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ESTIMATING THE COST OF DIAGNOSING AND MONITORING PREECLAMPSIA USING THE PROTEIN-TO-CREATININE (PRCR) URINARY DIPSTICK TEST AND STANDARD OF CARE PROTEIN-ONLY URINARY DIPSTICK TEST

BY

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THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF A MASTER OF SCIENCE PUBLIC HEALTH MONITORING AND EVALUATION DEGREE

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DECLARATION

I hereby declare that, except for specific references that have been properly acknowledged, this submission is my work and that, to the best of my knowledge, it contains no material that has been previously published by another person or that has been accepted for the award of any other degree from the University or elsewhere.

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DATE

DEDICATION

Dedicated to my Mother, Father, Josiah, Keziah, and my entire family members.

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ABSTRACT

BACKGROUND: Gestational hypertension (also known as pre-eclampsia) remains the leading cause of maternal and perinatal morbidity and mortality in many low and middle-income countries (LMICs), killing 76,000 women and 500,000 babies annually. Furthermore, women in lowresource countries are at a higher risk of developing hypertensive disorders of pregnancy and preeclampsia compared with those in high-resource countries. Pre-eclampsia is characterized by high blood pressure and elevated levels of protein in the urine. It is usually diagnosed if blood pressure is above 140/90mmHg and a higher amount of protein in one's urine (proteinuria) significantly more than 30 mg/dL after 20 weeks of conception. In recent years, the testing for urinary protein excretion has become essential to the care of pregnant women, predominantly for those who are at higher risk of developing pre-eclampsia.

OBJECTIVE: This study estimated the cost associated with the diagnosis and monitoring of preeclampsia among pregnant women using a Protein-to-creatinine (PrCr) urinary dipstick test and standard of care Protein-only urinary dipstick test in three selected hospitals in Ghana.

METHODS: The study used a cross-sectional design with a micro-costing approach to estimate the financial cost which entails direct cost and economic cost which entails direct and indirect cost of the Protein-to-Creatinine (PrCr) urinary dipstick test and standard of care Protein-only urinary dipstick test for diagnosing and monitoring pre-eclampsia. Using a random sampling technique, 60 healthcare professionals were sampled from Korle-Bu Teaching Hospital, Greater Accra Regional Hospital, and Koforidua Regional Hospital. All analyses were done from the healthcare provider perspective. Microsoft Excel was used to analyzed data using simple statistical techniques such as summation, mean and frequencies and percentages.

RESULTS: The financial cost of running the PrCr test for the three facilities by the healthcare professionals during data collection is GHS170.75 ($27.74) with an average cost of GHS2.85 ($0.46) per test and the cost of running the Protein-only test is GHS167.05 ($27.14) with an average cost of GHS2.78 ($0.45) per test. The total economic cost of the PrCr test for the three facilities by the healthcare professionals during data collection is GHS304.77 ($49.52) with an average cost of GHS5.16 ($0.84) per test respectively. Also, the total economic cost of running the Protein-only test is GHS341.38 ($55.46) with an average cost of GHS5.75 ($0.93) per test.

CONCLUSION: The study concludes that there is not much difference in the cost of running a PrCr and a Protein-only test despite the fact that the economic cost of running a protein-only test is higher than that of PrCr test and the financial cost of running a PrCr test is higher than that of a Protein-only test.

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LIST OF ABBREVIATIONS

BMI	-	Body Mass Index
HELLP	-	Hemolysis, Elevated Liver Enzyme, Low Platelet Count
HICS	-	High-Income Countries
ICER	-	Incremental Cost-effective ratio
IUGR	-	Intrauterine Growth Restriction
LMICS	-	Low- and Middle-Income Countries
MIC	-	Middle Income Countries
PATH	-	Program for Appropriate Technology in Health
PIGF	-	Placental Growth Factor

PRCR	-	Protein to Creatinine Ratio
SFLT-1	-	Soluble Fms-Like Tyrosine Kinase-1
SDG	-	Sustainable Development Goals
UPCR	-	Urine Protein: Creatinine Ratio
VEGF	-	Vascular Endothelial Growth Factor
WHO	-	World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background of the Study

Pre-eclampsia (PE) is among the major contributing factors to maternal and infant mortality and death, affecting many pregnant women (Stefańska et al., 2020). According to Say et al. (2014), Pre-eclampsia affects 2–8% of pregnancies worldwide, with pre-eclampsia accounting for 9% of maternal mortality in Africa and Asia alone. Concerning the global viewpoint, most fatalities related to hypertensive diseases of pregnancy occur in underdeveloped nations (World Health Organization, 2018). The incidence of pre-eclampsia according to the World Health Organization (WHO) is seven times more common in low-middle-income countries (LMICs) than in most highincome countries (Tolcher et al., 2019). Pre-eclampsia is a complex multifactorial disease that develops after the 20th week of pregnancy(Machano & Joho, 2020).

(Ömeroğlu et al., 2021) find that pregnant women with a blood pressure of 300 mg/24-h and a P/C ratio of 0.3 had a considerably earlier gestational age at delivery and a significantly shorter latency period (the time between diagnosis of hypertension and delivery). Patients with proteinuria of 300 mg/24-hour and a P/C ratio of 0.3 had significantly worse neonatal outcomes. Protein levels in 24hour urine were considerably higher in pregnant women with a P/C ratio of less than 0.3, and there was a strong positive connection between 24-hour proteinuria and P/C (r = 0.382, p0.001). Consequently, hypertensive pregnant women, with a protein loss of 300 mg in 24-hour and a P/C ratio in spot urine of 0.3 are associated with poor perinatal outcomes. The consequences of preeclampsia underpinned by the hypertensive health status of the pregnant women with proteinuria of 300 mg/day and spot urine P/C ratio of 0.3 are ferret with early birth risk.

Also, angiogenic growth factor (PlGF) and soluble fms-like tyrosine kinase-1 (sFlt-1) have been discovered to have a crucial role in the development of pre-eclampsia, elevated sFlt-1, and reduced PlGF have been seen in women diagnosed with pre-eclampsia (Samara, Hazen & Tang, 2011). This suggests that they might be used as biomarkers to validate the diagnosis of pre-eclampsia. Elevated sFlt-1 has also been demonstrated to be able to distinguish between women with preeclampsia and those with gestational hypertension, signifying that it might be useful in the differential diagnosis. (Caillon et al., 2018). Also, Vatish et al. (2016) indicated the temporal sequence of changes in maternal vascular function and circulating levels of PlGF and sFlt-1 in women who later develop pre-eclampsia, as well as the link between these parameters in women who later develop pre-eclampsia. The new PE test consists of two new biomarkers, PlGF and sFlt1, which can be quantitatively assessed using an automated system widely accessible in hospitals and laboratories (Elecsys/Cobas, Roche Diagnostics) and evaluates the levels of PlGF and sFlt-1 growth factors in pregnant women (Hadker, Garg, Costanzo, Miller, Foster, Van Der Helm, et al., 2010).

Additionally, a multicenter case-control study (Verlohren, et al., 2010) find that the quantities of sFlt-1 and PIGF in maternal blood substantially distinguished healthy women from women with PE. For testing after 20 weeks of pregnancy, an estimated sensitivity of 82% and a specificity of 95% was found (Verlohren et al., 2010).

Furthermore, Vatish et al. (2016) investigated the economic cost assessment for pre-eclampsia by assessing the effect of adopting the soluble fms-like tyrosine kinase (sFlt-1) to placental growth factor (PlGF) ratio test for guiding pre-eclampsia care into clinical practice in the United Kingdom (UK). Evidence suggests that when compared to a no-test situation, the introduction of the sFlt1/PlGF ratio test into clinical practice is estimated to save £344 per patient (Vatish et al., 2016). Most of the cost savings come from improved diagnostic accuracy and a reduction in needless

hospitalization. The sFlt-1/PlGF ratio test was introduced into clinical practice in the UK, and it was found to save money by avoiding needless hospitalization of women at low risk of preeclampsia (Vatish et al., 2016). Furthermore, the test guarantees that high-risk women are identified and treated accordingly.

According to De Silva et al. (2014), there are many options for assessing proteinuria, which includes random (spot) urine samples, PrCr, albumin-albumin ratio, dipstick testing, screening at routine antenatal appointments, and random urinary PrCr testing, also used when there are more reasons to suspect pre-eclampsia. The 24-hour urine collection is regarded to be the yardstick for the determination of proteinuria in pregnancy. However, its cumbersome nature and frequent inaccuracies have resulted in the promotion of PrCr (Côté et al., 2008). This has a high possibility of influencing care and results, particularly in developing countries where most pre-eclampsia deaths occur and tools to improve diagnosis and care are needed. Morris et al.(2012) suggested that a spot urine test could be employed to determine the ratio of protein-to-creatinine (PrCr) and thus advance the accuracy of proteinuria detection compared to Protein-only measurement by just fine-tuning for dilution of urine samples of patients. According to Morris et al. (2012), findings from using a PrCr measurement have earlier revealed a close relationship with the existing reference standard for proteinuria determination, that is, the 24-hour urine collection test.

1.2 Statement of the Problem

Pre-eclampsia is a multisystem illness that affects 2%–5% of pregnant women and is one of the primary causes of maternal and perinatal morbidity and death, particularly when it occurs early in pregnancy (Stefańska et al., 2020). Over the past decade, studies have focused on the cost of

reproductive health components concerning reproductive healthcare, such as maternal and newborn health, family planning, the cost of hospital maternity services, the determination of appropriate prices for reproductive health services, and the effect of user fees on maternity services (Dalaba et al., 2015; Dalinjong et al., 2018; Gomez et al., 2015; Heil et al., 2021; Hewett et al., 2016)

Other research has examined antenatal care and the costs incurred by low- and high-risk pregnant women (Aikins et al., 2015). The WHO revealed that more than 280,000 women in LMICs countries continue to suffer economically and eventually die each year due to complications associated with childbearing (Lozano et al., 2011). However, there appears to be limited empirical evidence of the cost of treatment and diagnosis as several studies focused on developed nations (De Silva, et al., 2014;Fox et al., 2017; Morris et al., 2012; Poon et al., 2021). On this basis, this study explores the context of pre-eclampsia as a case using the Ghanaian context.

Again, the measurement of 24-hour urine proteins has long been regarded as the gold standard for proteinuria quantification in pre-eclampsia test diagnosis (Amin et al., 2014). The collection of a 24-hour urine sample, on the other hand, is difficult for the patient and prone to pre-analytical mistakes, resulting in erroneous findings or variances in the assay's applicability (Cheung, Leung & Choi, 2016). To confirm proteinuria, protein-to-creatinine (PrCr) urinary dipstick tests and standard of care Protein-only dipsticks are commonly utilize (Lowe et al., 2010; Teeuw et al., 2022).Although a suitable cutoff value for the urine dipstick test was recently established, the benefits and drawbacks of proteinuria testing are still being disputed (Gangaram, Naicker & 2009). Each analytical technique appears to have certain drawbacks, such as inaccuracy owing to daily protein secretion changes, mistakenly positive/negative findings, economic and financial cost savings, and ease of sample testing (Vatish et al., 2016; Côté et al., 2008). Drawing inference to the cost-saving drawbacks and the need to investigate empirically, the study is underpinned by the

need to compare the financial and economic costs of diagnosing pre-eclampsia using the Proteinto-Creatinine urinary dipstick test and standard of care Protein-only urinary dipstick test.

Additionally, in low-resource settings, there are not enough sophisticated laboratories for testing and diagnosing, and there is very scanty functioning equipment, which makes pre-eclampsia determination inaccessible and expensive (Salam et al., 2015)

1.3 General Objective

The study sought to estimate the cost of diagnosing and monitoring pre-eclampsia using the Protein-to-creatinine urinary dipstick test and standard of care Protein-only urinary dipstick test.

1.4 Specific Objectives

The specific objectives were to:

1. Estimate and compare the financial costs of diagnosing pre-eclampsia using a Protein-toCreatinine urinary dipstick test and standard of care Protein-only urinary dipstick test.

2. Estimate and compare the economic costs of diagnosing pre-eclampsia using Protein-tocreatinine (PrCr) urinary dipstick test and standard of care Protein-only urinary dipstick test

1.5 Research Questions

1. What are the differences between the financial costs of diagnosing pre-eclampsia using a Protein-to-Creatinine urinary dipstick (PrCr) test and the standard of care for a Protein-only urinary dipstick test?

2. What are the differences between the economic costs of diagnosing pre-eclampsia using a Protein-to-Creatinine (PrCr) urinary dipstick test and a standard of care Protein-only urinary dipstick test?

1.6 Significance of the Study

Given inadequate available data regarding costs associated with pregnancy-related conditions in Ghana, especially gestational hypertension, also known as pre-eclampsia, this study could fill in the knowledge gap regarding the cost of pre-eclampsia testing with Protein-to-Creatinine urinary dipstick test and Protein-only urinary dipstick test. This study will also give an informed viewpoint; thus, the cost analyses will help highlight the extent of the cost these pregnancy-related conditions have on the individual and society, thus informing the need for taking relevant actions regarding healthcare management—a contribution to empirical research or knowledge in a contextualized case of Ghana.

Several studies have emphasized the need for more responsiveness to be drawn to pregnancyrelated conditions as a major public health problem. Showing cost estimates of the new preeclampsia diagnostic test from the healthcare provider perspective can contribute to health facility responsiveness to addressing economic and financial cost barriers. This provides valuable information or implications for healthcare management and practice.

The study will either validate or disagree with the dipstick test utilization features of how costeffective or ineffective it is, as it is deployed as a primary screening tool due to its ease and low cost. The study will consolidate evidence for policy implications on its usage in Ghana. On the other hand, it will contribute to evidence in comparing whether the PrCr test is quicker and cheaper approach for detecting and quantifying proteinuria. As a result, the study contributes to policy decisions in Ghana regarding the cost of using either the Protein-only test or the PrCr test as beneficial for assessing proteinuria in pregnant women with hypertension.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Definition of Pre-Eclampsia

Pre-eclampsia is a condition that affects pregnant women. Pre-eclampsia is typically characterized as the onset of hypertension and the development of new proteinuria in a previously healthy woman (Gupte & Wagh, 2014). Pre-eclampsia is diagnosed using a variety of criteria that have been described in the literature and advocated by various professional groups. As a result, a variety of distinct recommendations for the diagnosis and therapy of pre-eclampsia have been developed by professional groups all around the world (Sammour, El-Kabarity, Fawzy & Schindler, 2011).

Pre-eclampsia can be categorized further based on maternal and neonatal morbidity and mortality:

- Pre-eclampsia as early symptoms (delivery at <34+0 weeks after conception).
- Preterm pre-eclampsia (with a gestational age of <37+0 weeks).

- Pre-eclampsia after late-onset (delivered at ≥34+0 weeks of pregnancy).
- Term pre-eclampsia (with a gestational age of ≥37+0 weeks).

A Bayes-based method-derived model that integrates maternal variables and a range of biological markers assessed at 11–13^{+6} weeks of gestation may successfully predict early-onset and preterm pre-eclampsia. Early-onset and premature pre-eclampsia rates can be lowered by 80% and 60%, respectively, when these high-risk women (with an estimated risk of 1:100) are treated with 150 mg aspirin each night from 11–14^{+6} weeks of pregnancy until 36^{+0} weeks of pregnancy (Rolnik et al., 2017) . This first-trimester "screen and prevent" strategy for pre-eclampsia has been endorsed by the International Federation of Gynecology and Obstetrics (FIGO), and its practical guidelines were released in 2019 (Poon et al., 2019).

Pre-eclampsia (PE) is a pregnancy-related multisystem illness marked by the start of hypertension and substantial proteinuria after 20 weeks of pregnancy(Caillon et al., 2018; Stefańska et al., 2020). Proteinuria is not required for pre-eclampsia assessment; however, it is found in roughly 75% of instances. PE is established when there is a de novo hypertensive scenario after the 20th week of pregnancy, along with proteinuria and/or signs of maternal acute kidney damage, liver dysfunction, neurological symptoms, hemolysis or thrombocytopenia, and/or fetal growth limitation (Leeman et al., 2016). In certain circumstances, pre-eclampsia can develop or be identified for the first-time during labor or shortly after delivery (Brown et al., 2018). PE is generally diagnosed and defined clinically by measuring non-specific signs and symptoms, primarily hypertension and proteinuria (American College of Obstetricians and Gynecologists 2013).

PE has a variety of clinical presentations and outcomes, ranging from early-onset severe and fastprogressing PE with pre-term birth to late-onset PE (Vogel et al., 2014). PE is still a leading cause of maternal, fetal, and neonatal morbidity and death. Intrauterine growth restriction (IUGR), eclampsia, and HELLP syndrome (hemolysis, increased liver enzymes, and low platelet count) are

all serious and life-threatening problems that can arise (Vogel et al., 2014). Because there are few effective therapeutic options other than delivery, clinical management might be difficult. PE's pathophysiology is complicated and not entirely understood.

While more evidence is becoming available and encouraging outcomes have been shown with sFlt-1 and PlGF, soluble endoglin and vascular endothelial growth factor (VEGF) have not been proved to be therapeutically beneficial in the treatment of PE. Despite its pathophysiological implications, there has been no evidence of an increase in soluble endoglin in the context of PE or HELLP syndrome. The use of VEGF as a strategy to manage PE looks to be in jeopardy as well. Because of the many assays available for total or free, physiologically active VEGF detection, there are analytical challenges in VEGF measurement (Vogel et al., 2014). The importance of detecting s-Flt-1, PlGF, and the s-Flt-1/PlGF ratio for the diagnosis and prognosis of the illness has been examined to assist clinicians in identifying individuals at high risk of PE who need to be closely monitored. The sFlt-1/PlGF ratio, interestingly, appears to perform better than single markers in predicting the risk of PE (Rana et al., 2012). Several procedures have been developed for first-trimester screening of women at high risk of PE to introduce if appropriate, low-dose acetylsalicylic acid and to predict or rule out the diagnosis of PE during the second trimester or later (Ghosh et al., 2012).

2.3 Burden of Pre-eclampsia Globally

2.3.1 Pre-eclampsia Pathophysiology

Pre-eclampsia is a well-known risk factor for both maternal and newborn problems in the long run. Even when symptoms have subsided, there is an increased risk of severe maternal cardiovascular, cerebrovascular, and vascular illness (Wu et al., 2017). Furthermore, despite the lack of research, some studies have shown that children who are prenatally exposed to pre-eclampsia have an

elevated risk of long-term cardiovascular, pulmonary, neuropsychiatric, gastrointestinal, and endocrinological morbidity (Beharier et al., 2016).

Pre-eclampsia is a complicated, diverse condition with a poorly known cause. The scope of these best practice recommendations does not include details on the many etiological possibilities (Dröge et al., 2021). The finding of a disrupted angiogenic and antiangiogenic balance in women who are predisposed to pre-eclampsia and its complications has provided crucial insight into the disease's etiology. Pre-eclampsia patients have high amounts of fms-like tyrosine kinase 1 (sFlt-1) in their blood and low levels of placental growth factor (PLGF). In pregnant rats, iatrogenic overexpression of sFlt-1 causes hypertension, proteinuria, and glomerular endothelial dysfunction, all of which are histological hallmarks of pre-eclampsia. The use of recombinant human PLGF (rhPLGF) to restore the angiogenic mix in a baboon model of pre-eclampsia (uterine ligation) alleviated pre-eclampsia signs including hypotension and proteinuria. In experimental models (primates and mice), the use of small interfering RNAs (siRNAs) reduces blood pressure and proteinuria by suppressing sFlt-1 expression. The extracorporeal removal of excessively elevated sFlt-1 in women with early-onset pre-eclampsia resulted in the disease being prolonged in humans (Thadhani et al., 2016). Several lines of data support the idea that a disrupted angiogenic mix is important to the disease's etiology as a result, sFlt-1 and PLGF have been developed as disease indicators for diagnosis, prognosis, and prediction.

2.4 Type of Test and Diagnosis of Pre-Eclampsia

Many techniques for proteinuria assessment are readily accessible in daily practice: (1) dipstick, (2) 24-hour urine protein test, and (3) urine protein-to-creatinine ratio or PrCr test. Urine test strips are used in the first method. A standard test strip comprises up to 10 chemical pads that serve for the analysis of different parameters (e.g., proteins, pH, erythrocytes, leukocytes, nitrites, glucose, ketones) (e.g., proteins, pH, erythrocytes, leukocytes, nitrites, glucose, ketones). The test can be

read within 60–120 s after dipping the strip in a urine sample. The chemical pads change colour after being immersed in the sample, and the results are interpreted by a comparison of the pad colour with the colours presented in the dipstick analysis guide. A 24-hour urine protein test requires a 24-hour collection of a urine sample. Then, from the entire volume of the 24-hour urine sample, one aliquot is extracted and examined. The PrCr test, like the dipstick test, is based on the examination of a random urine sample, but it delivers quantitative data, like the 24-hour urine protein test. By analyzing the protein-to-creatinine ratio, the PrCr test has been validated for use as an estimate of 24-hour urine protein levels from a single random urine sample (Stefańska et al., 2020). When possible, automated dipstick urinalysis is used to assess proteinuria in clinical practice; if this is not possible, a thorough visual dipstick urinalysis will suffice (Stefańska et al., 2020). The PrCr test should be determined if the test is positive ('1+', 30 mg/dL). A PrCr test concentration of 30 mg/mmol (0.3 mg/mg) is considered abnormal (Kamińska et al., 2020). A negative dipstick test is typically acceptable, and no more PrCr tests are necessary at that time. Proteinuria is not essential for pre-eclampsia diagnosis. Proteinuria of greater than 5 g/24-hour has been linked to worse newborn outcomes (Brown et al., 2013).

The measurement of 24-hour urine proteins has long been regarded as the gold standard for proteinuria quantification (Amin et al., 2014). The collection of a 24-hour urine sample, on the other hand, is difficult for the patient and prone to pre-analytical mistakes, resulting in erroneous findings or variances in the assay's applicability (Cheung et al., 2016). To confirm proteinuria, the urine dipstick test or the UPCR is commonly used (Lowe et al., 2015). A suitable cut-off value for the UPCR has recently been established (Kumari, Abha & Ritu, 2013). Nevertheless, the benefits and drawbacks of proteinuria testing are still being debated (Gangaram et al., 2009).

An easy-to-use PrCr radiometric urine dipstick test has been developed by Life Assay Diagnostics and its collaborators. The PrCr urine dipstick test comprises two detection pads that have been

specially developed to detect precise quantities of protein and creatinine in urine. The chemical composition of the pads interacts in such a manner that a color shift occurs, which matches a certain color block on the product label. The proteinuria result for a woman is then calculated using a simple colorimetrichart that correlates to the specific protein-creatinine ratios. Based on input from target users in Ghana during PATH's (Program for Appropriate Technology in Health) earlier usability assessment research, the colorimetric has already undergone some early improvement (Brown et al., 2018; Lowe et al., 2015).

The PrCr radiometric urine dipstick test is a low-cost, highly sensitive, and specific screening tool designed to help low- and middle-income nations make better prenatal care decisions for PE. The PrCr dipstick test's properties are like WHO standards and those of the present Protein-only dipstick test, making market acceptance simpler (PATH) The test will make more accurate proteinuria screening available in prenatal care settings, allowing more women at risk to be identified and appropriate treatments to be given to those who are critically in need of it (Stefańska et al., 2020; Cheung et al., 2016).

The strengths and weakness of the test types revealed that the dipstick test is cost-effective, simple to use, and widely used (Kavuru et al., 2020). However, it has the disadvantage of being ineffectual in terms of precision and accuracy (Hernández-Díaz et al., 2009). The PrCr test is the most reliable, much faster, and comparably accurate method for identifying and quantifying proteinuria, as well as saving money and time (Teeuw et al., 2022).

2.5 Burden of Pre-eclampsia in Ghana

Adu-Bonsaffoh and Seffah (2015) indicated that in Ghana, pre-eclampsia is still a serious public health problem because it is linked to high maternal death and morbidity. In Korle-Bu Teaching Hospital (KBTH), Accra, Ghana, researchers determined and correlated the proportion of

unwanted pregnancies among pre-eclamptic women with the burden of pre-eclampsia. According to the findings, there were 269 women with hypertensive disorders during pregnancy, with 177 (65.8%) having pre-eclampsia. Unintended pregnancy was shown to be prevalent among women with pre-eclampsia in 32.6% of cases. During the research period, 36 maternal fatalities occurred, 14 of which were caused by pre-eclampsia (38.9%). Adu-Bonsaffoh and Seffah (2015) findings averred that unplanned pregnancy accounts for a considerable amount of the pre-eclampsia burden in Ghana, resulting in high maternal morbidity and death.

Pre-eclampsia is one of the most prevalent causes of maternal and fetal death and morbidity in Ghana. A four-month case-control study at Korle-Bu Teaching Hospital among pre-eclampsia and healthy pregnant women, blood pressure of pre-eclamptic women differed significantly from that of healthy pregnant women, which is responsible for PE and its consequences on mortality and morbidity among Ghanaian women (Darkwa et al., 2018).

Finally, pre-eclampsia is a leading cause of maternal morbidity and death globally, yet little is known about how patients feel about their diagnosis (Joshi et al., 2020). There were 150 individuals in all, with 88.7% (133) having pre-eclampsia and 11.3% (17) having eclampsia. Participants were 32 years old on average, had two children, and had 5.4 prenatal visits on average. About 74% of women reported having a pregnancy issue, Only 32% of pre-eclampsia participants were able to accurately identify their diagnosis, and no participants diagnosed with eclampsia were able to correctly identify their diagnosis (Joshi et al., 2020). The study concluded that education by health workers is linked to better achievement on a pre-eclampsia/eclampsia knowledge test— a recipe for mortality and morbidity reduction in Ghana. Patient awareness of pre-eclampsia and eclampsia is critical for initiatives to support informed healthcare decisions, promote early prenatal care, and increase self-recognition of warning symptoms, all of which contribute to lower morbidity and death.

2.6 The Empirical Review on Cost analysis of Preeclampsia

Fox *et al.* (2017) looked at the cost of pre-eclampsia in the health care system. They used secondary data to estimate the cost incurred in pre-eclampsia from the viewpoint of the health payer (Health payer are organizations such as health plan providers, Medicare, and Medicaid that set service rates, collect payments, process claims and pay provider claims).

Preeclampsia-infected individuals and those without preeclampsia were chosen from the Irish cohort of women enrolled between November 2008 and February 2011 for this study. Fox *et al.* (2017) revealed that women with preeclampsia require more maternity services. Concerning cost, the findings of the study revealed that the average cost of pregnancy with issues of pre-eclampsia was estimated at €5243 per case whereas pregnancies without preeclampsia were estimated at €2452 per case. Also, the study revealed that the cost of preeclampsia at the national level is between €6.5 million and €9.1million. From the findings of the study, postpartum recorded the highest cost (€4.9–€6.9 million), this was followed by antepartum care with a cost of €0.9–€1.3 million and peripartum care (€0.6–€0.7 million). Fox et al. (2017) therefore concluded that the maternity cost of women with preeclampsia is higher than women who do not have preeclampsia. Although, Fox *et al.* (2017) looked at the cost of pre-eclampsia in the health care system, they did not look at the cost involved in running a pre-eclampsia test. The findings of this study were in line with the findings of (Fox & Callander, 2020).

Fox and Callander (2020) in their study looked at the variance in government expenditure on mothers who do not have hypertensive disorders of pregnancy and those who have hypertensive disorders of pregnancy. They used an administrative dataset from Australia, specifically Queensland and found out that the expenditure of the government on mothers who do not have hypertensive disorders of pregnancy is extremely lower than government expenditure on women who have hypertensive disorders of pregnancy. They reiterated that the cost of government

expenditure on women who have the hypertensive disorder of pregnancy is $14,388 while those who do not have is $11,395. They added that the difference in the cost can be attributed to experiences during the era of birth ($8696 and $6509). This study was centred on the cost incurred by the government on mothers who have hypertensive disorders during pregnancy and those who do not have hypertensive disorders during pregnancy of which pre-eclampsia could an example. However, the study did not focus directly on pre-eclampsia as well as the cost involved in running a test to detect pre-eclampsia.

Zakiyah *et al.* (2015) also did an evaluation on information on the health economics of preeclampsia screening, diagnosis, and treatment choices. He focused on papers published between 1994 and 2014 in three electronic databases (PubMed, EMBASE, and the Cochrane Library). Besides, only English-language articles with comprehensive pre-eclampsia economic analysis were considered for inclusion. Three studies were centred on the cost and treatment of preeclampsia. Two were centred on the evaluation of magnesium sulphate while two looked at the cost induction of labour vs expectant monitoring. Three studies also focused on screening and diagnosing pre-eclampsia. The studies on magnesium sulphate were inconclusive in terms of cost. However, the studies on induction of labour in term of pre-eclampsia was more costly than expectant monitoring. This study provided a comprehensive overview of economic issues of preeclampsia from a broader perspective ranging from treatment options to screening. However, this study, reviewed a variety of topics with several limited papers and this prevented the comparison that could have been made.

Zakiyah *et al.* (2022) looked at the cost involved in using a new screening test (biomarker-based screening test) for pre-eclampsia from the perspective of a healthcare payer in Ireland, the UK, Sweden and the Netherlands. revealed that the cost involved in this new test strategy is less costly compared to the one they normally use. They concluded that the new test for screening

preeclampsia is less costly and this can be attributed to the effectiveness of aspirin, the accuracy of the new test and regular antenatal care.

Hadker *et al.* (2010) in their study also looked at the financial impact of using new serum tests and standard practice to diagnose pre-eclampsia. They adopted a decision model in which a cohort of 1000 pregnant women who were receiving obstetrics in the UK was simulated. The economic impact of the novel pre-eclampsia test (Roche Diagnostics, Rotkreuz) and the current diagnostic test were modelled. According to Hadker *et al.* (2010, p, 2) "the novel PE test constitutes two novel biomarkers Placenta Growth Factor (PlGF) and soluble fms-like tyrosine kinase-1 (sFlt-1) which can be quantitatively analyzed using an automated system widely available in hospitals or laboratories (Elecsys/Cobas, Roche Diagnostics) and measures the levels of PlGF and sFlt-1 growth factors in pregnant women." A hybrid research approach was adopted where data for model inputs were obtained from published literature and public databases. Interviews with obstetricians, laboratory managers, and healthcare payers were used to validate model inputs and fill utilization related data gaps.

Their findings revealed that the cost associated with the management of normal pregnancy with the new test is £1,781 per patient whereas the standard practice is £2,726. This depicted a costsaving of £945 per pregnant woman when the new test is used. They added that this savings cost could be aligned to the enhanced performance of the new test and its ability new test's improved performance and its ability to classify pregnant patients.

Hodel *et al.* (2020) looked at the inpatient cost associated with confirmed and suspected cases of pre-eclampsia in hospitals in Swiss in the year 2016. The cost incurred by patients suspected to be having pre-eclampsia and those who have been diagnosed with it were determined by using data from the controlling and finance departments. The cases were grouped into three categories which entail "patients with suspected preeclampsia who were discharged without delivering, (patients

with diagnosed preeclampsia followed by vaginal induction, and patients with diagnosed preeclampsia followed by cesarean delivery. A sample of 301 cases was used of which 12% were those suspected of pre-eclampsia and were later discharged a few days later without giving birth. Their findings revealed that costs for cases of suspected preeclampsia were the lowest, averaging CHF 7,159/EUR 6,658, followed by CHF 12,124/EUR 11,275 for cases of preeclampsia with vaginal delivery, and CHF 19,352/EUR 17,997 for preeclampsia with cesarean section. Also, the findings of this study revealed that the total medical cost was CHF 4.7 (EUR 4.4) million and in all the patient groups, the actual patient cost was higher than the revenue that inpatient care providers get from payers for rendering such services. Again, this study did not look at the cost incurred in running a Pre-eclampsia test.

This present the review literature of the study and it entails definition of preeclampsia, Preeclampsia pathophysiology, type of test and diagnosis of preeclampsia, burden of pre-eclampsia in Ghana and the empirical review on cost analysis of pre-eclampsia.

CHAPTER THREE

3.0 METHODS

3.1 Study Design

The study was a cross-sectional study which used a micro-costing approach to estimate the financial and economic cost of diagnosing and monitoring pre-eclampsia using the PrCr urinary dipstick test and standard of care Protein-only urinary dipstick test.

3.2 Study location

This study was conducted in three referral hospitals in Ghana. Korle-Bu Teaching Hospital was one of these hospitals. The Korle-Bu Teaching Hospital, which first opened its doors on October 9, 1923, has grown to become Africa's third-largest hospital and Ghana's top national referral center. The hospital, which has a capacity of 2000 beds, now employs over four thousand medical and health personnel's, with an average of one thousand five hundred clients on daily basis attendance, around two hundred and fifty of whom are hospitalized for advance treatment (KBTH, 2014). Korle-Bu Teaching Hospital is situated in Ghana's Greater Accra Region, in the Ablekuma Locality of Accra Metropolis. The hospital has twenty-one clinical and diagnostic divisions, including obstetrics and gynecology department where the study took place.

Greater Accra Regional Hospital (Ridge) is one of the regional hospitals in Ghana. It is in the Accra Metropolis of Ghana's Greater Accra Region, on Castle Road, North Ridge. It is divided into seven (7) major departments. Each department has units and subunits.

The Koforidua Regional Hospital is located in the New Juaben Municipality in Ghana's Eastern Region. East Akim Municipality is bordered to the north by East Akim Municipality, Akuapim North District to the east and south, and Suhum-Kraboa Coaltar District to the west, which comprises an approximate land area of 110 square kilometers. It is a regional hospital with sixteen (16) departments. It is a secondary referral institution with a total bed capacity of 360 beds that acts as a referral center for about sixteen (16) district hospitals in the Eastern Region.

These hospitals were chosen because they had a referral function, a substantial volume, and the infrastructure needed to undertake this research. The total number of deliveries made in these facilities each year is greater than thirty thousand annually (>30,000) and the estimated average incidence of hypertensive disorders of pregnancy is about 8% or 2,400women.

3.3 Study Population

The study population consisted of healthcare professionals and included nurses and midwives in the Korle-Bu Teaching Hospital, Greater Accra Regional Hospital, and Koforidua Regional Hospital. These respondents were chosen for the study because they normally attend to people who have pre-eclampsia.

3.3.1 Inclusion Criteria

- Healthcare workers who were responsible for running PrCr urinary dipstick test and standard of care Protein-only urinary dipstick tests such as midwives, laboratory technicians, nurses and other cadres of healthcare workers who provide in-patient care.
- Willing to provide written informed consent for study participation.

3.3.2 Exclusion Criteria

- Healthcare professionals (nurses and midwives) who used or supervised the use of PrCr urinary dipstick tests and were unwilling to provide written informed consent for study participation.
- Healthcare professionals (nurses and midwives) who provided services to pregnant women using the standard of care Protein-only dipstick test and PrCr urinary dipstick test but were not available at work on the day of training were excluded.

3.4 Sample Size Determination

Sixty (60) healthcare professionals (nurses and midwives) across the three study sites were interviewed on the use of both standards of care Protein-only dipsticks and PrCr urinary dipstick tests. Twenty healthcare professionals from Korle-Bu teaching hospital (20), Thirty-three (33) healthcare professionals from Koforidua Regional hospital, and seven (7) health professionals from Greater Accra Regional Hospital were selected and interviewed.

3.5 Sampling Method/Procedure

Purposive sampling, a kind of non-probability sampling was used in this investigation. This study used a purposive sampling approach to interview midwives and nurses who handle the tests and were available at the time of data collection. The choice of selecting purposive sampling could be attributed to the fact that the participants involved in this study were known and could be identified easily.

3.6 Data Collection Procedure

Structured questionnaires were used for data collection. There were both open-ended and closedended questions on the surveys. Data was collected from healthcare workers responsible for running Protein-to-creatinine urinary dipsticks and standard of care Protein-only urinary dipstick tests such as midwives and nurses who provided in-patient and outpatient care. After meeting the prospective healthcare provider, the researcher introduced herself and politely explained the purpose and benefit of the study. Informed consent was obtained from all study participants.

Data collection was carried out by the researcher herself. The questionnaires were administered to healthcare workers responsible for running Protein-to-creatine urinary dipstick test and standard of care Protein-only urinary dipstick test such as midwives, and nurses who provided in-patient and outpatient care. At the end of each data collection day, the researcher reviewed all the filledout questionnaires and verified them to ensure completeness and accuracy.

Table 1: Study Variables

Financial Cost Variables	Cost of gloves
	Cost of Sample container
	Cost of PrCr test strip
	Cost of absorbent paper
Economic Cost Variables	
	Cost of time of running the PrCr dipstick test when the client leaves to collect the sample until the test result is available.
	Cost of time to run the PrCr dipstick test
	Cost of time to relay the PrCr dipstick test result and counsel the client
	Cost of gloves
	Cost of Sample container
	Cost of PrCr test strip
	Cost of absorbent paper

3.7 Data Collection Tool

A structured questionnaire was used for the data collection and it took about 20 minutes to administer. The questionnaire was divided into four sections and covered a wide range of financial and economic cost questions. The sections are described briefly below:

Section 1: Background

Questions under this section included affiliated institutions and the position/rank of healthcare providers.

Section 2: Resources used for Protein-only urine dipstick strip test

Questions under this section considered the estimation of quantities of supplies that health care professionals use per client when urine screening was done using the Protein-only dipstick test.

Section 3: Costs for proteinuria testing using the Life Assay Diagnostics Test PrCr urinary dipstick test

Questions under this section considered the estimation of quantities of supplies that healthcare professionals use per client when urine screening was done using the PrCr dipstick test.

3.8 Quality Control

Adequate safeguards and guarantees were put in place to guard and guarantee data accuracy and quality, reducing bias. These actions involved pretesting of questionnaires and data entry into an excel spreadsheet by the lead researcher. Every day, all completed data was checked and entered. Additionally, the dataset was cleaned prior to analysis. Every day, all completed data was checked and entered. Before analysis, the dataset was also cleansed. To prevent unauthorized persons from accessing the surveys, they were kept under lock and key. Again, three years after the study's conclusions are published, the surveys are anticipated to be deleted.

Pretesting of Questionnaires:

To ensure that the questionnaires were clear to respondents, the questionnaires were pretested at one of the nation's hospitals; called 37 military hospitals located on the main road between Kotoka International Airport and Central Accra which has an environment comparable to the study area. During the pre-testing phase, the research assistants distributed fifteen questionnaires. Based on the results of the pretest, the questions were reshuffled and further explained. This was done to guarantee that the questionnaire was well-understood and appropriately conducted.

3.9 Data Processing and Analysis

The information gathered was screened thoroughly, validated serialized, and coded into Microsoft Excel. The data set was cross-checked for mistakes using individual hard copies after it was entered to ensure that every specified variable was in its proper position. The data were analyzed using statistical techniques such as summation, mean, frequencies and percentages. The results were presented in the form of tables and charts.

Cost Analysis

Cost analysis involved only the healthcare provider perspective (which is the cost incurred for using the Protein-only dipstick test and PrCr test).

The cost analysis was done for both financial and economic costs. An analysis of the economic costs and direct and indirect costs that were incurred for both tests were identified. All recurrent and capital costs were also appropriately identified. Thus, costs incurred on inputs that had a lifespan exceeding one year constituted the capital costs (vehicle cost, office space, projectors). In contrast, cost incurred on input with less than one (1) year useful lifespan were considered as recurrent cost (e.g., stationaries). In this study no capital items were identified, even though timer/clock was used, healthcare workers relied on the time on their phone and quantifying this, the cost was found to be negligible. Therefore, cost of timer was not included in the analysis.

In addition, the opportunity cost associated with health providers who were trained as part of the project, and any compensation (e.g., allowances) were treated as a direct recurrent cost to the project.

3.10 Study Limitation

1. limited empirical evidence and publication are comparing the PrCr test and the Protein-only test.

2. The study adapted a smaller sample size of sixty (60) since the study focused on three (3) facilities as part of the trial that will necessitate the implementation of PrCr test.

3.11 Ethical Consideration

This study was covered by the Ethical approval obtained for the main study titled 'Evaluating the clinical utility and operational fit of the LifeAssay Diagnostics Test- it™ PrCr urinary dipstick test to assess the risk of pre-eclampsia in referral hospitals in Ghana" which obtained approval from the Ghana Health Service Ethics Review before the onset of the study. The School of Public Health provided an introduction letter to obtain authorization and approval from the Medical Director of the Korle-Bu Teaching Hospital, Ridge Hospital, and Koforidua Regional Hospital.

3.11.1 Declaration of Conflict of Interest

In terms of this study, there was no conflict of interest.

3.11.2 Potential Risk/Benefits and Compensation

There has been no risk to either the study population or society as a result of this study. The outcomes are supposed to benefit both the people and society in a variety of ways. To begin, the respondents were given information regarding the estimated cost of pre-eclampsia using the PrCr urinary dipstick tests and Protein-only urinary dipstick tests. Secondly, quantifying the cost of preeclampsia using the PrCr test and Protein-only test informs policymakers and the government about the disease's economic burden. This would assist communities in planning and budgeting for pregnancy-related issues. Other than a word of thanks, there was no sort of reward for participants in the research.

3.11.3 Privacy and Confidentiality

The goal of the study was communicated to respondents, and they were given assurances that their name and privacy would be maintained. Participants' privacy was preserved since codes rather than

their names were utilized to identify them. Interviews were conducted in confined spaces. To reduce participant traceability, data were reported as aggregates.

3.11.4 Voluntary Consent/ Withdrawal

Before any data was gathered, research participants gave their written informed permission. The study's participation was entirely optional, and respondents had the option of opting out at any time.

CHAPTER FOUR

4.0 MONITORING AND EVALUATION ISSUES OF THE STUDY

4.1 Description of the Programme

Prenatal care on a larger scale now is based on healthcare paradigms created in the early twentieth century. The UK Ministry of Health produced a Memorandum on Antenatal Clinics in 1929, advising that women be visited at 16 weeks of pregnancy, then 24 and 28 weeks, biweekly until 36 weeks, and finally weekly until birth. Even though no specific reason for the time or clinical content of visits was provided, these recommend

ations created the pattern of prenatal care that is being followed across the world today (Poon et al., 2021).

A prevalent belief has persisted that prenatal care should be focused on the third trimester of conception when the majority of clinical problems manifest and unfavourable results can be diagnosed. Pre-eclampsia monitoring is now based on a 90-year-old treatment protocol that mandates females to be examined for hypertensive and proteinuria at each clinical consultation.

Though, in the event of an early-onset ailment, this technique identifies high blood pressure and pre-eclampsia at a later phase of presentation, restricting the mother and the unborn baby from receiving optimal care, such as blood pressure stabilization, prophylactic corticosteroid for fetal lung maturation, and transfer to a tertiary referral unit, before the need for immediate delivery, which is the only definitive treatment for this impairment symptom of pre-eclampsia. Over the last ten years, significant progress has been made in developing techniques for risk assessment and prediction of pre-eclampsia in high-risk women, as well as short-term monitoring in women who have pre-eclampsia signs and symptoms (Poon et al., 2021).

4.2 Implementation of lifeassay test-it™ PrCr Urinalysis Dipstick Test

The Life Assay Diagnostics (LAD) Test-It PrCr dipstick detects protein and creatinine to assess proteinuria in a simple and economical urine-based test. As previously stated, it is critical to normalize protein measurements with creatinine to account for a patient's level of hydration. This product is cost equivalent to the standard of care protein-only dipsticks at $0.06–0.10 per test. The LAD PrCr urinary dipstick should be completely submerged in a well-mixed sample of urine for a short length of time before being let to stand for the reaction to occur (60 seconds). The LAD PrCr dipstick gives you results in 60 seconds and has an easy-to-read colorimetric scale that helps you make quick clinical decisions. For visual examination, the reagent pads would be compared to the colorimetric scale or read by an automatic reader. Protein results are graded as 0 (negative), 1+ (30 mg/dL), 2+ (100 mg/dL), 3+ (300 mg/dL), or 4+ (2000 mg/dL).

Creatinine results are graded as 0 (10 mg/dL), 1+ (50 mg/dL), 2+ (100 mg/dL, 3+ (200 mg/dL), or 4+ (300 mg/dL). Based on these readings, a protein-to-creatinine ratio can be determined and classified as either “normal” or “abnormal/proteinuria.” As per current guidelines, clinical

proteinuria is defined as a ratio result of ≥0.3.

The LifeAssay Test-it™ PrCr Urinalysis Dipstick test product has received the CE (Conformité Européene) mark and is registered in South Africa and Kenya. It is currently pending regulatory approval with the Ghana FDA and has been issued a temporary import permit for in-country sale and use, pending final approvals.

4.3 Implementation of Standard of Care Protein-only Dipstick Test

In Ghana and at the research locations, protein dipsticks are routinely utilized in ANC. We anticipate that a variety of protein dipstick products will be employed at the referral hospital study sites, depending on availability (e.g., Healgen URS- 10T, URIT 11Vet). The performance of the protein dipsticks in this study will be pooled across all product types.

The specific protein dipstick tests that are used as part of the standard of care will be recorded on study data collection forms. Like the other dipstick tests in this study, results graded into categories (0, 1+, 2+, 3+, 4+) that correspond to different levels of protein in mg/dL, as described in each test's Instructions for Use. The ISSHP guidelines specify that a protein dipstick result of ≥1+ (30 mg/dL) is considered "positive" for proteinuria.

4.4 Type of Evaluation

Formative evaluation, process evaluation, and impact evaluations are the types of evaluations employed in any given program. For this study, a cost evaluation was used to estimate the cost of diagnosing and monitoring pre-eclampsia using the Protein-to-Creatinine urinary dipstick and standard of care Protein-only urinary dipstick tests. It compared the financial and economic costs of both tests.

4.5 Description of the Conceptual Framework

Direct cost involves a cost that is directly related to the implementation of the intervention. Example: training of staff, item purchase and usage of existing resources. The direct cost is madeup of the capital cost; cost incurred for a period beyond one financial year. For example, the cost of transport (vehicle), office space and equipment for training. The recurrent cost consists of the cost incurred for one year. Example training of staff, purchase of materials such as test strips, absorbent paper, gloves. Opportunity cost consists of costs that are forgone in satisfying the best alternative, for example, usage of the existing conference room by staff, usage of the existing vehicle for a different purpose, time usage, and supervising service. The indirect cost consists of the cost that is not directly related to the intervention; for example, time usage.

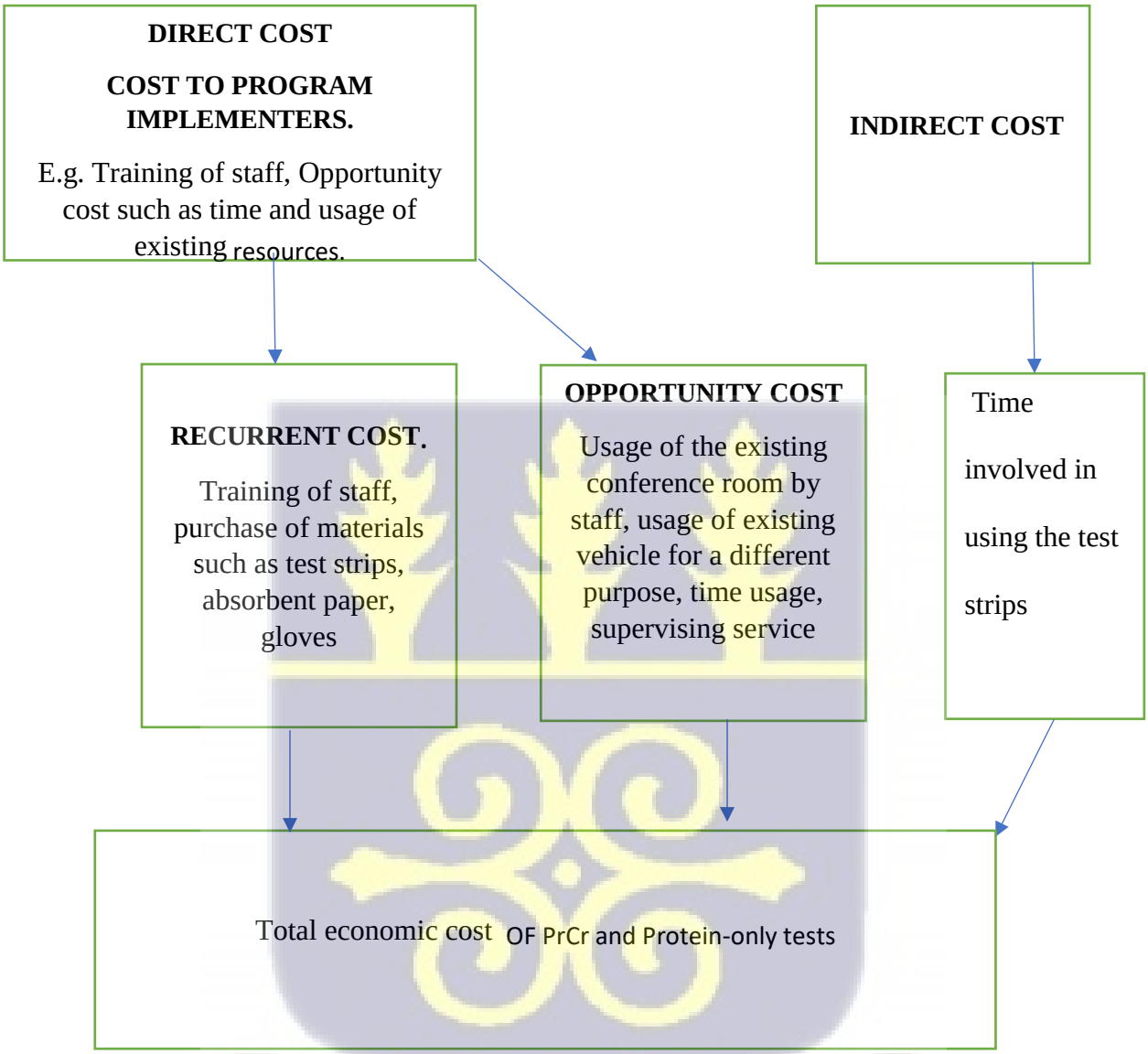

Figure 1: Conceptual Framework for Diagnosing Pre-eclampsia

Table 2. Logic Model

Inputs	Activity	Output	Outcome	Impact

Nurses Midwives, and Gloves, tissues	The direct cost of each of the items Protein-only materials and test items to be listed	The direct cost is assigned to each specific test materials items	The amount of specific direct costs involved was ascertained for Protein-only test.	Average cost and Total Cost and the cost profile calculated by the health facility
			Amount of cost of the gloves, Protein-only test strip	
			Amount of cost of sample container- Amount of cost for Protein-only test strip	
			Amount of cost of Protein-only test strip	
			The amount for the cost of absorbent paper, Protein-only test strip	

Time	The processes and activities of the indirect cost of each of the items Protein-only materials to be listed.	The indirect cost is awarded to each specific test material or process due to the time variable.	The tentative indirect cost of time associated with Protein-only Test is arrived at.	The indirect cost of time is available and helped the management in its analysis and decision making on the Proteinonly Test.
			The cost of time of running Protein-only dipstick test determined or is available The cost of time to run the Protein-only dipstick test and relay the result to the client The cost of time to relay the Protein-only dipstick test result and counsel the client is determined	Clients and management are educated and well-informed about time factors of Protein-only dipstick test and relay results with counselling undertaken.
Nurses Midwives, test strips , absorbent paper	The direct cost of each of the items PrCr test strip and materials items to be listed	The direct cost is awarded to each specific test materials items of Cost of the gloves-PrCr test strip, Cost of sample container-PrCr test strip	The direct amount of cost specific PrCr test items is known	The average cost and total cost and the cost profile are calculated by healthcare management for comparative decision making

		Cost of PrCr test strip and Cost of the absorbent paper-PrCr test strip		with a Protein-only dipstick test
Time	The time for activities as an indirect cost of each of the PrCr dipstick tests is listed	The indirect cost is calculated for each specific PrCr dipstick test activities	The actual indirect time/cost involved in PrCr test only is predetermined and communicated	Cost and comparative test policy decision is arrived at

Table 3: indicators of Pre-eclampsia

Type of indicator	Indicator	How indicator will be measured	Means of verification
Activity indicator	Number of PrCr test strips used for the diagnosis of preeclampsia compared to the standard of care Protein-only dipstick test.	Count and reconcile the aggregate number of clients tested with PrCr test weekly.	Count and reconcile the test result using the client test profile database from the Hospital Laboratories.
Input indicator	Time spent on testing using PrCr test versus standard of care Protein- only dipstick test.	The cost of time of running PrCr dipstick test when the client leaves to collect the sample until the test result is available	Aggregate evaluation of the lap time per each PrCr test conducted.
Input indicator	The monetary value of PrCr test per client versus standard of care Protein-only dipstick test.	Measuring the time of indirect cost and indirect cost of the two approaches of testing.	Use the cost structure differences of average cost, the total cost of the PrCr test and Protein-only test.

CHAPTER FIVE

5.0 RESULTS

5.1: Total Economic Cost of PrCr Test by Health Facilities

The total economic cost of the PrCr test was GHS 304.77 ($49.52) of which the direct cost constituted 56% and indirect cost constituted 44% as shown in Figure 2.

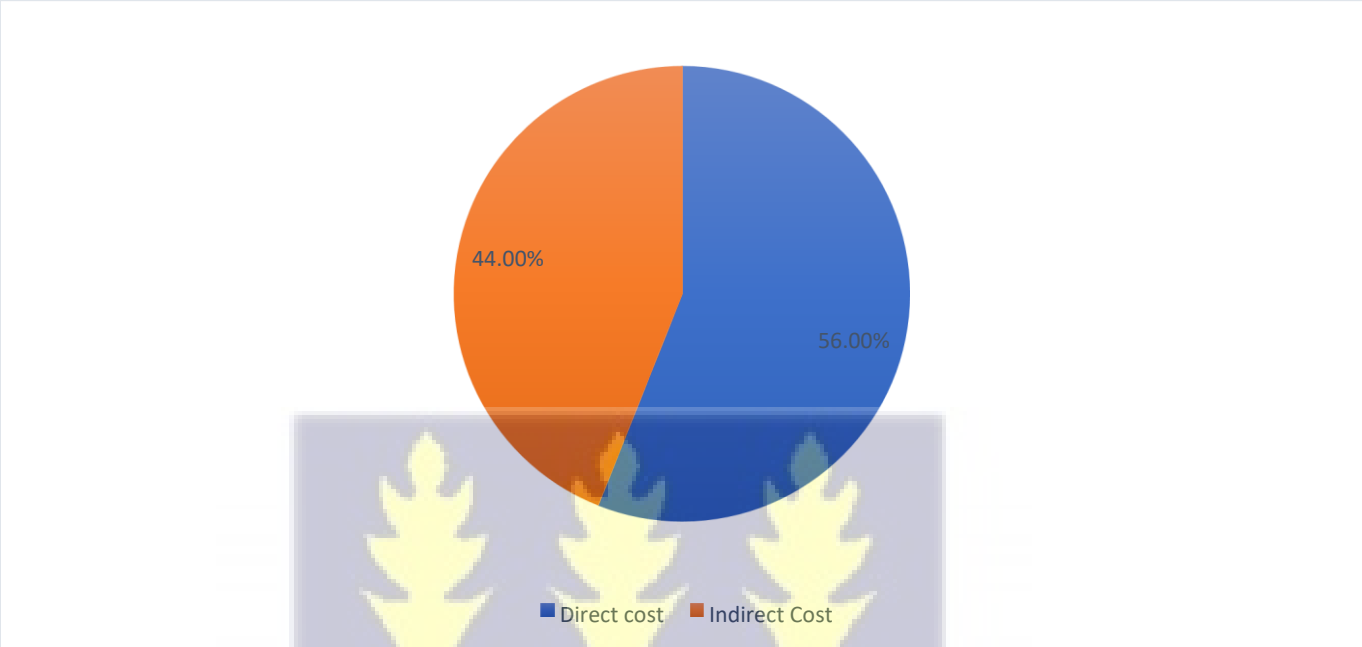

Figure 2: Proportion of Direct and Indirect Cost of PrCr Test

Direct cost: The total direct cost of running a PrCr test was GHS170.75 ($27.7) Table 4 depicts a total direct cost of GHS170.75 ($27.7) with an average direct cost of GHS2.85 ($0.46). From Table 4, the highest direct cost was accounted for by the cost of the PrCr test strip (GHS70.15), followed by the cost of the gloves (GHS 60.35), the cost of the sample container (GHS37.65), and the cost the of the absorbent paper (GHS 2.6). Also, the total indirect cost of running a PrCr test was GHS134 ($21.77) with an average cost of GHS 2.31 ($0.36). The highest indirect cost incurred in running a PrCr test was the cost of time of running the PrCr dipstick test when the client leaves to collect the sample until the test result is available. This amounted to GHS 64.41 ($10.46), followed by the cost of time to relay the PrCr dipstick test result and counsel the client and then cost of time

to run the PrCr dipstick test. These two tests had a cost of GHS51.18 ($8.32) and GHS18.43 ($2.99) respectively.

Table 4: Total Economic Cost of Running PrCr Test

COST COMPONENT	TOTAL COST		AVERAGE COST		COST PROFILE
	GHS	US$	GHS	US$	%
Direct					
Cost of the gloves	60.35	9.81	1.01	0.16	19.80
Cost of sample container	37.65	6.12	0.63	0.10	12.35
Cost of PrCr test strip	70.15	11.39	1.17	0.19	23.02
Cost of absorbent paper	2.6	0.42	0.04	0.01	0.85
sub-total	170.75	27.74	2.85	0.46	56.03
Indirect cost					
cost of time of running the PrCr dipstick test when the client leaves to collect the sample until the test result is available.	64.41	10.46	1.09	0.18	21.13
cost of time to run the PrCr dipstick test	18.43	2.99	0.32	0.05	6.05
cost of time to relay the PrCr dipstick test result and counsel the client	51.18	8.32	0.9	0.15	16.79
sub-total	134.02	21.77	2.31	0.38	43.97
Total cost	**304.77**	**49.51664527**	**5.16**	**0.84**	**100**

5.2 Total Economic Cost of Running Protein-only Test

The total economic cost of Protein-only test was GHS341.38 ($ 55.46) of which the direct cost constituted 48.93% and indirect cost constituted 51.07% as shown in Figure 3.

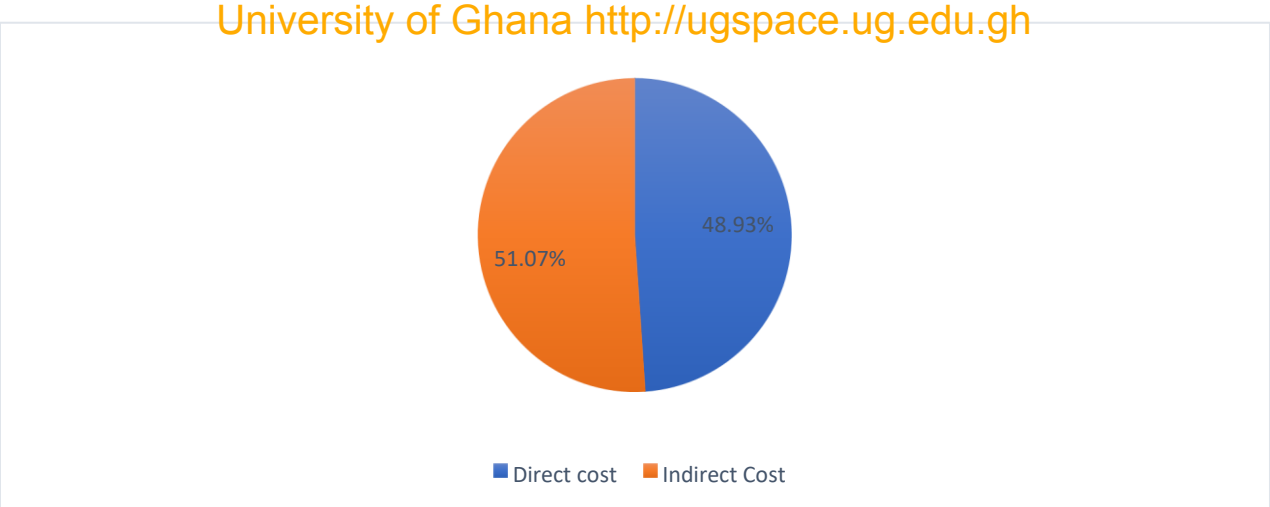

Figure 3: Proportion of Direct and Indirect Cost of Protein-only Test

Direct cost: The total direct cost of running a Protein-only test was GHS167.05 ($ 27.14) The direct cost as shown in Table 5 depicts, a total direct cost of GHS167.05 ($ 27.14) with an average direct cost of GHS 2.78 ($ 0.45). From Table 5, the highest direct cost was accounted for by the cost of gloves GHS72.20 ($11.73), followed by the cost of Protein-only test strips GHS54.70 ($8.89), cost of sample containers GHS37.65 ($6.12) and then cost of absorbent paper GHS2.50 ($ 0.41).

As shown in Table 5, the total indirect cost of running a Protein-only test was GHS174.33 ($ 28.33) with an average cost of GHS2.31 ($ 0.36). The highest indirect cost incurred in running a Proteinonly test was the cost of time of running a Protein-only dipstick test when the client leaves to collect the sample until the test result is available GHS84.32 ($13.70), This is followed by the cost of time to relay the Protein-only dipstick test result and counsel the client GHS51.84 ($8.42) and then the cost of time to run the Protein-only dipstick test and relay result to the client GHS38.17 ($6.20).

Table 5: Total Economic Cost of Running Protein-only Test

COST COMPONENT	TOTAL COST		AVERAGE COST		COST PROFILE
	GHS	US$	GHS	US$	%

Direct					
Cost of the gloves	72.20	11.73	1.20	0.20	21.15
Cost of sample container	37.65	6.12	0.63	0.10	11.03
Cost of Protein-only test strip	54.70	8.89	0.91	0.15	16.02
Cost of absorbent paper	2.50	0.41	0.04	0.01	0.73
sub-total	167.05	27.14	2.78	0.45	48.93
Indirect cost					
Cost of time of running Protein-only dipstick test when the client leaves to collect the sample until the test result is available	84.32	13.70	1.43	0.23	24.70
Cost of time to run the Protein-only dipstick test and relay the result to the client	38.17	6.20	0.64	0.10	11.18
Cost of time to relay the Protein-only dipstick test result and counsel the client	51.84	8.42	0.91	0.15	15.18
sub-total	174.33	28.32	2.97	0.48	51.07
Total cost	**341.38**	**55.46**	**5.76**	**0.94**	**100.00**

5.3 Comparison between the Financial Costs of PrCr Test and Protein-only Test

The study compared the financial cost incurred in diagnosing preeclampsia when using the Proteinto-Creatinine urinary dipstick test and standard of care Protein-only urinary dipstick test. In the event of achieving this objective, the study compared the average cost and total cost of using the Protein-to-Creatinine urinary dipstick test and the standard of care Protein-only urinary dipstick

test.

Table 6: Comparison between the Financial Costs of the PrCr Test and Protein-only Test.

	TOTAL COST		AVERAGE COST	
	GHS	US$	GHS	US$
PrCr Test	170.75	27.74	2.85	0.46
Protein-only	167.05	27.14	2.78	0.45
Difference	**3.7**	**0.6**	**0.07**	**0.01**

From the findings of the study, the total financial cost of running a PrCr test is more expensive than a Protein-only test and the difference is GHS3.7 and $0.6 respectively.

5.4 Comparison between the Economic Costs of PrCr Test and Protein-only dipstick Test

The study compared the economic cost incurred in diagnosing pre-eclampsia when using the Protein-to-Creatinine urinary dipstick test and standard of care Protein-only urinary dipstick test. In the event of achieving this objective, the study compared the average cost and total cost of using the Protein-to-Creatinine urinary dipstick test and the standard of care Protein-only dipstick test. The study went further to find out whether there is a significant difference between the economic cost incurred using the Protein-to-Creatinine urinary dipstick test and the standard of care Proteinonly urinary dipstick test.

Table 7: Comparison between the Economic costs of the PrCr test and Protein-only

		TOTAL COST		AVERAGE COST	
		GHS	**USD**	**GHS**	**USD**
PrCr Test:					
	Direct Cost:	170.75	27.74	2.85	0.46
	Indirect Cost	134.02	21.77	2.31	0.38
	Sub Total	304.77	49.52	5.16	0.84

Protein-only Test:					
	Direct Cost:	167.05	27.14	2.78	0.45
	Indirect Cost	174.33	28.32	2.97	0.48
	Sub Total	341.38	55.46	5.75	0.93
Difference		**36.61**	**5.94**	**0.59**	**0.09**

From the findings of the study, it is obvious that the total economic cost of running a Protein-only test is more expensive than the PrCr test and the difference is GHS36.61 and $5.94 respectively. Regarding the average economic cost, the findings of the study revealed that the average economic cost of running the Protein-only test is more expensive than the PrCr test and the difference is GHS 0.59 and $0.09 respectively.

CHAPTER SIX

6.0 DISCUSSION

6.1 Total Economic cost of running PrCr Test

This study investigated the cost incurred by diagnosing and monitoring pre-eclampsia using the PrCr and Protein-only test strip in three facilities in Greater Accra and the Eastern Region to provide information for possible decision making and to know the cost incurred in running these tests. The total cost of the PrCr test was GHS304.77($49.52) with a direct cost of GHS170.75 ($27.7) representing 56% and an average cost of GHS2.85($0.46). Direct costs can be defined as all costs that can be directly attributed to an intervention. The direct cost items constituted the cost of gloves, cost of the sample container, cost of PrCr test strip and cost of absorbent paper. The cost of the PrCr test strip constituted the largest component of the direct cost with an amount of

GHS70.15 ($11.4), followed by the cost of gloves GHS60.35 ($9.8), the cost of the sample container GHS37.65 ($6.12) and absorbent paper GHS2.6 ($0.42). The cost of the PrCr test strip being higher than the rest of the items could be attributed to the fact that it was imported and not readily available on the market. Besides, the market price is even quoted in dollars depicting that it is rarely available here in Ghana. However, the least price was the cost of absorbent paper and this could be as a result of it being produced in Ghana and its availability on the market.

Likewise, the total indirect cost of running a PrCr test was GHS134 ($ 21.77) representing 44% of the overall total cost with an average cost of GHS2.31 ($ 0.38). The indirect cost consists of the cost that is not directly related to the intervention; for example, time usage. The highest indirect cost incurred in running a PrCr test was the cost of time of running the PrCr dipstick test when the client leaves to collect the sample until the test result is available and this amounted to a cost of GHS64.41 ($10.46) This higher cost could be attributed to the client's delay in bringing the urine, the client not being able to bring out urine at the time it was needed or perhaps also when the client brought the urine the midwife or nurse was attending to a different thing. The second highest indirect cost was the cost of time to relay the PrCr dipstick test result and counsel the client GHS51.18 ($8.3) and the lowest time spent was the cost of time to run the PrCr dipstick test GHS18.43 ($2.99). This is because just only 60 seconds are spent running the test.

6.2 Total Economic cost of running Protein-only test.

The total cost of running the Protein-only test was GHS341.38 ($55.46) of which the direct cost constituted 48.93% and indirect cost constituted 51.07%. The total direct cost of running a Protein-only test was representing 48.93% of the total cost with an average direct cost. From the findings, the cost of gloves constituted the greatest component of direct cost. This could be a result of the COVID-19 pandemic since there was a shortage of personal protective equipment and also in collecting the data, Likewise, it was observed that most of the midwives and nurses used two pairs

of gloves when running the protein-only tests. The second highest direct cost of running a Proteinonly test was the cost of test strips GHS54.70 ($8.89). This was followed by the cost of sample containers of GHS37.65 ($6.12) and then the cost of absorbent paper of GHS2.50 ($0.41). The idea behind the least cost of absorbent paper is because these papers are produced in Ghana and the supply is very high which makes it readily available.

The total indirect cost of running a Protein-only test was GHS174.33 ($28.32) with an average cost of GHS2.97 ($0.48). The highest indirect cost incurred in running a Protein-only test was the cost of time of running a Protein-only dipstick test when the client leaves to collect the sample until the test result is available. This could be because the client's delay in bringing the urine or the client not being able to bring out urine at the time it was needed. Besides, this could also be attributed to the view that, when the client brought the urine, the midwife or nurse was attending to a different client. The next highest indirect cost was the cost of time to relay the Protein-only dipstick test result and counsel the client. The least cost was the cost of time to run the Proteinonly dipstick test and relay the results to the client.

6.3 Comparison between the Financial costs of the PrCr test and Protein-only test.

The financial cost is a type of cost, which is considered direct expenditure. It does not consider an opportunity cost; which is a cost forgone to satisfy the best alternative. In this study, the direct cost of running the PrCr test and Protein-only test component consisted of the cost of gloves, cost of the sample container, cost of PrCr test strip, cost of the Protein-only test strip and cost of absorbent paper. The direct cost of running the PrCr was GHS170.75 ($27.74) with an average of GHS2.85 ($0.46) and the cost of also running the Protein-only test was GHS167.05 ($27.14) with an average of GHS2.78 ($0.45) and difference of GHS0.07 ($0.01). From the findings of the study, it is obvious that the total financial cost of running a PrCr test is higher or more expensive than a Protein-only test and the difference is GHS3.7 ($0.6).

The financial cost difference between both the PrCr test and the Protein-only test can be attributed to the cost of test strip and absorbent paper. Much of the difference was on the test strip because with a difference of GHS15.45 ($2.5). The cost difference was GHS2.5 ($0.41) for absorbent paper when running both the PrCr test, the absorbent paper and the Protein-only test was difference of GHS0.1 ($0.01). However, this difference happens to be insignificant.

Although, the PrCr test strip has a higher cost than the Protein-only test strip, the cost of gloves for running the Protein-only was higher than that of the PrCr test strip and this can be attributed to the fact that more gloves were used in the Protein-only test than the PrCr test. Likewise, the average cost for running both the PrCr test and Protein-only test had a difference of GHS0.07 ($0.01).

6.4 Comparison between the Economic cost of PrCr dipstick test and Protein-only tests.

The economic cost is the inclusion of financial cost and opportunity cost; that is the cost forgone to satisfy the best alternative. That is, the economic cost entails both direct and indirect costs. The total economic cost of the PrCr test was GHS304.77 ($49.52) with an average cost GHS5.16 ($0.84) respectively. Also, the total economic cost of running the Protein-only test was GHS341.38 ($55.46) with an average cost of GHS5.75 ($0.93) with a difference of GHS0.59 ($0.09) respectively.

This indicates that the total economic cost of running a Protein-only test is more expensive than the PrCr test as shown in table 7. This could be a result of the time usage (indirect cost) of the Protein-only test.

6.5 Total and Average time of running PrCr test and Protein-only test

The total time involved in running the Protein-only dipstick test when the client leaves to collect the sample until the test result is available in the three facilities was 405 minutes 47seconds with an average time of 6 minutes while in PrCr test, the total time was 306minutes 43seconds with an average time of 5minutes, 2seconds. The total time to run the Protein-only test and relay the result

to the clients was 181 minutes 5 seconds with an average time of 3 minutes while in running the PrCr test, the time total was 81 minutes with an average of 1minutes 4 seconds.

Likewise, the total time involved in relaying the Protein-only test and counsel the client was 258 minutes with an average time of 4 minutes, 5 seconds while in running the PrCr test, the total time to relay the PrCr test result and counsel the client was 257 minutes with an average of 4 minutes, 5 seconds. The difference in the total time was 1 minute. However, the difference of 1minute is not significant.

In conclusion, the time involved in running the Protein-only test is higher than the PrCr test this can be attributed to the fact that the cost of time in running the Protein-only dipstick test when the client leaves to collect the sample until the test result is available is higher than that of PrCr test with a total time difference of 99 minutes 04 seconds with an average time difference of 1 minute 67 seconds.

CHAPTER SEVEN

7.0 CONCLUSION AND RECOMMENDATION

7.1 Conclusion

The cost difference between the Protein-to-Creatinine urinary dipstick test and the Protein-only urinary dipstick test was examined. From the findings of the study, the financial cost of running a PrCr test is relatively higher or more expensive than a Protein-only. However, the total economic cost of running a Protein-only test is more expensive than the PrCr test. The study, therefore, concludes that even though the financial cost of running a PrCr test is higher than Protein only, there is the need to adopt the use PrCr test in testing for pre-eclampsia since the PrCr test is more accurate than the protein test and the cost difference between the two tests is not extremely high.

7.2 Recommendations

The study recommends as follows:

1. The PrCr test strip was imported, making it more expensive and rarely available. The study recommends that pharmaceutical companies can produce some in Ghana to reduce the cost and make it readily available.

2. The high economic cost of time can be resolved by reducing time costs by increasing the precision of the testing process. There is a need to enhance health professional training for resource-effective-based testing to reduce time and material costs.

3. The study recommends that any recurring costs, such as single-use components and maintenance costs, that limit the cost-effectiveness of these materials and devices used in conducting the test

must be reduced.

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APPENDICES

APPENDIX 1: PARTICIPANTS' INFORMATION SHEET AND CONSENT FORMS

ESTIMATING COST OF DIAGNOSING AND MONITORING PREECLAMPSIA USING THE PROTEIN-ONLY AND PROTEIN-TO-CREATININE (PRCR) URINARY DIPSTICK TEST: A CASE STUDY OF SELECTED FACILITIES IN TWO REGIONS.

Background and Purpose

My name is Bridget Nkrumah Boateng, a student from the School of Public Health, University of Ghana, Legon. I am conducting a study on the Cost of diagnosing preeclampsia using PrCr urinary dipstick test at Korle-bu Teaching Hospital, Koforidua Regional hospital and Ridge Hospital.

The study will involve answering questions from a closed and open-ended questionnaire about the cost incurred because of preeclampsia using the Protein-to-Creatinine urinary dipstick test (PrCr) and Protein-only urinary test. No Coercion will be used to obtain a response from participants. It will be appreciated if you could participate in this study. This is academic research that forms part of my work for the award of a master's degree in Public Health Monitoring and Evaluation.

The study will not pose any potential risk to study participants or society. The study participants as well as the society will benefit from this study. Study respondents will know how much it cost when test preeclampsia when using both tests. Also, your response will be helpful in policy planning and formulation of recommendations to appropriate authorities to help subsidize the cost involved in preeclampsia testing.

Right to Refuse

Participation in this study is voluntary and you can choose not to answer any individual question or all questions. You are at liberty to withdraw from the study at any time. However, I will encourage you to fully participate in the study since your answers are

important to help estimate the cost involved in using both tests. It is your right to ask questions and be giving satisfactory answers for any part of the process you do not understand.

Confidentiality: The information you would provide is going to be treated with strict confidentiality. Apart from myself and the principal investigator, no one else shall have access to the information since it shall be under lock and key.

Ethical approval: As part of our study to conform with standard practice and to ensure your safety, ethical approval has been sought from the Ethics Review Committee, Ghana Health Service. In case you need any further information or have an issue with the survey, you may contact the principal investigator or my supervisor or the administrator of the Ghana Health Service Ethics Review Committee respectively.

1. Bridget Nkrumah Boateng, Principal Investigator, University of Ghana, School of Public Health, 0245449981,0546047237. bnboateng001@gmail.com.
2. Prof. Justice Nonvignon, Supervisor, University of Ghana, School of Public Health,0249832313, jnonvignon@ug.edu.gh
3. Nana Abena Apatu, Administrator, Ethics Review Committee, Ghana Health Service (0503539896) ethics.research@ghsmail.or

APPENDIX II: CONSENT FORM

I acknowledge that I have read or have had the purpose and contents of the Participant's" Information Sheet read, and all questions satisfactorily explained to me in a language I understand (English). I fully understand the contents and any potential implications as well as my right to change my mind (i.e. withdraw from the research) even after I have signed this form. I voluntarily agree to be part of this research. Name of

Participant……

Participants‟ Signature ……... OR Thumb Print……

Date…….

INTERPRETERS' STATEMENT

I interpreted the purpose and contents of the Participant's‟ Information Sheet to the aforenamed participant to the best of my ability in English, language to his/her proper understanding.

All questions, appropriate clarifications sorted by the participant and answers were also duly interpreted to his/her satisfaction.

Name of Interpreter……

Signature of Interpreter……. OR Thumb Print …….....

Date…… Contact Details……

APPENDIX III QUESTIONNAIRE

ESTIMATING COST OF DIAGNOSING AND MONITORING PREECLAMPSIA USING THE PROTEIN-ONLY AND PROTEIN-TO-CREATININE (PRCR) URINARY DIPSTICK TEST: A CASE STUDY OF SELECTED FACILITIES IN TWO REGIONS.

Guide B: Study site staff, costing

Thank you for participating in this interview. We would like to ask you questions to enable us to estimate the costs of screening for pre-eclampsia using the Life Assay Diagnostics Test-it™ PrCr urinary dipstick test and the urine dipstick strip test. Your answers will be used to inform policy recommendations on the introduction of the test in Ghana. As a reminder, we anticipate that the discussion will last about 20 minutes.

Section 1. Background		
1.1	Affiliated institution	☐ Greater Accra Regional Hospital (Ridge) ☐ Koforidua Regional Hospital ☐ Korle Bu Teaching Hospital
1.2	Respondent's Position/Title	☐ Principal Midwifery Officer ☐ Senior Midwifery Officer ☐ Midwifery Officer ☐ Senior Staff Midwife ☐ Staff Midwife ☐ Maternity ward Supervisor ☐ Doctor ☐ Other, specify: _____
Section 2. Resources used for protein-only urine dipstick strip test		
2.1	Please estimate the quantities of each of these supplies that you use per client when urine screening is done using the protein-only dipstick test.	
2.1.1	Gloves	
2.1.2	Sample collection container	
2.2	Does the same staff who ordered the test also run and interpret the results?	☐ Yes ☐ No
2.2.1	If NO: who typically is responsible for running and interpreting the test result?	☐ ANC nurses ☐ Midwives ☐ Medical officers
		☐ Doctor ☐ Laboratory technicians ☐ Other, specify:_____
2.3	Please estimate the quantities of each of these supplies that you use per client when running the protein-only dipstick test.	
2.3.1	Gloves	
2.3.2	Test strip	
2.3.3	Absorbent paper	
2.3.4	Other: specify	
2.3.5	Other: specify	

2.4	Approximately how much time does it take to run a protein-only dipstick test from the time the client leaves to collect the sample until the strip test result is available?	
2.5	While waiting for the client to complete collecting the sample for the proteinonly dipstick test, do you attend to other clients?	
2.6	Approximately how much time does it take for you to run the protein-only dipstick test and relay the results to the client?	
2.7	Approximately how much time does it take for you to relay the results to the client and counsel them on the next steps?	
2.8	Do you typically have to repeat the protein-only dipstick test for any clients during the same visit?	
2.8.1	If YES: For what proportion of clients would you estimate you have to repeat the protein-only dipstick test?	
Section 3. Costs for proteinuria testing using the LifeAssay Diagnostics Test-it™ PrCr urinary dipstick test		
3.1	Please estimate the quantities of each of these supplies that you use per client when urine screening is done using the PrCr dipstick test.	
3.1.2	Gloves	
3.1.2	Sample collection container	

3.2	Does the same staff who ordered the PrCr dipstick test also run and interpret the results?	☐ Yes ☐ No
3.2.1	If NO: who typically is responsible for running and interpreting the PrCr dipstick test result?	☐ ANC nurses ☐ Midwives ☐ Medical officers ☐ Doctor ☐ Laboratory technicians ☐ Other, specify:_____

3.3	Please estimate the quantities of each of these supplies that you use per client when running the PrCr dipstick test.	
3.3.1	Gloves	
3.3.2	Test strip	
3.3.3	Absorbent paper	
3.3.4	Other: specify	
3.3.5	Other: specify	
3.4	Approximately how much time does it take to run a PrCr dipstick test from the time the client leaves to collect the sample until the test result is available?	
3.5	Approximately how much time does it take for you to run the PrCr dipstick test?	
3.6	Approximately how much time does it take for you to relay the results to the client and counsel them on the next steps?	
3.7	Do you typically have to repeat the PrCr dipstick test for any clients during the same visit?	
3.7.1	If YES: For what proportion of clients would you estimate you have to repeat the test?	
3.8	Over the past 6 weeks, how many PrCr dipstick tests have been discarded because of exposure to temperatures out of the recommended ranges?	
3.9	Over the past 6 weeks, how many PrCr dipstick tests have been discarded because of expiration?	
Section 4. Wrap up / conclusion		
Is there any other information about costs that you would like to share with us?		

Thank you for your time and participation in this interview. As a reminder, all information shared with us during this interview will be kept confidential and will only be used for research purposes. No information generated from this activity will be directly associated with the individual.

Cost of Items from various hospitals

	RESOURCES	**QUANTITY**	**PRICE (PACK)**

Greater Accra Regional Hospital	Gloves		
	The protein-only dipstick test strip		
	Sample collection container		
	Absorbent paper/tissue		
	The protein-to-Creatine dipstick test strip		
Koforidua Regional Hospital	Gloves		
	A protein-only dipstick test strip		
	Sample collection container		
	Absorbent paper/tissue		
	A protein-to-Creatine dipstick test strip		
Korle Bu Teaching Hospital	Gloves		
	A protein-only dipstick test strip		
	Sample collection container		
	Absorbent paper/tissue		
	the protein-to-Creatine dipstick test strip		

APPENDIX IV: ETHICAL CLEARANCE

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

My Ref. GHS/RDD/ERC/Admin/App 122/026
Your Ref. No.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Digital Address: GA-050-3303
Mob: +233-50-3539896
Tel: +233-302-681109
Email: ethics.research@ghsmail.org
9th February, 2022

Bridget Nkrumah Boateng
C/o University of Ghana
Department of Health Policy, Planning & Management,
School of Public Health
P.O. BOX LG 13 Legon, Accra, Ghana

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 025/01/22**
Study Title	Estimating Cost of Diagnosing Preeclampsia Using the Protein-To- Creatinine (PrCr) Urinary Dipstick Test. A Case Study of Selected Facilities in Two Regions
Approval Date	9th February, 2022
Expiry Date	8th February, 2023
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
Dr. James Akazili
(Head, Ethics & Research Management Department)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra