

**PREVALENCE OF COVID 19 INFECTION, MATERNAL CHARACTERISTICS
AND NEONATAL OUTCOMES AMONG PREGNANT AND POSTPARTUM
WOMEN UNDER INVESTIGATION FOR COVID 19 INFECTION AT THE
KENYATTA NATIONAL HOSPITAL: A CROSS-SECTIONAL STUDY**

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2023

DECLARATION

This research dissertation is my original work done under the guidance of my supervisors and has not been presented for a degree or in any other university.

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Signature:  **Date:** 20th June, 2023

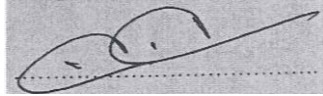
CERTIFICATE OF SUPERVISION

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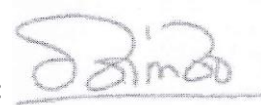


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DEDICATION

This work is dedicated to my mom (Jerusha Apiyo Osom), who pushed to the very end, for my sake.

To my twin brothers too, Ronald Osom and George Osom, for being the formidable mentors that they have always been.

LIST OF ABBREVIATIONS AND ACRONYMS

ACE2:	Angiotensin Converting Enzyme 2
ACOG:	American College of Obstetrics and Gynecology
ARDS:	Acute Respiratory Distress Syndrome
CDC:	Centre for Disease Control
COVID-19	Coronavirus Disease
DC:	Dendritic cells
G-CSF:	Granulocyte Colony Stimulating Factor
KNH:	Kenyatta National Hospital
MERS	Middle East Respiratory syndrome coronavirus
RT/PCR:	Real-time reverse transcription polymerase chain reaction
ICU	Intensive Care Unit
NICU:	Newborn ICU
NBU:	Newborn Unit
RNA:	Ribonucleic acid
SARS COV-2:	Severe Acute Respiratory Syndrome Coronavirus 2
WHO:	World Health Organization

LIST OF TABLES AND FIGURES

Tables

Table 1. Classification of COVID-19 patients	18
Table 2. Study variables	30

Figures

Figure 1. Conceptual framework	13
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TABLE OF CONTENTS

DECLARATION	1
SUPERVISOR’S APPROVAL.....	Error! Bookmark not defined.
DEPARTMENTAL APPROVAL	3
LIST OF ABBREVIATIONS AND ACRONYMS.....	3
LIST OF TABLES AND FIGURES.....	7
TABLE OF CONTENTS	8
DEFINITION OF OPERATIONAL TERMS.....	11
ABSTRACT.....	Error! Bookmark not defined.
CHAPTER ONE	14
1 INTRODUCTION	14
1.1 Background	14
CHAPTER TWO	16
2 LITERATURE REVIEW	16
2.1 Coronavirus disease (Covid-19).....	16
2.2 Epidemiology of COVID-19.....	16
2.3 Disease manifestation.....	18
2.4 COVID-19 in pregnancy	18
2.5 Pulmonary manifestations of COVID-19 in Pregnancy.....	21
2.6 Perinatal and neonatal outcomes	21
2.7 Treatment of Covid-19.....	23
2.8 Conceptual framework	24
2.9 Statement of the problem	24
2.10 Research question.....	25
2.11 Objectives.....	25

2.11.1	Broad objective	25
2.11.2	Specific objectives	25
CHAPTER THREE.....		26
3	METHODOLOGY	26
3.1	Study design.....	26
3.2	Study area.....	26
3.3	Study population	27
3.3.1	Inclusion criteria	27
3.3.2	Exclusion criteria	27
3.4	Sample size calculation and formula.....	28
3.5	Sampling technique	29
3.6	Data collection.....	29
3.6.1	Tool.....	29
3.6.2	Quality assurance	31
3.7	Ethical considerations	31
3.7.1	Ethical clearance	31
3.7.2	Confidentiality	31
3.8	Data management.....	32
3.9	Data analysis	32
3.10	Dummy Tables	32
3.11	Study dissemination plan	32
3.12	Study closure plan	32
3.13	Study timelines.....	Error! Bookmark not defined.
3.14	Study budget.....	54
REFERENCES.....		53

APPENDICES	56
Appendix 1. Questionnaire	60

DEFINITION OF OPERATIONAL TERMS

Adverse perinatal outcome: The presence of any of the following: stillbirth, low birth weight, preterm birth, neonatal intensive care unit admission/new born unit admission, or birth asphyxia.

Adverse neonatal outcome: The occurrence of either of the following: low birth weight, preterm delivery, low Apgar score at first and fifth minutes after birth, or presence of severe neonatal conditions.

Apgar score: An Apgar score gives an acceptable and easy method to report the status of a newborn immediately after birth and how it responded to resuscitation in case it was done. The 5-minute Apgar score is used to indirectly diagnose birth asphyxia.

ABSTRACT:

Background: The risk of developing viral respiratory infections such as the novel Coronavirus (COVID-19) and progression to severe pneumonia has been shown to increase in pregnancy secondary to physiological, immunological, together with cardiopulmonary system changes. The pregnant state has also been shown to increase the incidence of kidney failure, intensive care unit admission and death. In Kenya, the perinatal outcomes of pregnancies of women under investigation for COVID-19 infection are under-explored. Owing to the current minimal understanding of COVID-19 effects during pregnancy, there is need to guide management decisions based on previous encounters and outcomes. This study sought to determine the maternal characteristics, admission and perinatal outcomes in COVID-19 disease.

Study objective: To determine the maternal characteristics, prevalence of COVID-19 infection and the associated maternal and neonatal outcomes among women under investigation for COVID-19 at Kenyatta National Hospital (KNH) between April 2020-June 2021.

Methodology: This was a cross-sectional study among pregnant and postpartum women under investigation for COVID-19 infection, admitted at KNH between April 2020-June 2021. The study included all patients under investigation for COVID-19 admitted during the study period for the determination of prevalence. In the other part of the study, the maternal and neonatal characteristics of 56 COVID positive mothers were compared with those of 62 COVID negative mothers. Data was abstracted from archived health records and uploaded to version 25 of the Statistical Software for Social Scientists (SPSS) for analysis. Prevalence was determined by calculating the proportion of COVID positive cases from the total samples and 95% confidence interval estimates determined using the Clopper Pearson method. Chi square test was used to compare categorical maternal characteristics and maternal and neonatal outcomes and odds ratio interpreted as measure of association. Independent samples t-test was used to compare length of hospital stay and oxygen saturation. Statistical significance was set at 95% confidence level with a p-Value <0.05 considered.

Results: During the study period, 348 women were investigated for COVID-19 infection through RT-PCR testing. Of these patients, 56 were diagnosed with COVID-19 disease, translating to a prevalence of 16.1%. Data of 118 women (56-COVID positive and 62 COVID negative) was used for comparative analysis. The mean age of the COVID-19 positive patients was 29.6±6.4 years. Most women with COVID-19 disease were multigravida at 73.2% with 76% presenting in the third

trimester. The commonest co-morbidity was pre-eclampsia at 23.2%. The average length of hospital stay was 11.8 ± 10.6 days with 17.9% being transferred to the ICU. 76% of the COVID-19 positive women delivered via caesarean section, with 43.5% being preterm deliveries. In the comparative analysis, demographic data such as age, education level, and marital status of both arms were similar. Reproductive and medical data such as parity, presence of comorbidities such as HIV, diabetes, and hypertension were comparable between the two arms. Bivariate comparative analyses revealed that the odds of a caesarean delivery for COVID-19 positive women was comparable to that of COVID-19 negative women. The occurrence of maternal complications such as APH and PPH and the length of hospital stay were comparable between the two groups, but maternal deaths occurred at a higher degree if women had COVID-19 disease. The neonatal outcomes of COVID-19 positive and COVID-19 negative women were similar in most cases apart from preterm live births, with an odds ratio of 3.79 (95% CI=1.01-11.7) if women had COVID-19 disease.

Conclusion: The prevalence of COVID-19 among expectant and postpartum women investigated for COVID-19 was 16.1%. The commonest symptoms of Covid-19 infection in pregnancy were cough and difficulty in breathing. Most women were in the third trimester. The risk of preterm birth was higher in the COVID positive arm before adjusting for demographic factors. There were no other significant differences in the demographic characteristics, maternal and neonatal outcomes.

CHAPTER ONE

1 INTRODUCTION

1.1 Background

In the last month of 2019, numerous cases of pneumonia began being registered in Wuhan, China(1). Within 3 months, the WHO had pronounced that the specific disease named Covid-19 was a pandemic and a global health threat (2). It is believed to have begun as an outbreak of a zoonotic transmission to humans in the food market based in Wuhan, China. This was reported to have a high rate of spread with minimal contact between persons. Symptoms would then develop in 2-14 days in patients (4), mostly fever, dry cough, and unusual fatigue, and would either subside and resolve, or rapidly progress to dyspnea, and even acute respiratory distress syndrome (ARDS). Preliminary testing was done through bronchoalveolar lavage, and by whole genome sequencing, virus culture and RT-PCR. It was noted to be a new virus, different from the SARS and MERS coronavirus(1). After a few days, numerous cases with similar symptomatology appeared in various cities in China. They reported having been in Wuhan or had contact with individuals who had been in Wuhan. In Kenya, the first confirmed case was reported on 13th March 2020.

Zhao et al. noted that “more than half of non-survivors of the Covid-19 illness had chronic medical illnesses, including hypertension, diabetes, coronary heart disease and malignancies”.88% of these patients presented with fever (4). In a systematic review by Akhtar et al., they concluded that “infection with Covid-19 in pregnancy led to an increased risk in pregnancy complications such as preterm pre-labor rupture of membranes, preterm birth, and maternal death in rare cases” (5). They noted no evidence to support vertical transmission of the Covid-19 infection to unborn children although its presence has since been confirmed.

Viral pneumonia is one of the principal causes of pregnancy deaths globally. Due to the novelty of this disease, there are very few studies related to the disease evolution and outcomes in the general population and pregnancy in particular. Initially, cesarean delivery was recommended for

Covid-19 positive mothers. This was in an attempt by the obstetricians to offer the best outcome for their patients. However, consistent evidence has shown that this may not be true as “the number of neonates with intrauterine mother to child transmission of Covid-19 was not significant even for vaginal births” (6).

CHAPTER TWO

2 LITERATURE REVIEW

2.1 SARS-COV-2 Disease (Covid-19)

SARS-COV-2 disease (Covid-19) refers to a serious respiratory infection which results from severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) - a sarbecovirus from the coronaviridae family – it is the seventh coronavirus that can infect humans. Coronaviruses are enveloped RNA viruses, some of which afflict humans. Others circulate among mammals such as bats and camels. Rarely, zoonotic spread of coronaviruses from animals to humans and eventually humans to humans is possible, the latter occurring via respiratory droplets that become airborne when people cough or sneeze. The interval between infection and onset of symptoms in SARS-COV-2 ranges between 2-14 days, with an average of 5 days. Transmission can occur during the incubation period. Covid-19 virus effects mainly manifest in the respiratory system, but systemic spread is common. Lower respiratory tract infection presents with fever, dyspnea, and a dry cough. Patients also have headache, dizziness, and unusual fatigue, with gastrointestinal symptoms such as vomiting and diarrhea. Respiratory symptoms range from mild to severe and can progress from mild respiratory illness with dry cough to significant hypoxia with ARDS (7).

2.2 Epidemiology of COVID-19

There is an age-related response to the disease, with the elderly showing higher mortality (8). Children have been shown to have a much lower incidence, with most of them suffering the disease as a mild respiratory illness, and being asymptomatic altogether. The intention of medical management has been reported to be mainly supportive since no consensual therapy has been availed.

The WHO emergency dashboard indicates 512,607,587 confirmed cases as at 5th May 2022. 323,806 are in Kenya with 5,649 deaths up-to this date.

The pregnancy statistics in Kenya related to COVID-19 disease are sparse. The Kenya Obstetrical and Gynecological Society, the professional body in Kenya that advances excellence in sexual reproductive health for all, gave a practice advisory in March 2020. They noted that information about Coronavirus disease is limited especially in dealing with its effect on pregnant mothers and infants. They have however strongly advised on the need for vaccination in pregnancy due to the risk and benefit analysis that indicates that the effects of the vaccine may be less harmful when compared to COVID-19 infection in unvaccinated pregnant mothers. The national guidelines on the treatment of Coronavirus disease in pregnancy is also in use (9). The Kenya Covid 19 RMNH guidelines was developed in April 2020 to guide the continuity of family planning services and reproductive, maternal, and newborn care at this time of the pandemic (9).

The symptomatology in those who are infected ranges from minimal to severe respiratory distress to multi-organ failure. Together with the lung symptoms, pulmonary embolism and thrombosis have been seen to accompany severe disease. This is consistent with the fact that fibrinogen levels and D-dimers are elevated in severe disease (10).

The vascular endothelium tends to promote vessel dilatation, anti-aggregation and lysis of fibrin. They also express ACE2. Importantly, up-to thirty percent of lung cells are endothelial cells. Viral invasion seems to be aided through microvascular permeability. This comes as a result of endothelial injury (11).

Dendritic cells (DCs), epithelial cells, and alveolar macrophages are the major components of the innate immunity in the airway. DCs and macrophages seem to fight viruses until activation of adaptive immunity (12). Severely ill patients with SARS-CoV-2 disease have been shown to develop lymphopenia, mainly a marked reduction in peripheral blood T cells. They can also have high concentrations of pro-inflammatory cytokines like G-CSF and interleukin-6 in plasma (13). The more severe the illness in a patient, the higher the IL-6 levels are. Severely ill patients were noted to have cytotoxic T-cells which could kill the virus. However, they also contributed to lung injury.

On computerized tomography (CT) imaging, a ground glass appearance of the lungs is demonstrated even in asymptomatic patients. However, due to the increased irradiation, it is left for use after all other diagnostic modalities have been exhausted.

2.3 Disease manifestation

Patients are classified as per severity of respiratory infection as mild, moderate severe and very severe as presented in Table 1 below(14).

Table 1. Classification of COVID-19 patients

Asymptomatic	COVID nucleic acid test positive. Individuals without clinical signs. Normal chest imaging.
Mild	Symptoms of acute upper respiratory tract infection (fever, fatigue, sneezing, myalgia, cough, sore throat, runny nose) or digestive symptoms (abdominal pain, nausea, vomiting, and diarrhea)-CURB score of zero. Outpatients
Moderate	Pneumonia (frequent cough, fever) with or without the need for supplemental oxygen, chest CT shows lesions. Requiring hospitalization
Severe	Pneumonia with hypoxemia (SpO2 level is less than 92%), need for ICU care, with ARDS
Very severe or Critical	Need for immune modulators. Presence of multiple organ failure.

2.4 COVID-19 in pregnancy

In the context of infectious diseases, coronavirus in pregnancy is classified as a risky state. Due to the immunological changes of pregnancy, which are usually immunosuppressive, there is a risk of increased vulnerability to various pathological micro-organisms and their attendant complications. The effects of covid-19 illness on pregnancy are undescribed in our setting.

Based on historical lessons, it was anticipated that pregnancy would lead women to have higher rates of complications and even mortality. This has not been the case. However, in view of the

historical findings, it is prudent to keep vigil and study the perinatal and other manifestations and outcomes of COVID-19 disease in pregnancy.

The American college of Obstetrics and gynecology (ACOG) and the CDC came up with clinical assessment guidelines for patients under investigation for COVID-19 disease. This includes triaging high-risk patients, putting into consideration, their epidemiologic factors.

Clinically, the presentation of Coronavirus in pregnancy has been noted to mirror that of the general population (15). This with the fact that dyspnea, fatigue, nausea, and vomiting are usually encountered in pregnancy hence can blur or delay the diagnosis. The classification of severity of disease is no different in pregnancy; however, there is the interplay of a growing fetus whose health should be guaranteed.

From the available literature, the SARS-COV-2 prevalence in those who are pregnant seems to be low with a rate of between 3.9% and 7.9% reported worldwide. In Southern Connecticut, USA, 3.9% (30/770) of all pregnant women screened on admission tested positive for COVID 19 , 73.3% of whom presented with asymptomatic infections (16). In another study, the coronavirus prevalence among those who had symptoms of the disease and the asymptomatic obstetric patients was evaluated in labor and delivery units of academic and community hospitals in the United Kingdom (17). From the data, Goldfarb and others found the prevalence of COVID 19 to be 7.9% (11/139) among symptomatic women. The proportion of asymptomatic COVID 19 patients was significantly lower at around 1.5-2.7% in academic hospitals and 0.6-1.8% in community hospitals.

In a prospective cohort study by Prabhu et al in New-York city, they found a prevalence of 10.4% among universally tested pregnant women(18). While these data show a low rate of infection in the developed world, the situation in Africa is unclear as data is limited.

In an ongoing systematic review on the maternal and perinatal outcomes of coronavirus in pregnancy, it has been noted that pregnant and recently pregnant women were less probably to present with the symptoms of myalgia and fever than in those who are not pregnant but in the reproductive age (19).

However, pregnant women with COVID-19 disease have been noted to have a higher propensity to get intensive care unit admission. Those with pre-existing chronic conditions, with a raised body mass index and an increased maternal age were at risk of severe COVID-19 disease. COVID-19 disease has also been noted to lead to a high incidence of preterm births as compared to those without the disease(20).

The incidence of SARS-COV-2 in the first, second, and third trimester of pregnancy is widespread. Among infected women, the risk of adverse neonatal outcomes is correlated with placental infection with the SARS-CoV-2, particularly in trimester two, even though data is limited.

During early pregnancy (first trimester), there is a lower risk of harm from coronavirus infection as compared to second trimester pregnancy, even though data is limited. In a 2020 published report of a multiparous French woman aged 35 years with SARS-CoV-2 at seven weeks gestation, pregnancy was allowed to proceed without fetal sequelae although strengthened COVID-19 monitoring was recommended (9). In the case of a multiparous woman aged 43 years from Thailand with COVID-19, a pregnancy termination was required in the second trimester of pregnancy (19weeks gestation) (21). Even though vertical transmission was not ascertained, placental pathology revealed a normal morphology but showed an inflammatory histology with an active SARS CoV-2 infection. In another second trimester study, a woman of 28 years with coronavirus infection delivered a stillbirth, with placental pathology showing mixed inflammatory infiltrates (monocytes and neutrophils) and fibrin deposition (22). Funisitis was present in the absence of fungal and bacterial infections, but fetal autopsy revealed neither malformations nor a coronavirus infection of the thymus, liver, and lung. Fetal development was noted to be normal in the third trimester after resolution of the SARS-CoV-2 and normalization of clinical symptoms (23).

2.5 Pulmonary manifestations of COVID-19 in Pregnancy

In pregnancy, patients with notable symptoms are to have a prompt clinical evaluation as per ACOG. This includes assessing for compromise of the lungs by doing a physical examination, analysis of the blood gases and a use of a pulse oximeter to establish the partial pressure of oxygen. An accompanying radiological evaluation is also needed.

Due to the pregnant state, the resting minute ventilation is increased, leading to relative hyperventilation hence a decline in arterial pCO₂. The arterial pCO₂ decline is also accompanied with a decrease in serum bicarbonate, which is compensatory. There is also a pO₂ rise. Hence the normal pregnancy acid base status is usually of a compensated alkalosis of the respiratory system. This has to be considered in all critical patients. In pregnancy, oxygen supplementation in Covid-19 has to put into consideration both maternal and fetal status. An oxygenation goal that is higher than the normal is the target in order to benefit the fetus, as per the WHO.

There is also a recently described phenomenon of ambulatory patients with “silent hypoxia”, where patients with a clinically normal respiratory system have low sPO₂ levels. In appearance, they are noted to be clinically stable, but they can deteriorate rapidly. This has necessitated the society of fetomaternal medicine to propose that there is need to have those on home-based care under very close observation and monitoring.

2.6 Perinatal outcomes

Adverse perinatal outcomes have been observed with COVID-19 disease, with an accompanying mortality risk that is higher in the second and third trimester. In a systematic review of 18 case reports published between February 12 and April 4 2020, Zaigham and Anderson reported one intrauterine death and one neonatal death, translating to a perinatal death rate of 5.5% and neonatal mortality rate of 5.5% (24). Juan et al. reported a few spontaneous miscarriages and one neonatal death among 177 women delivered mostly via caesarian section at 28 to 41 weeks gestation (25). Azarkish and Janghorban reported one neonatal death (0.6%), one miscarriage, and one stillbirth from a sample of 102 third trimester pregnancies (26), while Ahmed and Jabbar reported a

mortality rate of 0.8%, with 8% of the studied neonates testing positive for SARS-CoV-2 virus. According to Panichaya et al. (21) and Baud et al. (22), miscarriage, stillbirth, and perinatal/neonatal mortality in general is commonest when the placenta is infected with the SARS-CoV-2 virus inducing an inflammatory reaction. Vertical transmission has not been reported in many studies (21), but neonatal infections are possible due to contamination (27).

Most children born to women exposed to the SARS-CoV-2 virus have a normal morphology (21). However, the risk of NBU admission seems to be pronounced, with incidence rate greater than 33% reported in literature. While evaluating the outcomes of 177 cases, Juan et al. (25) reported the need for NBU admission to exceed 33%, mostly due to neonatal asphyxia, but without a SARS-CoV-2 diagnosis. Ahmed and Jabbar (27) reported the need for NICU admission to reach 14.8%, mostly due to a low birth weight, in a systematic review of 19 articles published between 1 January and 20 June 2020. Even though lung radiography was suggestive of COVID-19 in 12.2% of neonates studied by Ahmed and Jabbar, they did not find any evidence of mother to child transmission.

In a systematic review by Ahmed and Jabbar, close to 13% of neonates born to mothers who had a SARS-COV-2 diagnosis had a low birth weight (<2500 grams). Juan et al. (15) reported several cases of small babies in 2020, while 42.3% of babies in a 2020 systematic review by Smith et al. (18) had a low birth weight. According to Dubey et al. (19), Europe leads in the rate of low birth weight (36%) due to COVID-19, followed by China and the USA. Data from Africa is limited.

Preterm births are a common occurrence with COVID-19 in pregnancy with rates of between 15% and 56% reported in the USA, China, and in Europe (19). In a 2020 study in Baghdad Iraq, 26.4% of neonates of COVID-19 positive mothers were born preterm (17). In a systematic review of literature by Smith et al. (18) 61.1% of deliveries were preterm, while the risk of preterm deliveries was higher with COVID-19 in a review of published studies by Akhthar et al. (20). Intrauterine/fetal distress and poor Apgar scores were other common findings (18,20).

2.7 Treatment of Covid-19

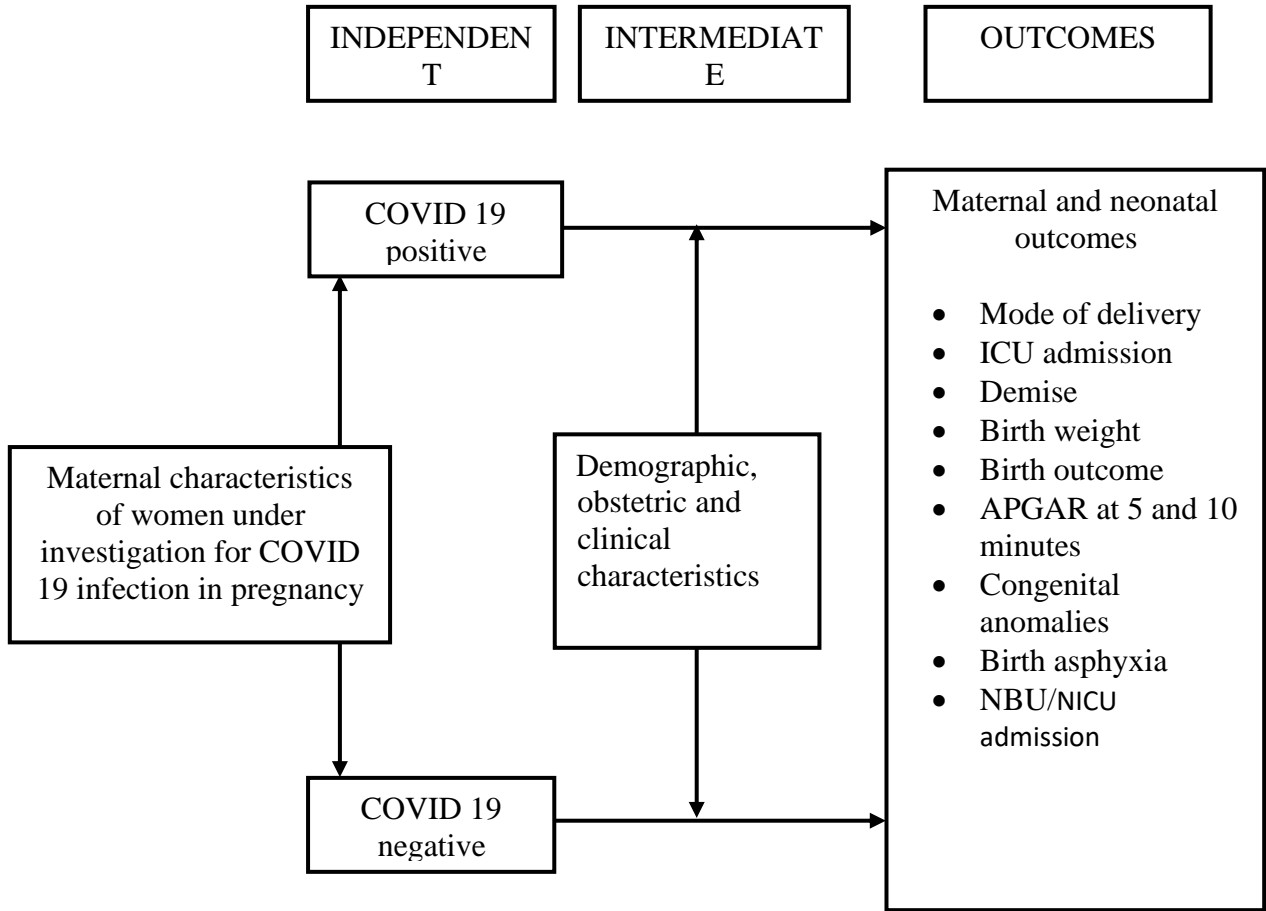
There have not been any proven definitive antiviral therapies for coronavirus infection to date (28). Many hospitals include antibiotic therapy as a prophylactic measure against bacterial superinfection. A World Health Organization (WHO) research forum held in the second month of 2020 on COVID-19 proposed that there was need to have large randomized trials on the various interventions geared towards management of coronavirus (29). During the WHO solidarity trials, various drugs including remdesivir, lopinavir and hydroxychloroquine were observed to be ineffective or had very little effect on the patient outcomes. The endpoints included those patients who were initiated on ventilation, the amount of time spent in hospital and the overall mortality(30).

Ivermectin, an antiparasitic has also been used, owing to its availability and affordability. Since this is a completely new virus, the efficacy based on clinical outcomes and the importance and effectiveness of Ivermectin in COVID-19 disease are unpredictable. Ivermectin use in the management of coronavirus can be considered an astute use of already existing drugs, which would be quite commendable. However, it would be prudent to conduct well designed large trials, preferably randomized, in order to establish its efficacy (30)

It is to be noted that there are well documented complications that arise from tracheal intubation such as ventilator associated pneumonia. There is also ventilator induced lung injury (VILI), alongside the others such as effects of sedation and being bedridden. All these increase the overall mortality. Therefore, in deciding to intubate a patient ,it should be considered the last resort ,when the benefits have been established to outweigh the risks (31).

Oxygen delivery in COVID-19 disease is done via high flow nasal cannula as per the international guidelines. This can also be done via helmet continuous positive airway pressure ,and has been noted to reduce the need for intubation compared to high flow nasal cannula (32).

2.8 Conceptual framework



2.9 Statement of the problem

The WHO emergency dashboard indicates 512,607,587 confirmed cases as at 5th May 2022. Out of these, 323,806 are in Kenya with 5,649 deaths up-to this date.

Even though Kenya has made strides in the care of cases with 318,042 recoveries made by 5th May 2022, there are few studies on COVID-19 disease in pregnancy. In a practice advisory by the Kenya Obstetrical and Gynecological Society in March 2020, it was noted that there is paucity of

data on COVID-19 disease, specifically regarding its impact on pregnant women and their infants((9). This study attempts to fill this knowledge gap.

2.10 Research question

What is the prevalence of COVID-19 infection, maternal characteristics and perinatal outcomes among pregnant and postpartum women under investigation for COVID-19 infection at the Kenyatta National Hospital between April 2020 and June 2021?

Objectives

2.10.1 Broad objective

To determine the prevalence of COVID 19 infection, maternal characteristics and perinatal outcomes among pregnant and postpartum women under investigation for COVID-19 infection at the Kenyatta National Hospital between April 2020 and June 2021.

2.10.2 Specific objectives

Primary objectives

Among pregnant and postpartum women investigated for COVID-19 infection at KNH:

- To determine the prevalence of COVID 19 infection
- To describe the maternal characteristics: socio-demographic, obstetric and clinical characteristics of those confirmed with COVID-19 infection
- To describe the maternal and neonatal outcomes of those confirmed with COVID-19 infection.

Secondary objective

Among pregnant and postpartum women with COVID-19 infection and those without COVID-19 infection at KNH:

- To compare the maternal characteristics, maternal and neonatal outcomes

CHAPTER THREE

3 METHODOLOGY

3.1 Study design

A cross-sectional study of pregnant and postpartum women under investigation for COVID-19 infection at Kenyatta National Hospital between April 2020 and June 2021 was done. Secondary data was recorded and analyzed to determine the prevalence of COVID 19 in this group of patients and whether COVID 19 infection in pregnant and postpartum women is related to adverse maternal and neonatal outcomes such as caesarian section deliveries, congenital anomalies, birth asphyxia, NBU and NICU admission.

3.2 Study location

This study was carried out at Kenyatta National Hospital (KNH), the national and largest public referral hospital found within Kenya. KNH is found in the Upper Hill area of the capital city, Nairobi; five kilometers from the Nairobi Central Business District and serves residents of the Nairobi Metropolitan area in an 1800-bed capacity unit. KNH is also the learning hospital for students of the University of Nairobi, Faculty of Health Sciences, and has several units where over 1500 patients are seen every day. Herein, pregnant and postpartum mothers with symptoms or exposure to COVID-19 and those diagnosed to have the disease are admitted for management. The study site was the KNH health records department. KNH maternity wards have a records unit where medical, reproductive, and gynecological data of patients are archived before being transferred to the health records department.

3.3 Study population

These were women admitted to the KNH clinic 66 (COVID maternity unit) and later in the maternity wards with symptoms or exposure to COVID-19 between April 2020 and June 2021. All pregnant and postpartum women who met our inclusion criteria were targeted.

3.3.1 Inclusion criteria

- Pregnant and postpartum women admitted at KNH clinic 66/Maternity wards between April 2020 and June 2021.
- Symptoms or exposure to COVID 19 disease.
- COVID 19 RT-PCR testing done and results are available.
- Complete sociodemographic, clinical and obstetric data.

3.3.2 Exclusion criteria

- More than 10% missing data in files, that is admission symptoms and diagnosis, absence of pregnancy details including patients with an absent file volume. 10% was taken as the maximum threshold based on the contents of our questionnaire.

3.4 Sample size calculation and formula

Fisher (1981) formula was used to calculate our sample size (N) at a 95% confidence interval (CI) with a margin of error of 5%. The anticipated prevalence of COVID-19 among pregnant women was adopted from a 2020 study by Goldfarb et al., reporting a prevalence of 7.9%.

Formula

$$n = \frac{Z^2 \times p(1 - p)}{d^2}$$

Assumptions

- n: Sample size
- P: The prevalence of Covid-19 (7.9%) Z²:
Normal variate for alpha at 95% CI (1.96)
- d: Precision (5%)

Sample size calculation

$$n = \frac{96^2 \times 0.079(1 - 0.079)}{0.05^2} = 112$$

One hundred and twelve (112) participants will be required.

3.5 Sampling technique

All files for patients investigated for COVID-19 disease during the study period were retrieved. 348 files which had RT-PCR results were collected. Consecutive sampling was used to obtain 118 files. Hospital files in clinic 66/health records department were checked for completeness and eligibility and a number from 1 to 118 allotted to each patient file which fulfilled the inclusion criteria. These files then underwent data abstraction.

3.6 Data collection

3.6.1 Tool

This was a questionnaire designed to record the demographic, medical, and reproductive characteristics of women admitted with symptoms of Covid-19 disease at KNH maternity unit. Questions were closed ended and structured to record the following data: demographic factors such as maternal age and education level, medical factors such as presence of comorbidities, reproductive factors such as parity and neonatal outcomes such as Apgar score at 1, 5 and 10 minutes, birth weight and need for admission to the NBU/NICU. Perinatal outcomes included perinatal mortality and mode of delivery. Variables are presented in detail in Table 2.

3.6.2 Data collection procedure

Data abstraction and recording was done at the health records of Kenyatta National Hospital. This commenced after study approval from the KNH/UON Ethics Research Committee. Patient files were retrieved and data abstracted and recorded in the questionnaire by the primary investigator and a trained research assistant, specifically a clinical officer. The research assistant was trained before deployment. Data collection process took three months.

3.7 Study variables

Variables			
Demographic characteristics	Age	Age in years	
	Education level	No formal education	
		Primary	
		Secondary	
		Tertiary	
Marital status	Married		
	Single		
	Divorced/widowed		
Obstetric characteristics	Parity		
	Gestation/Trimester	Gestation in weeks	
	ANC attendance	Yes	
		No	
Clinical characteristics	Number of contacts		
	Comorbidity present	Yes	
		No	
	Type of comorbidity	HIV	
		Diabetes	
Chronic Kidney Disease			
Maternal outcomes	Mode of delivery	Spontaneous Vaginal Delivery (SVD)	
		Caesarian section	
Neonatal outcomes	Maternal complications		
		Birth outcome	Live birth
			Stillbirth
	Preterm birth		
	Birth weight	Weight in grams	
	Apgar at 1 minute		
Apgar at 5 minutes			

Apgar at 10 minutes
Congenital anomalies
Asphyxia
NBU admission
NICU admission

3.7.1 Quality assurance

To ensure data quality and integrity, only experienced study staff were involved in data collection. The principal investigator and a registered study clinical officer formed the study team. The study clinical officer was trained on data collection before deployment. All questionnaires were checked for completeness and disparities clarified before filing and submission of questionnaire for analysis.

3.8 Ethical considerations

3.8.1 Ethical clearance

The KNH/UON Ethics Review Committee was approached for ethical approval prior to initiation of the study. The KNH administration was also approached and approval for the study sought before commencement.

3.8.2 Confidentiality

The confidentiality and privacy of all participants was upheld throughout the study. The names, identification numbers, and other personal identifiers were not recorded on the data collection tools. Instead, participants were identified using unique study codes, which will not be disclosed during data analysis and dissemination.

3.9 Data management

Paper documents (questionnaires) were secured in spring files for safe storage. The spring files are locked in cabinets. Digital tools such as databases are password protected and stored on the cloud. Data (both paper and digital) will be stored for 10 years before destruction.

3.10 Data analysis

Maternal characteristics such as age, educational level, marital status, parity, comorbidities, were summarized as frequency distributions with percentages, and the Clopper Pearson method used to compute corresponding 95% confidence intervals. Perinatal outcomes, including perinatal mortality, mode of delivery, birth weight, Apgar scores at 1, 5 and 10 minutes, and need for admission to NBU/NICU were summarized as frequency distributions with percentages and Logistic regression used to compare occurrence by maternal characteristics. Comparative analysis was done at 95% confidence interval.

3.11 Study dissemination plan

A dissertation will be submitted to the University of Nairobi, in the department of obstetrics and gynecology for the award of a degree. A manuscript will be published in a peer reviewed journal and a report submitted to the KNH/UON ERC and KNH administration. Data will also be presented in a local or international conference of Obstetrics and Gynecology.

3.12 Study closure plan

Study tools such as questionnaires will be prepared for storage. Paper documents will be filed and digital files password protected and stored in cabinets or the cloud respectively. A study closure letter will be drafted and submitted to the KNH/UON ERC.

CHAPTER FOUR

RESULTS

Recruitment schema

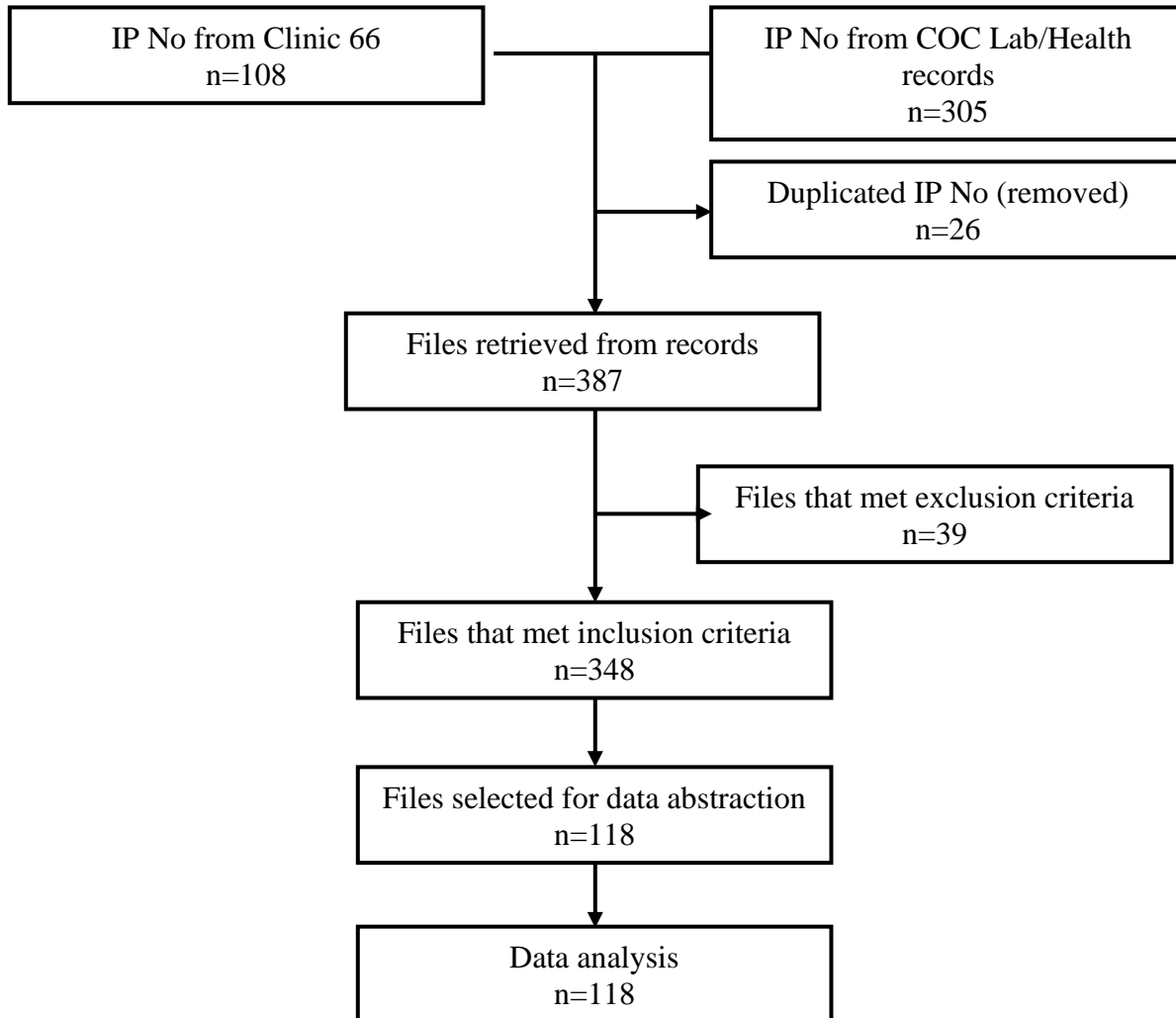


Fig 4.1. Recruitment schema

Prevalence of COVID 19

There were 348 women investigated for COVID-19 at Kenyatta National Hospital with symptoms of or travel from a hotspot between April 2020 and June 2021. They underwent a SARS-CoV-2 RT-PCR test through a nasopharyngeal swab. Fifty-six (56) had positive COVID-19 results, translating to a prevalence of 16.1% (95% CI=12.4%-20.4%)

Figure 4.1.

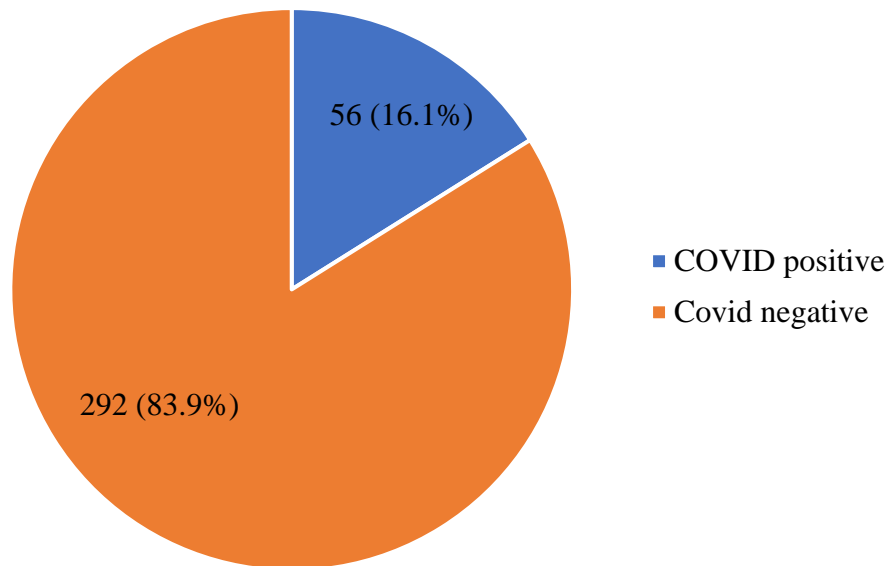


Figure 4.2. Prevalence of COVID 19 among women under investigation for COVID-19 infection at KNH.

Maternal characteristics of COVID positive pregnant and postpartum women

Demographic characteristics

The mean age was 29.6 ± 6.4 years (age range of 17-41 years). Most of the participants were in age group of 30-34 years (26.8%) and 35+ years (26.8%), married (83.9%), and had a secondary level of education (50.0%).

Table 4.1. Demographic characteristics of COVID positive patients seen at KNH in 2021

		Frequency (N=56)	Percent
Age	Mean (SD)	29.6±6.4	17-41
Age band	<20 years	3	5.4
	20-24 years	9	16.1
	25-29 years	14	25.0
	30-34 years	15	26.8
	35+ years	15	26.8
Education level	No formal education	1	1.8
	Primary	12	21.4
	Secondary	28	50.0
	Tertiary	15	26.8
Marital status	Married	47	83.9
	Single	9	16.1

Obstetric factors

The majority were multigravida (73.2%) and gravid (89.3%). Among those who were gravid, the majority were in the third trimester (28+ weeks) of pregnancy (76.0%), 97.3% of whom had attended antenatal care (ANC) (90.4%). The majority (86.2%) had <6 contacts by 28 weeks of gestation (Table 4.2).

Table 4.2. Obstetric factors of COVID 19 positive women seen at KNH in 2020/2021

		Frequency (N=56)	Percent
Parity	Primigravida	15	26.8
	Multigravida	41	73.2
Pregnancy status	Gravid	50	89.3
	Postnatal	6	10.7
Gestation	Trimester 1 (0-13 weeks)	1	2.0
	Trimester 2 (14-27 weeks)	11	22.0
	Trimester 3 (28+ weeks)	38	76.0
ANC attendance (28+ weeks)	Yes	36	97.3
	No	1	2.7
	Not indicated	1	
ANC contacts	<6	25	86.2
	6+	4	13.8
	Not indicated	7	

Clinical factors

Preeclampsia/eclampsia, HIV, and cardiac diseases were reported in 13 (23.2%), 4 (7.1%) and 3 (5.4%) patients as comorbidities. Most had mild disease (51.8%) with the majority presenting with cough (70.6%), difficulty in breathing (58.8%) or fever (43.1%). Mean oxygen saturation was 92.00±6.4 percent. Ten (10) participants (17.9%) were transferred to intensive care unit (ICU). The mean length of hospital stay was 11.8±10.6 days (Table 4.3)

Table 4.3. clinical factors of COVID-19 positive women seen at KNH in 2021

		Frequency (N=56)	Percent
Comorbidities	Preeclampsia/eclampsia	13	23.2
	HIV	4	7.1
	Cardiac disease	3	5.4
	Diabetes	2	3.6
	Hypertension	2	3.6
	PTB	1	1.8
	DVT	1	1.8
	Hypothyroidism	1	1.8
	Convulsive disorder	1	1.8
	Bipolar mood disorder	1	1.8
	Asthma	1	1.8
	AKI	1	1.8
	HELLP	1	1.8
	Achalasia	1	1.8
	Knee malignancy	1	1.8
Fibroids	1	1.8	
COVID-19 classification	Asymptomatic	5	8.9
	Mild	26	46.4
	Moderate	6	10.7
	Severe	9	16.1
	Very severe	10	17.9
Symptoms	Cough	36	70.6
	Difficulty breathing	30	58.8
	Fever	22	43.1
	Chest pain	7	13.7
	Sore throat	5	9.8
	Headache	4	7.8
	Vomiting	4	7.8
	Nausea	3	5.9
	Malaise	1	2.0
	Joint pain	1	2.0
Oxygen saturation	Mean±SD	92.00±6.4	
Maternal transfer to ICU	Yes	10	17.9
	No	46	82.1
Length of hospital stay in days	Mean±SD	11.8±10.6	

Maternal outcomes

The majority (50.0%) delivered at KNH. About 46.0% were discharged as ANC or died with a fetus, while 4.0% had a miscarriage. Among those who delivered at KNH, the majority (76.0%) underwent a caesarean section, predominantly due to abnormal fetal heart rate (FHR) tracing (42.1%) or the presence of a previous caesarean scar (36.8%). Overall, most deliveries were term live births (47.8%). The Main maternal complications were maternal mortality (8.0%), acute kidney injury (8.0%), and postpartum hemorrhage (6.0%).

Table 4.4. Maternal outcomes of COVID-19 positive women at KNH in 2020

		Frequency (N=50)	Percent
Pregnancy outcome	Delivered	25	50.0
	Discharged as ANC/dead with fetus	23	46.0
	Miscarriage	2	4.0
Mode of delivery	Caesarean section	19	76.0
	Vaginal delivery	6	24.0
Indications for CS	Previous scar	8	42.1
	Abnormal FHR tracing	8	42.1
	APH	1	5.3
	Abnormal labour	2	10.5
Birth outcome	Term stillbirth	2	8.7
	Term livebirth	11	47.8
	Preterm livebirth	10	43.5
	Not reported	2	8.0
Complications	Maternal death	5	8.0
	AKI	4	8.0
	PPH	3	6.0
	Anemia	3	6.0
	APH	2	4.0
	Puerperal sepsis	1	2.0
	HELLP	1	2.0
	Pulmonary edema	1	2.0
	PPROM	1	2.0
	ICH	1	2.0
	Hypovolemic shock	1	2.0
	Cardiac arrest	1	2.0

	DVT	1	2.0
	Hepatic encephalopathy	1	2.0

Neonatal outcomes

Most babies had a normal birthweight (45.0%) and good Apgar scores at one minute (72.0%), five minutes (80.0%), and ten minutes (83.3%). NBU/NICU admission (32.0%), asphyxia (16.0%), and stillbirth (7.1%) were the most common adverse neonatal outcomes.

Table 4.5. Neonatal outcomes of COVID positive women at KNH in 2021, n=25

		n (%)
Birth weight in grams	Extremely low birth weight	1 (5.0)
	Very low birth weight	1 (5.0)
	Low birthweight	7 (35.0)
	Normal	9 (45.0)
	Macrosomia	2 (10.0)
	Not indicated	5
Apgar at 1 minute	Poor	7 (28.0)
	Good	18 (72.0)
Apgar at 5 minutes	Poor	5 (20.0)
	Good	20 (80.0)
Apgar at 10 minutes	Poor	4 (16.7)
	Good	20 (83.3)
	Not reported	1
Adverse outcomes	NBU/NICU admission	8 (32.0)
	Asphyxia	4 (16.0)
	Still birth	4 (7.1)
	Congenital anomalies	1 (4.0)

Association between maternal characteristics and COVID 19 status

COVID positive patients were more likely to be in age group 30-34 years (OR=1.91 (95% CI=0.66-5.53)) and 35+ years (OR=1.43 (95% CI=0.54-3.96)) compared to 25-29 years, less likely to have a secondary education (OR=0.71 (95% CI=0.27-1.74)) or primary education (OR=0.52 (95% CI=0.17-1.44)) compared to a tertiary education, and less likely to be single compared to married (OR=0.66 (95% CI=0.28-1.57)) but the differences were not significant (Table 4.6).

Table 4.6. Association between demographic characteristics COVID 19 at KNH

		Covid + (N=56)	Covid – (N=62)	OR (95% CI)	p-Value
Age band	<20 years	3 (33.3)	6 (66.7)	0.57 (0.14-2.4)	0.479
	20-24 years	9 (32.1)	19 (67.9)	0.54 (0.18-1.49)	0.259
	25-29 years	14 (46.7)	16 (53.3)	Reference	
	30-34 years	15 (62.5)	9 (37.5)	1.91 (0.66-5.53)	0.246
	35+ years	15 (55.6)	12 (44.4)	1.43 (0.54-3.96)	0.502
Education level	No formal education	1 (16.7)	5 (83.3)	0.15 (0.01-1.10)	0.070
	Primary	12 (41.1)	17 (58.6)	0.52 (0.17-1.44)	0.227
	Secondary	28 (49.1)	29 (50.9)	0.71 (0.27-1.74)	0.468
	Tertiary	15 (57.7)	11 (42.3)	Reference	
Marital status	Married	47 (49.5)	48 (50.5)	Reference	
	Single	9 (39.1)	14 (60.9)	0.66 (0.28-1.57)	0.373

Association between obstetric characteristics and COVID 19 at KNH

The odds of having COVID 19 was higher among multigravida compared to primigravida (OR=1.58 (95% CI=0.71-3.59)), gravid compared to postnatal women (OR=1.35 (95% CI=0.51-3.52)), and women in trimester 2 compared to trimester 3 (OR=1.60 (95% CI=0.57-4.84)), Antenatal care attendance was associated with increased odds of COVID 19 by 1.64 times (95% CI=0.54-4.76), and ANC attendance (OR=3.38 (95% CI=0.48-44.9)) but the associations were not statistically significant.

Table 4.7. Association between obstetric characteristics and COVID 19 at KNH

		Covid + (N=50)	Covid - (N=52)	OR (95% CI)	p- Value
Parity	Primigravida	15 (41.7)	21 (58.3)	Reference	
	Multigravida	35 (53.0)	31 (47.0)	1.58 (0.71-3.59)	0.2726
Status	Gravid	50 (49.0))	52 (51.0)	1.60 (0.57-4.84)	0.3909
	Postnatal	6 (37.5)	10 (62.5)	Reference	
Gestation	Trimester 1 (0-13 weeks)	1 (33.3)	2 (66.7)	Reference	
	Trimester 2 (14-27 weeks)	11 (50.0)	11 (50.0)	2.00 (0.21-31.3)	1.000
	Trimester 3 (28+ weeks)	38 (50.7)	37 (49.3)	2.05 (0.23-30.4)	1.000
	Not indicated	0	2		
ANC attendance	Yes	36 (52.9)	32 (47.1)	3.38 (0.48-44.9)	0.305
	No	1 (25.0)	3 (75.0)	Reference	
	Not indicated	1	2		
ANC contacts	<6	25 (48.1)	27 (51.9)	0.93 (0.25-3.46)	1.000
	6+	4 (50.0)	4 (50.0)		
	Not indicated	7	1		

Association between clinical characteristics and COVID 19

COVID positive women were 2.40 times (95% CI=1.08-5.28) more likely to be coughing compared to COVID negative women (p=0.030). Other symptoms such as vomiting, fever, headache, malaise, sore throat, nausea, and difficulty breathing were comparable between the COVID positive and COVID negative participants. The COVID positive patients were more likely to have comorbidities (OR=1.04 (95% CI=0.52-2.09)), moderate (OR=1.20 (95% CI=0.19-5.39)) or severe (OR=1.20 (95% CI=0.27-5.93)) COVID classification, and be transferred to ICU (OR=1.13 (95% CI=0.44-2.90)) compared to COVID negative women but the differences were not significant.

Table 4.8. Association between clinical characteristics and COVID 19 at KNH

	Category	Covid + (N=56)	Covid - (N=62)	OR (95% CI)	p- Valu e
Comorbidities	Yes	24 (48.0)	26 (52.0)	1.04 (0.52- 2.09)	0.919
	No	32 (47.1)	36 (52.9)	Referenc e	
HIV	Yes	4 (44.4)	5 (55.6)	0.88 (0.26- 3.16)	0.851
	No	52 (47.7)	57 (52.3)	Referenc e	
Diabetes	Yes	2 (50.0)	2 (50.0)	1.11 (0.17- 7.28)	0.917
	No	54 (47.4)	60 (52.6)	Referenc e	
Hypertension	Yes	2 (50.0)	2 (50.0)	1.11 (0.17- 7.28)	0.917
	No	54 (47.4)	60 (52.6)	Referenc e	
Preeclampsia/eclampsia	Yes	13 (44.8)	16 (55.2)	0.87 (0.36- 1.99)	0.744
	No	43 (48.3)	46 (51.7)	Referenc e	
COVID-19 classification	Asymptomatic	5 (45.5)	6 (54.5)	Referenc e	0.676
	Mild	26 (38.8)	41 (61.2)	0.76 (0.23- 2.54)	
	Moderate	6 (50.0)	6 (50.0)	1.20 (0.19- 5.39)	

	Severe	9 (50.0)	9 (50.0)	1.20 (0.27- 5.93)	0.812
	Very severe	10 (0.0)	0 (0.0)	-	-
Symptoms					
Vomiting	Yes	4 (33.3)	8 (66.7)	0.51 (0.16- 1.62)	0.292
	No	47 (49.5)	48 (50.5)	Referenc e	
Fever	Yes	22 (47.8)	24 (52.2)	1.01 (0.47- 2.18)	0.977
	No	29 (47.5)	32 (52.5)	Referenc e	
Headache	Yes	4 (100)	0 (0.0)	-	-
	No	47 (45.6)	56 (54.4)	Referenc e	
Cough	Yes	36 (56.3)	28 (43.8)	2.40 (1.08- 5.28)	0.030
	No	15 (34.9)	28 (65.1)	Referenc e	
Malaise	Yes	1 (100)	(0.0)	-	-
	No	50 (47.2)	56 (52.8)	Referenc e	
Sore throat	Yes	5 (50.0)	5 (50.0)	1.11 (0.33- 3.71)	0.877
	No	46 (47.4)	51 (52.6)	Referenc e	
Nausea	Yes	3 (27.3)	8 (72.7)	0.38 (0.10- 1.36)	0.153
	No	48 (50.0)	48 (50.0)	Referenc e	
Difficulty breathing	Yes	30 (53.6)	26 (46.4)	1.65 (0.78- 3.62)	0.200

	No	21 (41.2)	30 (58.8)	Reference	
Chest pain	Yes	7 (43.8)	9 (56.3)	0.83 (0.31- 2.39)	0.734
	No	44 (48.4)	47 (51.6)	Reference	
Joint pains	Yes	1 (100)	(0.0)	-	-
	No	50 (47.2)	56 (52.8)	Reference	
Other	Yes	12 (66.7)	6 (33.3)	2.56 (0.88- 7.44)	0.077
	No	39 (43.8)	50 (56.2)		
Oxygen saturation	Mean±SD	92.0±6.4	82.2±32.9		0.254
Maternal transfer to ICU	Yes	10 (50.0)	10 (50.0)	1.13 (0.44- 2.90)	0.803
	No	46 (46.9)	52 (53.1)	Reference	0.050
Length of hospital stay in days	Mean±SD	11.8±10.6	11.1±15.9		0.765

Association between COVID 19 and maternal outcomes

COVID 19 positive patients were 3.78 times (95% CI=1.01-11.73), $p=0.03$ more likely to deliver a preterm livebirth ($p=0.036$) before adjusting for demographic and obstetric factors. After adjustment, the difference was not statistically significant. Other maternal outcomes were comparable before and after adjusting for demographic and obstetric factors.

Table 4.9. Association between COVID 19 and maternal outcomes

		Covid +	Covid -	OR (95% CI)	p- Value	AOR (95% CI)	p- Value
Mode of delivery		n=25	n=40				
	CS	19 (46.3)	22 (53.7)	2.59 (0.81- 8.27)	0.088	1.43 (0.28- 7.24)	0.664
	Vaginal	6 (25.0)	18 (75.0)	Reference			
Indications for CS		n=19	n=22				
Previous scar	Yes	7 (50.0)	7 (50.0)	1.25 (0.32- 4.93)	0.7352	1.22 (0.15- 10.2)	0.856
	No	12 (44.4)	15 (55.6)	Reference			
Abnormal FHR tracing	Yes	8 (47.1)	9 (52.9)	1.05 (0.30- 3.58)	0.9382	2.51 (0.36- 7.52)	0.353
	No	11 (45.8)	13 (54.2)	Reference			
APH	Yes	1 (25.0)	3 (75.0)	0.35 (0.03- 2.61)	0.6099	0.00 (0.00-)	1.000
	No	18 (48.6)	19 (51.4)	Reference			
Abnormal labour	Yes	2 (40.0)	3 (60.0)	0.75 (0.12- 4.04)	1.000	5.59 (0.28- 113.7)	0.262
	No	17 (47.2)	19 (52.8)	Reference			
Birth outcome		n=25	n=40				
	Term stillbirth	2 (28.6)	5 (71.4)	0.91 (0.16- 5.79)	1.000	0.46 (0.03- 6.86)	0.571
	Term livebirth	11 (30.0)	25 (69.4)	Reference			
	Preterm stillbirth	0 (0.0)	4 (100)	-	-	-	-

	Preterm livebirth	10 (62.5)	6 (37.5)	3.79 (1.01-11.7)	0.030	2.87 (0.51-16.2)	0.232
	Not reported	2	0				
Maternal complications		n=50	n=52				
Maternal death	Yes	5 (100)	0 (0)	-	-	-	-
	No	45 (46.9)	52 (53.1)	Reference			
Acute kidney injury	Yes	4 (57.1)	3 (42.9)	1.42 (0.36-5.86)	0.712	4.41 (0.31-62.0)	0.272
	No	46 (48.4)	49 (51.6)	Reference			
PPH	Yes	3 (75.0)	1 (25.0)	3.26 (0.47-43.0)	0.358	1.77 (0.13-24.7)	0.671
	No	47 (48.0)	51 (52.0)	Reference			
Anemia	Yes	3 (75.0)	1 (25.0)	3.26 (0.47-43.0)	0.358	6.02 (0.34-105.2)	0.219
	No	47 (48.0)	51 (52.0)	Reference			
APH	Yes	2 (28.6)	5 (71.4)	0.39 (0.08-1.99)	0.437	0.16 (0.02-1.69)	0.126
	No	48 (50.5)	47 (49.5)	Reference			
Puerperal sepsis	Yes	1 (100)	0 (0.0)	-	-	-	-
	No	49 (48.5)	52 (51.5)	Reference			
HELLP	Yes	1 (33.3)	2 (66.7)	0.51 (0.03-4.53)	1.000	0.00 (0.00-)	1.000
	No	49 (49.5)	50 (50.5)	Reference			

Pulmonary edema	Yes	1 (50.0)	1 (50.0)	1.04 (0.05-20.1)	1.000	0.00 (0.00-)	1.000
	No	49 (49.0)	51 (51.0)	Reference			
PPROM	Yes	1 (50.0)	1 (50.0)	1.04 (0.05-20.1)	1.000	1.23 (0.05-32.6)	0.900
	No	49 (49.0)	51 (51.0)	Reference			

Association between COVID 19 and neonatal outcomes

Neonatal outcomes such as birth weight and Apgar at 1, 5, and 10 minutes and adverse birth outcomes such as asphyxia, congenital anomalies, NBU/NICU admission, and stillbirth deliveries were comparable among COVID positive and COVID negative women.

Table 4.10. Association between COVID 19 and neonatal outcomes

		Covid + (N=25)	Covid - (N=40)	OR (95% CI)	p- Value	AOR (95% CI)	p- Value
Birth weight	Extremely low birth weight	1 (20.0)	4 (80.0)	0.56 (0.04-4.78)	1.000	0.00 (0.00-)	1.000
	Very low birth weight	1 (50.0)	1 (50.0)	2.25 (0.11-44.8)	1.000	0.53 (0.08-3.49)	0.508
	Low birthweight	7 (36.8)	12 (63.2)	1.31 (0.36-4.56)	0.754	0.00 (0.00-)	1.000
	Normal	8 (33.3)	18 (66.7)	Reference			
	Macrosomia	2 (50.0)	2 (50.0)	2.25 (0.30-15.9)	0.584	1.87 (0.09-36.3)	0.680
	Not indicated	5	3				
Apgar at 1 minute	Poor	7 (30.4)	16 (69.6)	0.58 (0.21-1.67)	0.426	0.15 (0.02-0.96)	0.046
	Good	18 (42.9)	24 (57.1)	Reference			
Apgar at 5 minutes	Poor	5 (26.3)	14 (73.7)	0.46 (0.16-1.44)	0.266	0.05 (0.00-0.72)	0.027
	Good	20 (43.5)	26 (56.5)	Reference			
Apgar at 10 minutes	Poor	4 (28.6)	10 (71.4)	0.46 (0.14-1.55)	0.352	0.14 (0.01-1.43)	0.096
	Good	20 (46.5)	23 (53.5)	Reference			
	Not reported	1	7				
Adverse outcomes							
NBU/NICU admission	Yes	8 (44.4)	10 (55.6)	1.41 (0.49-4.33)	0.539	0.59 (0.12-3.04)	0.530
	No	17 (36.2)	30 (63.8)	Reference			

Asphyxia	Yes	4 (44.4)	5 (55.6)	1.33 (0.37-5.27)	0.724	0.74 (0.08-6.81)	0.788
	No	21 (37.5)	35 (62.5)	Reference			
Congenital anomalies	Yes	1 (100)	0 (0.0)	-	-	-	-
	No	24 (37.5)	40 (62.5)	Reference			

CHAPTER FIVE

DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

Discussion

The first objective was to determine the prevalence of COVID-19 among pregnant women admitted with symptoms or exposure to COVID-19 at Kenyatta National Hospital. From the data, 56 of the 348 women admitted with symptoms or exposure to COVID-19 between April 2020 and June 2021 were found to have COVID-19 disease after nasopharyngeal swab testing by RT-PCR for SARS-COV-2, translating to a prevalence of 16.1%. Hcini et al. reported a higher prevalence of 27.0% in a 2021 single-center prospective comparative study in South America at the West French Guiana Hospital Center (33). In the United States of America, Goldfarb et al. reported a lower prevalence of 7.8% in a randomized controlled trial of symptomatic pregnant and postpartum women in 2020 (17). The differences in COVID-19 prevalence could be explained by the differences in infection rates reported in South America (higher) compared to Africa. While COVID-19 infection rates have been shown to be higher in the USA compared to Africa, universal testing could explain the lower prevalence reported by Goldfarb et al. The higher figure in our set up could be attributed to the fact that Kenyatta National Hospital was initially the designated facility for the care of COVID-19 patients and those under investigation.

The second objective was to determine the maternal characteristics of the COVID-19 positive patients. The mean age was 29.6 years with most mothers having secondary education and were married. In Egypt, Bahaa-Eldin found a mean age of 29.3 years while in Kuwait, Yadav et al found a mean age of 25.4 years (34)(35). Most mothers with COVID-19 had a mild illness, similar to what was seen by Yadav et al in India. However, they were more likely to present with moderate or severe disease compared to COVID-19 negative patients, who were found to be more likely to present with mild disease. The commonest symptoms were cough, difficulty in breathing, fever and chest pain, all of which were more likely to manifest among COVID-19 positive women compared to COVID-19 negative women. COVID-19 negative women were more likely to

develop constitutional symptoms such as dizziness, nausea, and vomiting compared to COVID-19 positive women.

This is comparable to the findings of Aayed et al. in Kuwait where cough, chest pain, and fever were common symptoms for COVID-19 infection in pregnant women(36). It was also comparable to the findings of Mullins et al. in the United Kingdom where cough and fever were the commonest symptoms for COVID-19 infection in gravid women(37).

In our study, most women with COVID-19 disease were in the third trimester at 76%, with 22% in the second trimester. We had no admissions in the first trimester. Mullins et al in the united kingdom found 37.1% and 61.8% in the second and third trimester respectively(37). Aayed et al found 34.6% and 51.3% in the second and third trimesters(36). There have been various explanations for the frequency of third trimester admissions, including the growing fetus with attendant increase in the number of complications, and worsening of the respiratory effort due to stenting of the diaphragm.

The data showed that COVID-19 in pregnancy was associated with adverse neonatal outcomes, mainly preterm live birth. When the incidence of preterm birth was compared between COVID-19 positive and COVID-19 negative women, COVID-19 positive women demonstrated a 3.79-fold (95% CI=1.01-11.7) increase in the odds of preterm live birth before adjusting for demographic factors compared to COVID-19 negative women. The finding was comparable to the findings of Yadav et al. in India in 2020 and Chin et al. in the USA in 2021 of a statistically significant association between COVID-19 positivity and having a higher risk of preterm births. The use of antenatal corticosteroids has been recommended for fetal lung maturation in patients at risk of having a preterm delivery by various professional societies(39, 40) . However, Apgar score at 5 was more likely to be good for COVID-19 positive women compared to COVID-19 negative women because they were more likely to deliver via a caesarian section.

The secondary objective was to evaluate the maternal and neonatal outcomes of women with COVID-19 compared to women who did not have COVID-19. From the data, the incidence of adverse maternal outcomes such as APH, PPH, puerperal sepsis, and pulmonary edema was comparable between the two arms. COVID-positive women also bore a comparable risk of PROM, HELLP, and transfer to intensive care units (ICU), but were more likely to deliver via a caesarian

section, though this was not significant. Yadav et al. in 2020 found a comparable risk of ICU admission between COVID positive and COVID negative Indian women, but a higher risk of caesarian section deliveries with COVID-19(35). A systematic review carried out in China by Juan et al that included 324 COVID positive pregnant women reported a 78% caesarean delivery rate(25)However, the data contradicted findings of Al-Matary et al. in Saudi Arabia in 2020 and Martinez-Perez et al. in Spain in 2020 of a lower odds of caesarian deliveries among COVID positive women(39)(40). Chinn et al in the USA in 2021 reported significantly higher ICU admission rates among COVID-19 positive women than COVID-19 negative women (41)

Study limitations included the lack of universal testing, which could have led to a selection bias with under-reporting of the asymptomatic COVID positive mothers and their outcomes. Some of the women were discharged before delivery and were not followed up at KNH hence their perinatal outcomes were not captured.

CONCLUSION

The prevalence of COVID-19 among pregnant and postpartum women investigated for COVID-19 was 16.1%. Most mothers presented with mild symptoms of Covid-19 infection. The commonest symptom at presentation was cough. The risk of preterm birth and maternal death was higher in the COVID positive arm. There were no other significant differences in the demographic characteristics, maternal and perinatal outcomes. Our findings were comparable with other studies done in other countries with regards to demographic characteristics, preterm birth and caesarean section deliveries among the COVID positive mothers.

RECOMMENDATIONS

There is need for regular antenatal and medical follow up in pregnancy, particularly in COVID-19 to ensure favorable outcomes in preterm deliveries.

There is need for sensitization on vaccination, and adherence to the COVID-19 measures including keeping the recommended social distance, masking and hand-washing. All these measures are strongly advanced by the Kenya Obstetrical and Gynecological Society (KOGS)

A study with universal testing should be undertaken to capture the asymptomatic COVID positive mothers and their outcomes.

A prospective study to follow up mothers up-to delivery would also give more information on the outcomes.

STUDY TIMELINES

Ethical approval	September 2021
Data collection	September 2021
Data analysis	October 2021 to March 2022
Results presentation to faculty	May 2022

STUDY BUDGET

<u>Activity</u>		<u>Cost</u>
Proposal development	Printing/photocopy costs	10,000
Data collection	Research assistant @ 1000/day for 30 days	30000
Data analysis	Statistician	30000
Thesis development	Printing/photocopy costs	10,000
	Contingency fund (10% of budget)	8000
TOTAL		88,000

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APPENDICES

Appendix 1. Questionnaire

MATERNAL CHARACTERISTICS AND PERINATAL OUTCOMES AMONG PREGNANT WOMEN UNDER INVESTIGATION FOR COVID-19 INFECTION AT THE KENYATTA NATIONAL HOSPITAL

(Fill all sections)

Study number.....

Date.....

COVID-19 status

Suspected

Diagnosed

COVID-19 classification

Asymptomatic

Mild

Moderate

Severe

Demographic characteristics

1. Age in years

2. Education level

- No formal education
- Primary
- Secondary
- Tertiary

3. Marital status

- Married
- Single
- Divorced/widowed

Reproductive characteristics

4. Parity.....

5. Gestation in weeks/Trimester.....

6. ANC attendance

- Yes
- No

If yes, number of contacts

7. Length of hospital stay.....

Medical characteristics

8. Comorbidity present

Yes

No

If yes, type:

a) HIV

Yes

No

b) Diabetes

Yes

No

c) Chronic Kidney Disease

Yes

No

d) Hypertension

Yes

No

e) Other (specify).....

Birth outcomes

9. Mode of delivery

Spontaneous Vaginal Delivery (SVD)

Caesarian section

10. Maternal transfer to ICU

Yes

No

11. Birth outcome

Live birth

Stillbirth

Preterm birth

12. Birth weight in grams

13. Apgar at 1 minute

Apgar at 5 minutes

Apgar at 10 minutes.....

14. Maternal complication present

Yes

No

If yes, which complication

a) PPH

Yes

No

b) APH

Yes

No

c) Placenta Abruption

Yes

No

d) Other (specify).....

Perinatal outcomes

15. Adverse outcome present

Yes

No

If yes, which one:

a) Congenital anomalies

Yes

No

b) Asphyxia

Yes

No

c) NBU admission

Yes

No

d) NICU admission

Yes

No

e) Other (specify).....

16. Oxygen saturation at time of examination

17. Progression and eventual outcome

.....
.....
.....

Appendix II



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
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Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/uonknh.erc>
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/300

1st September , 2021

Dr. Okech Moses Osom
Reg. No.H58/88235/2016
Dept. of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi



Dear Dr. Osom

RESEARCH PROPOSAL: MATERNAL CHARACTERISTICS, PERINATAL AND NEONATAL OUTCOMES AMONG PREGNANCIES SUSPECTED OF AND THOSE DIAGNOSED WITH COVID-19 DISEASE AT THE KENYATTA NATIONAL HOSPITAL(P527/06/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 1st September 2021 – 31st August 2022.

This approval is subject to compliance with the following requirements:

- i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- iii. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- v. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- vii. Submission of an executive summary report within 90 days upon completion of the study.

Protect to discover

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Yours sincerely,



PROF. M.L. CHINDIA
SECRETARY, KNH- UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obstetrics and Gynaecology, UoN
Supervisors: Prof. Omondi Ogutu, Dept. of Obstetrics & Gynaecology, UoN
Prof. Obimbo Madadi, Dept. of Human Anatomy & Medical Physiology, UoN

Protect to discover



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Research & Programs: Ext. 44705
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Study Registration Certificate

1. Name of the Principal Investigator/Researcher
..... DR MUSA CABE
.....
2. Email address: Tel No.
3. Contact person (if different from PI).....
4. Email address: Tel No.
5. Study Title
..... MATERNAL CHARACTERISTICS
..... OUTCOMES AMONG PREGNANT
..... DIAGNOSED WITH
.....
6. Department where the study will be conducted
(Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.

Name: MUSA Signature [Signature] Date 9/9/2021
8. KNH UoN Ethics Research Committee approved study number 1022/1/2021
(Please attach copy of ERC approval)
9. I DR MUSA CABE commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.

Signature [Signature] Date 9/9/2021
10. Study Registration number (Dept/Number/Year) 1022/1/2021
(To be completed by Medical Research Department)
11. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.