Study Protocol

Trial Title: Adaptation and feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania

Clinical trials.gov number: XXXXX

Protocol Version: Protocol Version 4 (14 July 2022)

Chief Investigator:	Dame Tina Lavender Professor of Maternal and Newborn Health Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L35 QA Telephone: +44 07874852886 E-mail: tina.lavender@lstmed.ac.uk
Joint Chief Investigator	Dr Paschal Mdoe Director of Hospital Services and Head of Research Haydom Lutheran Hospital, Tanzania E-mail: pfmdoe@gmail.com
Senior Programme Manager:	Mr Roy Daley Telephone: +44 151 832 1691 E-mail: roy.daley@lstmed.ac.uk
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Versions

Version	Key changes	Date
0.1	First draft	29.11.2021
0.2	Background and objectives	08.12.2021
0.3	Structure and flow (signposting section about eligibility and recruitment)	16.12.2021
0.4	Details about facilities, completion of questionnaires	04.01.2021
0.5	Improve clarity of design section	06.01.2021
0.6	Review recruitment section and questionnaires	18.01.2022
1	First official version	24.01.2022
2	Second official version	16.03.2022
3	Third official version Change of AE and SAE based on LSTM SOP.	14.04.2022
4	NIMR-IRB review	14.07.2022

Chief Investigator

I give my approval for the attached protocol entitled "Adaptation and feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania" Version 4 dated 14.07.2022

Name: Prof Dame Tina Lavender

Signature: 

Date: 14th July 2022

Dr Paschal Mdoe

Signature: 

Date: 14th July 2022

Site Principal Investigator Statement of Compliance:

I have read the attached protocol entitled "Adaptation and feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania " Version 4dated 14.07.2022 and agree to abide by all provisions set forth therein.

I agree to comply with the conditions and principles of Good Clinical Practice as outlined in the European Clinical Trials Directives 2001/20/EC and the GCP Directive 2005/28/EC and will ensure all local regulatory approvals are obtained prior to the case recruitment.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

Name: Dr. Paschal Mdoe

Signature: 

Date: 14th July 2022

Table of contents

1. Key contacts

Insert full details of the key research project contacts including the following; please add/remove headings as necessary.

Chief Investigator	**Dame Tina Lavender** Professor of Maternal and Newborn Health Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L35 QA Tel: +44 07874852886 E-mail: tina.lavender@lstmed.ac.uk
Sponsor	**Denise Watson** Governance and Ethics Assistant Research Governance and Ethics Office Liverpool School of Tropical Medicine Room 221, 2nd Floor LLSA, Daulby Street, Liverpool Tel: 00 44 151 702 9396 Email: denise.watson@lstmed.ac.uk
Funder(s)	**Rozz Bloom** Global Health Research Programme National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: nihrglobalhealth@nihr.ac.uk
Programme Manager	**Roy Daley** Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L35 QA Tel: +44 151 832 1691 Email: roy.daley@lstmed.ac.uk
Statistician	**Maia Lesosky** Professor of Biostatistics and co-director GHTU Liverpool School of Tropical Medicine Email: maia.Lesosky@lstmed.ac.uk
Independent Scientific Committee	

2. Research Team and Collaborators

Institution	Research member	Expertise
Liverpool School of Tropical Medicine	Prof Dame Tina Lavender	Prof of Maternal and Newborn Health
	Prof Maia Lesosky	Prof of Biostatistics and co-director GHTU
	Dr Tracey Mills	Senior Lecturer in Maternal and Newborn Health and Capacity Strengthening Lead
	Dr Carol Bedwell	Senior Lecturer in Midwifery and Global Women's Health & CEI Lead
	Dr Natalie Tate	Post-Doctoral Research Associate
	Valentina Actis Danna	Research Associate
	Shangwe Kibona	PhD student / Based in Tanzania
The University of Manchester	Dr Elizabeth Camacho	Senior Research Fellow in Health Economics
The University of Liverpool	Prof Andrew Weeks	Prof of Obstetrics and Gynaecology
Catholic University of Health and Allied Sciences, Mwanza, Tanzania	Dr Rose Laisser	Senior Lecturer in Midwifery / Dean
Haydom Lutheran Hospital, Tanzania	Dr Paschal Mdoe	Director of Hospital Services & Head of Research
Muhimbili University of Health Allied Sciences (Tanzania)	Happiness Saronga	Lecturer in Health economics
Kamuzu University of Health Sciences	Milcah Mwamadi	CEI co-lead
Terre Innovative Healthcare S.r.l (PANDA developer)	Dr Giovanna Stancanelli	CEO / MD, public health specialist

3. Abbreviations

AE	Adverse Event
ANC	Antenatal care
CEI	Community Engagement and Involvement
CHW	Community Health Workers
CTIMP	Clinical Trial of an Investigational Medicinal Product
DHS	Demographics and Health Survey
FGD	Focus Group Discussion
HCP	Health Care Professional
HIC	High Income Countries
ICT	Information and Communication Technology
ISRCTN	International Standard Randomised Controlled Trial Number
LSTM	Liverpool School of Tropical Medicine
Mhealth	Mobile Health
MoHSW	Ministry of Health and Social Welfare
PANDA	Pregnancy and Neonatal Diagnostic Assessment
PI	Principal Investigator
PIS	Participant Information Sheet
PNC	Postnatal Care
QPCQ	Quality of Prenatal Care Questionnaire
REC	Research Ethics Committee
RMC	Respectful Maternity Care
SAE	Serious Adverse Event
TWG	Technical Working Group
WHO	World Health Organisation
WHEM	Women's Health Empowerment Model
WRA	White Ribbon Alliance

4. Study synopsis

Title of Clinical Trial	Adaptation and feasibility of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania
Sponsor	Liverpool School of Tropical Medicine, LSTM
Clinical Trials Number	
Area of Investigation	Antenatal care
Primary Objective	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 contents to increase the number of ANC contacts between woman and health provider and reduce episodes of severe perinatal morbidity and mortality in Tanzania.
Study Design	1. Adaptation of PANDA e-health system. 2. Feasibility study
Outcome Measures	Primary • Recruitment and retention of women in the study • Fidelity of adapted PANDA e-health system • Acceptability of PANDA among women and health providers • Resources involved in delivering intervention Exploratory outcomes • Proportion of women having ≥ 4 antenatal contacts • Maternal satisfaction with prenatal care received through PANDA • Severe perinatal morbidity (NICU admission) and mortality outcomes (stillbirth, early neonatal death) • ANC referrals and intrapartum transfer rates
Sample size	Feasibility study: 40 women per phase, per site (160 women);
Summary of Eligibility	Inclusion - All pregnant women (aged 18 and above) booked or planning to start their ANC at the study sites regardless of gestation and parity. Exclusions - Women unable /declining to participate
Intervention	PANDA E-health system embedding respectful care components (Mobile application, Point of Care with diagnostic tools, Web-based medical Unit)
Procedures, screening, enrolment	All pregnant women attending antenatal care in target facilities
Treatment Period	1. Adaptation of PANDA e-health system (12 months) 2. Feasibility study: standard care (2 months + follow up); intervention (2 months + follow up) total: 12 months.
End of Trial	6 months after intervention period
Criteria for withdrawals	Withdrawal of woman's consent

5. Lay summary

Background: In Tanzania, most women attend one antenatal visit 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 approached and treat them during the visit.
In recent years, applications and software have developed to support provision of healthcare services and newborn care. Through these e-health solutions health professionals can be facilitated in the diagnosis and treatment of complications early in pregnancy and are supported in providing health education. The interactive nature of some mobile solutions facilitates provision of respectful care and better communication between the woman and the health professional, encouraging continuous attendance to visits.
Aim: To assess the feasibility of a full-scale evaluation to assess the effectiveness of the Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system including respectful care prompts to increase the number of antenatal contacts between woman and health provider and reduce episodes of severe perinatal morbidity and mortality in Tanzania.
Methods: The study has 2 phases: 1) adaptation and refinement of the e-health system and 2) feasibility study. 1) During the adaptation/development phase we will work with healthcare providers, service's users groups and stakeholders to a) observe current ANC practice in study sites; b) tailor PANDA to the study context, including embedding respectful care component into PANDA, c) explore acceptability and practicalities of PANDA use through focus group discussions with women and healthcare professionals; d) test appropriate data collection processes in the local setting. 2) In the feasibility phase we will conduct a pre and post cohort design to allow implementation of the intervention in two sites. We will a) assess usability and feasibility of the PANDA e-health system to provide high quality ANC, according to national and WHO recommendations; b) assess the fidelity to, and acceptability of the respectful care components embedded into the e-health system; c) assess the feasibility of a full-scale trial, to assess the effectiveness of the intervention to support early and sustained access to ANC and improve birth outcomes for women; d) survey health facilities to provide information on site clusters and confirm sample size estimates for the evaluation phase (clustered trial); e) explore and observe caregivers' experiences of using the PANDA system and perception of impact on service delivery, job satisfaction, decision-making, teamwork; f) measure women's satisfaction of antenatal care received; g) identify resources associated with PANDA use and its implementation.
Ethics: Approval will be sought at LSTM and from the Ministry of Health and the National Institute for Medical research in Tanzania, participating University, district health offices and all facilities involved.
Analysis: *Observations* will be coded and analysed through the framework approach. *Focus group discussion and interviews* will be recorded, translated and transcribed verbatim and analysed through the framework approach. *Personal and clinical data* will be compared descriptively, using frequencies, and percentages for categorical variables and means, standard deviations, medians and ranges for numerical variables. Analysis will focus on the estimation of confidence intervals for difference between the groups and the estimation of variances to inform the design of the full-scale trial. Women's scores for *quality of antenatal care* will be compared among groups. *Health economics:* intervention log and facility surveys will be used to map resources necessary to deliver the intervention.
Sample size: During adaptation, maximum variation sample is adopted to include all relevant groups (healthcare workers, managers, district health officers, women) stakeholders and service users to ensure acceptability and discuss PANDA implementation strategy. We will conduct observations of current ANC (3 in each facility, 6 in total) and six FGDs (3 with women, 24-30 participants; 3 with HCP, 18-24 participants) to adapt PANDA to the Tanzanian setting. In the piloting phase, sample size is determined pragmatically according to accepted criteria for feasibility studies. 160 women (40 women per phase per site) will be included in each site. 20-30 interviews will be conducted with health providers from primary facilities and the referral unit.

Impact: The study will inform the implementation of the clustered trial testing the effectiveness of PANDA e-health system to increase antenatal contact between women and providers and reduce episode of severe perinatal morbidity and mortality.

6. Background

Globally, 2 million babies were stillborn and 2.4 million died within 28 days after birth in 2019 (1). Ninety-eight percent of these perinatal deaths occur in LMICs, with Sub-Saharan Africa and South Asia bearing the greatest burden (2). The death of baby before or soon after birth is a traumatic event for parents, families and communities. Long-lasting disenfranchised grief, physical and psychological distress are often experienced by parents(3).

Several studies have demonstrated an increased risk of perinatal death among women who did not attend antenatal care (4, 5), had less than four ANC visits or a later initiation (6-9). Antenatal care (ANC) has been associated with improved pregnancy outcomes, when commenced early in pregnancy and continued through to birth (6, 10). For instance, during ANC women are offered testing and diagnosed for infections, including syphilis and HIV, blood pressure is monitored as well as prevention and treatment of mother-to-child transmission of HIV. Antenatal care also offers the opportunity to educate women about pregnancy, birth and newborn care and to develop an individualised birth plan which consider personal needs and wishes, resulting in a positive experience of care for the woman, the baby and her companion (11).

Attending four or more ANC contacts is one of the targets of the Every Newborn Collaboration for 2025 (12). Since 2016, WHO has moved from the Focused Antenatal Care Model (minimum of 4 visits) to recommending at least eight ANC contacts throughout pregnancy(11). The new model focuses on the provision of respectful, individualised and woman-centred care. This has also resulted in reconsidering the encounter between the woman and the provider as “contact” to account for the interpersonal relationship between the two and to allow this “contact” to take place whenever is suitable (facility, home, community etc.). Evidence has also demonstrated that more encounters during pregnancy are likely to improve safety through detection of complications as well as facilitate rapport building, trust and communication, ultimately accelerating provision of respectful and supportive care to the woman (11).

Tanzania bears an extremely high burden of perinatal deaths, with an estimated 40,480 stillbirth and 42,814 neonatal deaths annually, corresponding to a stillbirth rate of 18.8 per 1000 birth and a neonatal mortality rate of 20.1 per 1000 live birth respectively (2). According to the most recent Demographic and Health Survey (DHS) (13), 77% of stillbirth and almost 60% of newborn deaths occur to women living in rural areas. More than 30% of perinatal deaths (including stillbirth and early newborn deaths) happened to younger mothers (age 18-25) in their first pregnancy, and a considerable proportion (20%) belongs to the lowest level wealth quintile (13).

In Tanzania, most women attend one ANC visit (98%) but only half (51%) attend four or more. Less than a third (24%) commenced antenatal care in their first trimester and 26% did not seek care until at least the sixth month of pregnancy. Urban women tend to attend 4 or more visits and commence their ANC earlier than rural women (13). Perception of pregnancy as a normal physiological and social life event, not affecting the woman’s wellbeing, and previous experience of healthy pregnancies provides no reason for early visits, until threats or complications arise (14). Some women might also not be aware of when to start and how many visits are recommended (15). Among families of low socio-economic status, and those living distant to the facility, indirect costs for transport and drugs can deter attendance or attending completely (16). Additional barriers to early initiation include women limited decision-making power, cultural beliefs, lack of male partner

support and fear of HIV testing and disclosure. Further attendance of subsequent visits is also conditioned by previous experience of care received (14).

6.1 Previous work

During the NIHR Group on Stillbirth prevention and Management in Sub-Saharan Africa (16/137/53) we conducted exploratory work in Tanzania and Zambia around women's experience of maternity care and revisited the three Delays Model (17) to understand how delays influence intrapartum transfers and care pathways. Qualitative findings confirmed women perceived barriers outweighed the benefits of antenatal attendance, describing negative past experience, disrespectful care, difficulties accessing transport, long waiting times, lack of privacy during visits and poor environment as deterrents to attendance (18). Moreover, our meta-synthesis indicated that antenatal care visits were not always individualised and did not account for women's level of empowerment in planning for labour and childbirth (19).

These findings informed the design of a discreet choice experiment to elicit women's preference of ANC, with domain and attributes informed by our evidence and input from stakeholders and CEI groups (publication under review). Quantitative data from 254 women (of which half were living in a rural areas) confirmed that proximity to the clinic and providers' respectful manners were priority influences. 'Think Aloud' interviews revealed that lack of engagement of younger, less educated women and those living in rural areas compromised decision making, birth preparedness and understanding of complications. Relational care was not prioritised and communication between clinical teams and community and tertiary facilities was often sub-optimal. As reported by others (20) women's uptake of ANC services is influenced by good quality and respectful care, building trusting relationships with healthcare workers, continuity of care and flexible clinic appointments. These components are critical to contribute to the reduction of maternal and perinatal morbidity and mortality in LMICs.

6.2 E-health in maternal and newborn care

In recent years, e-health solutions delivering maternal and newborn health services have spread in many countries. Mobile health or mHealth refers to the use of a mobile phone or an electronic device and other Information and Communication Technology (ICT) to support and deliver healthcare services (21). Investments in broadband and increase penetration of mobile phones in LMICs, offer the opportunity to reach individuals living in context with limited infrastructure, and/ or poorly educated (22). Through Mhealth other important barriers such as geographical distance, social marginalisation and financial issues can also be addressed (22).

Twelve common m-health and ICT applications have been identified, covering various aspects of service delivery, including data collection and reporting, creation of electronic health records, promotion of education and behaviour change, improving communication among providers and client-providers interaction, enabling sensors and point-of-care diagnostics and facilitating supply chain, human resources and logistics management (23). M-health interventions targeting pregnant and postnatal women through messaging and alerting, have shown to improve antenatal and postnatal service utilisation, increase attendance of subsequent visits and promote health-seeking behaviours (24).

A systematic review of 14 studies implementing Mhealth in LMIC, mapped various Mhealth solutions to assess their effectiveness (21). For instance, mobile applications have enabled collection and storage of women and newborn health details, immediately available for diagnosis and treatment. Communication between facilities, through SMS, facilitated smooth referrals and has helped in the transmission of test results between facilities and clients, reducing the turnaround time for diagnosis and treatment of HIV in infants. M-health has also been used as an educational tool to improve

midwives' clinical practice, facilitate problem-solving and access clinical and peer information resources (21).

Pregnancy and Newborn Diagnostic Assessment (PANDA) is a telemedicine system enabling practitioners, allied healthcare professionals and Community Health Workers (CHW) to provide antenatal care to vulnerable populations and people living in LMICs (25). The system consists of a smartphone technology attached to a portable set of diagnostic tools, connected remotely to a centralised system (Medical Unit) (Figure 1) (25).

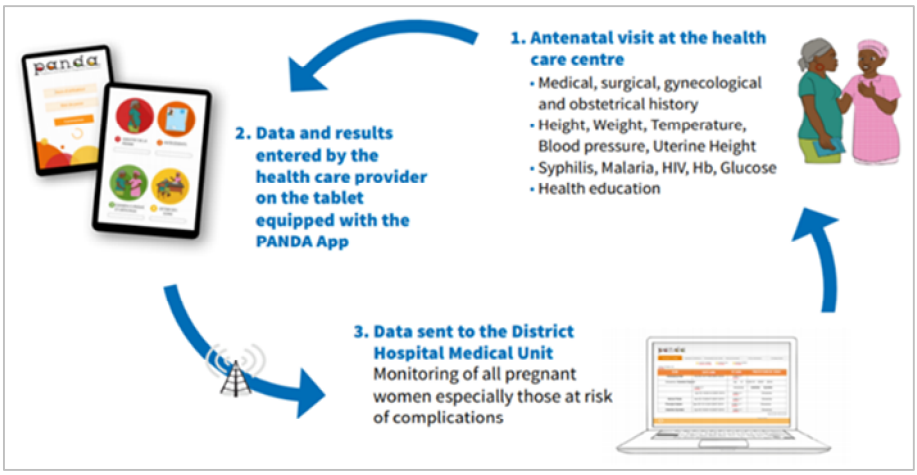

Figure 1 – PANDA e-health system

Its user-friendly interface, structured in modules allows collection of personal data and obstetric information, testing and identification of risk factors and complications and remote supervision. Prompts around birth preparedness and complication readiness, enhance opportunities for health education. A pictorial design encourages active participation and interaction between the woman and the provider. Potential PANDA advantages include reduction of health provider errors and omissions by standardising ANC pathways in line with local MoHSW and WHO guidelines; timely identification of complications; respectful communication between health providers, pregnant women, and companions; remote supervision and coaching of health providers; automated electronic medical records for each woman; and mapping based on geographic location, stage of pregnancy and risks.

Small feasibility studies have been conducted in Burkina Faso (26), Madagascar (27) and Italy (28), in addition to an unpublished non-randomised study carried out in South Tanzania (25). Piloting (28) with 150 asylum seekers arrived in Italy revealed acceptability of the system, in terms of length of visit and quality of health education on nutrition, personal hygiene and family planning. However, involved participants demanded more clarity around birth details, signs and symptoms of labour and complications requiring hospitalisation. Overall satisfaction index was high among women, whereas evaluation of caregivers' experiences was not included, despite informal appreciation of the system during informal meetings. In Madagascar (27), PANDA enabled collection of an extensive amounts of personal and medical data and creation of individual file for 100 pregnant women. The in-built system of flagging abnormal results to the provider, during the visit, enabled referral and follow up in subsequent visits. An intuitive interface enabled low level providers to conduct the visits and collect information. It was reported that both women and HCW were satisfied with the system, although details about how satisfaction was measured were limited. The study did not include a control group, nor explored acceptability of the e-health system among providers and clients. Qualitative findings from Burkina Faso (26) confirm women's preference to attend a prenatal clinic delivered through PANDA, for improve communication and interaction with the provider, the quality of health education, and the possibility of being tested free of charge and receive immediate results. The latter was also

appreciated by CHW for their ability to provide a good service and minimising errors in data collection (26).

These studies suggest PANDA's potential to provide a comprehensive antenatal service to pregnant women by lower cadre of healthcare providers, including identification of risky pregnancies and follow up, and delivering of health education. Versatility and portability of the system's components could also facilitate the implementation of four or more antenatal contacts. This would align with WHO recommendations and improve access to care, one of the key influencers identified in our study. Robust pre-evaluation, comparing PANDA against standard care, measuring satisfaction and acceptability among women and healthcare professionals and assessing recruitment and retention, is currently lacking. Furthermore, to date, there have been no economic evaluations of PANDA use. Terre Innovative (PANDA developers) recommend an update of the PANDA system to incorporate new ICT as well as to tailor PANDA to context-specific elements of the implementation site. This will also provide an opportunity to incorporate relational care through specific prompts and instructions around respectful attitudes and processes, currently absent or less obvious in PANDA.

7. Study aim and objectives

7.1 Aim

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 woman and health provider and reduce episodes of severe perinatal morbidity and mortality in Tanzania.

7.2 Objectives

1. Phase 1: Development and adaptation of the PANDA e-health system embedding respectful contents to be context-specific and tailored to the Tanzanian setting
   - 1.1 To explore the current ANC practice in Tanzania to inform revision and update of the PANDA e-health system.
   - 1.2 To revise the PANDA e-health system to be context-specific according to national and WHO recommendations.
   - 1.3 To explore HCP and women's acceptability of PANDA e-health system.

2. Phase 2: Feasibility of the adapted PANDA e-health system. The objectives are:
   - 2.1 To assess recruitment and retention of women into the study
   - 2.2 To explore the acceptability, implementation and uptake of PANDA app
   - 2.3 To assess the fidelity of the adapted PANDA e-health system
   - 2.4 Explore impact of the research on practice / services and delivery of the intervention
   - 2.5 To explore caregivers' experience of using the PANDA system
   - 2.6 To adapt and validate an appropriate tool to measure women's rating of quality of antenatal care and respectful care.

8. Theoretical underpinning

This study is underpinned by the MRC updated Framework for development and evaluation of complex intervention(29), the new WHO monitoring framework for ANC(30), the WRA Respectful Maternity Care Charter(31) and the Women Health Empowerment Model (WHEM)(30).

The MRC updated Framework(29) (Figure 2) provides guidance through main phases of complex intervention research. Six core elements (blue circle – figure 2), indicated by the Framework, will be carefully considered at each stage of the research development and evaluation including: context, programme theory, stakeholders and service users' engagement, key uncertainties, refinement of intervention and economic considerations.

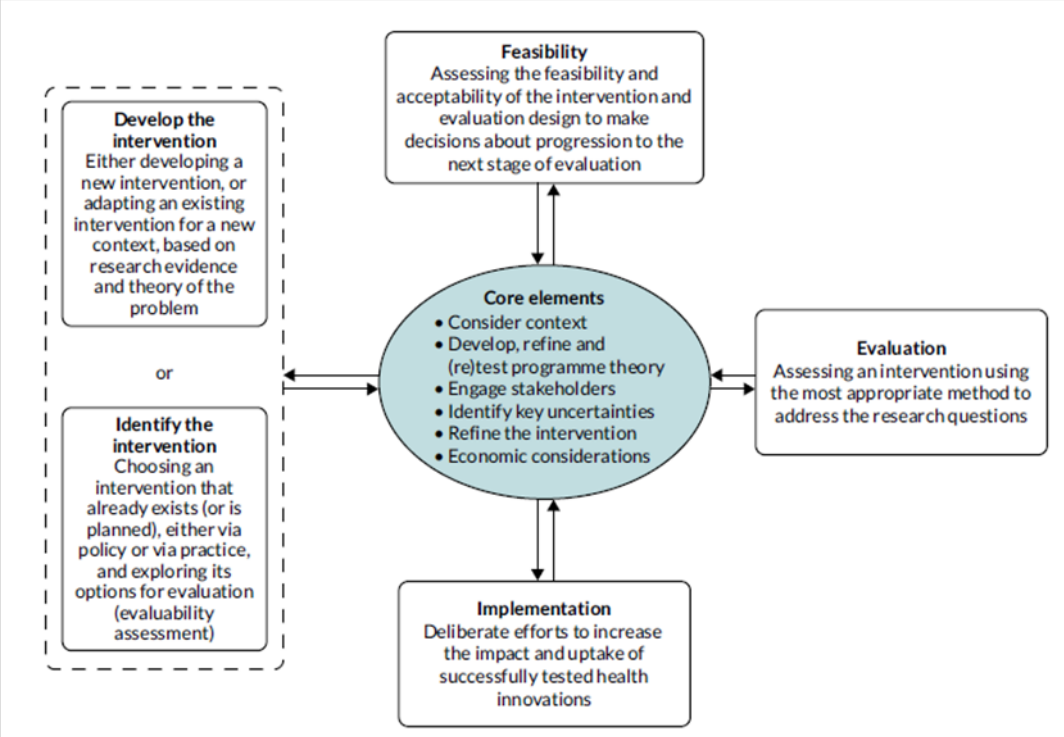

Figure 2 – MRC updated framework for evaluation of complex intervention

The WHO new recommendations on ANC (32) were used to design PANDA as a standard ANC visit with comprehensive recording of personal and clinical information, screening and diagnosis, and provision of health education to the woman and her companion. Prompts within the modules enable interaction and personalisation of care plans(25). These guidelines will also underpin the PANDA update, planned in the pre-feasibility phase.

The new WHO monitoring framework for ANC (30) (Figure 3) was developed to assist the implementation of the WHO new ANC model, including contents and care processes.
This framework will guide inclusion of key indicators in the current study and the future evaluation trial to facilitate comparability of outputs and outcomes at national and global levels.

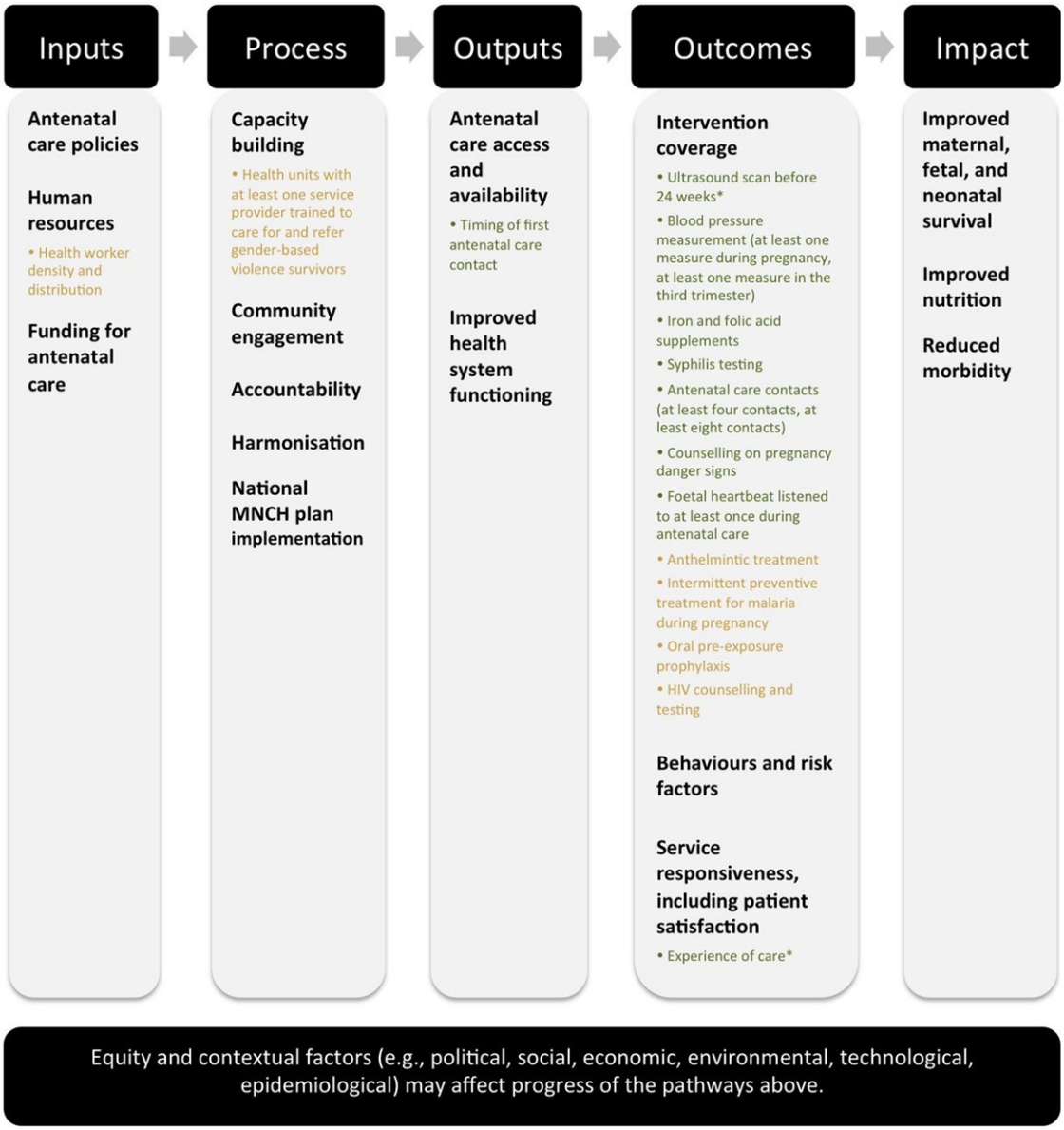

Figure 3 – WHO Monitoring framework depicting core and context-specific indicators for the WHO ANC model [core indicators are in green]

The Respectful Care Charter (31) will guide identification of respectful care elements and prompts to be added to PANDA. The Women Health Empowerment Model (19) (Figure 4) depicts key components that should be considered in the formulation of individualised birth plans.

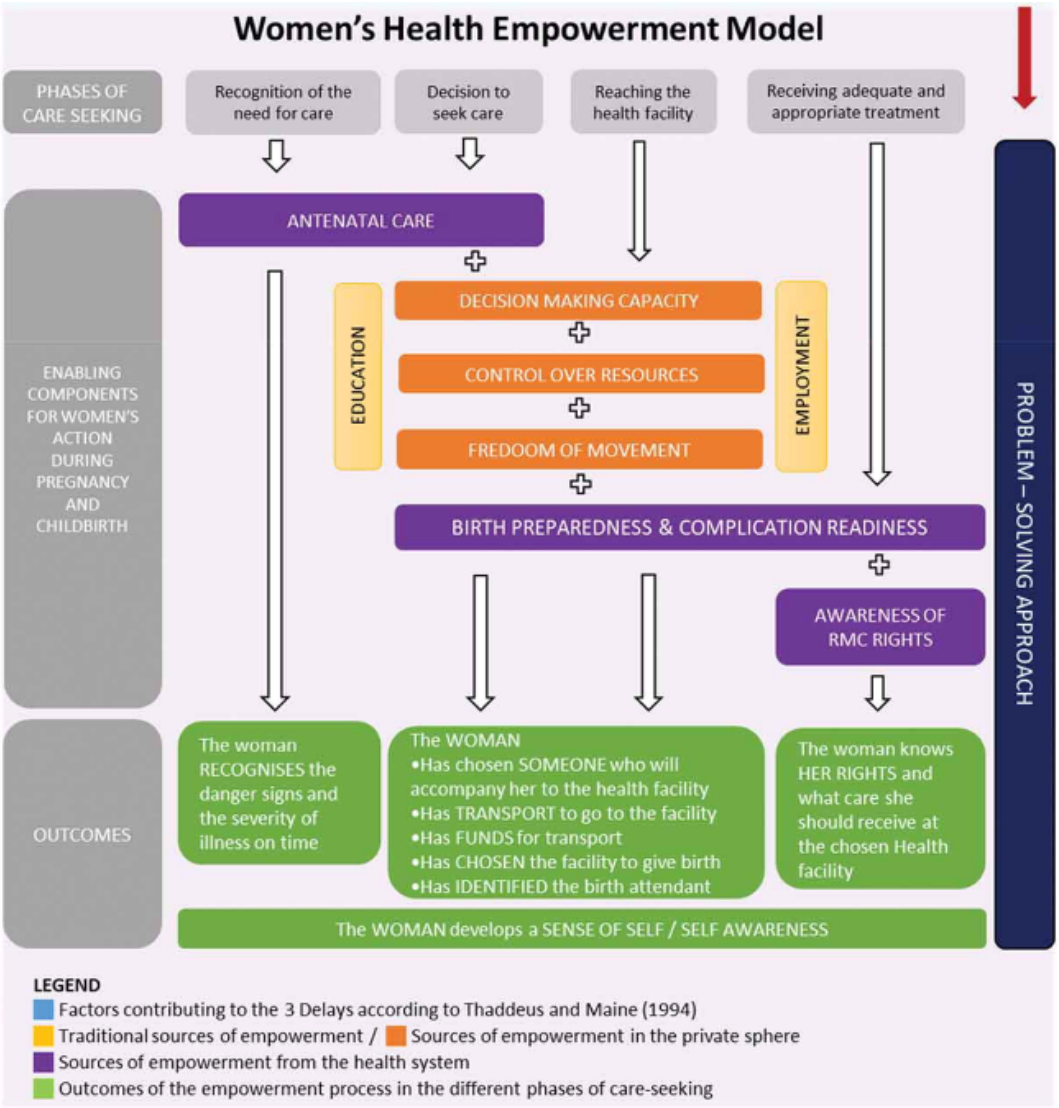

Figure 4 – Women's Health Empowerment Model

These include woman's level of education and employment status, decision-making capacity regarding health-related matters, ability to control and use financial resources, freedom of movement such as leaving the house alone to access care, birth preparedness and complication readiness and awareness of respectful care rights. This model will be used to revise the health education module of PANDA and in assessing women's experience of care received through PANDA. An audit trail will be maintained to detail the date, rationale and source of any changes made.

9. Study design

This study will be conducted in 2 phases over a 24-month period.

Phase 1 Adaptation: we will conduct a participatory study engaging stakeholders and the community engagement and involvement group over 12 months to adapt the PANDA e-health system. A technical working group (TWG) will begin the initial revision of the PANDA modules (personal and obstetric data, screening and health education) and integration of respectful care components. Preliminary observations of standard ANC delivered in the study sites will also be carry out to tailor

PANDA to the context. A co-production process with stakeholders and CEI will follow with the aim to develop a PANDA prototype. The PANDA prototype will be shared and reviewed with healthcare professionals and women through focus group discussions (FGDs) to explore acceptability and how to implement PANDA in practice. FGDs findings and further engagement with stakeholders will inform refinement of PANDA and operationalisation in study sites to commence feasibility testing. Adaptation and co-production processes are described in detail at section 10 (pg. 18) of this protocol.

Phase 2 Feasibility study: we will conduct a prospective mixed-methods study. A pre- and post-cohort design, over 12 months will be carried out to allow implementation of the intervention (PANDA) in two study sites and one referral centre and assessment of feasibility. Details of the feasibility study are provided in detail at section 10 (pg. 23) of this protocol.

9.1 Setting

The study will be undertaken at Dongobesh Hospital, a district council hospital and 2 primary care facilities in Manyara, located in the North-East of Tanzania. DHS data for Tanzania indicates women living in rural areas are more likely to discontinue ANC attendance due to distance, indirect costs of transport, fear of HIV testing and disclosure and previous experience of disrespectful care (13). Manyara region, being a prevalent rural setting, constitutes an ideal location to improve antenatal engagement and women's experiences of care.

Dongobesh Hospital is a district facility, located in Mbulu District Council, Manyara region and serves a population of about 150,000. It is a referral facility to the surrounding primary health facilities. DH provides antenatal care services to around 1025 pregnant women annually and had 897 births in 2021. In 2021, there were 26 stillbirth and 14 neonatal deaths. Staffing in the obstetric departments includes 2 medical officers, 1 assistant medical officer, 9 nurse-midwives (organised in three shifts) and 4 medical attendants. The hospital conduct both normal birth and caesarean section, with a rate of 10.2% in 2021. Dongobesh Hospital will host the Medical Unit within the Department of Obstetrics and Gynaecology. Appointed staff (Senior Medical Officer) will review ANC records collected by healthcare professionals in the two facilities testing the intervention.

Two primary facilities (Maghang and Muslur dispensaries) will be involved in the feasibility testing. These dispensaries are about 20 km from Dongobesh district hospital to which they refer patients to. Around 630 women attend antenatal care at each facility, corresponding to 50 each month, of which half are at their first visit. Staffing in both places including two nurse midwives, two medical officers and one clinical officer who are involved in the care of women. These facilities conduct normal vaginal birth, in 2021 there were 168 normal vaginal birth. Both facilities have a record of less than five stillbirths and less than five neonatal deaths per annum.

The district hospital and the two facilities will not be involved in the clustered trial.

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9.2 Participants

Phase 1: Adaptation

During the adaptation phase, study participants will include healthcare professionals and women.

We will conduct preliminary observation of current antenatal care delivery (n = 3 per study site, 6 in total) to inform the adaptation and development of the PANDA prototype. Thereafter, focus group discussions (n=6, 3 with each cohort) with pregnant women (n = 24-30) and healthcare professionals

(N = 18-24) will be used to explore acceptability of the PANDA prototype and practicalities of its use in study sites.

Phase 2: Feasibility study

During the recruitment period we will approach as many eligible women meeting the inclusion criteria as possible. We will aim to recruit up to 40 women in each phase per site (total sample 160), who are pregnant and are currently attending or need to start their ANC at the study facility. We will assess the feasibility of data collection and in phase 2, observe and explore experiences of receiving ANC through the PANDA app in terms of contents, length of the visit, providers' behaviour and satisfaction with care, and study participation.

In phase 1, up to 80 women (40 per site) having the current pattern of ANC at the target facility, in the period preceding the introduction of the intervention will be recruited.

In phase 2 (intervention) up to 80 women (40 per site) will be recruited. Healthcare workers delivering ANC through PANDA in the included facilities and providers at the referral facility (up to 20 in total) will also be recruited to complete a short questionnaire survey / interview, at the end of the study, to explore experience of the intervention (at the primary facility and referral level) and participation in the research.

Each site will be asked to complete a questionnaire to capture the resources required to implement the PANDA system.

10. Study phases and methods

10.1 Adaptation of PANDA e-health system (Year 1)

Objectives

1.1 To adapt the PANDA e-health system to be context-specific, provide high-quality ANC according to national and WHO recommendations in consultation with stakeholders and CEI in Tanzania.
1.2 To discuss and agree with stakeholders and CEI about respectful care components and embed them into PANDA e-health system

Methods
Adaptation of PANDA (Figure 2) involves the updating of the ICT platform, revision of each of the 4 modules (personal data, obstetric history, screening and health education), and incorporation of respectful care contents to take into account our findings on women's key influencers to attend antenatal care (18). These components are partially included in the current version of PANDA. Potential changes could involve language, contents of the visit, data related to previous and current pregnancy, health education etc. Women's value for respectful and dignified care is key in their choice to start antenatal care and attend subsequent visits. Introducing these elements as prompts during the visit and before conducting any procedures (testing, blood pressure check, vaginal examination etc.) is likely to encourage attendance and improve women's experience of care. Health workers will also be supported around respectful behaviours and attitudes. In adding these elements, we will balance contents against length of visit to avoid make it unacceptable (i.e. too long) to women as documented in preliminary studies (27).

The adaptation phase will have four segments (Figure 5) including research activities (purple boxes):

1) Observation of current usual antenatal care
2) Co-production and agreement of PANDA prototype
3) Focus group discussion with women and health professionals
4) Refinement and operationalisation of PANDA e-health system.

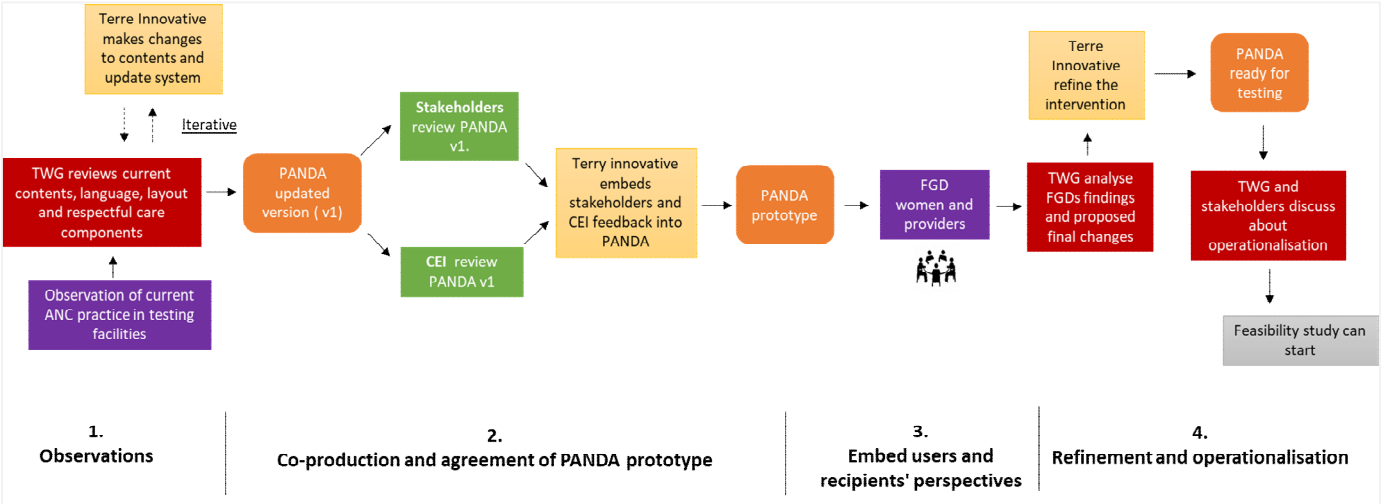

Figure 5 – Adaptation of PANDA e-health system to the Tanzanian setting

For each segment of the adaptation process, rationale, methods, participants and data collection are presented below. Eligibility criteria and recruitment of participants is described at section 11, pg. 27, of this protocol.

10.1.1 Observations of standard ANC (year 1, month 1-2)

Objective: to observe and capture provision of current ANC to inform revision and update of the PANDA e-health system to be context specific and relevant to users and receipients.

Rationale

We will use non-participant observations (33) to explore context, processess, behaviour and communication between the health professionals and the women during provision of current usual antenatal care at the two testing facilities. Use of observations is appropriate to visualise nuances of people's interaction that could not be easily captured through other approaches. For instance, if the woman is greeted at the start, if the companion is acknowledged, whether verbal consent is asked before any procedure, whether an opportunity for asking questions is offered, whether the woman ask questions and how she asks (low voice feeling intimidated, normal voice with confidence etc.), and provider's reaction to clients' question.

Participants

Healthcare professionals providing standard ANC in the two study sites and pregnant women who attend their antenatal clinic visit will be observed during a routine visit at the outset by a research midwife, external to the staff's clinic. Eligibility criteria and details about recruitment are provided at section 11, pg. 27.

Method

Observation will take place in the ANC clinic room. To avoid selectivity, researcher midwives will observe ANC provision throughout the day (from opening time to closure) and on different days to

enable observations of different providers. Observation will not interfere with provision of routine care. Prospective consent from each HCP delivering routine ANC and the woman attending the visit, will be sought on the day of the observation, before the visit starts by a member of the research team. This member will not be known by the staff, but the facility staff would have been de-briefed about the study at the outset, upon reception of study approval from the facility. If the woman or HCP declines to be observed, the researcher will exit the ANC clinic room before the visit begins, without implications for the participants. Each participant will receive an information sheet and will be asked to provide their written informed consent.

Data collection

Each observation will follow three stages [32]: it will begin with a descriptive observation, in which the researcher will carry out a broad scope observation to get an overview of the setting in which the visit takes place (atmosphere, room layout, door open / close, presence of privacy curtains, presence of couch / cleanliness etc.). It will then move to a focused observation, in which more attention will be paid to a narrower portion of the activities of interest, the content of the visit, (for instance whether screening is performed and this is properly communicated to the woman). Lastly, selected observation will focus on the interaction between the woman and provider (manner, behaviour, attitudes) and communication, tone of voice and language. This will help to investigate the relationship among the elements selected as being of greatest interest. An observation grid, adapted from our previous studies conducted in Tanzania and Zambia (34) will assist notetaking. The grid will be piloted during 2 observations (1 per facility) and modified as required. Observations' findings will be analysed through the framework approach(35) and will be used to generate prompts to be included in the PANDA application.

10.1.2 Co-development and agreement of PANDA prototype (year 1, month 3-5)

Objective: to use the study findings (observation and previous qualitative data) and engagement with stakeholders and CEI groups to co-develop the PANDA prototype to ensure is aligned with WHO recommendations (11) and MOH guidelines (36) and relevant to the Tanzania's context, including incorporating the appropriate ICT features for potential integration into the DHS2.

Participants: for this phase of the adaptation process, we will not recruit participants but engage in a co-production process with stakeholders and CEI.

Stakeholders

A stakeholder's group of 6-10 participants will be convened at the outset. This will include a representative of the Reproductive and Child Health Section (Ministry of Health), District Medical Office/District Reproductive and Child Health Coordinator, Ministry IT personnel, clinicians, midwives, community leaders and CHW and the CEI lead. The group will be facilitated by the Tanzania co-PI. Letters of invitation will be sent to identified health professionals, community leaders and policy makers with professionals' interest or expertise in this area. Stakeholders will consider every component of the e-health system, with particular attention to barriers and facilitators for its implementation and integration into the existing DHS2 platform.

Community Engagement and Involvement group

Learning from our recent experience in creating CEI groups in low-income settings (37) through the NIHR Group on Stillbirth prevention and Management in Sub-Saharan Africa (16/137/53) we will create a CEI group of 8-10 pregnant women. Women will be identified at the referral hospital through the clinical care team and in the community, through CHW, to ensure representativity of rural population, including women not attending antenatal care (unbooked women). The CEI group will identify a lead who will participate in the stakeholder group. The research team will provide training and support to the group to ensure confidentiality and that a sensible approach is used to

address any issue discussed. CEI members will contribute to updating of the e-health system, identification of respectful care components, interpretation of FGDs findings and operationalisation of PANDA implementation. CEI will also contribute to define the recruitment strategy as well as to review participants information sheets, questionnaires and interview guides, to ensure the language is understandable to the participants. They will support interpretation of findings and dissemination to lay audience.

Methods
A technical working group (TWG), including UK and Tanzania research team and Terre Innovative will be setup at the outset of this workstream. Terre Innovative will create an account for each member of the TWG to enable downloading of the application (on an android device with a SIM card) and of the Medical Unit on a desktop or computer laptop bellowing to the hospital. Through a series of virtual meetings, Terre Innovative will explain how the PANDA works, its functionalities and potentials. UK and Tanzania team will "play" with e-health system and meet virtually to review each of the module (contents and layout) and provide specific feedback. Revision will ensure contents aligns with WHO recommendations on ANC (11) and Tanzania MOH most recent guidelines (36). The TWG will also use the experiences and suggestions of Terre Innovative drawing from previous testing in LMICs.

Results of the preliminary observations and findings of the discreet choice experiment around women's preferences for ANC and respectful care domains, will help to formulate specific prompts, which could include the following (Table 2):

Table 2 – RMC domains and potential prompts to be incorporated into PANDA e-health system

RMC domains	**Potential Prompts in PANDA app**
- Engaging with effective communication - Providing dignified care	- At the beginning of the visit introduce yourself to the woman and the companion (if present) - During the visit, refer to the woman using her name - Near the end of the visit ask the woman if she has questions / allow time to think and formulate questions - At end of the visit greet the woman (and her companion) before she leaves
- Prospective provision of information and seeking informed consent - Engaging with effective communication - Respecting women's choices	- Explain to the woman the reason to measure blood pressure / rapid testing / conducting a vaginal examination - Explain the woman what the procedure of taking blood pressure include (each step) - Ask for a verbal informed consent before starting the procedure - Ask the woman if she understood the explanation
- Preserving woman's dignity	- Ensure the door is closed before starting the visit - Ensure curtains are closed before performing an abdominal and vaginal examination - Ask the woman if she wants her companion to be present during the visit / respect her choice

Additional elements could include specific questions around decision making power in the family, control of financial resources, freedom of movement to access care (alone or accompanied) and awareness of RMC rights during clinics and birth.

The team will also be introduced to the Pregnancy Logbook, a booklet containing health education information, used by Terre Innovative in Madagascar (27). The TWG will decide whether to include

this as part of the intervention or to drop it, in case it constitutes a duplicate to an existing resource material provided to women in Tanzania.

Feedback will be discussed and shared with Terre Innovative for updating. We anticipate an iterative process between UK/Tanzania team and Terre Innovative. An audit trail will be kept for any change made to the e-health system. This internal consultation and revision will lead to an updated PANDA version (Panda_v1). At this stage, stakeholders and CEI groups will be involved to review it.

The TWG will organise a face-to-face meeting with the stakeholders' group to review PANDA. Contents of the modules, including aspects of birth preparedness will be discussed to assess whether they are adequately covered in PANDA or need inclusion in the education module or elsewhere as appropriate. Stakeholders will also review layout and the ICT underpinning the system. This will be relevant for potential integration into the Tanzania Health Information System. The same version of PANDA (Panda_v1) will also be reviewed by the CEI group, during a face-to-face meeting, to ensure the tool is relevant to women. Engagement with stakeholders and CEI will produce a list of feedback and suggestions, aimed at adapting PANDA to the Tanzanian context. This will be agreed and shared with Terre Innovative for updating. This consultation process will conclude with an agreed PANDA prototype to be formally discussed through focus group discussions with women and providers to explore acceptability of the PANDA prototype and practicalities of its use.

10.1.3 Focus Groups Discussions with women and health professionals

Objective: to explore HCP and women's acceptability of PANDA e-health system and how it can be implemented in practice, during the feasibility study.

Rationale

Focus group discussions are appropriate to understand how people feel or think of an issue, product or service(38). Discussion is facilitated to gain perceptions and ideas on a specific area, and to enable participants to freely express themselves, responding to each others ideas and comments, in a non-threatening environment. Participants usually share unique characteristics to be included. FGDs rather than individual interviews are preferred at this stages to enable PANDA users (HCP) and recepients (women) to discuss acceptability and practicality of PANDA use, consider different perspectives and needs.

Participants

A purposive sample of 24-30 pregnant women attending antenatal care and of 18-24 healthcare professionals delivering antenatal care in facilities in Manyara region will be invited to take part in one of the 6 FGDs (8-10 participants per group) conducted by the research team during the adaptation phase. Details about eligibility criteria and the recruitment process are provided at section 11, pg. 27 of this protocol.

Method

FGDs will be used to explore acceptability and practicalities of PANDA use. Women at various gestational age will be recruited and involved in one of the three FGDs (8-10 participants in each) to assess the PANDA prototype in terms of layout, contents, lengths of the visit, and respectful care components. Specific questions around the difference between first and subsequent visits will be included as lengths and contents varies, so as the duration of the visit. We will aim to have fairly homogenous groups, including pregnant women at their first pregnancy (primipara), pregnant women who already had children, and pregnant women who have not attended antenatal care in their current or previous pregnancies. This will enable different perspectives and needs to be considered during adaptation and feasibility of PANDA.

Healthcare workers of various level (hospital managers, doctor, midwives, community health workers) working in facilities in Manyara region will also be involved in one of the three FGDs to explore views, acceptability and practicalities of PANDA use. We will aim to have maximum variation to enable different cadres to share their views around the link between PANDA app and the referral unit.

Data collection
A member of the research team will organise the FGDs (3 with each cohort) at a time and venue convenient to all participants. A minimum of 4 and a maximum of 10 participants will be invited to take part. Informed consent will be sought before starting the FGDs, the researchers will emphasise the nature of FGDs, limiting full confidentiality and privacy of information to be maintained, thus encouraging participants to only share information they are confortable with. FGDs will be moderated by two researchers, one asking questions and facilitating the discussion, the other taking notes about verbal and non-verbal communication and observing group dynamics. The discussion will be audio recorded with a digital device, upon written informed consent from all participants. Use of pseudonyms, selected by the participants or researchers, during the FGDs will prevent discosure of identifiable data. Demographic data will also be collected by the researchers before starting the FGDs, to describe the characteristics of the study sample.

10.1.4 Refinement and operationalisation of PANDA e-health system

Objective: to refine PANDA e-health system and work with stakeholders to operationalise its use in study sites.

Methods
FGDs findings will be analysed and used to formulate final changes to PANDA e-health system, which will be agreed and shared with Terre Innovative. They will make these modifications and deliver a final product ready for testing. At this stage we will organise a face to face meeting with the stakholders' group to discuss operationalisation of PANDA e-health system in the study sites. This will be summarised in implementation strategy document. We do not anticipate to engage with study participants in this last segment of the adaptation process.

10.2 Feasibility study (Year 2)

The feasibility study will adopt a pre- and post-cohort design over 12 months period. Phase 1 and Phase 2 will be carried out with a temporal separation to avoid contamination (See timeline pg. 41 of this protocol)

10.2.1 Control phase (month 1-6)

Objective: to collect data on standard ANC provision for comparison with intervention group and assess recruitment and retention of women in the study.

Participants
In month 1 we will recruit up to 40 eligible pregnant women, from each site, booked or planning to start their ANC visits at participating facilities. Eligibility criteria and recruitment process is described at section 11, pg. 27-28 of this protocol.

Methods
Some women will attend more than one visit, others only one visit. According to the Tanzanian standard of care, details of each ANC clinic visit attended by the woman are recorded in the ANC

register. If the woman has consented to participate in the study, de-identified records of each visit (from booking to birth) attended at the clinic will be extracted prospectively by the researcher midwife and input into an electronic Case Report Form (CRF), using Research Electronic Data Capture (REDCap), a web-based dataset hosted at LSTM.

At recruitment, all women will also be asked to fill and sign a Consent to contact form to be followed up after birth. Details on place of birth, reason to referral / transfer, and pregnancy outcome will be collected for all women irrespective of the place where they give birth. Pregnancy outcomes will be extracted from the Birth register by the research assistant and input into an electronic CRF, through REDCap.

The research team will keep track of women's expected date of birth. For those women giving birth in one of the study sites, the research team will follow them up in the postnatal ward. After birth, and following written informed consent, the woman will be asked to complete a paper-based exit questionnaire to rate the quality of antenatal care received, including assessing respectful care components, and a short questionnaire about her participation to the study. Women with low literacy level will be assisted by a member of the research team to complete these questionnaires. For those women not giving birth in one of the study sites, the consent to contact form will be used to contact them. Following verbal consent, the woman will be asked to provide her birth outcome and to complete the same questionnaires via telephone or during a face-to-face meeting organised at her preferred time and venue.

Questionnaire's scores will be used to identify a sub-sample of women (n = 12-16) to be invited to participate in a qualitative interview exploring in depth their experience of receiving standard ANC and take part in the study. We aim for maximum variation including women with high scores, as well as women underscoring the care received to understand drivers and barriers to antenatal care engagement and make potential adjustments for the clustered trial. The research assistant / midwife will use the consent to contact form to contact the woman and, upon verbal consent, plan a time and venue suitable for the woman to meet for the questionnaires and potentially having a one-to-one interview. This will be conducted in local language, recorded and transcribed verbatim. The Framework approach will be used to analyse these interviews.

10.2.2 Intervention (month 7 -12)

Objective: to assess recruitment and retention of women in the study

Participants

In month 7 we will recruit up to 40 eligible pregnant women, from each site, booked or planning to start their ANC visits at participating facilities. Eligibility criteria and recruitment process is described at section 11, pg. 27-28 of this protocol.

Method

PANDA e-health system includes three components (Figure 6)

1) The PANDA app – icon-based Android application
2) The Point of Care– solar backpack containing diagnostic tools
3) The Medical Unit– java database hosted inside the referral hospital.

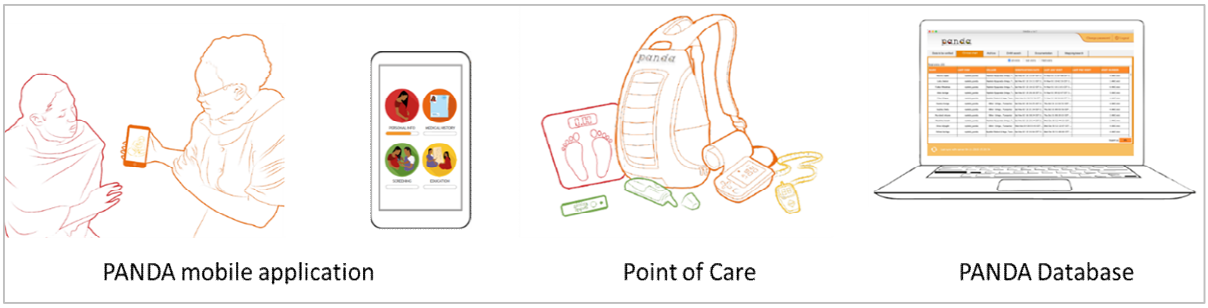

Figure 6 – PANDA app, Point of Care and Medical Unit.

Implementation of PANDA will follow the following process. Study specific android mobile phones or 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 (n. of tablets per facility to be confirmed) and each facility will receive an adequate number of Points of Care (TBC) (solar backpack) to be used during the visit. The Point of Care include the medical equipment for ANC screening (Cradle device for blood pressure, rapid test for HIV, malaria and syphilis, weighting scale, height measurement device, thermometer, and glucometer with strips). Airtime will be included to ensure providers have internet connection to send data to the server. A bar code will also be procured and will be sticked 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. The devices and Point of Care will be stored in the facility. Based on Terre Innovative' s experience of PANDA testing in Tanzania, no record of theft or loss were recorded. A risk management policy will be in place to avoid damage and loss of these equipment.

Healthcare workers in study sites will be given the option to choose whether to learn PANDA and use it for antenatal care or to continue providing routine care. Use of PANDA will be recommended but we will also collect information about reason for declining participation. During month 7 (year 2) healthcare professionals trained on PANDA will start using the application and Point of Care to conduct antenatal care visit with pregnant women. Based on Terre Innovative' s experience, recruitment and data collection can start simultaneously with use of PANDA. Providers working in study sites, who usually deliver ANC, will be the one implementing PANDA. They will be invited to an interactive training workshop (contents based on the existing resources and to be refined during the adaptation process) to understand the intervention. Training will be provided to healthcare providers working at the testing facilities, willing to take part in the study. A combination of virtual and face to face training sessions, based on geographic location of staff / facility and COVID-pandemic will be organised in month 7 to train staff about PANDA. These sessions will cover PANDA modules, respectful care prompts, use of diagnostic tools and reporting, information to provide during the health education session and retrieval of data during subsequent visits. HCPs will also be explained that when the visit is completed, and internet is available, data will be sent wirelessly to the medical unit database, enabling staff at that level, to map the pregnancies of the target population for risk location and timing, and implement customised treatment plans when necessary. Simulation of fake visits will be included in the training to ensure HCPs explore each feature of the app and become confidence with its use. Staff in charge of the medical unit will also receive training around data monitoring and verification, identification of risk pregnancies and action plans.

The intervention will be implemented in both site in month 7, after completion of the control phase. We will start recruitment when PANDA is implemented and aim to include a group of up to 40 pregnant women per study site. Women who consented to take part in the study will receive every

ANC (first and subsequent visits) through PANDA until birth, an electronic medical record will be created and stored at the Medical Unit. If the woman had already had 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.

At recruitment, all women will also be asked to fill and sign a Consent to contact form to be follow up after birth. Details on place of birth, reason to referral / transfer, and pregnancy outcome will be collected for all women irrespective of the place where they give birth. Pregnancy outcomes will be collected through PANDA by the clinical team.

The research team will keep track of women's expected date of birth. For those women giving birth in one of the study sites, the research team will follow them up in the postnatal ward. After birth, and following written informed consent, the woman will be asked to complete a paper-based exit questionnaire to rate the quality of antenatal care received through PANDA, including assessing respectful care components and a short questionnaire about her participation to the study. Women with low literacy level will be assisted by a member of the research team to complete these questionnaires. For those women not giving birth in one of the study sites, the consent to contact form will be used to contact them. Following verbal consent, the woman will be asked to provide her birth outcome and to complete the same questionnaires via telephone or during a face-to-face meeting organised at her preferred time and venue.

Questionnaire's scores will be used to identify a sub-sample of women (n = 12-16) to be invited to participate in a qualitative interview exploring in depth their experience of receiving standard ANC through PANDA and take part in the study. We aim for maximum variation including women with high satisfaction scores, as well as women unsatisfied with the care received to understand drivers and barriers to antenatal care engagement and make potential adjustments for the clustered trial. The research assistant / midwife will use the Consent to contact form to contact the woman and, upon verbal consent, plan a time and venue suitable for the woman to meet and potentially having a one-to-one interview. This will be conducted in local language, recorded and transcribed verbatim. The Framework approach will be used to analyse these interviews

Observations

We will use non-participant observations(33) to explore context, processess, behaviour and communication between the health workers and the woman during provision of antenatal care through PANDA at the two testing facilities. Use of observations is appropriate to visualise nuances of people's interaction that could not be easily captured through other approaches. For instance, if the woman is greeted at the start, if the companion is acknowledged, whether an opportunity for asking questions is offered, if the woman engages with PANDA app and the nature of engagement, whether the diagnostic tools are used and provider's reaction to clients' questions.

Method

Observation will take place in the ANC clinic room. To avoid selectivity, research midwives will observe ANC provision throughout the day (from opening time to closure) and on two different days to enable observations of different providers. Observation will not interfere with provision of routine care. Prospective consent from each HCP delivering ANC through PANDA and the woman attending the visit, will be sought on the day of the observation, before the visit starts. If the woman or the HCP prefer not to be observed, the researcher will not enter the ANC clinic room before the visit begins, without implications for the participants. Each participant will receive an information sheet and will be asked to provide their written informed consent.

Data collection

Each observation will follow three stages [32]: it will begin with a descriptive observation, in which the researcher will carry out a broad scope observation to get an overview of the setting in which the visit takes place (atmosphere, room layout, door open / close, presence of privacy curtains, presence of couch / cleanliness etc.). It will then move to a focused observation, in which more attention will be paid to a narrower portion of the activities of interest, the content of the visit, (for instance whether screening is performed and this is properly communicated to the woman). Lastly, selected observation will focus on the interaction between the woman and provider (manner, behaviour, attitudes, communication, tone of voice and language and engagement with the PANDA app. This will help to investigate the relationship among the elements selected as being of greatest interest. An observation grid, adapted from previous studies (34)will help notetaking. The grid will be piloted during 2 observations (1 per facility) and modified as required. Observation's findings will be analysed through the framework approach(35). These will be compared with the observations conducted during the adaptation phase to identify change in attitudes and practice and consider if further adaptation of PANDA e-health system is needed before commencing the clustered trial.

11. Study Participants

11.1 Inclusion and exclusion criteria

Inclusion and exclusion criteria for each phase of the study are indicated in the following table:

Table 1 – Participants' Inclusion and exclusion criteria for adaptation and feasibility phases.

Phase	Inclusion criteria	Exclusion criteria
Adaptation	*Observations* **Women** - Pregnant - Attending care in facilities and in the surrounding communities in Manyara region - Age 18 years or over at the time of recruitment - Willing and able to participate **Healthcare professionals** - Nurses, midwives, doctors, support workers delivering ANC in facilities and communities in Manyara region *Focus group discussions* **Women** - Pregnant - Attending care in xx facilities and in the surrounding communities in Manyara region - Not planning to attend antenatal care in their current pregnancy (unbooked) - Age 18 years or over at the time of recruitment - Willing and able to participate - **Healthcare professionals**	- Women with established obstetric complications as identified by the clinical team - Women under 18 years of age - Healthcare providers only providing intrapartum and postnatal care - Women under 18 years of age

	- Nurses, midwives, doctors, support workers delivering ANC in facilities and communities in Manyara region - Facility managers working in maternal health department, including management of antenatal services in facilities in Manyara region	- Providing antenatal care study sites - Managing maternal care services in study sites.
Feasibility study	**Women** - Pregnant - Attending care or planning to book for care in study facilities in Manyara region. - Age 18 years or over, at the time of recruitment - Willing and able to participate **Healthcare professionals** (Nurses, midwives, doctors, support workers) - Delivering ANC care in primary facilities and district hospitals in Manyara region. - Delivering ANC in study facilities using PANDA - Managing PANDA medical unit at the district hospital in Manyara region.	- Women with established obstetric complications as identified by the clinical team - Women under 18 years of age - No exclusion.

11.2 Recruitment

Adaptation phase

Women

Observations: Posters about the study will placed at the facility in waiting rooms and corridors. Eligible women attending antenatal clinics in one of the two study sites, will be identified and approached via a member of the clinical care team on their arrival at the facility who will introduce the study. In the study sites many women will not attend more than one antenatal visit, and there may be up to 3 months gap between visits Therefore if the woman is interested in receiving further information the clinical team will signpost her to a member of the research team present at the facility on the same day. The researcher will visit the woman while she waits for her antenatal visit and provide a verbal explanation of the study supported by a written information sheet (PIS) which will be available in the local language. The woman will be encouraged to discuss with her family/others (including other women present at the clinic) and provided additional opportunities to ask questions. She will be informed that her participation is voluntary and a decision not to take part in the research will have no impact on her current or future healthcare provision. After a period of not less than 1 hour (the usual waiting time to be seen by the clinician), contact will be re-initiated to confirm whether she would like to take part. If the woman agrees that her visit is observed, the researcher will enter the antenatal clinic room. At any point, and despite having given a written consent, the woman can decide to discontinue the observation, without any implication for her visit or subsequent appointments. The consent form will be completed immediately prior to the observation. If the researcher establishes the participant has limited writing skills, fingerprint will be used to confirm consent

Focus group discussion: eligible women *(24-30)* will be identified and approached through the clinical care team, during their visit at the study facilities or in the communities through the community engagement and involvement groups (CEI). If the woman is interested in receiving further information, she will be asked to complete a 'Consent to Contact form' outlining her preferred time and method for contact (phone call, SMS) which will be put in sealed box for the research assistant/midwife to collect at the facility. If the woman has been identified in the community the Consent to Contact form will be sealed in a envelop and provided to the research midwife by a member of the CEI group. From the first contact, the research assistant/midwife will ascertain the potential participant's preferred method for initiate further contact about the study (call, SMS, what's app). If no response is received, no more than 2 attempts (voice message, SMS) will be made before the research midwife will assume the participant does not wish to proceed. No further contact with the participant will be made. The research assistant / midwife will contact the woman as agreed, provide a verbal explanation of the study supported by a written information sheet (PIS) which will be available in the local language. The woman will be encouraged to discuss with her family/other and provide additional opportunities to ask questions. She will be informed that her participation is voluntary and a decision not to take part in the research will have no impact on her current or future healthcare provision. After a period of not less than twenty-four hours, contact will be initiated (as agreed) to confirm whether she would like to take part. If she agrees, the research midwife / assistant will arrange a time and venue to meet with a minimum of 4 and maximum of 10 other pregnant women to confirm consent and conduct the focus group discussion. The consent form will be completed immediately prior to the focus group.

Healthcare workers

Observations: Workshop will take place in study facilities prior to study commencement to inform healthcare professionals about the study. Posters will also be displayed in staff facing areas, providing research contact details and inviting those who are interested in participating to contact the researcher directly. From the first contact, the researcher will ascertain the potential participant's preferred method for initiating further contact about the study (e.g., midwife to call/SMS, participant to call/SMS). The research assistant will contact the healthcare professional as agreed, provide a verbal explanation of the study supported by a written information sheet (PIS) which will be available in the local language. The healthcare professionals will be encouraged to discuss with her family/ others and colleagues and provided additional opportunities to ask questions. She/He will be informed that her participation is voluntary and a decision not to take part in the research will have no impact on her current or future employment. After a period of not less than twenty-four hours, contact will be initiated (as agreed) to confirm whether he/she would like to take part. If he/she agrees, a convenient date and time will be agreed for observation to take place. HCPs will be reassured that any decision taken (be observed or not) will not affect their professional practice. At any point, and despite having given a written consent, the HCP can decide to discontinue the observation, without any implication for his/her professional activity. In this case, the researcher will exit the room. The consent form will be completed immediately prior to the observation. Data collected until that point will be included in the analysis unless the healthcare professional request to exclude them.

The same procedure will be followed to recruit participants for the FGDs. However, posters will be placed in facilities in Manyara region. These healthcare professionals will not be the ones using PANDA in the feasibility study. The two groups will be kept separate to reflect the situation of the cluster trial, in which HCP will received a training on PANDA, without previous knowledge of the e-health system. If the healthcare worker agrees to participate to a FGD a date, time and venue will be arranged with a minimum of 4 and maximum of 10 HCP to confirm consent and conduct the FGD.

Feasibility study

Women

Control group: Posters will be place in women facing areas in study facilities. All eligible women attending the study sites for antenatal care during the recruitment period (1 months maximum) will be identified and approach via a member of the clinical care team, during their usual visit, and be introduced to the study. If the woman is interested in receiving further information, she will be asked to complete a 'Consent to Contact' form which will be posted in a sealed box for the researcher to collect. From the first contact, the research assistant/midwife will ascertain the potential participant's preferred method for initiate further contact about the study (call, SMS, what's app). If no response is received, no more than 2 attempts (voice message, SMS) will be made before the research midwife will assume the participant does not wish to proceed. No further contact with the participant will be made.

The research assistant/midwife will contact the woman as agreed, provide a verbal explanation of the study supported by a written information sheet (PIS) which will be available in the local language. The woman will be encouraged to discuss with her family/other and provide additional opportunities to ask questions. She will be informed that her participation is voluntary and a decision not to take part in the research will have no impact on her current or future healthcare provision. After a period of not less than twenty-four hours, contact will be initiated to confirm whether she would like to take part. If she agrees a meeting will be arranged with the research midwife. The consent form will be completed at this initial meeting and the research assistant / midwife will contact the woman as agreed to arrange the follow up visit.

If the woman agrees to take part, her medical record (de-identified data only) will be extracted from the ANC register at the facility and transferred into an electronic Case Report Form built in REDCap by a researcher midwife/assistant. Extraction and transfer of her records into REDCap will also occur for every subsequent visit until she gives birth. Identification of the woman's data between visits will be done through the standard ANC number assigned to the woman at the first visit and recorded on her ANC card and the register.

The research team will keep track of women's expected birth date. Women may give birth in one of the study sites (booking facility or referral hospital), at home or elsewhere. For those women giving birth in the study sites, the research team will follow them up in the postnatal ward. After birth, and following written informed consent, the woman will be asked to complete a paper-based exit questionnaire to rate satisfaction with antenatal care received, including respectful care components, and a short questionnaire about her participation to the study. Women with low literacy level will be assisted by a member of the research team to complete these questionnaires. For those women not giving birth in one of the study sites, the consent to contact form will be used to contact them. Following verbal consent, the woman will be asked to provide her birth outcome and to complete the same questionnaires via telephone or during a face-to-face meeting organised at her preferred time and venue. In this instance, details about the reason of referral / transfer to another facility or for giving birth at home will also be collected. Pregnancy outcomes will be extracted from the Birth register by the research assistant an input into an electronic CRF, through REDCap.

Questionnaires' scores will be used to identify a sub-sample of women (n = 12-16) to be invited to participate in a qualitative interview exploring in depth their experience of receiving standard ANC and take part in the study. We aim for maximum variation including women with high satisfaction scores, as well as women unsatisfied with the care received to understand drivers and barriers to

antenatal care engagement and make potential adjustments for the clustered trial. The research assistant / midwife will use the Consent to contact form to contact the woman and, upon verbal consent, plan a time and venue suitable for the woman to meet and have a one-to-one interview. Following written informed consent, the interview will be conducted in local language, recorded and transcribed verbatim. The Framework approach will be used to analyse these interviews.

Intervention group: The same recruitment process will be followed for the intervention group. This group will be offered an ANC visit through PANDA as alternative to standard ANC. Through PANDA, an electronic medical record recording identifiable data (for instance name, address, phone number) will be created. Identifiable data will remain in Tanzania and will only be accessible to the medical personnel in charge of the woman's care. This will be possible as PANDA allows different type of access to the users. The Participant Information sheet will provide detailed information about this. During the visit the woman will also receive a barcode label (to be attached to the existing ANC card or the PANDA Pregnancy logbook – to be confirmed during the adaptation phase) which will be used to retrieve information in subsequent visits.

Recruitment: Posters will be place in women facing areas in study facilities in month 7. All eligible women attending the study sites for antenatal care during the recruitment period (1 month maximum) will be identified and approach via a member of the clinical care team, during their usual visit (conducted with PANDA), and be introduced to the study. If the woman is interested in receiving further information, she will be asked to complete a 'Consent to Contact' form which will be posted in a sealed box for the researcher to collect. From the first contact, the research assistant/midwife will ascertain the potential participant's preferred method for initiate further contact about the study (call, SMS, what's app). If no response is received, no more than 2 attempts (voice message, SMS) will be made before the research midwife will assume the participant does not wish to proceed. No further contact with the participant will be made.

The research assistant/midwife will contact the woman as agreed, provide a verbal explanation of the study supported by a written information sheet (PIS) which will be available in the local language. The woman will be encouraged to discuss with her family/other and provide additional opportunities to ask questions. She will be informed that her participation is voluntary and a decision not to take part in the research will have no impact on her current or future healthcare provision. After a period of not less than twenty-four hours, contact will be initiated to confirm whether she would like to take part.

If she agrees to take part in the study a meeting will be arranged with the research midwife. The consent form will be completed at this initial meeting and the research assistant / midwife will contact the woman as agreed to arrange the follow up visit.

If the woman agrees to take part to the study, her medical record (without identifiable information) with details of each ANC visits will be shared with the research team and included in the analysis.

If the woman does not agree to take part to the study, her electronic medical records will not be shared with the research team and included in the analysis.

The research team will keep track of women's expected birth date. Women may give birth in one of the study sites (booking facility or referral hospital), at home or elsewhere. For those women giving birth in the study sites, the research team will follow them up in the postnatal ward. After birth, and following written informed consent, the woman will be asked to complete a paper-based exit questionnaire to rate the quality of antenatal care received through PANDA, including respectful care components and a short questionnaire about her participation to the study. Women with low literacy level will be assisted by a member of the research team to complete these questionnaires. For those women not giving birth in one of the study sites, the consent to contact form will be used

to contact them. Following verbal consent, the woman will be asked to provide her birth outcome and to complete the same questionnaires via telephone or during a face-to-face meeting organised at her preferred time and venue. In this instance, details about the reason of referral / transfer to another facility or for giving birth at home will also be collected. Pregnancy outcomes will be collected through PANDA by the clinical team.

Questionnaires scores will be used to identify a sub-sample of women (n = 12-16) to be invited to participate in a qualitative interview exploring in depth their experience of receiving standard ANC through PANDA and take part in the study. We aim for maximum variation including women with high satisfaction scores, as well as women unsatisfied with the care received to understand drivers and barriers to antenatal care engagement and make potential adjustments for the clustered trial. The research assistant / midwife will use the Consent to contact form to contact the woman and, upon verbal consent, plan a time and venue suitable for the woman to meet and have a one-to-one interview. Upon written informed consent, the interview will be conducted in local language, recorded and transcribed verbatim. The Framework approach will be used to analyse these interviews

Observations: the same procedure used in the adaptation phase will be followed.

Healthcare workers

Primary facility (delivering ANC using PANDA): Due to limited number of healthcare workforce in primary facilities in LMICs, including Tanzania, it is likely that some or all healthcare providers delivering standard ANC will also be using PANDA e-health system. Their engagement and experience of using this mobile health solution is essential to assess study process and feasibility of the intervention. Therefore, prospective consent to take part in this study will be sought at the beginning of the study and agreed with facility management and each individual.

Workshop will take place in study facilities prior to study commencement to inform healthcare professionals about the study. Verbal and written information will be provided at this stage. Posters will also be displayed in staff facing areas, providing research contact details and inviting those who are interested in participating to contact the researcher directly. After a period of no less than 24h, those professionals interested to take part in the study will be contacted by the research team, who will arrange for an initial meeting to confirm consent and provide specific details about each study phase, methods of data collection (observations pre and post, interview pre and post) and participation to the PANDA workshop. They will also be asked to complete a resource utilisation questionnaire at the start of PANDA implementation. We anticipate remarkable commitment from staff, thus adequate compensation for additional time and resources will be provided. For instance, for completion of participants and intervention logs staff will receive 15000/= TSH for each completed log. For participation to survey and interviews evaluating standard care and PANDA staff will be reimbursed for their time / transport, as in previous studies conducted in Tanzania. The agreed amount was discussed with partners and aligns with Good clinical practice.

Referral facility (hosting Medical Unit): Healthcare professionals working in the maternity care of the district hospital will be informed about the study, during an initial workshop, facilitated by the research team at the beginning of the study. Written and verbal explanation will be provided and they will be asked to re-contact by their preferred method once they have had time to consider participation and no less than 24 hours later. Those professionals who agree to participate in the study will be contacted by the research team, who will arrange for an initial meeting to confirm consent and provide specific details about PANDA Medical Unit and its management.

All staff who provide antenatal care to women but are not directly involved in the delivery of the intervention will be informed about the research during the initial workshop. At the end of the intervention phase, all health workers in the target facilities will be invited in writing to complete a short, anonymous paper-based questionnaire to assess awareness of research, experience of the intervention and to capture wider impact on practice. The questionnaire will be accompanied by participant information; return will be taken as confirmation of consent.

Observations
The same process as outlined in the adaptation phase will be followed.

11.3 Participants who withdraw consent

At the point of recruitment, all potential participants will be informed that participation in the research is voluntary and that they can withdraw consent at any time without giving any reason, without their current or future care or legal rights being affected. Data collected up to the time participant leaves the study or is lost to follow up will continue to be included in the findings, unless the participant requests that it is withdrawn. Participants will be informed that no data can be removed once the findings are anonymised and sent for publication.

12. Data collection, source data and confidentiality

12.1 Recruitment and retention

A **participant log** (one per target facility) of women who fulfill the eligibility criteria, women who are invited to participate in the study, those recruited and any participants who leave the study before completion will be kept. Reasons for non-recruitment (e.g. refusal to participate, language barrier) will also be recorded. Reason for non-participation will also be collected.

Permission will be sought to collect data on reasons for non-participation from women who have provided contact details but decline to take part. During the course of the study, reasons for withdrawal and loss to follow-up will be documented. For those women who did not gave birth on one of the study site, reason for choosing a different facility will also be recorded.

12.2 Demographics and clinical data

Usual care: demongraphic and clinical data are routinely collected in the ANC register and include the following information: 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 urine (urine dip stick) and physical examination. A electronic case report form created in REDCap will be used to extract demographic, obstetric and medical details and screening results from the ANC register.

PANDA: Demographics and obstetric details will be authomatically collect 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 include: age, ethnicity, spoken language, address / location of visit, marital status and education. Medical history include details about previous and index pregnancy, including

place of birth, vaccinations, onset of labour, mode of birth, maternal and infant outcomes, antenatal and postnatal complications. Screening section includes meansurement 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 include monitoring of the baby, including fundal heigh 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) might be added or removed during the adaptation phase. Data will be collected at recruitment, and for each subsequent visits schedule 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 (heigh, 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 having gaps in the data routinely collected.

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, referrals. This will permit assessment of feasibility of comparison and assessment of the potential for selection bias in sample taking part in the research.

12.3 Acceptability of study processes and the intervention

Acceptability of study processes and the intervention will will be captured by semi-structured face to face (or telephone) interviews with:

- Women participating in the study during phase 2 (up to 20;) after birth.
- Health workers and others involved in the delivery of the intervention (up to 10) at the end of phase 2.

Interviews will be conducted at the participant's preferred venue (home, private room in the hospital), using topic guides and audio-recorded with consent. Women will be interviewed in the local language(Swahili) or English by a bilingual research assistant. Health workers will be interviewed in English or local language. Interviews will be translated where necessary and transcribed verbatim. Field notes and reflexive diaries will be completed by the research assistant as soon as possible after the interview to support interpretation of the data.

12.4 Uptake and additional impact of the intervention on the practice and environment of care

An **intervention log** completed by healthcare providers delivering PANDA and the one managing the Medical Unit / or extract from PANDA will summarise all study related activities to determine what was done, when and by whom. For HCP using PANDA app and Point of Care, this will include number of visit conducted and sent to the server, average length of visits, n. of referrals. For HCP managing the Medical Unit this will include record reviewed, action taken on women with complications etc.

A short questionaire survey of health workers providing antenatal care but not directly involved in delivering the intervention at the end of phase 2 will be conducted.

12.5 Women's rating of quality of antenatal care, respectful care and perceptions around participation to the study

Quality of Antenatal Care: to measure women's rating of the quality of antenatal care, in terms of environment, provision of information, interaction, screening and diagnosis and communication between women and providers we will used the Quality of Prenatal Care Questionnaire(39). This is a valid and reliable self-report tool to comprehensively measure the quality of antenatal care. Developed in Canada and further tested with Australian population, the questionnaire includes 46-items, divided into 6 sub-scales meansuring different dimensions of quality including information sharing, anticipatory guidance, sufficent time, approachability, availability and support and respect. Validation with an Australian population provided acceptable internal consistency reliability overall (Cronbach's alpha 0.97) and for each of the six factors (Cronbach's alpha = 0.74 to 0.95)(40). The tool has also been used in Nigeria to measure satisfaction of prenatal care of 500 women at 36 weeks gestation or within 6 weeks post-partum(41).

Respectful antenatal care: assessment of respectful care components, which consider the WRA Respectful Care Charter(31), including dignified care, adequate communication and trust between women and providers we will used the Person Centred Prenatal Care Scale (PCPCS) (42). Adapted from the Person-Centre Maternity Care Scale validated in Kenya (43), this version focuses on prenatal experience of care among women of colour living in the US, obtaining high content validity and reliability (Cronback alphas >0.8). There are 2 versions of the scale, a 34-item and a 26-items, both including 3 sub-scales for assessing "dignity and respect", "communication and autonomy" and "responsive and supportive care". PCPCS will be used for exit interviews.

During the adaptation phase we will review both tools with the CEI. We will consider appropriatness of questions, whether they can be self-administered or the research midwife / asisstant has to be present, and whether a translation is needed. We will also record the time needed to complete and decide whether to use both tools in their entirety or one or more sub-scales during the feasibility study and cluster trial.

A short questionnaire asking women to rate their experience to take part in the study, including engagement with PANDA e-health system will be conducted.

12.6 Health economics

The equipment required to implement the PANDA system will be provided to the hospitals by the research team. Records will be kept of all equipment provided and the cost to do so. Therefore only the human resources associated with implementing the PANDA system will be captured additionally. The intervention log, as described above, will be used to collect the majority of this information. In addition, healthcare providers who implement the PANDA system will be asked to complete a suvey 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. Finally, the training logs (described above) will be reviewed.

13. Outcomes

The key outcome for the adaptation phase will be the updated PANDA agreed with women, healthcare professionals, stakeholders and CEI.

The key outcomes for feasibility will be include:

- Recruitment and retention of women and health professionals in the study.
- Acceptability and uptake of ANC through PANDA e-health system and experience of study processes will be explored through interviews and questionnaire from women, healthcare staff and others involved with the delivery of PANDA.
- The characteristics of clinical, and resource utilisation measures will be examined including confirming estimates of parameters needed to compute an estimate of sample size for the full-scale study.

14. Analytical considerations

14.1 Analysis

Recruitment and retention

Participant log data will be used to assess recruitment to targets and retention rates. A full scale trial would be considered feasible if recruitment targets were met and a rate of 70% retention achieved. Interview data will clarify possible barriers to recruitment and retention, which can be addressed in preparation for a definitive trial. If recruitment targets are not met or retention is below 70% but at least 60%, we will consider whether any identified barriers could be addressed to improve recruitment and/or retention to acceptable levels and hence make a full-scale evaluation trial potentially feasible; in this situation, the success of strategies to overcome these barriers would be expected to be assessed during an internal pilot phase.

Intervention adaptation and acceptability of participation, the intervention and quality of implementation

These will be explored through analysis of the observations grid, FGDs transcript (Phase1) and intervention log, interviews, observations and field notes (Phase 2) using an inductive approach. Data will be analysed using the framework method (44), a systematic approach comprising five interlinked phases which allow the researcher to move from descriptive accounts to conceptualisation of meaning within the data. During familiarisation, the immersion in the data allows the researcher to identify an overview of main ideas or concepts. This allows the development of a draft theoretical framework. In the third stage, the draft framework is applied back to the raw data to determine fit, known as indexing, and refine as needed. The data are them summarised into thematic charts. In the final phase, data are synthesised through the process of mapping and interpretation (45). Stages 1-4 will be conducted by two researchers, independently, before the review of the charts and confirmation of the overall interpretation and with the input of the wider research team in stage 5. This is to ensure that the key messages conveyed remain truthful to the participant's accounts; transcripts will not be returned to the participants for member-checking. Data will also help determine the appropriateness of proposed outcomes measures. Participants' views and experiences of completing questionnaires and diaries will contribute to evaluating the burden of trial assessments and inform data collection methods for the main trial. The views and experiences of women and staff delivering the intervention will be used to determine acceptability of the intervention and fidelity of the components as delivered in practice compared with those planned, including any impacts on wider services. This data will also identify any areas where further refinement of the intervention is needed.

Quality of care and clinical data

Quantitative data will be inputted into an electronic system (REDCap) and analysed in SPSS / R. Outcome measures will be compared descriptively, using frequencies and percentages for

categorical variables and descriptive statistics including means, standard deviations, medians and ranges for numerical variables. Data from QPCQ and/ or PCPS will be compared to determine whether characteristics are comparable across different measures. This will include a comparison between rates of missing data and their component items. Analysis will focus on the estimation of confidence intervals for differences between the groups and the estimation of variances to inform the design of the full-scale trial.

Health economics

Data collected via the survey, intervention logs, and training logs will be assessed in terms of quality and completeness. The design of the survey and logs will be reviewed to identify changes which will improve data quality for the main trial. Responses to the survey question about whether it is manageable to implement the PANDA system in current workloads will be reviewed and where possible, will be taken into account to improve sustainability before the main trial.

15. Sample size

In phase 1 (adaptation) we will adopt a maximum variation sample to include all relevant groups (healthcare providers, health managers, district health officers, women), stakeholders and service users (CEI group) to ensure acceptability and discuss the implementation strategy of PANDA.

A formal power calculation is not appropriate for a feasibility study, therefore the total sample size of 160 women (40 per site, per phase) and 20 health providers has been determined pragmatically according to the accepted criteria for feasibility studies (46).These numbers will allow implementation of the intervention in two sites and estimation of recruitment/ retention rates and uptake [31]. Our target to recruit 40 women per phase accounts for 10-15 % drop out. This would result in a final sample size of 30 to 35 women per phase. This aligns with accepted criteria for feasibility studies suggesting a sample size between 20 to 40 individuals.

16. Data monitoring, quality assurance and ethics

16.1 Study Management

This study will be subject to the audit and monitoring regime of the sponsor, Liverpool School of Tropical Medicine. Formal monitoring via a data monitoring committee will not be undertaken during this feasibility study as the anticipated risk of harm is low. Howerver we will engage with Global Trial Unit at LSTM to advice on every aspect related to the preparation of the clustered trial.

The Internatonal Advisory Board of the NIHR Unit on Prevention of Stillbirth and Neonatal Death at LSTM, chaired by Dr Yana Richens OBE, will provide technical support and advice on the conduct of the feasibility study and full trial. The Advisory Board will review the study protocol prior to commencement of the research and any amendments, receive progress updates, advise on issues arising with the study conduct and dissemination of the findings in preparation for a full trial.

The study will be managed by Professor Lavender with support from the research team and country principal investigators. A start up meeting with UK and local research teams will be held in-country (Manyara, Tanzania). The Tanzania country lead and co-PI leads will be responsible for day to day co-ordination of trial activity, supported by research assistants. Virtual meetings between the CI/UK research team and Country leads will be conducted fortnigtly initially and at least monthly for the duration of the research. The wider research team, including all co-applicants and the Africa research leads, research assistants will meet virtually bi-monthly to review progress and compliance with research governance.

16.2 Research team

Professor Dame Tina Lavender: Chief Investigator responsible for overall study management, research governance, supervision of the research. Supervise training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination.

Prof Maia Lesosky: Co investigator, supervise analysis of the quantitative data, provide statistical advice and guidance for the design of the full trial.

Dr Paschal Mdoe: Principal investigator Manyara, responsible for overall study management, research governance and supervision of research in Tanzania. Supervise training and supervison for delivery of the intervention, qualitative and clinical analysis, interpretation and dissemination.

Dr Rose Laisser: co investigator Tanzania, responsible for overall study management, finance, research governance and supervision of research in Tanzania.

Dr Tracey A Mills : Co investigator, support for Chief investrigator, set up, training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination

Dr Carol Bedwell: Co investigator, support for Chief investrigator, set up, training and supervision for delivery of the intervention, qualitative and clinical analysis, interpretation, reporting and dissemination.

Dr Elizabeth Camacho: Co investigator (lead health economist), design and oversee health economics components of feasibility study, design and oversee analysis of data for economic evaluation in main trial.

Happiness Saronga: co-investigator Tanzania, support health economics and cost-effectiveness components, advice on design of econoomic evaluation for main trial

Ms Valentina Actis Danna: Co applicant; trial manager at LSTM responsible for day to day management of the study under the supervision of the CI. Administration of REDCap, management and analysis of quantitative data.

Dr Natalie Tate: Co applicant; trial manager at LSTM responsible for day to day management of the study under the supervision of the CI.

Dr Giovanna Stancanelli: collaborator / PANDA developer. Collaborate to updating, installation and implementation of PANDA e-health system in Tanzania. Facilitate training and supervision of delivery of the intervention.

16.3 Reporting and monitoring

16.3.1 Safety reporting

Phase 1 is a participatory and qualitative study with no intervention component and therefore no adverse event reporting is proposed during this phase.

During phase 2 LSTM SOP Handling and Reporting Safety Concerns in Clinical Trials will be followed. The following definitions will apply:

16.3.1.1 Adverse Events (AE) in non-CTIMPs

Definition:

Any untoward medical occurrence in a participant that does not necessarily have a causal relationship with the study procedures. This includes unfavourable and unintended signs or symptoms (including an abnormal laboratory finding) and symptoms or disease temporally associated with the study procedure.

For this study the following is a list of expected maternal and neonatal adverse events which will be recorded but not reported during the feasibility phase only:

Common pregnancy related complications:

- Anaemia defined as haemoglobin level <110 g/L at booking, <105 g/L in 2nd and 3rd trimesters, <100 g/L postpartum
- Hypertension
- New onset/gestational diabetes
- Small for gestational age fetus (Estimated fetal weight <10th centile by ultrasound)
- Fetal malpresentation
- Vaginal bleeding/APH/ placenta praevia identified on ultrasound scan
- Premature rupture of membranes
- Bacterial or viral infection
- Labour related complications including 3rd or 4th degree perineal tear

Post-natal complications:

- Post-partum haemorrhage
- New onset postpartum hypertension
- Wound infection (c-section or perinatal tear)
- Urinary or faecal incontinence
- Breast complications
- Obstetric fistula

Neonatal complications

- Jaundice
- Feeding problems
- Bacterial or viral infections
- Respiratory complications including neonatal respiratory distress syndrome
- Hypoxic-Ischemic Encephalopathy

16.3.1.2 Serious Adverse Event (SAE) in non-CTIMPs

Definition:

Any adverse event (see definition above) that:

a) results in death,

b) is life-threatening,

c) requires hospitalisation or prolongation of existing hospitalisation,

d) results in persistent or significant disability or incapacity
e) consists of a congenital anomaly or birth defects
f) OR is otherwise considered medically significant by Prof Dame Tina Lavender or Dr Paschal Mdoe or Dr Rose Laisser

The following are expected serious maternal adverse events for the study population which will be recorded but not reported for further investigation:

Pregnancy related complications:
Admission to hospital for anaemia.
Admission to hospital for hypertension.
Admission to hospital with new onset/ gestational diabetes
Admission to hospital for monitoring or care related to small for gestational age foetus (Estimated fetal weight <10th centile by ultrasound)
Admission to hospital with fetal malpresentation
Admission to hospital with vaginal bleeding/APH/ placenta praevia/premature rupture of membranes (identified clinically, or on ultrasound scan)
Admission to hospital for investigation or treatment of bacterial or viral infection
Admission to hospital for elective birth.
Prolongation of admission or readmission related to labour related complications e.g., perineal tears or PPH

16.3.2 Recording and reporting

Adverse events will be recorded in study documentation (CRF) by the research assistants and collated for each participant on an Adverse Event Form at the end of the study. AE will be assessed for seriousness, causality, severity and expectedness by the PI. Adverse events will be reviewed at the end of the study by the NIHR Unit International Advisory Board and the Sponsor.

Serious Adverse Events (other than those listed above) will be recorded on a SAE report form and reported by the research assistant to the local PI who will report to the CI as soon as possible after becoming aware (normally within 24 hours). Verbal reporting will be followed with a detailed written report.

SAEs will be reported to the to the Sponsor and Research Ethics Committee (REC) if in the opinion of Professor Dame Tina Lavender, they are:

Related - that is resulted from administration of any research procedures
AND
Unexpected –that is, the type of event is not listed in the protocol as an expected event

A **SAE** meeting these criteria with be reported in writing using the Serious Adverse Event Report as soon as possible and within 15 days of the CI becoming aware of the SAE. SAEs will be reviewed by the Sponsor using their standard criteria and a specific course of action will be recommended for the study and implemented by the Investigators.

17. Ethical considerations

Research governance approvals from LSTM and approval from CUHAS and National Institute of Research in Tanzania will be obtained before commencing research. We will also seek formal approval from facility involved and the District Health Authority.

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP), Safeguarding and within the laws and regulations of the country in which the research is conducted. We will ensure participants that confidentiality and anonymity would be maintained and pseudonym will be used to replace their names. Data will be collected and stored in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislated to protect personal information.

LSTM as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting. In accordance with LSTM Data Management policy a Data Management Plan has been developed for this study.

18. Dissemination and publication policy

Dissemination of study progress and results will include academic and non-academic means, including conference presentations, 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 (47) and ensure equitable authorship between countries (48), 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:

2. No raw data can be shared with anyone outside the core team prior to publication
3. Hard copy or electronic copies of any results cannot be disseminated beyond the immediate research team prior to publication
4. 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
5. Any press releases should be notified to the NIHR 14 days in advance of them happening
6. All publications should have a statement outlining how the data can be accessed
7. All publications must contain the statement below:

"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".

19. Budget Justifification

This budget is for annual activities of the study.

Tanzania team:

1. Study PI (1, 5%). Responsible for study oversight -- $3,300/year
2. Research Manager (1, 100%). Responsible for all the regulatory issues, study coordination, and reporting -- $14,304/year
3. Field Research Assistant (6, 100%). Responsible for the day-to-day conduct of the field research -- $23,040/year
4. Field Research Officer (2, 100%). Responsible for leading the field research -- $9,600/year
5. Data Manager (1, 25%). Responsible for managing the data collection and data collection devices -- $2,337/year
6. Transport reimbursement of the healthcare workers (10% TE) $5,096/year

Transport

7. Transport costs -- $3,184/year

Other costs:

8. Site preparation; Meeting with the TAMISEMI, Regional and District authorities to inform about the study, and seek their endorsement. Site preparation and staff training on the use of the PANDA app -- $8000
9. Costs for regulatory applications and reporting (NIMR fees), stationaries, post costs, etc. The first application, amendments, and annual extensions -- $1700
10. Other expenses/unforeseen -- $1000
11. Total annual + 10% Institutional overhead - $15,054

20. Timelines

Adaptation and feasibility study

<table>
<tr><td colspan="4">Year 1</td><td colspan="4">Year 2</td><td colspan="4">Year 3</td></tr>
<tr><td colspan="2">2021</td><td colspan="4">2022</td><td colspan="4">2023</td><td colspan="2">2024</td></tr>
<tr><td>Q1 Jul-Sep</td><td>Q2 Oct-Dec</td><td>Q3 Jan-Mar</td><td>Q4 Apr- Jun</td><td>Q1 Jul-Sep</td><td>Q2 Oct-Dec</td><td>Q3 Jan- Mar</td><td>Q4 Apr- Jun</td><td>Q1 Jul- Sep</td><td>Q2 Oct-Dec</td><td>Q3 Jan-Mar</td><td>Q4 Apr-Jun</td></tr>
<tr><td></td><td>Start up</td><td>Ethics</td><td colspan="10"></td></tr>
<tr><td colspan="2"></td><td colspan="4">PANDA adaptation</td><td colspan="6"></td></tr>
<tr><td colspan="2"></td><td>TWC</td><td>CEI Stakeholders review</td><td>FGDs</td><td>PANDA prototype</td><td colspan="6"></td></tr>
<tr><td colspan="5"></td><td>Protocol amendment approval</td><td colspan="5">Feasibility study</td><td></td></tr>
<tr><td colspan="5"></td><td></td><td>Control data collection</td><td>Follow up control</td><td>Int data collection</td><td>Follow up intervention</td><td></td></tr>
<tr><td colspan="9"></td><td>Approved protocol for cluster trial</td><td></td></tr>
</table>

Feasibility timeline

Month											
1	2	3	4	5	6	7	8	9	10	11	12
Recruitment Control group											
	Follow up control group until birth										
						Start PANDA Recruitment Intervention group					
							Follow up control group until birth				

References

1. UNICEF, WHO. Ending preventable newborn deaths and stillbirths by 2030: Moving faster towards high-quality health coverage in 2020-2025. Geneva: UNICEF, WHO, 2020.

2. UN IGME UNI-aGfCME. Stillbirth Estimates 2020 [cited 2021 18 March]. Available from: https://data.unicef.org/topic/child-survival/stillbirths/.

3. Cacciatore J. Psychological effects of stillbirth. Seminars in Fetal and Neonatal Medicine. 2013;18(2):76-82. doi: 10.1016/j.siny.2012.09.001.

4. Wondemagegn AT, Alebel A, Tesema C, Abie W. The effect of antenatal care follow-up on neonatal health outcomes: a systematic review and meta-analysis. Public health reviews. 2018;39(1):33. doi: 10.1186/s40985-018-0110-y.

5. Adi Galgallo D, Gura Roka Z, Boru WG, Ransom J. Descriptive analysis of effect of uptake of comprehensive antenatal care services on neonatal mortality, Kenya. African Journal of Midwifery and Women's Health. 2019;13(3):1-5. doi: 10.12968/ajmw.2017.0043.

6. Kuhnt J, Vollmer S. Antenatal care services and its implications for vital and health outcomes of children: evidence from 193 surveys in 69 low-income and middle-income countries. BMJ Open. 2017;7(11):e017122. doi: 10.1136/bmjopen-2017-017122.

7. Dube K, Lavender T, Blaikie K, Sutton CJ, Heazell AEP, Smyth RMD. Identification of factors associated with stillbirth in Zimbabwe – a cross sectional study. BMC Pregnancy and Childbirth. 2021;21(1):662. doi: 10.1186/s12884-021-04102-y.

8. Chuwa FS, Mwanamsangu AH, Brown BG, Msuya SE, Senkoro EE, Mnali OP, et al. Maternal and fetal risk factors for stillbirth in Northern Tanzania: A registry-based retrospective cohort study. PLOS ONE. 2017;12(8):e0182250. doi: 10.1371/journal.pone.0182250.

9. Lavender T, Bedwell C, Kasengele CT, Kimaro D, Kuzenza F, Lyangenda K, et al. Respectful care an added extra: a grounded theory study exploring intrapartum experiences in Zambia and Tanzania. BMJ Global Health. 2021;6(4):e004725. doi: 10.1136/bmjgh-2020-004725.

10. Tekelab T, Chojenta C, Smith R, Loxton D. The impact of antenatal care on neonatal mortality in sub-Saharan Africa: A systematic review and meta-analysis. PLOS ONE. 2019;14(9):e0222566. doi: 10.1371/journal.pone.0222566.

11. World Health Organization. WHO recommendations on antenatal care for a positive pregnancy experience. Geneva, Switzerland: World Health Organization,, 2018 978 92 4 154991 2.

12. UN IGME UNI-aGfCME. 'Levels & Trends in Child Mortality: Report 2020, Estimates developed by the United Nations Inter-agency Group for Child Mortality Estimation'. New York: United Nations Children's Fund, 2020.

13. Ministry of Health CD, Gender, Elderly and Children (MoHCDGEC) [Tanzania Mainland], , Ministry of Health (MoH) [Zanzibar], National Bureau of Statistics (NBS), Chief Oot, Government Statistician (OCGS), ICF International. Demographic and Health Survey and Malaria Indicator Survey (DTHS - MIS) 2015-16. Dar es Salaam, Tanzania

Rockville, Maryland, Usa2016.

14. Finlayson K, Downe S. Why do women not use antenatal services in low- and middle-income countries? A meta-synthesis of qualitative studies. Plos Med. 2013;10(1):e1001373-e. doi: 10.1371/journal.pmed.1001373. PubMed PMID: 23349622.

15. Mgata S, Maluka SO. Factors for late initiation of antenatal care in Dar es Salaam, Tanzania: A qualitative study. BMC Pregnancy and Childbirth. 2019;19(1):415. doi: 10.1186/s12884-019-2576-0.

16. Konje ET, Magoma MTN, Hatfield J, Kuhn S, Sauve RS, Dewey DM. Missed opportunities in antenatal care for improving the health of pregnant women and newborns in Geita district, Northwest Tanzania. BMC Pregnancy and Childbirth. 2018;18(1):394. doi: 10.1186/s12884-018-2014-8.

17. Thaddeus S, Maine D. To far to walk: Maternal Mortality in Context. Soc Sci Med. 1994;38(8):1091 - 110.

18. Laisser R, Woods R, Bedwell C, Kasengele C, Nsemwa L, Kimaro D, et al. The tipping point of antenatal engagement: A qualitative grounded theory in Tanzania and Zambia. Sexual & Reproductive Healthcare. 2022;31:100673. doi: https://doi.org/10.1016/j.srhc.2021.100673.

19. Actis Danna V, Bedwell C, Wakasiaka S, Lavender T. Utility of the three-delays model and its potential for supporting a solution-based approach to accessing intrapartum care in low- and middle-income countries. A qualitative evidence synthesis. Glob Health Action. 2020;13(1):1819052. doi: 10.1080/16549716.2020.1819052.

20. Shimoda K, Horiuchi S, Leshabari S, Shimpuku Y. Midwives' respect and disrespect of women during facility-based childbirth in urban Tanzania: a qualitative study. Reprod Health. 2018;15(1):8. Epub 20180110. doi: 10.1186/s12978-017-0447-6. PubMed PMID: 29321051; PubMed Central PMCID: PMC5763614.

21. Feroz A, Perveen S, Aftab W. Role of mHealth applications for improving antenatal and postnatal care in low and middle income countries: a systematic review. BMC Health Services Research. 2017;17(1):704. doi: 10.1186/s12913-017-2664-7.

22. Eysenbach G. CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions. J Med Internet Res. 2011;13(4):e126. doi: 10.2196/jmir.1923.

23. Labrique AB, Vasudevan L, Kochi E, Fabricant R, Mehl G. mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. Global Health: Science and Practice. 2013;1(2):160. doi: 10.9745/GHSP-D-13-00031.

24. Lee SH, Nurmatov UB, Nwaru BI, Mukherjee M, Grant L, Pagliari C. Effectiveness of mHealth interventions for maternal, newborn and child health in low- and middle-income countries: Systematic review and meta-analysis. Journal of global health. 2016;6(1):010401. doi: 10.7189/jogh.06.010401. PubMed PMID: 26649177; PubMed Central PMCID: PMC4643860.

25. Terre Innovative Healthcare S.r.l. Pregnancy And Newborn Diagnostic Assessment, 2021 [cited 2021 26/11]. Available from: https://www.terreinnovative.com/panda-burkina.

26. Ouédraogo AM, Compaoré R, Somé A, Dahourou DL, Cissé K, Tougri H, et al. Acceptability and satisfaction with pregnancy and newborn diagnostic assessment (PANDA) system providing prenatal care in Burkina Faso. The Pan African medical journal. 2020;37:361-. doi: 10.11604/pamj.2020.37.361.25167. PubMed PMID: 33796175.

27. Anne Caroline Benski GS, Stefano Scaringella, Josea Le´a Herinainasolo, Je´romine Jinoro, Pierre Vassilakos, Patrick Petignat, Nicole C Schmidt. Usability and feasibility of a mobile health system to provide comprehensive antenatal care in low-income countries: PANDA mHealth pilot study in Madagascar. Journal of Telemedice and Telecare. 2016;0(0):1-8. doi: 10.1177/1357633X16653540.

28. Borsari L, Stancanelli G, Guarenti L, Grandi T, Leotta S, Barcellini L, et al. An Innovative Mobile Health System to Improve and Standardize Antenatal Care Among Underserved Communities: A Feasibility Study in an Italian Hosting Center for Asylum Seekers. J Immigr Minor Health. 2018;20(5):1128-36. Epub 2017/11/17. doi: 10.1007/s10903-017-0669-2. PubMed PMID: 29143900.

29. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. 2021;25:57. doi: 10.3310/hta25570.

30. Lattof SR, Moran AC, Kidula N, Moller A-B, Jayathilaka CA, Diaz T, et al. Implementation of the new WHO antenatal care model for a positive pregnancy experience: a monitoring framework. BMJ Global Health. 2020;5(6):e002605. doi: 10.1136/bmjgh-2020-002605.

31. WRA. Respecful Maternity Care: the universal right of childbearing women. White Ribbon Alliance, 2011.

32. WHO. WHO Recommendations: intrapartum care for a positive childbirth experience. Geneva: World Health Organisation, 2018 2018. Report No.: CC BY-NC-SA 3.0 IGO.

33. Feng Liu SM. "Nonparticipant Observation". In: Wiebe AJMGDE, editor. Encyclopedia of Case Study Research. Thousand Oaks: SAGE Publications, Inc.; 2010. p. 610-2.

34. Lavender T, Bedwell C, Blaikie K, Actis Danna V, Sutton C, Kasengele CT, et al. Journey of vulnerability: a mixed-methods study to understand intrapartum transfers in Tanzania and Zambia. BMC Pregnancy and Childbirth. 2020;20(1):292. doi: 10.1186/s12884-020-02996-8.

35. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology. 2013;13(1):117. doi: 10.1186/1471-2288-13-117.

36. MoHCDGEC MoH, Community Development, Gender, Elderly and Children [Tanzania Mainland],. Antenatal Care Guidelines. 2018.

37. Bedwell C, Lavender T. Giving patients a voice: implementing patient and public involvement to strengthen research in sub-Saharan Africa. Journal of Epidemiology and Community Health. 2020;74(4):307. doi: 10.1136/jech-2019-212525.

38. Kruegar R., Casey M. Overview of Focus Groups. Focus groups : a practical guide for applied research. 3rd Ed. ed: Thousand Oaks, Calif. : Sage Publications, ©2000.; 2000. p. 3-18, 167-8.

39. Heaman MI, Sword WA, Akhtar-Danesh N, Bradford A, Tough S, Janssen PA, et al. Quality of prenatal care questionnaire: instrument development and testing. BMC Pregnancy and Childbirth. 2014;14(1):188. doi: 10.1186/1471-2393-14-188.

40. Sword W, Heaman M, Biro MA, Homer C, Yelland J, Akhtar-Danesh N, et al. Quality of prenatal care questionnaire: psychometric testing in an Australia population. BMC Pregnancy Childbirth. 2015;15:214. Epub 20150910. doi: 10.1186/s12884-015-0644-7. PubMed PMID: 26357847; PubMed Central PMCID: PMC4566370.

41. Bello OO. Quality of Antenatal Care: Comparison between Secondary and Tertiary Health Facilities in Ibadan, Nigeria Open Journal of Obstetrics and Gynecology. 2018;8(6):559-71. doi: 10.4236/ojog.2018.86063.

42. Afulani PA, Altman MR, Castillo E, Bernal N, Jones L, Camara TL, et al. Development of the person-centered prenatal care scale for people of color. American Journal of Obstetrics & Gynecology. 2021;225(4):427.e1-.e13. doi: 10.1016/j.ajog.2021.04.216.

43. Afulani PA, Diamond-Smith N, Golub G, Sudhinaraset M. Development of a tool to measure person-centered maternity care in developing settings: validation in a rural and urban Kenyan population. Reproductive health. 2017;14(1):118-. doi: 10.1186/s12978-017-0381-7. PubMed PMID: 28938885.

44. Richie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. Analyzing Qualitative Data New York: Routledge; 1994. p. 173-94.

45. Richie J, Spencer L, O'Connor W. Analysis: Practices,Principles and Processes. In: Richie J, Lewis J, editors. Qualitative Research Practice: A Guide for Social Science Students and Researchers London: Sage; 2003.

46. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. Stat Methods Med Res. 2016;25(3):1057-73. doi: 10.1177/0962280215588241. PubMed PMID: 26092476; PubMed Central PMCID: PMC4876429.

47. Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. J Pharmacol Pharmacother. 2010;1(1):42-58. PubMed PMID: 21808590.

48. Morton B, Vercueil A, Masekela R, Heinz E, Reimer L, Saleh S, et al. Consensus statement on measures to promote equitable authorship in the publication of research from international partnerships. Anaesthesia. 2021;n/a(n/a). doi: https://doi.org/10.1111/anae.15597.