**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**SCHOOL OF ALLIED HEALTH SCIENCES**

****

**PREVALENCE OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFIECIENCY AMONG PREGNANT WOMEN IN HO MUNICIPALITY**

**A PROJECT RESEARCH PROPOSAL**

**BY**

**MACHIESTAY-DZREGAH ELORM BRIAN UHAS20184287**

**DEPARTMENT OF MEDICAL LABORATORY SCIENCES**

**APRIL, 2022**

P. M. B. 31,

Ho, Volta Region,

Ghana.

April, 2022

The Chairman,

Research Ethics Committee (REC),

Research Operations Office, Institute of Health Research

University of Health and Allied Sciences

Dear Sir/Madam,

**LETTER OF INTRODUCTION:**

**MACHIESTAY-DZREGAH ELORM BRIAN (UHAS20184287)**

This is to introduce Mr. Machiestay-Dzregah Elorm Brian, a Medical Laboratory Science student from the Department of Medical Laboratory Sciences in the School of Allied Health Sciences, University of Health and Allied Health Sciences.

As part of his undergraduate study requirement, he shall be conducting a prospective cross-sectional study on the topic **“****Prevalence of Glucose-6-Phosphate Dehydrogenase Deficiency among Pregnant Women in Ho Municipality”**

The study topic is approved by the supervisor, and the attached protocol has been admitted at the departmental review for onward submission to UHAS-REC for ethical review and approval.

We will therefore be most grateful if we are given the necessary assistance to enable us to conduct the proposed research.

Thank you.

Yours faithfully,

**HEAD OF DEPARTMENT SUPERVISOR**

Dr. Huseini Wiisibie Alidu Mr. Anold Togiwe Luuse

Signature…………………… Signature……………………

Date………………………… Date…………………………

P. M. B. 31

Ho, Volta Region Ghana.

April 26, 2022.

The Chairman

Research Ethics committee (REC)

Research Operations Office, Institute of Health Research

University of Health and Allied Sciences

Dear Sir/Madam,

**SUBMISSION OF PROJECT PROTOCOL FOR ETHICAL CLEARANCE:**

**MACHIESTAY-DZREGAH ELORM BRIAN(UHAS20184287)**

I am Appiah Machiestay-Dzregah Elorm Brian, final year Medical Laboratory Science student from the Department of Medical Laboratory Sciences in the School of Allied Health Sciences, University of Health and Allied Sciences.

As part of my undergraduate study requirement, I will be conducting a prospective cross-sectional study on the topic **“Prevalence of Glucose-6-Phosphate Dehydrogenase Deficiency among Pregnant Women in Ho Municipality”**

I will therefore be most grateful if the attached study protocol is ethically approved to enable me conduct this research.

Thank you.

Yours faithfully,

………………………

Machiestay-Dzregah Elorm Brian.

**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**NEW PROTOCOL SUBMISSION FORM**

**Requirements:**

1. A new protocol must be submitted to the REC **at least three months before** the proposed commencement date of the research to ensure you have clearance before the proposed start date.
2. All sections of this form must be completed and guidelines for submission strictly followed before the protocol can be considered for review.
3. **16 bound copies** of the application dossier (cover letter, completed protocol submission checklist, completed New Protocol Submission Form, the study protocol, and other documentation) should be submitted at the Institute of Health Research by the submission deadline for the month. Printing should be one-sided.
4. A soft copy of your application dossier (cover letter, completed protocol submission checklist, completed New Protocol Submission Form, the study protocol, and other documentation) **as one pdf file** should be emailed to [*rec@uhas.edu.gh*](mailto:rec@uhas.edu.gh)by the submission deadline for the month.





|  |  |  |
| --- | --- | --- |
| **1.1** **Title of Study:** | **PREVALENCE OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY AMONG PREGNANT WOMEN IN HO MUNICIPALITY** | |
| **1.2 Principal Investigator (PI)** | | |
| Full Name  *(Surname First, Title, Qualifications)* | **Machiestay-Dzregah Elorm Brian** | |
| Postal Address: | PMB 31, Ho, Volta Region, Ghana | |
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| **1.3 Co-Investigator(s)** | |  |
| **First Co-Investigator** | |  |
| **Name of 1st Co-Investigator:**  *(Surname First, Title, Qualifications)* | **Arnold Togiwe Luuse, Mr** | |
| Postal Address: | PMB 31, Ho, Volta Region, Ghana | |
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| **1.4 Proposed Study/Research Information** | | |
|  | | |
| Type of Proposal | **☒** Student Research ☐ Grant Application  ☐ Faculty Research | |
| Student Status *(for student applicants only)* | ☒ Undergraduate ☐ Masters ☐ PhD | |
| Type of Research/Study: | ☐ Clinical Trial ☒ Biomedical/Epidemiological Study  ☐ Social Science Research ☐ Others (specify) | |
| Location of Research/Study:  *(Region, District, Towns)* | *Region: Volta Region*  *District(s): Ho Municipal*  *Towns: Ho* | |
| Duration of Research/Study: | Study Start Date: May 22, 2022  End Date: August 22, 2022 | |
| Source(s) of Funding:  *(Name, Postal Address, and Email)* | Department of Medical Laboratory Sciences of University of Health and Allied Sciences | |



*As the Principal Investigator / Co-investigator / Researcher/ Student Investigator on this project, your signature on the proposal confirms that:*

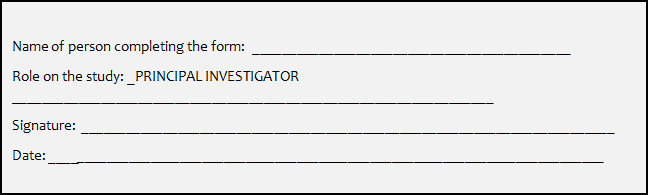
*You will ensure that all procedures performed under the study will be conducted in accordance with all relevant policies and regulations that govern research involving human participants.*

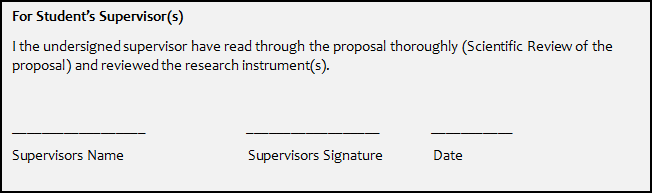
*You understand that if there is any change from the project as originally approved you must submit an amendment to the REC for review and approval prior to its implementation. Where you fail to do so, the amended aspect of the study is invalid.*

*You understand that you will report all serious adverse events associated with the study within seven days verbally and fourteen days in writing.*

*You understand that you will submit progress reports each year for review and renewal. Where you fail to do so, the REC is mandated to terminate the study upon expiry.*

*You agree that you will submit a final report to the REC at the end of the study.*

PP



**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**SCHOOL OF ALLIED HEALTH SCIENCES**

**DEPARTMENT OF MEDICAL LABORATORY SCIENCE**



**PREVALENCE OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY AMONG PREGNANT WOMEN IN HO MUNICIPALITY**

**BY**

**MACHIESTAY-DZREGAH ELORM BRIAN**

**A PROJECT PROPOSAL SUBMITTED TO THE SCHOOL OF ALLIED HEALTH SCIENCES OF THE UNIVERSITY OF HEALTH AND ALLIED SCIENCES, HO, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF THE BACHELOR OF MEDICAL LABORATORY SCIENCES DEGREE.**

**JANUARY, 2022**

# 

# DECLARATION

I hereby declare that this research proposal is the result of my original work and that no part has been presented for another degree in this university or elsewhere.

**NAME SIGNATURE DATE**

Machiestay-Dzregah Elorm Brian ……………………. ……………………..

(UHAS20184287)

Mr. Arnold Togiwe Luuse …………………… .…………………

(Supervisor)

# ABSTRACT

**Background:** Glucose 6-phosphate dehydrogenase (G6PD) is a cytoplasmic enzyme that help prevent oxidative damage of cells by stimulating free radical detoxification. It catalyzes the production of nicotinamide adenine dinucleotide phosphate (NADPH), which is necessary for maintenance of reduced glutathione (GSH) levels. By this mechanism, oxidative damage to red cells and hemolysis is prevented. G6PD deficiency is the commonest inherited red cell enzymopathy worldwide. Around 400 million people are affected globally with the highest prevalence in the tropics and subtropics. The condition is sex linked because the gene coding for the enzyme is on the X-chromosome and so manifests in heterozygous males and homozygous females. The G6PD test results of study participants would be taken from the Ho Teaching Hospital and analyzed. This study is expected to provide information for the prevalence of G6PD enzymatic defect among pregnant women in Ho Municipality.

**Aim:** To estimate the prevalence of Glucose-6-Phosphate Dehydrogenase Deficiency among pregnant women in Ho municipality

**Methods:** This study will be a retrospective cross-sectional study which seeks to estimate the prevalence of G6PD among pregnant women in the Ho Municipality. Available hospital records with regards to the G6PD results of the study participants will be taken from the Ho Teaching Hospital. Subsequently, the resultant data gathered will be analyzed using the software, Prism 8 (GraphPad, San Diego, USA). Statistically significant differences would be assigned to p-values < 0.05.

**Expected Outcome:** The research seeks to estimate the prevalence of G6PD deficiency among pregnant women in Ho Municipality. The implications or outcome of this research shall be duly stated; detailed statistics or information on the prevalence of G6PD among pregnant women should be established.

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# CHAPTER ONE

# INTRODUCTION

## 1.1 Background

Glucose-6-phosphate dehydrogenase (G6PD) is an enzyme found in the cytoplasm and is involved in the prevention of oxidative damage of the cells by stimulation of free radicals’ detoxification. It is the enzyme that catalyzes the production of nicotinamide adenine dinucleotide phosphate (NADPH), which is important for maintaining reduced levels of glutathione (GSH). This process is necessary to protect erythrocytes from oxidative damage and to reduce the susceptibility of erythrocytes to hemolysis (Monteiro et al., 2014). Over 400million people worldwide are affected by G6PD. G6PD deficiency contributes to hyperbilirubinemia and jaundice in newborns, which put infants at risk for acute bilirubin encephalopathy in the first few days of life and this may lead to kernicterus spectrum disorder or even death (Lauden et al., 2019). Kernicterus spectrum disorder is characterized by hearing deficits, behavior problems, and neurologic damage.

Some of the manifestations of G6PD deficiency in pregnancy may be increased urinary tract infections, neonatal jaundice, preeclampsia, hydrops fetalis and still birth. (Chintapatla et al., 2012) reported that in 25% early pregnancy women and in up to 65% of women in late pregnancy, low erythrocyte G6PD levels were found.

G6PD deficiency may also cause morbidity in pregnant women receiving antimalarials like dapsone or primaquine, by causing hemoglobinuria and hemolysis. Clearly, these factors mentioned above adds to the public health burden in this condition.

For the above-mentioned reasons, it is necessary to assess the prevalence of Glucose-6-Phosphate Dehydrogenase Deficiency in pregnant women and this study is done to provide information for the prevalence of G6PD enzymatic defect among pregnant women attending the Ho Teaching Hospital.

## 1.2 Problem statement

Glucose-6-Phosphate Dehydrogenase Deficiency affects over 400 million people worldwide and the World Health Organization (WHO) recommends population screening in regions where the prevalence is equal to or higher that 3-5% in males. It is also estimated that the prevalence of G6PD deficiency in Africa ranges from 15 to 25%. The WHO also estimates the prevalence of G6PD in Ghana to be 15-26%.

In patients who are G6PD deficient, the ability of the red cells to protect itself from oxidative stress is reduced. This is due to the fact that individuals who are G6PD deficient produce lower than normal amount of NADPH, which in turn affects the capacity of the red cells to generate reduced or fully functional glutathione (GSH) which protects the cells from lysis. Due to the high prevalence of malaria in the sub-Saharan region especially Ghana, the world health organization(WHO) has recommended sulfurdoxine-pyrimethamine (SP) to be used as a prophylaxis for pregnant women (Mikomangwa et al., 2020). Like any other malaria drug, SP has been known to cause oxidative stress which can result in hemolytic anaemia dangerous to pregnant women who are deficient in G6PD.  Unfortunately, G6PD deficiency is not usually tested in most pregnant women before the drugs are administered as the prevalence of G6PD deficiency in the district is unknown.

## 1.3 Justification

When one is exposed to an oxidant drug, the need for NADPH and glutathione (GSH) increases(Winkler et al., 1986). A deficiency of G6PD enzyme compromises the body’s ability to meet this need and the results is the oxidation of hemoglobin to methemoglobin. Heinz Bodies are formed from the precipitation of the methemoglobin and the Heinz bodies attach to the red cell membrane causing damage by hemolyzing the red cell (Christopher et al., 1990).

Pregnant women especially primigravidae are the major risk group for malaria in endemic countries. The World Health Organization (WHO) recommends the use of the drug Sulphadoxine-Pyrimethamine (SP) for Intermittent Preventive Treatment in pregnancy to prevent malaria (IPTp) (Deloron et al., 2010). SP has been reported to cause acute hemolysis in patients with G6PD deficiency and this results in significant reduction of hemoglobin (Hb)(Chan et al., 1976). For the above-mentioned, it necessary to estimate the prevalence of G6PD deficiency in Pregnant women in the Ho municipality to add to scientific knowledge and also to put the necessity of testing pregnant women for G6PD deficiency before administering the WHO recommended drug in context.

## 1.4 Aim

To estimate the prevalence of Glucose-6-Phosphate Dehydrogenase Deficiency among pregnant women in Ho municipality.

## **1.5 Specific Objectives**:

To determine:

* Frequency of G6PD deficiency among pregnant women visiting the Ho Teaching Hospital
* To determine the G6PD enzyme activity among pregnant women visiting the Ho Teaching Hospital

# 

# CHAPTER TWO

# LITERATURE REVIEW

## 2.2 General overview:

Among the most common human genetic enzyme defects, G6PD deficiency (G6PDd) affects more than 400 million people. This X-linked genetic condition is characterized by reduced G6PD enzyme activity, which may remain asymptomatic. Red blood cells obtain reduced glutathione (GSH) only from the G6PD/reduced nicotinamide adenine dinucleotide phosphate (NADH) pathway (Williams et al., 2013). A defect of the G6PD enzyme has several physiologic effects. It results in decrease level of reduced glutathione (GSH) which makes the red blood cells (RBCs) vulnerable to oxidative damage and eventually hemolysis or anemia (Engwa et al., 2017). It has also been reported that a third of children with G6PD deficiency develop neonatal jaundice. Severe neonatal jaundice if not treated could lead to kernicterus, a well-known cause of death (Mohanty et al., 2004). G6PD deficiency makes red cells more susceptible to oxidative hemolysis that could be triggered by certain drugs, such as primaquine (PQ) and other 8-amino quinolone drugs (Amoah et al., 2016).

## 2.3 G6PD deficiency and its effects

The effects of G6PD deficiency are numerous and they include neonatal hyperbilirubinemia, acute hemolysis, chronic hemolysis among others(Frank, 2005).

Neonatal hyperbilirubinemia is prevalent twice as that of the general population in males who carry the defective gene and in homozygous females but occurs almost rarely in females who are heterozygous(Mason, 1996).

The mechanism by which G6PD deficiency causes neonatal hyperbilirubinemia is not completely understood(Reclos et al., 2000). Other mechanisms including G6PD deficiency appear to play a more significant role hyperbilirubinemia development even though hemolysis may be observed in neonates who are G6PD deficient and jaundiced(Kaplan et al., 2001). Infants who are G6PD deficient and have a mutation of uridine diphosphoglucuronate glucuronosyltransferase-1 gene promoter (UDPGT-1) are susceptible to hyperbilirubinemia secondary to decreased liver clearance of bilirubin. In Gilbert disease, UDPGT-1 is the enzyme affected. G6PD deficiency can result in an increase to the risk and earlier onset of hyperbilirubinemia, which may require exchange transfusion or phototherapy(“Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation,” 2004).

Infection, fava beans, or exposure to an oxidative drug cause acute hemolysis. Haemolysis occurs after one is exposed to the stressor but does not continue even though the infection persists or the ingestion is not stopped(Corchia et al., 1995). This is thought to be the fact that older erythrocytes having the greatest enzyme deficiency undergo hemolysis first. Afterwards, younger erythrocytes and reticulocytes with higher levels of enzyme activity are able to sustain the oxidative damage without hemolyzing. The result of acute hemolysis may be back or abdominal pain and jaundice secondary to an increase in unconjugated bilirubin(Chiu, 2007). Although people who experience hemolysis after fava beans ingestion can be presumed to have G6PD deficiency, hemolysis is not apparent in all of them. G6PD class II variants commonly experience favism. Fava beans are thought to cause oxidative damage by an unknown component, which could be vicine, convicine, or isouramil(Peters & Van Noorden, 2009).

Infection commonly causes acute hemolysis in persons with G6PD deficiency, although the exact mechanism implicated is unknown. Oxidants may be released during phagocytosis and cause oxidative stress to the erythrocytes. The most common infectious agents that cause hemolysis include Salmonella, *Escherichia coli,* beta-hemolytic streptococci, rickettsia infections, viral hepatitis, and influenza A.

## 2.3 Effect of G6PD deficiency in pregnancy

Some manifestations of G6PD deficiency in pregnancy may be increased urinary tract infections, preeclampsia, neonatal jaundice, hydrops fetalis and still birth(Perkins, 1971). (Chintapatla et al., 2012) reported that low erythrocyte G6PD levels were found in 25% of women in early pregnancy and in up to 65% of women in late pregnancy. Other serious complications such as infertility, fetus malformations and even its death have also been reported as effects of G6PD deficiency in pregnancy(Kuliszkiewicz-Janus & Zimny, 2003). The mechanisms by which most of these complications result from G6PD deficiency in pregnancy specifically is not clearly elucidated.

# CHAPTER THREE

# METHODOLOGY

## 3.1 Study design:

This study would be a retrospective cross-sectional study which will estimate the prevalence of G6PD deficiency among pregnant women attending the Ho teaching Hospital

## 3.2 Study site and location

### 3.2.1 Location and Area

The study shall be conducted in the antenatal clinic of the Ho Teaching Hospital. The Ho Teaching Hospital is situated in the Ho Municipality in the Volta region of Ghana. The municipality is located between latitudes 6o 20” N and 6o 55” N and longitudes 0o 12’E and 0o 53'E sharing boundaries with Adaklu and Agotime-Ziope Districts to the South, Ho West District to the North and West, and the Republic of Togo to the East. Its total land area is 2,361km2 thus representing 11.5 % of the region’s total land area.

## 3.3 Subjects/study population

All pregnant women aged 15 to 45 years who attend antenatal clinic at Ho Teaching Hospital would be considered and be recruited into the study.

## 3.4 Inclusion and Exclusion Criteria

### 3.4.1 Inclusion

**3.4.1.1**Pregnant women 15-45 years who visit the antenatal clinic of the Ho Teaching Hospital would be considered and be recruited into the study.

### 3.4.2 Exclusion

**3.4.2.1** non-pregnant women will be excluded.

**3.4.2.2** pregnant women with severe anaemia will also be excluded.

## 3.5 Data collection/ Procedure

Participants medical record will be assessed to obtain data from laboratory tests performed over time in the Ho Teaching Hospital; this will include their G6PD results. Information from medical records will be entered into datasheet for analysis.

## 3.6 Data handling: coding

All necessary data will be assigned a special code. A code will be assigned using this format:

First, the abbreviation **“PW’’** will be assigned to each participant’s data and this will be  
followed by a **forward slash (/)** then a three-digit number (**e.g., 001**) representing the order of admittance into the study. The abbreviation **PW** stands for **PREGNANT WOMAN. Eg. Of code: PW/002**

* 1. Statistical Analysis

All data will be presented using bar graphs and tables. Analysis of data will be performed using the Prism 8 (GraphPad, San Diego, USA) software. Statistically significant differences would be assigned to p-values < 0.05.

3.8 Dissemination of resultsAt the end of the study, the outcome of the research would be disseminated in the form of  
presentation at the departmental level- Department of Medical Laboratory Sciences- and then submission of a monograph to the same department within the School of Allied Health Sciences (SAHS) of the University of Health and Allied Sciences (UHAS). In addition, results may be disseminated through seminars and workshops. A manuscript of the outcome of the research will be drafted and submitted for peer-review for publication

## 3.9 Ethical considerations

Theresearch study protocol would be submitted for ethical clearance from the Research Ethics Committee (REC) of the University of Health and Allied Sciences.

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# TIMELINES/SCHEDULE OF ACTIVITIES

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ACTIVITY | JULY  DEC, 2021 | APRIL, 2022 | MAY-  JUNE, 2022 | JUNE/  JULY 2022 | JULY  2022 | AUG,  2022 |
| Writing of Research proposal |  |  |  |  |  |  |
| Submission of research proposal for ethical clearance |  |  |  |  |  |  |
| Data collection and entry |  |  |  |  |  |  |
| Data analysis |  |  |  |  |  |  |
| Thesis writing |  |  |  |  |  |  |
| Submission of thesis to Department |  |  |  |  |  |  |

# PROPOSED BUDGET

|  |  |  |  |
| --- | --- | --- | --- |
| ITEM | COST PER ITEM (GHC) | QUANTITY | TOTAL COST (GHC) |
| Printing of research proposal | 13.00 | 3 | 39.00 |
| Transportation |  |  | 50.00 |
| Thesis printing | 20.00 | 3 | 60.00 |
| Prism 8 software | 400.00 |  | 400.00 |
| Miscellaneous cost |  |  | 300.00 |
| TOTAL COST |  |  | **GHC.849 .00** |

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**RESEARCH OPERATIONS OFFICE**

**INSTITUTE OF HEALTH RESEARCH**

**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (REC)**

**PROTOCOL CONSENT FORM**

Section A- **BACKGROUND INFORMATION**

|  |  |
| --- | --- |
| Title of Study: | **PREVALENCE OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY AMONG PREGNANT WOMEN IN HO MUNICIPALI** |
| Principal Investigator: | **MACHIESTAY-DZREGAH ELORM BRIAN** |
| Certified Protocol |  |

**What happens after the study?**

At the end of the study or research, final findings will be presented to the Department of

Medical Laboratory Sciences of the School of Allied Health Sciences, UHAS, Ho in the form of a presentation and also a monograph in partial fulfillment of departmental requirements for the award of bachelors’ degree. In addition, findings of this research may be presented at workshops or seminars or even a copy will be sent to academic journals in the form of a manuscript for the purpose of publishing.

**Contact for Additional Information**

For the purpose of further clarification with regard to the research, you can contact Machiestay-Dzregah Elorm Brian, Madina – Accra, brianmachiestay@gmail.com.

You can also contact the supervisor, Mr. Arnold Togiwe Luuse, P.O Box 31, University of Health and Allied Sciences, 0544545395, taluuse@uhas.edu.gh

If you have any questions about your rights as a research participant in this study you may

contact the Administrator of the Research Ethics Committee, IHR, University of Health and

Allied Sciences at rec@uhas.edu.gh or +233- 362-196-193.