

UNIVERSITY OF GHANA SCHOOL OF PUBLIC HEALTH

Determinants of Anti-fungal use in the Ga-South Municipality;

Implications for antimicrobial stewardship

by

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DECLARATION

Except for references to other people's work, which are duly acknowledged, the researcher declares that this dissertation is his own original work, and has not been submitted in whole or in part for another degree in this university or in another university.

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ABSTRACT

Introduction; One of the foremost and important steps towards rational anti-fungal use and conservation is drug utilization research. A lot is known about the determinants and patterns of use of antibiotics. However, only few studies have investigated consumption of antifungals in a given population.

Methods; the current study is a cross-sectional drug utilisation study of 304 clients purchasing anti-fungal products from retail community Pharmacies. A structured questionnaire was used to assess patient's knowledge and attitude towards self- medication with anti-fungals, and to collect data on factors that may be associated with obtaining anti-fungals without prescription. A semi-structured interview guide was employed to explore pharmacists' perspectives on their patients receiving antifungals without a valid prescription. At 95% confidence interval and with a p –value of 0.05, multiple logistic regression analysis was performed to determine predisposing factors to obtaining antifungals without prescription.

Results: The t prevalence of obtaining antifungal medicines without a prescription was 0.74 (SE: 0.025, 95% CI: 0 .69- 0 .79). Average monthly income, health insurance status and educational status were associated with obtaining medicines without prescription even when adjusted for age and sex.

Conclusion: Antifungal medicines are frequently obtained from community pharmacies without a valid prescription from a physician. This has the potential to result in irrational dispensing and irrational drug use and increase the risk of adverse events, which may contribute to the development of resistance

DEDICATION

To my mum, Paulina Asamoah.

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I want to use this medium to express my heartfelt gratitude and profound indebtedness to the Almighty God, and to the many wonderful people who contributed in one way or the other to the success story of this project work; to study participants and my supervisor. A special mention of Pharm Anita Nhyira and Ms Juliet Aba Nyame. God bless you.

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ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
AS	Antimicrobial Stewardship
ASP	Antimicrobial Stewardship Programme
BNF	British National Formulary
HBM	Health Belief Model
HIV	Human Immuno-deficiency Virus
HUM	Healthcare Utilization Model
MCA	Medical Counter Assistants
OTC	Over the Counter
PLwHA	People Living with HIV/AIDS
WHO	World Health Organisation

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CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND TO THE STUDY

As an integral component of drug utilization research (DUR), pharmaco-epidemiological studies attempt to create a bridge between clinical pharmacology and epidemiology. DUR attempts to address the medical, economic and social issues pertaining to the distribution and use of medicines in large populations. The ultimate aim is to provide empirical data on the extent, nature and determinants of drug exposure to promote the safe, effective and rational use of medicines. Medical concerns encompass the actual or potential risks that are inherent in pharmacotherapy, while the social component focuses on judicious use of medicines. Economic issues, on the other hand, deals with the cost of drug treatment to the individual and the society (Wettermark et al., 2016; WHO, 2003).

There is not a single universally accepted definition of Antimicrobial stewardship (AS). However, regardless of how it is defined, AS is primarily a well- coordinated, concerted efforts by all stakeholders of healthcare delivery, geared towards the optimization of the treatment of infections while minimizing antimicrobial misuse and its consequences, particularly, the development of resistance by previously susceptible organisms (Doron & Davidson, 2011; George & Morris, 2010; Wettermark et al., 2016; WHO, 2003). Over the past few decades, we have witnessed a substantial stagnation and decline in the development of new antifungal agents. In sharp contrast to this unfortunate development, the development of resistant strains of disease causing pathogens has risen rather rapidly. When one considers the effect of antimicrobial resistance on the economies of health, the significance of Antimicrobial Stewardship Programmes (ASP) can never be

overemphasized. Besides the poorer clinical outcomes of resistant infections in terms of morbidity and mortality, resistant infections also put a huge strain on national and family budgets (Puleston, 2017; Rice, 2009; Roberts et al., 2009).

Even though pathogenic fungi are ubiquitous in our environment, there are very efficient protective mechanisms in the human species against fungal invasion and subsequent multiplication. Fungi can only infect and multiply in host tissues when these barriers are adequately compromised (Kasner et al , 2013).

The risks of serious and opportunistic fungal infections have increased in recent years. The epidemiological shift towards degenerative and chronic conditions has resulted in prolonged hospitalizations for some patients. This development plus modern invasive and aggressive clinical procedures such as surgery or cancer chemotherapy, organ transplant, coupled with indiscriminate antibiotic use and stressful lifestyles means that many people are immunocompromised (Dier & Goyvaerts, 2017; Fisher, 2011; Leventakos, Lewis, & Kontoyiannis, 2010; Pappas et al., 2010; Steinke, & Davey, 2017; Sun & Singh, 2011). Moreover, according to Kanafani & Perfect (2008), systemic mycoses cause significant morbidity and mortality among HIV/AIDS and other immunocompromised patients.

Due to economic and capacity constraints, countries in Sub-Sahara Africa contribute quite less to the development of novel antimicrobials. Consequently, it has become not only imperative but long overdue for health professionals in this region to advocate for the implementation of pragmatic measures aimed at conserving the limited antimicrobials available. This is especially important because unlike many developed countries, where the disease burden is largely lifestyle related,, Sub-Saharan Countries are faced with a burden of communicable diseases, in addition to a huge burden of non-communicable diseases.

1.2 PROBLEM STATEMENT

The number of opportunistic fungal infections in immunocompromised patients is well documented elsewhere to be on the rise (Bhutta, 2008; Kwamin et al, 2013; Mushi, Bader, et al., 2017; Pappas et al., 2010; Sun & Singh, 2011) . As explained earlier, this development is attributed to indiscriminate use of broad spectrum antibiotics, aggressive treatment of malignant diseases and increase in incidence of immunocompromised states such as acquired immune deficiency syndrome (AIDS), diabetics and cancer. Moreover, mild to moderate fungal infections such as tinea and foot rot are common in the community, even among people with no known immune deficient disease.

For this reason, the development of fungal strains that are resistant to current treatments should be avoided or at least delayed at every cost. Without empiric information about how these medications are dispensed and used in the community, policy makers will be deficient in addressing indiscriminate or irrational use. Beside the development of resistant strains of fungi, many systemic antifungals are associated with some important toxicity and adverse drug reactions (Canada, 2013; Dier & Goyvaerts, 2017; Gupta & Lyons, 2015; Khoza, Moyo, & Ncube, 2017; Kim, Choi, Lee, & Lee, 2017). As a result, misuse can put consumers at risk of adverse drug reactions, especially in the community where drug monitoring and patient follow up is not feasible and many adverse drug reactions go unreported. For example, oral ketoconazole has been associated with significant hepatotoxicity, which may potentially warrant liver transplantation or death. It can also cause adrenal insufficiency and interact with so many other drugs (Canada, 2013; Gupta & Lyons, 2015). As a result, many countries have updated their guidelines to restrict the

use of oral ketoconazole as last resort to the treatment of serious, systemic mycoses only (Gupta & Lyons, 2015). In sharp contrast, ketoconazole is available over-the-counter in Ghana.

The foremost step to anti-fungal stewardship is to understand the dynamics of the drug consumption, so that knowledge obtained can be factored into legislations and policy implementation. A lot is known about the determinants and patterns of use of antibacterials. However, only few studies have investigated consumption of antifungals in a given population (Dier & Goyvaerts, 2017; Gross et al., 2015; Munoz, Valerio, Vena, & Bouza, 2015; Mushi, Masewa, Jande, Mirambo, & Mshana, 2017). Most of these studies are hospital based. To the best knowledge of the author, no single study has attempted to describe the consumption of antifungals in Ghana. Existing literature on antimycotic utilisation were conducted predominantly outside Sub Saharan Africa, and the findings and its relevance to Ghana may differ, given legal, cultural, socio-economic, professional training and clinical practice differences. The current study aims to fill this knowledge gap.

1.3 CONCEPTUAL FRAMEWORK

The Andersen Healthcare Utilization Model (HUM) and the Health Belief model (HBM) could adequately explain why many people utilize community Pharmacies for primary healthcare, especially in the developing countries. According to Anderson, utilisation of any health service is determined by factors that predispose them to use the services. These include enabling factors which enable or impede use, and their perceived or evaluated need for care. The HBM puts emphasis on the individual's own belief and perception about health related states or events, and the strategies at hand to manage those. By extension, an individual's access to and use of antimicrobials in the community is explicable by need of care and many enabling factors. The burden of diseases in Ghana has forced a paradigm shift in the community pharmacists' roles toward a more clinical approach. Because regulatory structures are not strong, indiscriminate dispensing of antimicrobials, often without prescription and sometimes by unqualified personnel is very common (Kassi, 2016).

The Model below attempts to conceptualize the factors that drive the dispensing and utilization of antimicrobials, with a focus on community Pharmacies in Ghana. The framework is modeled on the Andersen Healthcare Utilization Model and situated within the context of the Healthcare system of Ghana.

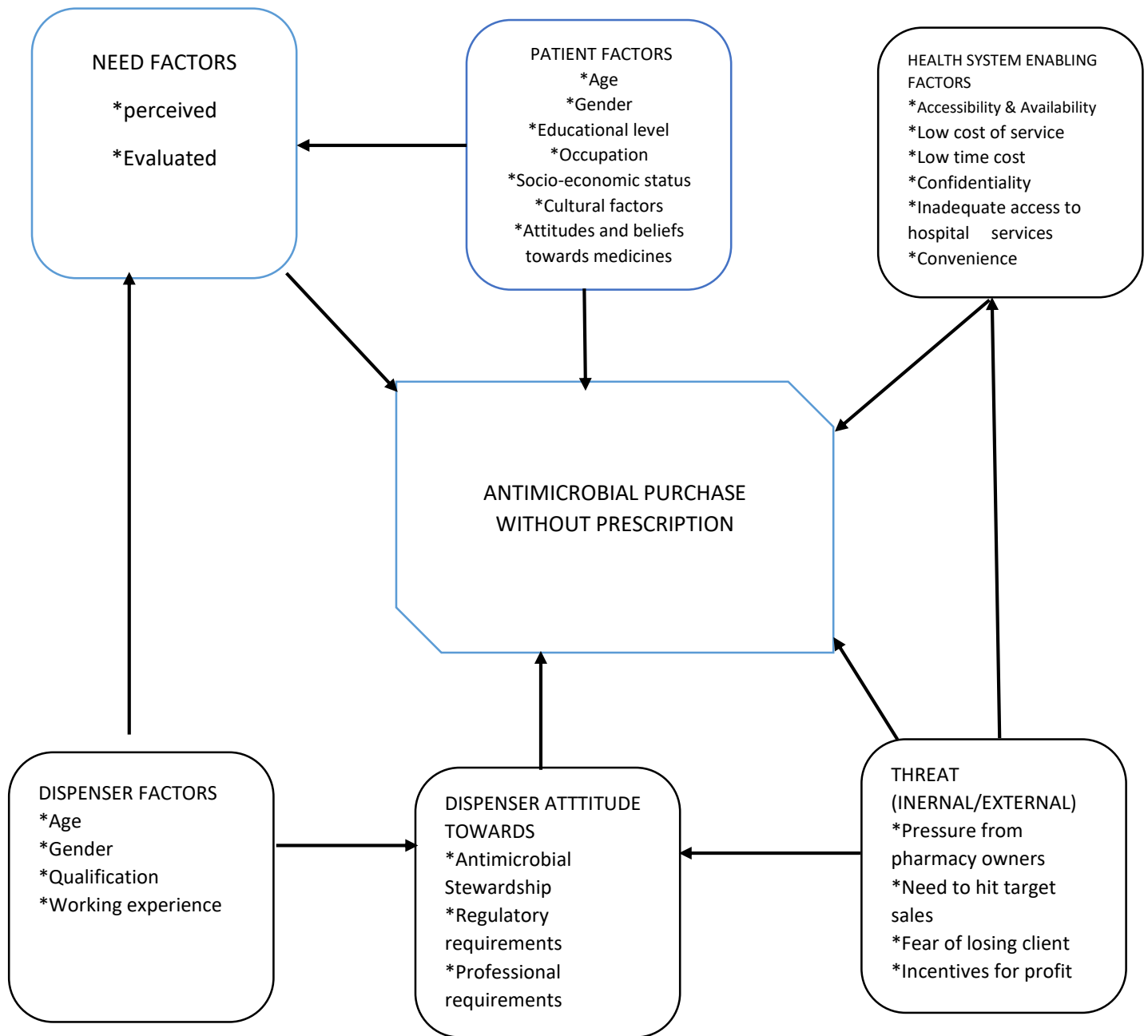


Figure 1; Conceptual model for the study

The conceptual framework is of multifaceted factors that could explain why people choose to self-medicate with antimicrobials by purchasing OTC from retail pharmacies instead of seeking a physician’s advice. Predisposing factors are those individual characteristics that predispose one to

using a pharmacy as a source of primary care after evaluating their own need of care. These factors, including history of previous use are very important determinants of self-medication. When the tendency to self-medicate is obvious, many health system enabling factors also facilitate use of retail Pharmacy outlets. For example, these outlets are widely distributed in the community (as opposed to limited number of hospitals).

. Moreover, individual characteristics of the Pharmacist or Pharmacist assistants also predispose them to dispensing antimicrobials without prescription. Retail Pharmacy in Ghana is a delicate balance between professionalism and profiteering. Because of the desire to hit set sales targets and the fear of losing a client, irrational dispensing of antimicrobials is common.

1.4 OBJECTIVES FOR THE STUDY

The current study sought to investigate the prevalence and predictors of obtaining antifungal medicines without prescription from community Pharmacies and to explore why pharmacists dispense antifungal agents without prescriptions. Specifically, the study aims to;

1. Determine the prevalence and factors associated with obtaining antifungal medicines from community pharmacies without prescription
2. Describe the consumption of antifungal medicines from retail community Pharmacies.
3. Determine patients attitude and perception about obtaining antifungal medicines without prescription
4. Explore community Pharmacists' perspectives on antifungal dispensing without prescription

1.5 RESEARCH QUESTIONS

1. What proportion of antifungal medicines are obtained OTC in retail Pharmacies?
2. Why do patients purchase antifungal medicines OTC from retail Pharmacies?
3. What are the factors that could predispose a patient to obtaining antifungal agents OTC?
4. What is the perception of community pharmacists on dispensing antifungal medicines OTC?

1.6 HYPOTHESIS

H₁: More than 70% of antifungal medicines are dispensed OTC

H₁: Patients who have history of use of antifungals, low levels of education, lower levels of income and are not on health insurance are more likely to obtain antifungal medicines OTC

H₁: Women and people aged less than 30 are more likely to purchase antifungal medicines OTC than men and those aged 30 years or more

1.7 JUSTIFICATION

A personal observational and that of other colleagues in the health sector provides some anecdotal evidence to suggest that antimicrobial stewardship is very poor in many community Pharmacies. In Ghana, financial and opportunity cost of seeking healthcare from hospitals is generally perceived to be high. Many people prefer to visit community Pharmacies as their first point of call for many ailments, including suspected 'minor' infections.

Community based Pharmacies present many advantages. First, they are extensively distributed at vantage points in the communities. You do not need to book an appointment and Pharmacists do not charge for consultation.

In order to ensure universal access to pharmaceutical services, authorities have permitted the establishment of several retail community Pharmacies and chemical shops (over-the-counter medicine sellers). Many of these facilities are unable to employ the services of pharmacists at all times and are often manned by people with very minimal training in drug use. Where personnel are duly qualified, excessive commercial awareness has the potential to breed irrational drug

selection and use. Basically, the business driven retail pharmacy service has turned many pharmacies into a mere point of sale where one can self-diagnose and walk in to demand a drug including antimicrobials.

Proliferation of medicines outlet in the face of weak regulatory enforcement of drug sales and inadequate number of qualified Pharmacists to man these outlets create a conducive environment for irrational drug use.

CHAPTER 2

LITERATURE REVIEW

2.1 BURDEN OF FUNGAL INFECTIONS

Even though fungi are generally ubiquitous in our environment, many of them merely live in commensal symbiosis with humans and only become pathogenic when the host immune system is compromised. For example, *Candida spp* readily colonize genital and gastrointestinal mucosa of ‘healthy’ host without causing disease (Fridkin, 2005; Kasner et al., 2013). Over the past three decades however, we have witnessed an increase in the incidence of both mild to moderate fungal infections, and serious, life threatening invasive mycoses (Bhutta, 2008; Kwamin et al., 2013; Mushi, Bader, et al., 2017; Pappas et al., 2010; Sun & Singh, 2011). This has been attributed to an increase in immunocompromised states and increased use of invasive and aggressive medical technologies and therapies. Indiscriminate use of broad spectrum antibiotics, cancer chemotherapy, prosthetic devices and solid organ transplants are important risk factors of opportunistic fungal infections (Dier & Goyvaerts, 2017; Fisher, 2011; Leventakos et al., 2010; Pappas et al., 2010; Steinke et al., 2017; Sun & Singh, 2011).

Because most fungal infections are not serious or debilitating, many fungal infections go unreported and only a few attempts have been made to give morbidity and mortality estimates of fungal disease in the general population. The Global Action Fund for Fungal Infections (2017) asserts that over a billion people worldwide are affected by fungal diseases. This culminates into about 11.5 million life threatening infections and over 1.5 million deaths annually.

In Thailand, approximately 2% of the population is estimated to be affected with non-cutaneous fungal infections each year (Beardsley et al, 2014). A similar prevalence is reported for Ireland

(Dorgan, Denning, & McMullan, 2015). The situation is different for Nigeria, where estimates is as high as over 11.8% , with significant morbidity and mortality especially among PLWHA. The situation in Nigeria may not be different for other Sub-Sahara African countries including Ghana, particularly because the prevalence of HIV/AIDS remains high in the sub-region. Fungal infections remain the most important opportunistic infections among PLWHA.

Each year, about 700,000 deaths from fungal infections in AIDS occur, representing nearly half the total cases (Beardsley et al., 2014; Fridkin, 2005; Global Action Fund for Fungal Infections, 2017; Klimko et al., 2015; M., M., J., & D.W., 2013). The most important fungi responsible for majority of cases are *Aspergillus*, *Candida*, *Cryptococcus species*, *Pneumocystis jirovecii*, *Histoplasma capsulatum* and *Mucormycetes* (Beardsley et al., 2014; Fridkin, 2005; Global Action Fund for Fungal Infections, 2017; Klimko et al., 2015; M. et al., 2013). *Candida* species remain the fourth most important cause of hospital-acquired bloodstream infections while *Aspergillus fumigatus* remains the most frequent cause of infection (Warnock, 2007). It is worth noting that authors of all these prevalence studies bemoan lack of high quality epidemiological data. In Ghana, there is paucity of data that attempt to estimate the overall burden of fungal diseases. This notwithstanding, Pesewu and colleagues employed a cross-sectional study of five tertiary level hospitals in Ghana to ascertain the burden of fungal diseases. They found out that *Tinea* infections accounted for more than 60% of reported cases, followed by *Candida* infections (6%). Among People Living with HIV/AIDS (PLWHA), fungal lung infection was more prevalent (International Society for Human and Animal Mycology, 2015).

Despite the significant morbidity and mortality presented by infectious fungal diseases, epidemiological studies of fungal diseases and anti-fungal therapies are generally lacking. Unlike many other disciplines, there is no universally acclaimed Authority on Public Health mycology

both at the national level or international level. Even the World Health organization has no special programme on mycology. Schools of public health and tropical medicine barely cover fungal disease in their curricula (Global Action Fund for Fungal Infections, 2017).

2.2 ANTIFUNGAL MEDICINES UTILIZATION

There are over 100,000 fungal species identified in the environment, but only about 100 of them are pathogenic to humans. Fungi of medical importance more often cause superficial infections, particularly of the skin, scalp, nails and mucous membranes. Deep-seated infections involving organs like lungs and brain (example, pulmonary aspergillosis or cryptococcal meningitis) only manifest in susceptible patients whose immune systems are heavily compromised (Fridkin, 2005; Kwamin et al., 2013; Leventakos et al., 2010; Mushi, Bader, et al., 2017; Pappas et al., 2010)

Because fungi cells are eukaryotes (just like human host cells), there are only a few target sites for medications to selectively target, making antifungal medicines relatively toxic to humans. Moreover, treatment of fungal infections present some challenges because fungal organisms multiply quite slowly and fungal infections often occur in tissues that are poorly penetrated by antimicrobial agents (Sundriyal, Sharma, & Jain, 2006).

Antimicrobial stewardship strategies have been shown to improve antimicrobial utilization (Kaki et al., 2011). Drug utilization on the other hand varies with country and population. The types of antifungal used vary with population and the country being studied. Self-medication tendencies and behaviours vary considerably with various socio-economic variables (Yousef, Al-Bakri, Bustanji, & Wazaify, 2008). A cross-sectional drug utilization study from South Africa revealed that the most common antifungal agent prescribed was Fluconazole (42.1%), followed by Nystatin

(53.07%) and Griseofulvin (26.74%) (Truter & Graz, 2014). In another study in Tanzania, Fluconazole was the antifungal agent most commonly obtained OTC and clotrimazole was the commonly prescribed antifungal (Mushi et al, 2017). Evaluation of antifungals in the surgical intensive care unit in the USA also had Fluconazole being the mostly prescribed (1846 patient - days) followed by Amphotericin B (201 patient-days), itraconazole (71 patient-days) and Caspofungin (42 patient-days) (Garey et al., 2006).

A survey conducted among Spanish dentists also revealed that the most commonly prescribed antifungals for the treatment of oral candidiasis between May and November 2006 was Miconazole (59.3%) followed by Nystatin (57.7%) (Martínez-Beneyto, López-Jornet, Velandrino-Nicolás, & Jornet-García, 2010). These studies confirm the fact that the kinds of antifungals used vary with population, country and the type of fungal infection.

In the Mwanza city study, patients received multiple antifungals agents over the counter, particularly for suspected infections of the skin (Mushi et al., 2017). Thus, with skin fungal infections, patients were more likely to receive multiple antifungals. In that same study, more than half of participants obtained their medicines over-the-counter (Mushi et al., 2017).

Among drugs that are being self-medicated are Antifungals especially those that are used for vaginal infections. The lifetime prevalence of candida vaginitis remains high, especially among sexually active women, and it is associated with high exposure to antibiotics usage (Saporiti et al., 2001). Since vaginal infections are very common in women, vaginal antifungals are mostly being self-medicated. A study which was conducted in 20 Finland pharmacies on women buying OTC vaginal antifungals revealed 49% of them had used them during the previous 6 months (Sihvo et al, 2000). Easy access to these OTC antifungal medicines is associated with a delay in accurate diagnosis and unnecessary financial costs (Ferris et al., 2002).

Many studies document unnecessary prescribing and dispensing of antifungals. For instance, in a study conducted to assess the use of antifungals in 100 adult inpatients in a tertiary care institution revealed that in 16% of the cases, antifungals were unnecessarily prescribed (Valerio et al., 2014). The use of non-prescribed antimicrobials can presage danger and put at risk the populace to changes in antimicrobial effectiveness (Emeka et al., 2014).

The most important modifiable risk factor for the development of fungal strains that are resistant to current therapy is drug utilization (Kanafani & Perfect, 2008). The number of antimycotic drugs that are available for systemic infections are very limited (May & Rose-ackerman, 2002). Stewardship programmes to preserve their effectiveness and optimize treatment outcomes is very crucial (Ramkhalawon, 2015; Septimus & Owens, 2011).

In a cross-sectional study in Saudi Arabia, community pharmacists demonstrated a general lack of awareness of the conventions that prohibit them from dispensing antibiotics without prescription even though the participants acknowledge the public health impact of dispensing antibiotics without prescription (Hadi et al., 2016). Increased use of antifungals, with associated inappropriate use has been observed in many different parts of the world (Dier & Goyvaerts, 2017; Gross et al., 2015; Munoz et al, 2015; Mushi, Masewa, Jande et al, 2017).

More than 50% antimicrobials are not used appropriately, and this adds considerable cost to patients while facilitating development of resistant pathogens, increasing morbidity and mortality and unjustified cost (Ramkhalawon, 2015). Despite the problem of fungal infections being difficult to treat, a number of successful antimycotic agents are in clinical use. These can broadly be divided into the synthetic agents and the antifungal antibiotics. The synthetic ones include flucytosine, the azoles (e.g. miconazole, ketoconazole, fluconazole, itraconazole, and voriconazole), the

allylamines (terbinafine) and echinocandins (caspofungin, micafungin, anidulafungin). The antifungal antibiotics are griseofulvin and polyenes (Amphotericin B, nystatin, and natamycin (Ghannoum & Rice, 1999; Kanafani & Perfect, 2008; Sundriyal et al., 2006).

2.4 ANTIMICROBIAL RESISTANCE

Antifungal resistance continues to grow and evolve and complicate patient management, despite the introduction of new antifungal agents (Pfaller, 2012). The most important modifiable risk factor for the development of fungal strains that are resistant to current therapy is drug utilization (Kanafani & Perfect, 2008). Also, the number of antimycotic drugs that are available for systemic infections are very limited (May, 2002). The mechanisms of resistance include alteration in drug target, alteration in sterol biosynthesis, reduction in the intercellular concentration of target enzyme and overexpression of the antifungal drug target. Over half of all antimicrobial use is inappropriate, adding considerable cost to patient care and leading to increased selection of resistant pathogens, morbidity and mortality and unjustified cost (Ramkhalawon, 2015). Thus, inappropriate use of antimicrobials, including antifungals, contributes to development of antifungal resistance, increased mortality and morbidity and may also lead to toxicity associated with unnecessary medication exposure and increase costs (Munoz et al., 2015; Ramkhalawon, 2015). An example of this resistance case is that of a study that showed that fluconazole –resistant (MIC>6ug/ml) blood stream isolates of *Candida albicans* and *C. glabrata* obtained from cancer patients were cross resistant to the root drugs miconazole, clotrimazole and tioconazole but remained susceptible to butoconazole (Cross, Park, & Perlin, 2000).

A cross-sectional study enrolling 382 college-age women to investigate the relationship between use of OTC azole –based antifungal drugs and vaginal colonization by drug-resistant *Candida*

revealed that a small number of resistant *Candida* species isolates were obtained from women with a history of multiple exposures to OTC antifungals; given the widespread use of these products and this may be emerging concern (Mathema et al., 2001). On the other hand, self-medication is a global phenomenon and potential contributor to human pathogen resistance to antimicrobials (Bennadi, 2013). Stewardship programmes to preserve their effectiveness and optimize treatment outcomes is very crucial (Ramkhalawon, 2015; Septimus & Owens, 2011).

2.5 ROLE OF HEALTHCARE PROFESSIONALS

In a cross-sectional study in Makkah Province, Saudi Arabia, it was revealed that community pharmacists demonstrated a general lack of awareness of the regulations and policies prohibiting the sale of antibiotics without prescription even though the participants approve the Public Health impact of dispensing antibiotics without prescription (Hadi et al., 2016). Physicians on the other hand, observe several disadvantages of self-treatment with unnecessary use of vaginal antifungals and use for the wrong indications most often reported (Sihvo et al., 2000). Hence, Physicians and community Pharmacists have a role to play in this context. Rampant irrational use of antimicrobials of which antifungals are a part, without medical guidance may result in greater probability of inappropriate, incorrect or undue therapy, missed diagnosis, delays in appropriate treatment hence it would be safe if people who are using it have sufficient knowledge about dose, time of intake, side effect on overdose and this is the work of healthcare professionals like the doctors, pharmacists etc (Bennadi, 2013). The healthcare professionals can aid in intensifying awareness and helping to implement legislations to promote judicious and safe practices with respect to antifungals.

Community pharmacies are usually the first port of call in dispensing antifungals and so the rate at which antifungals are being sold OTC will be dependent on them. Private pharmacies are the

first line of healthcare in many communities, commonly selling antimicrobials alongside other prescription-only drugs like steroids without medical supervision (Chalker et al, 2005). Another study in Greece revealed that antimicrobials can be very easily bought in Greek Pharmacies without a prescription since during all 72 visits into pharmacies, antimicrobials (100%) were served without comments made by the pharmacist or no reason given for the intended use of the requested antimicrobial (Plachouras et al., 2010). Similar study conducted in Great Cairo, Egypt showed that antimicrobials are frequently dispensed from community pharmacies in Egypt even without appropriate prescriptions and for appropriate indications (Sabry, Farid, & Dawoud, 2014). Out of 1573 medicines dispensed in private pharmacies in Dar-es-Salaam, 16% were anti-infectives and 7% of the anti-infectives were antifungals dispensed due to recommendation (51%), request by client (22%) and prescription from physicians (27%) (Kagashe, Minzi, & Matowe, 2011). Thus, there is always a higher rate of OTC antifungals being dispensed against prescription antifungals. This brings to light self-medication attitudes of patients with fungal infections, Patients' attitudes towards the role of community pharmacists has an effect on the rate at which OTC antifungals are used.

A study to investigate the Jordanian population's attitudes towards the role of community pharmacist and their use and perceptions of OTC drugs revealed that more than half of the interviewed sample (56.8%) stated that they would always follow the directions on the packet of the OTC product rather than consulting from the community pharmacist and 62.7% of participants reported that they would seek advice from a pharmacist when the condition was not serious enough to visit the doctor (Wazaify et al, 2008). This makes it evident that patients rarely consider community pharmacies as health care facilities. As such, unregulated dispensing by unqualified personnel is of particular concern. Because most modern industrialized countries stringently limit

availability of antimicrobials to the general public, many less developed countries do not have or enforce such policies and Ghana is of no exception (Wachter, Joshi, & Rimal, 1999).

Most pharmacists are unaware about the illegality of dispensing antifungals without prescriptions. A survey in Makkah province, Saudi Arabia to evaluate Community Pharmacists knowledge, attitudes and practices towards dispensing antimicrobials without prescription (DAwP) revealed that out of the 189 community pharmacists, more than two-thirds (70.5%) were not aware that DAwP is an illegal practice (Hadi et al., 2016). The Prescribers, specifically, Doctors have a role to play in the prescription of antimicrobials in the hospitals since it can help curb improper and unnecessary use of antifungals. Understanding the determinants of antimicrobial prescribing behavior (APB) will help design, adopt and implement quality improvement interventions in antimicrobial stewardship programs. To understand key determinants of antimicrobial prescribing in a hospital setting, semi-structured interviews conducted with doctors (n=10), pharmacists (n=10) and nurses and midwives (n=19) in 4 hospitals in London revealed that APB was governed by 'prescribing etiquettes' (set of cultural rules where the behavior of clinical leaders or seniors influenced practice of junior doctors (Charani et al., 2013). Hence interventions need to address the prescribing etiquettes and use clinical leadership within existing clinical groups to influence the practice.

In summary, inappropriate prescribing patterns and dispensing of antimicrobials worldwide support the need for strict enforcement of Pharmacy laws through improved inspection processes and they highlight the need for evidence-based guidelines and educational interventions to improve antimicrobial of which antifungals are a subset in order to improve antimicrobial prescribing and dispensing practices.

2.6 ANTIMICROBIAL STEWARDSHIP

In an era in which antimicrobial resistance is increasing, judicious antimicrobial use is the responsibility of every healthcare provider (Hamilton et al., 2015). An Observational study conducted in Australia revealed that the introduction of the antimicrobial stewardship programs (ASP) resulted in an immediate 17% reduction in broad-spectrum antimicrobial use in the intensive care unit and a 10% reduction in broad-spectrum antimicrobial use outside the intensive care unit in a tertiary referral centre (Cairns et al., 2013). These programs are essential as they promote the appropriate use of antimicrobials by selecting the appropriate dose, duration and route of administration (Drew, 2009). The appropriate use of antimicrobials can limit the potential for emergence of antimicrobial resistance as well as health care costs and drug-related adverse events while improving clinical outcomes. This takes on added importance in conjunction with patient attitudes and desires and is particularly evident in the ambulatory setting, where patients frequently demand antibiotics (Fishman, 2006).

Such programs are administered by multidisciplinary teams composed of physicians, clinical pharmacists and clinical microbiologists (MacDougall & Polk, 2005). Pharmacists may be tasked to lead Antimicrobial Stewardship Programs development and implementation with little or no support from physicians or any other hospital personnel whose involvement on Antimicrobial Stewardship Program (ASP) teams is recommended (e.g., clinical microbiologists, infection control specialists, hospital epidemiologists). A study carried out to assess improved drug-utilization and cost outcomes achieved by a antimicrobial stewardship program (ASP) led by a pharmacist revealed that in the absence of other personnels like the physician and clinical microbiologists, the pharmacist-led ASP achieved substantial reductions in antimicrobial utilization of four commonly used antimicrobial agents (Waters, 2015). A study to evaluate the

development of pharmacist-led antimicrobial stewardship activities in English hospitals revealed that the increasing role of specialist pharmacists and general pharmacists in antibiotic stewardship in acute care in England has enabled hospitals to deliver on the antibiotic stewardship agenda, although opportunity remains to expand this role further and ensure greater multidisciplinary engagement (Wickens et al., 2013).

2.7 FACTORS INFLUENCING SELF MEDICATION

The role of gender in self-medication has been investigated in studies with mixed results. Gender had no influence on self-medication behavior in one study (Kumar et al, 2016). This is in contrast other studies where females were more likely to self-medicate (Badiger et al, 2012; Banergee et al, 2012). Shafie et al, (2018) also demonstrated significant associations between self-medication practices and participant's income and age. The practice was more common in the older people (>55 years) and those with lower levels of income. Employing logistic models, Nguyen & Thang (2017) established a positive relationship between the self-medication behavior and participants' high school degree or vocational certificate, married status, and income and inverse relationship with employed status, the number of children, the geographical distance from home to the nearest hospital, doing exercise, and living in a central region.

In a systematic review of the prevalence, possible reasons, and outcomes of self-medication and self-prescription with antibiotics, age, sex, level of education, and income level were common determinants of self-medication behavior (Alhomoud et al, 2017). In the same review, the prevalence of self-medication was reported to be higher among men in most studies. Most studies also showed that the prevalence of self-medication increased in individuals with a low educational

status and low or medium income (Alhomoud et al, 2018). In another systematic review of literature, the authors revealed that participants with higher income, higher education level and having insurance were reported to be more likely self -diagnose and self –medicate. Also in the same review, Female gender, older age, and prior knowledge of antibiotics were identified as independent risk factors of self-medication with antibiotics (Limaye et al, 2017)

CHAPTER 3

METHODS

3.1 DESIGN

The current study employed both quantitative and qualitative approaches for different aspects of the study. It was a cross-sectional drug utilisation study of retail community Pharmacies in the Ga-South Municipality of the greater Accra region of Ghana.

3.2 STUDY SITE

The study was conducted in selected community Pharmacies in the Ga South Municipality. The Municipality stretches over a total land surface area of approximately 413.76 sq km in the South Western Part of Greater Accra, with about 25 major communities. The Municipality is largely urban, with more than 80% of the people living in the urban part of the Municipality (Ghana Statistical Service, 2014). Based on figures from the 2010 Housing and population census, the projected population for the Municipality stands at 385,741 (2014). The Municipality is faced with the problem of inadequate access to health care for the majority of the population.

3.3 STUDY PARTICIPANTS

3.3.1 INCLUSION CRITERIA

The study population were adults (over 18 years old) living in Ga- South Municipality, with no disabilities that would prevent understanding the questionnaire. Adult patients who were supplied with antifungal products in community Pharmacies at the time of data collection were invited to participate in the study.

For all Pharmacies selected as data collection site, Pharmacists with a minimum of one year post qualification experience were interviewed.

3.3.2 EXCLUSION CRITERIA

The study excluded those patients who were supplied with injectables and creams or ointments combined with other anti-infectives. Patients who obtained antifungals from wholesale Pharmacies, Pharmacies associated with clinics or licensed over-the counter-medicine seller facilities were not included. Children and adolescents shall not be included in the study.

3.4 SAMPLING

A simple random technique was employed to select retail Pharmacies as data collection centres. A full list of licensed retail community Pharmacies in the Municipality (N=124) was obtained from the Pharmaceutical Society of Ghana. Consecutive numbers were assigned to each pharmacy on the list and 15 computer aided random numbers were generated from the list. Where a selected Pharmacy declines to allow data collection in their facility, a new random number was generated from the remainder of the pharmacies in the list.

This approach was necessary to ensure that all Pharmacies have equal chance of being selected as study site so that generalizability is possible and selection bias is minimized. Consecutive sampling was then employed to enroll first twenty eligible participants from each data collection centre.

Pharmacists working in these selected pharmacies with at least a year's working experience were also interviewed.

3.4.1 SAMPLE SIZE CALCULATION

Prevalence of self-medication with antibiotics among tertiary level students in Accra (Ghana) was reported to be 70% (Donkor et al, 2012). Using that as the estimate of the true prevalence of the current study, the sample size was estimated using the formula below;

$$n = (Z^2 \times P (1 - P))/e^2$$

where:

- Z = value from standard normal distribution corresponding to desired confidence level ($Z=1.96$ for 95% CI)
- P is expected true proportion (70% or 0.7)
- e is desired precision (0.05).

Therefore,

$$n = (1.96^2 \times 0.7 (1 - 0.7))/0.05^2$$

$$n = 323$$

Adjusting for non-responses, the estimated sample size was increased by 5%. This yielded a sample size of 339.

3.5 DATA COLLECTION

Data were taken from April to mid-June 2018. Prior to data collection, the PI met staff of the selected facilities to discuss the entire research aims and objectives as well as procedure with them. Since the study merely aimed to take data on medicine distribution patterns and patient related factors, the presence of the investigator did not affect dispensing behavior. Without interfering with usual dispensing practices, adults who were supplied with antifungal products were invited to participate in the study.

The data collection instrument was a questionnaire designed to meet the stated objectives of the study after an extensive review of literature of similar studies done for antibiotics (See appendix A for questionnaire). Data was collected through face-to-face interview using a guided questionnaire. The questionnaire was made up of three sections. The first section took patient demographics and necessary drug related information such as name of drug, type of infections, prescription status, type of antifungal dispensed, number of antifungals and other antimicrobials dispensed. The second section sought to measure patient's knowledge and attitude towards obtaining antifungals without prescription and the final section recorded previous history of antifungal use within the past six months.

The counseling rooms of the retail Pharmacies were used for the interviews to ensure privacy. To assist patients to recollect history of use, sample packages of available anti-fungal products were displayed. The principal Investigator was assisted by eight trained Pharmacy Graduates (interns) in the data collection.

With the Pharmacists, A qualitative, semi-structured in-depth interview guide was employed as data collection tool. This data collection procedure allows uniformity in data for easy

categorization and analysis, and at the same time gives informants the freedom to express their views in their own terms. The interview covered areas such as why pharmacists dispense antifungals without prescription, what measures they put in place to ensure rational dispensing and why they think patients demand from them instead of visiting physicians (see Appendix for interview guide).

All qualitative interviews were conducted by the PI to ensure consistency in data collection. The PI met respondents at their own convenient place and time to conduct the interviews. Data was digitally recorded with a stereo digital voice recorder and transcribed ad verbum into a MS-Word document. Data generation and recruitment of participants continued until the researcher was convinced that thematic saturation had been achieved; the point at which new data is no longer contributing to the findings due to repetition of themes and comments by participants.

3.6 QUALITY CONTROL

Prior to the start of the data collection process, training sessions on questionnaire administration were organized for the Research Assistants (RA). This covered basic research ethics, communication and obtaining cooperation from respondents. This was then followed by training that applies to the current study. Topics covered were reinforced by assessments of knowledge retained and with group discussion and interaction, trainer demonstrations, and classroom practice and discussion. The PI intermittently and randomly supervised data collection sites. Regularly scheduled meetings to discuss data collection issues were also held on four occasions. Data collected was collated and entered promptly into Microsoft Excel for cleaning.

3.7 DATA PROCESSING

The Medscape™ Drug and Disease Reference application software and the British National Formulary 74 (BNF) were used to identify and classify medicine into therapeutic groups. The data was entered and cleaned using Microsoft Excel software and analyzed using STATA Version 15. Most of the data was categorized, summarized and presented using simple descriptive statistics (mean +/- standard deviation (SD), and proportions). Where deemed appropriate, the chi-square test and the kruskal-wallis equality-of-populations rank test were utilized to find any associations between nominal categorical variables and ordinal categorical variables respectively. At 95% confidence interval, logistics regression analysis was performed to determine predisposing factors to obtaining antifungals without prescription.

For the qualitative component, important themes arising from the responses were extracted using thematic content analysis. According to Braun & Clarke (2006), thematic analysis extracts

important patterns within a given data set. It minimally organizes and describes the data set in rich detail. Analysis was performed through the process of coding the transcripts in six phases to create meaningful patterns. These phases are: familiarization with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report.

3.8 ETHICAL CONSIDERATION

Ethical Clearance for the commencement of the study was obtained from the Ghana Health Service Ethical Review Committee (ID: GHS-ERC 138/12/17). Permits were obtained from the various Pharmacies for the commencement of the study, and where requested, a copy of the study proposal were provided to the Pharmacies involved. Each of the study participants were served with an introductory letter from the Department of Epidemiology and Disease Control of the School of Public Health. This assured participants that the study was for academic purposes only and also authenticated the investigator. Respondents were assured that information they provided will be treated with utmost confidentiality. None of the respondents were be identified by name or by any means. Participants consented to their participation by signing an Informed Consent Form (Available as Appendix).

For the qualitative component of the study involving community Pharmacists, neither names nor any other identifying information was associated with the audio or the transcript. Participants were not identified by any personal detail given. Where specific statements are quoted for emphasis in data analysis, transcripts were distinguished by special identification codes generated for participating pharmacists. This study involved the use of audio recordings for the purpose of pooled data analysis only. Only the Principal investigator had access to this data. The data was

stored on a personal computer in an encrypted folder and each file was password protected. The data will be destroyed immediately after the final report of the study is complete.

There was a risk that participants may share some personal information by chance, or that they may feel uncomfortable talking about some of the topics. From the onset, participants, were assured that their participation in the research project is entirely voluntary and that they do not have to answer any question if they feel the question (s) are too personal or if talking about them makes them uncomfortable.

If the person consented to participate in the research project, they had the right to withdraw at any time without a need to explain why and without prejudice. Where a participant decided to withdraw, their information/data were also withdrawn from the project, unless they consent to retention of their data/information.

Prospective participants were made to understand that they will not suffer any consequence if they decline to participate in the study or decide to withdraw the study.

There was no direct benefit to participants; however, their participation furnished us with important knowledge as to the extent, nature and determinants of antifungal medicines exposure, with the ultimate aim of ensuring rational and safe use of drugs. This information will help regulators and health professionals know areas that can be improved so that antifungal medicines use is optimized and risk of use are minimized.

3.9 PILOT STUDY

The study was piloted in three retail Pharmacies in the Municipality, one purposefully selected from each of three constituencies. Prior to piloting, face and content validity of the questionnaire were performed by two academics with expansive skills and experience in survey research and four eligible participants. Four participants from each of the three Pharmacies were selected for the piloting and Cronbach's alpha ($\alpha=7.2$) was run for the 12 participants to ascertain the internal consistency of the questions. Based on the feedback from the piloting, questions were reworded, reformatted, and reordered and re-tested, where necessary.

CHAPTER 4 RESULTS

4.1 BACKGROUND

Overall, 352 study subjects were invited to participate in the study. However, 48 subjects declined to participate citing varied reasons. These reasons included lack of time (n=39), lack of interest (n=9), and confidentiality concerns (n=12). Six of them did not give any reason. Exactly 40 of those who refused to participate in the study were females and the rest were males.

A total of 311 questionnaire guided interviews were conducted, but 7 questionnaires not analyzed due to incomplete information.

4.2 DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS

The 304 participants who completed the interview comprises of 73.36% females and 26.64% males. They received a total of 389 antifungal medicines, representing an average of about 1.3 antifungal medicines per person. Majority of the respondents (69.74%) were 30 years or below and most of the respondents (73.03%) earned less than 1,000 Ghana cedis a month on average. However, more than 60% of respondents were either employed or self-employed with only about 5% unemployed or retired. Majority of the respondents either held a university degree or a senior high school certificate (35.31% and 34.6% respectively) About 64% of respondents were either not enrolled on any health insurance scheme (n=88) or had their membership of an insurance scheme expired (n=107).

The demographic characteristics are summarized in *table one* below

Table 1: Demographic characteristics of participants

Demographics	Frequency (%)
Sex	
Males	81 (26.64)
Females	223 (73.36)
Age (years)	
18-30	212 (69.74)
31-40	53 (17.43)
41-50	23 (7.57)
51-60	13 (4.28)
above 60	3 (0.99)
Highest educational status	
Senior high or lower	138 (45.39)
Polytechnic	36 (11.84)
college/university	107 (35.2)
Postgraduate	23 (7.57)
Employment status	
Employed	126 (41.45)
Self-employed	70 (23.03)
Retired/unemployed	15 (4.93)
Student	93 (30.59)
Health insurance status	
Yes and It's active	109 (35.86)
Yes but expired	107 (35.2)
No	88 (28.95)
Average monthly income (cedis)	
less than 500	98 (32.24)
500 to less than 1000	124 (40.79)
1000 to less than 2000	51 (16.78)
2000 to less than 3000	16 (5.26)
3000 to 5000	15 (4.93)

Source: field survey, 2018

4.3 PREVALENCE AND FACTORAS OF OBTAINING ANTIFUNGAL MEDCINES WITHOUT PRESCRIPTION

4.3.1 PREVALENCE

The proportion of participants that obtained antifungal medicines without a prescription was 0.74 (SE: 0.025, 95% CI: 0 .69- 0 .79). This means that 26% of the respondents obtained their antifungal medicines with a valid prescription from a physician. The remainder obtained by a recommendation of a Pharmacist (30.92%), the recommendation of a Medical Counter Assistant (15.79%) or by demand by patient (27.30%).

4.3.2 CHI-SQUARE TEST OF ASSOCIATIONS

The chi-square test of association was utilized to find any associations between participants' demographic features and obtaining antifungal medicines without prescription. The results are shown in the *table two* on next page.

Table 2; Association between prescription status and demographic features

Prescription status	Highest educational status attained			
	Senior high or lower	Diploma	First degree	Postgraduate
With prescription	24 (17.39)	14 (38.89)	32(29.91)	9 (39.13)
Without prescription	114 (82.61)	22 (61.11)	75(70.09)	14(60.87)
$\chi^2 (3) = 11.3373, p= 0.010^*$				
	Age category (years)			
	18-30	31-40	40 or more	
With prescription	49 (23.11)	20 (37.74)	10 (25.64)	
Without prescription	163(76.89)	33 (62.26)	29 (74.36)	
$\chi^2 (3) = 4.7164, p= 0.059$				
	Average monthly income (Ghana cedis)			
	Less than 500	500 to less than 1000	1000 to less than 2000	2000 or more
With prescription	28 (28.28)	24 (19.35)	23 (45.10)	4 (13.33)
without prescription	71 (71.72)	100(81.82)	28 (54.90)	26 (86.67)
$\chi^2 (3) = 15.2890, p = 0.002^*$				
	Health Insurance status			
	Insured	Uninsured		
With prescription	40 (36.70)	39 (20.00)		
Without prescription	69 (63.30)	156 (80.00)		
$\chi^2 (1) = 10.1348 p = 0.001^*$				
	Employment status			
	Self-employed	Unemployed/retired	Employed	
With prescription	24 (34.29)	30 (27.78)	25 (19.84)	
Without prescription	46 (65.71)	78 (72.22)	101 (80.16)	
$\chi^2 (2) = 5.1608 p= 0.076$				

Note: * $p < 0.05$ considered statistically significant results.

Numbers in parentheses indicate column percentages

Source: field survey, 2018

4.3.3 PREDICTORS OF OBTAINING ANTIFUNGALS WITHOUT PRESCRIPTION

A logit model was used to model the log odds of “obtaining antifungal medicines without prescription” as a linear combination of educational status, health insurance status, average monthly income and employment status, controlling for age and sex. The coefficients (β) were exponentiated to give odds ratios. A “link test” conducted after the regression did not provide any evidence of specification error in the model suggesting a linear relationship between the logit of the outcome variable and the predictor variables. The model as a whole fits the data well (N=304, LR χ^2 (10) = 39.09, p -value < 0.000). Results of the regression are shown in the *table 3* below:

Table 3; Predictors of obtaining antifungals without prescription

Demographic features	Crude odds ratios			Adjusted odds ratios**		
	OR	p -value	95% CI	OR	p -value	95% CI
Educational level						
(base: senior high or lower)						
Diploma	0.331	0.007*	0.148 - 0.738	0.346	0.018*	0.144-0.835
First degree	0.493	0.022*	0.270- 0.903	0.418	0.011*	0.214-0.816
Post graduate	0.327	0.021*	0.127-0.843	0.268	0.012*	0.964-0.746
Insurance status						
(Base: insured)						
Uninsured/expired	2.317	0.002*	1.373-3.917	2.135	0.010*	1.190-3.808
Monthly income(cedis)						
(Base; less than 500)						
500-1000	1.643	0.119	0.880-3.068	0.732	0.033*	1.064-4.155
1000-2000	0.480	0.041*	0.237-0.971	0.360	0.699	1.951-0.368
Above 2000	2.563	0.106	0.820-8.014	2.917	0.012*	1.40-15.85

Note: * $p < 0.05$ considered statistically significant results.

** *Odd ratios adjusted for sex, age and employment status*

Source: Field work, 2018

4.4 ANTIFUNGAL CONSUMPTION

4.4.1 ANTIFUNGALS DISPENSED

Fluconazole was the most commonly dispensed antifungal agent (n=120), followed by clotrimazole (n=91) and griseofulvin (n=48), with econazole (n=11) being the least dispensed (**fig 2**). Out of the 120 times that fluconazole was dispensed, 26 were obtained by prescription, with the remainder being obtained either by patient demand (n=32), pharmacist recommendation (n=38) or MCA recommendation (n=24) (**fig 3**). The sales value of the three hundred and eighty-nine (389) antifungal medicines was 8,400 Ghana cedis (Range: 3-200, Mean 27.63, SD=25.00 cedis).

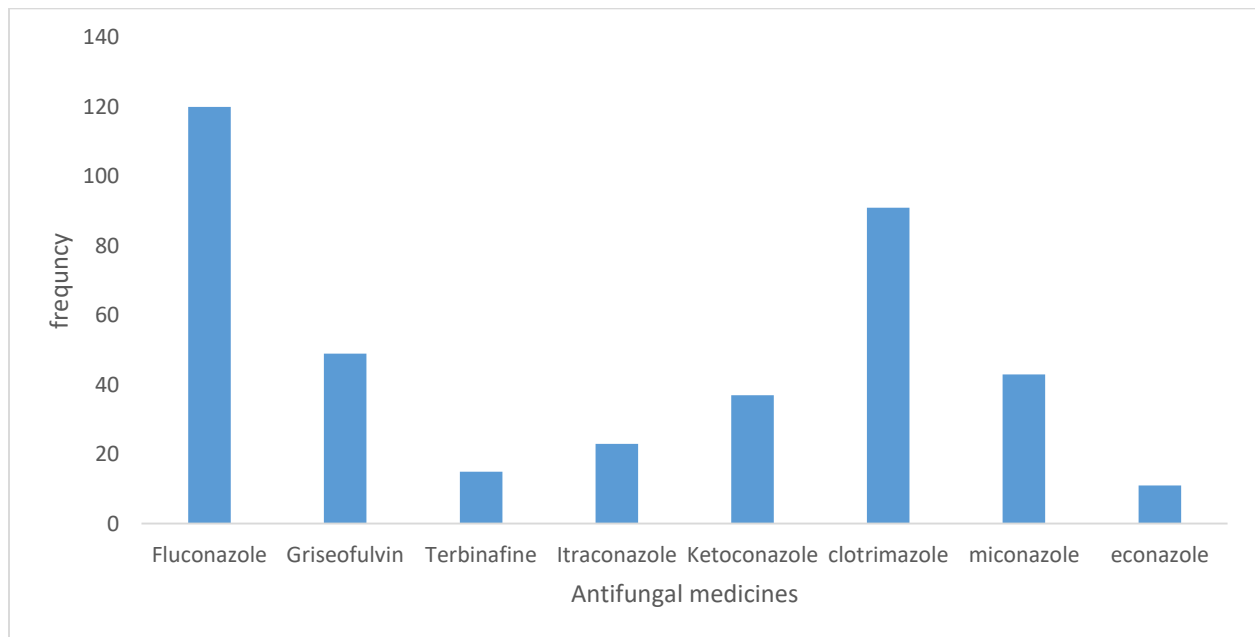


Figure 2; Antifungal medicines dispensed

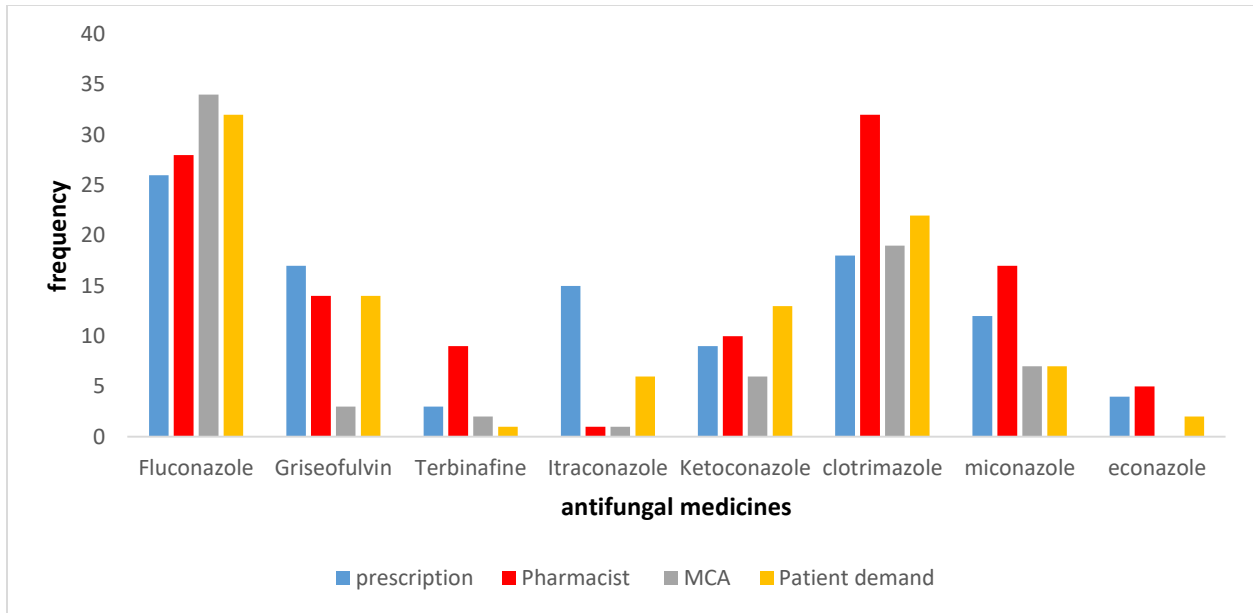


Figure 3: How antifungal medicines were obtained

4.4.2 REPORTED CONDITIONS FOR WHICH MEDICINES WERE OBTAINED

Oral Ketoconazole was frequently dispensed for perceived or evaluated fungal infections of the skin (29/38) (*figure 5*). Only one incidence of oral candidiasis was reported in one female and this was treated with fluconazole with a prescription from a physician. The most commonly reported case of fungal infection were symptoms of vulvo-vaginal candidiasis in females (n=177), with the majority occurring in women of younger between the ages of 18-30 years. This were mostly treated with fluconazole (n=118) and/or clotrimazole (n=73). The next most commonly reported case of fungal infection is fungal skin infections (dermatophytosis, including tinea cruris)(n=98) (*see fig 4*).

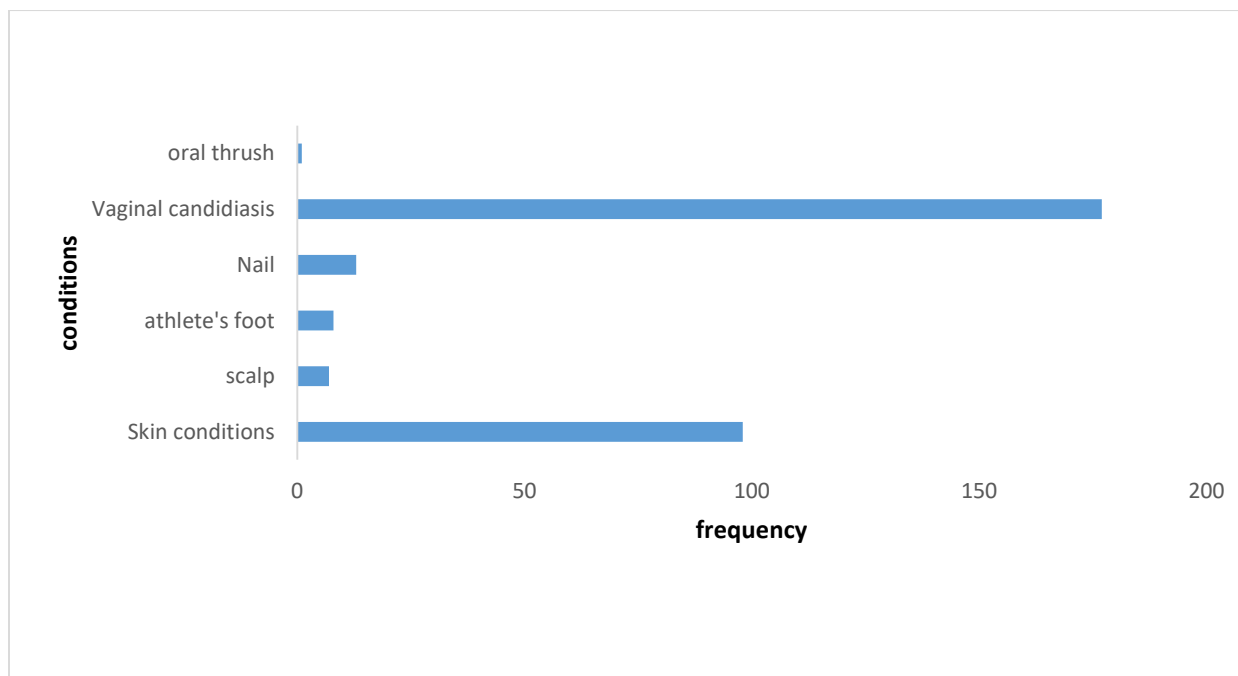


Figure 4: Fungal infections treated

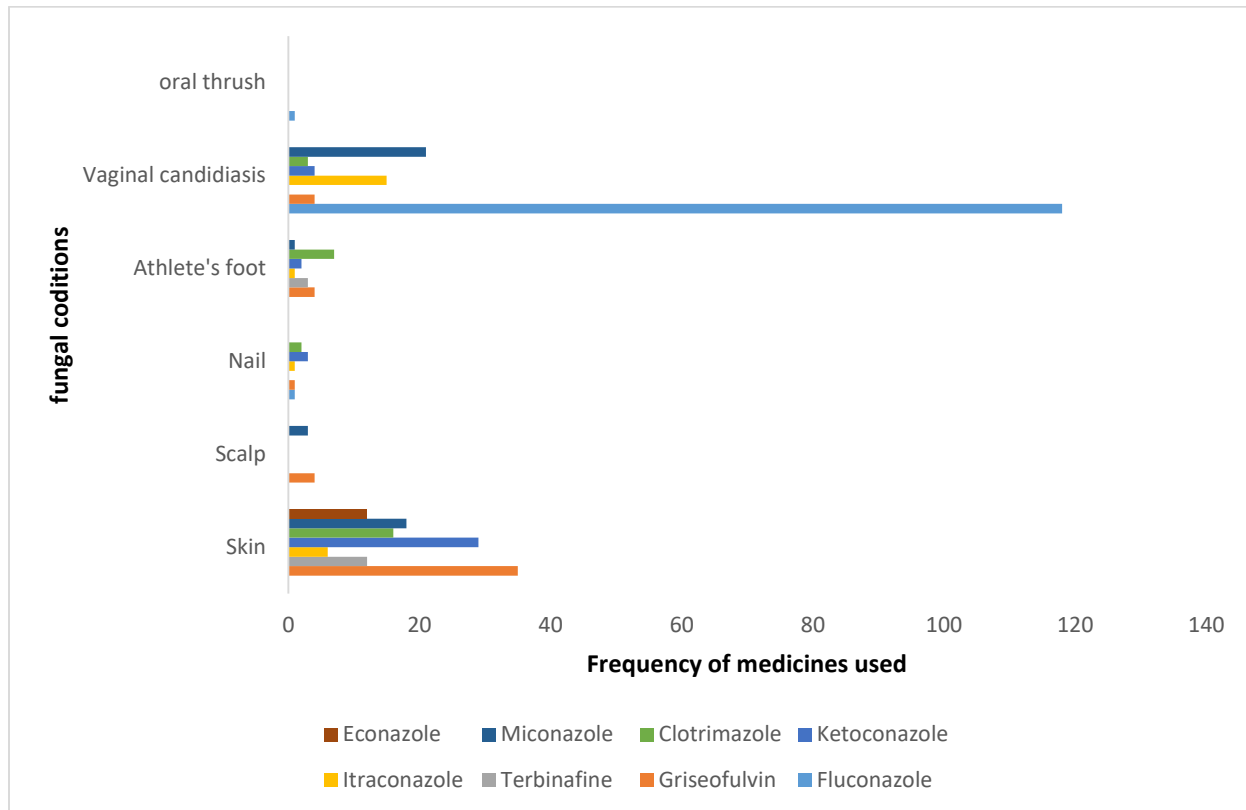


Figure 5: Medicines and conditions treated

4.4.3 CONCOMITANT USE WITH OTHER MEDICINES

Approximately 12% of respondents (n=37) received other class of medicines, particularly oral antibiotics concomitantly with antifungals. The most frequently dispensed groups of antibiotics were the nitroimidazole groups (n=17, e.g. metronidazole), the tetracyclines (n=12, e.g. doxycycline) and the quinolones (n=8, e.g. ciprofloxacin). The cephalosporins (n=6, e.g. cefuroxime) and penicillins (n=3, e.g. ampicillin) were less frequently dispensed concomitantly with antifungal medicines. About 4% (n=13) of the respondents also received antihistamines (e.g. cetirizine).

4.5 PATIENTS PERCEPTION AN ATTITUDE TOWARDS ANTIFUNGAL MEDICINES

4.5.1 PERCEPTIONS

More than half (66.12%) of respondents believe that antifungal medicines can be purchased without a doctor's prescription and less than half of respondents (39.47%) believe that it is okay to stop taking an antifungal medicine when symptoms improve. Almost half (49.34%) of participants believe that antifungals are good any itching conditions of the skin (refer to table 4)

Table 4; Perceptions about antifungals

Item	Yes n (%)	No n (%)	Uncertain n (%)
Antifungals are taken to treat infection	271 (89.14)	19 (6.25)	14 (4.61)
Antifungals are good for any itching conditions of the skin	150 (49.34)	104 (34.21)	50 (16.45)
Antifungals can be purchased without a doctor's prescription.	201 (66.12)	68 (22.37)	35 (11.51)
It is okay to stop taking an antifungal when symptoms improve.	120 (39.47)	163 (53.62)	21 (6.91)
Antifungals do not have serious side effects	72 (23.68)	128 (42.11)	104 (34.21)

Source; Field survey, 2018

4.5.2 SOURCES OF INFORMATION ABOUT ANTIFUNGAL MEDICINES

The study participants frequently resort to their Pharmacists (n=187), friends and family relative (n=92) and previous use of medicines as a source of information about their medicines use. Other sources included internet (n=86), physicians (n=70) and the package leaflet (n=57). (*see fig 6 on next page*).

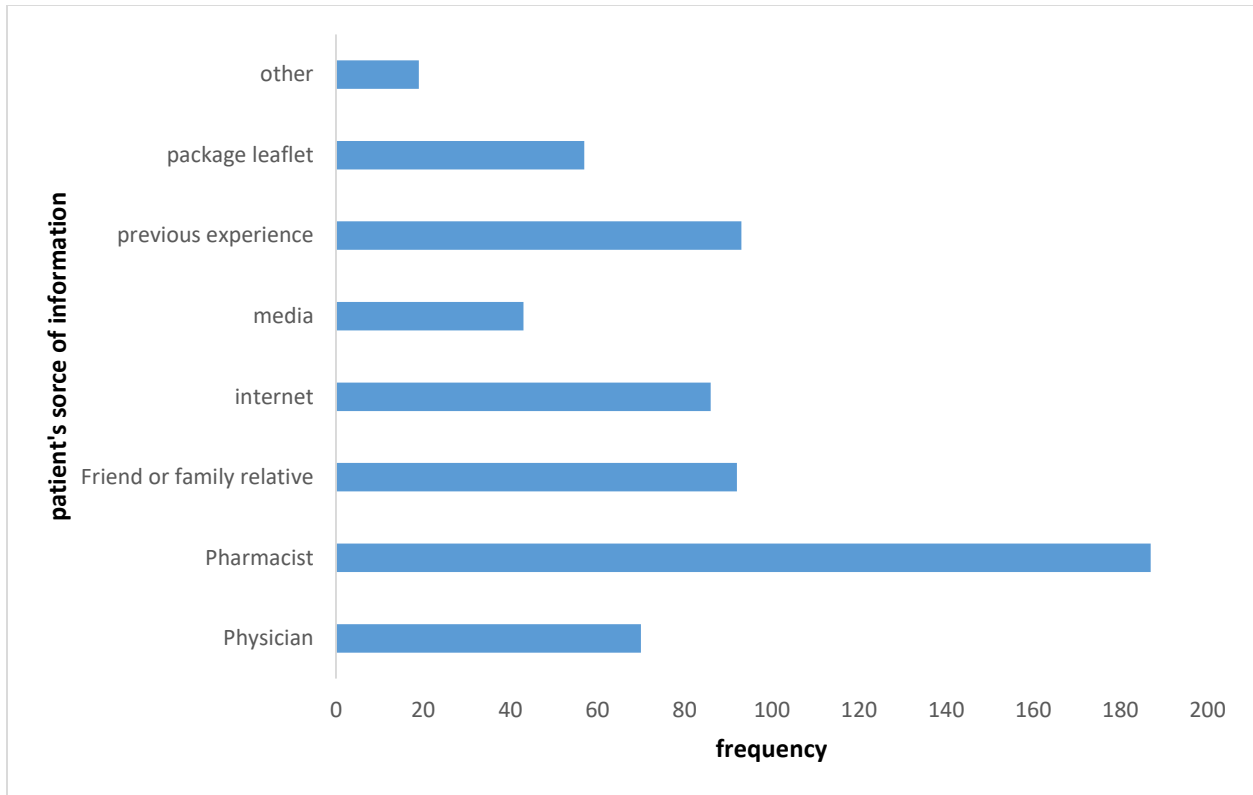


Figure 6: Sources of information on drug use

4.5.3 ATTITUDES

A six-item, five-point likert scale ($\alpha=0.72$) was developed to measure the attitude of respondents towards self-medication with antifungal medicines. The results are shown in the table 5

Table 5; Attitude towards self-medication with antifungals

Item	Strongly disagree n (%)	Disagree n (%)	Uncertain n (%)	Agree n (%)	Strongly Agree n (%)
Anti-fungal medicines should be available over the counter	43 (14.14)	58 (19.08)	40 (13.16)	111(36.51)	52 (17.11)
Getting medicines over the counter saves time and it works for me	27 (8.91)	52 (17.16)	32 (10.56)	102 (33.66)	90 (29.70)
When someone at home has similar symptoms, I can pass on my left over medicine to him or her	116 (38.16)	88 (28.95)	35 (11.51)	46 (15.13)	19 (6.25)
Once my symptoms are okay, it is advisable to stop taking an antifungal	69 (22.70)	89 (29.28)	38 (12.50)	72 (23.68)	36 (11.84)
Expensive antifungals are more effective and have less side effect	45 (14.80)	100 (32.80)	75 (24.67)	51 (16.78)	33 (10.86)
The effectiveness of treatment would be reduced if a full course of antifungal was not completed?	50 (16.50)	42 (13.86)	45 (14.85)	85 (28.05)	81 (26.73)

Table 6; Association between attitude items and demographics

item	Age <i>p-value</i>	Educational status <i>p-value</i>	Income <i>p-value</i>	Sex <i>p-value</i>	Health insurance status <i>p-value</i>
Anti-fungal medicines should be available over the counter	0.40	0.86	0.72	0.71	0.25
Getting medicines over the counter saves time and it works for me	0.01 ^a	0.44	0.25	0.18	0.025 ^a
When someone at home has similar symptoms, I can pass on my left over medicine to him or her	0.01 ^a	0.0002 ^a	0.036 ^a	0.0003 ^a	0.0422 ^a
Once my symptoms are okay, it is advisable to stop taking an antifungal	0.09	0.05	0.19	0.61	0.54
Expensive antifungals are more effective and have less side effect	0.06	0.0022 ^a	0.36	0.34	0.40
The effectiveness of treatment would be reduced if a full course of antifungal was not completed?	0.31	0.0009 ^a	0.11	0.52	0.0467 ^a

p-values calculated through Kruskal-Wallis equality-of-populations rank test

^a *p < 0.05 considered statistically significant results.*

Source: field survey, 2018

A composite index of attitude, calculated as the sum of the individual scores of each of the six items of the likert scale, yielded a mean value of 17.88 (SD=5.10, range: 7-30, CI:17.30-18.45)

4.5.4 HISTORY OF USE

More than half (67.76, n=206) of study participants reported previous use of antifungal agents over the past six months. Out of this number, 72.33% (n=149) used antifungal without obtaining prescription from a physician. Participants who obtained antifungal medicines without prescription or had a history of use without prescription cited various reasons for their behavior. The reasons are as shown in figure 7:

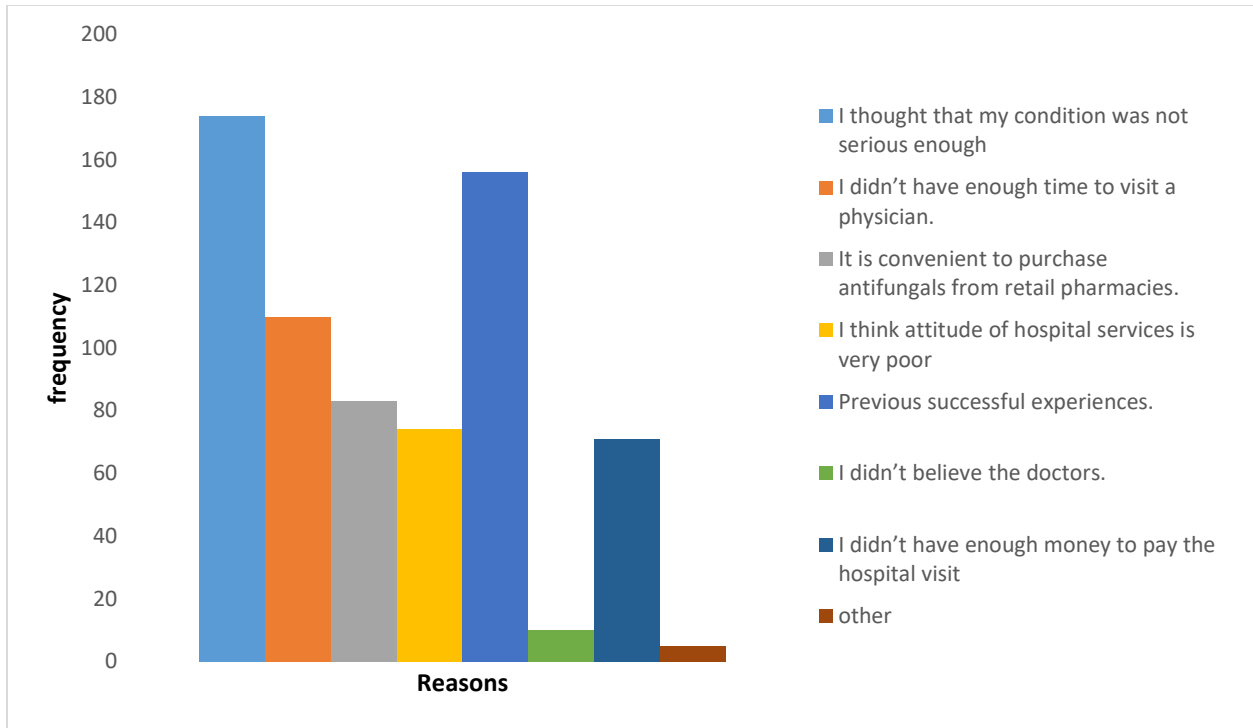


Figure 7: Reasons for obtaining medicines without prescription

4.6 COMMUNITY PHARMACISTS' PERSPECTIVES ON ANTIFUNGAL DISPENSING WITHOUT PRESCRIPTION

Eleven interviews were conducted among Pharmacists. Characteristics of participants are shown in the table below;

Table 7; Demographic features of pharmacists

Participant Id	Gender	Age (Years)	Years Of Community Practice	Qualifications
PH1	Male	33	8 years	Bpharm
PH2	Male	27	2 years	Bpharm, MSc
PH3	Male	26	2 years	Bpharm
PH4	Female	26	1 year	Bpharm
PH5	Male	25	1 year	Bpharm
PH6	Female	28	4 years	Bpharm
PH7	Male	30	6 years	Bpharm, Mphil
PH8	Female	32	7 years	Bpharm
PH9	Male	29	3 years	Bpharm
PH10	Female	34	8 years	Bpharm
PH11	Female	25	1 year	Bpharm

Source: field Survey, 2018

The findings are organized into five themes and some sub-themes. The themes are presented in turns and illustrative text from respondents transcripts are presented for each theme. Pharmacist's identifier codes and age are displayed in parentheses.

1. Attitude towards dispensing antifungal medicines without prescription

Pharmacists demonstrated divided opinions towards dispensing antifungal medicines without prescription. Those who favored dispensing antifungals OTC believed that pharmacists are adequately trained to treat non-serious fungal infections. Those who did not favor that highlighted the risk of misuse and adverse effects

...Well I believe pharmacist in their own capacity have the ability to prescribe medication, even without a prescription, to recommend some medication without prescription and antifungals are one of them [PH4, 26]

...Not at all! We shouldn't dispense them. Antifungals are a group of medicines with some serious adverse effects that we often take for granted [PH7, 30]

2. Practice

Attitudes notwithstanding, antifungals were dispensed without prescription, sometimes by pharmacy support staff even though participants asserted that antimicrobials should only be dispensed by Pharmacists or under their direct supervision.

For me what I actually do is that I always probe to establish a reason for the demand. If I am satisfied that my patient truly need it I just go ahead and give. I must admit that a few occasions you may simply dispense on demand without any queries but honestly I mostly find out why they need the drug. I know my MCAs sometimes just give on demand but for me I will mostly make few enquiries before dispensing [PH1, 33]

MCAs have been trained to assist pharmacist in dispensing medications. However, they do not have extensive training on the pharmacology and toxicology of medicines. Their knowledge on therapeutic doses, contraindications, side effects of drugs, as well as cautions associated with drug use are limited... MCAs should not be allowed to dispense antifungals [PH2, 27]

3. Impact

Even though they dispensed without prescription, participants were aware of the risks associated with that practice. They agreed that irrational dispensing, misuse by clients, risk of adverse outcomes and ultimate development of resistance could occur.

You see, as I said earlier on, you may argue several points in favor of dispensing them [antifungals] without prescription. But if we are not careful, it will become a culture such that people will prefer to visit the pharmacy instead of the hospital for just everything. And then also if the medicines are too available, people misuse them. This is an antimicrobial and resistance can be an issue [PH8, 32]

The consequences can be many and varied. At least, I can readily name incomplete treatments, poor treatment outcomes, antimicrobial resistance, retreatments, and increased costs among many others [PH3, 26]

4. Drivers

Participants highlighted reasons they dispense without prescription as explained below:

a. Regulatory factors

Participants claimed that they were not aware of any regulation that prohibit them from dispensing antifungals over the counter. They also bemoaned the lack of effective supervision of dispensing practices in the country

...Even chemical shops [OTC medicine sellers] are hiding them and selling them when they are not supposed to, what has the [pharmacy] council done about it? So how much more than me a pharmacist? [PH 11, 25]

Also, as far as I can remember, most of the antifungal drugs are not really classified as Prescription only medicines by the FDA. That may be the case in other jurisdictions but I am sure the FDA understands our unique situation and has decided to allow us to dispense them without prescription [PH5, 25]

b. Commercial awareness

The fear of losing a client and not hitting target sales were important driving force of dispensing. Participants were skeptical about clients adhering to referrals. They believed clients will always get the medicines elsewhere if they are denied their demand for medicines and referred them

[smiles] They will go and get the drug elsewhere and come back to show it to you and that's three losses in one [giggles]. First, you will miss an opportunity to help a client, second you miss the opportunity to make sales and if you are not careful you will lose a loyal client altogether. Don't forget the retail pharmacy is also a business besides the fact that it's more or less a health care centre [PH1, 33]

c. Health system factors and patient welfare

Participants believed that pharmacist-led services provide an affordable, and widely available and convenient alternative to hospital services

...Our health system has been crippled with many many many basic challenges that have not been addressed for decades. For example, when you consider the Doctor-Patient ratio in this country, you'd realize that the doctors have simply been "swallowed". This does not encourage patients to attend hospitals because they claim the services over there are very poor. Most of these people, by assessment, never go to these hospitals even when we refer them [PH3, 26]

5. Poor stewardship

Participants do not have or enforce any formal stewardship programmes for antifungals. Participants admitted a lack of attention with antifungals when it comes it to rational medicines use as compared to antibiotics.

.....and also we have probably not read in-depth about the seriousness of their side effects so when they come and ask for it we just give it to them [PH9, 29]

[Oooohh] we do not really have an official policy or guidelines but at least we make sure that a pharmacist is involved in the dispensing of antifungals and especially antibiotics most of the time. Occasionally when the place is very busy MCAs do it yes but mostly when I am around I take charge of dispensing all anti-infectives [PH10, 34]

CHAPTER 5

DISCUSSION

This chapter interprets the findings of the research in light of the conceptual model as an analytical framework. It evaluates the implications of the findings and also compares and contrasts the results with that of other studies and literature.

5.1 SUMMARY OF MAIN FINDINGS

Antifungal medicines were mostly dispensed OTC (without valid prescription from a Physician). Patients who had lower levels of education, not enrolled on any health insurance scheme and earned higher income had higher odds of purchasing antifungal medicines without prescription. Patients attitude towards self-medication was fairly moderate and many participants had history of use of antifungal medicines within the last six six months. Fluconazole was the most frequently dispensed agent, and it was frequently used to treat vaginal candidiasis. Ketoconazole was mostly used to treat suspected skin conditions. Community Pharmacists dispensed without prescription because of commercial awareness and health system challenges, even though they acknowledge the potential risk of dispensing them OTC. Antifungals are also sometimes dispensed by unqualified personnel, and sometimes on patient demand. Regulation and stewardship measures are generally weak or non-existent according to the Pharmacists interviewed.

5.2 METHODOLOGICAL VALIDITY

The current study is the first attempt to describe antifungal consumption in a Ghanaian population. The study employed quantitative and qualitative approaches to different aspects of the study to widen the scope and corroborate and enrich the data. Random sampling of pharmacies approach was employed to minimize selection bias and to ensure generalizability. The major limitation is the lack of generalizability that is inherent in any qualitative study and challenges of recall. The study also focuses on dispensing, which may not necessarily be a good indicator of consumption.

5.3 COMPARING FINDINGS WITH OTHER STUDIES

Medical literature is replete with studies on antibiotic utilization in many parts of the world. However, there is paucity of information on the use of other antimicrobial agents, particularly drugs for treating fungal infections. The current study is the first work on irrational antifungal use in Ghana. In the current study only 26% of the respondents obtained their antifungal medicines with a valid prescription from a physician. The point prevalence of over-the-counter use was therefore 74%. This finding is quite higher than as reported in other studies. In a similar study conducted in Mwanza City, Tanzania, the reported rate was 55.5% (Mushi, Masewa, et al., 2017). However, the findings are consistent with studies of self-medication in general in many Eastern Mediterranean countries as reported in a systematic review by Khalifeh et al. In that review, the authors report values in the range 35.4% to 83% in countries such as Jordan, Pakistan, Iran and Saudi Arabia (Khalifeh, Moore, & Salameh, 2017). A 70% prevalence of self-medication with antibiotics among tertiary level students in Accra, Ghana is also documented elsewhere (Donkor, Tetteh-Quarcoop, Nartey, & Agyeman, 2012). However, results from many developed countries are generally low. Prevalence of between 3% and 22% has been recorded for countries like Spain, Lithuania, Denmark and the USA (Babatunde et al., 2016). There is enough evidence from this study and the other various studies discussed above to support the assertion that the use of antimicrobial agents without medical advice, and irrational utilization of antimicrobials is relatively higher in the developing countries as compared to the developed countries. This is not difficult to understand, when one considers the health system challenges of many African countries including Ghana. Ghana has a universal healthcare system, which has been touted as the most successful healthcare system in Africa by Bill Gates. The National Health Insurance Council

(NHIC) was established by the National Health Insurance Act, 2003 (Act 650) to ensure universal access to basic healthcare services to all residents of Ghana.

Despite the progress made in healthcare over the years, in the state of the nation's address delivered by President John Mahama on February 13th 2013, he stated that Ghana's healthcare system still lacks adequate health professionals with some service deficiencies despite the human capacity development programmes being implemented. In 2012, there was one doctor available for every 10,452 people and one nurse to 1,251 people (Report on the Ghana Shared Growth and Development Agenda, 2010 – 2013). There is inadequate number and uneven distribution of health facilities in the country; well over half of all hospitals are located in one of two regions, Ashanti and Greater Accra (Sato 2012). Another major public health challenge that may be peculiar to Ghana is the availability of all kinds of medicines on the open market, including prescription only medicines. This is compounded by very weak regulatory structures.

In the context our deficient healthcare system therefore, obtaining medicines OTC, when well informed and done properly could potentially offer some benefits to patients and to the health system. First, it has the potential to reduce the time cost and monetary cost associated with hospital care in the country, it can reduce the burden on prescribers to focus on more serious conditions and it can promote patient empowerment towards self-care and management of minor ailments. However, ill-informed self-medication is associated wrong diagnosis and irrational medicine use including overuse, underuse, and prolonged duration of use, drug interactions and polypharmacy. Improper self-medication is one of the few individual behaviors that can have repercussions in the general population. Another problem is that when this behavior is not checked, it could create an unwelcomed culture where community Pharmacies is frequently utilized even for conditions that may require a higher form of care. In the current study for example, the proportion of participants

obtaining antifungal medicine without a prescription was significantly higher among those with history of use without prescription ($pr= 0.78$, 95% CI= 0.72-0.84) than those with no history ($pr=0.69$, 95% CI=0.60-0.78), ($z=1.76$, $p\text{-value}=0.0389$). About 12% of respondents ($n=37$) also received other class of medicines, particularly oral antibiotics concomitantly with antifungals. This is largely due to the fact that symptoms of many sexually transmitted infections and Urinary tract infections are not specific. As a result, in a poor resource setting where laboratory support is largely unavailable, the syndromic approach to the management of many suspected genito-urinary tract infection becomes very rational. However, this approach is also not without set-backs. First, there is the risk of overtreatment. Also, many antifungal drugs have the potential to adversely interact with other medicines, and this risk is increased with polypharmacy.

The azole group of antifungal agents remains the antimycotic agent that is frequently dispensed in this and many other studies. The clinical efficacy and safety of fluconazole in particular has resulted in widespread use (Mushi, Masewa, et al., 2017,). The most commonly reported case of fungal infection were symptoms of vulvo-vaginal candidiasis in females ($n=177$), which were mostly treated with fluconazole ($n=118$) and/or clotrimazole ($n=73$).

In principle, Knowledge and Attitudes are good predictors of behavior. People are generally more knowledgeable about topics that interest them and are likely to hold strong attitudes as a consequence (McLeod 2014; Hogg & Vaughan 2005). Within the context of the study, it was anticipated that participants' level of knowledge in self-medication and attitudes towards same will reflect in their tendency of obtaining antifungal medicines without prescription. It is however worth noting that knowledge and attitude have not always successfully predicted behavior. In the current study, a composite index of attitude, calculated as the sum of the individual scores of each of the six items of the likert scale, yielded a mean value of 17.88 (SD=5.10, range: 7-30, CI:17.30-

18.45) out of a possible 30. Participants with scores less than 15 were classified as “unfavorable attitude” and 15 or more were classified as “favorable” attitude towards obtaining medicines over the counter. The odds of obtaining antifungal medicines was no different in either group (OR=1.01, p-value=0.789 95% CI= 0.60- 1.97), even when controlled for age, income and educational status.

Age and sex have been touted as important predictors of self-medication in one study (Donkor et al., 2012) In this study however, using a stepwise, backward elimination logistic regression approach, predictors of obtaining antifungal medicines without prescription were average monthly income, health insurance status, educational level and employment status. It is clear from the findings that obtaining antifungal medicines without prescription is more closely associated with socio-economic variables rather than individual characteristics such as sex, age and attitudes. This is also evident from the reasons participants gave for obtaining antifungal medicines. The most cited reasons were participants belief that the condition isn't serious (n=174), previous experience with the drug (n=156), time constraints (n=110) and convenience (n=83). Others include perceived poor hospital services and attitudes of practitioners (n=74), financial constraints (n=71) and lack of trust in medical practitioners (n=10). Clearly, these are issues related to health system and socio-economic climate.

Data from the interviews of the pharmacists clearly demonstrate many risk factors of irrational dispensing. Pressure from business-minded Pharmacy owners and the desire to achieve sales targets can influence Pharmacists and support staff to irrationally select and dispense antimicrobials. In the current study, MCAs, who are only trained and legally mandated to dispense OTC (Class c) medicines, actually recommended 15.79% of antifungal medicines. About 27.30% of medicines were also obtained on patient demand. This revelation is a cause for concern. MCAs

are not adequately trained to appreciate the pharmacology and toxicology of antimicrobials, and the pathology of fungal diseases. The risk of irrational dispensing is high when unqualified personnel recommend and dispense antifungal medicines.

The community Pharmacists also admitted to poor regulation of the practice especially of OTC medicine sellers. Also, antifungals do not receive adequate attention the same way antibiotics do when it comes to antimicrobial stewardship.

5.4 IMPLICATIONS FOR ANTIMICROBIAL STEWARDHIP AND PUBLIC HEALTH

1. The findings suggest the potential to result in irrational dispensing and irrational drug use and increase the risk of adverse events, which may contribute to the development of resistance. For example, oral ketoconazole is widely available OTC for the management of suspected skin fungal infections according to the study. In many countries in Europe and the USA Today, oral ketoconazole is only indicated for severe endemic mycoses, where other drugs are not available or feasible. This is due to several serious side effects associated with the drug including severe hepatic injury, endocrine gland suppression, several drug interactions and death. However, this study revealed that ketoconazole is available OTC.
2. Age, sex and attitude towards self-medication were not associated with the odds of obtaining antifungals without prescription. Socio-economic variables such as income, educational status, health insurance status and employment status were the predictors of obtaining antifungal medicines without prescription. What this means is that public education on rational drug use should target everyone. It also means that educating the public without addressing the underlying socio-economic and health system issues may achieve very little.

3. Patients appear to rely largely on information from Pharmacy staff about their medicines. Other sources include family and friends, previous use and rarely, package leaflet. This places community Pharmacists in a unique position to promote safe and rational use of medicines, as they are more available, accessible, and closer to members of the community than other health professionals. Pharmacists should therefore be trained and empowered to provide comprehensive medication counselling to their patients.
4. Suspected symptoms of vulvo-vaginal candidiasis was the most reported case in non-pregnant women particularly between the ages of 18-30 years. Young women should be educated on the risk factors for this disease. This include indiscriminate use of broad spectrum antibiotics, vaginal douching and washing with soaps, impaired immunity, hyperglycaemia among others. Education should cover lifestyle changes such as using cotton underwear and loose fitting underwear, avoiding indiscriminate use of antibiotics, monitoring blood sugar and HIV status for those severe, recurrent cases.

CHAPTER SIX

CONCLUSION AND RECOMMENDATION

In this section, key findings of the current study are highlighted and recommendations are also given where necessary, to address important issues.

6.1 CONCLUSION

The proportion of patients who obtain antifungal medicines OTC is significantly high. Antifungal medicines being obtained frequently from community pharmacies without a valid prescription from a physician has the potential to result in irrational dispensing and irrational drug use and increase the risk of adverse events, which may contribute to the development of resistance. Community Pharmacists dispensed without prescription because of commercial awareness and health system challenges, even though they acknowledge the potential risk of dispensing them OTC. Antifungals are also sometimes dispensed by unqualified personnel, and sometimes on patient demand. Regulation and stewardship measures are generally weak or non-existent according to the Pharmacists interviewed.

6.2 GENERAL RECOMMENDATIONS

1. The regulatory bodies should collaborate with practice groups to develop and adopt a comprehensive and feasible antimicrobial stewardship plan for retail community pharmacies
2. High quality Continuous Professional Development (CPDs) lectures for Pharmacists and support staff should cover areas under management of fungal diseases and antifungal drugs, including rational use of antifungal medicines and should keep up to date with latest evidence base for antifungal medicines.
3. The regulatory Authorities should not permit Retail Pharmacies to operate without a Pharmacist manning the place at all times.
4. Effective and proper referral systems between community Pharmacies and hospitals. This will ensure a multidisciplinary approach to patient management and antifungal stewardship.

6.3 RECOMMENDATIONS FOR FURTHER RESEARCH

1. Further studies are required to establish how Pharmacists expertise and clinical knowledge can be fully utilized to ensure appropriate use of antimicrobials and improve stewardships
2. Research into simple diagnostic tools that can be used in a community pharmacy setting to improve diagnosis of fungal infections before treatment may be useful
3. A household based study to ascertain actual consumption behavior will be useful

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APPENDICES

A; INFORMED CONCENT FORM (ICF) (FOR PATIENTS)

This ICF is for people who are supplied with anti-fungal medicines and are willing to take part in a study. The Form has two parts:

- A. Information Sheet (to share information about the study with you)
- B. Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form.

Part I: Information Sheet

Introduction

You are invited to participate in a research project entitled — Determinants of Anti-fungal use in the Ga-South Municipality; Implications for antimicrobial stewardship.

The study is being conducted by Okyere Amoaning Harry of the University of Ghana, as part of requirements for the award of the Master of Public Health (MPH) degree.

Purpose of the Study

We want to know the antifungal medicines that you are going to use or used previously and understand why you got them with or without a prescription.

Procedure

This research will involve your participation in an interview session that is expected to last for not more than 10 minutes. You will provide some personal details and answer some few questions by ticking your choices from a range of possible responses. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except the researcher will have access to the information documented during your interview.

Risk

There is a risk that you may share some personal information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

Benefits

There will be no direct benefit to you, but your participation is likely to help us know areas that health professionals can improve so that patients use these medicines appropriately and minimize any undesired effects.

Incentives

You will not be provided any incentive to take part in the research

Confidentiality & Information Dissemination

Information you provide will be treated as confidential and nothing will be attributed to you by name. However, information obtained from the entire research will be presented to faculty

members at a seminar of the University of Ghana, School of Public Health. I may then publish the results so that other interested people may learn from the research.

Right to Refuse or Withdraw

You may stop participating in the study at any time that you wish to.

Who to contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following;

Ms Hannah Frimpong'

Administrator

Ghana Health Service Ethical Review Committee Secretariat, Accra

Tel; (+233) 50 704 1223 /243235225

Dr. Reginald Quansah

027 262 0401

Yaw121@yahoo.co.uk

Mr. Harry Amoaning Okyere

026 200 3185

haokyere@st.ug.edu.gh

Part II: Certificate of Consent

Participant Declaration

By signing this consent form it means the following:

1. I have read this form thoroughly and understand it.
2. I know my rights have not been waived by signing.
3. I have had all of my questions answered and I know whom to ask if I have more questions.
4. I want to join the study.
5. I know I can leave the study at any time and do not have to give a reason.

Signature of Participant

Date Day/month/year

Researcher Declaration

I confirm that the potential participant has thoroughly reviewed the fact sheet and has given consent voluntarily to participate in this research. A copy of this ICF has been provided to the participant.

Signature of Researcher

Date Day/month/year

Thank you for participating in our research study!

B. QUESTIONNAIRE

Hello:

You are invited to participate in a research study. The study is being conducted by Okyere Amoaning Harry of the University of Ghana as part of requirements for the award of the Master of Public Health (MPH) degree. Completion of this survey will take about 5-10 minutes. You are invited to be part of the study because you have been supplied with antifungal medicine and we are interested in knowing your views on self-medication with these drugs.

Please indicate your willingness to participate in the study by signing the attached consent form. Your survey responses will be strictly confidential and data from this research will be reported only in aggregates. Your information will be coded and will remain confidential.

Thank you very much for your time and support.

Please start with the survey by providing the following details about yourself

Section 1A: Demographic characteristics

1. Sex: Male Female

2. Age: ____ 18-30 31-40 41-50 51-60 above 60

3. Educational status_____:

Junior high school or lower Senior High School/ Secondary technical

Polytechnic College /University Postgraduate

4. Your employment status_____: Employed Self-employed

Retired/unemployed Student Other _____

5. Average monthly income (Ghana Cedis)

less than 500 500 to less than 1000 1000 to less than 2000
 2000 to less than 3000 3000 to 5000 above 5000

6. Are you registered on the NHIS or any private Health Insurance Scheme?

Yes and it is active Yes but expired No

7. Drug is obtained by _____:

Prescription from a doctor Pharmacist's recommendation
 Pharmacy support staff recommendation Patient demand

SECTION 1B Drug related details

8. Generic name(s)

Fluconazole Griseofulvin Terbinafine
itraconazole
 Ketoconazole clotrimazole miconazole
 other.....

9. Route of administration

By mouth skin hair nail intravaginal
foot
 eye/ear

10. Cost.....

Section 2A:

Please indicate your responses to the following questions about antifungals by ticking the appropriate responses

Statements	Yes	No	Uncertain
14. Antifungals are taken to treat infection			
15. Antifungals are good for any itching conditions of the skin			
16. Antifungals can be purchased without a doctor's prescription.			
17. It is okay to stop taking an antifungal when symptoms improve.			
18. Antifungals do not have serious side effects			

19. Sources of information you master about antifungal use (you can choose more than one):

- Physician
- Pharmacist
- Friend or family relative
- Internet
- Media (Television, Broadcast)
- Previous experience
- Package insert
- Others (please specify) _____

SECTION 2B

Please tick to indicate the extent to which you agree or disagree to the following statements about antifungal use

Statements	Strongly disagree	Disagree	Uncertain	Agree	Strongly agree
20. Anti-fungal medicines should be sold with prescription					
21. Anti-fungal medicines should be available over the counter					
22. Getting medicines over the counter saves time and it works for me					
23. When someone at home has similar symptoms, I can pass on my left over medicine to him or her					
24. Once my symptoms are okay, it is advisable to stop taking an antifungal					
25. Do you agree expensive antifungals are more effective and have less side effect?					
26. Do you agree the effectiveness of treatment would be reduced if a full course of antifungal was not completed?					

Section 3: The recent use of antifungals (within the past 6 months).

Could you recall that in the last 6 months?

27. Have you taken any antifungals? yes no

28. Did you take antifungal without prescription from a doctor? Yes No

29. Where did you obtain antifungals without physicians' prescriptions? (You can choose more than one)

Purchased from pharmacy family or friends

Leftovers Others _____

30. For which symptoms you took antifungal without physicians' advice? (You can choose more than one)

Skin problem Nail problem

Hair problem Vaginal discharge

foot rot Oral candidiasis

other.....

Thank you for participating in our study!

C. INTERVIEW GUIDE FOR PHARMACISTS

Interview guide (for pharmacists):

Do you think that community pharmacists should dispense antifungal agents without prescriptions? Why?
What are the reasons that lead community pharmacists to dispense antifungals without prescription?
What do you expect if you deny a patient demand for antifungals and advise the patient to consult a physician first?
What is the role of health authority in controlling dispensing practices?
Do you think that pharmacists are aware of the impact of their patients obtaining antifungal medicines without prescription?
What are the reasons that make patients ask for antifungals from pharmacies rather than consulting doctors from your point of view?
What measures do you have in place to ensure rational dispensing and use of antifungals?

D. ICF FOR PHARMACISTS

This ICF is for community pharmacists who are being invited to take part in a study. The Form has two parts:

- A. Information Sheet (to share information about the study with you)
- B. Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form.

Part I: Information Sheet

Introduction

You are invited to participate in a research project entitled — Determinants of Anti-fungal use in the Ga-South Municipality; Implications for antimicrobial stewardship.

The study is being conducted by Okyere Amoaning Harry of the University of Ghana, as part of requirements for the award of the Master of Public Health (MPH) degree.

Purpose of the Study

We want to understand your perspectives on dispensing of antifungal agents without a valid prescription to your patients

Procedure

This research will involve your participation in an interview session that is expected to last for not more than 30 minutes. You will provide some personal details and answer some few open ended questions which will be digitally recorded in audio format. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential. This study involves the use of audio recordings for the purpose of pooled data analysis only. Only the Principal investigator (Harry Amoaning Okyere) and his supervisor will have access to this data. Neither your name nor any other identifying information will be associated with the audio or the transcript. This data will be stored on a personal computer in an encrypted folder and each file will be password protected. The data will be destroyed immediately after the final report of the study is complete.

Risk

There is a risk that you may share some personal information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

Benefits

There will be no direct benefit to you, but your participation is likely to help us know areas that health professionals can improve so that patients use these medicines appropriately and minimize any undesired effects.

Incentives

You will not be provided any incentive to take part in the research

Information Dissemination

Information you provide will be treated as confidential and nothing will be attributed to you by name. However, pooled information information obtained from the entire research will be presented to faculty members at a seminar of the University of Ghana, School of Public Health. I may then publish the results so that other interested people may learn from the research.

Right to Refuse or Withdraw

You may stop participating in the study at any time that you wish to.

Who to contact

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027 262 0401

Yaw121@yahoo.co.uk

Mr. Harry Amoaning Okyere

026 200 3185

haokyere@st.ug.edu.gh

Part II: Certificate of Consent

Participant Declaration

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3. I have had all of my questions answered and I know whom to ask if I have more questions.
4. I want to join the study.
5. I know I can leave the study at any time and do not have to give a reason.

Signature of Participant

Date Day/month/year

Researcher Declaration

I confirm that the potential participant has thoroughly reviewed the fact sheet and has given consent voluntarily to participate in this research. A copy of this ICF has been provided to the participant.

Signature of Researcher

Date Day/month/year

Thank you for participating in our research study!