SCHOOL OF PUBLIC HEALTH
COLLEGE OF HEALTH SCIENCES
UNIVERSITY OF GHANA

PERCEPTION AND EXPERIENCE WITH GENERIC MEDICINES SUBSTITUTION AMONG PATIENTS WITH HYPERTENSION AT THE KORLE BU TEACHING HOSPITAL

BY

MARILYN AKOLGO
10703526

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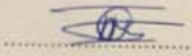
DECLARATION

I, Akolgo Marilyn declare that apart from references to other people's works which have been duly acknowledged, this desertion was written independently by me under supervision and has not been submitted for the award of any degree in any institution.

2nd August, 2021

MARILYN AKOLGO
(10703526)

DATE



02/08/2021

DR. IRENE KRETCHY
(SUPERVISOR)

DATE

DEDICATION

I dedicate this research work to God almighty for meeting the needs of this work at every stage of it.

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I dedicate this research work to God almighty for meeting the needs of this work at every stage of it.

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I thank the almighty God for providing me with the grace for me to come this far with this dissertation.

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LIST OF ABBREVIATIONS

ACA	American Cardiology Association
AHA	American Heart Association
AHM	Anti-hypertensive medicine
BMQ	Belief about Medicines Questionnaire
BP	Blood pressure
DBP	Diastolic blood pressure
HPT	Hypertension
SBP	Systolic Blood Pressure

ABSTRACT

Background: Generic medicines are essential for their economic value for both government reimbursement and patient medicine expenditure. Generic substitution is mostly met by suspicion sometimes by patients with concerns about effectiveness or side effects.

Objective: This study sought to investigate beliefs, perceptions and experiences about generic substitution and the impact on medication adherence.

Methods: A cross-sectional study was conducted among 351 patients with hypertension aged 18 years and above at the Korle Bu Teaching Hospital using a mixed-method study design with the qualitative aspect being conducted among 17 participants. The quantitative data were analyzed using STATA version 15. Data from the qualitative study were coded and analyzed thematically.

Results: Most patients were aged between 60-79 years, taking 2 antihypertensive medications and had hypertension for more than10years. About a third of the participants did not experience side effects at the time of data collection and considered information received about generic substitution sufficient. The majority of the participants had positive views about generic medicines. Receiving sufficient information about generic substitution correlated significantly with adherence ($p=0.022$). Most (51.8%) of the patients believed they should take part in deciding between generic or originator medicines. Significant associations between this statement and the educational level ($p<0.05$), income level ($p<0.001$), valid insurance coverage ($p<0.05$) and the presence of other diseases ($p<0.05$) were observed. The majority (82.3%) did not mind generic substitution with a local or imported generic as long as it was effective. The predetermined categories for the qualitative data analysis were along the following themes: awareness of generic substitution, the effectiveness of generic substitution and generic substitution in relation to adherence,

Participants in the qualitative study narrated that generic substitution did not challenge their adherence but their only concern is about the experience of new side effects that could occur after generic substitution.

Conclusion: This study showed patient satisfaction with information about substitution was generally an important factor in medication adherence but concerns about the incidence of new side effects with the practice were highlighted. Moreover, patients had positive views about generic medicines being efficacious and viewed as non-threatening to safety and adherence. This information gathered from patients is essential for healthcare professionals to shape their interactions with patients with regards to their drug management when generic switching is required.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The WHO defines a generic product as ''a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights''(Shargel, & Kanfer, 2014). Generic substitution is a process usually initiated by the pharmacist by which a different brand or unbranded product is dispensed instead of the branded drug the physician prescribes. This means the same chemical component with the same dosage and form from a particular company is interchanged with one marketed by a different company (Roberts et al., 1987). Generic medicines make up more than 65% of the pharmaceutical market worldwide and are responsible for 66% of prescriptions dispensed in the United States (Shrank et al, 2009) while 62.6 % were prescribed by their generic names in a study conducted in Ghana (Afriyie, 2014). It is a very common practice in Ghana for prescribed medicines to be substituted mostly by a pharmacist and sometimes upon request by the prescriber or patient.

Although generic drugs are expected to be identical, knowledge, attitude and experience with generic drugs and generic substitution could influence adherence in patients with hypertension. Kesselheim et al demonstrated in two different studies, the negative effect of changes in tablets colours and forms on adherence among epileptic patients and in post-myocardial infarction (MI) patients in the subsequent study (MI) patients (Kesselheim et al., 2013). This should be a concern for patients with hypertension since poor compliance to antihypertensive medicines prescribed is an important contributor to suboptimal blood pressure control (Gupta et al, 2010) and a considerable proportion of CVD events (9% in

Europe) could be linked to non-adherence to antihypertensive drugs (Chowdhury et al., 2013).

Prevalence of nonadherence to hypertensive drugs in Ghana has been reported to be from about 58.6 to 93.25% (Kretchy et al, 2014; Obirikorang et al., 2018). Non-adherence decreases the effectiveness of drugs and causes a significant challenge in reaching controlled blood pressure levels (Bosworth et al., 2011). Many of the factors affecting adherence are due to patients' lack of understanding of hypertension and its treatment, health-seeking behaviours and self-perceived beliefs on hypertension and antihypertensive medication (Olowookere et al., 2015)). Their beliefs about treatment therapies are especially in relation to the necessity of medication, the side effects of the drug and fear of complications (Aikens & Piette, 2009). There are limited studies that have explored the influence of perception and experience of generic medicines on adherence. Generic substitution could potentially have a negative effect on medication adherence due to suspicions and misconceptions, including lack of clarity about them being fake (Håkonsen & Toverud, 2011). There is no similar study in Ghana and therefore it is necessary to explore the influence of perception and experience with generic substitution on adherence especially among patients with hypertension because of the high nonadherence among this group.

1.2 Problem statement

The use of generic substitution is hugely being supported by government and health agencies but it is mostly viewed with mistrust by healthcare providers and consumers (Meredith, 2003). Generic medicines are mostly viewed as not comparable to brand medicines (Coney et al 2007) and factors which involve perceived substandard to standard manufacturing processes and poor patients' knowledge about generic medicines could be attributable reasons (Coney et al., 2007; King & Kanavos, 2002).

The right knowledge of generic medicines as being similar in quality, efficacy and safety as their originator counterparts together with clinical interchangeability are essential factors for generics to be acceptable. Unfavourable perception negative beliefs have been reported to be the main threats to patient acceptance and use of generic medicines (Dunne & Dunne, 2015; Frisk, Rydberg, Carlsten, & Ekedahl, 2011; Hassali et al, 2009; Heikkilä et al, 2007). In Finland, for example, there was a gap (77% versus 66%) between consumers that approved the switching of generic medicines and those who rejected the generics with regards to their disapproval of safety of drugs that are generics again, considering participants' favourable views with respect to the effectiveness of generic drugs, a disparity (66% against 43%) was observed (Heikkilä et al., 2007).

In South Africa, a qualitative study conducted to examine the knowledge of consumers regarding medicines quality and their use of generic medicines showed that respondents had poor knowledge regarding generic drugs and believed that their quality is substandard, with some consumers even referring to them as "fake" medicines, principally due of their lower cost or due to some of them being offered by the government health facilities at no cost to them (Patel et al., 2010). An approval and direction from the prescriber were a principal factor in the acceptance of generic substitution. On the other hand, the recommendations by the pharmacist or drug dispensers had a minimal influence on generic substitution acceptance by patients (Patel et al., 2010).

The standard treatment guidelines of Ghana and the National Health Insurance Authourity recommends the prescription of medicines by generic names. This provides the freedom of choice between the numerous generic brands available in the Ghanaian pharmaceutical market. Therefore, it is not uncommon that consumers of medicines are faced with the decision of accepting generic substitution of their medicines and particularly for patients with hypertension who have their drugs refilled routinely on a monthly or more basis.

There is a need to assess patients' perception and experience of generics medicines substitution among patients with hypertension in Ghana. The need to examine the implication of these factors on adherence to antihypertensive therapy is also essential because generic substitution may lead to adherence problems due to changes in physical appearance such as the colour of tablets or packaging and shape of the medicine. This may consequently result in the development of complications such as stroke, renal failure and heart failure.

This study seeks to examine the views about generic medicines, perception and experience with generic medicine substitution among patients with hypertension in Korle Bu Teaching hospital and their influence on adherence.

1.3 Justification

There are several studies about patient perception about generic medicines in other parts of the world but very sparse studies in Africa and a published study in Ghana is not available currently. Despite several studies to explain the reasons for non-adherence to medications among patients with hypertension in Ghana, the influence of the perception of generic medicines substitution has not been given attention in Ghana and it is, therefore, essential for assessment of this factor to aid of generic substitution practice and the enhancement adherence to hypertensive medications among patients.

This study seeks to provide information about the knowledge that patients with hypertension have about generic medicines, their attitude and experience with generic substitution and how these influence medication adherences. This study will provide information about patient perception and experience of generic medicines substitution as the end-user of generic medicines which is a major factor in shaping generic substitution practice and improve their adherence to their hypertensive medicines. Healthcare professionals with an

understanding of the perception and experiences patients have about generic medicines substitution will be encouraged to give some education about generic medicines in their interactions with patients.

1.4 Research questions

This study sought to answer the following questions:

1. What are the beliefs about generic medicines among patients with hypertension?
2. What is the perception of generic medicine substitution among hypertensive patients?
3. What is the relationship of beliefs about generics and medication adherence?
4. What experience have they had with generic medicines substitution in relation to adherence?

1.5 Study objectives

1.5.1 General objective

The general aim of this study was to assess the perception and experiences of generic medicines substitution among patients with hypertension and the relationship with antihypertensive drug adherence.

1.5.2 Specific objective

The specific objectives of this study were:

1. To assess beliefs about generic medicines among patients with hypertension.
2. To examine the perception of generic medicines substitution among hypertensive patients
3. To investigate the relationship of beliefs about generic medicines, perception about generic substitution and adherence

4. To explore the experience of patients with generic medicines substitution in relation to adherence

1.6 Conceptual framework

Apart from the sociodemographic characteristics of an individual that has been found to influence adherence to medicines, several other factors such as perception (belief) and experience influence an individual's adherence to medication.

The construction of the conceptual framework for this study is adopted from the ABC model which suggests that an attitude towards an object is influenced by three (3) elements: affect, behaviour and cognition (Jain, 2014; van den Berg et al, 2006). The affective component denotes the emotional response (liking/disliking) towards an object or event. The behavioural component involves a person's response (favourable/unfavourable) to do something regarding an object or event. The cognitive component is an evaluation of the entity that constitutes an individual's opinion or attitude (belief/disbelief) about the object. Using this model, patients' adherence to their antihypertensive medicines could potentially be influenced by a combination of their beliefs (cognition) about generic medicines or generic substitution which could directly result in a favourable or unfavourable behaviour (perception) towards generic medicines or generics substitution and consequently their feelings (experience) with regards to the process of generic substitution and effectiveness the different generic brands.

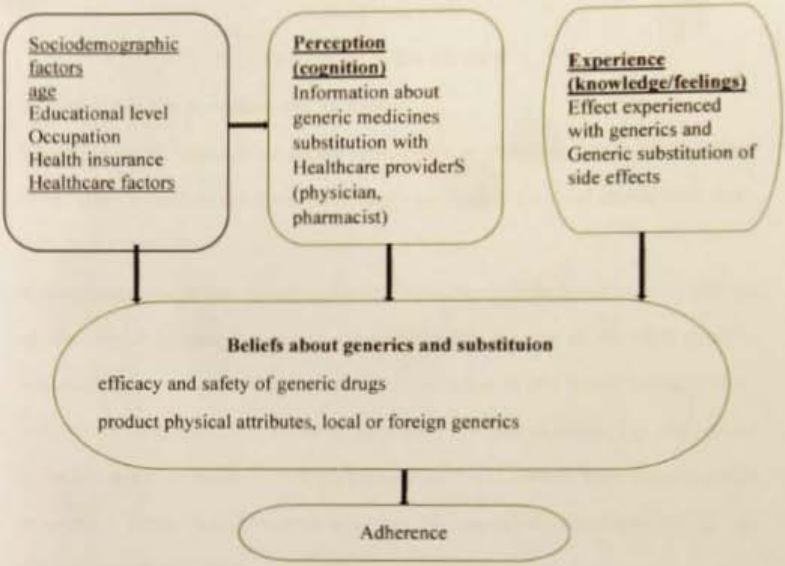

Figure 1.1: Conceptual framework for generic substitution and adherence

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Definition of hypertension and its burden

The World Health Organization defines hypertension as a condition where blood pressure (BP) , which is the force exerted by circulating blood against the blood arteries of the body, is too high (WHO, 2019).

It is represented with two numbers: the first being the systolic blood pressure (the top number) which indicates how much pressure blood is exerting on the walls during a heartbeat and the second being the diastolic blood pressure (the bottom number) which indicates the force exerted on the artery walls while the heart is resting. The diagnosis of hypertension is when both systolic blood pressure (SBP) and diastolic blood pressure (DBP) measured is greater than 140mmHg and 90mmHg respectively (140/90mmHg) on two different days (WHO, 2019).

The standard treatment guideline used in Ghana defines hypertension as a condition where the blood pressure of an adult is consistently higher than 140/90 mmHg in persons without non-diabetes or above 130/80 mmHg in individuals with diabetes, relying on the mean of two or more correctly measured blood pressure readings (MOH, 2017).

Hypertension is usually called a silent killer because it does not have any signs and symptoms accompanying it in most cases but in some cases, people experience headaches, nosebleeds, dizziness, palpitations. Severe hypertension is accompanied by symptoms such as tiredness, nausea, vomiting, confusion, nervousness, chest pain, and muscle tremors (Zampaglione et al, 1996).

Hypertension results from modifiable causes such as unhealthy diets (excessive consumption of foods containing high sodium content, saturated fats, trans fats, inadequate consumption of fruits and vegetables), lack of exercise, tobacco and alcohol intake, and

obesity (Mayega et al., 2012; Pilakkadavath & Shaffi, 2016). Non-modifiable risk factors include a family history of hypertension (Ranasinghe et al Cooray, 2015), sex (Doumas et al., 2013), ethnicity (being black) (Hertz et al., 2005), increasing age (over 65 years) (Vokonas et al., 1988) and co-morbid diseases such as diabetes or kidney disease (Tsimihodimos et al, 2018)

Uncontrolled hypertension can result in adverse consequences such as stroke, heart attack, heart failure and kidney damage (Wang et al., 2016).

2.1.1 Hypertension-a global epidemic

About 1.13 billion people have been estimated to have hypertension worldwide and about two-thirds live in middle-income countries (WHO, 2019). One in four men and one in five (5) women had hypertension in 2015 and fewer than that have uncontrolled hypertension (WHO ,2019). It is estimated that 25% of the adult population globally have BP >140/90 mm Hg, a total of 972 million people, with the developed countries of North America and Europe contributing to the highest prevalence (Kearney et al., 2005). The global prevalence of hypertension has been suggested to increase by 9% in men and 13% in women, to 29% of the population, and the overall number of adults with hypertensive to increase by 60% to 1.56 billion by 2025 (Kearney et al., 2005).

Generally, hypertension is most common among blacks, with an estimated prevalence of 59% and 56% in black men and women, respectively. White, Asian, and Hispanic men have a prevalence of 47%, 45%, and 44%, respectively and white, Asian, and Hispanic women have an estimated prevalence of 41%, 36%, and 42%, respectively (Whelton 2018). The highest proportion of this rise is predicted to occur in economically developing countries, with Asia and Africa contributing to 75% of those people in the future (Kearney et al., 2005).

In addition to the increased burden of hypertension in developing countries, the increased progression of the heightened risks evident in regions such as sub-Saharan Africa and South Asia is shown by the fact that hypertension changed from the fourth leading risk factor in 1990 to the first position in 2010 (Pencegahan Rasuah Malaysia et al., 2014).

Hypertension has consistently topped the outpatient department attendance from 2011 to 2014 in Ghana (Nonvignon et al., 2018). Cardiovascular diseases are the leading cause of non-communicable disease mortality with about 35,000 deaths or 15% of the overall mortality (Nonvignon et al., 2018).

2.2 Management of hypertension

The treatment of hypertension includes both pharmacological and non-pharmacological strategies. Non-pharmacological treatment includes dietary and increased physical activity is recommended for all patients (de Lima et al., 2013; WHO,2019)

2.2.1 Non-pharmacological management of hypertension

The corrections of the dietary imbalance, physical inactivity, and consumption of excess alcohol that results in high BP is the most essential strategy to avoiding and management of high BP and achieved with or without pharmaceutical therapy (Whelton et al., 2004). Nonpharmacological management only is particularly beneficial for the prevention of hypertension and also elevated BP in adults, and high BP management in adults with mild hypertension (Whelton et al., 1998). The most important interventions being weight loss (Neter et al., 2003), the DASH (Dietary Approaches to Stop Hypertension) diet (Blumenthal et al., 2010; England et al., 1997; Sacks et al., 2001), sodium reduction (Mozaffarian et al., 2014; Whelton et al., 1998), potassium supplementation (Aburto et al., 2013; Whelton,

1997), increased physical activity (Cornelissen & Smart, 2013), and a decreased intake of alcohol l(Roerecke et al., 2017; Xin et al., 2001)

2.2.2 Pharmacological management

Antihypertensive pharmacotherapy is propelled by the development of many medicines' classes for hypertension and large-scale outcomes trials providing evidence of their value on cardiovascular disease morbidity and mortality (Ettehad et al., 2016). Physicians have a variety of antihypertensive medications of various drug groups which can be formulated as a single or fixed-dose combination to choose from. Generally, pharmacotherapy for hypertension starts with first-line antihypertensive medicines as a non-drug therapy or by combining the different classes (Garjón et al., 2017). Combination management may be desirable in patients with pretreatment BP this is in the higher levels. Antihypertensive medicines used for first-line management consist of angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, dihydropyridine calcium channel blockers, and thiazide diuretics (Guo & Hu, 2014). Patients with heart failure and decreased left ventricular ejection fraction or post-myocardial infarction also benefit from the beta-blockers. Some guidelines have given recommendations with beta blockers as first-line antihypertensive medications (de Lima et al., 2013; McCormack, Krause, & O'Flynn, 2012). The choice relies on the efficacy and tolerability of the individual medication. It has been recommended that calcium channel blockers and diuretics may be the first line in blacks and ethnicity correlates with the response to antihypertensive medicine (Flack et al., 2010; James et al., 2010)

In the pharmaceutical market, one type of medicine becomes available as different brands from more than one pharmaceutical company either than the innovator company that discovered it as a result of the expiry of the patent of the innovator company. Drugs from

the innovator company are referred to as innovator brands while copies of the same medicines made by other companies are called generic brands.

2.2.2.1 Generics and branded medicines

Medicines generally employed in the management of illnesses are developed and manufactured by pharmaceutical companies. The development process starts from initially discovering the active ingredient (chemical compound) to a product approved for marketing by a regulatory body. The other stages in between discovery and approval include preclinical research (labouratory and animal testing) and clinical research (clinical trials) (Rousseaux & Bracken, 2013). Innovator drugs or brands are drug products manufactured by the pharmaceutical company that developed the product from discovery through to clinical trials and its usually awarded a patent for up to 20 years while generic drugs with the same compound that are manufactured and sold after the expiration of the patent without the trouble of labouratory and clinical trials (Morrison, 1990). Generic medicines refer to products marketed under the international nonproprietary names ("unbranded" generics) or with a brand name by a pharmaceutical company that is not the originator and without a license from the originator (usually referred "branded" generics). Branded generics are sold widely and consist of the highest proportion of generic medicines in many lower and middle-income countries (LMICs) (Kaplan et al, 2016).

WHO describes a generic medicine as "a pharmaceutical product, generally meant to be an equivalent to an innovator product which is produced without a license from the innovator company and sold after the expiration date of the patent or other exclusive rights" (Shargel & Kanfer, 2014). The Food and Drug Administration (FDA) in the USA has indicated that "A generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use"

(Shah, 2013). Lastly, the European Medicines Agency (EMA) which is the main regulatory body for pharmaceuticals in the European Union, considers a generic medic as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies".

The use of generic pharmaceutical products consists of over half of the total quantity of pharmaceutical products consumed globally but contributes 18 % of the overall cost of the pharmaceutical market. There are variations in the proportions according to the region and country, but the distribution of generic pharmaceutical products is usually greater than their innovator counterparts in many regions, making it one of the most consumed healthcare products globally (Gorokhovich & Shankar, 2013).

Generic medicines can cost up to 90%less than their equivalent innovator brands according to some studies that were conducted in the European markets (Shafie & Hassali, 2008; Simoens & De Coster, 2006). Studies on the cost of medicine in lower and middle-income countries (LMICs) have found high prices for originator medicines in many settings, mostly 2 to 5 times greater than cheapest-priced generic medicines (Cameron et al., 2009). They are therefore economically important for governments and other third-party reimbursements since they reduce drug budgets. Most governments around the world have instituted policies that encourage the prescription and substitution of generic drugs (Godman et al., 2010; Sermet et al., 2010). This has led to the decrease in out-of-pocket payments for medication through generic substitution and the increase in medication adherence which has been effectively demonstrated in some studies (Briesacher et al., 2009; Gagne et al., 2014; Hershman et al., 2014).

On the other hand, generic substitution may have negative effects on adherence due to misconceptions that innovator brands are superior to generics and therefore casting doubts on the effectiveness of generics (William H et al., 2009).

2.2.2.2 Adherence to antihypertensives

Adherence is the degree to which an individual is following instructions in taking medication, following diet and/or lifestyle changes from a health care provider (Sabaté, 2003). Poor adherence reduces the therapeutic effects of essential medications and has been shown as a significant barrier in reaching better patient outcomes (Bosworth et al., 2011; Cutler, David M, 2010). Clinical trials have provided evidence that the management of mild-to-moderate hypertension can decrease the risk of stroke by 30 to 43% (Collins & MacMahon, 1994; Peart et al., 1992; Singer, 1992) and of myocardial infarction by 15% (Peterson et al., 1995). Other adverse complications of uncontrolled hypertension can also be avoided or reduced by effective treatment. Examples of the benefits of treatment include a decrease in the risk of cardiac failure, dementia (Peterson et al., 1995), maintaining the function of the kidneys and avoiding blindness in patients with diabetes and hypertension (Bergström, Alvestrand et al., 1986; Holman et al., 1998). Non-adherence is the ultimate factor associated with uncontrolled blood pressure.

Generic substitution can potentially interrupt a patient's medication plan and affect adherence (Håkonsen & Toverud, 2011; Thiebaud et al., 2005) which can influence clinical and safety outcomes and costs of management overall (Ansell, 2008; Sabaté, 2003). One of the central issues is that generic medicines usually come with different names, sizes, shapes, colours, tastes, smells, and packaging from one another, and also their innovator counterpart, which can lead to worry, suspicion, and difficulty among certain patient populations and result in poor adherence (Desmarais et al., 2011). Subgroups of patients

who have been stabilised on a branded medicine for a long time, those managed for a serious or chronic disease, those with conditions without symptoms (hypertension), people being managed for psychological dysfunctions, those taking numerous drugs, and the older aged patients have less favourable attitudes toward generic substitution (Kesselheim et al., 2013).

2.2.2.3 Beliefs, perceptions and experience with generic medicines.

Patients' belief about treatment is a powerful influence on the need to adhere to the treatment. According to Baroletti and Dell'Orfano (2010), patients are more likely to adhere to therapy if they have a positive perception towards it. Patients already have their preformed beliefs about the disease and management (Robert Horne & Weinman, 1999) which impact patients' assessment of their medicines and their value (Benedetti et al., 2011) or adverse outcomes and their adherence to the treatment (Colloca & Benedetti, 2007). The consumers of medicines are the patients and therefore their awareness, perceptions and attitude regarding generic medicines and their interchangeability is important for their utilization and consequently their adherence.

According to Alrasheedy et al., (2014) many patients desire original innovator medicines to generic medicines in many countries around the world. A literature review was extensively conducted between the 1990 and 2013 in the databases of Scopus, PubMed, ISI Web of Knowledge, Proquest, and the Wiley online library for relevant original papers. Just 53 published studies were selected finally in the review, consisting of 24 studies from Europe, 10 from North America, 6 from Asia, 5 from Australia and New Zealand, 5 from the Middle East, 1 from Africa, 1 from Latin America, and 1 from the Caribbean region. The findings revealed that negative perceptions about generics were reported in almost all countries with some variations. A substantial percentage of patients reported challenges in the use of generics products due to the negative opinions (Alrasheedy et al., 2014).

A study that employed a qualitative method in western Australia conducted among the elderly (≥65yrs) about their perceptions about generic medicines revealed that many participants mistrusted them and considered them to be inferior compared to their counterpart innovator brand (Bulsara et al., 2010).

Another research in New York was conducted to assess the beliefs about generic drugs among the elderly (aged 65 years or more) who were covered by Medicare (insurance for adults that are older and incapacitated by the government of USA). This study employed an interview-based questionnaire and findings revealed that those who agreed that the safety of generic drugs is similar were 45.8%. Additionally, those who accepted that generic medicines are as effective as brand medicines were just 11.6%. Those that strongly or somewhat agreed that generic medicines cause more side effects than brand medicines were 46.6%. Factors such as race, lower educational status, lower-income level, Medicaid insurance coverage, poor health literacy and communications skills of physicians were correlated with negative beliefs and perceptions about generic medicines (Iosifescu et al., 2008).

In Auckland, Babar et al (2010) conducted a study to assess the perceptions, knowledge, and attitudes of consumers towards generic medicines. A statistically significant correlation was found between educational level, respondent ethnicity, age and knowledge of generic medicines. This research also found that 36.0% indicated that they were uncomfortable if the physical characteristics (colour and shape) of their medicine changed and 16.2% reported their health care professionals advised them to continue taking the same brand. This study also revealed that generic substitution was most likely accepted by respondents that had a greater awareness of generic drugs and participants with an educational level that is higher. The authors finalised that many of the respondents in their study had poor

knowledge about generic medicines (Babar et al., 2010). The perception of generic drugs and health professional's advice were the factors that mainly contributed to the approval of generic switching as well as the use of generic medications (Babar et al., 2010).

In Finland, one study that examined the experiences and opinions of customers that have refused generic substitution and those that have accepted generic substitution revealed that 28% of customers accepted and 72% of the consumers did not accept generic substitution (Heikkilä et al., 2007). The main factors for this were the cheapness and the fact that the pharmacist suggested generic medicine. The disagreement for substitution was because of positive experiences with previous drugs used and a preference to first have a discussion with their prescriber regarding the generic substitution. In a different study, 81% of the respondents viewed cheaper generics to be as effective as branded medications and 85% disagreed generic substitution was a risk to drug safety (Heikkilä et al., 2011). In both studies, males and participants aged less than 60 years were found to have a positive attitude toward the switching of generics.

Studies have also been conducted in Norway to examine consumer attitudes and experiences with generic substitution. A study authored by Kjønniksen et al (2006) revealed that 36% of the respondents indicated one or more negative experiences with generic substitution, for example, more intolerable side effects or a decreased therapeutic effect. A substantial 21% of the consumers claimed an overall negative experience with switching. The unpleasant experiences were not found to be associated with the age or gender of study participants or the number of drugs. Participants who were provided with information from their prescribers or the pharmacy regarding generic substitution accepted generic switching mostly (Kjoenniksen et al., 2006). A different study was with 174 Norwegian patients (50–80 years) who had had their branded antihypertensive drug substituted with a non-branded equivalent. Concerning the therapeutic effect, just 8% of the participants believed that the

substituted medicine had a different effect, and apart from one participant, they claimed a suboptimal effect after switching generics. About 15% of patients recounted they experienced new or more adverse events (Toverud et al., 2011)

Ibrahim et al (2012) carried out a research to assess patients' knowledge and perceptions of generic drugs in South Australia and found that about 67% scarcely demanded generic substitution at the community pharmacy in filling up their prescription medicines. A considerable proportion (47%) claimed they required greater education about generic medicines. Again, a meaningful (27.2%) said the healthcare professionals did not reveal the switching of generics to them. About half (52%) of the participants did not agree with the quality of generic medicines as poor and again, those who disapproved that the effectiveness of the brand medicines is better than their counterpart generics drugs were 49%. On the other hand, around half (53%) indicated they did not agree with generic drugs causing higher adverse events. Participants who supported the view that they prefer to consume medicines that are generic compared to those that are brand medicines were just 29.7% (Ibrahim et al., 2012).

A survey conducted in the USA to investigate views and generic drug information provided and the uptake of medicines that are generic among patients (n=2500) who were commercially insured found that, about a third of the respondents had the opinion that the value of generic drugs was better compared to original medications. Regardless of the fact showing recognition of generic medicines, participants who desired their personal consumption were only 37.6%. Only 29.9% of the patients supported the view that the effectiveness of brand medications is better than generic medicines. Again, with regards to communication with the health professional regarding drugs that are generic, about half (53.7%) of respondents indicated that the prescribers were silent or rarely made mention of generic medicines to them. On the other, respondents who claimed there was rare

communication about generics by the pharmacist were 52%. It was concluded that despite most patients have knowledge about the benefit together with the cost value of generic medicines, a small proportion is willing to accept medicines that are generic and therefore educational efforts that focus on the two factors potentially will be successful in advancing the use and acceptance of generic medicines (Shrank et al., 2009).

2.2.2.4 Perception of Generic medicines influence on adherence

Three studies were conducted in Norway to assess how generic substitution influences adherence. In the first study, personal interviews with 174 participants aged 50-80 years who had their brand name antihypertensive medicines switched to generics was examined using a semi structured questionnaire. One third of the patients reported that generic substitution caused a challenge with recalling to take their medicines every day (Håkonsen et al., 2009). In the second study, 83 Pakistani immigrants between the ages of 40 to 80 years who are taking medications for hypertension, diabetes and cholesterol were interviewed. Generic substitution was claimed to make it difficult to consistently take their medication and nonadherence was more frequent among patients who were not fluent in Norwegian and agreed to switch to generics in the pharmacy (Håkonsen & Toverud, 2011). The third research conducted in Oslo, Norway using a qualitative method interviewed 22 patients taking antihypertensive medications with an experience of consuming brand and switching to a generic at least once. The results showed that the majority of the participants did not adhere to their medicines. Some of them had negative opinions about the efficacy, quality and safety of generic medicines (Toverud et al., 2011). These studies revealed adverse effects of generic substitution on adherence.

A literature review of studies between the year 2000 and 2011 in Western countries with the objective to summarise the perspective of patients on generic substitution was conducted. A search was carried out in MEDLINE, Embase and SciVerse Scopus for peer reviewed and original articles published between 1 January 2000 and 1 March 2011. The study identified 20 studies for inclusion. The results of the study revealed that a simple fraction of the participants was not comfortable with generic substitution and lack of knowledge about generic substitution decreased the patient's ability to comply with their medications. The conclusion of this investigation was that, suboptimal adherence maybe a result of the adverse experiences with generic substitution among majority of the patients (Håkonsen & Toverud, 2012)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

A cross-sectional mixed-methods study was conducted using quantitative and qualitative approaches, a structured questionnaire was used to gather information on demographic characteristics, beliefs, perceptions, previous experience about generic medicines substitution and adherence among patients with hypertension at the outpatient department of the Korle Bu Teaching Hospital (KBTH).

In-depth interviews using a semi-structured guide were also used to explore the experiences of generic substitution and implication on adherence.

This mixed method study design was employed to provide a comprehensive evaluation of the problem. The quantitative study will provide numerical quantification of attitudes and beliefs. The qualitative study explores the narratives of their experiences which provides information that triangulate quantitative data and uncover underlying reasons that cannot be captured by the quantitative evaluation.

3.2 Study area

The study was carried out in the outpatient medical department and the polyclinic of the KBTH. The KBTH is the premier and largest teaching hospital in Ghana located in the Accra Metropolitan District of the Greater Accra Region. It is the only tertiary hospital in the southernmost part of Ghana which serves the people of Accra, and surrounding regions in the southern parts of Ghana. It has an estimated annual outpatient attendance of up to 72,371 patients and a daily attendance averaging 200 patients a day (Korle Bu Teaching Hospital, 2012).

3.3 Study population

Participants aged 18 years or more and diagnosed with hypertension and attending the outpatient departments of the KBTH were sampled for this study.

Inclusion criteria

Ghanaian male and female patients diagnosed as hypertensive only or hypertensive with other comorbid conditions who were 18years and above, and reporting for treatment at KBTH were selected. Patients who have been taking antihypertensive drugs for at least six (6) months with a prescription of at least one antihypertensive medication.

Exclusion criteria

Mentally challenged persons and incapacitated people were excluded from this study.

3.4 Sample size

The sample size for the quantitative study was determined using the Cochran formula (1967) which was calculated as follows.

The sample size was determined using the formula: $N=\frac{Z^2P(1-P)}{D^2}$

Where

N = sample size

P = assumed prevalence of compliance

D = significant level at 95% confidence interval

Z= Z value on the z table at the chosen alpha level of 0.05 which is 1.96

The sample size was estimated using the prevalence of adherence. Using a reported prevalence of 33.3% in Ghana and Nigeria (Boima et al., 2015) and a margin of error of 5% and at a 95% confidence level, the minimum sample size was calculated as follows:

- $N=\frac{Z^2P(1-P)}{D^2}=\frac{1.96\times2\times0.333(1-0.333)}{0.05\times2}=351$

- Assuming a 10% non-response rate
- N= 351 ×1.1= 386

A total of 351 respondents were included in this study.

A total of 17 participants selected from the sample recruited for the quantitative study and in-depth interviews were conducted for the qualitative study. **The same sample was used for the qualitative study because this is relevant for the purpose of triangulation of data (Sandelowski, 2000).**

3.5 Sampling procedure

With the help of the nurses, a daily attendance list was generated using the folder numbers of hypertensive patients reporting at the OPD. Using the inclusion and exclusion criteria as a guide, a sampling frame was obtained from the list of patients who presented on the day and selection from the frame by systematic random sampling.

Purposive sampling was used to select respondents from the quantitative study participants for the qualitative study.

3.6 Data collection method

3.6.1 Data collection tools

A structured questionnaire constructed under an iterative manner and pretested for comprehensiveness was used. The questionnaire was pretested at the University of Ghana Hospital in Legon. The questionnaire had a total of 30 items organised into four sections with 5 items for the beliefs about generic medicines, 9 items for perception about generic substitution and 5 items about medication adherence.

Section A covered respondents' socio-demographic characteristics such as age, educational level, income bracket and medical characteristics such as duration of hypertension,

comorbidities, current medication, number of medications (see appendix 2). To ensure participants were clear about the meaning of the originator brands and generics, the definitions and some pictures of original and common generics brands on the market were included in the relevant sections. Section B focused on beliefs about generic medicines which was adapted from the belief about generic medicines scale developed by Figueiras et al (2009) to assess lay beliefs about generic medicines by identifying the type of core beliefs which are linked to the use of generic medicines. The generated scale assessed the efficacy of generic medicines. The belief about generic medicines scale response was scored on a 5-point Likert scale (1=strongly agree, 2=agree, 3=neutral, 4=disagree and 5=strongly disagree) and scores were calculated by averaging respondents' answers to the five questions. Total scores were created by the addition of responses to each other (range, 5-25). To rate the scale in the same direction some items were reversed (items 5,3,2). Higher scores indicate negative beliefs. The scale was assessed for internal reliability using Cronbach's alpha with a resultant coefficient of 0.75.

Section C covered perception about generic medicines substitution. This evaluated their views regarding communication about generic substitution and preferences. Responses are framed as a five-point Likert scale (1=strongly agree, 2=agree, 3=neutral, 4=disagree and 5=strongly disagree). Perception about generic substitution was considered as favourable (1 and 2), unsure (3) and unfavourable (4 and 5) for the scores. How was the scale scored and what is the categorization?

Section D covered medication adherence and measured using the Medication Adherence Report Scale 5 (MARS 5) which was developed by (Horne & Weinman, 2002) and a Cronbach's alpha of 0.748 for this study was determined. Participants rated their frequency with which they engaged with each of the five-item adherence related behaviours namely; 'forgetting', 'changing dosage', 'stopping', 'skipping' and 'taking medication less than

prescribed' on a five-point Likert scale (where 5 = never, 4 = rarely, 3 = sometimes, 2 = often and 1 = 'always) (see Appendix 4). Scores for each item was aggregated to give a final score ranging from 5-25. Higher scores representing high extent adherence (Brandstetter et al., 2017; Chan et al., 2019). Scores were categorized into 3 groups as low adherence (<15), moderate adherence (>15-24) and high adherence (25).

The patients' medications were reviewed for current medications and patients were encouraged to show their current medications to the interviewer. The day's blood pressure reading was also recorded.

A semi-structured interview guide (see appendix 4) was used for the qualitative study and it covered the following themes; participants' perception of their drug adherence, participants' experience about generic substitution and the potential influence of generic substitution on their drug adherence.

3.6.2 Data Collection Technique

Data were collected through researcher-administered patient interviews using a structured questionnaire for the quantitative study. A social distancing protocol of at least 2 meters apart between participant and researcher was ensured. The areas where interviews took place were regularly cleaned and disinfected with soap and 70% alcohol. The wearing of facemasks and regular use of sanitiser and handwashing by the research team and participants were strictly followed. The time to complete a questionnaire was about thirty (30) minutes to one (1) hour.

To reduce face to face interaction as a result of concerns with the season of the COVID 19 pandemic, the phone numbers of participants were collected, and interviews of participants were carried out on phone by the researcher using a semi-structured interview guide with the aid of an audio recorder and a notebook. Participants were informed about the audio

taping of responses for transcription purposes and to aid in checking for the accuracy of responses captured. The time lasted between thirty (30) to forty-five (45) minutes.

3.6.3 Data Processing and Analysis

Questionnaires for the quantitative study were pre-coded and double entered into excel by two different data entry personnel to reduce errors. Data cleaning was carried out and imported into STATA version 15. Participants' sociodemographic and medical characteristics were summarized using descriptive statistics with frequencies and percentages for categorical variables and means for continuous variables and presented as means and standard deviations for normally distributed data.

Univariate and multivariate analysis was used to explore the association between independent factors and outcome variables. Chi-square test of independence was conducted to test for association between the categorical independent variables and outcome variables. Logistic regression was conducted to evaluate the relationship between predictor variables and medication adherence. All statistical tests were done at a 5% significance level.

Data for in-depth interviews were recorded and transcribed verbatim. The analysis was done line by line for content according to predetermined categories; communication about generic medicines, effectiveness of generic medicines, generic substitution in relation to adherence. Data was manually entered into Microsoft Word and Excel. Codes were generated to get a better overview of the information collected. The initial codes were reviewed and organized into the predetermined themes by the principal researcher and an assistant to produce the final report.

3.7 Ethical Considerations

Ethical clearance was sought from the Korle Bu Teaching Hospital Institutional Review Board (RBTH-IR-B/00051/2020) before the commencement of the data collection. Participation in the study was strictly voluntary. Participants reserved the right to withdraw from the study at any point during the study. Information about the study was provided to participants and their questions were adequately addressed. Informed consent was sought from persons who agreed to participate by signing a written consent form before proceeding with the research process. The contact details of the investigator and administrator of the Ethical Review Board of the Korle Bu Teaching Hospital was made available to participants in case they needed to make further enquiries. A copy of a signed consent form was given to the participant and the other kept for future reference by the researcher. Participants were assured of the confidentiality of the information they provided since no name identification was included in the questionnaire. The participants were not identified by name on the questionnaire, interview transcript or any report generated. A code was assigned to participants and the list linking participant identification to codes was stored differently from coded project documents. All data collected were stored electronically under password protection which was changed routinely to ensure security. Hard copies were only accessible by the principal investigator by placing them under lock and key in a restricted room.

The risks involved in this study were minimal with probable psychological discomfort from recounting experiences. There was no monetary compensation for the participants. The principal investigator had no conflicts of interest in the conduct of this study.

3.8 Quality Control

Research assistants with the relevant background and motivation were trained in administering the questionnaires. Financial and material motivation was ensured for

improved working relationships. Recorders were checked for proper functioning a day before every data collection day. The objectives of the study were explained to the researched assistance and they were cautioned to ensure confidentiality throughout the study. The questionnaires were double-checked for completeness as they are received. Where the research assistants needed more training, it was done before the day of data collection. The data collected were entered twice into Windows Excel to reduce errors in the data entry process. Participants were given codes to avoid double inclusion.

CHAPTER FOUR

4.0 RESULTS

INTRODUCTION

4.1 Sociodemographic and medical characteristics of participants

A total of 351 participants were interviewed for the quantitative study. Table 1 shows the sociodemographic and medical characteristics of the respondents.

The majority of the participants were between the ages 60-79, were female (79.6%), had basic education (37.6%) and fell within the income brackets of GHC 500-999.00 (39.3%). Most of the participants had valid health insurance (97%), had a duration of hypertension >10years (33.3%) and were on two hypertensive medicines (72%). A considerable proportion had no additional chronic disease (45%) and experienced side effects (27%).

Table 4.1a sociodemographic characteristics of participants

	No.	%
Age group (in years)		
18-39	7	2
40-59	133	37.9
60-79	191	54.4
80+	20	5.7
Total	351	100
Gender		
Female	269	76.6
Male	82	23.4
Total	351	100
Educational Level		
None	42	12
Basic	132	37.6
Secondary	130	37
Tertiary	47	13.4
Total	351	100
Income (GhC)		
<500	104	29.6
500-999	138	39.3
1000-2999	91	25.9
>GHC3000	18	5.1
Total	351	100
Health insurance coverage		
No	10	2.8
Yes	341	97.2
Total	351	100
Duration of hypertension		
6mths-1yr	51	14.5
1-5yrs	111	31.6
6-10yrs	72	20.5
>10yrs	117	33.3
Total	351	100
Number of antihypertensives		
One	135	38.5
Two	176	50.1
Three or more	40	11.4
Total	351	100

Table 4.1b Medical characteristics of participants

	No	%
Other chronic diseases		
None	159	45.3
Diabetes mellitus	108	30.8
Hypercholesterolaemia	73	20.8
Asthma	6	1.7
Other (lumbago,prostate disease)	5	1.4
Total	351	100
Experience of side-effects		
No	256	72.9
yes	95	27.1
Total	351	100
Received sufficient information about generic substitution		
No	134	38.2
yes	217	61.8
Total	351	100

4.2 Belief about generics scale

Table 4.2 shows the frequency of response categories for each of the items used to assess beliefs about generic medicines. A majority (74.64%) reported favourable views about the efficacy of generics being the same as the originator medicines generics, while negative beliefs were found for the items: generics made with lower quality (53.85%) and generics being cheaper because they are less efficacious (66.95%). In contrast, 12.82% had negative beliefs about the efficacy of generic medicines while 16.24% had a positive belief that generics were cheaper because they were less efficacious.

Table 4.2 Reported beliefs about generic medicines

Items	Strongly agree n (%)	Somewhat agree n (%)	Not sure n (%)	Somewhat disagree n (%)	Strongly disagree n (%)	Cronbach's alpha	mean ±SD
The efficacy of generic medicines is the same as the originator medicines	158(45.0)	103(29.4)	45(12.8)	27(7.7)	18(5.1)	0.686	1.980±1.162
Generic medicines take longer time to be efficacious.	12(3.4)	38(10.8)	127(36.2)	109(31.0)	65(18.5)	0.662	3.507±1.022
Generic medicines are made with lower quality substances	17(4.8)	44(12.5)	102(29.1)	116(33.1)	72(20.5)	0.642	3.524±1.000
Generic medicines have better-quality control than originator medicines	2(0.6)	11(3.1)	204(58.1)	111(31.6)	23(6.6)	0.824	3.405±0.686
Generic medicines are cheaper because they are less efficacious	15(4.3)	42(11.8)	60(17.1)	157(44.8)	77(20.0)	0.633	3.684±1.074
						0.748	**3.210±0.474**

4.3 Perception of generic substitution

In assessing the patient's opinions on the preferred communication, about half disagreed predominantly that the physician should ask them about the generic preference (50.8%) (Table 4.3). There was a significant correlation (<0.001) between patients' educational level, income bracket and whether or not they should ask about their preference (see Table 4.4). As education or income increased, there was an increased preference to be consulted.

A considerable proportion (51.8%) agreed that they should have the option to choose between generic and originator (Table 4.3). A chi-square statistic found a significant correlation between the educational level ($p<0.05$), income level ($p<0.001$), valid insurance coverage ($p<0.05$), additional chronic disease ($p<0.05$) of the respondents and whether they should be given the option to choose between the generic and originator (see Table 4.4).

More than a third agreed that they did not mind substitution to an equivalent local one (82%) (Table 4.3).

About a third disagreed that generic substitution reduced their ability to take their medicines (74.6%).

Most patients (74.4%) believe that generic substitution was safe because the products were produced by reputable companies (Table 4.3). There was a significant relationship between the opinion that generic substitution is safe and educational status ($p<0.05$). Therefore, a patient with higher educational status tended to think that generic substitution was safe.

A greater proportion (74.6%) of the patients disagreed with the statement that their ability to take medicines is reduced by generic substitution (Table 4.3). A significant association ($p<0.05$) found between this view and educational level ($p<0.05$) and income level ($p<0.05$) (Table 4.4). As the educational level and income level increased, patients did view their ability to take medicines as recommended to be reduced by generic substitution.

A greater proportion (60.6%) of the respondents preferred generic substitution with the cheaper (see Table 4.3). A significant relationship with educational level ($p<0.05$), income bracket ($p<0.001$) and the presence of additional chronic disease was found with preference for cheaper generics($p<0.01$) (Table 4.4).

Barely half of the participants did not prefer generic replacement with expensive medicine because it is the best (54.2%) (Table 4.3). A relationship that was significantly correlated with income ($p<0.01$) and education ($p<0.001$) (Table 4.4).

Just about a half (51%) of the participants preferred generic substitution with locally produced generics (Table 4.3).

Education ($p<0.01$), income ($p<0.01$) and duration of hypertension ($p<0.05$) were found to be significantly related to adherence (Table 4.4).

Table 4.3 Distribution of perception about generic substitution

Items	Strongly agree n (%)	Somewhat agree n (%)	Not sure n (%)	Somewhat disagree n (%)	Strongly disagree n (%)	alpha	mean(std)
Physicians should ask patients about their preference for generic or originator	38(10.8)	65(18.5)	23(6.6)	89(25.4)	89(25.4)	0.663	3.627(1.426)
Patients should have the option of choosing between generic and originator	40(11.4)	81(23.1)	48(13.7)	81(23.1)	101(28.8)	0.663	3.348(1.396)
I don't mind generic substitution of medicine to an equivalent one that is locally produced as long it is effective	137(39.0)	152(43.3)	20(5.7)	28(8)	14(4.0)	0.669	1.946(1.06)
Generic substitution is safe because the products are produced by reputable manufacturers	59(16.8)	167(47.6)	82(23.4)	35(10.0)	8(2.3)	0.699	2.333(1.94)
Generic substitution reduces my ability to take my medicines as recommended	22(6.3)	24(6.8)	43(12.3)	119(33.9)	143(40.7)	0.338	3.960(1.8)
I prefer generic substitution with the cheapest medicine available for the treatment	103(29.3)	110(31.3)	28(8.0)	67(19.1)	43(12.3)	0.262	2.536(1.5)
I prefer generic substitution with a more expensive medicine because it is the best	51(14.5)	63(17.9)	47(13.4)	108(30.8)	82(23.4)	0.652	3.305(1.4)
I prefer generic substitution with locally produced medicines	61(17.4)	118(33.6)	91(25.9)	48(13.7)	33(9.4)	0.703	2.641(1.191)
I prefer generic substitution with an imported from the UK/US/GERMANY rather than local medicines	65(18.5)	99(28.2)	91(25.9)	50(14.2)	46(13.1)	0.721	2.752(1.278)

Overall	**0.702**	**2.939(0.462)**

Table 4.4: The statistically significant correlations using chi-square test between statements and each category of variables investigated.

ITEMS	Age	educational level	income bracket	valid national health insurance	duration of hypertension	Total number of medicines	other chronic diseases
Physicians should ask patients about their medicine preference	NS	32.64***	17.48***	NS	NS	NS	NS
Patients should have the option of choosing between generic and originator	NS	31.03*	36.25***	9.69*	NS	NS	31.28*
I don't mind generic substitution of medicine to an equivalent one that is locally produced as long it is effective	NS	NS	NS	NS	NS	NS	NS
Generic substitution is safe because the products are produced by reputable manufacturers	NS	21.7*	NS	NS	NS	NS	NS
Generic substitution reduces my ability to take my medicines as recommended	NS	NS	24.71*	9.98*	NS	NS	NS
I prefer generic substitution with the cheapest medicine available for the treatment	NS	23.05*	35.01***	NS	NS	NS	27.73*

I prefer generic substitution with a more expensive medicine because it is the best	NS	26.83**	49.98***	NS	NS	NS	NS
I prefer generic substitution with locally produced medicines	NS	NS	NS	NS	NS	NS	NS
I prefer generic substitution with imported generics from the UK/US/GERMANY rather than local medicines	NS	29.79**	26.73**	NS	21.93*	NS	NS

NS: not significant, *: P<0.05, **: p<0.01, ***: p<0.001

4.4 Adherence to antihypertensive medication

Summary description of adherence to antihypertensive medicines distribution can be seen as shown in Table 4.5. About 37.4% indicated that they forget to take the medicine while 37.89% sometimes.

Based on the patient report, about half (55%) of the respondents had high adherence to their medicines with an average score of 25 (Table 4.5).

Table 4.5: Frequency of distribution of the medication adherence report scale (MARS 5)

Question	Always	Often	Sometimes	Rarely	Never
	n (%)				
1.0 I take less than instructed	1(0.28)	1(0.28)	28(7.98)	28(7.98)	248(70.66)
2.0 I have stopped taking it for a while	4(1.14)	25(7.12)	101(28.77)	98(27.92)	123(35.04)
3.0 I miss out a dose	1(0.28)	1(0.28)	133(37.89)	102(29.06)	89(25.36)
4.0 I alter the dose	1(0.28)		27(7.69)	92(26.21)	231(65.81)
5.0 I forget to take it	3(0.85)	25(7.12)	130(37.04)	80(22.79)	113(32.19)

Adherence-Categorisation	n (%)
Low adherence	101(28.)
Moderate adherence	57(16.2
High adherence	193(55.)
Total	**351(100**

4.5 Factors related to adherence

The univariate analysis of sociodemographic factors that affect adherence found significant associations with age (p=0.036), gender (p=0.004) and income level (p=0.015) (Table 6a). The medical variables that were found to be significantly related to adherence were the duration of hypertension (p=0.009), and sufficient information about the generic substitution (p=0.010) (Table 6.6b). Beliefs about generic medicines did not show any significant relationship with adherence (Table 6.6b).

The adjusted multiple logistic regression model revealed that the duration of hypertension, gender, the presence of other chronic diseases and satisfaction with information with generic substitution were significantly associated with adherence (Table 6.6a & b). There was a doubling of the odds of adherence among males (aOR: 2.1.95%CI:1.2-3.6). Participants that with a ten (10) or more years duration hypertension had 80% decreased odds of adherence. Respondents that considered the information about generic substitution as sufficient had 70% increased odds of adherence. (Table 6.6a &b).

Table4.6 6a: Sociodemographic characteristics and adherence relationship

	Univariate						Multivariate	
	Low	Moderate	High					
	n (%)	n (%)	n (%)	Total	chi-square	p-value	aOR (95%CI)	P-value
Age group (in years)								
18-39	1(1.0)	1(1.8)	5(2.6)	7(2.0)			ref	
40-59	48(47.5)	26(45.6)	59(30.6)	133(37.9)			0.5(0.1-2.8)	0.432
60-79	50(49.5)	25(43.9)	116(60.1)	191(54.4)	13.495	0.036	1(0.2-5.3)	0.958
80+	2(2.0)	5(8.8)	13(6.7)	20(5.7)			2(0.3-13.5	0.498
Total	101(100)	57(100)	193(100)	351(100)				
Gender								
Female	87(86.1)	47(82.5)	135(69.9)	269(76.6)			Ref	
Male	14(13.9)	10(17.5)	58(30.1)	82(23.4)	10.994	0.004	2.1(1.2-3.6)	0.011
Total	101(100)	57(100)	193(100)	351(100)				
Education Level								
None	11(10.9)	6(10.5)	25(13.0)	42(12.0)				
Primary	50(49.5)	22(38.6)	60(31.1)	132(37.6)				
Secondary	31(30.7)	22(38.6)	77(39.9)	130(37)	10.507	0.105		
Tertiary	9(8.9)	7(12.3)	31(16.1)	47(13.4)				
Total	101(100)	57(100)	193(100)	351(100)				
Income (GhC)								
GHC < 500	37(36.6)	14(24.6)	53(27.5)	104(29.6)			Ref	
GHC 500-999	43(42.6)	20(35.1)	75(38.9)	138(39.3)			1.3(0.8-2.2)	0.275
GHC 1000-2999	17(16.8)	23(40.4)	51(26.4)	91(25.9)	15.722	0.015	1.5(0.8-2.9)	0.221
>GHC3000	4(4)	0(0.0)	14(7.3)	18(5.1)			3.1(0.8-11.5)	0.098
Total	101(100)	57(100)	193(100)	351(100)				

aOR: Adjusted Odd Ratio; CI: Confidence interval, ref=reference

Table 4.6b: Factors that are associated with adherence

	Univariate						Multivariate	
	Low	Moderate	High					
	n (%)	n (%)	n (%)	Total	chi-square	p-value	aOR(95%CI)	P-value
Valid Health insurance								
No	1(1.0)	2(3.5)	7(3.6)	10(2.8)				
Yes	100(99.0)	55(96.5)	186(96.4)	341(97.2)	1.773	0.412		
Total	101(100)	57(100)	193(100)	351(100)				
Total number of medicines								
1	17(16.8)	11(19.3)	35(18.1)	63(17.9)				
2-5	83(82.2)	46(80.7)	157(81.3)	286(81.5)				
>5	1(1.0)	0(0.0)	1(0.5)	2(0.6)	0.789	0.940		
Total	101(100)	57(100)	193(100)	351(100)				
Duration of hypertension								
6mths-1yr	8(7.9)	3(5.3)	40(20.7)	51(14.5)			Ref	
1-5yrs	41(40.6)	18(31.6)	52(26.9)	111(31.6)			0.2(0.1-0.5)	<0.001
6-10yrs	21(20.8)	12(21.1)	39(20.2)	72(20.5)	17.043	0.009	0.3(0.2-0.8)	0.010
>10yrs	31(30.7)	24(42.1)	62(32.1)	117(33.3)			0.2(0.2-0.8)	0.008
Total	101(100)	57(100)	193(100)	351(100)				
Number of antihypertensives								
One	37(36.6)	19(33.3)	79(40.9)	135(38.5)				
Two	57(56.4)	30(52.6)	89(46.1)	176(50.1)	4.803	0.308		
Three or more	7(6.9)	8(14.0)	25(13.0)	40(11.4)				
Total	101(100)	57(100)	193(100)	351(100)				
Other chronic diseases								
None	42(41.6)	29(50.9)	88(45.6)	159(45.3)			Ref	
diabetes mellitus	25(24.8)	14(24.6)	69(35.8)	108(30.8)			1.5(0.9-2.5)	0.104
Hypercholesterolaemia	30(29.7)	14(24.6)	29(15.0)	73(20.8)	14.949	0.060	0.5(0.3-0.9)	0.015
Asthma	3(3.0)	0(0.0)	3(1.6)	6(1.7)			0.6(0.1-3.3)	0.592
Other	1(1.0)	0(0.0)	4(2.1)	5(1.4)			2.1(0.2-20.1)	0.508

Total	101(100)	57(100)	193(100)	351(100)				
Experience of side-effects								
No	75(74.3)	42(73.7)	139(72.0)	256(72.9)				
yes	26(25.7)	15(26.3)	54(28.0)	95(27.1)	0.187	0.911		
Total	101(100)	57(100)	193(100)	351(100)				
Received sufficient information about generic substitution								
No	51(50.5)	18(31.6)	65(33.7)	134(38.2)			Ref	
yes	50(49.5)	39(68.4)	128(66.3)	217(61.8)	9.199	0.010	1.7(1.1-2.5)	0.022
Total	101(100)	57(100)	193(100)	351(100)				
Beliefs about generics								
negative	42(42.0)	21(36.8)	76(39.2)	137(39.6)				
Moderate	38(38.0)	27(47.4)	75(38.7)	140(39.9)	2.117	0.710		
High	20(20.0)	9(15.8)	43(22.1)	72(20.5)				
Total	100(100)	57(100)	194(100)	351(100)				

aOR: Adjusted Odd Ratio; CI: Confidence interval, Ref: reference

4.6 Experience of generic substitution and implication for adherence

Communication about generic substitution influence on adherence

Respondents generally reported that the pharmacy staff or prescribers were silent about the generic substitution. Patients who can read usually take notice of the drug name and recognize that it is the same medicine but from a different company.

> *"When I take the medicines after being served in the pharmacy, I notice it is the same medicine, amlodipine 5mg, and the same 5mg was also on the box I was taking previously"* (F, 62 years)

> *"I saw that... when I read the label, I could tell that the company had changed, the pharmacist or doctor didn't say anything"* (F, 55 years).

Others noticed changes in physical attributes of the medicines such as the change in colour of the packaging and only received the information from the pharmacy staff about the generic substitution when they inquired about the change.

> *"They don't explain it... so one time I asked the man I buy it from, and he told it is the same medication but from different companies" (M, 70 years)*

> *"the pharmacy people do not tell you anything if they serve you a different generic when I see the change in the box and I ask them that tell you that it is the same one but a different company"* (F, 70 years)

Effectiveness of generic medicines

The main descriptor of effectiveness was regarding side effects experienced by patients. They associated the effectiveness of the medicines with the absence of side effects. Terms used to describe the effectiveness was '*it works*" or "*no problems*".

Some of the participants recounted that the effectiveness of foreign and local products was similar in response to the questions about their views on the effectiveness of generics. They considered that the absence of side effects with these products meant they are similar.

> *"I have personally not noticed any difference in the effectiveness in my condition with the different generics where it is a local one or a UK one. I have taken denk brand and I can't say it better than the other local one like Ernest chemist one. I generally have not experienced side effects with medicines my medicines"* (F, 35 years)

> *"They are all work for me .... whatever they give me works well for me"* (F, 62 years)

A considerable number of respondents reported that they have had events where they have experienced new side effects when they received a different generic. The occurrence of such events described generally involved local generics.

> *"With the local one about 20 minutes or 30 minutes after taking it, I could hear my heartbeat and I would sit down for a while, other times too when I sleep or lay down, I could see the effect of the drug. it is okay with the foreign medicine"* (F, 42 years)

> *"I was taking apart from the headaches my heart would also be beating so fast and it wasn't changed for me so I had to go and buy the foreign one, it was recently that the woman at the hospital gave me a different one which does not cause my heart to beat fast and I don't experience any headaches"* (M, 69 years)

However, one patient narrated an experience of an intolerable side effect with a foreign generic that he procured as a substitute from a community pharmacy.

> *"I have taken the foreign ones before. They said that one was better, and it was what I bought and that evening after taking it my heart was just beating very fast, so I took dandelion and garlic"* (Male, 70 years)

Generic substitution in relation to adherence

Almost all of the respondents recounted that substituting their medicines did not affect how they took the medicines as prescribed. A considerable number of the participants reported occasions where they experienced unpleasant side effects when they received a different generic but continued to take them as prescribed. Other patients that experienced unbearable side effects reported back to the hospital or pharmacy to complain and made efforts to obtain the generic brand that they had experienced no side effects.

> *"There is no problem when the colour changes but the fact that it will not have any negative effects on you is what is important to us. The colour changes does not really matter, for instance if I am given red today and the next day, I am given blue, and the blue works just like the red then there will be no problem but if the blue gives complications, that is when I would complain".* (F, 54 years)

> *"When I first started, the one that was being given to me was a local one and when I took it... the same drug made my body feel rigid and I couldn't walk. So, I complained, and it was changed for me. that one is a foreign one and after I took it, I was okay..... So anytime I go anywhere I tell them I want a foreign amlodipine one".*
>
> *"Since the change was done and I have been taking the amlonova, I have not experienced any serious effects, or I don't see much change. If I had seen some side effects, I would have gone back to the doctor to tell him that this is giving me problems.... I don't know if it is possible to take once a week but since I started, I have always been given a daily dose, so I have been doing that."* (F,49 years)

However, just one respondent detailed an experience of terrible side effects of palpitations and severe body aches that caused her to stop taking her medicines for about one week.

> *"I stopped taking it after two days due to the problem of palpitations and fatigue for about a week. I later visited a private hospital where I was advised to buy a UK one and I have not experienced that with the imported one".* (F, 44 years)

CHAPTER FIVE

5.0 DISCUSSION

This study presents the quantitative assessment of the lay beliefs about generic medicines among hypertensive patients, their perception and about substitution and identifies the relationship with medication adherence. It also provides qualitative information about their experience with generic substitution in relation to their adherence.

5.1 Beliefs about generic medicines

The participants generally showed moderate trust regarding the efficacy of generic medicines. There are several studies in developed countries that have investigated the views of patients about generic medicines but studies in this area are limited in developing countries (Alrasheedy et al., 2014; Colgan et al., 2015; Dunne & Dunne, 2015). Most participants in this study believed that generic medicines have the same efficacy as originator medicines and disagreed that generics were cheaper because they were less efficacious. This finding is rather contrary to the results of several studies in developed countries that have indicated that consumers had negative opinions about generic medicines (Alrasheedy et al., 2014; Colgan et al., 2015; Sewell et al., 2012; Toklu et al., 2012) where they viewed generic medicines to be less effective compared to their branded counterparts. Again, this is in contrast with the findings from South Africa that generics are treated as inferior products (Bangalee, 2015; Patel et al., 2010). The pharmaceutical market share of low and middle-income countries has been found to stand at 70- 80% compared to European countries that have as low as below 20%. The high share of the generic market could hugely influence the positive beliefs about generics found in this study (Kaplan et al., 2013).

5.2 Perception of generic substitution and relationship between sociodemographic factors

In this research, just about half of the patients (50.8%) did not support the view that doctors should ask about their generic preference when prescribing. Also, about a similar proportion (51.8%) of hypertensive patients agreed that patients should be allowed to choose between a generic and an originator. This was mostly reported by those with additional chronic diseases, high education and income levels and covered by the national health insurance. Patient communication with prescribers plays an essential role in the promotion of generic medicine use since their desires is an essential factor in the prescribing pattern (Kravitz et al., 2005; Paraponaris et al., 2004). On the other hand, consumers rarely discuss their medicine choices with physicians (Alexander et al., 2003; William H et al., 2009). Only about half of the respondents in this study thought they should participate in the decisions about their medication choices. This view was found to be mainly associated with educational and income level. This is supported and confirmed by a study conducted in Jordan which found that about a third of the participants desired to participate in the decision about their medication preference and to be given the option of selecting between an originator and a generic and those with higher educational level mainly reported that opinion (El-Dahiyat & Kayyali, 2013). A study in Sweden showed that among the highly educated, they were about 8 times more likely to participate in decision making about medicines (Anell et al., 1997). In another study, about 94 % of the participants had favourable views about some involvement in the decisions regarding their medicines with a significant correlation with respondents' level of education (Rosén et al., 2001). Furthermore, there is the belief that patients who participated in the decision-making process about their medicines were more likely to adhere to their treatment plan with the beneficial improvement in health outcomes (Sandman et al., 2012; Wilson et al., 2010). It is therefore

evident that patients need to participate in making decisions about their treatment. There is the need to develop practice standards on the part of physicians and pharmacists where the inclusion of patient treatment preferences is considered. Training such as continuous educational programmes should target improving the communication skills of healthcare professionals.

About a little above 80% of the participants did not mind substitution to a local or imported drug as long as it was effective. This indicates high interest in the effectiveness of the medicines rather than the origin. This confirms with a qualitative study by Smaoui *et al* (2016) where the country of origin was less important in consumers preference and trust in drugs (Smaoui et al., 2016).

Most of the respondents (64.4%) supported the view that generic substitution was as safe. This was mainly reported by those with high educational status. This is in line with a study conducted in Finland that revealed that 85% of consumers did not regard generic substitution as a danger to safety (Heikkilä et al., 2011). Moreover, most of the respondents did not consider generic substitution to hinder their ability to take their medicines as recommended (74.6%). This was mainly the view of those with low-income levels and with the national health insurance. This is rather contrary to some studies that have asserted that generic substitution has posed a challenge to the elderly with the change in packaging causing confusion and making the tracking of their medicines difficult. In a survey in the USA, patients raised concerns about the ineffectiveness of the new products, adverse effects and dissatisfaction with the process of generic switching (Johnston et al., 2010).

In this study, the majority preferred to be prescribed the cheapest medicine available (60.6%). This was the predominant opinion of the respondents with income level, educational status and burden by other chronic illnesses. Most of the respondents earned below GHC 1000 monthly income and therefore may not be able to keep up with the cost

of the high medicine. Again, the burden of other chronic diseases meant an increased number of medicines and consequently cost of procuring these medicines thus leading to the preference for the cheapest medicines. Furthermore, considering over 90% of the participants in this study are covered under the National Health Insurance which allows them to receive their medicines without or with little out of pocket payment at the point of service (Kanmiki et al., 2019; Nguyen et al., 2011), this can be assumed to be an underlying factor in their preference for cheaper medicines. Additionally, this study also found that a considerable proportion of the patients, particularly those with low educational and income levels, disagreed with desiring expensive medicines because they were better (54.2%). This finding is in contrast to a study by Patel *et al*,2010l in South African where participants did not desire cheap generics because of feeling like a second-class citizen with cheap medicines (Patel et al., 2010).

About half (54.2%) of the participants preferred generic substitution with locally manufactured ones. This indicates a good level of trust for locally produced medicines in Ghana. Their disagreement with this opinion can again be attributed to their inability to afford the expensive medicines since the majority of the respondents had lower income levels. Besides, just a little under 50% preferred generic substitution with imported medicines from countries like the UK, Germany and USA. Those with high educational status, income level and longer duration of hypertension shared this view predominantly. This is a reflection that participants equally have a fair level of trust for imported products.

It is clear from this study, that a meaningful proportion of hypertensive patients had positive attitudes toward the safety of generic substitution for locally produced and imported medicines. The sharing of decision making regarding the treatment preference between prescribers and patients has also been highlighted in this study.

5.3 Beliefs about generics, perception about generic substitution and adherence

Non-adherence to medication is a well-known challenge among patients with hypertension with several factors reported to play key roles in this phenomenon. This study found an adherence rate of 55% which is higher than other studies in Ghana on adherence among hypertensive patients (Bruce et al., 2015; Buabeng et al., 2004; Kretchy et al., 2014; Obirikorang et al., 2018). However, this is just a little lower compared to a review of adherence in a resource-limited setting which reported an overall rate to be 58% (Bowry et al., 2011). Although there are variations in the rates of adherence reported, suboptimal adherence is confirmed as a challenge among patients on chronic medication.

When examined individually, factors that were associated with adherence were age, gender, income level, duration of hypertension, additional chronic disease and patient satisfaction with information about generic substitution. However, after adjusting for these variables, only gender, additional chronic diseases and receiving sufficient information about generic substitution were the most related items.

This study did not show that the beliefs of respondents in generics medicines were significantly associated with adherence. The beliefs of patients with hypertension regarding the efficacy of generic drugs played no role in the adherence to their antihypertensive medication. This finding contradicts related studies in the other regions that have reported low adherence with the use of generic medicines (Beune et al., 2008; Briesacher et al., 2009). Again, studies across Ghana have highlighted the key role of medication beliefs in non-adherence which was not confirmed by this study (Atinga et al., 2018; Obirikorang et al., 2018).

The study found that patient satisfaction with the information received about generic substitution was a predictor of adherence. This finding is consistent with the results of a Norwegian study where it was reported that insufficiently informed patients about generic

substitution were a significant predictor of reduced adherence (Håkonsen et al., 2009). The study was however conducted in a smaller sample (174) among the elderly (50-80years) using a semi-structured questionnaire. This is suggestive that information provided to patients about their treatment plays a key role in adherence (Pascucci et al., 2010; Osterberg & Blaschke, 2005; Awad et al, 2015). The influence of generic substitution on adherence has been reported in other studies (Håkonsen & Toverud, 2012; Van Wijk et al., 2006) where generic substitution has been linked to poor adherence in about one-third of the patients as a result of negative experiences (Håkonsen & Toverud, 2012). The other study which was conducted in the Netherlands, assessed refill adherence among hypertensive patients using an electronic database and found that generic substitution was not implicated in poor adherence but the proportion of adherent patients were greater in the group that received generic substitution (Van Wijk et al., 2006). The differences in the results can be attributed to the difference in the methods used in reporting adherence with poor recall or hesitation of admitting non-adherence as the limitation of self-reported adherence (Garber, Nau, Erickson, care, & 2004; Rob Horne, 2006; Horne et al., 2007; Wang et al., 2004).

5.4 Experience of the generic substitution with adherence

The exploration of the experience of patients about generic substitution among patients with hypertension revealed variable effects generic among individuals. A considerable proportion of the hypertensive patients claimed that they had experienced new side effects at some point with generic substitution. This result is consistent with other studies where a meaningful proportion of patients reported experiencing new side effects with generic substitution (Håkonsen et al., 2009; Håkonsen & Toverud, 2011; Toverud et al., 2011). Furthermore, a review of studies about generic substitution by two authors: Weissenfied et al (2010) and Crawford et al (2005) revealed that up to 34% of patients experienced

additional events after facing a change in their generic or brand in the first study while there has not been mention of the majority of patients who switched without problems (Weissenfeld et al., 2010; Pamela et al, 2006).

Generally, participants reported that they did not have any challenges with the change in the packaging, colour or form of the drugs and did not consider that generic substitution hindered their adherence. This parallels a study which found that, out of about two-thirds of 28 patients that reported changes in size, shape, colour and packaging of their medication claimed confusion at least and mistakes in taking their medicines at worse (Chambers et al., 2014).

However, only one participant reported halting her medication for a week after receiving a medicine offered as a substitute that caused her to suffer some adverse effects. Though a conclusion cannot be done generally due to the limitation of a qualitative investigation, this could be a source of a potentially negative effect on adherence since other studies have highlighted the association of poor adherence with medication side effects (Kretchy et al, 2015; Mann et al, 2009; Morgado et al., 2010). The findings from two studies that investigated the effect of generic substitution on adherence revealed that adherence may be affected negatively by concerns and confusion with the new product after generic substitution which is rather an inconsistent reason for the potential non-adherence with this study (Håkonsen et al., 2009; Håkonsen & Toverud, 2011). A review of 20 studies by Hakosen and Toverud also revealed that generic substitution may lead to poor adherence as a result of negative experiences (Håkonsen & Toverud, 2012). The finding of this study has made it possible for the identification of problems with generic substitution at the personal level rather than at the population-based level.

5.5 Limitations

1. Self-reported adherence has the limitation of poor recall or overestimation of adherence by patients.
2. The study was conducted in a tertiary hospital which is the highest referral point for uncontrolled hypertension and therefore patients' beliefs and perceptions about generic substitution.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study shows that the information patients receive about generic substitution has a positive effect on drug adherence among hypertensive patients and patients desire to share in the decision about their preference for a generic or originator brand. Generic substitution can lead to the experience of new side effects with the newly substituted product which can have a potential consequential negative effect on drug adherence. Therefore, information about generic substitution should be provided to the patient when dispensing the products and each patient should be approached individually by health professionals concerning generics.

6.2 Recommendations

Policy

A review of the guidelines of the Ghana National Health Insurance (NHIS) to allow the prescription of specific generic brands, when necessary, since its guidelines mandate the prescription to be written by their international nonproprietary names which limit the flexibility of physician and pharmacist in providing patients with the generic brands they desire under insurance.

Clinical practice

1. Prescribers should initiate a shared decision-making process with patients about their preference with regards to generics and originator brands.
2. Health professionals should not carry out generic substitution without counselling or education of specific individuals with hypertension to improve adherence.

3. Medical records should include the particular generic brands received by patients to enable a better understanding of the effects of generic substitution.

Future Research

1. More research is needed to identify the impact of generic substitution on control of hypertension with generic substitution in a longitudinal study design.
2. The effect of generic substitution on adherence in other chronically consumed types of medications needs to be investigated.

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APPENDICES

Appendix 1: Consent Form

PERSONAL DETAILS			
Title	Surname	First Name	Others
Place of Birth			Sex - Male ☐ Female☐
Date of Birth (dd/mm/YY)			
Phone Number			
Home Address			
Email		Postal address	
Nationality			
Occupation			
Person to Notify in Case of Emergency	Name:		Telephone:

Applicant Information	
Title	Miss
Principal Investigator	Marilyn Akolgo
Address:	Department of Social and Behavioural Science/School of Public Health/University of Ghana

General Information About Research

This is a research study aimed at assessing the perception and experience of generic drug substitution among hypertension patients and its effect on medication adherence. This interview will require patients to respond to questions which should take about thirty (30) minutes to about forty-five (45) minutes for the questionnaire. A further 30-45min may be required for responding to interview questions if you are selected.

Blood pressure measurement for the day will be taken and you will need to show your blood pressure medications that you are currently taking as part of the research.

This interview involves audio taping your responses for transcription purposes and to aid in checking for the accuracy of responses captured.

A social distance of at least two (2) meters should be maintained and you are required to have a face mask on at all times. The frequent use of hand sanitisers or hand washing should be strictly adhered to while going through research procedures.

Possible Risk and Discomfort

This study may have a minimal psychological discomfort to participants due to recollection of experiences.

Possible Benefits

This research will give information about the perception and experience of generic substitution of antihypertensives among patients with hypertension and the impact on adherence. This will help health care providers to communicate and give patients the appropriate medicines which will potentially improve adherence to antihypertensive medication.

Confidentiality

Any information you give will be protected to the best of our ability. A code will be assigned to your name and therefore your name will not be associated with the transcribed responses, audiotape, transcript or in any report. Only the investigators involved in this research will be able to listen to the tape. Access to information collected will be limited to the principal investigators involved in this research which in the case of hard copies will be under lock and key in a cabinet located in a designated private office while the soft copies will be stored in a personal computer which will be password protected and password will be routinely changed for better security.
The information and tapes will be destroyed after five years of final publication of results of the study

Compensation

There is no monetary compensation for participating in this study.

Voluntary participation and the right to leave the research

Participation in this research is strictly voluntary and participants can withdraw from the study at any time during this study

Contact for Additional Information

If you have any pertinent questions concerning this study, you can please contact the principal investigator: Marilyn Akolgo on 0556035368 or email:makolgo@st.ug.edu.gh

Your Rights as A Participant

This research has been reviewed and approved by the Institutional Review Board of The Korle Bu Teaching Hospital (KBTH). If you have any questions about your rights as a research participant you can contact the IRB office between the hours of 8 am-5 pm through the landline 0302667660 or email address: rdo@kbth.gov.gh

Volunteer Agreement

The above document describing the benefits, risk and procedures for the research title: perceptions and experience of generic drug substitution and implication on adherence among hypertensive patients has been explained to me. I have been given an opportunity to have any questions answered to my satisfaction. I agree to participate as a volunteer.

_____

Name and signature Date:

If volunteers cannot read the form themselves, a witness must sign here:
I was present while the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

_____ _____

Name and signature of witness: Date:

I certify the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Name Signature of Person Who Obtained Consent: Date:

Appendix 2: Questionnaire

PERCEPTION AND EXPERIENCE WITH GENERIC MEDICINES SUBSTITUTION AMO PATIENTS WITH HYPERTENSION STUDY				
Participant Questionnaire form			Participant ID.....	
A: SOCIODEMOGRAPHIC CHARACTERISTICS				
1 Age (years)	18-39☐	40-59 ☐	60-79 ☐	80≥ ☐
2 Gender			Female ☐	Male ☐
3 Educational level	None ☐	Primary ☐	Secondary ☐	Tertiary ☐
4 Income brackets	GHC <500 ☐	GHC 500– 999 ☐	GHC 1000 – 2999 ☐	>GHC3000 ☐
5 Valid Health insurance coverage		Yes ☐		No ☐
MEDICAL CHARACTERISTICS				
6 Duration of hypertension	6mths-1yr ☐	1-5yrs ☐	6-10yrs ☐	>10yrs ☐
7 Total number of medicines	1 ☐	2-5 ☐		>5 ☐
8 Names of antihypertensives	1 Amlodipine ☐		2 Bendrofluazide ☐	
	3 Lisinopril ☐		4 Losartan ☐	
	5 Atenolol ☐		6. Nifedipine ☐	
	7. other			
9. Other chronic diseases	1 Diabetes mellitus ☐	2 Hypercholesterolemia ☐	3 Asthma ☐	
	4 others.....			
10 Do you experience side-effects		Yes ☐	No ☐	

DEFINITION OF ORIGINATOR AND GENERIC MEDICINES

Originator drugs are the first drugs developed from discovery containing its specific ingredient to receiv approval for use and whose efficacy, safety and quality have been established.

Generic medicines are created to be the same as an already marketed originator drug in dosage form safety, strength, route of administration, quality performance and characteristics and intended use ar may be manufactured by other different pharmaceutical companies than the originator drug.

Generic substitution is a pharmacist-initiated act of substituting a different generic brand or brand medicine instead of the brand that a patient has been taking previously.

11 Received sufficient information about generic substitution	Yes ☐	No ☐

SECTION B: BELIEFS ABOUT GENERIC MEDICINES

People have different beliefs about generic medicines. The following statements assess some of these opinions. Please indicate how much you agree or disagree with the following statements, by circling the appropriate number.

Strongly agree	Somewhat agree	Not sure	Somewhat disagree	Strongly disagree
1	2	3	4	5

1. The efficacy of generic medicines is the same as the originator medicines	1☐	2☐	3☐	4☐	5☐

2. Generic medicines take longer time to be efficacious.	1☐	2☐	3☐	4☐	5☐
3. Generic medicines are made with lower quality substances	1☐	2☐	3☐	4☐	5☐
4. Generic medicines have better-quality control than originator medicines	1☐	2☐	3☐	4☐	5☐
5. Generic medicines are cheaper because they are less efficacious	1☐	2☐	3☐	4☐	5☐

SECTION C:

PERCEPTION ABOUT GENERIC SUBSTITUTION

People have different opinions about generic medicines substitution. The following statements ass some

of these opinions. Please indicate how much you agree or disagree with the following statements, by ticking the appropriate number.

Strongly agree	Somewhat agree	Not sure	Somewhat disagree	Strongly disagree
1	2	3	4	5

1.Physicians should ask patients about their medicine's preference	1☐	2☐	3☐	4☐	☐
2. Patients should have the option of choosing between generic and originator	1☐	2☐	3☐	4☐	5☐
3.I don't mind generic substitution with medicine to an equivalent that is locally produced or imported as long as it is effective.	1☐	2☐	3☐	4☐	5☐
4.Generic substitution is safe because the products are produced by reputable manufacturers.	1☐	2☐	3☐	4☐	5☐
5.Generic substitution reduces my ability to take my medicines as recommended	1☐	2☐	3☐	4☐	5☐
6. I prefer generic substitution with the cheapest medicine available for the treatment of my hypertension.	1☐	2☐	3☐	4☐	5☐
7.I prefer generic substitution with a more expensive medicine because it is the better one	1☐	2☐	3☐	4☐	5☐
8.I prefer generic substitution with locally produced medicines	1☐	2☐	3☐	4☐	5☐
9. I prefer generic substitution with an imported rather than local medicines from UK/Germany/US	1☐	2☐	3☐	4☐	5☐

SECTION D: MEDICATION ADHERENCE REPORT SCALE 5(MARS 5)

PREFACE STATEMENT

Many people find a way of using their medicines which suits them. This may differ from the instruction on the label or from what their doctor had said. Here are some ways in which people have said they us their medicines. For each statement, please tick the box which best applies to you"

PLEASE TICK IN THE APPROPRIATE BOX

"always	Often	Sometimes	Rarely	Never
1	2	3	4	5

1.0 I take less than instructed	1☐	2☐	3☐	4☐	5☐
2.0 I have stopped taking it for a while	1☐	2☐	3☐	4☐	5☐
3.0 I miss out a dose	1☐	2☐	3☐	4☐	5☐

4.0 I alter the dose	1☐	2☐	3☐	4☐	5☐
5.0 I forget to take it	1☐	2☐	3☐	4☐	5☐

Appendix 3: Interview Guide

INTERVIEW

TITLE: PERCEPTION AND EXPERIENCE WITH GENERIC DRUG SUBSTITUTION AMONG HYPERTENSIVE |PATIENTS.

PREAMBLE-DEFINITION OF GENERIC MEDICINES SUBSTITUTION

Generic substitution is the act by which a different brand or unbranded product is dispensed instead of the branded drug prescribed or the brand that a patient is already taking.

Broad questions

1 How do you know about the generic substitution?

2 What is your view about the effectiveness of the medicines after generic substitution?

3 What is your opinion about the safety (side effects) with generic medicines substitution?

4 How do you view affordability with generic medicine substitution?

5 What concerns do you have about how generic substitution is communicated?

6 How has generic substitution affected your medication adherence?

Appendix 4: Ethical Clearance

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

My Ref. No. KBTH/MS/05/2450
Your Ref. No. ....

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

13th July, 2020

YNAKOLOO
DEPT. OF SOCIAL & BEHAVIOUR SCIENCE
SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF GHANA
LEGON

<u>PERCEPTION AND EXPERIENCE WITH GENERIC MEDICINES SUBSTITUTION AMONG PATIENTS WITH HYPERTENSION AT THE KORLE BU TEACHING HOSPITAL</u>

KBTH-IRB /00051/2020

Investigator: MARILYN AKOLOO

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled "Perception and Experience with Generic Medicines Substitution among Patients with Hypertension at the Korle Bu Teaching Hospital"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 30th June, 2021. You are to submit annual report for continuing review.

Sincerely yours,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB) FOR
CHAIR (KBTH-IRB)

cc: The Chief Executive Officer, KBTH

The Director of Medical Affairs, KBTH