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Feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania

Submission date 21/07/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 21/10/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/02/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aim

In Tanzania, most women attend one antenatal visit during pregnancy, but only half attend four or more. Women value the importance of antenatal care but their choice to attend subsequent visits is highly influenced by the visit's contents and how providers approach and treat them during the visit. M-health solutions, including applications and software, facilitate healthcare workers' ability to diagnose and treat complications early in pregnancy and support them in providing health education. The interactive nature of some mobile solutions facilitates the provision of respectful care and better communication between the woman and the healthcare worker, contributing to continuous engagement with services.

This study will assess the feasibility of a full-scale evaluation to assess the effectiveness of the Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system embedding respectful care prompts to increase the number of antenatal contacts between women and healthcare providers and reduce episodes of severe perinatal morbidity and mortality in Tanzania.

Who can participate?

1. Pregnant women aged 18 old and over, planned to book their antenatal care at study sites
2. Healthcare workers (midwives, nurses, clinical officers, doctors, support staff) providing standard antenatal care who are directly involved in the delivery of the study intervention or who provide antenatal care to women in facilities

What does the study involve?

Healthcare workers providing antenatal care to women and interested to take part in the study will be trained on using PANDA to deliver antenatal care/review antenatal care visits. This change in antenatal care provision will be introduced with a small group of women in two dispensaries in the Manyara region and compared with similar women who received standard antenatal care. The researchers will assess whether women are willing to take part and stay in the research study, whether the intervention works as planned, and the best way of assessing the effect on well-being and antenatal services.

What are the possible benefits and risks of participating?
This study will allow the researchers to understand how this e-health system works to improve antenatal contacts and respectful care in practice, whether changes are needed and if it is possible to do a larger research study to prove that it improves the antenatal experiences and is cost-effective. It is hoped that women in phase 2 of the study will find the antenatal care visit more inclusive, interactive and respectful, but it cannot be guaranteed that it will be.

Where is the study run from?
Haydom Lutheran Hospital, Manyara (Tanzania)

When is the study starting and how long it is expected to run for?
April 2022 to December 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof Tina Lavender (UK)
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
Feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania

Acronym
PANDA

Study objectives
To assess the feasibility of a full-scale evaluation to assess the effectiveness of the Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system, embedding respectful care and empowerment contents to increase the number of ANC contacts between women and health providers and reduce episodes of severe perinatal morbidity and mortality in Tanzania.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/06/2022, Liverpool School of Tropical Medicine Research Governance and Ethics Office, (Room 221, 2nd Floor LLSA, Daulby Street, Liverpool, UK; +44 (0)151 7029396; lstmrec@lstmed.ac.uk), ref: 22-012
2. Approved 02/06/2022, Catholic University of Health and Allied Sciences/Bugando Research and Ethical Committee (CREC) (PO Box 1464, Mwanza, Tanzania; +255 (0)28 298 3384; vc@bugando.ac.tz), ref: CREC/564/2022

Study design
Pre and post-mixed methods feasibility cohort-design two-site study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact detail to request a participant information sheet

Health condition(s) or problem(s) studied
Improving women's attendance and engagement with antenatal care services

Interventions

A mixed-methods 'before and after' study, conducted over 12 months, will assess whether a full-scale trial to test the effectiveness of an intervention to improve antenatal contacts between women and health providers in Tanzania is feasible.

Intervention: Pregnancy and Newborn Diagnostic Assessment (PANDA) includes three components:
1. the PANDA icon-based Android application
2. the Point of Care which includes a solar backpack containing diagnostic tools (device to measure blood pressure, rapid test for HIV, malaria and syphilis, weighting scale, height measurement device, thermometer, and glucometer with strips)
3. the Medical Unit: a java database hosted inside the referral hospital.
The device has been adapted (April 22 to Oct 22) in consultation with stakeholders and service users (Community Engagement and Involvement Group) to include respectful care components and ensure that is relevant and culturally appropriate to the Tanzanian setting.

Implementation of PANDA will follow the following process. Study-specific android mobile tablets will be procured and used solely for this purpose. SIM cards will also be procured to be inserted into the device using PANDA. PANDA app will be installed into these devices for the two facilities and each facility will receive an adequate number of Points of Care to be used during the visit. Airtime will be included to ensure providers have an internet connection to send data to the server. A bar code will also be procured and will be stuck to the woman’s pregnancy booklet. The woman will be reminded to bring her booklet to each subsequent visit as through the bar code the provider will be able to retrieve her data.

Study setting: 2 Dispensaries (Muslur and Endahargaghadat) and 1 referral hospital (Dongobesh Health Centre) in Manyara Region, Tanzania.

The study will be conducted in two phases:
Phase 1 ('Before' intervention: approx. Oct 2022 - Apr 2023) women will receive current antenatal care offered at the dispensaries.
1. To assess the feasibility of data collection, the researchers will approach as many pregnant women as possible planning to book for antenatal at the study site from October to November 2022, aiming to recruit 35 to 40 women per site (maximum 80 total sample for this phase)
2. De-identified records of each visit of women who consented to take part in the study will be extracted prospectively by the researcher. Women will also ask to provide their contact to be followed up after birth. Details on the place of birth, the reason for referral/transfer and pregnancy outcome will be collected for all women irrespective of the place where they give birth. Two weeks post-partum women will be contacted to complete questionnaires to rate the quality of ANC received, including assessing respectful care components and participation in the study. A sub-sample of women (12-16) will also be invited to participate in a qualitative interview.
3. Follow-up for phase 1 participants will be completed by April 2023.
4. Healthcare workers willing to take part in the study will be identified and trained on PANDA at the end of Phase 1 to minimise contamination between the study phases.
5. To allow overall comparison with participants recruited to the study, the researcher will seek permission to extract anonymised data for all women booked for antenatal care from October 2022 to July 2023 from the facility's antenatal register.

Phase 2 ('After' intervention phase: approx. May 2023 - Nov 2023); women will continue to receive current antenatal care and the intervention will be introduced in both facilities.
To assess the feasibility of data collection, acceptability of the intervention and recruitment and retention of participants as researchers will:
1) Approach as many pregnant women as possible planning to book for antenatal at the study

site from May to June 2023, aiming to recruit a further 35 to 40 women per site (maximum 80 total sample for this phase).
2) Participants who consented to take part in the study will receive every ANC (first and subsequent visits) through PANDA until birth, and an electronic medical record will be created and stored at the Medical Unit.
If the woman had already had a previous visit without PANDA, data about her previous visits will be extracted from the antenatal register and the antenatal card and input into PANDA. For any missing information, the woman will be asked at her subsequent visits.
3) Women will also ask to provide their contact to be followed up after birth. Details on the place of birth, the reason for referral/transfer and pregnancy outcome will be collected for all women irrespective of the place where they give birth. Two weeks post-partum women will be contacted to complete questionnaires to rate the quality of ANC received through PANDA, including assessing respectful care components and participation in the study. A sub-sample of women (12-16) will also be invited to participate in a qualitative interview.
4) Data for recruitment and the number of participants who stay in the study until completion will be collected
5) Non-participants observation to explore context, process, behaviour and communication between the healthcare workers and the woman during the provision of antenatal care through PANDA will be conducted.
6) Healthcare workers using the PANDA application and the Medical Unit will be invited to an interview (up to 20) at the end of the study.
7) Assess the wider impact on services and care in facilities by inviting all health workers providing antenatal care to women, but not directly involved in delivering the intervention, to complete a short questionnaire at the end of the study.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system

Primary outcome measure
1. Recruitment and retention of women in the study:
1.1. Women who fulfil the eligibility criteria, women who are invited to participate in the study, those recruited and any participants who leave the study before completion, recorded in a participant log at the following time points:
1.1.1. Control group: 80 pregnant women recruited at their first antenatal visit or in subsequent visits (November 2022)
1.1.2. Control group follow-up: 80 pregnant women followed up two weeks post-partum (Dec 22 – March 23)
1.1.3. Intervention group: 80 pregnant women recruited at their first or subsequent visits (April 23)
1.1.4. Control group follow-up: 80 pregnant women follow up two weeks post-partum (May – September 23)

1.2. Reasons for non-recruitment (e.g. refusal to participate, or do not consent to take part, language barrier) when approached at their first or subsequent antenatal visit at the facilities and recorded in the screening log. Permission will be sought to collect data on reasons for non-

participation from women and health workers who have provided contact details but declined to take part.

1.3. Reasons for withdrawal and loss to follow-up documented in participant log during the course of the study

Secondary outcome measures

1. Usual care (baseline – 6 months) demographic and clinical data routinely collected in the ANC register, at the first antenatal appointment, including age, civil status, address, education, obstetric data including last normal menstrual period, number of previous pregnancies and their outcomes, previous obstetric complications, medical conditions (including chronic and hereditary diseases), vaccination (including tetanus Toxoid), screening for Syphilis and HIV, records of blood pressure, haemoglobin level, fundal height, albumin in the urine (urine dipstick) and physical examination.
80 electronic case reports (one per participant) will be created in REDCap following enrolment into the study. Demographic, obstetric and medical details and screening results from the ANC register for first and subsequent visits and birth outcomes of all recruited women will be extracted from the register.

2. PANDA: (Implementation period: April – September 2023)
80 PANDA medical records (one per participant enrolled) will be created following enrolment into the study.
Demographics and obstetric details will be automatically collected through PANDA which creates an electronic medical record for each woman visited. The application includes 4 modules: personal information, medical history, screening and education. Personal information includes age, ethnicity, spoken language, address/location of the visit, marital status and education. Medical history includes details about previous and index pregnancy, including place of birth, vaccinations, the onset of labour, mode of birth, maternal and infant outcomes, and antenatal and postnatal complications. The screening section includes measurement values (height, weight, blood pressure and pulse, temperature, fundal height), screening for UTI, other infections, respiratory problems and TB, and rapid-test results for HIV, syphilis, malaria, gestational diabetes, and anemia. It also includes monitoring of the baby, including fundal height measurement, and recording of fetal movements. The education section is meant to give advice to the woman on hygiene, malaria prevention, danger signs during pregnancy, childbirth planning, breastfeeding, family planning and subsequent visits. Additional data, including COVID (testing, vaccination) have been added during the adaptation phase. Data will be collected at recruitment, and for each subsequent visit scheduled with the woman. A de-identified dataset of all women who consent to share their data will be extracted from the Medical Unit for analysis. During the implementation of PANDA, healthcare workers will input women's obstetric history and details of current pregnancy, including data of screening (height, blood pressure, weight etc) and diagnosis (HIV, malaria, syphilis) into PANDA. The same data will be recorded in the existing register held at the dispensary to prevent gaps in the data routinely collected.

3. Anonymised routinely collected clinical data for all women attending ANC in the included facilities during the study period will be extracted from the ANC and birth registers, using an electronic Case Report Form, created in REDCap. This will include maternal age, county of residence, occupation classification, medical and obstetric history (previous pregnancies, mode of birth) and index pregnancy data including HIV status, syphilis, malaria, anemia and tetanus vaccination, n. of ANC visits, and referrals. This will permit the assessment of the feasibility of comparison and assessment of the potential for selection bias in the sample taking part in the research. The number of anonymised records of all women booked for ANC in the included facilities between November 22 to September 23.

4. Acceptability of study processes and the intervention (phase 2) captured by questionnaires and semi-structured face-to-face (or telephone) interviews conducted two weeks postnatally with:
4.1. Women participating in the study during phase 2 (N up to 80; up to 40 per facility)
4.2. Healthcare workers using PANDA to deliver antenatal care (up to 10) at the end of phase 2 (August – September 2023)

5. Uptake and the additional impact of the intervention on the practice and environment of care captured between April/September 2023 by:
5.1. An intervention log completed by healthcare providers delivering PANDA and the one managing the Medical Unit / or extract from PANDA after each antenatal care visit conducted with enrolled women, will summarise all study-related activities to determine what was done, when and by whom. For HCP using the PANDA app and Point of Care, this will include the number of visits conducted and sent to the server, the average length of visits, and the number of referrals. For HCP managing the Medical Unit, this will include record review, action taken on women with complications etc.
5.2. A short questionnaire survey of health workers providing antenatal care but not directly involved in delivering the intervention (using PANDA) will be completed at the end of phase 2 (August – September 2023)
5.3. Environment, provision of information, interaction, screening and diagnosis and communication between the woman and provider measured using the Quality of Prenatal Care Questionnaire, a 46-item tool will be used to measure women's rating of the quality of antenatal care at the following time points:
5.3.1. Control group follow-up: number of women completing the QPCQ two weeks postnatally (Dec 22 to April 23)
5.3.2. Intervention group follow-up number of women completing the QPCQ two weeks postnatally (May – September 23)
5.4. The Person Centre Prenatal Care Scale, a 34-item tool will be used to assess the respectful care components including the provision of dignified care, adequate communication and trust between woman and provider at the following time points:
5.4.1. Control group follow-up: number of women completing the PCPCS two weeks postnatally (Dec 22 to April 23)
5.4.2. Intervention group follow-up: number of women completing the PCPCS two weeks postnatally (May – September 23)
5.5. A short questionnaire asking women to rate their experience to take part in the study, including engagement with the PANDA e-health system will be conducted at the following time points:
5.5.1. Control group follow-up: number of women completing the short questionnaire two weeks postnatally (Dec 22 to April 23)
5.5.2. Intervention group follow-up: number of women completing the short questionnaire two weeks postnatally (May – September 23)

6. Health economics: data will be captured to identify the key resources associated with the intervention including:
6.1. Human resources: the intervention log as described above will be used to identify persons and time spent attending training and conducting visits.
6.2. healthcare providers who implement the PANDA system will be asked to complete a survey to capture their perspective on the impact of the system on the time it takes to deliver antenatal care, any increases in staff provision required, and whether they think using the

system is manageable in current workloads.
Number of healthcare workers using PANDA, completing the survey by the end of phase 2 (August – September 2023)

Overall study start date
01/04/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Women:
1. Pregnant at the time of recruitment
2. Attending care or planning to book care in study facilities in the Manyara region
3. Age 18 years old and over at the time of recruitment
4. Willing and able to participate

Healthcare workers (Nurses, midwives, doctors, support workers):
1. Delivering ANC care in primary facilities and district hospitals in the Manyara region
2. Delivering ANC in study facilities using PANDA
3. Managing PANDA medical unit at the district hospital in the Manyara region

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Upper age limit
49 Years

Sex
Both

Target number of participants
Women total sample up to 160 participants, health workers up to 20

Total final enrolment
160

Key exclusion criteria
Pregnant women:
1. With established obstetric complications as identified by the clinical team
2. Aged 17 years old and under

Healthcare workers:
1. Only providing intrapartum and postnatal care

Date of first enrolment
25/07/2022

Date of final enrolment
30/10/2023

Locations

Countries of recruitment
Tanzania

Study participating centre
Haydom Lutheran hospital
P.o.box 9000 Haydom
Mbulu
Manyara
Manyara
Tanzania
2302

Study participating centre
Muslur Dispensary
Mbulu DC
Manyara
Manyara
Tanzania
2302

Study participating centre
Maghang Dispensary
Mbulu Manyara
Manyara
Tanzania
2302

Study participating centre
Dongobesh Health Centre
Mbulu DC Dongobesh Dongobesh
Mbulu
Manyara

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2302

Sponsor information

Organisation
Liverpool School of Tropical Medicine

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Sponsor type
University/education

Website
http://www.lstmed.ac.uk/

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination of study progress and results will include academic and non-academic means, including conference presentations, high-impact academic journal articles, social media and newsletter, among others. Research team and CEI members will both be involved in the dissemination. Findings will be presented during international multidisciplinary meeting including LAMRN conference, GLOW Conference, ICM etc. Papers will be submitted to open-access journals and will follow the Uniform Requirement for Manuscripts Submitted to Biomedical Journal and ensure equitable authorship between countries, including co-authorship of CEI members. Established linked with stakeholders and CEI, combined with our experience in writing for service users and the public, will results in the production of lay material for website, social media and newsletters. Feedback to participants and local stakeholders is of key importance, therefore we will organise a local dissemination workshop in Manyara at the end of the study. Participants, healthcare workers, district health officer, hospital managers, MOH, stakeholders and communities will be invited to attend.
Study members (those listed in this protocol and data collectors) will adhere to the following:
1. No raw data can be shared with anyone outside the core team prior to publication
2. Hard copy or electronic copies of any results cannot be disseminated beyond the immediate research team prior to publication
3. Results cannot be disseminated (written or oral) to external audiences without approval from the NIHR; this can be done through the UK team but requires 3 weeks' notice
4. Any press releases should be notified to the NIHR 14 days in advance of them happening
5. All publications should have a statement outlining how the data can be accessed
6. All publications must contain the following statement: "This research was funded by the National Institute for Health Research (NIHR) (NIHR unique award identifier) using UK aid from the UK Government to support global health research. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR or the UK Department of Health and Social Care".

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.0	14/07/2022	20/10/2022	No	No