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Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations: protocol of a multicentre prospective cohort study (MA-CoV project)

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ABSTRACT

Introduction Pregnant women are currently considered a vulnerable population to SARS-CoV-2 infection, with increased risk of severe COVID-19, preterm birth and maternal mortality. There is, however, a paucity of data on the burden of maternal SARS-CoV-2 infection in sub-Saharan countries. The objective of this study is to determine the prevalence and health effects of maternal SARS-CoV-2 infection in selected sites from Gabon and Mozambique.

Methods and analysis MA-CoV (MAternal CoVid) is an observational, multicentre prospective cohort study where 1000 pregnant women (500 per country) will be enrolled at the antenatal clinic visits. Participants will undergo monthly follow-up at each antenatal care visit, delivery and postpartum visit. The primary study outcome is the prevalence of SARS-CoV-2 infection during pregnancy. The clinical presentation of COVID-19 in pregnancy will also be characterised, and incidence of infection during pregnancy will be evaluated, as well as the risk factors of maternal and neonatal morbidity and mortality associated with SARS-CoV-2 infection and the risk of mother to child transmission of SARS-CoV-2. SARS-CoV-2 infection screening will be performed through PCR diagnosis.

Ethics and dissemination The protocol was reviewed and approved by the *Comité National d'Éthique pour la Recherche au Gabon*, *Comité Nacional de Bioética para Saúde de Moçambique* and the Ethics Committee of the Hospital Clinic of Barcelona (Spain). Project results will be presented to all stakeholders and published in open access journals.

Trial registration number NCT05303168.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The prospective longitudinal study design which covers the pregnancy and postpartum periods will allow us to assess both prevalence and incidence of SARS-CoV-2 infection and its health effects in pregnancy and perinatal outcomes.

⇒ The inclusion of participants from two different sub-Saharan countries will provide information on the differences in the distribution of SARS-CoV-2 infection.

⇒ The COVID-19 pandemic scenario presents several barriers and challenges due to the disease itself and the implementation of containment measures such as quarantine, social distancing and community containment. This may affect antenatal care attendance as well as hinder the implementation of the study.

⇒ As COVID-19 vaccination of study participants may limit our capacity to estimate the prevalence of the infection through SARS-CoV-2 serology, we will assess the prevalence of antibodies against the SARS-CoV-2 nucleocapsid protein, which reflects past SARS-CoV-2 infection.

INTRODUCTION

As of July 2022, more than 9 million COVID-19 cases and 170 000 related deaths have been reported in the WHO African region, while only 21% of the African population has been fully vaccinated.[1] However, the real burden of SARS-CoV-2 in Africa is probably still unknown and underestimated.

Pregnant women are at increased susceptibility of SARS-CoV-2 infection, particularly those with comorbidities such as pre-eclampsia and gestational diabetes mellitus.[2] This may be explained by the pregnancy-induced changes, which include a decreased lung volume, an increased risk for thromboembolic disease and immunological changes in order to allow for the growth of a semiallogenic fetus.[3] Effects of SARS-CoV-2 infection on maternal and neonatal health include

increased risk of admission to intensive care and need of mechanical ventilation, induced abortion, caesarean section (c-section), preterm birth, fetal growth restriction, postpartum haemorrhage and maternal mortality.[4–6]

Besides, mother to child transmission of SARS-CoV-2 is possible intrauterine, intrapartum and at the postpartum period.[7] Several studies have reported the detection of SARS-CoV-2 in the fetal side of the placenta, indicating transplacental fetal infection.[7] Of note, most of the evidence of these effects has been gathered in high-income countries.

In sub-Saharan Africa (SSA), SARS-CoV-2 overlaps geographically with endemic infectious diseases such as the HIV and malaria in a context of low SARS-CoV-2 vaccination coverage. For instance, coinfection with SARS-CoV-2 and malaria in pregnant women might have deleterious effects in the fetal development, considering the reported inflammatory and histological changes at the placental level found in both infections.[8 9] Additionally, there is evidence that immunosuppressed HIV-infected individuals are at increased risk of severe COVID-19 and death than non-infected individuals.[10 11] Importantly, the burden of HIV infection is concentrated in SSA.[12]

The information on the burden of SARS-CoV-2 infection in pregnancy in SSA countries is very limited. As to date, most of studies have been carried out in high-income countries, neglecting the particular characteristics of SARS-CoV-2 infection in pregnancy in low and middle-income countries. In this context, the present study was developed leveraging on an ongoing multicentre, two-arm, placebo-controlled, individually randomised trial aiming to assess the efficacy and safety of dihydroartemisinin-piperaquine as intermittent preventive treatment for HIV-infected pregnant women (NCT03671109).[13]

Study aims and hypotheses

The primary objective of the MAternal CoVid (MA-CoV) study is to determine the prevalence and incidence of SARS-CoV-2 infection during pregnancy. Secondary objectives include to describe the effects of maternal SARS-CoV-2 infection on pregnancy and perinatal outcomes, to characterise the clinical features of COVID-19 disease in pregnancy and to assess the potential vertical transmission and through breast feeding of SARS-CoV-2 from infected mothers to their offspring. The main study hypotheses are: (1) SARS-CoV-2 infection during pregnancy may influence maternal and perinatal outcomes, (2) SARS-CoV-2 clinical manifestations may be different in pregnant women compared with non-pregnant adults and (3) SARS-CoV-2 can be transmitted from mother to child prenatally and postnatally.

METHODS AND ANALYSIS

MA-CoV is an observational, multicentre prospective cohort study.

Study settings

The study will be carried out in Libreville and Lambaréné (Gabon) and in Manhiça (Mozambique). SARS-CoV-2-reported cases ranged from 48 000 in Gabon to 228 000 in Mozambique as per July 2022.[1] Additionally, HIV prevalence among pregnant women ranges from 6% in study sites of Gabon to 29% in study sites of Mozambique.[14 15] Malaria epidemiological indicators and SARS-CoV-2 and HIV prevalence in pregnancy in study sites are shown in table 1.

Study population

All pregnant women attending the study antenatal care (ANC) services will be screened for participation in the study. Inclusion criteria are (1) permanent resident in the study area and (2) willing to deliver in the study maternity wards. Pregnant women planning to move out the study area in the following 7 months from enrolment will be excluded.

Informed consent and recruitment

All participants will receive information about study procedures. A signed informed consent form (or thumb-printed with a witness if the woman is illiterate) will be obtained before any study procedures are carried out by study nurses in each site. The informed consent will cover the woman and the newborn infant. The study's informed consent is available in online supplemental material file 1. If the participant is under the legal age of maturity, she will sign the assent form and her legal guardian will sign the informed consent according to national ethics local policies.

After the study details are explained and informed consent is signed, a study identification card containing the individual study number and basic demographic

Table 1 SARS-CoV-2, malaria and HIV epidemiology in study countries

Country	Site	SARS-CoV-2-reported cases (country level)	*Plasmodium falciparum* infection prevalence in women at delivery*	HIV prevalence in pregnant women
Mozambique	Manhiça	228 000[1]	6%	29%[14]
Gabon	Lambaréné	48 000[1]	11%	6%[15]
	Libreville		NI	6%[15]

*Data from 2010 to 2012 in women receiving either two IPTp doses of mefloquine or SP (Tuikue-Ndam *et al*, unpublished).
IPTp, intermittent preventive treatment in pregnancy; NI, no information; SP, sulfadoxine-pyrimethamine.

information will be given to the participant in order to facilitate the identification at all study contacts.

Follow-up and measurement of outcomes

At baseline, the woman's demographic and obstetric information will be recorded in study-specific case report forms (CRFs) (online supplemental material file 2).

Physical and clinical examination at enrolment

The physical examination of the woman will include the following assessments: weight, height, gestational age by bimanual palpation and measurement of middle upper arm circumference. Ultrasound will be performed to determine the gestational age and confirm the pregnancy viability at enrolment if possible. COVID-19-suggestive symptoms will be assessed, and should the woman present them, a nasopharyngeal swab will be collected for detection of SARS-CoV-2 viral RNA. Additionally, a nasopharyngeal swab will be collected in a subsample of 100 study participants regardless of the presence of COVID-19 symptoms for screening of SARS-CoV-2 infection.

Baseline biological samples

At enrolment, a venous blood sample (5 mL) will be collected for analysis of haemoglobin level, SARS-CoV-2 total antibodies, malaria PCR (if the woman presents malaria-suggestive symptoms) and HIV viral load and CD4 cell count (if the woman is HIV infected).

Antenatal follow-up

Participants will receive the standard ANC package of interventions, which includes intermittent preventive treatment of malaria in pregnancy, and iron and folate supplementation, following national guidelines. During monthly ANC visits, COVID-19-suggestive symptoms will be assessed, and should the woman present them, a PCR to detect SARS-CoV-2 viral load will be performed.

Unscheduled visits

Study participants reporting being sick at the health facilities (including suspicion of COVID-19) will be seen by study personnel. Every unscheduled visit of the woman from enrolment until the postpartum visit will be recorded into a study CRF.

End of pregnancy and postpartum period

At the end of pregnancy, 5 mL of maternal blood sample will be collected for analysis of antibodies (IgG and IgM) against SARS-CoV-2, malaria parasitaemia and HIV viral load (in case the woman is HIV infected). Additionally, whenever possible, cord blood and placental tissue samples will be collected for SARS-CoV-2 serologic and PCR analysis, respectively.

Breast milk samples (3 mL) will also be collected within the first 3 days after delivery (colostrum) and at the postpartum visit (approximately 6 weeks after the end of pregnancy) for detection of SARS-CoV-2 by PCR. In addition, a neonatal throat swab will be collected at birth for SARS-CoV-2 analysis by PCR in infants born to COVID-19-positive mothers. A summary of study procedures is displayed in table 2.

Infant assessment

A neonatal throat swab will be collected at birth for SARS-CoV-2 analysis by PCR in infants born to COVID-19-positive mothers. Should the neonate present with symptoms and/or signs suggestive of acute respiratory infection during the first month of life, another throat swab will be collected for SARS-CoV-2 testing by PCR.

Laboratory tests

Detection of SARS-CoV-2

A real-time PCR (RT-PCR) COVID-19 assay diagnostic test will be performed at the study laboratories for detection of SARS-CoV-2 viral RNA. RT-PCR technology uses PCR for the amplification of specific target sequences and target-specific probes for the detection of the amplified RNA. The probes are labelled with fluorescent reporter and quencher dyes.

The Elecsys Anti-SARS-CoV-2 and Elecsys Anti-SARS-CoV-2 S assays (Roche Diagnostics) will be used for detection of total anti-SARS-CoV-2 spike (S) and nucleocapsid (N) antibodies through electrochemiluminescence immunoassays (ECLIA) intended for the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma.[16 17] This assay is a double-antigen sandwich ECLIA, which separates bound from unbound substances with streptavidin-coated microparticles before applying a voltage to the electrode.[16 17]

Malaria parasitological and haematological determinations

In case of malaria suspicion, thick and thin blood smears will be collected and stained with Giemsa's stain and examined for *Plasmodium* spp following standard procedures. Also, blood haemoglobin will be determined following local standard operating procedures.

Detection of HIV and quantitative determination of viral load

In HIV-infected women, quantitative PCR HIV viral load will be determined from the venous blood samples drawn at enrolment and at delivery. HIV viral load will be determined from plasma cryopreserved at −80°C using the devices in place in the study sites (such as COBAS AMPLICOR, AmpliPrep (Roche Diagnostics) or GeneXpert).

Immunological determinations related to HIV status

In HIV-infected women, CD4+ T cell count will be determined by flow cytometry after staining of whole blood with CD3, CD8 and CD4 fluorochrome-labelled antibodies and acquisition using FACSCalibur (BD Biosciences) and TruCOUNT tubes (Becton Dickinson, San Jose, California, USA) or MiniVIdas device.

Placental samples analysis

A placental sample will be collected for malaria histological analysis. The biopsies will be immediately placed in 25 mL of 10% neutral buffered formalin and kept at 4°C

Table 2 Study visits and procedures schedule

Study procedure	First ANC clinic visit	Routine ANC clinic visits	End of pregnancy	1 month after end of pregnancy	Unscheduled visits	Infant assessment (birth and 1 month)
Inclusion/ exclusion criteria check	X					
Written informed consent	X					
Demographics, socioeconomic/ medical history	X				X	
COVID-19 screening*	X	X			X	X
Record of medications/ morbidity	X	X	X	X	X	
Physical/clinical examination	X		X		X	
Gestational age	X	X	X		X	
Temperature				X	X	X
Blood pressure	X		X	X	X	
Weight	X	X		X	X	
Height	X					
MUAC	X			X		
Presence of proteins in urine	X					
CD4 count†	X					
HIV viral load†	X		X			
SARS-CoV-2 serology	X		X			
Malaria blood PCR	X					
Blood smear	‡	‡	X	X	‡	
Haemoglobin test	X		X	X		
Peripheral venous blood (mother)	X		X			
Cord blood			X			
Placental biopsy			X			
Placental impression smears			X			
Breast milk (SARS-CoV-2)			X	X		

*In participants with suggestive symptoms/signs of COVID-19 (fever, cough, shortness of breath, sudden onset of anosmia, ageusia or dysgeusia), except in a subsample of 100 participants at enrolment among whom it will be performed regardless of presence of symptoms.
†Only in HIV-infected women.
‡Only in women passively reporting sick AND presenting with malaria-related signs/symptoms (fever (≥37.5°C) or having a history of fever in the past 24 hours, arthromyalgia or headache), as per the national management guidelines.
ANC, antenatal care; MUAC, middle upper arm circumference.

until processed and embedded in paraffin wax by standard techniques. Paraffin sections will be stained with H&E, Giemsa's stain and the periodic acid-Schiff technique. Placental histology will include the examination of inflammatory signs (such as presence of neutrophils and monocytes) in the subchorial space and the umbilical cord connective tissue (funisitis) and analysis of intervillous fibrin deposition.[18]

Additionally, another placental sample will be collected for SARS-CoV-2 histopathological detection. The placental tissue will be placed in a sterile 150 mL bottle and kept in a −80°C freezer until the sample is processed. Placental histology will include the examination of inflammatory signs (such as presence of neutrophils and monocytes) in the subchorial space and the umbilical cord connective tissue (funisitis) and analysis of intervillous fibrin deposition.[18]

Data management

All the data will be collected using paper CRFs during the study visits, from interviews and clinical observation or measures taken to participants. Results from the laboratory analyses performed in collected participant's biological samples will also be collected and entered into the CRFs.

Data from the study source document will be double entered into the study database using the OpenClinica open source software V.3.1.4 (Copyright OpenClinica and collaborators, Waltham, Massachusetts, USA, www.OpenClinica.com). Subsequently, entered data will be systematically checked by data management team using error messages printed from validation programs and database listings. Quality control audits of all key safety and efficacy information in the database will be made prior to locking the database.

Study outcomes

The primary outcome of the study will be the prevalence of anti-SARS-CoV-2 N protein total antibodies at delivery. The secondary endpoints can be found in table 3.

Sample size

Considering 6 months of enrolment and recruitment rates of participants in ongoing clinical trials in the two study sites, it was expected to include approximately 1000 women in the study. Assuming a 5% prevalence of SARS-CoV-2 infection during pregnancy, this sample size would allow estimating the proportion of women with the infection with a 1.4% precision at the 95% confidence level.[19]

Statistical analysis

Infection by SARS-CoV-2 will be defined by presence of anti-SARS-CoV-2 N protein antibodies (total IgG, IgG and/or IgM) or by a positive SARS-CoV-2 PCR. Asymptomatic COVID-19 infection will be defined by presence of SARS-CoV-2 N antibodies and/or a positive COVID-19 PCR without COVID-19-associated symptoms. Women with baseline anti-SARS-CoV-2 N protein SARS-CoV-2 antibodies will be considered infected before study enrolment.

The sociodemographic characteristics of the study participants will be described using summary statistics. Continuous variables will be summarised using mean or median (depending on the distribution of the variable) and SD or IQR. Categorical variables will be described using frequencies and percentages. Proportions for categorical variables will be assessed using the χ^2 test or Fisher's exact test where appropriate. The Student's t-test or Wilcoxon rank-sum test will be used to compare means and medians, respectively, of continuous variables according to variable characteristics. Only records with information on the outcome of interest will be analysed.

Incidences of all-cause hospital admissions and all-cause outpatient attendance during pregnancy will be analysed using negative binomial regression and compared by SARS-CoV-2 infection status. The incidence of COVID-19 and clinical malaria episodes will be determined. The frequency of COVID-19 will be compared between HIV-infected and HIV-uninfected women using a negative binomial regression. The proportion of women with adverse pregnancy outcomes will be compared by SARS-CoV-2 infection status using a modified binomial regression. These analyses will be done unadjusted and adjusted by baseline significant variables (age, gestational age, gravidity, rapid plasma reagin test, anaemia and literacy, study intervention) and clinically relevant factors depending on the outcome for control of confounding factors. Incidences of hospital admissions in the neonate will also be analysed using negative binomial regression. Data analysis will be performed using Stata (StataCorp).[20]

Patient and public involvement

Patients will not be directly involved in the design, conduct, reporting or dissemination plans of the study.

Table 3 Study endpoints

Primary endpoint	► Prevalence of anti-SARS-CoV-2 nucleocapsid (N) protein antibodies (IgG and/or IgM positive) against SARS-CoV-2 among pregnant women at delivery.
Secondary endpoints	► PCR-confirmed SARS-CoV-2 infection among pregnant women at recruitment. ► Incidence of SARS-CoV-2 infection during pregnancy. ► Maternal and neonatal morbidity and mortality due to SARS-CoV-2 infection during pregnancy. ► Pregnancy and perinatal adverse outcomes. ► Rate of vertical transmission of SARS-CoV-2 from infected mothers to their offspring during the prenatal and perinatal periods. ► CD4 cell counts and HIV viral load. ► Malaria parasitaemia at delivery (from maternal sample collected at delivery).

DISCUSSION

At the onset of the COVID-19 pandemic, the extent of the risks in pregnancy was uncertain. In this context, the MA-CoV study was conceived to address fundamental questions on the burden and effects of SARS-CoV-2 infection during pregnancy. MA-CoV is an international, prospective observational cohort study that plans to follow pregnant women living in study areas of Gabon and Mozambique, where malaria and HIV infections are endemic and the real burden of SARS-CoV-2 infection is still unknown. Participants will be followed at monthly ANC visits, until 6 weeks after end of pregnancy. Additionally, the presence of antibodies (IgG/IgM) against SARS-CoV-2 in blood samples will be determined. The clinical presentation of COVID-19 in pregnancy will also be characterised, and incidence of infection during pregnancy will be evaluated, as well as the risk factors of maternal and neonatal morbidity and mortality associated with SARS-CoV-2 infection and the risk of mother to child transmission of SARS-CoV-2. Recruitment is expected to finish in September 2022, while patient follow-up is expected to be completed in May 2023.

The effects of SARS-CoV-2 infection on maternal and neonatal health have been described mostly by studies performed in high-income countries, and include increased risk of admission to intensive care, abortion, c-section, preterm birth, fetal growth restriction, postpartum haemorrhage and maternal mortality.[4–6] A retrospective cohort study analysing routine data that was performed in six SSA countries reported similar findings.[21] Moreover, the clinical presentation of COVID-19 among non-pregnant women has been well described in the literature, which will allow us to compare our study findings with reports from settings with similar epidemiological characteristics. In addition, interaction of COVID-19 with other global epidemics such as HIV is particularly relevant in the African region, given that it has the highest world incidence of HIV infection, being women of reproductive age at higher risk.[12] Recent studies have shown that HIV infection is associated with a significant increased risk of contracting SARS-CoV-2. In addition, immunosuppressed HIV-infected individuals have been shown to have higher incidence of severe COVID-19 and death than non-HIV-infected individuals.[10 11 22] Importantly, the study performed in six countries of SSA found that pregnant women with HIV had an increased risk of admission to intensive care.[21]

Pregnant women still face disproportionate inequalities in access to and quality healthcare. The most essential maternal and reproductive health interventions do not reach yet the poorest and most vulnerable women, girls and children in the developing world. This results in marked poor understanding of the particular characteristics and health outcomes for this vulnerable group in many settings. The MA-CoV study constitutes a unique opportunity to improve the understanding of the effects of COVID-19 in pregnancy in pregnant women, while it will also assess other potential mechanisms of SARS-CoV-2 transmission such as vertical transmission during pregnancy and through breast feeding. Thus, this study has the potential to produce an immediate beneficial public health impact at both regional and global levels.

Limitations

The COVID-19 pandemic scenario presents several barriers and challenges due to the disease itself and the implementation of containment measures such as quarantine, social distancing and community containment. To avoid this situation, relevant stakeholders will be meaningfully engaged from the very beginning and all throughout the process. Moreover, local and national health authorities' recommendations are being issued on the basis of ensuring continued provision of ANC, HIV prevention, testing and treatment services.

Southern Mozambique is an area with high rates of population movement between countries such as Eswatini and South Africa, where women represent a large part in some areas.[23] Thus, some participants may be lost to follow-up despite efforts to reduce bias. However, this will be considered during the data analysis. In case of high rates of participants lost to follow-up, we will conduct analyses between the baseline characteristics of retained and lost participants.

ETHICS AND DISSEMINATION

The study is conducted in accordance with the European Medicines Agency/International Council for Harmonization Guideline on Good Clinical Practice and in total agreement with the applicable international, European Union and national law of all the participating countries. The study protocol (V.1.0, 18 August 2021) and the informed consent forms have been reviewed and approved by the institutional and national ethics committees of Gabon (077/2021/CNE/SG/P) and Mozambique (61/CBNS/22) and the Hospital Clinic of Barcelona (HCB/2021/0942, Spain). The study is registered on ClinicalTrials.gov (NCT05303168). The findings of the study will be submitted for publication in a peer-reviewed journal within 12 months of study completion through an open access mechanism, or otherwise made available publicly in compliance with H2020 open access requirements. Primary project raw data will be published in the project website.[24] At no stage will data containing personal information of research participants be released. After concluding the study's data analysis, findings will be made available to all partners, key stakeholders and Ministries of Health. The project members will actively disseminate information to the scientific community through reports, presentations at scientific forums and publications in international open access journals.

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Competing interests None declared.

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