news articles

Question 4: Does this study examine care provided to pregnant women with Preeclampsia/eclampsia (PE/E)/or at high risk for PE/E (HRPE/E)?

a) If yes, **INCLUDE**
b) **EXCLUDE** if study does not focus on care provided to pregnant women with PE/E or at HRPE/E

Question 5: Does this study examine digital technologies to support pregnant women with preeclampsia/eclampsia or at HRPE/E

a) **INCLUDE** studies that are focused on use of digital technologies to support pregnant women with PE/E or at HRPE/E. Digital technologies may include:

- Telephone communication
- Video communication
- Text messaging (asynchronous)
- Email messaging (asynchronous)
- Portals, apps, and other applications
- Remote monitoring

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- Devices
- Predictive models
- Provider-provider communication through one of the above modalities
  - Synonyms: digital health, virtual care, virtual visits, eVisits, telehealth, telemedicine, eConsultation, mobile health, mHealth, teleconsultation, teleconference, telecommunications, tele* (e.g., telepsychiatry, teledermatology, etc), videoconferencing, video visits, phone, telephone, electronic consultation, online consultation, e-mail, text messaging, asynchronous messaging, secure messaging, direct messaging, messaging

b) **INCLUDE** studies focused on using digital technologies for early diagnosis, screening, and management of pregnant women with PE/E or HRPE/E.

c) **INCLUDE** studies that used digital technologies to support pregnant women with PE/E or at HRPE/E

d) **EXCLUDE** studies focused on digital health interventions that do not explicitly focus on pregnant women with PE/E or HRPE/E

Question 7: Is this study based on low-and-middle-income contexts?

.

See list of countries by income classification here: https://data.worldbank.org/country/XN

a) If yes, **INCLUDE**
b) **INCLUDE** if study focused on high and middle income together.
c) **EXCLUDE** if based on only high-income country context

Supplementary File 2 - Search Strategy

1. Pregnant Women/
2. exp pregnancy/
3. (pregnan* adj3 ("at risk" or "at-risk" or "high risk" or "high-risk")).tw,kw.
4. exp Eclampsia/
5. exp Pre-Eclampsia/
6. (Pre Eclampsia or preeclampsia or pre-eclampsia or pre eclampsia or eclampsia or gestosis or proteinuria or toxemia*).tw,kw.
7. or/1-6
8. Telemedicine/
9. Medical informatics/
10. Digital health.mp.
11. mHealth app.mp.
12. predictive model.mp.
13. CLIP.mp.
14. informatics/
15. exp Telecommunications/
16. Monitoring, Ambulatory/
17. exp Telemetry/
18. Monitoring, Physiologic/
19. exp Computer Communication Networks/
20. Mobile Applications/
21. Smartphone/
22. Cell Phone/
23. (tele-monitor* or telemonitor* or telemed* or tele-med* or teleinterpret* or tele-interpret* or telecomm* or tele-comm* or telemetry).tw,kw.
24. (mhealth* or m-health* or ehealth* or e-health* or telehealth* or tele-health*).tw,kw.
25. (mobile adj3 (health* or technolog* or app* or solution* or phone* or communicat*)).tw,kw.
26. (remote* adj3 (transmi* or transfer* or tele* or monitor* or consult* or follow-up or program* or connect* or web-base* or "web base*" or term)).tw,kw.
27. (monitor* adj3 (home or remote or distan* or ambulatory or tele* or online or on-line or "on line" or phone or digital* or Skype or electronic* or implant* or wireless* or web-base* or "web base*")).tw,kw.
28. (interven* adj3 (remote* or distan* or tele* or online or on-line or "on line" or phone* or digital* or Skype or electronic* or wireless*)).tw,kw.
29. (smartphone* or "smart phone*" or bluetooth* or Internet* or phone* or text messag*).tw,kw.
30. ((app or apps or application*) adj3 (mobile or electronic or software)).tw,kw.
31. ((digital* or electronic* or online* or on-line* or "on line" or Internet) adj3 (health* or solution* or transmit* or transmiss* or transfer* or device* or connect*)).tw,kw.
32. (broadband adj3 (device* or capab*)).tw,kw.
33. (multi-media* or multimedia*).tw,kw.
34. (self monitor* or self-monitor*).tw,kw.
35. or/8-34
36. 7 and 35
37. developing countries/
38. low-and-middle-income countries.mp.
39. LMICs
40. Honduras/
41. Angola/
42. Papua New Guinea/
43. Algeria/
44. India/
45. Philippines/

46. Bangladesh/
47. Kenya/
48. Sao Tome and Principe.mp.
49. Benin/
50. Kiribati.mp.
51. Senegal/
52. Bhutan/
53. Kyrgyzstan/
54. Solomon Islands.mp.
55. Bolivia/
56. Laos/
57. Sri Lanka/
58. Cabo Verde/
59. Lesotho/
60. Tanzania/
61. Cambodia/
62. Mauritania/
63. Timor-Leste/
64. Cameroon/
65. Micronesia/
66. Tunisia/
67. Comoros/
68. Moldova/
69. Ukraine/
70. "Democratic Republic of the Congo"/
71. Mongolia/
72. Uzbekistan
73. Cote d'Ivoire/
74. Morocco/
75. Vanuatu/
76. Djibouti/
77. Myanmar/
78. Vietnam/
79. Egypt/
80. Nepal/
81. West Bank and Gaza.mp.
82. El Salvador/
83. Nicaragua/
84. Zambia/
85. Eswatini/
86. Nigeria/
87. Zimbabwe/
88. Ghana/
89. Pakistan/
90. (Angola or Honduras or Papua New Guinea or Algeria or India or Philippines or Bangladesh or Kenya or Sao Tome and Principe or Benin or Kiribati or Senegal or Bhutan or Kyrgyz Republic or Solomon Islands or Bolivia or Lao PDR or Sri Lanka or Cabo Verde or Lesotho or Tanzania or Cambodia or Mauritania or Timor-Leste or Cameroon or Micronesia or Tunisia or Comoros or Moldova or Ukraine or Democratic Republic of the Congo or Mongolia or Uzbekistan or Cote d'Ivoire or Morocco or Vanuatu or Djibouti or Myanmar or Vietnam or Egypt or Nepal or West Bank and Gaza or El Salvador or Nicaragua or Zambia or Eswatini or Nigeria or Zimbabwe or Ghana or Pakistan).tw,kw.
91. or/37-90
92. 36 and 91

93. exp animals/ not humans.sh.
94. 92 not 93
95. remove duplicates from 94

Supplementary File 3 - Data Abstraction Form

1. Author, year
2. Journal
3. Study design (observational, experimental, protocol paper)
4. Study setting/country (LMICs)
5. Study population/Health Condition (PW at HRPE/E)
6. Study Objective
7. Number of participants (Sample)
8. Study period
    - Duration of intervention
    - Duration of data collection
9. Digital health intervention (DHI) used
    - Type of DHI (Predicative model, mHealth applications, devices)
    - Intervention validation (Yes/No)
    - Targeted primary user of intervention (health care provider/pregnant women)
    - User training on use of digital health intervention (Yes/No)
    - Function of digital health intervention
10. Study outcomes
    - Maternal and fetal health outcomes
    - Intervention feasibility/usability/fidelity/acceptability
11. Framework/model used
12. Study limitations
13. Comments

Supplementary File 4 - Overview of the Included Articles

Reference	Year	Study Title	Type of Study Design	Objective	Setting	N	Health Condition	Purpose of Digital Health Intervention
Musyoka et al. [25]	2019	A 24-hour ambulatory blood pressure monitoring system for preeclampsia management in antenatal care	Prospective experimental study	The study sought to implement a 24-hour ambulatory blood pressure monitoring solution for preeclampsia management, using a smartwatch in conjunction with a mobile and cloud-based application.	Kenya	N=30	preeclampsia	Monitoring
Lim et al. [24]	2015	Usability and Feasibility of PIERS on the Move: An mHealth App for Pre-Eclampsia Triage	Observational	The aim of this study was to assess the usability of PIERS on the Move PotM (with mid-level health workers) for iteratively refining the system.	South Africa	N=37	preeclampsia	Predicting
Vousden et al. [34]	2018	Evaluation of a novel vital sign device to reduce maternal mortality and morbidity in low-resource settings: a mixed method feasibility study for the CRADLE-3 trial	Observational	Prior to the CRADLE 3 trial start, a mixed-methodology feasibility study was undertaken to finalise the intervention and implementation processes which were guided by the Expert Recommendations for Implementing Change (ERIC) project	Zimbabwe, Ethiopia, India	Number of HCP trained=204	Preeclampsia, eclampsia and shock	Monitoring
Nathan et al. [26]	2018	The CRADLE vital signs alert: qualitative evaluation of a novel device designed for use in pregnancy by healthcare workers in low-resource settings	Observational	This qualitative study aimed to determine the usability, feasibility and acceptability of the CRADLE VSA among a variety of users and in diverse socio-economic settings, considering these five clusters of influence. This will inform future device modifications and successful dissemination of the CRADLE VSA for routine use.	India, Mozambique, Nigeria and South Africa	N=205	Preeclampsia and shock	Monitoring
Feroz et al. [20]	2020	Exploring perspectives, preferences and needs of a telemonitoring program for women at high risk for preeclampsia in a	Protocol paper	The study aims to explore the perspectives, preferences, and needs of telemonitoring (TM) for pregnant women at HRPE in Karachi, to inform future implementation strategies.	Pakistan	N=30	Preeclampsia	Monitoring

		tertiary health facility of Karachi: a qualitative study protocol						
Dunsmuir et al. [19]	2014	Development of mHealth Applications for Pre-Eclampsia Triage	Observational	This paper describes the design process of two versions of the POTM application, the original version application referred to as POTM), and a simplified, community-based version for the Community Level Interventions for Pre-eclampsia cluster randomized controlled trial (application referred to as CLIP POTM),	Nigeria, Mozambique, Pakistan, and India	Projected +30,000 pregnant women 500 community HCPs	Preeclampsia	Predicting
Jonas et al. [21]	2016	Smartphone-based diagnostic for preeclampsia: an mHealth solution for administering the Congo Red Dot (CRD) test in settings with limited resources	Prospective experimental study design	The study proposes an innovative mobile health (mHealth) solution that enables the quantification of the congo red dot test as a batch laboratory test, with minimal cost and equipment.	Resource poor settings	N=273	preeclampsia	Monitoring
Thakor et al. [32]	2009	Hypertension Detector for Developing Countries	Observational	A prototype of a low-cost device engineered specifically for semi-literate volunteers in developing countries has been created.	Africa, Southern Asia, and the Middle East	-	Preeclampsia	Monitoring
Nathan et al. [27]	2015	An accurate semiautomated oscillometric blood pressure device for use in pregnancy (including pre-eclampsia) in a low-income and middle-income country population: the Microlife 3AS1-2	Observational	The study aims to assess the accuracy of the Microlife 3AS1-2 blood pressure device in pregnancy and pre-eclampsia in a low-resource setting.	South Africa	N=45	Preeclampsia	Monitoring
Nathan et al. [28]	2018	Early warning system hypertension thresholds to predict adverse outcomes	Observational	The study aims to evaluate the association between blood pressure (BP) measurements and adverse outcomes in women with pre-eclampsia.	South Africa	N= 1547	Preeclampsia	Monitoring

		in pre-eclampsia: A prospective cohort study						
Payne et al. [29]	2014	A Risk Prediction Model for the Assessment and Triage of Women with Hypertensive Disorders of Pregnancy in Low-Resourced Settings: The miniPIERS (Pre-eclampsia Integrated Estimate of RiSk) Multi-country Prospective Cohort Study	Observational	The objective of the miniPIERS study was to develop and validate a simplified clinical prediction model for adverse maternal outcomes among women with HDP for use in community and primary health care facilities in LMICs.	LMICs	N= 2,133	Preeclampsia	Predicting
Bellad et al. [17]	2020	Community level interventions for pre-eclampsia (CLIP) in India: A cluster randomised controlled trial	Experimental study (RCT)	The objective of the Community-Level Interventions for reeclampsia (CLIP) India cluster randomised controlled trial (cRCT) was to test the hypothesis that implementing community-level, evidence-based care focused on pregnancy hypertension would reduce all-cause maternal, fetal and newborn mortality and major morbidity, without causing harm	India	N=14,783 pregnancies	Preeclampsia	Monitoring and Predicting
Qureshi et al. [30]	2020	Community-level interventions for pre-eclampsia (CLIP) in Pakistan: A cluster randomised controlled trial	Experimental study (RCT)	The aim of the Community-Level Interventions for Pre-eclampsia (CLIP) cluster randomised controlled trial (cRCT) in Sindh Province, Pakistan was to reduce maternal and perinatal mortality and major morbidity by 20% or more in intervention (vs. control) clusters, through a community-level intervention to address triage, (initial) treatment, and transport (to facility) of women with pregnancy hypertension.	Pakistan	N= 35,974 women	Preeclampsia	Monitoring and Predicting
Khowaja et al [22]	2015	Economic evaluation of Community Level Interventions for Pre-eclampsia (CLIP) in South Asian and African countries: a study protocol	Protocol paper	The study aims to conduct an economic evaluation alongside of the CLIP Trial, to inform decision makers not only of clinical outcomes but the cost required to obtain those outcomes.	Nigeria, Mozambique, Pakistan, and India	N= 154,000	Preeclampsia	Monitoring
Khowaja et al [23]	2016	The feasibility of community level	Observational study	The study aimed to describe the health system, identify community and individual barriers and facilitators that influence care of pregnant women	Nigeria, Mozambique,	N= 337 (health facilities)	Preeclampsia	Monitoring

		interventions for pre-eclampsia in South Asia and Sub-Saharan Africa: a mixed-methods design		in the community, in preparation for the conduct of a community-based cluster randomized trial	Pakistan, and India	N= 100 (IDIs) N= 123 (FGDs)		
Von Dadelszen et al. [33]	2020	The PRECISE (PREgnancy Care Integrating translational Science, Everywhere) Network's first protocol: deep phenotyping in three sub-Saharan African countries	Protocol paper	This paper describes the protocol that underpins the clinical research activity of the Network, so that the investigators, and broader global health community, can have access to 'deep phenotyping' of women as they advance through pregnancy to the end of the puerperium.	Gambia Kenya Mozambique	N= 600 (each country)	Preeclampsia, and eclampsia	Monitoring
Abejirinde et al [16]	2018	Pregnant women's experiences with an integrated diagnostic and decision support device for antenatal care in Ghana	Observational	This paper therefore explores the experiences of women exposed to the B4M device, to answer the research questions: i) How did women experience the use of Bliss4Midwives during their routine antenatal care consultations? ii) What influence did Bliss4Midwives have on woman-provider relationships and on ANC service utilization?	Ghana	N=30	preeclampsia, gestational diabetes and anaemia	Monitoring
Bellad et al [18]	2017	Maternal and Newborn Health in Karnataka State, India: The Community Level Interventions for Pre-Eclampsia (CLIP) Trial's Baseline Study Results	Observational	To describe baseline demographics and health outcomes prior to initiation of the CLIP trial and to improve knowledge of population-level health, in particular of maternal and neonatal outcomes related to hypertensive disorders of pregnancy, in northern districts the state of Karnataka, India.	India	N= 5,469	Hypertension disorders of pregnancy, preeclampsia	Monitoring and Predicting
Sharma et al [31]	2017	A process evaluation plan for assessing a complex community-based maternal health intervention in Ogun State, Nigeria	Observational	To evaluate implementation processes of the complex CLIP intervention, assess mechanisms of impact and identify emerging unintended causal pathways.	Nigeria	N= 32,785	preeclampsia	Monitoring and Predicting

Supplementary File 5- Digital Health Intervention Characteristics

Reference	Digital health intervention	Validated	Intervention use for	Technological component(s)	Targeted primary user	User training
Musyoka et al. [25]	24-hour ambulatory blood pressure monitoring system	Validated	Blood pressure data collection	F1 smart wristwatch Blood Pressure Monitoring Mobile Application Cloud Data center Caregiver's smartphone	Expectant mother and the caregiver	Not specified
Lim et al. [24]	Pre-eclampsia Integrated Estimate of RiSk (PIERS) on the Move (PotM)	Not specified	Demographics (gestational age at presentation), clinical signs (blood pressure, SPO2 and dipstick proteinuria), and symptoms (chest pain or dyspnoea, headache or visual disturbances, vaginal bleeding with abdominal pain)	mHealth platform	Mid-level health workers	Yes
Vousden et al. [34]	CRADLE (Community blood pressure monitoring in Rural Africa & Asia: Detection of	Validated	Measures blood pressure, pulse and calculates the mothers risk of shock A traffic light Early Warning System display alerts users to	Microlife CRADLE VSA device	Healthcare providers	Yes

	underlying pre-Eclampsia and shock) Vital Sign Alert		abnormalities in the vital signs results.			
Nathan et al. [26]	Microlife® CRADLE (Community blood pressure monitoring in Rural Africa & Asia: Detection of underLying pre-Eclampsia and shock) Vital Signs Alert (VSA)	Validated	Device accurately measures blood pressure and pulse. Traffic lights within the device help healthcare workers identify women who need additional treatment for these conditions	Microlife® CRADLE VSA device	Healthcare providers	Yes
Feroz et al. [20]	Hypothetical elemonitoring program	Not specified	Blood pressure measurement	-	Pregnant women and caregiver	-
Dunsmuir et al. [19]	MiniPIERS AND FullPIERS models Two versions of the POTM application, 1) Original version (application referred to as POTM), 2)Simplified, community-based version for the Community Level Interventions for Pre-eclampsia cluster randomized controlled trial (application referred to as CLIP	Not specified	Mean BP, SpO2, gestational age, proteinuria, symptoms.	Smartphone, mobile health applications (POTM/CLIP POTM), Research electronic data capture server	Community-based health care providers	Yes

	POTM)					
Jonas et al. [21]	Smartphone-based diagnostic test (Congo Red Dot) for preeclampsia	Validated	urine markers	mHealth solution for administering the Congo Red Dot (CRD) test	Modestly trained personnel	Yes
Thakor et al. [32]	New device (Hypertension Detector for Developing Countries), intraarterial, sphygmomanometers, assorted automatic blood pressure devices, and proteinuria measurement	Not specified	Blood pressure measurement	-	Semi-literate volunteers with minimal training	Yes
Nathan et al. [27]	Microlife 3AS1-2 blood pressure device	Validated	Measures blood pressure	Device	Staff with minimal training	Yes
Nathan et al. [28]	CRADLE Vital Signs Alert (VSA)	Validated	Measures BP and pulse to facilitate prompt recognition of abnormalities in vital signs	Device Traffic light early warning system	Healthcare providers	yes
Payne et al. [29]	miniPIERS risk prediction model	Validated	miniPIERS (measures demographics, symptoms and signs).	Mobile health application	Mid-level health workers	yes
Bellad et al. [17]	CLIP intervention package included miniPIERS model, PIERS On the Move (POM) tool, and	Validated	Measure BP, pre-eclampsia symptoms and dipstick proteinuria	mobile-based CLIP POM mobile health application (app),	Community health workers	yes

	Microlife BP 3AS1-2 device			central REDCap server		
Qureshi et al. [30]	CLIP intervention package included miniPIERS model, Microlife BP 3AS1-2 device and PIERS On the Move (POM) mobile health (mHealth) application	Validated	BP measurement and pulse oximetry	POM mHealth application	Lady health workers	Yes
Khowaja et al [22]	CLIP intervention package PIERS On the Move (POM) mobile health (mHealth) application	Validated	Measure BP, pre-eclampsia symptoms and dipstick proteinuria	POM mHealth application	Community-based health care providers	Yes
Khowaja et al [23]	CLIP intervention package PIERS On the Move (POM) mobile health (mHealth) application	Validated	Measure BP, pre-eclampsia symptoms and dipstick proteinuria	POM mHealth application	Community-based health care providers	Yes
Von Dadelszen et al. [33]	CRADLE BP device, pulse oximetry and TraCer platform, POM mHealth application	Validated	CRADLE VSA semi-automated and validated BP device will be used for all clinical measurements of blood pressure (BP) in the study pulse oximetry POM platform to provide time-of-disease	POM mHealth application	Healthcare providers	Yes

			risk estimates to hypertensive pregnant women using PIERS models			
Abejirinde et al [16]	Bliss4Midwives' (B4M)	Not specified	non-invasive device for measuring haemoglobin via infrared sensors mounted on a finger clip; a self-inflating blood pressure cuff; and an automated reader for urinary protein and glucose through dipsticks.	Data from all diagnostic devices are automatically or manually linked to an android tablet equipped with decision support algorithms	Midwives and community health nurses	Yes
Bellad et al [18]	Community Level Interventions for Pre-Eclampsia (CLIP) Package	Not specified	Measuring blood pressure	mHealth platform	Community-based health activists ASHAs	Not specified
Sharma et al [31]	Community Level Interventions for Pre-Eclampsia (CLIP) Package	Not specified	Blood pressure measurement	PIERS On the Move (POM) mHealth tool, Microlife VSA blood pressure device	Community health workers	Yes

Supplementary File 6 - Outcomes of Digital Health Interventions

Reference	Study Title	Study outcomes pertaining to digital health intervention use	Framework/model used
Maternal and fetal health outcomes (4 studies)			
Nathan et al. (2018) [28]	Early warning system hypertension thresholds to predict adverse outcomes in pre-eclampsia: A prospective cohort study	Of 1547 women with pre-eclampsia, 33.0% of women triggered a red light on admission and 78.6% at their highest BP. Severe hypertension and adverse outcomes were common across yellow and red categories. Comparing admission red to yellow lights, there was a significant increase in kidney injury (OR 1.74, CI 1.31–2.33, trend test p=.003), magnesium sulfate use (OR 3.40, CI 2.24–5.18, p < .001) and CCU admission (OR 1.50, CI 1.18–1.91, p < .001), but not for maternal death, eclampsia, extended perinatal death or preterm delivery.	No framework described
Bellad et al. (2020) [17]	Community level interventions for pre-eclampsia (CLIP) in India: A cluster randomised controlled trial	The primary outcome did not differ between intervention and control arms (adjusted odds ratio (aOR) 0.92 [95% confidence interval 0.74, 1.15]; p = 0.47; intraclass correlation coefficient 0.013). There was no intervention-related safety concerns following administration of either methyldopa or MgSO4, and 401 facility referrals. Compared with intervention arm women without CLIP contacts, those with ≥8 contacts suffered fewer stillbirths (aOR 0.19 [0.10, 0.35]; p < 0.001), at the probable expense of survivable neonatal morbidity (aOR 1.39 [0.97, 1.99]; p = 0.072).	No framework described
Qureshi et al. (2020) [30]	Community-level interventions for pre-eclampsia (CLIP) in Pakistan: A cluster randomised controlled trial.	The primary outcome did not differ between intervention (26·6%) and control (21·9%) clusters (adjusted odds ratio, aOR, 1·20 [95% confidence interval 0·84- 1·72]; p = 0·31). There was reduction in stillbirths (0·89 [0·81-0·99]; p = 0·03), but no impact on maternal death (1·08 [0·69, 1·71]; p = 0·74) or morbidity (1·12 [0·57, 2·16]; p = 0·77); early (0·95 [0·82-1·09]; p = 0·46) or late neonatal deaths (1·23 [0·97-1·55]; p = 0·09); or neonatal morbidity (1·22 [0·77, 1·96]; p = 0·40). Improvements in outcome rates were observed with 4–7 (p = 0·015) and ≥8 (p < 0·001) (vs. 0) CLIP contacts.	No framework described
Bellad et al. (2017) [18]	Maternal and newborn health in Karnataka state, India: the community level interventions for pre-eclampsia (CLIP) Trial's baseline study results	A majority of the women reported institutional deliveries (96.0%), largely attended by skilled birth attendants. The maternal mortality ratio of 103 (per 100,000 livebirths) was observed during this study, neonatal mortality ratio was 25 per 1,000 livebirths, and perinatal mortality ratio was 50 per 1,000 livebirths. Despite a high number of institutional deliveries, rates of stillbirth were 2.86%.	No framework described
Usability and acceptability (5 studies)			

Musyoka et al. (2019) [25]	A 24-hour ambulatory blood pressure monitoring system for preeclampsia management in antenatal care. Informatics in Medicine Unlocked.	Content richness has a slightly positive linear effect on Perceived Ease of Use, while there is a slightly negative relationship between Content Richness and Perceived usefulness. Overall, the 24-hour ambulatory blood pressure monitoring system has shown great potential for actual adoption in healthcare systems in developing countries, given its simplicity and affordability.	Technology Acceptance Model
Lim at al. (2015) [24]	Usability and Feasibility of PIERS on the Move: An mHealth App for Pre-Eclampsia Triage.	Overall, users felt the app was usable using the Computer Systems Usability Questionnaire; median (range) values for Study 1 = 2 (1-6) and Study 2 = 1 (1-7). Usability problems were often related to mobile phone features (eg, scroll wheels, touch screen use).	LambdaNative framework for app development
Nathan et al. (2018) [26]	The CRADLE vital signs alert: qualitative evaluation of a novel device designed for use in pregnancy by healthcare workers in low-resource settings.	Most HCWs perceived the CRADLE device to be easy to use and accurate. The traffic lights early warning system was unanimously reported positively, giving HCWs, Pregnant women and families understanding of vital signs and confidence with decision-making. Some described manual inflation as tiring, particularly when measuring vital signs in obese and hypertensive women (n=4) and a few South African HCWs distrusted the device's accuracy (n =7).	Diffusion of innovation model Three delay model
Thakor et al. (2010) [32]	Hypertension Detector for Developing Countries.	The study developed a prototype of a low-cost device engineered specifically for semi-literate volunteers in developing countries. Preliminary testing has shown reliable hypertension detection and plans have been made for field testing in rural communities this August 2010 in Nepal.	No framework described
Dunsmuir et al (2014) [19]	Development of mHealth applications for pre-eclampsia triage. IEEE J Biomed Health Inform.	The paper outlines the POTM application development process. The paper concludes that the successful development of an mHealth tool, must consider the user and the setting in which it is deployed. CLIP POTM began with a single specification document, but study discovered differing requests from the different countries with their cultural differences, leading to modified application versions for each country.	LambdaNative Framework for developing application
Intervention Feasibility and Fidelity (7 studies)			
Vousden et al (2018) [34]	Evaluation of a novel vital sign device to reduce maternal mortality and morbidity in low-resource settings: a mixed method feasibility study for the CRADLE-3 trial	Intervention was implemented with high fidelity (85% of HCP trained, n=204). Results indicated a good understanding of device use with 75% of participants scoring >75% (n=97; 90% of those distributed). Interviews with HCPs reported that the intervention improved capacity to make clinical decisions, escalate care and make appropriate referrals.	Medical Research Council framework and logic model
Khowaja et al (2016) [23]	The feasibility of community level interventions for pre-eclampsia in South Asia and	The study highlight enabling factors including need for community mobilization, awareness raising programs, institutional support, community safety nets for	Normalization process theory

	Sub-Saharan Africa: a mixed-methods design.	emergency funds, and system integration. Whereas, impeding factors included delays in care seeking, knowledge gaps, lack of trained human resource, cultural myths and misconceptions, high cost of care, and poor health service quality.	
Abejirinde et al (2018) [16]	Pregnant women's experiences with an integrated diagnostic and decision support device for antenatal care in Ghana.	Pregnant women generally valued the availability of diagnostic services at the point-of-care. The intervention made women feel listened to and cared for. Process outcomes of the B4M encounter also showed that it was perceived as improving the skills and knowledge of the health worker, which facilitated trust in diagnostic recommendations and was therefore believed to motivate referral compliance.	No framework described
Sharma et al (2017) [31]	A process evaluation plan for assessing a complex community-based maternal health intervention in Ogun State, Nigeria.	This paper offers robust measures of the process indicators, external validity of conclusions about effectiveness can best be complemented by efficacy studies using a RCT. The methodology allows to examine the internal validity of the efficacy of the intervention by assessing the implementation (quantity and quality) of what is delivered.	Logic model, Diffusions of innovations and realist evaluation theories
Nathan et al (2015) [27]	An accurate semiautomated oscillometric blood pressure device for use in pregnancy (including pre-eclampsia) in a low-income and middle-income country population: the Microlife 3AS1-2	The Microlife 3AS1-2 device achieved an overall B/A grade in pregnancy (including pre-eclampsia), passing the British Hypertension Society protocol requirements and achieving the International Organization for Standardization standard with a mean difference and SD of −3.8±7.3 and −1.5±6.2mmHg for systolic and diastolic pressures, respectively. The device can be recommended for use in pregnancy, including preeclampsia. Also, it fulfils the requirements of WHO for an automated blood pressure device suitable for use in a low-resource setting.	No framework described
Payne et al (2014) [29]	A risk prediction model for the assessment and triage of women with hypertensive disorders of pregnancy in low-resourced settings: the miniPIERS (Pre-eclampsia Integrated Estimate of RiSk) multi-country prospective cohort study.	The miniPIERS model was well-calibrated and had an area under the receiver operating characteristic curve (AUC ROC) of 0.768 (95% CI 0.735–0.801) with an average optimism of 0.037. External validation AUC ROC was 0.713 (95% CI 0.658–0.768). A predicted probability $25% to define a positive test classified woman with 85.5% accuracy. The miniPIERS model shows reasonable ability to identify women at increased risk of adverse maternal outcomes associated with the hypertensive disorders of pregnancy	Three delay model
Jonas et al. (2016) [21]	Smartphone-based diagnostic for preeclampsia: an mHealth solution for administering the Congo Red Dot (CRD) test in settings with limited resources.	The results suggests that combining smartphone-based image analysis with molecular-specific disease features represents a cost-effective application of mHealth that has the potential to fill gaps in access to health care solutions that are critical to reducing adverse events related to PE in resource-poor settings	No framework described