Centre for Maternal and Newborn Health

Liverpool School of Tropical Medicine

Trial Protocol

Randomised stepped wedge trial to assess the effectiveness of healthcare provider training on the availability and quality of Antenatal (ANC) and Postnatal Care (PNC) in Chad

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1. Overview (Lay Summary)

Maternal and perinatal morbidities and deaths remain a challenge especially in lower- and middle-income settings, including Chad. Antenatal and postnatal care offered in healthcare facilities (HCFs) by trained healthcare providers (HCPs) is an essential platform for addressing the health needs of women and babies at the time of pregnancy and the immediate period after the baby is born. The services are expected to include not only advice and screening, but also testing and treatment for conditions and diseases such as malaria, HIV and tuberculosis (TB) as well as hypertension, anaemia and other complications. The essential beneficial components of care should be offered and provided to each woman and/or her baby at the time of her visit to the clinic, so that the appropriate treatment can be started to help the mother and prevent illness in the baby. If all services are offered as part of what is called integrated care, the woman and her baby receive all the required care during the same clinic-visit, and probably, by the same HCP, and does not have to come back to another clinic or at another time.

In practice however, although many women spend quite a lot of time at the HCF each time they visit, they often do not receive all the necessary components of care. Both the content and the quality of care are at times insufficient; this may due to a lack of knowledge, skills and / or confidence among HCPs in how best to provide all aspects of care, or gaps with how the services are organised.

To improve the quality and availability of care, a common strategy in LMIC is to provide HCPs with in-service competency-based practical training workshops. However, commonly used tests for evaluation of trainings do not assess whether there is behavioural change in clinical practices. A powerful tool to explore it is to directly observe consultations and the provision of care.

The objective of this trial is to evaluate the effectiveness of 'Skills and drills' competency-based ANC-PNC training of healthcare professionals for the improvement of practice in the delivery of ANC-PNC essential components during ANC and PNC visits.

2. Justification for research

2.1 Background

2.1.1 Integrated ANC and PNC

Although significant progress has been made with increased global coverage of interventions to improve maternal and newborn health (MNH), there is wide recognition that further improvement in outcomes will depend on the ability to address the gap between coverage and quality. Improving the quality of healthcare services and making quality an integral component of scaling-up of interventions that are known to be effective is crucial if health outcomes for mothers and babies are to improve.

Of the 50 essential interventions for reproductive, maternal, newborn and child health for which there is evidence of effectiveness and which can be expected to have a significant impact on maternal, newborn and child survival, 16 (including the specific components of the antenatal care package) are expected to be implemented as part of ANC and 12 as part of PNC (PMNCH, 2011). These are meant to be implemented as a continuum of integrated care, inclusive of the recognition and management of obstetric complications (including pre-eclampsia, haemorrhage, anaemia, preterm birth), as well as the burden of infectious disease (including Syphilis, HIV/AIDS, Tuberculosis (TB) and malaria) (WHO 2016, Lancet 2016).

The provision of ANC and PNC for mothers and babies during and after pregnancy aims to prevent, identify, and, manage conditions that cause maternal and neonatal morbidity and which may result in, or contribute to, maternal mortality, stillbirth and neonatal death. Pregnant women represent the highest number of users globally at HCF level with over 86% of all women attending ANC at least once and 65% attending four times or more (Global UNICEF database, 2019.

2.1.2 Availability of integrated services for ANC and PNC in LMIC

In 2017 and 2018, CMNH-LSTM conducted HCF assessment surveys in Togo, Ghana, Chad, Afghanistan, Niger to assess the availability, quality and uptake of ANC and PNC including for HIV, TB and malaria (van den Broek et al 2018abcd, 2019).

Across all surveyed countries, the general findings provided new evidence to support emerging international recognition that, in practice, in many settings, the proposed continuum of care is not available or is of sub-standard quality (WHO, 2018; Singh et al, 2016). Two important modifiable factors which are likely to contribute to this are: many HCPs do not have the updated capacity (knowledge and skills) to be able to provide evidence-based integrated services for ANC and PNC to mothers and babies, and, the components of care required (consumables, drugs, equipment) may not all be in place.

New models of care for ANC and PNC call for improving the integration of screening and testing of infectious disease (including Syphilis, HIV/AIDS, Tuberculosis (TB) and malaria)

(WHO 2016, Lancet 2016), moving away from more vertical disease-oriented approaches of provision of care. (WHO 2002, WHO 2018). In parallel, CMNH-LSTM has developed a mapping of the key components of ANC and PNC through review of current international guidelines for essential components of ANC and PNC (WHO 2018). This mapping was conducted via a scoping review of the literature (including international and national guidelines for the provision of ANC and PNC) and via a series of consensus-building workshops (international workshop Liverpool 2017 including UN partners and Global Fund, in-country workshops in Afghanistan, Chad, Ghana and Togo) **(Appendix 1)**. These components as compiled and presented reflect the minimum essential care packages required to be in place (available) during ANC and PNC in LMIC for mothers and babies.

2.1.3 Maternal and Newborn Health in Chad

Chad continues to face challenges with high mortality rates and poor outcomes in maternal and child health. Establishing a baseline of information on the availability and quality of care offered in healthcare facilities across the country was therefore a key priority for the government to ensure better understanding of the current situation and to identify gaps which need to be addressed in order to ensure strategic action is taken to improve health care and healthcare outcomes during and after pregnancy.

Uptake of antenatal and postnatal care is relatively limited: six out of ten women attend / complete at least one ANC visit and the proportion falls to three out of ten for four visits prenatally, compared to 86% and 62% globally. Postnatally, the statistics are even less adequate, with 16% of mothers and under 5% of babies receiving a postnatal visit within the first 48 hours of delivery (INSEED, 2016).

Just one in five deliveries are conducted in healthcare facilities and a quarter are assisted by a skilled birth attendant (INSEED, 2016) indicating limited engagement with more formal health services. The number of maternal deaths per 100,000 live births (maternal mortality ratio) is estimated to be 856, placing Chad in the 227th position of 229 countries globally. For newborn mortality, Chad ranks 221st of 225 countries globally based on 2017 statistics (World Bank, 2020). This suggests that there are considerable gaps with regard to care for women and babies, which require concerted effort to improve availability but also quality of care, a determinant that has been widely identified for preventing mortality and morbidity among mothers and newborns (WHO, 2013).

Table 1: Maternal health indicators in Chad

Indicator	Value
AN care – at least 1 visit (%) *	62.5
AN care – 4+ visits (%) *	31.0
PNC visit within 2 days for baby (% of all births) *	4.5
PNC visit within 2 days for mother (% of all births) *	16.0
Births in health care facilities (%) *	21.7

Indicator	Value
Births attended by skilled personnel (%) ** (2010)	24.3
Maternal mortality ratio (per 100,000 live births) ** (2015)	856
Neonatal mortality rate (NMR), deaths per 1,000 live births* (2018)**	34.2

*Source: DHS-2014-15 (INSEED, 2015)
**Source: (World Bank, 2020)
*** Source: (Unicef 2020)

For specific diseases, the three of main focus, namely HIV, TB and malaria, data for the overall population suggest that with prevalence rates at 1.6% for HIV, and incidence rates of 154 (per 100,000 population) for TB and 189 (per 1000 population at risk) for malaria, pregnancy and the pre- and postnatal periods create a unique opportunity for women and their babies to access the necessary care to prevent, diagnose and manage these conditions.

Table 2: HIV, TB and Malaria indicators in Chad

Indicator	Value
HIV prevalence among adults, aged 15-49/100,000 population (%) (2010) *	1.6
Deaths due to HIV/AIDS per 100,000 (2012) *	116
Malaria incidence/1000 population at risk(2017)**	188.61
Number of reported deaths due to malaria (2017)**	2,088
TB incidence /100,000 population* (2017)**	154
Number of deaths due to TB, excluding HIV/100,000 population* (2017)**	28

* Source: http://apps.who.int/gho/data/node.country.country
** Source : http://apps.who.int/gho/data/node.main.A1367?lang=en
*** Source : http://apps.who.int/gho/data/node.main.1317?lang=en

In close partnership with the Ministry of Public Health in Chad (Ministère de la Santé Publique - MSP) and the CSSI-CRASH consortium, a baseline survey of 60 healthcare facilities in twelve regions (Batha, Borkou, Ennedi Est, Hadjer-Lamis, Kanem, Logone Oriental, Mandoul, Mayo-Kebi Est, Mayo-Kebi Ouest, Moyen Chari, N'Djamena, Tandjile) conducted by CMNH-LSTM in 2018 (van den Broek et al, 2019), demonstrated relative service provision. However, it raised concerns over the unfulfilled potential for identifying those who need support in the area of HIV, TB and malaria during antenatal and postnatal periods. This was despite good availability of consumables and medicines, which indicates a strong platform for improvement in content and quality with integration across these three diseases. Several essential components of ANC-PNC, including screening for infectious diseases but also screening for pre-eclampsia and anaemia were not routinely provided to women during and after pregnancy and their newborns. This lack of quality care led to the development of the ANC-PNC and quality

improvement training packages that will be delivered to more than 350 healthcare providers in 60 healthcare facilities in this program, with an appropriate performance framework to follow-up key-indicators around ANC-PNC, with regard to HIV, TB and malaria in particular.

Overall, with 6,936 ANC visits (of which 3,248 attending for the first/booking visit) and 826 PNC visits in the month of the survey – giving an estimate of 93,144 women annually – there is a wide scope for reaching a substantial population of women and babies to provide them with both basic services and disease-specific care.

There was good availability of services reported for the three diseases; 90% facilities offered HIV screening and 78.3% also offered treatment; 91.7% healthcare facilities offered malaria screening and treatment; 35% offered TB screening and treatment. However, it was evidenced that despite the full availability of rapid diagnostic tests for HIV (100%), the systematic screening for HIV in ANC was incomplete: HIV tests were conducted for 2,501 women at ANC (1,791 among them at booking visit – 55% of all women coming for ANC1) and 237 (28.7%) at PNC. Besides, 15.5% of women were tested for syphilis at ANC1, and none at PNC, even though 60% of healthcare facilities had rapid diagnostic tests. Furthermore, there was no screening for TB in ANC or PNC (1 woman - ~0%), suggesting that there are missed opportunities for identifying positive cases linked to the clinical screening and the decision to test women. For malaria, 413 (12.5%) women were tested for malaria at ANC and 17 (2.1%) at PNC with all those testing positive starting treatment. The high positivity rate among women tested (47.5%), suggested that the low proportion of women tested in ANC and especially in PNC could result in missed opportunities to identify and treat women. Again, there was a reported good availability of malaria testing kits (80%), therefore ruling out lack of availability as a sole explanation for this. Regarding provision of intermittent preventive treatment of malaria in pregnancy (IPTp), 54% of eligible women received prophylaxis in ANC, despite Sulfadoxine-pyrimethamine (SP) being found in 94.3% of healthcare facilities. This is indicative of the opportunity to improve the provision of basic and disease specific care.

In terms of infrastructure, consumables and medications, there was good provision of basic elements for providing care with nearly all facilities having chairs (86.7%), desks (90%) and examination couches (93.3%) and 81.7% of facilities having curtains for protecting privacy of patients. Most facilities had measuring tapes for fundal height (95%), stethoscopes (83.3%), and adult weighing scales (88.3%). However, other basic equipment such as thermometers (16.7%) and pregnancy/EDD wheel (40%) were missing in a good proportion of healthcare facilities. This suggests a somewhat inconsistent environment for service provision.

2.2 Description of trial interventions

To improve the availability and quality of integrated ANC and PNC, CMNH-LSTM has developed competency based in-service training workshops for HCPs providing ANC and PNC at health facility level.

To ensure improved capacity for the delivery of ANC and PNC, HCPs will receive in-service competency-based training to increase knowledge and skills on how to provide women- and baby-friendly, evidence-based, integrated ANC and PNC care.

ANC-PNC competency-based training package was developed by a multi-disciplinary, multi-national team of experts at CMNH-LSTM. Following a process of internal and external expert peer-review this was piloted successfully and further adapted for participating countries (**Box 1**).

As part of the piloting of this training package, knowledge assessments (Multiple Choice Questions tests, MCQs) were conducted for 206 HCP and skills were tested (Objective Structured Clinical Examinations, OSCEs) for 45 HCPs across four countries (including Chad), immediately before and after the training to understand the initial level of competencies of HCPs and note any changes recorded following the training. This showed that 85% of HCPs improved their knowledge score and 82.5% improved their skills (unpublished information).

Box 1: Competency-based ANC-PNC training workshop

Comprehensive competency-based participatory learning ANC-PNC workshop package includes:

- Participant and Facilitator Manuals (in English and French)
- Generic timetable for a 3-day (for smaller groups up to 15 participants) or 5-day (for larger groups up to 30 participants) workshop with content covered the same for each workshop
- Mannequins and teaching equipment
- Teaching aids and job aids
- Tools for assessment of knowledge and skills (MCQs and OSCEs)

In line with an adult-learning participatory approach the workshop content and mode of delivery includes:

Didactic lectures (15%), competency-based active learning (65%) consisting of hands-on demonstration of skills, scenarios, discussions and workshops; mentoring (10%) and self-evaluation and assessment (10%).

In-service training will be provided in each setting by CMNH-trained Master Trainers using the standardised workshop timetables and teaching materials.

This trial has been designed to assess the effect of the ANC-PNC training on the delivery of the full ANC-PNC package at all visits. Based on the observations of ANC-PNC visits, the trial aims to provide a more specific picture of the quality of care than knowledge and skills assessments, especially around components that are not captured in routine data collection, such as clinical practice (looking for signs of TB or malaria) or respectful maternity care. The aim is to generate high-level evidence on the efficacy of the trainings that could be used for advocacy and future scale-up.

2.3 Trial hypotheses and objectives

For this implementation research study, the hypothesis is that training of HCPs on 'Skills and drills' competency-based ANC-PNC will improve the delivery of integrated services of ANC and PNC.

2.3.1 Objectives

The primary objective is to estimate the impact of 'Skills and drills' competency-based ANC-PNC training of healthcare professionals on professional practice in the delivery of ANC-PNC essential components during ANC and PNC visits (for a full list of those, please refer to Appendix 1).

Outcomes to be assessed will include:

- Delivery of essential components at ANC visits
- Delivery of essential components at PNC visits

3. Methodology

3.1 Trial setting

3.1.1 Selection of participating HCFs

In consultation with the Ministry of Health public or private HCFs in N'Djamena have been identified. The facilities are: 1) designated to provide ANC and PNC, and 2) in a state of readiness to provide ANC and PNC (i.e. equipment and consumables in principle in place).

The above criteria will be observed to provide a sample of primary and secondary or above healthcare facilities to include all levels of service provision. Based on the previous engagement in Chad, of the 20 HCF from N'djamena included in the initial facility assessment, at least 18 will be included in the trial. There will be a possibility to include up to 20 HCF, depending on advice from the Ministry of Public Health, to balance the risk of attrition should any HCF from the sample decide to withdraw during the trial. All sample size calculation (see relevant sections below) assumed 18 HCFs, hence our calculation is conservative as a larger sample would only reduce the difference detectable. The current list of HCFs is provided in **Appendix 4**.

3.1.2 Selection of participating women

All women aged 18 years-old or more coming for an ANC or PNC visit will be eligible to be included in the trial and the care they receive observed. Exclusion criteria include:

- Age less than 18 years-old
- Refusal of client for her care to be observed to the study

- Any expression of physical or psychological distress under the idea of being observed during consultation while receiving information

3.2 Trial type and design

3.2.1 Trial design

A multi-dimensional incomplete stepped wedge cluster randomised trial design (SW-RCT) in a cohort of HCPs will be used to assess the effects of the intervention (Training in ANC and PNC). The study duration will be 12 months with each step being 6 or 7 weeks in duration. Each HCF will receive the intervention (ANC-PNC training) and be observed following a defined schedule. The participants will be HCPs at the participating HCFs, for whom assessments are obtained in each assessment period through observing them in the provision of ANC-PNC services. The design is summarised in **Table 3.**

The benefits of the stepped wedge design in terms of feasibility and level of proof have been described previously (Hargreaves et al 2015, Hemming et al 2015, Prost et al 2015). Each HCF will provide data for both the control and the intervention state, which increases the efficiency of the trial. Estimates of intervention effects are expected to be more precise than in a parallel trial design.

Table 3: Summary of trial design

Intervention	**Training in ANC and PNC**
Design	Multi-dimensional incomplete SW CRT
	Cohort
Sampling units	Primary: 18 HCFs Secondary: 36 to 54 HCPs (2 to 3 per HCF and per step) Tertiary: clients (3 to 4 observations per HCP and per step)
Data measurement per HCF	Delivery of essential components during sampled ANC-PNC visits
No. and duration of steps	Six steps, eight assessment periods – each 1.5 months long (6-7 weeks)
Trial duration	12 months
Primary Outcome	Proportion of essential components delivered during ANC-PNC visits

3.2.2 Clusters

Delivery of essential components will be assessed through the observation of ANC-PNC visits by external data collectors. At each healthcare facility at least two HCPs (three for bigger facilities) will be observed in four of the eight assessment periods. For each HCP four HCP-

client interactions (ANC or PNC visits) would be observed in at least three of the four assessment periods for their HCF.

The design to be deployed is a cluster randomised design since the HCPs for whom data are to be collected are clustered, by HCF. For the assessment of delivery of essential components by an individual HCP at a single HCF in each step, a second level of clustering arises: the data obtained from observation of up to 4 different ANC-PNC visits also forms a cluster as described in **Figure 1.**

Figure 1: Schematic representation of sequences available to randomise to HCFs

Group	Assessment period							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
A	O	T	O		O		O	
B		O	T	O		O		O
C	O		O	T	O		O	
D		O		O	T	O		O
E	O		O		O	T	O	
F		O		O		O	T	O

O = Observation
T = Training

3.2.3 Other aspects of the trial

The results from the baseline survey conducted in 2018 were used to assess the HCF ability to provide the essential components of ANC-PNC. Availability of equipment and consumables to be able to provide the services was assessed as part of this previous study. Based on this previous assessment, some basic equipment and commodities will be provided to minimise the risk that the essential components of ANC and PNC cannot be provided in principle (**Appendix 5**). Although the implementation programme will not be able to refurbish HCFs or provide additional human resources, where smaller pieces of equipment (e.g. thermometer) are not in place, these will be provided as a 'one-off' by the programme through a catalytic facility improvement fund in the period immediately before the trial commences. All healthcare facilities are to receive the same type of equipment, with amounts according to the facility level and volume. This will be documented e.g. what type of equipment was provided and when.

Availability (or not) of all required components for each component of ANC and PNC **(Appendix 1)** will be assessed during the trial on a quarterly basis. Each healthcare facility will receive a compensation in utilities for hygiene and sanitation such as soap or disinfectant solutions for mopping the floor for an equivalent of $20per quarter for a focal point to send copies of their routine anonymous data from registers, as well as report on availability of

equipment and consumables necessary for the delivery of ANC-PNC essential components. Observation days will offer opportunity to conduct quality assurance on this process. The tool used to collect this data is described in **Appendix 3**. Data will be used in analysis to assess the effect attributable to the availability of equipment and consumables in the delivery of essential component.

Furthermore, the CMNH-LSTM implements quality improvement (QI) methods, notably healthcare provider-led standard-based audits, that is a crucial part of its cross-cutting capacity building strategy. Standard-based audits promotes the delivery of quality ANC and PNC package and can thus influence the outcome of this trial. To avoid any bias between groups, all healthcare facilities enrolled in the study will receive their QI training in standard-based audit prior to the launch of the study. Training in standard-based audits should therefore not be a potential confounding factor in the outcomes assessed. Any standard-based audit conducted by a facility during the trial will be documented. Of note, another stepped-wedge cluster randomised trial is currently conducted by the CMNH-LSTM in Togo to assess the effectiveness of standard-based audits in improving quality of care.

3.3 Randomisation and assessment periods

Each HCF will be randomised to a Group (A, B, C, D, E, F) which determines the assessment periods (2 to 7) in which the ANC-PNC training workshop will take place. All randomisations will be done using the runiform() function in Stata.

Each Group will then be assessed in alternating assessment periods, timed so that assessment does not occur in a period in which training is delivered, since this is a 'transition' month for which data would not be useful for analysis. For those randomised to Groups A, C and E observation of ANC-PNC visits will commence at the beginning of the trial (assessment period 1). For those randomised to Groups B, D and F, it will commence after one and a half months (assessment period 2). All healthcare staff providing ANC and/or PNC in participating HCFs will attend the 'skills and drills' training workshop to ensure they have the knowledge and skills to provide integrated ANC and PNC (including able to provide each essential component as set out in **Appendix 1**).

3.4 Outcomes

This trial will have two primary outcomes, one around essential components for ANC, and one for essential components for PNC.

Outcome 1 (ANC): Essential components included in the composite measure of integrated services specific to ANC visits are listed below.

- EC1 = Respectful maternity care indicators:
  - Introductions, greeting the woman, consent, questions
- EC2 = Screening for Pre-eclampsia:
  - Measure BP

  - Test urine for proteinuria
- EC3 = Screening for, prevention and management of Anaemia:
  - Measure Haemoglobin
  - Provide ferrous sulphate with folic acid
- EC4 = Screening for, prevention and management of Malaria:
  - Checked for clinical symptoms and test for Malaria if relevant
  - Provide treatment if needed
  - Provide bed nets if not provided yet
  - Provide Intermittent Presumptive treatment
- EC5 = Screening for, prevention and management of HIV:
  - Test for HIV
  - Provide Prevention of mother to child transmission care (PMTCT)
  - Provide anti-retroviral drugs (ARV) for mother if needed
- EC6 = Screening for, prevention and management of Syphilis:
  - Test for syphilis
  - Provide antibiotics if needed
- EC7 = Screening for, prevention and management of Tuberculosis (TB):
  - Checked for clinical symptoms and test for TB
  - First line TB drugs or referral if needed
- EC8 = Prevention of Tetanus in mother:
  - Tetanus toxoid vaccination
- EC9 = Screening and counselling for mental health and domestic violence:
  - Screening tools
  - Counselling services
- EC10 = Estimation of BMI:
  - Assess maternal height
  - Assess maternal weight
- EC11 = Prevention of post- and pre-term birth:
  - Estimate gestational age
- EC12 = Assessment of foetal wellbeing during pregnancy,Screening for multiple pregnancy, abnormal lie and presentation during pregnancy:
  - Assess growth using fundal height measurement
  - Assess foetal heart rate (FHR)
  - Abdominal palpation
- EC13 = Provide advice on birth preparedness and danger signs of pregnancy:
  - Consultation

The outcome for each ANC visit will be a score which measures the proportion of the above components that was delivered during that visit (EC_ANC).

The score will measure the proportion of essential components delivered in full. All thirteen essential components listed above are applicable for ANC. Some essential components

involve multiple components, at least one of which is always applicable; some components are only applicable to a subset of clients, eg HCP counsels the woman about mental health is only applicable if the client's response to a previous question is cause for concern. All essential components will carry a weight of 1. The overall score will be derived by aggregating the weighted scores for each essential component which will then be converted to a percentage. Six essential components are binary; hence the score can only be 0 (not achieved), or 1 (achieved and single weighted); in some cases the determination of this involves an algorithm. The other seven essential components are not binary as they have sub-components assessed independently and thus may be partially achieved and carry an intermediate score, eg a multiple of 0.25 for essential component 1 (respectful maternal care).

Outcome 2: Essential components included in the composite measure of integrated services specific to PNC visits are listed below.

- EC1b = Respectful maternity care indicators:
  - Introductions, greeting the woman, consent, questions
- EC2b = Screening for Pre-eclampsia:
  - Measure BP
- EC3b = Screening for, prevention and management of Anaemia:
  - Measure Haemoglobin
  - Provide ferrous sulphate with folic acid
- EC4b = Screening for, prevention and management of Malaria:
  - Checked for clinical symptoms and test for Malaria if relevant
  - Provide bed nets if not provided yet
- EC5b = Screening for, prevention and management of HIV:
  - Test for HIV
  - Provide Prevention of mother to child transmission care (PMTCT)
  - Provide anti-retroviral drugs (ARV) for mother and baby
- EC6b = Screening for, prevention and management of Syphilis:
  - Test for syphilis
  - Provide antibiotics if needed
- EC7b = Screening for, prevention and management of Tuberculosis (TB):
  - Checked for clinical symptoms and test for TB
  - First line TB drugs or referral if needed
- EC8b = Prevention of Tetanus in mother and baby:
  - Tetanus toxoid vaccination
- EC9b = Screening and counselling for mental health and domestic violence:
  - Screening tools
  - Counselling services
- EC10b = Provide advice and support regarding breastfeeding:
  - Consultation

- EC11b = Offer postpartum contraception:
  - Consultation
- EC12b = Monitor newborn growth:
  - Weigh the baby
- EC13b = Clinical examination of the mother:
  - Examine the mother
- EC14b = Clinical examination of the baby:
  - Examine the baby
- EC15b = Immunization status checked and required vaccinations offered and provided if required
- EC16b = Provide advice on danger signs in the mother and baby:
  - Consultation

The outcome for each PNC visit will be a score which measures the proportion of the above components that was delivered during that visit (EC_PNC). This score will be derived in a similar manner to the score for ANC, the difference being that three essential components used for ANC will be dropped and six others added.

The observation tool is detailed in **Appendix 2**.

3.5 Trial participants

3.5.1 Healthcare providers

Training participants will be the HCPs from target HCFs. To respect routine service delivery in the participating HCF, training in ANC and PNC will be provided to ideally 80% of the HCPs providing ANC and PNC within the appropriate step. Only the HCP trained within the steps will be observed as part of the trial. Other HCP will be trained as part of the implementation program but will not be observed.

3.5.2 Women who have received ANC or PNC

To assess the delivery of essential components during ANC-PNC visits, the observation will happen at the time women receive ANC or PNC at the HCF. Although the care provided by the HCPs is the focus, the clients who are receiving care will be asked to consent to the visit being observed. Observation will not be done for every woman: All eligible visits will be observed, unless consent is declined, until the four visits have been observed for each participating HCP. We anticipate that up to 12 women (up to 4 visits per HCP, with 2 to 3 HCPs observed per HCF) will be observed at each HCF in each step when delivery of care is observed and assessed.

3.5.3 Recruitment and consent seeking, including withdrawal, voluntary participation, confidentiality of data

Informed consent

With healthcare facilities pre-identified for the trial using the inclusion criteria specified in Section 3.1.1, the sensitisation and consent seeking of HCFs and HCPs will be done well in advance of the trial. This will involve sharing relevant study information in writing but also engaging in discussions. The final shape of the trial will be agreed with inputs from the MoH as well as other local partners to ensure its suitability and feasibility. Once healthcare facilities which meet the inclusion criteria are identified, their managers will be contacted to invite them to take part in the trial.. All information sheets will be shared with heads of facilities and any identified key-staff prior to the launch of the trial. The purpose and level of effort required from the participating healthcare facilities will be explained ahead of the start of the trial, so the in-charge is able to make an informed decision on committing their healthcare facility to the trial.

The consenting process for the healthcare facility manager will cover all elements of the trial, including details and organisation of the intervention and the required inputs concerning the conduct of the trial and data collection processes. Once explained, opportunities to familiarise with the trial information, ask questions and seek further clarifications as needed will be encouraged. In-country and LSTM staff will be on stand-by to address any queries and provide details as needed. The facility in-charge (or another relevant member of the leadership team) will be asked to provide consent on behalf of the healthcare facility. The data collection processes and details will be explained and discussed in detail as part of visits conducted to each of the HCF by the study team. The stepped-wedge calendar will be explained to them and at least 1 week before the beginning of each step, the study team will contact the facility that will have ANC-PNC observed to plan for the data collector's visit. No observation will be conducted unexpectedly, and data collectors will work based on the staff roster to ensure the participating healthcare providers are observed.

The confidentiality and privacy of the observed facility staff, as well as patients will be stressed. It will also be explained that the data collection, while centring around care provided, will not collect any non-anonymised details from patients. All involved will receive all information detailing the purpose of the assessment, what is involved, and that the research team will be available to answer any questions.

Consent from healthcare providers will be sought before the launch of the trial, then refreshed before conducting each day of observation, and consent from clients before asking for inputs each visit observed. Each day of observation, the information about the study will be shared with each participating healthcare provider.

Clients will be women who receive antenatal or postnatal care either/both for themselves or/and their baby. The purpose of the data collection will be explained by the data collector both to the HCP and the client, including the type of information that will be collected, as well

as the voluntary nature of their participation. It will be reiterated that participant confidentiality and anonymity will be upheld.

All participants will be given the opportunity to ask questions, which will be fully answered. Due to the nature of the observation, time given for decision-making may be limited, but care will be taken to minimise any pressure for considering whether to participate from the women. To allow the women time to consider participating to the study, information will be given at different point of contact in the facility whenever possible, such as during registration or health promotion sessions. They will be allowed as long as they wish to decide and should have all the waiting time to reflect. Due to the usual capacity of healthcare facilities in Chad, ANC-PNC are usually crowded with women waiting a long time, and consultation kept short. All women will be informed that they can take time and decide later to be observed, however, there is a low chance that any would find worth to leave and come another day for the visit, due to the time and resources consumed. For women who may not be able to read and write, consenting will take place with the assistance of an independent witness.

The total number of HCPs to be trained and observed will be up to 54. At each HCF up to 12 women will be observed in each of four assessment periods. Thus, the total number of women asked to consent to be observed will be between 576 and 864**.**

Information on the availability of equipment and consumables for ANC-PNC components under assessment, will be retrieved from routine data records and directly from HCP. This step will therefore not require obtaining client consent.

Voluntary participation and right to withdraw

The head of the facility, healthcare providers, for observation and retrieval of information from patient-held records, will be informed of the voluntary participation and their right to withdraw without any consequences.

Clients for observation will be informed of the voluntary participation and their right to withdraw at any time during the observation without any consequences. However, it will not be possible to retrieve data once fully anonymised.

Confidentiality and anonymity

All patient data and/or information on individual patient outcomes collected will be recorded anonymously. No aspect of the assessment will involve non-anonymised patient details. Data collectors will observe sensitive confidential information (e.g. results of HIV tests). They will be required to maintain the confidentiality of all such information. In the unlikely event that non-anonymised data are accidentally collected, they will be destroyed and excluded from analysis.

It will not be possible, given the intention of this trial, to anonymise facility data. That is, facility names will be captured. However, the intention of this trial is to facilitate work that will improve the functioning of facilities for improved care, which is within the mandate of these facilities. While the standard reporting and any trial publications will not use facility names in the reporting, if required, for the use of the MoH the facility-level details, however,

will be collated and the final analysed data set will be shared using password protected files to limit the risk of disclosing the details to unintended audiences.

3.6 Sample size calculations

Number of HCPs for observation

The methodology knowledge base for stepped wedge trial designs is still relatively limited (Taljaard et al 2017). Quantities which need to be specified when designing them include: the number of clusters (HCFs) to participate; the number of steps; the number of steps per HCF in which assessments are made. For the current trial the number of HCPs to be observed and the number of assessments made per HCP per step are also needed. The most critical of these is the number of clusters to participate. Although the literature regarding sample size is in its infancy there is clear consensus that with few clusters the design lacks robustness (Barker et al, 2016 and Martin et al 2016). There are up to 20 HCFs available in which to conduct the trial. The incompleteness of the proposed trial design may compromise the integrity of the trial if fewer clusters are used. Thus, all available HCFs are planned to be included but calculation will be done on a minimum of 18 HCF for a conservative approach.

The number of steps possible is limited to six because it is not feasible to conduct more than six training sessions with the budget available. The duration of each step is set at six or seven weeks rather than one month to allow enough time for data collectors to accommodate with the observed HCP's roster and schedules within the appropriate steps.

In principle, the target number of HCPs for observation for each primary outcome should be three per HCF, however recognising this may not be feasible (especially in smaller facilities with limited staff present), the minimum number of HCPs to participate has been set at two per HCF, accepting that both HCPs would be required to take part in the trial and accept being observed completing both ANC and PNC visits in all four assessment periods planned for their HCF; this number is both feasible for this trial and expected to ensure adequate robustness to examine the hypotheses of interest (Girling and Hemming 2016).

Observation of each HCP in multiple assessment periods will improve the power of the trial to detect an improvement in outcomes, since underlying differences between individual HCPs will be able to be modelled using random HCP effects. However, shift patterns will limit the availability of participating HCPs, so at some HCFs it may be necessary to conduct observations on two different dates within a step to be able to observe at least two HCPs in each assessment period. In facilities where both ANC and PNC clients are seen by each participating HCP observations for both primary outcomes will be able to be completed using the same HCPs. For other facilities, where ANC and PNC clinics are completed by different sets of staff on any given shift it may be preferable to recruit 4 to 6 HCPs, some to be observed providing ANC and others PNC. This would enable HCPs in both clinics to be observed on some observation days, thereby reducing the number of observation days in the assessment period. **Box 2** summarises the sample size planned.

Each interaction (ANC and PNC) observed will be assessed for the corresponding primary outcome.

The R shiny app (Hemming, 2019) was used in February 2020 to perform power calculations for this design, using a continuous response, with a standard deviation of σ. The standard deviation, σ, is the square root of the total variance, which aggregates the various components of variance. The app is not designed for the additional level of observation within HCP, so the data considered for purposes of sample size calculation is the mean across four observations for each HCP at the HCF.

Box 2: Sample size details

Number of clusters (HCFs):	18
Number of steps:	6 (8 assessment periods)
Duration of steps:	6-7 weeks
For each HCF:	
Number of HCPs per primary outcome*:	3 (or 2)
Number of periods in which care at HCF is assessed:	4 (periods 1, 3, 5 and 7 or 2, 4, 6 and 8)
Number of HCPs assessed for each primary outcome per assessment period:	At least 2
Number of HCP-client interactions assessed for each primary outcome per HCP assessed in an assessment period	4

* where clinics combine ANC and PNC clients the same HCPs can be used for both; where ANC and PNC clinics are separate different sets of HCPs may be used.

Table 4 indicates the standardised differences detectable with this design if 3 HCPs are observed in each assessment period at each HCF. Additionally, **Table 5** indicates differences detectable if only 1 HCP is recruited and observed for each HCF.

Several different sets of values for the various ICCs have been considered, based on those estimated from the analysis of data for compliance with standards in Malawi. The stepped wedge trial in Malawi using Standards-based audits estimated the within period ICC (the correlation between responses for pairs of individuals within the same cluster and step) to be 0.16 and the CAC (cluster autocorrelation: correlation between pairs of population means from the same cluster in different steps) to be 0.38. As that trial was cross-sectional the intra-cluster autocorrelation (IAC: correlation between responses from an individual in different steps) was not estimable.

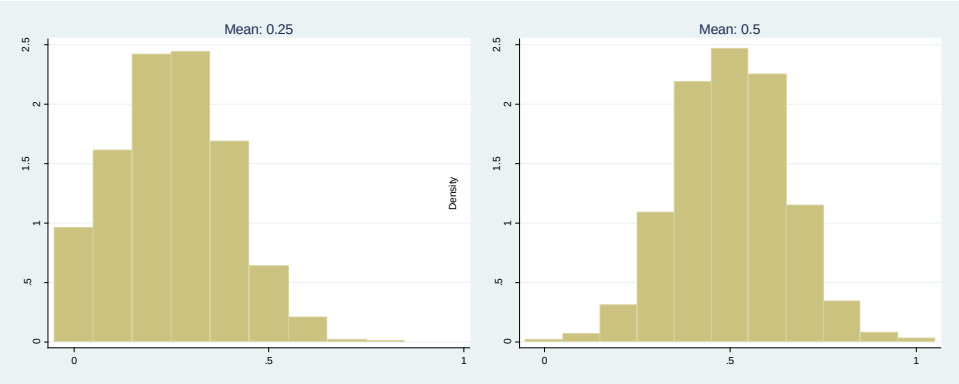
Table 4: Standardised differences detectable with 80% power using a continuous response in a closed cohort design

Within period ICC	CAC	3 HCPs observed in each assessment occasion		1 HCP observed in each assessment occasion	
		IAC=0.6	IAC=0.8	IAC=0.6	IAC=0.8
0.2	0.02	0.64	0.60	0.86	0.73
	0.4	0.62	0.57	0.83	0.70
0.4	0.4	0.75	0.72	0.90	0.82
0.5	0.1	0.81	0.81	0.95	0.90
	0.9	0.50	0.44	0.67	0.55

Based on the range of combinations which were estimated for that trial it is expected that with this design an improvement of 0.81σ, would be detectable with at least 80% power if all three HCPs at each HCF are assessed on each assessment occasion. If only one HCP per HCF participates the improvement detectable with 80% power would be 0.95σ. The magnitude of σ depends on at least three sources of variation which are aggregated into the total variance (σ^2): residual variation (σ^2_{error}), and the variances for each of the random effects for: HCF (σ^2_{HCF}), HCP within HCF ($\sigma^2_{HCP|HCF}$), and possibly HCF by month ($\sigma^2_{HCF*month}$).

The residual variation (σ_{error}) is assumed not to exceed 0.2 for individual assessments, so the residual variation for means for assessment of 4 visits would not exceed 0.1. For the random effects we assume that each of σ_{HCF}, $\sigma_{\text{HCP|HCF}}$ and $\sigma_{\text{HCF*month}}$ does not exceed 0.15 in value. (A standard deviation for HCPs ($\sigma_{\text{HCP|HCF}}$) of 0.15 would occur if the means for HCPs in a given month have a range of about 0.6 and 65% of the means are within a range of 0.3, within a possible range of values of 1.0 (Figure 2 displays two such distributions). With these values the overall standard deviation would then not exceed 0.28 =sqrt(0.01+0.0225*3), when means of 4 observations for 3 HCPs per HCF are used and an improvement of 0.81*0.28=0.23 would be detectable with at least 80% power. For other scenarios the upper limits on the difference detectable is indicated in the table below. If all HCPs are assessed as assumed the absolute differences detectable with 80% power are likely to be smaller than indicated in the table, since the variances are unlikely to take values as large as assumed.

Figure 2: Examples of distributions with standard deviation of 0.15



However, it is expected that some HCFs will only have two HCPs able to participate in the trial, and that in some steps when assessment is planned some HCPs will not be assessed due to logistic reasons. These reductions in the volume and structure of data would increase the difference detectable. Sample size formulae are not available to adjust the sample size if some HCPs are not assessed on all planned occasions. To examine the likely impact of such shortfalls in the planned sample size two small simulations were performed to examine the impact on standard errors of the estimated intervention effect and thus of the difference detectable:

i) A reduction in the number of HCPs available at half of the HCFs from 3 to 2;
ii) Observation of only one (of 3) HCPs per HCF in each assessment period.

For each scenario a dataset was generated using the design details and an intervention effect of 0.1 (approximately 1 additional item addressed on average). Each dataset was analysed as planned. For each dataset ten subsets were then also derived and analysed as planned.

The impact of a reduction in the number of HCPs participating per HFC was consistent with the reduction in sample size with the average increase in the standard error of the estimate being 10%. The difference detectable would similarly be expected to increase by 10% if only 2 HCPs participate in nine of the HCFs.

The impact of only observing one of three HCPs on each assessment occasion was amplified beyond that expected based on sample size alone. On average the standard error more than doubled, whereas based on sample size changes an increase of 73% would be expected. This amplification is due to the reduction in the numbers of participants observed longitudinally to just one or two of the three.

These simulations indicate that there is greater value in ensuring that each HCP who participates is observed in multiple assessment periods than in increasing the number of HCPs who participates or the number of replications of observations beyond 4.

Table 5 indicates that if one HCP rather than three participate per HCF there would be some increase in the difference detectable; this would depend on the ICCs involved, but would not exceed about 35%. By contrast if different HCPs are observed in different assessment periods

the difference detectable increases more substantially. Therefore for outcomes observed only in ANC or PNC interactions there will be greater power to detect a given difference if the same HCP is observed in each assessment period, or if all participating HCPs are able to be observed completing a single assessment for each secondary outcome than if different HCPs are observed in the planned assessment periods.

Table 5: Differences detectable

Observations / HCP	Upper limit on standard deviation	Difference detectable (>80% power)	
		3 HCPs / HCF	1 HCP / HCF
4	√(0.01+0.0675)=0.278	0.23	0.26
1	√(0.04+0.0675)=0.328	0.27	0.31

Covid-19 situation and impact on sample size

In terms of data collection, the attendance of ANC-PNC could also be reducted due to restrictions or to the fear of perceived risks associated with coming to seek care; if not enough women seek care, this would, in turn, impact the power of the study. The steps were defined as 6-7 weeks long to allow ample opportunity for interactions to be observed, there is thus some capacity for data collectors to add visits if needed to reach the necessary 3-4 observations per healthcare provider. The moderate number of necessary subjects seems to pose a low risk.

There is very low but existant risk that any gathering is prohibited. If that happens, the capacity of the program to deliver training while respecting the steps within the trial would be compromised. Trainings would have to be postponed until authorized, which would in turn affect the difference detectable. Although this is a non-negligible risk to the study, there may be leeway to reduce the length of the steps to enable the planned steps to be completed. At worst-case scenario, if any gathering is prohibited for the whole duration of the study, the intervention will ultimately not be able to be delivered to all HCFs and the trial would be aborted. Regarding capacity-building however, training would still resume as soon as possible so healthcare providers still have the benefits of it. As of 13th of May 2020, no indication from the MoH has suggested that all gatherings would be prohibited.

3.7 Data collection

Data sources

The main sources of information will include:

1. Observation of ANC-PNC visits for assessment of delivery of care. The tools will be developed ahead of the trial start. Following consultation with in-country partners, they will be converted onto a standardised platform (paper or electronic) for use for data collection.

All data collection will be undertaken by clinically trained data collectors external to the HCF with supervision from CSSI-CRASH and remote support from LSTM. To enhance acceptability of observations and minimize any potential unease for the women to be observed, the data collectors will be exclusively females. Data collectors will receive training on data retrieval and collection; with regard to observation of ANC-PNC visits, specific training on research methods covering consenting, ethical aspects of observation, data anonymization, rapport building, and observation techniques will be provided. As specified in this document, data collection will take place at specified time points. For the observation, we expect data be collected for 4 consecutive clients coming for ANC per HCP observed for ANC and the same for PNC. In each assessment period there would be a total of 8 to 12 clients per facility for each consultation type (through as many visits as needed to observe 2 to 3 HCPs per facility). The data collection tools will therefore aim to capture the service provision of the HCP observed. Anonymous ID codes within HCF will be agreed and applied in the final database for each HCP observed.

2. Healthcare facility records and register review for extracting data on equipment, consumables, medications as well as elements of infrastructure availability, staff availability (by cadres and type of services provided; though no personal details of individual staff members), and uptake of services (number of women attending for ANC and PNC services, morbidities and mortalities related to pregnancy and childbirth, specific aspects of care provisions (all as pooled data for a specified month, with no individual details extracted).

Data collection

Before commencing either intervention the HCFs selected to participate in the trial will be surveyed to ascertain the availability of human resources and the components identified as in principle needed for the delivery of the essential components defined.

Delivery of essential components will be assessed through the observation of ANC-PNC visits by external data collectors. At each healthcare facility at least two healthcare providers will be observed in each assessment period. For each assessment period one observation day will be scheduled for each HCF to be assessed in the period. All participating HCPs on duty within the HCF will be observed completing four ANC/PNC visits on each of these days. If only one participating HCP is observed an additional observation day will be scheduled within the same assessment period to observe at least one more participating HCP within the HCF. Each HCP should be observed in at least three of the four assessment periods for their HCF. The observers will plan with the healthcare facilities to observe four consultations for each HCP who is on duty in accordance to rosters.

The availability of equipment and consumables for each component of care for ANC-PNC services quarterly (every 2 steps in the trial schedule) will be assessed on the first possible day of the following quarter. This data will allow for the analysis to assess if the delivery of essential components was linked or not by the availability of equipment and consumables. Finally, the number of women attending for and receiving care will be extracted quarterly

using the official routine facility registers. The healthcare facility assessment tool for equipment, consumables and use of services has been developed in line with the specific ANC-PNC service provision elements and with usual facility assessment tools used by CMNH-LSTM in baseline assessment (See **Appendix 3**).

Covid-19 situation

As of 13th of May, borders are closed and international flight barred, public transportation interrupted and meetings of 50 people or more prohibited. Our focal point from MoH and implementation partners from CSSI-CRASH consortium have so far not advised against conducting the study, which will be set only within N'Djamena and thus not require any inter-regional travels that may be impeded in the future. To date no other measures that could impede the delivery of this trial have been identified.

Data collectors will observe all regulations from healthcare facilities, district, regional and national COVID-19-related guidelines. Prior to the commencement of this study a robust COVID-19 risk assessment, in line with LSTM Research Governance & Ethics guidance. In addition, COVID-19-related risks and situations will be included in the regular safeguarding assessment before data collection. Close monitoring will be done in partnership with MoH and CSSI-CRASH to ensure that the latest guidelines are followed, and trial adapted as and when required. No research activities will be carried out if they contravene the guidelines until the situation settles. LSTM Ethics Committee will be informed about the revised timeline.

Data collectors are expected to visit facilities in-country COVID-19 guidelines allow. There are still many unknowns when this virus will come to an end, Data collectors will be expected to wear surgical masks as a minimum, as well as respect physical distancing from both healthcare providers and clients alike to ensure they pose a minimal risk of transmission during the observation. Training on barrier measures, hygiene and infection prevention and control will be part of their initial inception and refreshed regularly. If there is not enough space to allow physical distancing to be up to guidelines, they will not carry the observation. However, all facilities in the sample will be visited prior to the trial in order to ensure that this is in principle possible.

There is a potential impact of Covid-19 and containment measures on the delivery of the intervention by the CMNH international and/or national team, the retention of healthcare providers, as well as data collection. The number of participants to attend ANC-PNC is 32 per training. With facilitators, this should be a maximum of around 40 people at the same time which is still under the national guidelines. However, shall the situation evolve, it should be possible to scale down the size of the training to ensure that the number of participants complies with country guidelines. Although this would raise the cost associated with the training, substantial savings should be made on the budget as a result of reduced international travels to Chad during the ongoing pandemic to cover it. The CMNH team is working in the meantime on a full review of its training package in order to discuss country-specific contents with CSSI-CRASH and the MSP, and plan for a contingency solution where

the in-country team, CSSI-CRASH staff and previously trained Master trainers would be refreshed and supported remotely to be able to adapt to the changing environment and carry out the interventions.

3.8 Statistical analysis

Period is defined as the assessment period of the trial which observation occurred, or for which measurement took place. Data will be omitted from analysis when values are missing for either the outcome or a covariate required for the analysis of that data value. Missing data will not be replaced.

For each ANC/PNC visit observed the proportion of essential components addressed will be calculated (ECall). Data analysis will be performed using Stata version 14.2 or later. To derive an estimate of the benefit of providing ANC-PNC training, linear regression within a generalised linear mixed model (GLMM) framework will be used to analyse the primary outcome data (ECall). GLMMs are appropriate in the context of stepped wedge trial designs as they allow for clustering and address confounding of intervention effects and time (Hemming et al 2015). The analysis will include a binary intervention factor which indicates if the data were collected pre- or post- ANC-PNC training and fixed effects for study month to account for any underlying secular trend. Random effects will be included for HCF (cluster), HCP within HCF and HCF by month interaction. The effects of the intervention will be reported as an adjusted (for month, HCF and HCF by month clustering) odds ratios (OR), with 95% confidence intervals.

Reporting will follow CONSORT guidelines for reporting stepped wedge trials current at the time of publication of the results (currently Hemming et al, 2018), Available data will be analysed using an intention to treat approach and also as implemented, if there are any protocol deviations, to assess the sensitivity of results to the analysis approach adopted.

The baseline delivery of essential components has been assumed to be around 50% as the precision of estimates is poorest for this value. If the level is below 50% there will be greater potential for improvement and greater power to detect an improvement of a specified magnitude. However, if the level is close to 100% it will not be possible for a statistically significant benefit of the intervention to be demonstrated. In such circumstances administrative analyses will be conducted.

3.9 Quality assurance

3.9.1 Data collection and processing

Generally, data used in the trial will be managed with the overall technical oversight provided by the international team in CMNH-LSTM, responsible for the budget and workplan. Beyond logistics, the team will provide paper forms and/or electronic devices (tablets) with robustly designed and pre-tested tools (on Survey CTO as a platform) and will ensure that complete

and consistent data sets are collected and uploaded to LSTM secure servers. LSTM will train the two data collectors for observation, in partnership with the Ministry of Public Health and CSSI-CRASH.

Once the data collection team has been organised, a national central-level team from CSSI-CRASH, linked to the Ministry of Public Health and CMNH-LSTM, will oversee the day-to-day quality assurance. This joint team will oversee data uploading in N'Djamena and ensure quality assurance and report progress to LSTM and, if necessary, facilitate in-country communication for any issues encountered. All healthcare facilities will be informed of the contact details of their local 'data contact', who will be the go-to person for any queries relating to data issues.

The M&E officers in charge of observation and data collection will be responsible for uploading data correctly and on time (according to a pre-agreed schedule), and that all data is has been checked for accuracy before uploading from the tablets to the LSTM server. They will be responsible for escalating any issue to the local coordinator and further to LSTM to allow for timely inputs on problem-solving.

Platforms for data collection will (preferably) be electronic, where additional validations and checks can be in-built into the tools, further enhancing the quality of data collected. The logistics and training requirements of the different platforms for the study team will be agreed ahead of the data collection process. At present, plans for Chad are that electronic data collection is undertaken with back-up paper forms available in case of equipment malfunction.

Support mechanisms for ensuring quality of data collection will be devised with the support of CSSI-CRASH and where possible periodic visits to N'Djamena will be conducted to offer support, in addition to the ongoing remote support via mobile communication platforms.

Data transfer will be agreed and monitored in cooperation with the CMNH-LSTM team, who use trackers and QA systems on all studies to ensure checks and balances of data received but also cleaning of data contents.

Data cleaning will be undertaken by trained research assistants using Standard Operating Procedures developed specifically for the tools used in the field; the checks will include verification of missing data, outliers but also responses which otherwise can be classed as non-conformities. These will be managed by consulting where necessary with the teams on the ground for corrections which can be made by on-the-ground follow up, while management of those that cannot be verified will be discussed on a case-by-case basis with the senior statistician to minimise data loss or risk of introducing bias, while maintaining data quality. All changes will be noted, and both the original and final datasets preserved for audit purposes.

3.9.2 Data analysis

Data analysis will be conducted using quality assured scripting in Stata, which will be kept for any verifications. Data analysis will be conducted by a senior statistician at LSTM, with support and ongoing discussions with the team in Liverpool and on the ground to provide timely inputs for interpretation of the results.

3.9.3 Data storage and transportation

Data collected by healthcare facilities and utilised for their quality improvement activities, will be managed and stored locally according their agreed standards. Both individual devices and servers are password protected and data encrypted in transfer to minimise any risk of data exposure. For any paper records, secure location for their storage will be identified and systems for transport of the paperwork agreed to protect the data.

Data shared with LSTM for the trial, will be stored in line with standard LSTM data management and storage procedures. If used, paper forms will be scanned and stored electronically in limited access locations on LSTM servers, which are backed-up regularly. Following confirmed receipt, any paper forms will be disposed of in accordance with in-country regulation on safe disposal of records. Electronic data will be kept securely on LSTM servers, backed-up regularly. Once data work has been completed and forms uploaded, tablets will be cleared of any data, and working and final datasets will be stored on LSTM system, with access restricted to the core research team, under the guardianship of the M&E team. In-country partners will receive a copy of the final dataset as well as any other materials which are to be shared under the partner agreement. Any other data sharing will need to be agreed with the PI and conform to the data sharing policies. Following the completion of the trial, all data will be kept for a minimum of 5 years at LSTM.

An audit trail of data and any changes due to cleaning will be stored alongside the trial documentation.

3.9.4 Trial specific requirements

Although a trial, this study will not include aspects such as adverse reaction reporting or end of study treatment.

3.10 Ethical considerations

Several ethical concerns have been identified for this trial.

Vulnerable participants

All pregnant and recently delivered women accessing care may be vulnerable, particularly if these women are adolescents (under 18 years). Care will be taken to ensure that participants are fully aware of their right to refuse participation in observation of visits. Participants may be pregnant, and as such, care will be taken to ensure their comfort throughout the consultation, including providing suitable seating and water. Observation of a consultation

will immediately end should the participant be experiencing any distress due to the observation.

Confidentiality and anonymity

The assessment does not include collecting any personally identifiable data from individual respondents, which limits the risk of confidentiality breach. As previously stated, the two medically trained data collectors will receive appropriate training to ensure that the impact on consultations of their presence to observe them is minimised. The purpose of the trial will be explained to HCP at the time of entrance to the facility and assurances will be made the assessment is a positive experience to those included in it and does not affect service provision or increase workloads of staff in facilities in as far as it can be done. Every effort will be made to ensure participant data are treated with confidentiality and anonymity, including the use of unique study ID numbers in lieu of names and disassociation of any identifying information with data intended for analysis.

Further ethical considerations and approaches to their management are covered below.

Potential adverse effects, discomfort or risks	**Steps to be taken to minimize adverse effects, discomfort and risks**
Healthcare facility heads and subsequently staff may feel coerced into taking part in the trial for fear of repercussions from higher levels of authority.	For healthcare facilities selected for the trial, a consultation linked to informed consent will take place ahead of the start of the trial. This will explain the objectives of the research, as well as the requirements from them to take part and clarify the nature of participation being voluntary. These negotiations will involve the local MoHs to ensure all sides are included in the communication and the decisions made are clear to all parties. Capacity building and training of staff in principle offer positive outcomes to the institutions and staff involved, while the negative aspects (such as time for the implementation) are to be managed in a supportive manner, so the hope is that healthcare managers and staff will want to benefit from the intervention, but they will be given a free choice as to whether they are willing to commit to the trial. Any withdrawals once the trial commences will be accepted and records amended to reflect those. It will be communicated clearly to those involved in healthcare facilities that there are no negative repercussions from refusing to participate or withdrawing a healthcare facility from the trial.
HCPs may feel over-burdened with having to provide data or	The guiding principle for organising data collection activities will be to ensure a minimal additional burden of effort and time for HCP staff and service provision. During

Potential adverse effects, discomfort or risks	Steps to be taken to minimize adverse effects, discomfort and risks
help the data collector access register and records.	observations, the data collectors will not intervene in any manner with the conduct of the ANC-PNC visits besides seeking informed consent and giving standardized feedback at the end of the day. All data collection tools are as simplified as possible, so a clinically trained data collector does not need assistance to fill them during observation. In case a specific component needs checking from the patient booklet, the observer will have convened with the HCP of a certain time in the visit to look for specific information (e.g. previous HIV status noted). Observers will have good knowledge of patient documentation to take the shortest time possible. Besides, the programme and intervention is designed to ensure as much as possible that any other type of data needed is already being collected as part of HCP every-day care practices e.g. patient assessment data, routine register data. The sample size (number of women/babies for which data is aggregated) is small with a maximum of 12 observations per step per facility to be performed.
Staff observed or assisting with data collection may not feel comfortable providing information that is likely to cast the health facility's performance in a negative light, for fear that this may have repercussions for them.	It will be communicated to all staff observed or assisting in the assessment that data collected will be kept confidential and anonymous for any specific person. It will be stressed that their personal performance is in no way under review, and any findings about the health facility will not be linked back to them in any way. The overall outcomes relating to quality of care across the selected healthcare facilities will be shared with the Ministry of Health, but under the agreement that this will be without repercussions for health facility staff. The intention of this data is to help the Ministry support health facilities in the consistent provision of quality maternal and newborn care, which will be emphasised to participants.
The presence of a trial element in a facility may affect the way care is provided: The observation of ANC-PNC visits raises the potential for bias; healthcare	The guiding principle for organising data collection activities will be to ensure minimal effect on staff and service provision. Although it is envisaged that local staff will be observed in the time of their duty, it will be stressed that the observation has no control or inspection purpose. As part

Potential adverse effects, discomfort or risks	Steps to be taken to minimize adverse effects, discomfort and risks
providers' behaviour may be affected by having evaluators present (Hawthorne effect); assessment activities may affect the provision of care by distracting staff from their activities.	of the introduction of the trial team and before each day of observation, staff will be alerted to the fact that honest and reliable data are necessary for understanding the situation and to assess the effect of trainings. Staff observed or not will be alerted to pay attention and if necessary, report any noted changes or unnatural behaviour either observed or reported. With regard to facility record retrieval, historical data only will be extracted, therefore the risk of even potentially linking the findings to any individual will be minimised, but the same training on purpose of data collection and integrity of data will be provided. Additionally, external supervision of data collection will be deployed periodically to support the activities and provide scope for refresher training if needed to ensure data quality. To support facility staff and compensate their time spent retrieving data for the quarterly follow-up (essential components of care and use of services), a basic quarterly incentive fee will be provided to the HCF to be redistributed to the HCP. At any time if the HCP or the data collectors feel the conduct of the observation do clash with service provision, it will be interrupted immediately.
The presence of an external observer could cause stress to the women receiving antenatal or postnatal care.	Every client will be informed in advance of the observation that her participation is always voluntary and that she is free to end it at any point. It will also be reiterated that she can decide to stop the observation at any time during the consultation if she is not comfortable. If clients ever feel discomfort or distress in any way, the observations will end without consequence to the client , plus every effort will be made to ensure the necessary follow-up steps are taken to manage the individual situations at the level of the healthcare facility. Previous studies involving observations in Niger by CMNH-LSTM showed no particular stress caused to clients by external observers. To enhance acceptability of observations and minimize any potential unease for the

Potential adverse effects, discomfort or risks	Steps to be taken to minimize adverse effects, discomfort and risks
	women to be observed, the data collectors will be exclusively females.
There is a potential impact of the consent in terms of waiting time, as we want appropriate, complete and transparent information to be given to participants, as well as questions to be answered.	The number of consultations observed per HCP will not exceed 4 on any given day, which if we estimate 10 minutes for informed consent will affect a maximum of 40 minutes total across the day, and not impacting on all clients. For small-volume facilities, 2 providers will be observed in each step, so this could impact on two days every 6-7 weeks and for big facilities 3 providers. Other aspects of the clinic should not be impacted. During an observation, data collectors will appear as any staff member standing or sitting in the room for external people and providers alike, capturing data on their tablets. To minimize the impact on waiting lines, information will be given at different point of contact in the facility whenever possible, such as during registration or health promotion sessions. Thus the consent itself would be much less than 10 minutes. Whenever possible and confidentiality maintained, consent will also be retrieved prior to the time of consultation, so should have no impact at all on waiting time for women other than the participant.
There is a potential for uncovering poor standards of care delivered to clients as part of the observation- may cause distress among HCP.	If poor practices are observed or reported in the data collected, these will be fed back to incorporate at healthcare facility level. There may be an ethical imperative to feedback the deficiency directly to the HCP. The data collector will intervene immediately during the consultation if any immediate threat to the health of the client appears, such as giving medications despite medical contraindication or on a harmful dosage. For less pressing misses in the provision of care (e.g. incomplete integration of screening for diseases, sub-standard means of communication between client and provider) which are outcomes of this very study, the strategy applied will be for feedback to be provided as standard, to each HCP observed, at the end of each observation day. This would be an intervention which would be applied consistently throughout the trial, and this in itself could improve the quality of care for the Control status. It is however unlikely that such feedback would result in much improvement in

Potential adverse effects, discomfort or risks	Steps to be taken to minimize adverse effects, discomfort and risks
	the outcomes of interest or a major bias in the results. Thus, the potential for the intervention to yield further improvements is still expected to hold. If a client is put at risk, individual performance issues may need to be addressed; a process for dealing with them will be agreed with each facility in-charge and managers to ensure that any immediate issues are dealt with in an urgent but non-punitive manner for those providing the care, as far as possible, as part of the standard management system. For any immediate care needs identified in the observation, the medically trained data collectors, will consult with the HCPs to direct the woman to relevant care within the HCF or refer for treatment in line with standard care before she leaves. The overall results are not going to be available immediately – instead all tests are uploaded onto the server, where no names or individual details will be available to link them to the results. If the analysis indicates low levels of competencies, these will be reported to the Ministry in order to undertake a capacity building programme aimed at improving the services. This will be done by presenting findings in a generalized report which would limit the risk of exposing any specific person or facility and ensure individuals are protected from any negative repercussions. Instead, identifying gaps in competencies will provide grounds for refresher training being organised by the Ministry to build staff capacity and therefore be of benefit to healthcare providers and, in turn, patients.
There may be minor risks associated with in-country travel, due to poor roads and infrastructure.	The sample of HCFs included in the trial is limited to N'Djamena for quality control and feasibility reasons, but this also reduces the risk associated with travel. Where travel is involved, experienced drivers with reliable 4X4 vehicles will be employed for the duration of the trips to transport any staff and data collectors. Travel will be limited to daylight hours. All drivers and members of the data collection team will be provided with an allowance to ensure they have sufficient phone credit at all times.

Potential adverse effects, discomfort or risks	Steps to be taken to minimize adverse effects, discomfort and risks
Security risks to international and national staff.	The security situation in Chad will be monitored closely to ensure all involved in the activities are safe. We will continue to consult relevant security updates and follow their recommendations and alert all staff to follow the required procedures. The national staff, although not under direct LSTM management, will also be alerted to any issues which may compromise their safety and LSTM will work with CSSI-CRASH to ensure appropriate procedures are followed for minimising any risks for those involved in the work on the ground. Again, limiting the work to N'Djamena allows for easier travel between trial sites.

3.11 Research team

The research team will need to be confirmed once the details of the studies have been discussed. The core team and indicative information on roles is included in tables below.

International team

Name	Position	Role
Pr. Shabbar Jaffar	Head of Department of International Public Health	Principal investigator
Mrs Sian Freer	Head of CMNH-LSTM	Technical oversight
Dr Alexandre Quach	Clinical Research Associate	Protocol development, Oversight of study procedures and data collection, Country programme management *Co-Investigator*
Dr Sarah White	Statistician	Protocol development, Statistical design, randomisation, data analysis *Co-Investigator*
Dr Barbara Madaj	Head of Monitoring and Evaluation	Oversight of M&E activities, oversight of Global Fund technical delivery *Co-Investigator*
Ms Hannah McCauley	Senior Research Associate	Oversight of ANC-PNC activities
Ms Kirsty Lowe	Research Associate	Oversight of ANC-PNC activities *Co-Investigator*

Mr David Horrocks	Senior Programme Manager	Oversight of operations and logistics
Dr Florence Mgawadere	Senior Research Associate	Oversight of quality improvement activities *Co-Investigator*
TBC	Research Assistant / Data officer	Support data collection, processing and analysis

National teams (to recruit) and partners

Name	Position	Role
TBC	Senior Technical Officer	Oversight of in-country activities, technical support
TBC	M&E officer	Conduction of data collection and support for M&E in-country
TBC	M&E officer	Conduction of data collection and support for M&E in-country
TBC	Programme Officer	Support of in-country activities relating to operations and logistics
TBC	Ministry of Public Health, Directorate for International Cooperation	In-country advisor
TBC	Ministry of Public Health, Director of Division of Reproductive Health and Vaccination	In-country advisor
M Jean-Pierre GAMI	Ministry of Public Health	In-country advisor
TBC	CSSI-CRASH	In-country advisor

4. Limitations

The following key limitations have been identified for the trial:

The composite measures used as outcomes split essential components to fit the trial design, but the primary outcome does not assess the quality of the intervention in a holistic way. Instead it is expected that they offer a good composite of integrated services that are meant to improve within ANC-PNC as a result of the trainings provided. Both outcomes address specific essential components that aim to be the most reflective possible of the full package of ANC and PNC visits.

Issues related to availability of equipment / kits will affect the performance of services but may not be fully within the control of the study team. Effort will be made to coordinate the supplies of the necessary materials; however, we recognise some shortages may affect the situation on the ground and affect the measurement of the effectiveness of the interventions. However, if after the initial supply provided by the study team, shortage arise and affect the delivery of essential components, it will be observed as such and analysed with intent to treat.

5. Publication and dissemination plans

The findings of the trial will be presented to key stakeholders in country, and particularly the MoH with aim to review the findings and inform the development of a MoH-led strategy for quality improvement in maternal and newborn care and the potential for development of a support to facilities to strengthen capacity to implement various quality improvement methods.

Once the trial is completed, the results will be shared via at least one peer-reviewed publication.

Additional communication via policy briefs, social media platforms relevant for wider audiences will be deployed. We also hope to present the findings at international events.

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Appendix 1: ANC and PNC - essential components of care packages

Signal Functions	Essential components	Essential equipment and consumables and other [1]
FOR BOTH ANC AND PNC		
1. Screening for pre-eclampsia	Measure BP	BP machine and stethoscope
	Test urine for proteinuria	Urine dip-stix, urine containers
2. Screening for, prevention, and, management of Anaemia	Measure Haemoglobin (Hb)	HemoCue machine and cuvettes, or laboratory measurement of HB e.g. coulter counter or HB colour chart
	Provide ferrous sulphate with folic acid	Ferrous sulphate tablets (preferably combined with folic acid) – any formulation for oral intake – adult dose
3. Screening for, prevention, and, management of Malaria	Test for malaria	Thermometer Malaria rapid test, or, malaria microscopy done in lab
	Provide bed nets	Bed nets
	Provide Intermittent Presumptive Treatment (IPT)	Sulphadoxine – Pyramethamine (SP) or equivalent anti-malarial tablets
4. Screening for, prevention, and, management of HIV	Test for HIV	HIV test kit – (single or with syphilis combined)
	Provide Prevention of mother to Child Transmission Care (PMTC)	Drugs[2]
	Provide anti-retroviral drugs (ARV) for mother and baby	Drugs [2]

[1] Assumes availability of non-sterile gloves, needles, syringes or capillary tubes, skin swabs, tourniquet and cotton wool available.
[2] All drugs as per national protocol – to be identified for each country

Signal Functions	Essential components	Essential equipment and consumables and other [1]
5. Screening for, prevention, and, management of Syphilis	Test for syphilis	Rapid test for syphilis (preferred dual with HIV – rapid test)
	Provide antibiotics	Procaine Penicillin for i.m. use
6. Screening for, prevention and management of Tuberculosis (TB)	Test for TB (sputum Ziehl-Neelsen stain or Gen expert point of care testing)	Sputum pots, Lab for sputum Ziehl-Neelsen staining or Gen expert point-of-care testing
	First line TB drugs	Drugs[2]
	BCG vaccination for newborn	BCG vaccination
7. Prevention of Tetanus in mother and baby	Tetanus toxoid vaccination	Tetanus toxoid vaccination
8. Prevention of Hepatitis B	Hep B vaccination	
9. Screening and counselling for mental health and domestic violence	Screening tools Counselling services	EPDS or other Screening tool for Mental health Screening tool for domestic violence Referral pathway for counselling
FOR ANC ONLY		
10. Estimation of BMI	Assess maternal height Assess maternal weight	Height measure Weighing scale (adult)
11. Prevention of post- and pre- term birth	Estimate gestational age	Pregnancy wheel Ultra sound scan at secondary/tertiary level
	Assess growth using fundal height measurement	Tape measure (with centimetres indicated)

Signal Functions	Essential components	Essential equipment and consumables and other [1]
12. Assessment of fetal wellbeing during pregnancy	Assess Fetal Heart Rate (FHR)	Pinard stethoscope or Doptone
13. Screening for multiple pregnancy, abnormal lie and presentation during pregnancy	Obstetric palpation	Ultra sound scan at secondary level
14. Provide advice on birth preparedness and danger signs of pregnancy	Consultation	Patient information material available on hand-held card or posters in health care facility or patient leaflets
15. Screening and management of gestational diabetes[3]	Measure blood glucose Provide dietary advice	Glucometer (can be combined with Hb measurement) Patient information material available on hand-held card or posters in health care facility or patient leaflets
FOR PNC ONLY		
16. Provide advice and support regarding breast-feeding (BF)	Consultation	BF advised (when not contra-indicated) Awareness of contra-indications among staff
17. Offer post-partum contraception	Consultation	IUD, progesterone only pill, Depo Provera, condoms
18. Monitor newborn growth	Weigh the baby	Weighing scale (baby), weight monitoring chart

[3] Optional possibly not universal and screening may be only for women considered at-risk, check with national guidelines

Signal Functions	Essential components	Essential equipment and consumables and other [1]
19. Clinical examination of the mother and baby	Examine the mother and baby	Examination area, couch
20. Provide advice on danger signs in the mother and baby	Consultation	Patient information material available on hand-held card or posters in health care facility or patient leaflets

Appendix 2: Tools for data collection for observation

Below is the observation checklist. Essential components are numbered slightly differently than appendix 1 for the construction of the score. The scoring attributes will not appear for the data collectors and only be used by the statistician at time of analysis. Each essential component is score 1, for a total of 13 essential components for ANC visits, and 16 for PNC visits. Essential components can be a sum of x number of subcomponents as indicated in the table. Each subcomponent needs all applicable questions to be observed (Please see examples of algorithms at the end of appendix).

Please note this tool is to be deployed on an electronic platform, therefore the formatting of the tool will be visually different to what is included here. All boxes starting with "If" will only appear depending on the answer to the relevant condition (e.g. treatment will only be asked for women tested positive). The "Not applicable" answer is available for questions which depend on the gestational age and type of visit. The tool will be deployed in FRENCH.

OBSERVATION

Variable label	Answers	Conditionality	Scoring
GENERAL			
Please select the region	[dropdown menu]		
Please select the name of the facility	[dropdown menu]		
If 'Other' facility, please specify	[free text]		
Date of survey	[select from calendar]		
Name of person completing form	[free text]		
Anonymous ID of HCP	[free text]		
ANC			
ANC general information			
First/subsequent contact	0 - Subsequent contact, 1 - first contact -99 INF		
Which subsequent visit was it?	2- ANC2, 3- ANC3, 4- ANC4, 5- ANC5, 6-ANC6, 7- ANC7, 7-ANC8	Only to appear if previous answer = 0 – Subsequent visit	
Gestational age (weeks)	[integer]		
Who gave information about gestational age	1 - Woman, 2 - Healthcare provider, 3 - Other (specify)		
If other, specify	[free text]		
Women arrival time in the facility	[time]		
Comments	[free text]		

ANC contact			
EC1: Respectful maternity care			**1 (sum of all subcomponents)**
RMC subcomponent 1			0.25 (Points given if all applicable questions are observed)
The healthcare provider (HCP) introduced themselves to the pregnant woman	0 - No, 1 - Yes		
The HCP greeted the pregnant woman (or answered if woman greeted first)	0 - No, 1 – Yes		
RMC subcomponent 2			0.25
The HCP asked the pregnant woman to take a seat	0 - No, 1 - Yes, -88 - Not applicable (no chairs)		
The HCP asked the pregnant woman if she came with a companion (or the woman already declared it herself)	0 - No, 1 – Yes		
If the woman had a companion with her, was the companion allowed to be with the pregnant woman during ANC consultation?	0 - No, 1 - Yes, -88 - Not applicable (no companion)		
RMC subcomponent 3			0.25
The HCP asked how the pregnant woman was and asked about any problems	0 - No, 1 - Yes,		
RMC subcomponent 4			0.25
The HCP explained to the woman what they would like to do, prior to all examination or investigation	0 - No, 1 - Yes,		
The HCP explained that the findings of any examination and/or investigation would be confidential	0 - No, 1 - Yes, -88 - Not applicable (no testing)		
The HCP explained the findings of investigations or examinations to the woman	0 - No, 1 – Yes		

EC2 = Screening for, prevention and management of Anaemia			**1**
Anaemia subcomponent 1			0.5
Blood taken to test haemoglobin level	0 - No, 1 - Yes		
If yes, HCP recognised and acted upon abnormal findings	0 - No, 1 – Yes, -88 Not applicable		
Anaemia subcomponent 2			0.25
Iron tablets and folic acid were given or prescribed for the pregnant woman	0 - No, 1 - Yes		
Anaemia subcomponent 3			0.25
HCP counselled the woman about dietary sources of iron	0 - No, 1 - Yes		
Anaemia: Not in scoring			
If the woman was referred, what was the reason?	comment		
EC3 = Screening for Pre-eclampsia			**1**
Preeclampsia Subcomponent 1			0.5
The pregnant woman had her BP measured and noted in booklet	0 - No, 1 - Yes		
If BP over 140/90 mmHg, HCP recognised and acted upon abnormal findings	0 - No, 1 – Yes, -88 – Not applicable (BP normal)	Only to appear if answer to previous question = 1-Yes	
Preeclampsia Subcomponent 2			0.5
The HCP checked urine for protein and noted in booklet	0 - No, 1 - Yes		
If yes, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes	Only to appear if answer to previous question = 1-Yes	
Preeclampsia: Not in scoring			
If the woman was referred, what was the reason?	comment		

EC4 = Screening for, prevention and management of Malaria			**1**
Malaria Subcomponent 1			0.5
HCP gave her the SP	0 - No, 1 - Yes	Only to appear if after 1st trimester	
HCP explained why it was important taking the SP	0 - No, 1 - Yes	Only to appear if answer to previous question = 1-Yes	
HCP asked the woman whether she has Insecticide treated bed net	0 - No, 1 - Yes		
If no, HCP provided Insecticide treated bed net	0 - No, 1 - Yes	Only to appear if answer to previous question = 1-Yes	
Malaria Subcomponent 2			0.5
Temperature taken using a thermometer and recorded in a booklet	0 - No, 1 - Yes		
Malaria testing was performed	0 - No, 1 – Yes		
If test done, did the woman test positive to malaria?	0 - No, 1 - Yes	Only to appear if test performed	
If test was positive, antimalarials given to the woman	0 - No, 1 – Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
If test was negative and woman had fever, treatment or complementary exams prescribed/given and noted in booklet	0 - No, 1 – Yes, -88 – Not applicable (Test positive, or test negative and woman had no fever)	Only to appear if test performed	
If the woman was referred, what was the reason?	Comment		
EC5 = Screening for, prevention and management of HIV			**1**
If follow-up visit and previously tested for HIV, HIV antibody status was checked and noted in booklet	0 - No, 1 – Yes		

If ANC1 or no status indicated in booklet, HIV testing was performed	0 - No, 1 – Yes, -88 – Not applicable (Status indicated in booklet already)		
HCP counselled the woman prior to HIV test	0 - No, 1 – Yes	Only to appear if test performed	
HIV test result was noted in booklet	0 - No, 1 – Yes	Only to appear if test performed	
Did the woman test positive to HIV?	0 - No, 1 – Yes	Only to appear if test performed	
If test positive, first line ARV treatment was prescribed or given and noted in booklet	0 - No, 1 – Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
If test positive, HCP counselled woman about PMTCT	0 - No, 1 - Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
If the woman was referred, what was the reason?	comment		
EC6 = Screening for, prevention and management of Syphilis			**1**
If follow-up visit, syphilis status was checked	0 - No, 1 - Yes		
If ANC1 or no status indicated in booklet, syphilis testing was performed	0 - No, 1 - Yes, -88 – Not applicable (Status indicated in booklet already)		
Did the woman test positive to syphilis?	0 - No, 1 - Yes	Only to appear if test performed	
If test positive, antibiotic treatment was given (or prescribed if not available in facility) and noted in booklet	0 - No, 1 - Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
If the woman was referred, what was the reason?	comment		
EC7 = Screening for, prevention and management of Tuberculosis			**1**
TB subcomponent 1			0.2
HCP ask if anyone in the household has TB	0 - No, 1 - Yes		
TB subcomponent 2			0.4

HCP ask the woman if she was coughing	0 - No, 1 - Yes		
If the woman has a cough, HCP asks if it is productive	0 - No, 1 – Yes, -88 = Not Applicable (no cough or not asked)		
If the woman has a cough, HCP asks about duration of cough	0 - No, 1 - Yes, -88 - Not Applicable (no cough or not asked)		
TB subcomponent 3			0.4
HCP asked about night fever	0 - No, 1 - Yes		
Subsequent questions to subcomponent 2 or 3			
If productive cough, or night fever, TB testing was performed	0 - No, 1 - Yes	Only to appear if productive cough or night fever	
If tested, what kind of testing was performed?	1- Sputum 2- GenXpert 3- Thorax radiography 4- Other (please specify), -88 - Not Applicable (test not performed)	Only to appear if productive cough or night fever	
If tested, did the woman test positive to TB?	0 - No, 1 - Yes, -88 - Not Applicable (test not performed)	Only to appear if productive cough or night fever	
If positive, the woman was offered treatment for HRZE quadritherapy TB and noted in booklet	0 - No, 1 - Yes, -88 - Not Applicable (test negative)	Only to appear if productive cough or night fever	
TB: Not included in scoring			
If the woman was referred, what was the reason?	Comment		
EC8 = Prevention of Tetanus in mother			**1**
HCP checked tetanus vaccination status	0 - No, 1 - Yes		
If no status reported or vaccinal status not up to date, HCP provided tetanus vaccination	0 - No, 1 - Yes, -88 - Not Applicable (5 injections for VAT already completed)	Only to appear if answer to previous = 1- Yes	
If the woman was referred, what was the reason?	Comment		
EC9 = Screening and counselling for mental health and domestic violence			**1**

Mental subcomponent 1			0.5
HCP asked the woman about her psychological well being (or listened if she raised it)	0 - No, 1 – Yes		
If the woman expressed concern about her psychological well-being, ie depression or anxiety, the HCP counsels the woman	0 - No, 1 – Yes	Only to appear if HCP asked or woman raised it	
If the woman expressed concern about her psychological well-being, ie depression or anxiety the HCP refers the woman for additional support	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
Mental subcomponent 2			0.5
HCP asked the woman if she is experiencing domestic abuse	0 - No, 1 – Yes		
If the woman expressed concern about domestic abuse, the HCP counsels the woman	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
If the woman expressed concern about domestic abuse the HCP refers the woman for additional support	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
EC10 = Estimation of BMI			**1**
If subsequent visit, HCP checked if BMI previously recorded	0 - No, 1 - Yes	Only to appear if subsequent visit	
BMI measured by HCP and noted	If ANC1, answers are only = 0 - No, 1 – Yes If subsequent visit answers are = 0 - No, 1 – Yes , -88 - Not applicable (BMI already noted)	If ANC1: This is the first question to appear If subsequent visit, this is the second question to appear	
If BMI under 18, HCP recognised and acted upon abnormal findings (e.g. provided nutrition advice	0 - No, 1 - Yes-88 - Not applicable (BMI normal or unchecked)		

and supplementation, or referred if signs of gravity)			
If BMI over 30, HCP provided nutrition advice	0 - No, 1 - Yes-88 - Not applicable (BMI normal or unchecked)		
EC11 = Prevention of post- and pre-term birth			**1**
HCP noted the gestational age in booklet	0 - No, 1 - Yes		
EC12 = Assessment of foetal wellbeing during pregnancy; Screening for multiple pregnancy, abnormal lie and presentation			
The HCP measured symphysis- fundal height	0 - No, 1 - Yes	Only appears if age of pregnancy > 16 weeks	
If fundal height measured, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
The HCP listened to foetal movements	0 - No, 1 - Yes	Only appears if age of pregnancy > 10 weeks	
If foetal heartbeat listened to, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
HCP asked the woman if she feels foetal movements	0 - No, 1 - Yes, -88 - Not applicable		
If yes, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
HCP did abdominal palpation	0 - No, 1 – Yes		
After abdominal palpation, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings during examination)	Only appears if previous answer = 1-Yes	
EC13 = Provide advice on birth preparedness and danger signs of pregnancy			**1**
Birth preparedness subcomponent 1			0.5
HCP explained the possible danger signs that could occur during pregnancy	0 - No, 1 – Yes		

Birth preparedness subcomponent 2			0.5
HCP discussed with the client where she will give birth	0 - No, 1 - Yes, -88 - Not applicable		
HCP advised client to prepare for birth (set aside money, arrange for emergency transportation)	0 - No, 1 - Yes, -88 - Not applicable		
HCP advised client to use a skilled health worker for delivery	0 - No, 1 – Yes		
HCP discussed family planning for after the current pregnancy	0 - No, 1 - Yes, -88 - Not applicable		
HCP advised pregnant woman of the date for her next ANC contact	0 - No, 1 - Yes, -88 - Not applicable		
Woman departure/exit time	[select time]		
Comments	[free text]		
PNC			
PNC - general			
Type of visit	1 - < 48 hours, 2- Day 6, 3- Week 6,		
Women arrival time in the facility	[select time]		
Comments	[free text]		
PNC contact			
EC1b: Respectful maternity care			**1**
RMC subcomponent 1			0.25
The healthcare provider (HCP) introduced themselves to the postnatal woman	0 - No, 1 - Yes		
The HCP greeted the woman (or answered if woman greeted first)	0 - No, 1 – Yes		
RMC subcomponent 2			0.25
The HCP asked the woman to take a seat	0 - No, 1 - Yes, -88 - Not applicable (no chairs)		
The HCP asked the woman if she came with a companion (or the woman already declared it herself)	0 - No, 1 – Yes		
If the woman had a companion with her, was the companion allowed to	0 - No, 1 - Yes, -88 - Not applicable (no companion)		

be with the woman during ANC consultation?			
RMC subcomponent 3			0.25
The HCP asked how the woman was and asked about any problems	0 - No, 1 - Yes,		
RMC subcomponent 4			0.25
The HCP explained to the woman what they would like to do, prior to any examination and/or investigation	0 - No, 1 - Yes,		
The HCP explained that the findings of any testing would be confidential	0 - No, 1 - Yes, -88 - Not applicable (no testing)		
The HCP explained the findings of all investigations or examinations to the woman	0 - No, 1 – Yes		
EC2b = Screening for, prevention and management of Anaemia			**1**
Anaemia subcomponent 1			0.5
Blood taken to test haemoglobin level	0 - No, 1 - Yes		
If yes, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
Anaemia subcomponent 2			0.25
Iron tablets and folic acid were prescribed for the woman	0 - No, 1 - Yes		
Iron tablets and folic acid were provided for the woman	0 - No, 1 - Yes		
Anaemia subcomponent 3			0.25
HCP counselled the woman about dietary sources of iron	0 - No, 1 - Yes		
Anaemia: not in scoring			
If the woman was referred, what was the reason?	comment		
EC3b = Screening for hypertension			**1**
The woman had her BP measured and noted in booklet	0 - No, 1 - Yes		

If BP over 140/90, HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (BP normal)	Only to appear if answer to previous question = 1-Yes	
EC4b = Screening for, prevention and management of Malaria			**1**
Malaria Subcomponent 1			0.5
HCP asked the woman whether she has Insecticide treated bed net	0 - No, 1 – Yes		
If no, HCP provided Insecticide treated bed net	0 - No, 1 – Yes		
Malaria Subcomponent 2			0.5
Temperature taken using a thermometer and recorded in booklet	0 - No, 1 – Yes		
Malaria testing was performed	0 - No, 1 - Yes		
If test done, was the woman tested positive to malaria?	0 - No, 1 - Yes	Only to appear if test performed	
If test was positive, antimalarials given to the woman	0 - No, 1 – Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
If test was negative and woman had fever, treatment or complementary exams prescribed/given and noted in booklet	0 - No, 1 - Yes, -88 – Not applicable (Test positive, or test negative and woman had no fever)	Only to appear if test performed	
SF5b = Screening for, prevention and management of HIV			**1**
HIV antibody status was checked	0 - No, 1 - Yes		
If no status indicated in booklet, HIV testing performed	0 - No, 1 - Yes, -88 – Not applicable (Status indicated in booklet already)		
HCP counselled the woman prior to HIV test	0 - No, 1 – Yes	Only to appear if test performed	
HIV test result was noted in booklet	0 - No, 1 - Yes	Only to appear if test performed	

Did the woman test positive to HIV?	0 - No, 1 - Yes	Only to appear if test performed	
If the mother is HIV positive, first line ARV treatment for mother was prescribed or given and noted in booklet	0 - No, 1 - Yes, -88 – Not applicable (Test negative)	Only to appear if test performed	
first line ARV treatment for mother was provided	0 - No, 1 – Yes	Only to appear if test performed on mother and positive	
HCP performed HIV testing for baby(ies) with nucleic acid testing	0 - No, 1 – Yes	Only to appear if test performed on mother and positive	
If the baby(ies) nucleic acid test is positive ART for baby commenced,	0 - No, 1 - Yes, -88 – Not applicable (baby Test negative)	Only to appear if test performed on mother and positive	
If the baby(ies) nucleic acid test is positive the mother is given PMTCT advice about exclusive breastfeeding or replacement feeding	0 - No, 1 - Yes, -88 – Not applicable (baby Test negative)	Only to appear if test performed on mother and positive	
EC6b = Screening for, prevention and management of Syphilis			**1**
Syphilis status was checked	0 - No, 1 – Yes		
If no status indicated in booklet, syphilis testing was performed	0 - No, 1 - Yes, -88 – Not applicable (Status indicated in booklet already)		
did the woman test positive for syphilis?	0 - No, 1 – Yes	Only to appear if test performed	
If test positive, antibiotic treatment was prescribed (or prescribed if not available in facililty) and noted in booklet	0 - No, 1 – Yes	Only to appear if test performed	
EC7b = Screening for, prevention and management of Tuberculosis			**1**
TB subcomponent 1			0.2

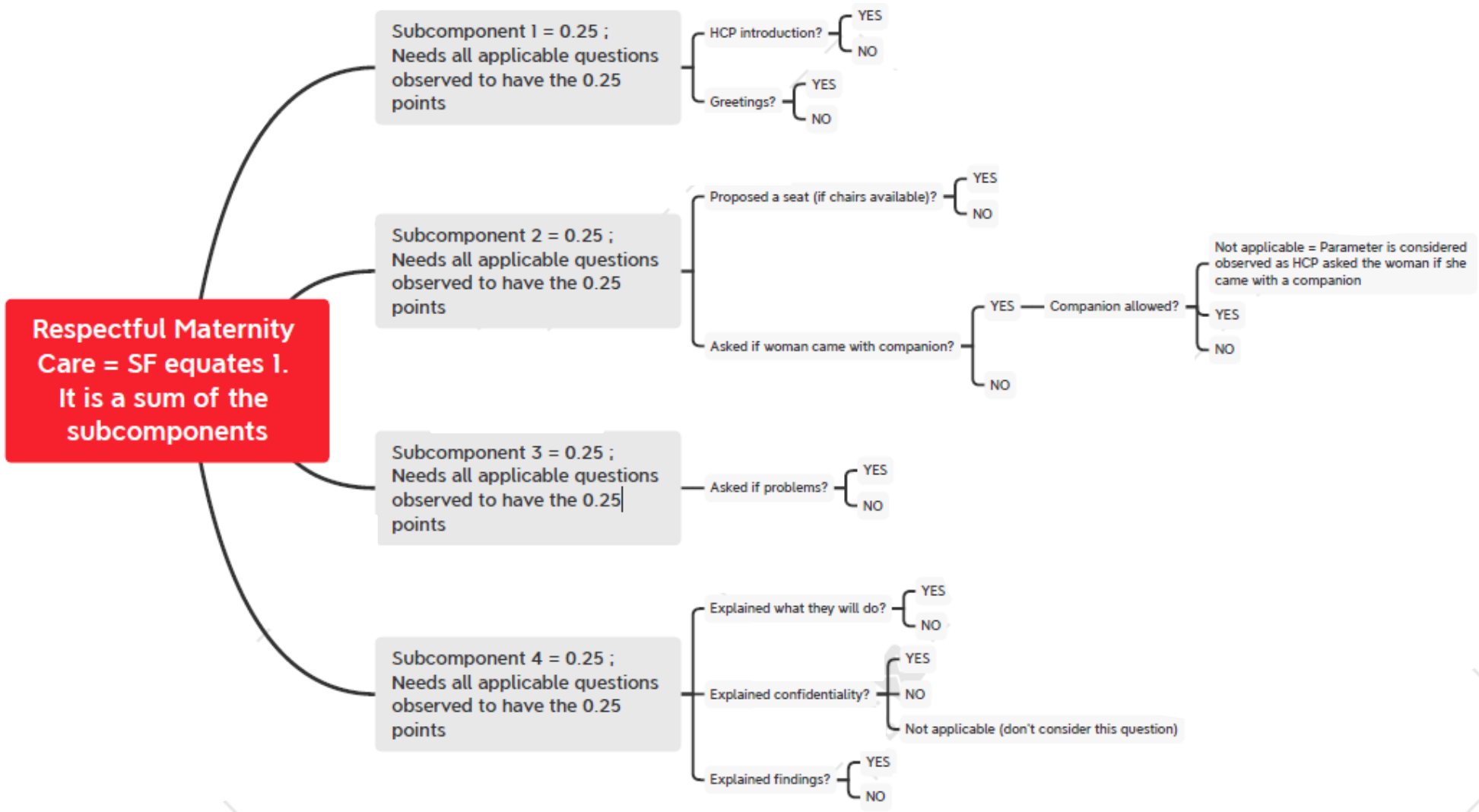
HCP ask if anyone in the household has TB	0 - No, 1 – Yes		
TB subcomponent 2			0.4
HCP ask the woman if she was coughing	0 - No, 1 – Yes		
If the woman has a cough, HCP asks if it is productive	0 - No, 1 - Yes, -88 = Not Applicable (no cough or not asked)		
If the woman has a cough, HCP asks about duration of cough	0 - No, 1 - Yes, -88 = Not Applicable (no cough or not asked)		
TB subcomponent 3			0.4
HCP asked about night fever	0 - No, 1 – Yes		
Subsequent questions to subcomponent 2 or 3			
If productive cough or night fever, TB testing was performed	0 - No, 1 – Yes	Only to appear if productive cough or night fever	
If tested, what kind of testing was performed?	1- Sputum 2- GenXpert 3- Thorax radiography 4- Other (please specify), -88 - Not Applicable (test not performed)	Only to appear if productive cough or night fever	
the woman was offered treatment for HRZE quadritherapy TB and noted in booklet	0 - No, 1 - Yes	Only to appear if mother's test positive	
prophylaxis was given (or prescribed if non available in facility) to baby, or baby referred	0 - No, 1 – Yes	Only to appear if mother's test positive	
EC8b = Prevention of Tetanus in mother			**1**
HCP checked tetanus vaccination status	0 - No, 1 - Yes		
If no status reported or vaccinal status not up to date, HCP provided tetanus vaccination	0 - No, 1 - Yes, -88 - Not Applicable (5 injections for VAT already completed)	Only to appear if answer to previous = 1- Yes	
EC9b = Screening and counselling for mental health and domestic violence			**1**
Mental subcomponent 1			0.5
HCP asked the woman about her psychological	0 - No, 1 - Yes		

well being (or listened if she raised it)			
If the woman expressed concern about her psychological well-being, ie depression, anxiety, the HCP counsels the woman	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
If the woman expressed concern about her psychological well-being, ie depression, anxiety the HCP refers the woman for additional support	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
Mental subcomponent 2			0.5
HCP asked the woman if she is experiencing domestic abuse	0 - No, 1 - Yes		
If the woman expressed concern about domestic abuse, the HCP counsels the woman	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
If the woman expressed concern about domestic abuse the HCP refers the woman for additional support	0 - No, 1 - Yes, -88 - Not Applicable (No concerns expressed)	Only to appear if HCP asked or woman raised it	
EC10b = Estimation of BMI			**1**
BMI measured by HCP	0 - No, 1 - Yes, -88 - Not applicable (BMI already noted)		
If BMI under 18 HCP recognised and acted upon abnormal findings (e.g. provided nutrition advice and supplementation, or referred if signs of gravity)	0 - No, 1 - Yes-88 - Not applicable (BMI normal or unchecked)		
If BMI over 30, HCP provided nutrition advice	0 - No, 1 - Yes-88 - Not applicable (BMI normal or unchecked)		
EC11b = Provide advice and support regarding breastfeeding			**1**
HCP gave mother advice on breastfeeding	0 - No, 1 - Yes		
EC12b = Offer postpartum contraception			**1**
HCP gave advice on family planning to the mother	0 - No, 1 - Yes		

HCP proposed family planning method to the mother	0 - No, 1 - Yes, -88 - Not applicable (already under FP)		
If the woman accepted, referred to FP room or contraception provided	0 - No, 1 - Yes, -88 - Not applicable (already under FP or refusal)		
EC13b = Clinical examination of the mother			**1**
Mother exam subcomponent 1			0.25
Breast examination	0 - No, 1 - Yes		
Check lochia	0 - No, 1 - Yes		
Mother exam subcomponent 2			0.25
HCP wash hands and wore gloves for examining the mother	0 - No, 1 - Yes		
Palpation of the abdomen to check uterine involution	0 - No, 1 - Yes, -88 - Not applicable		
HCP checked the perineum to look for scar of any perineal tear and/or episiotomy performed	0 - No, 1 - Yes		
HCP checked the abdomen to see if any wound from caesarean section	0 - No, 1 - Yes		
HCP recognised and acted upon abnormal findings with abdominal or perineum examination	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
Mother exam Subcomponent 3			0.5
HCP asked about urination and urinary continence	0 - No, 1 - Yes		
HCP asked about bowel function	0 - No, 1 - Yes		
HCP asked the woman about signs of Deep vein thrombosis in her legs	0 - No, 1 - Yes		
HCP gave the woman hygiene advice	0 - No, 1 - Yes		
HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable		
EC14b = Clinical examination of the baby			**1**
HCP observed hygiene measures before examining the baby	0 - No, 1 - Yes		

Have the newborn's eyes been checked?	0 - No, 1 - Yes		
Was the temperature of the newborn taken with a thermometer?	0 - No, 1 - Yes		
Has the HCP listened to the heartbeat of the newborn (auscultation)?	0 - No, 1 - Yes		
Did the HCP examine the abdomen of the newborn (palpation)?	0 - No, 1 - Yes		
Has the HCP checked the umbilical cord of the newborn?	0 - No, 1 - Yes		
Has the HCP checked if the newborn is passing urine	0 - No, 1 - Yes		
Has the HCP checked if the newborn has passed stools or opened its bowel?	0 - No, 1 - Yes		
Has the newborn been weighed?	0 - No, 1 - Yes		
HCP completed the baby's growth chart			
HCP recognised and acted upon abnormal findings	0 - No, 1 - Yes, -88 - Not applicable (no abnormal findings)		
EC15b = Immunization status checked and required vaccinations offered and provided			1
HCP checked whether newborn vaccines are up-to-date	0 - No, 1 - Yes		
HCP offered appropriate vaccination	0 - No, 1 – Yes, -88 Not applicable		
EC16b = Provide advice on danger signs in the mother and baby			1
HCP gave advice on danger signs (i.e. signs that indicate the baby is sick) to look out for in the baby	0 - No, 1 - Yes		
HCP gave the date of the next PNC contact to the mother	0 - No, 1 - Yes	Does not appear if PNC visit = W6	
Woman departure/exit time	[enter time]		
Comments	[free text]		

SCORING EXAMPLE: Respectful Maternity Care essential component



Appendix 3: Tool for data collection for availability of equipment and consumables necessary for each essential component of ANC-PNC

The tool is still under finalization. Please note this tool is to be deployed on an electronic platform, therefore the formatting of the tool will be visually different to what is included here. The tool will be deployed in FRENCH.

VARIABLE	QUESTION	VALUE	ANSWER
aa001	Date of survey		
aa002	For which assessment period are you collecting data?		
aa003	Please select the facility		List
ba001	Total number of ANC visits in [aa002calc]		
ba002	Total number of ANC 1 (booking) visits in [aa002calc]		
ba003	Total number of PNC visits in [aa002calc]		
ba004	Total number of deliveries in this facility in [aa002calc]		
ba005	Total number of babies born in [aa002calc]		
ba006	Total number of maternal deaths in [aa002calc]		
ba007	Total number of neonatal deaths (death before discharge) in [aa002calc]		
ba008	Total number of stillbirths in [aa002calc]		
ca001	What was the number of staff members providing ANC and PNC services in [aa002calc]?		
ca002	Total number of staff trained by Liverpool CMNH-LSTM in QI up to [aa002calc]		
ca003	How many of the [ca002] QI trained staff were still providing ANC/PNC services in this facility in [aa002calc]?		
ca004	Total number of staff trained during the study intervention in ANC/PNC?		
ca005	How many of the [ca004] ANC/PNC trained staff were still providing ANC/PNC services in this facility in [aa002calc]?		
da001		1	Yes

VARIABLE	QUESTION	VALUE	ANSWER
	Screening for pre-eclampsia - Available in [aa002calc]	0	No
da002	Screening for pre-eclampsia - Reason for non availability in [aa002calc]	2	No BP machine
		4	No urine dipstick
		5	Staff shortage
		99	Other reason
da003	Screening for anaemia with Hb measurement- Available in [aa002calc]	1	Yes
		0	No
da004	Screening for anaemia with Hb measurement - Reason for non availability in [aa002calc]	2a	No Hemocue machine
		2b	No hemocue cuvettes
		4	No lab measurement of Hb
		5	Staff shortage
		99	Other reason
da005	Management of anaemia - Available in [aa002calc]	1	Yes
		0	No
da006	Management of anaemia - Reason for non availability in [aa002calc]	1	No drugs
		2	No blood for transfusion
		5	Staff shortage
		99	Other reason
da007	Screening for malaria - Available in [aa002calc]	1	Yes
		0	No
da008	Screening for malaria - Reason for non availability in [aa002calc]	4a	No malaria rapid tests
		4b	No lab test using malaria smears
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da009	Prevention of malaria - Available in [aa002calc]	1	Yes
		0	No
da010	Prevention of malaria - Reason for non availability in [aa002calc]	2	No Insecticide-Treated Nets (ITNs)
		3	No SP
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da011	Management of malaria - Available in [aa002calc]	1	Yes
		0	No
da012	Management of malaria - Reason for non availability in [aa002calc]	1	No malaria drugs
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason

VARIABLE	QUESTION	VALUE	ANSWER
da013	Screening for HIV - Available in [aa002calc]	1	Yes
		0	No
da014	Screening for HIV - Reason for non availability in [aa002calc]	4a	No HIV rapid tests
		4b	No lab test
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		7	National or facility policies do not allow service to be offered
		99	Other reason
da015	Management of HIV - Available in [aa002calc]	1	Yes
		0	No
da016	Management of HIV - Reason for non availability in [aa002calc]	1	No HIV drugs
		5	Staff shortage
		7	National or facility policies do not allow service to be offered
		99	Other reason
da017	Screening for syphilis - Available in [aa002calc]	1	Yes
		0	No
da018	Screening for syphilis - Reason for non availability in [aa002calc]	4a	No rapid test for syphilis
		4b	No lab test
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		7	National or facility policies do not allow service to be offered
		99	Other reason
da019	Management of syphilis - Available in [aa002calc]	1	Yes
		0	No
da020	Management of syphilis - Reason for non availability in [aa002calc]	1	No drugs (penicillin)
		5	Staff shortage
		7	National or facility policies do not allow service to be offered
		99	Other reason
da021	Prevention of TB - Available in [aa002calc]	1	Yes
		0	No
da022	Prevention of TB - Reason for non availability in [aa002calc]	3	No BCG vaccination
		5	Staff shortage
		99	Other reason
da023		1	Yes

VARIABLE	QUESTION	VALUE	ANSWER
	Screening for TB - Available in [aa002calc]	0	No
da024	Screening for TB - Reason for non availability in [aa002calc]	4	No TB tests (sputum, x-ray, Genexpert)
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		7	National or facility policies do not allow service to be offered
		99	Other reason
da025	Management of TB - Available in [aa002calc]	1	Yes
		0	No
da026	Management of TB - Reason for non availability in [aa002calc]	1	No TB drugs
		5	Staff shortage
		7	National or facility policies do not allow service to be offered
		99	Other reason
da027	Prevention of tetanus in mother and baby - Available in [aa002calc]	1	Yes
		0	No
da028	Prevention of tetanus in mother and baby - Reason for non availability in [aa002calc]	1	No tetanus vaccine
		5	Staff shortage
		7	National or facility policies do not allow service to be offered
		99	Other reason
da029	Prevention of hepatitis B for mothers - Available in [aa002calc]	1	Yes
		0	No
da030	Prevention of hepatitis B for mothers - Reason for non availability in [aa002calc]	1	No hepatitis vaccine
		5	Staff shortage
		7	National or facility policies do not allow service to be offered
		99	Other reason
da031	Screening for mental health - Available in [aa002calc]	1	Yes
		0	No
da032	Screening for mental health - Reason for non availability in [aa002calc]	0	All clients refusal/not willing (if available but not performed)
		3	Lack of specific tools (for example Whooley, EPDS template)
		5	Staff shortage

VARIABLE	QUESTION	VALUE	ANSWER
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da033	Counselling for mental health - Available in [aa002calc]	1	Yes
		0	No
da034	Counselling for mental health - Reason for non availability in [aa002calc]	0	All clients refusal/not willing (if available but not performed)
		3	Lack of specific tools (for example Whooley, EPDS template)
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da035	Screening for domestic violence - Available in [aa002calc]	1	Yes
		0	No
da036	Screening for domestic violence - Reason for non availability in [aa002calc]	0	All clients refusal/not willing (if available but not performed)
		3	Lack of specific tools (for example HITS)
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da037	Counselling for domestic violence - Available in [aa002calc]	1	Yes
		0	No
da038	Counselling for domestic violence - Reason for non availability in [aa002calc]	0	All clients refusal/not willing (if available but not performed)
		3	Lack of specific tools (for example HITS)
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da039	Estimation of BMI (height and weight) - Available in [aa002calc]	1	Yes
		0	No
da040	Estimation of BMI (height and weight) - Reason for non availability in [aa002calc]	2a	No height measure
		2b	No weighing scale
		5	Staff shortage
		99	Other reason
da041		1	Yes

VARIABLE	QUESTION	VALUE	ANSWER
	Assessment of pre- and post-term birth - Available in [aa002calc]	0	No
da042	Assessment of pre- and post-term birth - Reason for non availability in [aa002calc]	2a	No pregnancy wheel/EDD wheel
		2b	No ultrasound scanner
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da043	Assessment of fetal wellbeing during pregnancy - Available in [aa002calc]	1	Yes
		0	No
da044	Assessment of fetal wellbeing during pregnancy - Reason for non availability in [aa002calc]	2a	No tape measure
		2b	No pinard stethoscope
		2c	No ultrasound scanner
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da045	Screening for multiple pregnancy, presentation & abnormal lie during pregnancy - Available in [aa002calc]	1	Yes
		0	No
da046	Screening for multiple pregnancy, presentation & abnormal lie during pregnancy - Reason for non availability in [aa002calc]	2	No ultrasound scanner
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da047	Provide advice on birth preparedness and danger signs of pregnancy - Available in [aa002calc]	1	Yes
		0	No
da048	Provide advice on birth preparedness and danger signs of pregnancy - Reason for non availability in [aa002calc]	5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da049	Screening for gestational diabetes - Available in [aa002calc]	1	Yes
		0	No
da050	Screening for gestational diabetes - Reason for non availability in [aa002calc]	4a	No glucometer
		4b	No glucometer strips
		4c	No Glucose Tolerance Tests
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da051	Management of gestational diabetes - Available in [aa002calc]	1	Yes
		0	No
da052		1	No anti-diabetic drugs

VARIABLE	QUESTION	VALUE	ANSWER
	Management of gestational diabetes - Reason for non availability in [aa002calc]	5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da053	Provide advice and support regarding breastfeeding - Available in [aa002calc]	1	Yes
		0	No
da054	Provide advice and support regarding breastfeeding - Reason for non availability in [aa002calc]	5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da055	Offer post-partum contraception - Available in [aa002calc]	1	Yes
		0	No
da056	Offer post-partum contraception - Reason for non availability in [aa002calc]	0	All clients refusal/not willing (if available but not performed)
		3	No contraceptives available
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da057	Monitor newborn growth - Available in [aa002calc]	1	Yes
		0	No
da058	Monitor newborn growth - Reason for non availability in [aa002calc]	2a	No weighing scale (baby)
		2b	No height measure
		2c	No tape measure
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da059	Clinical examination of the mother and baby - Available in [aa002calc]	1	Yes
		0	No
da060	Clinical examination of the mother and baby - Reason for non availability in [aa002calc]	2	No examination area
		5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason
da061	Provide advice on danger signs postnatally in the mother and baby - Available in [aa002calc]	1	Yes
		0	No
da062	Provide advice on danger signs postnatally in the mother and baby - Reason for non availability in [aa002calc]	5	Staff shortage
		6	Staff do not have the skills to offer the procedure
		99	Other reason

VARIABLE	QUESTION	VALUE	ANSWER
ea001	Number of women using ANC services who had their blood pressure measured in [aa002calc]		
ea002	Number of women using ANC services with high blood pressure in [aa002calc]		
ea003	Number of women using ANC services who had their urine tested for protein in [aa002calc]		
ea004	Number of women using ANC services who tested positive for proteinuria in [aa002calc]		
ea005	Number of women using ANC services who had their haemoglobin measured in [aa002calc]		
ea006	Number of women using ANC services who had low haemoglobin (<10g/dL) in [aa002calc]		
ea007	Number of women using ANC services with low Hb who received treatment in [aa002calc]		
ea008	Number of women using ANC services who were tested for malaria in [aa002calc]		
ea009	Number of women using ANC services who tested positive for malaria in [aa002calc]		
ea010	Number of women using ANC services who tested positive and received treatment for malaria in [aa002calc]		
ea011	Number of women using ANC services that received SP for malaria prophylaxis (IPT) in [aa002calc]		
ea012	Number of women using ANC services tested for HIV (rapid and/or lab testing) in [aa002calc]		
ea013	Number of women using ANC services who tested positive for HIV (rapid and/or lab testing) in [aa002calc]		
ea014	Number of women using ANC services who tested positive and received HIV treatment in [aa002calc]		

VARIABLE	QUESTION	VALUE	ANSWER
ea015	Number of HIV positive women using ANC services who received prophylactic ART for Prevention of Mother-To-Child Transmission (PMTCT) in [aa002calc]		
ea016	Number of women using ANC services tested for syphilis in [aa002calc]		
ea017	Number of women using ANC services who tested positive for syphilis in [aa002calc]		
ea018	Number of women using ANC services who tested positive and received syphilis treatment in [aa002calc]		
fa001	Number of women using PNC services who had their haemoglobin measured in [aa002calc]		
fa002	Number of women using PNC services who had low haemoglobin (<11g/dL) in [aa002calc]		
fa003	Number of women using PNC services with low Hb who received treatment in [aa002calc]		
fa004	Number of women using PNC services who were tested for malaria in [aa002calc]		
fa005	Number of women using PNC services who tested positive for malaria in [aa002calc]		
fa006	Number of women using PNC services who tested positive and received malaria treatment in [aa002calc]		
fa007	Number of women using PNC services tested for HIV (rapid and/or lab testing) in [aa002calc]		
fa008	Number of women using PNC services who tested positive for HIV (rapid and/or lab testing) in [aa002calc]		
fa009	Number of women using PNC services who tested positive and received HIV treatment in [aa002calc]		
fa010	Number of HIV positive women using PNC services who received prophylactic ART for Prevention of Mother-To-Child Transmission (PMTCT) in [aa002calc]		

VARIABLE	QUESTION	VALUE	ANSWER
fa011	Number of women using PNC services tested for syphilis in [aa002calc]		
fa012	Number of women using PNC services who tested positive for syphilis in [aa002calc]		
fa013	Number of women using PNC services who tested positive and received syphilis treatment in [aa002calc]		

Appendix 4: Healthcare facilities selected for the trial

The list below is based on the healthcare facilities identified with the Ministry of Public Health (Ministère de la Santé Publique – MSP) for the 2018 Healthcare facility assessment (HFA).

ID	Facility	Type	Designation	Ownership
F01	Hôpital Mère-Enfant	Regional hospital (Delegation)	CEmOC	Public
F02	CHU Le bon samaritain	Regional hospital (Delegation)	CEmOC	Faith-based
F03	Hopital de l'Amitié Tchad-Chine	Regional hospital (Delegation)	CEmOC	Public
F04	Centre National de traitement des fistules	Regional hospital (Delegation)	CEmOC	Public
F05	N'Djamena Sud	District hospital	CEmOC	Public
F06	N'Djamena Nord	District hospital	CEmOC	Public
F07	N'Djamena Centre	District hospital	CEmOC	Public
F08	N'Djamena Est	District hospital	CEmOC	Public
F09	Notre Dame des Apôtres	District hospital	CEmOC	Faith-based
F10	Atrone	Health centre	BEmOC	Public
F11	Toukra	Health centre	BEmOC	Faith-based
F12	Abena Atetip	Health centre	BEmOC	Public
F13	Ardep Timan	Health centre	BEmOC	Public
F14	Bololo	Health centre	BEmOC	Public
F15	Diguel Est	Health centre	BEmOC	Public
F16	Hilé-Houdjadj	Health centre	BEmOC	Public
F17	Goudji	Health centre	BEmOC	Public
F18	Gaoui	Health centre	BEmOC	Public

Appendix 5: Healthcare Facility Improvement Fund (HFIF) – List of equipment and consumables

The following list of equipment and consumables is defined by the CMNH-LSTM experts as essentials to be provided within the HFIF at the beginning of the trial. The definitive list and amount attributed to each facility will be finalized in accordance with the MSP based on the latest update of the data retrieved during the previous HFA.

Essential equipment list for ANC

- Sphygmomanometer with standard and large cuff
- Stethoscope
- Thermometer
- Tape measure (plastic and flexible)
- Pinard stethoscope
- Examination couch
- Curtain
- Adult weighing scales
- Sheets/material for privacy
- Fetal doppler and batteries

Essential equipment list for PNC

- Sphygmomanometer with standard and large cuff
- Stethoscope
- Thermometer
- Tape measure (plastic and flexible)
- Examination couch
- Curtain
- Sheets/material for privacy
- Baby weighing scales
- Thermometer

Essential consumables for ANC and PNC

- Urine dipsticks (detect protein as a minimum)
- Alcohol rub for hands
- Pre injection alcohol swabs
- Non-sterile + sterile gloves
- Microbiology swabs
- Cotton wool/small gauze swabs
- Needles 21 gauge for IM injection
- 1, and 5 ml syringes
- Blood bottles and needles for venous samples
- Needles- neonate 23 or 25 gauge for IM injection
- Sterile scissors and staple removers