UNIVERSITY OF CAPE COAST

THE READABILITY AND COMPREHENSIBILITY OF PATIENT INFORMATION LEAFLETS FOR OVER-THE-COUNTER DRUGS FOR SOME COMMON ILLNESSES

MARIAN AMPONSAAH FRIMPONG

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BY

MARIAN AMPONSAAH FRIMPONG

Thesis submitted to the Department of English of the Faculty of Arts, College of Humanities and Legal Studies, University of Cape Coast, in partial fulfilment of the requirements for the award of Master of Philosophy Degree in English.

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DECLARATION

Candidate's Declaration

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

Candidate's Signature: ..... Date: .....

Name: Marian Amponsaah Frimpong

Supervisors' Declaration

We hereby declare that the preparation and presentation of the thesis were supervised in accordance with the guidelines on supervision of thesis laid down by the University of Cape Coast.

Principal Supervisor's Signature: ..... Date: .....

Name: Prof. Lawrence K. Owusu Ansah

Co-Supervisor's Signature: ..... Date: .....

Name: Prof. William Kodom Gyasi

ABSTRACT

Patient Information Leaflets (PILs) are key communication tools in healthcare delivery. Even though readable PILs can enhance effective communication between pharmaceutical companies and the patients who use their products, there are limited number of studies on the readability and comprehensibility of PILs in Ghana. This study investigated the readability and comprehensibility of PILs of over-the-counter drugs for seven common illnesses in Ghana. Using non-experimental descriptive design, the researcher conveniently selected 68 PILs and measured their readability using SMOG and Flesch Kincaid Grade Level readability metrices. The researcher measured the lexical density and syntactic complexity of the selected leaflets using Coh-Metrix. From the scores of the readability formulae, the researcher discovered that the PILs were difficult to read and readers required at least fourteen years of formal education in order to find the leaflets comprehensible. Also, the lexical density and syntactic complexity of the selected leaflets were beyond average, suggesting that readers would have difficulty reading and understanding the leaflets. Moreover, there were no statistically significant differences among the PILS in terms of lexical density and syntactic complexity, suggesting that all the leaflets were of similar difficulty. Also, the researcher discovered through an interview with twenty consumers of these over-the-counter drugs that they found the leaflets difficult to read due to the unfamiliar words used in the leaflets. There is the need for information leaflets to be written at an easy-to-read level so that users of the leaflets can read and understand them.

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DEDICATION

To my children, Nana Amosa and Ama Frimpomaa

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CHAPTER ONE

INTRODUCTION

This chapter presents the context of the study by discussing health communication and the significance of the study for health care delivery. Also, the chapter covers readability and comprehensibility as key factors to the production and understanding of written health communication.

Background to the Study

Humans desire good health because it is the best way to live for long. Due to the need to combat sickness and diseases that threaten human health, health institutions are the priority of most states around the globe (Oppenheim et al., 2017; Gyasi & Bangmarigu, 2020). However, health care delivery requires effective communication between health practitioners and patients. Over the last several decades, the application and study of the relationship between communication and health has rapidly developed and expanded (Bernhardt, 2004). This has become prudent because people are keen on hearing about issues pertaining to their health in order to prolong their lives.

Available research reveals that every year many people either suffer certain health problems associated with the intake of high dose of some medication or even die as a result (Bradley et al., 1994; Kyei et al., 2013; Auta et al., 2011). The use of effective health communication can aid in curbing these health issues. For instance, through short documentaries on television, public service announcement and talk shows on the radio, masses of Ghanaians are made aware of health-related issues or diseases such as cholera, malaria and the corona virus. The public service announcement on the need for people to sleep under treated mosquito net is a kind of health communication that seeks to

change the behaviour of people to improve healthy living. Also, the call from health professionals for the general public to practice hand washing with soap under running water for at least 20 seconds, the frequent use of hand sanitizers to disinfect hands and the wearing of face masks to prevent the contraction and spread of the recent pandemic, Covid-19, is another example of public service announcement that seeks to get the masses informed on what needs to be done for them to stay safe and healthy. Giving out this information relating to peoples' health is a prudent measure as it helps in taking health-related decisions.

The need to establish a link between communication and health resulted in it being a field of communication. The area of health communication is of utmost importance as it is recognized as vibrant, hypothetically driven, practical and has contributed immensely to the shaping of national policies (Sparks, n.d.). According to Schiavo (2013), health communication is a strategic way of disseminating relevant health information to people, for them to adopt healthy practices in order to advance their health by making healthy choices. Thus, people are made aware of diseases and positive health behaviours through critical evaluation of accurate, accessible and understandable information on health. The U.S. Department of Health and Human Services in 2001 considers health communication as the art of informing, influencing and motivating people, institutions or public audience on a health issue. Health communication provides the needed theoretical and practical perspectives for handling communication on health issues. Effective health communication is key to addressing health related issues especially when the health issues are the result of unhealthy practices of people.

Health professionals attempt to reach out to people by offering them information about their health (Komen, 2007). Their goal is to transmit knowledge, attitude and skills while changing peoples' behaviour towards health issues with the idea of improving their health (Kreps & Sivaram, 2008). Many health communication professionals have focused on the improvement and dissemination of messages on health in their quest to reshape people's attitude towards health issues (Sparks, n.d.). These professionals mostly relay the information on health to the public through verbal, print or multi-modal means.

Patient information leaflet is an example of a print health communication tool (Gyasi, 2013). The leaflet conveys information about a drug or medication from the manufacturer to the consumer. Thus, through patient information leaflets, the manufacturer of a medication gives vital information on the components, indications and possible side effects of a drug (Gyasi, 2013). Most healthcare settings, including pharmaceutical companies, use written health information materials with the hope that patients will fully comprehend information presented on the leaflets. It is obligatory to put package leaflets in all medicine packages. Since effective communication is sharing information effectively without hindrance, it is necessary that manufacturers use language in a way that is understandable to the less educated consumer. The use of clear and precise language is key in the development of effective and appropriate material. This is because if consumers do not understand what they read on how to use a medication; the end result can be fatal. One aspect of language that has a bearing on comprehension is readability.

McLaughlin (1969) refers to readability as the feature that makes a text easy to read and understand to a group of people. Thus, the interaction between the words that are written and a group of people with shared characteristics. Klare (1963) defined readability as "the ease of understanding or comprehension due to the style of writing." This implies that readability can include factors such as the font, print type and choice of paper a writer decides to use. Readability of any text is key to both the writer and the reader. Readability enhances writers' effective communication with readers, and in the same vein, it facilitates the level of comprehension of text by a reader. Health issues bother on life and death, so it is imperative that the language used in writing patient education material be readable and comprehensible to consumers.

Comprehension is the reason for reading (DuBay, 2004). It is the ability to understand communication. Duke (2003) defines comprehension as a process which involves meaning making by readers as they link what they already know, their past experiences, what the writer wishes to put across and what they think about the written text as they interact with the text. Thus, meaning derived from a text is based on the reader with factors like "the readers' background, prior knowledge, interest, level of education and general reading ability" (Jones, 1997) having a bearing on the construction of meaning by the reader. People can be well educated and have mastery in their field of work and still not fully comprehend difficult medical information. According to Janan and Wray (2012, p. 134), comprehension on the part of the reader is understanding of words, phrases and ideas in a text. This demonstrates that comprehension resides with the reader whereas readability resides in the text.

Readability of a written text is determined mostly by using readability formulae. Readability formulae are mathematical indexes that measure the average sentence length over the word length to return a score that helps in predicting the reading level of a text (DuBay, 2004). With readability formulae, a manufacturer can predict beforehand the level of difficulty the readers will have in reading and comprehending a text. The basic assumption of the formulae is that, easy to read text are more comprehensible than difficult to read text. Therefore, depending on the score of the text, manufacturers can have a fair idea as to the success a group of readers will have with their information leaflet. The fact that their scores are dependent on a measure of the syntax and lexical complexity of a text is vital. This is because the terminologies that may be used in composing the text may be technical and less intelligible to the person without a Science educational background. Therefore, considering the readability of patient information leaflets is prime to the achievement of effective health communication.

Most healthcare settings including pharmaceutical companies use written health information materials (Wilson, 2008). Patients are expected to fully comprehend the information presented in these materials. To ensure the comprehension of health information by targeted users, communicators must know how to reach out to them by writing in a readable manner. Wilson (2008) is of the view that information written in simple terms or with simple words is preferred by even highly literate individuals. This is because it takes a considerably shorter time to read and is easy to understand. The use of medical terminologies is unavoidable as healthcare professionals; however, excessive use of these terms can obscure the message being delivered hence defeating its

objective of communication. The audience of the message must be considered because the more manufacturers know about their consumers, the better suitable material they tend to produce. The manufacturers should thoroughly understand the varied literacy levels of the audience, their level of education, degree of literacy and primary (native) language (Kreps & Sivaram, 2008) to aid in the production of a relevant material. Using many polysyllabic words when shorter ones would do can make print material unreadable. Koh (2009a, 2009b) asserts that communicating in plain language will make people embrace the message advocated by health professional.

The studies above have indicated the importance of health communication in improving the quality of health care. The studies have provided evidence that written communication could be rendered ineffective if the language use is too difficult to understand, even though the studies in and around the world and Ghana especially are limited. The present study therefore, investigates the language of patient information leaflets from a readability perspective in order to establish the extent to which language complexity could hinder effective health communication.

Statement of the Problem

The need for Patients Information Leaflets (PILs) is key in healthcare since health professionals will not always be around the patient who takes the medication. Studies conducted in this area have revealed that these leaflets are generally difficult to read and understand. Studies like Bradley et al. (1994), Kyei et al. (2013), Auta et al. (2011) among others have found readability of patient information leaflets difficult. Gyasi (2013) examined the readability of medical leaflets of common malaria drugs sold in Cape Coast, Ghana and found

that they were difficult to comprehend. Also, in a study at a district general hospital in UK, Williamson et al. (2010) found that the readability of patients' information leaflets was above patients' comprehension. Furthermore, Wilson (2008) studied a low-cost income community clinic in a Midwestern urban area, and found that patients' information leaflets were written too high for the less educated adult. A study by Bradley et al. (1994) on the readability of the leaflets of over-the-counter (OTC) drugs available on the UK market al.so confirmed that the leaflets were above the mean reading age of the general adult population.

With these different studies, there is an inherent call for effective communication through the use of plain language. Even though the call for plain language started in the field of law (Byrne, 2008), it has transcended to all fields including health.

The plain language movement on health is geared towards creating an awareness among health professionals about the relationship between literacy and health. It prompts health professional to help serve people with low literacy skills more effectively by using plain language and clear verbal communication. Failure to understand and follow medication instructions can have a direct effect on an individual's health and wellbeing. Plain language is a way of organizing and resenting information so that it makes sense in terms of organization and flow and is easy to read (Cheung, 2017). It has been established in this study that health related materials of which Patient Information Leaflets (PILs) are examples of should be written at a level not more than the 8th grade which is equivalent to 2nd year in the Junior High School in Ghana so that greater number of people can read and understand what they read since it has been found that

even people with high literacy level prefer easy-to-read materials as they spend less time reading them.

The call for plain language led to the development of readability formulae (Flesch, 1943) so it can be said that the call for plain language is as old as readability. For manufacturers of PILs to get through to their consumers, they should make it a point to communicate with words and constructions that does not pose any level of difficulty to readers. For instance, instead of writing, *Neuralgia which accompanies fractures of the fibula indicates the advisability of administering an analgesic*, it can be written as, *Giving pain relieves to patients with broken legs help make them more to be comfortable* (Cheung, 2017).

According to Longhram and McDonald (2011), plain language makes a text simple to read and understand and are devoid of legalese, personal pronouns, sentence length, and other style guidelines. Despite the call for language of public documents such as PILs to be made simple, there is less implementation of plain language requirements in health information leaflets (Gyasi, 2013).

An existing literature on the readability of PILs conducted in Ghana is that of Gyasi (2013) whose work was on the readability of PILs of common malaria drugs used in Cape Coast, Ghana. He discovered that malaria leaflets were written at a difficult-to-read level. While his study was based on only malaria information leaflets, there is the need for further studies which will investigate the information leaflets of other common ailment in Ghana to ascertain their readability and comprehensibility to patients. This is crucial because issues regarding the use of medicine are a matter of life and death. The

health consequences of unreadable health information leaflets juxtaposed with the available studies on how difficult health information leaflets are in other parts of the world, this study seeks to find out if the generalization made in other parts of the world on the readability of health information leaflets also applies to Ghana. There is the possibility that Ghanaians who read these patient information leaflets do not understand what they read; hence the need to analyze readability of these leaflets. However, there is no known study in Ghana yet that examined the readability of the patient information leaflets and the comprehensibility difficulties readers face in using the leaflets for relevant information about the drugs they use to treat common ailments.

In this research, attention is given to the readability and comprehensibility of 68 Patients Information Leaflets (henceforth PILs) of over-the-counter (henceforth OTC) drugs of seven (7) common illnesses in Ghana. These illnesses are common cold (flu or catarrh), cough, body pains, diarrhoea, heartburns, sleeplessness and constipation. This study explores the readability of PILs of OTC drugs which are patronized by the people of Kumasi. It is also to assess the comprehensibility of these leaflets to consumers of the drugs.

Purpose of the Study

The purpose of this study is to examine the readability of PILs for OTC drugs of seven common illnesses. Using readability formulae, the researcher determined the frequency of complex syntactic structures and polysyllabic words in the PILs. This is done to establish the extent these linguistic categories influence the level of readability of the PILs. The researcher further sought to determine the perception of consumers concerning the usefulness of these PILs

by ascertaining from them if they read or do not read these PILs and the reason(s) for their choice.

Research Objectives

The study sought to examine the readability and comprehensibility of patient information leaflets on over-the-counter drugs with attention on seven common illnesses. The specific objectives of the study are as follows:

1. To determine the levels of lexical density and syntactic complexity of the PILs of OTC drugs and their effects on readability of these PILs.
2. To explore whether significant differences exist in the frequency of complex syntactic structures and polysyllabic words of PILs of OTC drugs.
3. To determine whether consumers read PILs of OTC drugs and find reason(s) for their response.
4. To find out if differences will exist in the readability levels of PILs of OTC drugs and the response from consumers of OTC drugs.

Research Questions

The study is based on these research questions:

1. What are the readability levels of PILs of OTC drugs?
2. What statistically significant differences are there in the lexical density and syntactic complexity of PILs of OTC drugs across illnesses?
3. What is the assessment of consumers on the comprehensibility of the PILs of OTC drugs?
4. What is the correlation between the readability of PILs of OTC drugs and responses of consumers on the comprehensibility of the PILs?

Significance of the Study

The issue of health is a matter of life and death hence health professionals attempt to communicate relevant information to the masses to create awareness. Patient information leaflets are examples of print or written communication. Thus, print is being used to relay a message from the manufacturer to the consumer. These PILs give detailed information on the composition, indication, dosage and side effects of a drug. If a consumer purchases a drug and cannot read and comprehend the information on the leaflets the outcome could be fatal.

The study contributes to extant literature on readability of health materials especially in Ghana, in that the researcher examines the readability and comprehensibility of health information leaflets. This work will contribute to health education not only in Ghana but also across the world. Also, the study is relevant in ascertaining how readability can help achieve effective health communication between producers of patient information leaflet and target users of the leaflets. Moreover, it is worthwhile to provide informed recommendation on the way forward to achieve effective health communication with patients when drug manufacturers compose leaflets. It will help sound an alarm if there is the need for these leaflets to be produced with readability in mind for their intended purpose to be realized.

Furthermore, the present study will provide practical evidence to support the need for patient information leaflets to be composed in a readable manner. The present study does that by providing manual analysis of the leaflets to reveal the syntactic and lexical features that render the text of PILs difficult. Also, the use of primary data from readers of PILs has provided reliable evidence that a

majority of end users of PILs are not finding the PILs readable, thereby difficult to understand.

Scope of the Study

In the study, the researcher will examine the readability and comprehensibility of PILs of OTC drugs. Many different medications are available for purchase without the prescription of a medical practitioner to be sold out. Such non-prescription drugs are commonly known as over-the-counter drugs. The researcher chose OTC drugs because they have gained more patronage by Ghanaians because of their non-prescriptive nature. This is because the Food and Drugs Authority, the body that regulates drugs in Ghana keeps increasing the drug list of OTC medication, for instance, anti-malarial that used to be Prescription Only Medication (POM) has been moved to OTC (Gyasi,2013) to allow easy access to the drugs for the killer disease. Also, PILs were chosen for the study because they are the health-related materials that come with OTC drugs.

Additionally, the researcher chose the common illnesses because they are illnesses that people have been regularly suffering from. It is to enable an in-depth discussion to be made on the selected illnesses, as the researcher cannot possibly work on all illnesses.

Lastly, SMOG and Flesch-Kincaid index were chosen for the readability analysis because SMOG is consistent with the analysis of health materials. It is also the only readability formula that measures 100% comprehension and it is very simple to use (Wang et al., 2013). Flesch Kincaid index is considered as the most accurate and extensively used formula (Travedi et al., 1996; Wilson, 2008).

Organization of the Study

The study is organized into five chapters. Chapter One, which is the introduction, focused on the background of the study, statement of the problem, purpose of the study, research objectives, research questions, significance of the study, scope as well as the organization of the study. Chapter Two (2) reviews the literature related to this study. The conceptual framework within which this study is situated as well as the empirical review. Chapter Three (3) discusses the methodology of the research. It covers research design, population, sample technique and size, data collection procedure and data analysis procedure. Chapter Four (4) analyses the data collected and discusses results of findings. The last chapter, which is Chapter Five, summarizes and concludes the entire research with recommendations for further studies. In all, a summary of each chapter is presented at the end of the chapter to facilitate better understanding.

Chapter Summary

This chapter has discussed health communication, readability and comprehensibility in the background. It went on to state the problem, outline the research objectives and questions of the study. The significance of the study, the scope of the study and organization of the study were also covered.

CHAPTER TWO

LITERATURE REVIEW

Introduction

This section examines the conceptual framework within which the study is situated. Here, I examined some communication models down to the one which was chosen for the study and the reason behind the choice. The chapter also explored some concepts related to the study, such as, readability, comprehension, health communication, lexical density and syntactic complexity. Also, this chapter discussed the fluency theory which was apt as the theoretical framework for the study. The chapter will conclude with a review of existing works on readability and comprehensibility of PILs.

Conceptual Framework

Communication

Communication plays a vital role in the dispensing of health-care. Communication can be dispensed verbally through the use of words. On the other hand, communication could be done through the use of non-verbal cues or written text to share meaning with others. In communication, messages are shared through channels such as mass media, social media, mobile phone applications, e-mail, text messaging, telepath services, face-to-face conversations and print materials (Dominick, 2007). With the emergence of technology, writers have a wide range of tools to use to reach the general masses just as manufacturers to consumers.

According to Baran (2013: 1), 'communication is the transmission of a message from a source to a receiver. This definition of communication posits communication as a linear process, there is always someone who wants to send

some form of information to another. To Ratzan (1994), communication begins with an action, declaring needs, sharing information, plans, views and fostering understanding while keeping connections. It is evident that Ratzan viewed communication as interactive or to the most extent transactional activity that seeks to create mutual understanding between or among participants. Dominick (2007) defined communication as a symbolic, interpretive, transactional process through which meaning is shared among people.

In this definition, the key components of communication are specified. First, communication is symbolic because it involves the use of symbols to represent actions, ideas, feelings and thoughts. Second, communication is interpretive because the symbols used must be interpreted for communicators to understand the meaning communicated. Third, communication is transactional because it involves the sending and receiving of messages among communicators. It involves feedback from receiver to source. Also, there is the need for meaning to be shared. In order words, the participants in a communicative encounter must understand the symbols used and the meaning assigned to those symbols in order to construct meaning. Furthermore, communication is a process because it involves a series of interconnected stages or events that lead to effective communication. The notion of communication as a process has informed scholars to explore how the various elements in the communication process interact.

The Communication Process

The communication process provides insight as to how the various elements of communication come to play in a communicative activity. The

communication process establishes the relationship between the elements of communication, which are basically sender, message, channel and receiver.

Wood (2009) categorized these into the transmission end and the receiving end. The transmission stage involves the sender who has a thought to share, s/he encodes the message, selects a channel and transmits the message to the receiver. The receiving end is the receiver who receives the message sent to him/her from the source. The receiver decodes the message and possibly send feedback to the source. Through the feedback, the source can alter the subsequent communication to meet the needs of the receiver. Communication process has ever been expanded by other scholars to include noise which is anything that seems to hinder effective communication among communicators. According to Dominick (2005), noise affects the message fidelity which is the accuracy with which a receiver receives the exact message intended by the sender. Therefore, Dominick (2005) is of the view that feedback is an effective tool in reducing noise.

Shannon and Weaver (1948) who were prime advocate of the element of noise identified three types of noise thus physical, semantic and mechanical noise. Physical noise is anything in the environment such as loud music, temperature among others that distracts the effectiveness of the message received. Semantic noise is the noise caused by wrong construction of sentences of a message. The mechanical noise is caused by faulty machine or channel that is used to send the message. Whatever the barrier or noise may be, one thing is certain that effective communication is minimizing the presence of noise in a communication. Therefore, health communication requires minimizing the barriers or noise.

Since the process of communication are basic to every form of communication, health communication is not an exception. Effective health communication is ensuring the reduction of noise and increasing message fidelity. This involves not only knowledge of handling mechanical and environmental noise but also semantic noise, especially the print mode which is dominated by written mode of communication. Understanding health communication in this context is relevant to help position the role of readability and comprehensibility in handling semantic noise in patient information leaflets.

Health Communication

According to Bernhardt (2004), health communication is a systematic growth, planned spreading and critical evaluation of important, precise, reachable and comprehensible health information, disseminated in the form of communication with people to improve their health. Communication is used to spread health related information like outbreak of disease, aiding people to practice healthy living as they make informed choices on their health. Healthy People (2010) defines health communication as the art and technique of informing, influencing and motivating individuals, institutions and public audiences about important health issues. Relaying of health care information is a positive trend as people look forward to be informed about their health needs and to be engaged in health-related decisions. Health communication encompasses the study and use of communication to inform and influence individuals to make communal decisions to enhance their health.

It is the aim of health professionals to impart relevant knowledge, positive attitudes and skills in order to help change behaviours and improve health care. Health communication raises awareness of health risks while

providing relevant solutions to them. It also provides the motivation and skills individuals need to reduce those risks. To the community, health communication influences public agendas by advocating policies and programs. It also helps in the improvement of public health care delivery and services. By so doing, it helps in bringing about desired changes in people's belief and behaviour as well as increases health promoting behaviours. Disease prevention, health promotion, health care policy and the business of health care are all part and parcel of health communication (Healthy People, 2010). The field of health communication focuses on two major elements: message production and processing and the creation of shared meaning about health issues (Sparks, n.d.). This has made it prudent for health communication scholars to focus on social influence and devote their efforts to the improvement and understanding of health messages, which will bring behavioural changes in the masses of people.

However, as established earlier, effective communication is the product of successful management of noise in order to reduce its impact on message fidelity. Health professionals and for that matter health communicators require knowledge of the communication process in their verge to communicate with the public on health issues. In order to understand the communication process scholars such as Aristotle, Berlo, Shannon and Weaver, Jacobson and many others have designed communication models to guide the study of communication process and to facilitate the understanding of the communication process for practical use of the knowledge.

Communication Models

A communication model is a graphical representation of the simple to complex process of communication in a way that establishes the relationship between or among the individual elements. Right from Aristotle to the most recent work on communication model, there has been a diverse representation of the process of communication with some new models proposing new elements that can help researchers and practitioners understand the communication process. The differences in the models may be largely due to the view that developers have about the concept of communication.

According to Wood (2009), there are four views of the communication process which are the linear, interactional, transactional and constructivist. The linear view considers communication as a one-way process where message travels from source to receiver. This linear view influenced Aristotle and Laswell's (1948) models of the communication process. The interactive model views communication as a sending and receiving process, hence a conversational process. This view largely influenced the feedback loop and the noise elements as important aspects of the communication process. Shannon-Weaver, Berlo among other models are based on the interactive view of the communication process. Transactional view considers the communication process as a simultaneous sending and receiving of messages in that either the sender or the receiver can be giving feedback to the other in order to create mutual understanding. The constructivist view considers communication as a process whereby meaning is constructed rather than shared; as Wood (2005, p14) put it "meaning resides in people not words". Knowing the essence of the communication process and for that matter the communication model in

achieving effective communication, the researcher seeks to review some of the models of communication down to the one used for this study.

Ancient Greek philosopher, Aristotle developed the first communication model and termed it as rhetoric. This model is composed of elements, which are the speaker, the speech, the audience and the effect. Aristotle's model of communication process is presented as follows:

The speaker plays an important role in the communication as s/he is expected to communicate in such a way that will influence the listeners to respond accordingly. He therefore has to be particular about his choice of words. His content must be carefully selected and organized to have a toll on his listeners to get his preferred feedback. The audience holds the key to the effectiveness of the communication as the determiner of whether or not communication took place. To exemplify, a politician giving a speech on a campaign platform to amass votes from citizens must know their needs and capitalize on that to win their votes. If the people need good drinking water, that is what the promise should be about and not good roads that the citizens do not probably need. If the message appeals to the needs of the audience, they will in turn act accordingly to the speaker's favour.

Aristotle outlined three rhetorical appeals or elements of a good communicator; ethos (credible characters of the speaker), pathos (emotional appeal of speaker) and logos (finding factual data on issues). This model is ideal for public speaking such as seminars, lectures, campaigns and advertisements. It covered elements of the communication process such as source, message,

audience and effect which is the intended purpose of the communication. It is speaker centered with the audience playing a passive role. There is no room for communication barriers (noise) and feedback. This model which is source dominated linear model may not be so helpful for health communication which involves the use of patient information leaflets to reach audience with relevant health information. Therefore, the work of Aristotle model was further developed by other scholars such as Shannon-Weaver, Laswell, Berlo, Schramm among others.

In 1960, Berlo also developed a communication model, the **SMCR** model. It emanated from Shannon-Weaver's model. The **S** stand for **Sender**, the **M** for **Message**, the **C** for **Channel** and the **R** for **Receiver**. His focus, however, was on the different aspects of the message being sent and gave no regard for feedback. Both sender and receiver are at par with each other as it is assumed, they have the same attitude, knowledge, social systems and culture hence a common understanding. This model does not recognize any barrier of communication. Berlo, however, pointed out certain details in each element that can hinder the communication process. To Berlo (1960), the source communicative skills, attitude, knowledge, social system and culture have impact on the message being sent.

Just like Aristotle's theory which presents source character (ethos), knowledge (logos) and emotional expression (pathos) as indicators of successful persuasion, Berlo viewed the factors stated in his model as indicators of the success of the communication process. To Berlo, a source who has good communication skills, adequate understanding of the topic, culture and social systems, is most likely to be an effective communicator. This is critical for PILs

producers because if they lose sight of these factors, their communication will be destructive rather than constructive.

For instance, if information leaflets contain ingredients that the producer lose sight of because of negligence, the possibility of misleading patients will be high. And since poor communication of health information can lead to adverse consequences, it is expedient that PILs producers consider the source characteristics with respect to the qualities mentioned by Berlo. In terms of the message, Berlo recommends adequate content, appropriate elements, such as clarity, completeness, concreteness, proper treatment, structure and code. In this case, the message should provide the right content that audience need to make inform decisions such as the ingredients used, the side effects, the dosage, the warnings among others. Apart from content, the message should be presented in the right structure.

Readability studies also posit that coherence has a bearing on reading ease and understanding of message. Therefore, patient's information leaflets should employ the appropriate structure preferably using the template of PILs. With the channel, Berlo proposed a channel that engages the five senses of the audience. The channel should be visible and colours used should appeal to the other senses. In terms of the receiver, Berlo expects the receiver to have similar qualities like the source if not the same. Even though this is not always possible especially with public documents such as PILs since the leaflets can be used by people with varied literacy level, it is worthwhile if producers can adopt a level of communication that appeal to the majority of readers ability.

This can be achieved if text of PILs grade levels is predicted using readability formulae such as Gunning Fog or SMOG formula to know the grade level of the leaflet before dissemination. Berlo's communication model is not appropriate to be used for this study because it failed to recognize the factors that can hinder effective communication which is of much relevance to this study. Also, it places the source and destination on the same level and expects them to have similar qualities which cannot be possible. All users of PILs cannot possibly have the same level of education or cultural background like the manufacturer to be able to understand the message being put across. Also, it failed to recognize the concept of feedback which is of most importance to every communication process. The image below captures Berlo's Model of communication process.

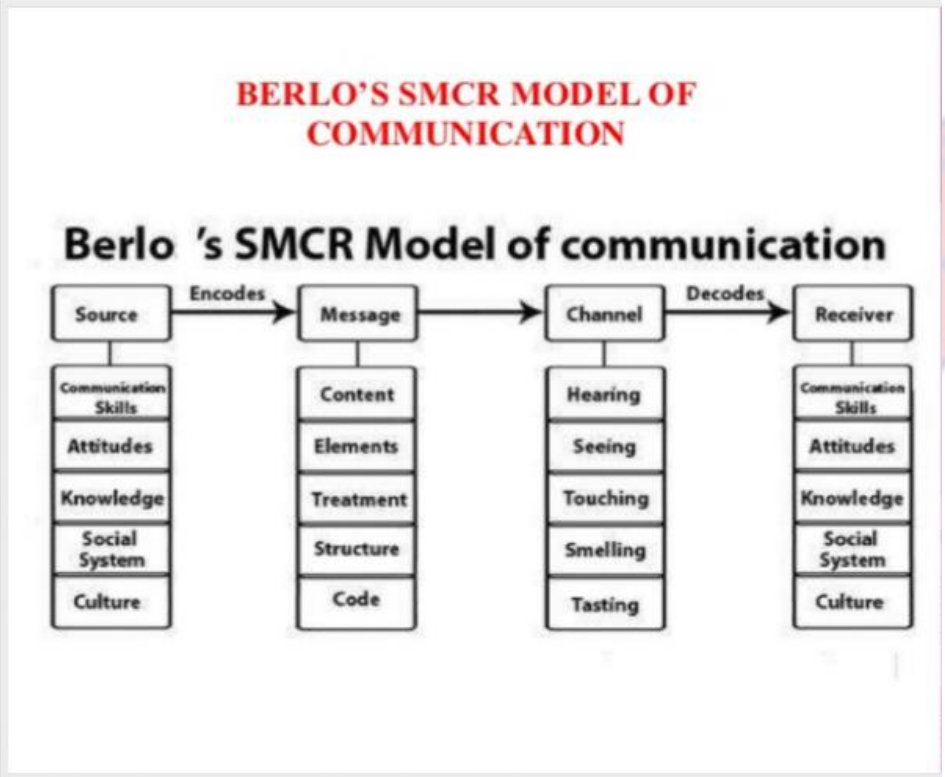


Figure 1: Berlo's SMCR Model of communication

Source: Google Image

Shannon Weaver's communication model was developed to enforce effective communication between the sender and the receiver. The communication process was catalogued as these by the Shannon-Weaver (1948):

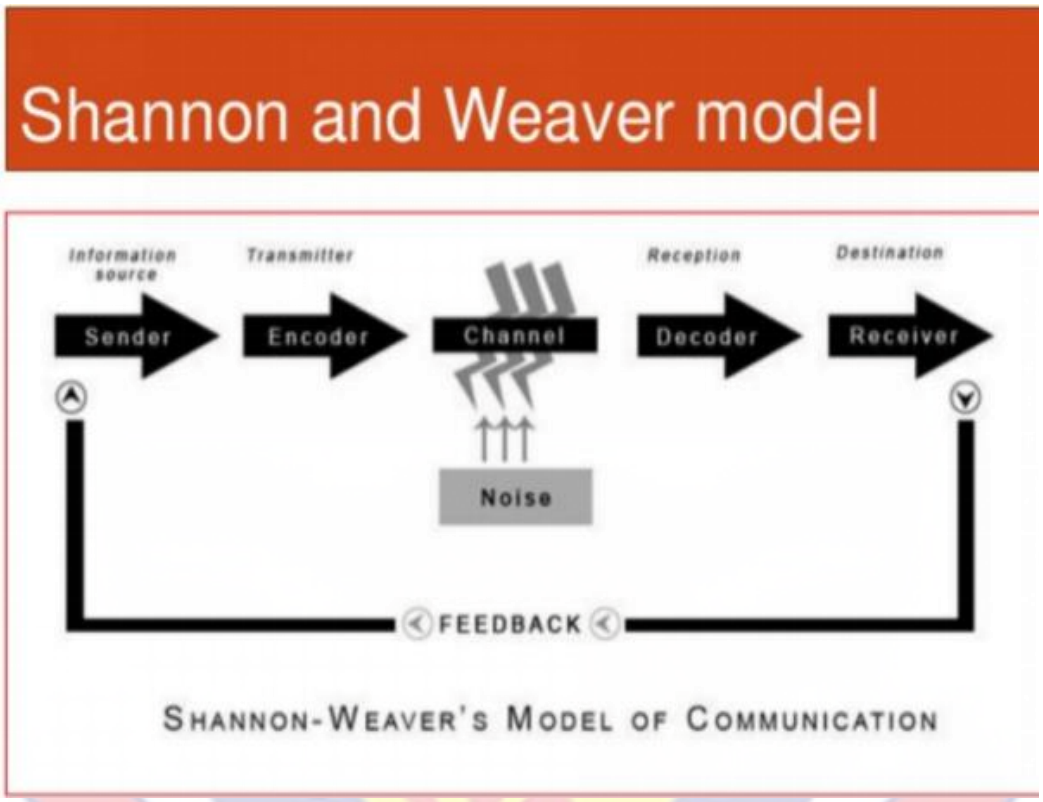


Figure 2: Shannon Weaver's Model of Communication
Source: Google Image

The sender is the information source. The one who produces a message to be communicated to the receiving party. The message may be of various types such as sequence of letters as in telegraphy, a single function of time as in radio or telephony or a function of time and other variables as in television (Shannon-Weaver, 1948). The information source selects a desired message out of possible messages. Selected text may contain written or spoken words, pictures or music. The channel through which the message will be sent is also chosen by the source which could be through electronic devices, printed materials or by

word of mouth. The channel is merely the medium used to transmit the message from the source to the receiver. It is up to the source to choose an appropriate channel devoid of obstacles that can facilitate the smooth delivery of the intended message.

Shannon-Weaver (1948) posits that there is a factor which affect or interfere with the communication process. This factor they refer to as noise. Noise is transferred from sender (encoder) to the receiver (decoder) through a channel. This may cause the receiver not receiving the exact or correct message. Noise operates on three levels as outlined by Shannon and Weaver; technical problem (level A), semantic problem (level B) and effectiveness problem (level C). Technical problems deal with the accuracy of the symbols transmitted during communication. Thus, how well the exact message sent by the source is able to reach the receiver just as it was sent. Semantic problems deal with how accurately the transferred characters carry the intended meaning of the sender. Thus, is the intended meaning of the message sent by the source understood or comprehended by the receiver. Effectiveness problems, on the other hand, deal with how the meaning derived from the message sent brought about a desired change. Is the conveyed meaning a success? Did the message have any impact on the receiver?

The receiver (destination) is the one whom the message is meant for. When the receiver receives the message, feedback may be given by taking a particular action or making some utterances. However, reader centered variables and text centered variables can set in to cause miscommunication. Reader centered variables may include the level of education of the reader, cultural background and health related issues such as eye sight. Text related variables

may also include the layout of text, font size and type, paper size and type, presentation of pictures and diagrams, spacing among others.

The discussion of these models of communication process has some implication for the current study. Therefore, the researcher adopts the Shannon Weaver model as a guide for the study. This is because this model recognizes that there can be a hindrance to the intended message from the perspective of the receiver stemming from the source or sender. Also, it recognizes feedback as an essential part of communication. Shannon-Weaver model of communication was created in 1948 when Claude Elwood Shannon wrote an article *"The Mathematical Theory of Communication"* with Warren Weaver in the Bell Technical Journal. The theory is also known as "Information theory" and is also referred to as "the mother of all models" (Al-Fedaghi, 2012). The model was specially designed to ensure effective communication in everyday life, hence its ability to describe how messages are lost and misrepresented in the communication process. This model has transcended to other domains such as human communication. Mortensen (1972) acknowledged that many in the behavioural sciences among a host of other disciplines have used this model, within a decade of its development, in countless interpersonal situations. It has, however, presented, for the first time, a common means of communication that encompasses such multiple discipline such as journalism, rhetoric, linguistics and speech and hearing sciences (Foulger, 2004).

The researcher found the communication process an appropriate conceptual framework for the study because PILs is a medium through which health professionals communicate with the masses. Also, because the lexical density and syntactic complexity that this research seeks to assess are typical

examples of the concept of noise in the Shannon-Weaver model. Foulger (2004) is of the view that, one of the reasons why any researcher will use this theory of communication is to identify the causes of noise and try to reduce it. Relating the Shannon-Weaver model of communication to this study, one can conclude on the following: the *message* is the information on the Patient Information Leaflets (PILs), the *sender* is the manufacturer, the *channel* is the PILs, the *receiver* is the consumer who purchases the drug and the *feedback* is any response that may be received from the consumer by the manufacturer or the health-care agent. Because the source is away from the receiver, the communication process delays hence feedback is not immediate to enable the source to modify the message to ensure that communication is understood. *Noise* is transferred from *a sender* (an encoder) to *a receiver* (a decoder) through *a channel*. In relation to this study, noise can be seen from the linguistic categories; lexical density and grammatical complexity of PILs. If there are too many words and the language used is complex, it may cause the receiver not comprehending the intended message.

Noise was categorized into three levels: A, B and C by this model. The appropriateness of the sender's choice of words and the accuracy of the information given on the PILs is on level A. Is the manufacturer of the PILs relaying relevant information on the medication to the consumer? Since PILs are mostly used to supplement health-care professional's oral information to patients (Smith et al.,1998), these PILs are supposed to be in handy because the prescriber will not always be around to give instructions or remind consumers of what was said about a medication, for example contraindications, dosage,

compositions etc. It is therefore up to the manufacturer to ensure that the information given on the leaflets is precise and relevant to the consumer.

On level B, is the consumer able to read and understand the message on the leaflet? Thus, this is the consumers' own interpretation as against the intended meaning by the manufacturer. Information, according to Shannon Weaver (1948), is a count of one's liberty to choose words in selecting a message. They added that it is most fascinating to figure out that about 50 per cent of English words are redundant. This means that in both writing and speaking we have the free will to choose about half of the letters and words we wish to use while the other half is really controlled by discipline-specific vocabulary although we do that unconsciously. This elaborates the fact that the manufacturers of these PILs are at liberty to communicate with words that the consumers of their medication can easily read and comprehend to enable them grasp the intended meaning. They are not limited to a certain amount of vocabulary or obliged to write in a conventional way. The use of plain and accurate language is prudent as it aids in the development of a worthwhile health education material. Inasmuch as medical terminologies are inevitable in every health communication, their excessive use can hinder the comprehension of the intended message. If they can be replaced with a more familiar word or phrase, their intended purpose can be realized.

On level C, which is the last level, is the effectiveness of the message on the PILs to the consumer. Is there a desired change after the use of the medication? After the use of the medication, was the consumer healed or relieved from any pain that necessitated the patronage. If the result was positive, the outcome will be for the consumer to purchase it directly from a pharmacy

or chemical shop when next the need arises and if the result becomes negative the consumer will then go back to the prescriber to discuss issues for immediate redress or will choose an alternative since there is a vast collection of alternatives to choose from. Because the manufacturers of these medications are away from their consumers, the communication process takes time. Feedback is not immediate for modifications to be made in the message.

Shannon and Weaver realized that communication concerns both syntax and semantics with the syntactic dimension coming from the manufacturer and the semantic dimension from the consumer. The importance of communication between the manufacturer and the consumer cannot be undermined hence the need for a great deal of understanding between them for the benefit of both. The manufacturer should therefore make all conscious efforts to make everything about his message clear and concise for easy readability and comprehensibility by the consumer.

There are several barriers of communication which challenge the communication process. If the receiver does not make meaning out of the message sent by the sender, then it can be said that communication has not achieved its desired goal, hence feedback will be affected. In much the same way, if a consumer purchases a drug and cannot read and comprehend the PIL that comes with the drug which is supposed to further consumers understanding about a medicines' composition, direction for use and possible side effects then the intended purpose of the PILs was not realized and the effect could be deadly. Poor communication is still blamed for accidents, failures, patients' dissatisfaction, complaints and litigation (Brown et al., 2006:26).

Like any other human inventions, the Shannon-Weaver model of communication has its own strengths and weaknesses. Even though it is said that the model is the most commonly used, other scholars have their own reservations and merits about the model (Al- Fedaghi, 2012). Drew (2020) is of the view that the model is now cyclical and not linear due to the addition of the concept of feedback by Weaver. The fact that the model has made communication easy by explaining how ideas can be misinterpreted in the communication process is a merit for Drew (2020). The concept of noise was commended as it helps in making the communication effective as people's attention are being drawn to the possible issue that can bring miscommunication. Comprehending the concept of noise is bound to help curb the numerous communication setbacks. Also, the two-way process in their communication concept makes it applicable in general communication (Mortesen, 1972). The fact that much attention is not given to feedback as compared to the message from the sender is a setback (Verdu, 2000). Despite the aforementioned limitations, the model is appropriate for the current study because it recognizes that there can be a hindrance to the intended message stemming from the sender through the channel called noise. The linguistic categories; syntactic complexity and lexical density that this research sought to assess are typical examples of noise in human communication.

Over-The-Counter (OTC) Medicines

In Ghana, there are three classifications of drugs to be dispensed to individuals. We have Prescription Only Medications (POMs), Pharmacy Medicines (PM) and over-the-counter medications (OTCs) (FDA website). POMs are the medicines that will be sold out only with a doctor's prescription,

PMs are those drugs that can only be dispensed by a pharmacist while OTCs are the drugs that any individual can walk into any of their sales points and purchase without a prescription or a pharmacist being around. Because of their non-prescriptive nature and their easy accessibility, OTCs are highly patronized by Ghanaians. They give individuals the ability to purchase drugs directly. Their readily accessibility is to offer individuals convenient access to medications to address their health concerns and to also make them active participants in their own health (Bradley et al.., 1999). They consist of a not too broad spectrum of medicines as compared to POMs and PMs. However, they are made up of the essential drugs needed readily to help address common illnesses. For example, anti-malaria which were POMs have been added to the list of OTCs (Gyasi, 2013) to make the accessibility of malaria drugs easy to help facilitate its cure.

There are two sales points for OTCs in Ghana; pharmacies and over-the-counter medicine shops. These OTCs are usually advertised on the media: radio, television, newspapers, billboards among others after being vetted by the Food and Drugs Authority (FDA), so individuals are open to a broad variety of medications for the cure of their common illnesses. All OTCs that can be found on the Ghanaian market that have been duly accepted by the FDA come with a leaflet that is supposed to contain every detail pertaining to the drug. The leaflet is what is referred to as the Patient Information Leaflets (PIL). Available research both in Ghana and abroad however, have proved that their readability is poor and need immediate revision (Alaqueel and Obaidi, 2017, Williamson et al.,2010).

The Patient Information Leaflet (PIL)

PIL is a paper inserted in the pack of a medicine which is ready for sales. The information on that paper is written in the national language(s) of the country where it is sold. They are written by pharmaceutical companies and have to meet the requirements of the medicine regulatory agencies in the country where they are issued. They contain every information on the drug. Since the doctor or pharmacist will not always be around to re-echo what was said during an interaction between them and their patients, it serves as a reference point for consumers to fall on anytime. In much the same way, when OTC drugs are purchased, pharmacists or sellers frequently give verbal advice and information about them but patients do not always remember what was said (Wilson, 2008) hence the need for the inclusion of the PIL to reinforce the verbal talk. PILs thereby give patients the liberty to absorb information at their convenience. The main purpose of a PIL is to give a functional, clear and understandable details on the usage of medicine to enable patients make healthy choices on their use. The need for the inclusion of PILs with every medication provided is because pharmacies are not the only sales point for OTCs but OTC shops too which are mostly managed by non-health professionals. These sellers unlike pharmacists cannot give a detailed verbal education on a medication so the PILs give more insight to the consumer.

It can be said to be a sort of communication medium between pharmaceutical companies and their consumers. It is not only patients who may learn from PILs. The Arthritis and Rheumatism Council's evaluation report comments on their PILs being used by young professionals to increase their own understanding and to learn ways of explaining arthritis conditions which they

can later use with patients (Clerehan et al., 2005). During a personal conversation with some sellers of OTC drugs in the Kumasi Metropolis, they emphasized that before they purchased a new drug from distributors, they read the PILs that come with the drug to educate themselves before they recommend that drug to their customers. This goes to show that PILs do not only inform but educate as well. Therefore, these PILs need to be understandable to the general public as it is the only alternate source of information about a drug. Ley (1982) posits that effective communication followed by written information normally advances patients' contentment. A good information leaflet therefore reduces anxiety and hinders the increase in side effects that can arise from the treatment. Adequate information should be given to patients and in a way that they can comprehend to enable them make healthy decisions. The Food and Drugs Authority regulates the issues on drugs in Ghana. In Ghana, just as most part of the world, PILs with proper information about the drug should come with all medicines.

However, available literature has it that these PILs have readability problems making it difficult to comprehend. The FDA have, together with the technical support of the World Health Organization (WHO), developed a guideline for use since 1st March 2013. This guideline shows a template that pharmaceutical companies should follow to produce their PILs. The template provides concrete guidelines to increase readability and patients' comprehension. While the guideline is valuable and important, they do not cover all important language aspects as it does not tell which words or constructions to use to promote readability. Below is the guideline:

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

{(Invented) name strength pharmaceutical form}*
{Active substance(s)}

Read all of this leaflet carefully before you start <taking> <using> this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider> <or> <pharmacist>.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>.>

In this leaflet:

1. WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR

2. BEFORE YOU <TAKE> <USE> {PRODUCT NAME}

Do not <take> <use> {product name}
- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of {product name}.>
- <if ...>

Take special care with {product name}
- <if you ...>
- <when ...>
- <Before treatment with {product name},...>

<Taking> <Using> other medicines
<Please tell your <doctor, health care provider> <or> <pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking> <Using> {product name} with food and drink

Pregnancy and breast-feeding
<Ask your <doctor, health care provider> <or> <pharmacist> for advice before taking any medicine.>

FDA PIL Template

Driving and using machines
<Do not drive <because...>.>
<Do not use any tools or machines.>

Important information about some of the ingredients of {product name}

3. HOW TO <TAKE> <USE> {PRODUCT NAME}

<Always <take> <use> {product name} exactly as your doctor or health care provider has told you. You should check with your <doctor, health care provider> <or> <pharmacist> if you are not sure.> <The usual dose is...>

<Use in children>

If you <take> <use> more {product name} than you should

If you forget to <take> <use> {product name}

<Do not take a double dose to make up for a forgotten <tablet> <dose> <…>.>

If you stop <taking> <using> {product name}

<If you have any further questions on the use of this product, ask your <doctor, health care provider> <or> <pharmacist>.>

4. POSSIBLE SIDE EFFECTS

Like all medicines, {product name} can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider> <or> <pharmacist>.

5. HOW TO STORE {PRODUCT NAME}

[For storage conditions statements see Appendix 3 (ref. Appendix III)]

Keep out of the reach and sight of children.

<Do not store above °C>, <Store in the original <container><carton>>

Do not use {product name} after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of that month.>

<Do not use {product name} if you notice {description of the visible signs of deterioration}.>

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. FURTHER INFORMATION

What {product name} contains

- The active substance(s) is (are)…

- The other ingredient(s) is (are)...

What {product name} looks like and contents of the pack

Source: FDA website

A variety of medicines already on the Ghanaian market contains PILs. It is, however, prudent for the information given on these PILs to be geared towards the patients' opinion, should be short and comprehensible (Bradley et al.,1994) and this is what this research seeks to evaluate. As indicated earlier, noise can be seen from the linguistic categories; lexical density and syntactic complexity of PILs. It is therefore important to examine these factors that can have a bearing on the effectiveness of PILs as a communication tool.

Lexical Density

Authors such as Strunk and White (2009: 12-13) asserted in their book, *The Elements of Style*, that "vigorous writing is concise." This implies that writing or drawing should be simple with no unnecessary words nor sentences to complicate meaning. This does not require a writer should make all sentences short, or that some details should be avoided or his subjects be treated only in outline but that he makes every word count. Thus, a writer should be concise, precise and go straight to the point in creating a write up. Relevant words should be used to convey relevant meaning. In so doing, important information that a reader needs to know should not be missed from a write-up. It should be detailed enough but should be void of any irrelevant information. Lexical density, according to Johansson (2008), is the estimate of the percentage of lexical items in a piece of writing. Halliday (1985) is of the view that the percentage of the number of lexical items per clause in a text as against the running words is lexical density. This is because Halliday considered lexical density at the clausal level. This means that the total number of words used in the text divided by the total number of clauses in the text will determine the lexical density of the text.

Ure (1971) refers to lexical density as "the proportion of words having lexical values (members of open-ended set) to the words with grammatical values (items representing terms in closed sets)." He further explains that lexical density is the proportion of words in written language which tells us more about a text. Lexical density is simply a count of the amount of details a piece of writing carries. The amount of words that a writer chooses to use to disseminate information to readers constitute lexical density.

From the definitions given by these scholars, it can be deduced that lexical density deals with a distinction between two types of words: lexical words or items and function or grammatical words or items. A lexical word or item according to Halliday (1985) is an item that "function(s) in lexical sets not grammatical systems: that is to say, they enter into an open not closed contrasts." They give meaning and also provides information on the purpose of a text. Reading only the lexical items in a text can give a gist of what the text is about. These lexical items or words include nouns, verbs, adjectives and adverbs. Nouns tell us about the subject, verbs tell us what the subject does while adjectives and adverbs tell us how the subject does it.

Ure (1971) and Ure and Ellis (1977) maintain that nouns, verbs, adverbs and adjectives are the word classes considered to have lexical properties. According to them, they are also called content words or open class words. Grammatical items or words, on the other hand, are non-lexical or function words which includes articles like *a, the,* prepositions like *on, in, at,* conjunctions like *and, or, but,* determiners like *many, any, another,* interjections like *ooh, congrats, thanks,* auxiliary verbs such as "*to be", "do", "have"*. They are said to give little or no information about what a text is about. They are also

referred to as 'binders' as they act like a glue which hold in place the lexical words in a text (Didau, 2013). Writing contains a greater count of lexical density than speaking (Ure, 1971). This is because written text is more descriptive and will naturally be full of content words.

Lexical density provides relevant perception about a text so far as it is not seen as the only means to judge a text quantitatively (Halliday, 1985). Lexical density is calculated by dividing the number of lexical words by the number of all words in each text. The result is a percentage of each text in a corpus. A higher lexical density shows a large amount of information-carrying words (lexical items) while a low lexical density shows a few information-carrying words (lexical items). There is a calculator that calculates lexical density online. A text is just fed into the calculator and it calculates the lexical density of the whole text and of each sentence as a part of the whole text. Lexical and grammatical items are the constituents of any text. Text with lot of lexical items is only comprehensible by well-educated individuals while text with low lexical items is easily comprehensible by average people. However, too low lexical items in a text hinders meaning and makes a piece of writing vague. A lexically densed text typically scores at around 56% or above.

Ure (1971) was used in determining the lexical density because it helps in considering lexical density from the word level which is consistent with readability formulae prediction of text difficulty to be the result of lexical and syntactic length.

$$LD = \frac{\text{Number of lexical words}}{\text{Total number of words}} \times 100$$

Syntactic Complexity

Syntactic complexity is a measure of how complex or dense the grammar used in a piece of text is. It is usually indicated by sentence length. The level of syntactic complexity that a reader can tackle is an indicator of the reader's syntactic development (Gyasi, 2017a). Kwong (1990) and Zhu (1979) observed that sentences are progressively sophisticated as children grow, with increases in complex modifications such as modifiers, verbs in serial expression, among others. The implication of this would be that as people grow, their ability to tackle greater syntactic complexity and read more difficult texts, can be expected to increase.

According to Feldman, James, Horning and Reder (1969), the idea of syntactic complexity is instituted to aid in the estimation of which grammar is acceptable for a particular set of ideas. Feldman, James, Horning and Reder (1969) however differentiated language complexity from syntactic complexity that language complexity deals with the content of a selected text while syntactic complexity deals with the structural form of the elements of the selected text. Therefore, measuring syntactic complexity involves examining the set of strings in a syntactic structure.

Review of Existing Literature on Lexical Density of Patient and Syntactic Complexity of Information Leaflets (PILs)

In their study, Clerehan at al. (2005) developed a framework based on a linguistic theory to enable them to assess the quality of written PILs. The framework which was based on the theoretical construct of Halliday (1994) Systemic Functional Linguistic was applied to a set of 18 leaflets about methotrexate treatment for rheumatoid arthritis sampled from 195 fully

registered members of the Australian Rheumatology Association (ARA). The sampled 18 leaflets were also those that were the most commonly prescribed drug from the association. They were given to two of the authors to analyse independently in accordance to the linguistic framework developed. The systemic theory considers how people use language to make meaning and how language is organized to enable meanings to be made. A lexical density analysis among others was performed on each of the methotrexate document. In the case where a PIL had more than a page, only the 1st page was analysed. Using Halliday (1985) formula for calculating lexical density, they found 5 leaflets to have a lexical density of 4- 4.9, 9 leaflets with 5- 5.9, and 6 or above for 4 leaflets. The average number of content words per clause was five or more for 13 out of the 18 leaflets analysed representing 72%, which is very high because the least level for all kinds of written English is approximately 3. Per the results, the leaflets basically showed to be written for people with high literacy level and scientific background. They recommended that PILs should not be densed as their density should be between the range of 3-4 as this score targets people with average literacy level.

Another study to investigate the readability of lexical density, lexical variation and keyness in PILs were conducted by Sartori (2013). Her aim was to understand how PILs were written and to focus on the possible distinction in Italian and English texts. 14 PILs were gathered from two different corpora; Italian texts and English texts. Each corpus consisted of seven PILs for self-treatment drugs (OTC) for the relieve of the symptoms for colds and flu. She chose the leaflets in relation to their active ingredients and recipients to enable the cooperation between the English and Italian texts which provided

information about equivalent drugs. In order for her to calculate lexical density, she used the formula:

$$LD = \frac{\text{Number of lexical words}}{\text{Total number of words}} \times 100$$

To enable her to calculate the number of lexical words, two lists of grammatical words, one for English and one for Italian, were used. After the calculations, it was realized that lexical density values for English texts were between 52.33 and 59.43 while that of the Italian text were between 52.32 and 61.17. Also, text length was seen as a possible element which influenced lexical density values in the English texts but this was not the case for the Italian texts. The Italian texts were, however, less accessible than the English texts due to their tendency of using formal register which increases the use of specialized terms, nominalization and propositional phrases which intend increases the difficulty of the texts that were investigated. The language used seems not to be comprehensible by patients with poor literacy skills and low levels of education. She therefore recommended a more direct and simpler language to be used to aid patients' comprehension.

Also, Hirsh et al. (2009) sought to obtain patients' feedback about the structure and quality of PILs and validate the usefulness of the Evaluation Linguistic Framework (ELF) for improving written communication with patients. Fifty (50) patients who attended one of two community-based rheumatologists in Melbourne, Australia were invited for the study by mail. They were of varying age, sex, level of education and the duration of their disease. Twenty-seven out of the fifty patients accepted to partake in the study,

thirteen refused to respond while ten declined the offer. The twenty-seven who honoured the invitation were engaged in a one-no-one interview and an organised round table discussion where they also completed a self-administered questionnaire. All discussions were recorded and put into writing. Nineteen PILs were gathered for the study with seven being prednisolone, eleven being sulphasalazine, one being methotrexate and another one on etanercept. During the interview, partakers were made to read aloud one sulphasalazine and one prednisone PIL and another one if need be. During the focus group discussion, participants were made to share their views on what they read during the interview. The questionnaire administered contained series of statements about the overall appearance of the leaflets and the ten possible "moves" or stages that the leaflets were identified with.

Their findings were that the participants found PILs to be an important part of doctor-patient interaction as it reinforces the information given by a doctor and not replace it. However, they wished doctors could explain the information provided on the PIL during consultation. The participants also found some medical terms to be terrifying which scared them off from reading the leaflet. They could not read some words which generally implied that the level of medical terms used in some of the leaflets were of great worry as it made the vocabulary used in the production of the leaflet technical. They again found some participants commenting during the interview and focus group discussion that some leaflets had no headings or dot points. They were also difficult to read because they contained too many words and were complicated and too "densed" making it difficult to find the information in them. These

available studies on the lexical density and syntactic complexity found the PILs densed and complex for readers.

Readability and Comprehension

One of the eminent contributors to readability studies, Edgar Dale in 1972, asserted that readability is as old as the hills and the written stories that have described them (Dale, 1972). McLaughlin (1969) refers to readability as the level at which particular people find certain text captivating and understandable. The class of people is the group of readers who are using the text. Depending on the text characteristics, the readers may find it comprehensible or otherwise. DuBay (2004) summarizes the notion of readability as what makes some text easier to read than others. It is the ease with which a reader can understand a written text. Readability of a text resides on the text and not the individual. Readability of any text is paramount if the true message the writer wants to put across to the reader can be understood.

According to Ley and Florio (1996), readability refers to how written text is being understood. The understanding comes from the interaction between the written words and how they trigger knowledge outside the text. Wray and Dahlia (2013) explain that readability is the characteristics of the text itself and comprehension as an indication of the readers' ability to make meaning of the text. Writers intend to transmit information to readers through a written piece, in much the same way, manufacturers wish to transmit information to consumers through medical information leaflets.

Readability can be said to be the components that influence the reading and comprehension of a piece of writing. Reader and text centered variables are examples of these components. Reader characteristics such as the reader's

background, prior knowledge, interest and general reading ability (Jones, 1997) are some of the factors which affect comprehensibility and they solely reside in the individual. Reader's level of education, degree of literacy, primary or native language and health conditions such as eye related problems are also factors that can hinder the easy comprehension of a written text. Text characteristics such as font size and style, paper type and size, choice of vocabulary, layout of the text, picture and diagram presentation can also obscure the understanding of a piece of writing.

Comprehension is the reason for reading. It is a known fact that one of the ways to improve comprehension of a text is to improve readability of that text. According to Liu et al. (2009), comprehension is a psychological process that entails decoding words and sentences, connecting ideas and generating meaning from a written text. Comprehension resides with the individual unlike readability which resides in a piece of writing. Comprehension is therefore, an individuals' ability to understand any piece of writing so that by the end of the reading episode, the individual can recall what as read and probably answer questions on it.

Vanderbilt University Medical Centre in their article, "Patient Education- Preparing New Material" suggested that to aid comprehension a text should be made to read like a one-on-one conversation and not a speech or a textbook. Writers were advised to use the passive and not active voice, for instance, *"Patients should expect these signs after taking this medication"* and not *"Expect these signs after taking this medication."* Titles, headings as well as sub-headings should be clear and actionable. This is because it makes the grasping of the key concepts easy at a glance for readers.

Readability influences comprehension very positively. According to DuBay (2004), readability is determining factor that withhold reader's interest to read an article that is not interesting. In other words, when reader's interest is low, readability contributes highly to text comprehension. It is assumed that if a text is written in the standard or acceptable grade level, which is the grade that is recommended for public document, it will be readable and comprehensible to most readers (DuBay, 2004). Nevertheless, readability resides with the text while comprehension resides with the reader. Worded differently, readability depends on text characteristics while comprehension depends on reader abilities. Therefore, readability influences comprehension if the text variables meet the readers' abilities.

The power to predict the readability of a text comes in handy when choosing appropriate texts for students as well as suitable text for an author's audience (Zamanian and Heydari, 2012). In an attempt to device ways of predicting readability of a text, readability scholars have developed readability metrics to this effect. There are over 200 readability formulas today which can be used to predict how readable a text is to read (DuBay, 2004; Zamanian & Heydari, 2012).

Readability and Readability Formulae

Readability can be determined by using readability formulae or indexes. In the 1920's, the use of sentence and word length as yardstick for measuring text complexity was discovered (DuBay, 2004). Readability formulae or indexes are many statistical procedures which foretell the reading ability needed to comprehend a particular text (Ley & Florio, 1996). According to Rush (1985) readability formulae are those which helps in identifying the difficulty a text

will pose to readers objectively using measurable instruments. Thus, these formulae can assess text that have a large range of content and prose styles.

Danielson (1987) explains that a readability formula is an arithmetic calculation that attempts to connect the understanding of the reader and the grammatical features of a piece of writing. They are often used as a guide to the preparation and assessment of written health information. These formulae have been in existence for years and have been used by many disciplines to calculate the readability of written text although they are not the only method used in assessing the understandability of materials. It has become common to evaluate written health information or any other text from other discourses with readability formulae. There is, however, no uniform guideline for the use of these formulae. Each of the formulae applies varied computations and techniques for validation. Their outcome may differ greatly due to the varied software processing, algorithms and the varied application of each formula. To use the formulae effectively, one has to understand their creation, application and expected understanding level (Wang et al., 2013).

Lorge (1949) notes two weaknesses of these formulae. He points out that the formulae do not directly evaluate conceptual difficulty and cohesion (Halliday & Hassan, 1976) which is very important to comprehension. Danielson (1987) is also of the view that even though the formulae are regarded as “necessary evil", they are not worth the attention they receive. This is because they must not be seen as the paramount instrument in measuring a text grade level as there are numerous factors which are relevant to the comprehension of reading that the formulae do not take into consideration. These factors include reader's motivation and familiarity with certain vocabulary which sometimes

overestimate the difficulty of the passage (Smith et al., 1998). They also do not take into account grammar, content or the ability of the readers (Bradley et al., 1999), suitability of materials such as organization, layout, graphics and cultural appropriateness (Wilson, 2008).

Apparently whether the reader can understand or not remains unknown. Also, Flesch and the others who designed the formulae emphasized that reader's background and purpose cannot be measured but they have an influence on the comprehension of a written text. Thus, readability formulae are not perfect as they fail to determine every aspect of the reader that have a bearing on readability and can be misapplied as they associate with features of words and sentences with no need learning anything about the reader. They are of the view that just a formula cannot address the numerous issues related to readability (Flesch, 1943; Lorge, 1944). Kincaid at al. (1975) warned that readability formulae are not to be used as a guide in writing but as a tool for assessment when the writing is done to facilitate effective revision. The formulae are not supposed to be applied to a piece of writing until the author is sure s/he is done with the drafting of the material. McLaughlin (1997) also advised writers to read aloud drafts to ensure that their text is clear and readable before applying a formula to it. Published literature on the use of these formulae focuses on reading grade levels without much consideration of their expected comprehension levels (Wang et al., 2013).

Studies that use these formulae often overlook the impact of the text sample size, selection and/or formatting on readability results. These factors may lead to underestimation or overestimation of the readability of written health information materials (Ley and Florio, 1996). Smith et al. (1998) are also

of the view that these formulae ignore the fact that patients know the vocabulary that comes with their illnesses and overestimate the complexity of the text. Similarly, these formulae do not take into consideration the inevitable nature of the medical jargons and technical terminology hence their failure to be an exact meter for measuring the readability for technical writing. (Plung, 1981).

In spite of the many factors that these formulae do not consider, they are still the most extensively used tool to assess the reading level of a piece of writing. They give an impartial contrast of texts over varied writing styles (Wong, 1999). They can also be the basis to revise texts by making sure that they do not have numerous lengthy words or sentences. According to Vieth (1988), vital journals in the technical communication field have answered the concerns on readability and its implications by assigning greater divisions and even whole sections of their journals to the topic of readability. Governments, insurance firms, medicare and the military have their attention on readability because they all rely on written communication. Fry (1987) discovers that the insurance industry in the US is also a prominent user of readability formulae because as of March 1984, 28 US states required that personal auto and homeowners' policies must have a Flesch Reading Ease score of about a 10th grade level. Not forgetting the fact that the Flesch Kincaid formula was developed for the US Navy to help with the production of readable materials for their recruits.

There is also an interest in readability on the part of manufacturers concerned about safety, product liability and proper product use as PILs became mandatory to accompany all new packaged medicines launched after 1st January, 1994 and to accompany all medicines that are dispensed in Britain by

December, 1998 (European Commission, 2009). Per the law, the readability levels of PILs yet to be produced must be stated using a recognized formula. The formulae still help in determining the grade reading level of a piece of writing to enable its complexity to be foreseen before issuance. It reveals the type of words and sentences that will pose difficulty to the reader's understanding. They are easily available online, easy to use and obtain results. Their simplicity accounts for their continuing popularity.

It must be noted that formulae are not the only means through which readability can be assessed. According to Ley & Florio (1996) formulae are not the only way of determining the comprehension level of a text. There are different methods like the cloze procedure, vocabulary used analysis and pre testing of materials with ad hoc comprehension tests among others. The cloze readability procedure proposed by Bormuth in 1968 is a possible predictor of readability which is similar to a conventional test, fill- in- the- blank (Ley and Florio, 1996). In the close procedure, every fifth word in a piece of written text is left out. It is up to the reader to find out that word. The score is the percentage of guessed words which are exactly correct. The vocabulary analysis replaces too difficult words with easier words. A vocabulary database ensure that too difficult words are replaced. It provides a school grade level at which a given word is likely to be understood. The most commonly used database use to analyse vocabulary is the Living Word Vocabulary (Dale & O'Rourke, 1982).

Discussion on Readability Formulae

DuBay (2004) established that there are over 200 readability formulae or indexes proposed by researchers to calculate readability across disciplines. Prominent among them includes the Flesch Reading Ease Readability formula which was developed by Rudolf Flesch, a writer and reading consultant and a supporter of the Plain English Movement in 1948. It is one of the oldest and considered the most accurate and extensively used formula. It is used to assess the difficulty of a reading text written in the English Language. The score indicates how difficult or easy a text is to read and understand. It is widely used in the academic setting. It measures reading from 100 (extremely easy) to 0 (very difficult to read). Flesch identified 60 as the minimum score for plain English. It comes with a conversion table which interprets scores. The formula is:

$$206.835 - 1.015\left(\frac{total\ words}{total\ sentence}\right) - 84.6\left(\frac{total\ syllabus}{total\ words}\right)$$

Gunning Fog Index also known as Fog index was developed in 1952 by Robert Gunning, an American businessman. Texts for a wide audience generally need a fog index less than 12 (around 18 years old US high school). The formula for calculating is:

$$0.4\left(\frac{words}{sentence}\right) + 100\left(\frac{complex words}{words}\right)$$

Spache Readability Formula was developed by G. Spache in 1953 through an article, *A New Readability Formula for Primary Grade Reading Materials*, published in the Elementary school journal. Since most of the readability formulae in use were applicable only for reading levels of grade 4 and beyond, he developed this formula to cater for grade level below 4. It was purposely created to measure the readability of primary texts. Its measure is

based on sentence length and number of unfamiliar words. Unfamiliar words are wording that 3rd grade and below do not recognize. Its formula is

$$(0.141x \text{ ASL}) + (0.086 \text{ x PDW}) + 0.839$$

ASL- Average Sentence Length **PDW**- Percentage of Difficult Words

Fry Graph Readability Index was designed by Edward Fry to 'save time'. It is plotted on a graph. It is a convenient method for those who have no computer. It measures reading level from 1st grade to college. It employs sentence length and number of syllables per 100 words. It involves only a count of syllables and of sentences in a series of 100-word samples plus simple computations of numbers which can be plotted on the graph. The reading grade level is found by plotting the average number of sentences and syllables on Fry Readability Graph.

Dale-Chall Readability Formula was designed by Edgar Dale and Jeanne Chall in 1948. It was developed to find the grade level of instructional materials such as books, pamphlets and newsletter. It was created for adults and children above 4th grade. It currently has a word list of 3000 familiar words that a text is validated against. The formula is unique in that it counts 'difficult words' as a measurement as compared to other formulas which uses word length. The formula defines 'hard words' as words which does not make it to a specific outlined list of 'familiar words' 4th graders are conversant with.

Flesch Kincaid Grade Level Index was developed by Rudolf Flesch and Peter Kincaid, a research psychologist, in 1975 as a grade level evaluation for the United States Navy. It is an improvement of the Flesch Reading Ease Grade Level by only Rudolf Flesch. It was first used by the army to assess the difficulty of technical manuals and soon became a United States Military standard. It is

extensively used in the field of education. It is the most reliable of all the readability formulae (Bravos, 2010). It converts the o-100 score into a U S grade level. The grade level is calculated with the formula:

$$0.39\left(\frac{total\ words}{total\ sentence}\right) + 11.8\left(\frac{total\ syllabus}{total\ words}\right)$$

Lastly, Simple Measure of Gobbledygook (SMOG) Readability Index was developed by McLaughlin in 1969 by means of an article, *SMOG Grading-A New Readability Formula* in the Journal of Reading. It is widely believed that SMOG was designed as a substitute for Gunning Fog index (DuBay, 2005). The formula was validated against the McCrabb's passages. He used a 100% correct- score criterion, that's, it predicts the grade level required for 100% comprehension whereas most formulae test for around 50% to 75% comprehension. Because it estimates 100% comprehension, the grade level score obtained is frequently one or two grades higher than the other commonly used formulae. The output of SMOG measure is expressed as the number of years of school education required in order to proficiently understand a written text. This is known as a SMOG grade which can then also point to an age equivalent estimate. The formula is based on sentence length and number of complex words (polysyllabic words).

The researcher will use the Flesch Kincaid grade level and the SMOG to analyse data gathered for the study. While the Flesch Kincaid grade level translates Flesch reading ease scores into grade level scores; the SMOG formula uses different mathematical calculations to predict the grade level that is appropriate based on Flesch reading ease levels. The SMOG formula uses a list of most familiar words as basis for predicting text difficulty. A text that has less of the familiar words with complex sentence structures will be scored difficult.

Using the two formulae to complement each other, the study will avoid the weakness that one formula will pose to the results of the study. Moreover, Wang et al. (2013) established in their work that, Flesch-Kincaid formula was the most commonly used formula and the SMOG performed consistently when applied on health materials hence the most commonly used formula to assess the readability of health materials (Hedman, 2008). They therefore recommended SMOG as best suitable to measure the readability of health documents because of its consistency of results, higher level of expected comprehension, use of more recent validation criteria for determining reading grade level estimates and its simplicity of use. Klare (1974) is also of the view that with the exception of the Dale-Chall formula, all the others can be fairly calculated with the SMOG grading being the easiest. Both formulae are easily accessible online.

Review of Existing Literature on Readability and Comprehensibility of Patient Information Leaflets (PILs)

With the aim of assessing the readability of patient information leaflets of over-the-counter medicines, Bradley et al., (1994) assembled fifty PILs from a selection of proprietary products currently available on the UK market. The leaflets were validated against six readability formulas; Dale Chall, Flesch Reading Ease, Gunning Fog, Fry, Raygor and SMOG. The leaflets were taken from a range of OTC Medicines and were assessed to see how suitable they were for patient use. Each of the leaflet was assessed using the readability test which involved examining and calculating elements of the leaflets such as the percentage of uncommon or infrequently used words, the average sentence length and the number of polysyllabic words. The values obtained were then validated against the readability formula which gave numerical answer. The

answer represented a grade level score of American education required by readers to understand the leaflet. Five was then added to the average reading age to obtain the grade level. The results show that the mean reading age was 14.8 years on the Fog test, 15.4 years on the Flesch test and 14.8 years on the SMOG test. Only a few usable data were obtained with the Fry, Fry extended and Gaynor tests because when applied to the leaflets the values fell outside the validated range quoted by the originators of the tests. The Dale Chall test was used in the initial part of the study but was subsequently discarded because of the difficulty in applying it in practice. The individual reading age values for the leaflets ranged from 10 to 20 years. These mean values are well above the mean reading age of the general adult population. It was recommended that manufacturers need to revise means to producing leaflets which are easier to read and understand in order to reach a wide majority of people.

Again, Travedi et al. (2014) examined the product labels of 40 non-prescription medications for readability and comprehensibility and other characteristics using the Flesch Kincaid formula which provides reading ease score and reading grade level score. The reading grade level score was further validated using the Gunning-Fog formula. For authentication, each readability score was generated twice and rounded to a whole integer. They found out that non-prescription medication labels which contains important information about components, risks and warnings are written in a language with poor readability and comprehensibility characteristics. The average reading ease score of the labels was 38 ¥ 12 and the average grade level required to understand the material was 16 ¥ 5. Only one of the labels was at reading grade level less than the eighth grade according to the Flesch Kincaid grade index. The average grade

level of education needed to understand the labels according to the Gunning-Fog formula was also above the eighth-grade reading level. When a qualitative assessment of selected labels was made, severe deficiencies such as poor organization and inundation with technical terms were found. Since available research shows that about a quarter of the US population could not read or understand materials below the 5th grade level, it is prudent for health-care materials to be produced in such a way that is comprehensible to the US general population. There is another issue of the health-care community facing the aging population who are also vulnerable to drug side effects, so if these labels are not produced with readability in mind its effect could be life-threatening. They therefore concluded that non-prescription medication labels are written in a language that is not comprehensible to the average member of the general public. They asserted the need for considerable improvement in the readability of these labels.

Wilson (2008) conducted a study with the purpose of determining the readability of Patient Education Materials (PEMs) used in community health-care settings that serve low-income populations. Five (5) free or low-cost community clinics from a Midwestern urban area serving low-income populace was the setting of her study. health-care providers from these clinics were asked to submit PEMs used most frequently for their clients which were written in English. However, those with lists, had incomplete and less than 30 sentences, or were duplications were excluded from the list. Forty-four (44) documents were received but the final sample had 35 unique PEMs. Three (3) readability formulas; SMOG, Flesch Kincaid and Flesch Reading Ease readability formulas were used to assess the readability of the PEMs. In analysing her data, SPSS

version 15.0 was used. Hand calculations were used to provide the grade level for SMOG and was compared to the outcome determined by a second researcher to determine interrater which was in absolute agreement. To determine if there were any differences in the readability of these PEMs, t tests were used. The strength of the relationship between the 3 readability formulas used were also assessed using a correlation coefficient. Her analysis revealed that, the mean grade level for Flesch-Kincaid and SMOG were 7.01 and 9.89 respectively which were both above the recommended 5th grade reading level. Reading grade level by SMOG was found to measure consistently 2 to 4 grade levels higher when the same PEM was measured with Flesch-Kincaid. The variability of the reading grade levels for the entire sample using SMOG and Flesch-Kincaid were 5 and 7 respectively. A wide range of Flesch Reading Ease scores reflected materials that were considered very easy (5th grade) to difficult (college level) with mean scores at least standard grade level for reading (8th and 9th grade).

Generally, it was noted that there was consistency in the association between the 3 readability formulas used. But their outcome reveals that the PEMs were above the recommended reading grade level (5th grade) of written health communication making them difficult for the average adult reader because a good number of them were written at a 9th grade reading level. Per the result of Wilson (2008), most of the patients who access health-care in the community clinics are likely not to benefit from the information contained in these documents. The need for authors to have readability in view when preparing such documents is therefore very important. This is especially the case when issues regarding heath which is a matter of life and death are involve.

Another interesting study on the readability of health-related text is Williamson et al. (2010). They explored the readability of Patients Information leaflets provided by a district general hospital in the UK using the Flesch and Flesch Kincaid methods. They hypothesized that these leaflets will be above the patients' comprehension and readability. Williamson et al. (2010) had their hypotheses confirmed when they downloaded all available leaflets from the hospital's website which amounted to 171 PILs. They were categorized into 21 groups with 8 leaflets in each category. Additionally, 20 newspaper articles from 10 top UK daily newspapers and 10 journal articles were also chosen at random and assessed and their average readability score was compared against the PILs. According to their study, the average reading age of the US and UK populations is the 8th grade (13-14 years old) which is Flesch Kincaid grade 8 and patient information should be aimed at grades 5-6 (10-11 years old) which is Flesch Kincaid grade 6.

Their findings were that the average Flesch readability of all the hospital PILs available was 60, with 7.8 (12- 13 years) Flesch Kincaid grade. Only 2 categories had their average leaflet at or below the recommended level for patient information (Flesch Kincaid grade 6). Most of the categories (18 out of 21) had their averages at an acceptable Flesch readability scores (60 or more). This posits that most leaflets should be readable but many will exceed the comprehension of their reader. Evidentially, the PILs are not of any benefit to a wide range of patients. They called for the need to revise these information leaflets so that they could serve their intended purpose for resources not to be wasted in their provision.

Kasesnik and Kline (2011) designed a study with the assumption that there is a problem with regards to inappropriate readability of texts in Slovenia. They therefore sought to determine the readability of Slovene texts, summaries of product characteristics, promotional materials, texts for promoting over-the-counter medication, patient information leaflets and materials in creating disease awareness. 1,474 materials were sampled from 10,396 products both of Slovene language and English language. The Flesch readability formula was modified to comply with the Slovene texts.

The results of the research showed low readability scores of the Slovene texts. The PILs were more readable than the Summary Products Characteristics (SmPC) irrespective of the language used even though the readability scores showed that they were all difficult to read. The Flesch score for the PILs was 10 while that of the SmPC was 11. When the Slovene texts were compared to the English ones, the English PILs had a score of 34 which mean difficult to read while the Slovene texts were marked as very confusing with a score of 5. Readability of the texts for promoting OTC medications were also rated difficult to read. The texts related to side effects of the medications were less readable than those describing the benefits irrespective of the chosen therapeutic group. Readability ease values of the benefits related to treatment of viral diseases and allergy treatment were 4 and 0 respectively, that for the risks for the treatment of viral diseases reached 19 while 17 was obtained for allergy related medicines.

On a whole, none of the researched items for the general public were close to primary school grade readability levels and therefore could not be described as easily readable. The Slovene algorithm revealed decreasing values of the readability ease as grade levels were higher. Per their findings, health-

related texts were not readable by the general public or complied with health-care professional needs. The study thereby confirm results from previous studies that Slovene PILs are difficult to read and understand. The English PILs were also described as difficult to read. It can be concluded that regardless of the language the PILs are not readable.

Alaqueel and Obaidi (2017) conducted a study with the objective to determine how well patients could correctly recognize and comprehend the various informative items in OTC PILs in Al Kharj, Saudi Arabia. They also had the quest to examine the layout and language characteristics from the perspective of experts and patients as well. From a list of 100 medicines which had been sold 100,000 times or more in 2011, 20 OTC Medicines were selected for the study. They were of different therapeutic indications and pharmaceutical forms and manufacturers. They were also obtained in hardcopy and the Arabic side photocopied to be used for the study. Patients were to answer questionnaires which were translated from English Language to the Arabic language by experts to be used to measure their assessment of the PILs. The help of experts was engaged to examine the PIL to extract it's characteristic related to the language and layout.

Data from the questionnaires and from the expert's examination were analyzed using SPSS for Windows version 15.9. 637 questionnaires were answered after 1150 were distributed to community pharmacies and 2 hospitals and 513 were returned.

They found out that 363 (75.8%) of the consumers who answered the questionnaires stated that finding specific information in the PILs was easy, 83 (17.3%) found it difficult while 18 (3.7%) found it very difficult. When asked

if there were any specific information that they wanted to know about the medicine but could not find in the PIL, 414 (86.4%) responded no while 47 responded yes. The percentage of the participants who understood the PIL ranged from 10.9% for the least to 87.3% for most commonly comprehensible information. It was also noted that the PILs offered a limited and incomplete amount of information regarding dosing instructions. There was a consistent use of a small font size and participants could not find and understand the information related to many items in the questionnaire. Only 1 question was answered correctly by over 80% of the respondents. In conclusion, patients had some difficulty recognizing and comprehending certain information items in the PIL supplied with OTC medication in Saudi Arabia.

They recommended that the issues outlined in this study should be taken into consideration in the future by regulatory authorities during the preparation and approval of the PIL. Otherwise, appropriate verbal and counselling will be needed from pharmacists to overcome the inadequate written information available on the PIL.

Cronin et al. (2010) assessed the readability of 45 common patient information leaflets for older people was compared to newspapers in Ireland. The SMOG readability formula was used to assess the language of the leaflets. The leaflets were conveniently sampled from a University Teaching hospital, a day hospital and a rehabilitation hospital. A comparison of the reading levels was made with the general reading test.

Their findings were that the mean readability level of the PILs were 12.57 (and a 9.38-16.33, standard deviation 1.74). This was comparable to the readability level of the broadsheet newspapers which have a mean of 12. All the

health information leaflets studied was written at a readability level of 9th grade or higher. This shows that the materials analyzed were written at an excessively high readability level. This is of particular relevance to the older population who are at a high risk of inadequate or marginal health literacy but have a higher requirement for health services and health information than younger adults. They recommended that leaflet authors should understand the ramifications of limited literacy and to use that knowledge to develop their leaflets.

In a quest to investigate ophthalmic patient's opinion of PILs, it's readability and comprehensibility, it's influence on patients' adherence or reluctance to medication intake, it's contribution to patients' education and to investigate which ocular disorder prompts patients to read the PIL, Kyei et al. (2013) conducted research to that effect. The three largest hospitals; the Central Regional Hospital, Bishop Ackom Memorial Christian Eye Centre and Our Lady of Grace Hospital which had eye specialist in the Central Region were selected for the study. The study was a hospital based cross-sectional survey. The population was ophthalmic patients reporting to the eye care facilities for review. Patients who were regular visitors for at least 3 months prior to the study were interviewed individually as and when they came in to seek eye care.

A total of 400 participants, 140 males and 260 females were used for the study. 188 were greater or equal to 60 years, 126 were adults (36-59 years) while 86 were young adults (18-35 years). Ninety-two participants agreed to read the PIL with 50 reporting that the choice of words used were difficult to understand as it contained a lot of medical terminology. Five (5) said the information were presented in another language other than English while 37 had problems with the font size. It was observed that majority of the leaflets had

scores between 0-29 indicating that the choice of words used were indeed very confusing. This might have been the reason why most patients declined to read the PIL. The low readability scores obtained required "a more academic and scientific reader to comprehend the PILs". However, 1 company's leaflets for analgesics were fairly easy to understand. They recommended the addition of pictogram and language modification in writing the PILs in order to improve patients understanding of the PILs. They also recommended laws to be enforced by the appropriate institutions to compel pharmaceutical companies to produce better PILs.

In Qatar, Munsour et al. (2017) conducted research on the readability and comprehensibility of Patients Information Leaflets for Antidiabetic medications. All available PILs for the treatment of diabetes mellitus from the government hospitals of Hamas Medical Corporation, primary health centers and private pharmacies were assembled. 45 PILs were legible for evaluation after duplicates were verified and removed. They were also the PILs of approved for marketing and used by the Pharmacy and Drug Control unit. Four readability formulas were used to assess the PILs. Flesch Reading Ease score was used for the readability while Flesch-Kincaid Grade Level, Gunning Fog and SMOG were used to estimate the comprehensibility of the PILs in terms of school grade levels. Their descriptive analysis involved a readability evaluation of the English PILs or English test of multilingual PILs for all envisaged medications using the FRE score.

This evaluation process was conducted by 2 pharmacy experts using the Delphi technique to achieve a consensus. They found 8 (17.8%) of the PILs to be in English, Arabic and French, 28 (62.2%) were in English and Arabic while

9 (20%) were in English only hence they were not readable by most of the patients in Qatar especially those with limited literacy level as it is an Arabic speaking country. The mean number of words contained in a PILs was 2293.82 ¥ 1533.83 with 256 words as the minimum for the generics and 8220 words as the maximum for the brand. The brand name products recorded the highest FRE scores as compared to the generic products. The comprehensibility of the evaluated PILs using the FKGL, Fog and SMOG showed the mean score of 10.96 ¥ 2.67, 15.02 ¥ 2.52 and 11.41 ¥ 1.6 respectively. There was a consistency in the outcome of the Evaluation which implied that individuals who completed 11th grade are those who will be able to comprehend the PILs.

This exceeds the recommended reading grade level for patients' education materials which should be the fifth to sixth grade. Generally, the study confirmed that the PILs were not readable to the general populace and recommended that regulatory authorities and policy makers make producers of these PILs declare an acceptable score of readability, comprehensibility and number of words based on a brand-name product so that their intend can be realized to achieve quality health care.

Smith et al. (1998) evaluated the readability and accuracy of PILs available in general practice for asthmatic patients. 163 leaflets were received to be worked on from 49 practices after 70 general practices from a Research Network were invited to present a copy each of their leaflets on asthma. The leaflets were reviewed for readability using the SMOG formula. They were also reviewed for compliance with the current British Thoracic Society (BTS) guidelines. Their findings were that the reading grade obtained from the SMOG ranged from 5 to 12 (mode 8, mean 8.66, SD 1.79).41 out of the 168 leaflets

contained inaccuracies while 21 were 90% or more accurate. Seventy-eight did not comply with the guidelines of the BTS while 58 fully complied to it. Out of the 41 leaflets which contained inaccuracies, 5 were from drug companies, 6 were produced by charity, 7 had outraged therapeutic advice, 3 had no publication date and all but 1 of the rest were at least 6 years old. Even though none of the inaccuracies highlighted posed serious threats to patients' wellbeing, they believe patients deserved more. They concluded that since five and half million people in Britain have reading difficulties and about 22% have low literacy level, the SMOG readability score which was above 5 makes the PILs not understandable by most of the populace. They recommended that 97% of the PILs reviewed needs revision in order to serve it's intended purposes. They also advised health professionals to read their leaflets before giving them out to patients to ensure accuracy.

Auta et al. (2011) assessed the readability of 45 malaria medicine information leaflets obtained from community pharmacies in Jos, Nigeria. The leaflets were of artemisinin-based preparation of antimalarial and the assessment was made in relation to the paper type, font type and size, use of symbols and pictograms and bilingual information. SMOG readability formula was used to assess the readability of the leaflets. The data was fed into Microsoft Excel 2007 spreadsheet containing the readability test formula (SMOG) to generate readability grade level for each leaflet. Their findings were that, malaria medicine information leaflets in Nigeria health sector are not readable to the average reader in Nigeria. This is because the readability grade level ranged from 9 to 16 with 14 as the top reading grade level. The mean grade level was 13.69 with a standard deviation of 1.70. It was also noted that 6.7% of the

leaflets were glossy and contained symbols and pictograms, 57.8% of the leaflets had a font size less than 8 which is considered the absolute minimum acceptable font size for medicinal leaflets in European countries (which this study also adopted) while just about 2.2% of the leaflets were written in both English Language and a major language in Nigeria. This means that most of the malaria medicine information leaflets are not readable to a better part of the Nigerian populace since a good number of the leaflets sampled required a tertiary level of education to comprehend them. They however recommended that these leaflets should be made readable since their migration from Prescription Only Medicines (POMs) to Over-The–Counter (OTC) as a way of promoting home management of malaria. To make the leaflets readable and useful, they should be produced in the consumers primary language since about 54% men and 74% women in Nigeria can read in one of the major languages. Instead, these leaflets are produced in English and French when only a few of the populace can read French. It is also their hope that policies will be put in place to design non-technical consumer information leaflets as other developed countries are practicing.

As part of her research, Sartori (2013) analysed 14 PILs quantitatively for lexical density and lexical variation and qualitatively for readability scores. Three readability indexes were used to measure the readability of these PILs. The PILs consisted of 7 each of English and Italian text. The Flesch Reading Ease and the Flesch Kincaid Grade Level were used to analyse the English PILs while Gulpease Index was used on the Italian PILs. The Flesch Reading Ease readability scores and the Flesch Kincaid grade level for each of the English corpus were obtained automatically from Microsoft Word online. Per their

findings, the Flesch Reading Ease scores gave an average score of 48.45 while the Flesch Kincaid Grade Level also revealed an average score of 9.5. This show that the English PILs are expected to be understandable by high school students (13^{th} and 14^{th} grade which correspond to 4^{th} year students in European high schools) which is fairly difficult. The Gulpease readability scores gave an average of 52 which means they have a medium difficulty level. When the readability values of the English and Italian texts were compared using her own created corpus, the Flesch Reading Ease and the Gulpease readability scores (506 and 49 respectively) indicated that both texts are expected to be comprehensible by users with a high school educational level. It therefore shows the presence of a problem. Although each measurement took into consideration a specific aspect of the texts' complexity, all scores demonstrated that the language used in the production of the PILs is quite difficult to understand. The results defy the purpose of the texts. They however proposed the use of a more direct and simpler language to facilitate patient's understanding as the PIL is an informative text for all types of readers. They noted that some pharmaceutical companies have a website that has a section that explains the language used in PILs but to some patients especially the elderly, PILs remain the primary source of information.

A study was also conducted by Gyasi (2013) on the readability of patient information leaflets of Malaria drugs in Cape Coast, Ghana. Seven leaflets of commonly used malaria drugs in the Cape Coast metropolis were sampled. The Flesch Kincaid reading ease and the Gunning Fog indexes were used to assess the readability of these leaflets. He found out that all the patient information leaflets sampled were difficult to read and defied their purpose. The Flesch

Kincaid Reading Ease showed values ranged from 10.4 to 36.3 which is equivalent to university education grade and a Gunning Fog score 14.2 to 18.8 which exceeds the grade level requirement for university graduate readers were the results obtained from the formulae. When the leaflets were tested for legibility, it was noticed that most of the leaflets were written with font size less than 10 which implied that they were generally not readable especially to those with sight problems. However, when the leaflets were tested for type of paper used, it was revealed that they were non glossy and non-coated papers which is very good because they enhance reading. Bilingual data analysis indicated none of the leaflets were written in any of the local languages in Ghana but a small quantity was written in only English Language with majority of the leaflets written in English Language and an international language which is not beneficial. Testing the leaflets for pictorial illustrations, none of them had pictures to enhance comprehension which was not helpful.

Gyasi (2013) recommended that since malaria drugs are now over-the-counter medicines, their leaflets should be produced to suit the readability and comprehensibility level of the average Ghanaian. He therefore encouraged the Ghana Health Services and the Food and Drugs Authority to formulate and enforce policies to that effect.

It is interesting to note that another study in the UK by Wong (1999) found the leaflets easy to read as it posed no difficulty to its users. He explored the readability of PILs prepared for marketed proprietary antiepileptic drugs. 12 PILs on Antiepileptic drugs (AEDs) were compared with six antiepileptic drugs articles from medical journals and six headline articles from some UK newspapers. Two readability formulae; Gunning Fog and Flesch reading ease

were calculated for each PIL and article. The results of the readability formula score were compared using the Kruskal-Wallis non-parametric test. This analysis was performed using SPSS for Window V7.5. Their finding was that the PILs had a statistically significant lower mean reading age compared to the medical articles and newspapers. The PILs had a mean reading age of 8.8 (Gunning Fog test) and mean readability score of 69 (Flesch Reading Ease index) respectively. The mean Gunning Fog test results indicates that the mean reading age of the PILs is at par with the UK adult population which is 9 years. This however shows that the PILs prepared for proprietary antiepileptic drugs in the UK are suitable for the reading age of the general adult population and are therefore readable as compared to the medical articles and newspapers. This they attributed to the fact that people with epilepsy are perceived to be mentally challenged hence the manufacturers might have made special efforts to simplify the PILs for them. They found this very encouraging as most studies of PILs for other health related sicknesses available in the UK found these PILs not readable.

This comprehensive review saw PILs difficult to comprehend because they were mostly written above the required grade level which is grade 8. Even with a law in the United Kingdom entreating manufacturers of PILs to declare the readability level with a standard readability formula, studies show that their PILs are still not comprehensible to the people with low education. This review captured the situation at the United Kingdom, United States of America, Slovenia, Saudi Arabia, Ireland, Qatar, Italy, Nigeria and Ghana and none except one study from the United Kingdom found the leaflet readable. The study by Wong (1999) is the only study the researcher found in the course of her

readings that found the leaflet comprehensible amidst other research conducted in the same country where the PILs were found not to be readable. Wong (1999) attributed the fact that their leaflets were found readable to the fact that people with epilepsy are perceived to be mentally challenged hence the manufacturers might have made special efforts to simplify the PILs for them. They found it encouraging as most studies of PILs for other health related sicknesses available in the UK market found these PILs not readable.

The researcher found their reason quite alarming because if there is actually something like "special efforts" that could be made to make PILs for epileptic patients readable, then what stops manufacturers of other PILs for other illnesses from adopting those same efforts to silent the subject of readability forever or maybe leave it for other materials either than health.

It is actually the work of Gyasi (2013) that necessitated this study. Since much work have not been done on readability of these PILs in Ghana for the appropriate entities to read their outcome and address issues raised, this study is to add a voice to the existing literature in Ghana by assessing the readability of PILs of common drugs for common illnesses bought over-the-counter. If any generalization can be made or any conclusion can be drawn as per other parts of the world where studies are scanty and have been found that these health materials are not readable, Gyasi (2013) is limited in scope for that since he worked on only 7 PILs of malaria drugs. This research assessed the readability of 68 PILs for 7 common illnesses. It went the extra mile to interview 20 consumers of these OTC drugs to find out from them if they read the PILs and if they do, whether they understand what they read. I believe the scope of this research is broader enough for any generalization to be made if the need arises.

It is the hope of the researcher to make useful findings and then continue to make relevant recommendations for the intended purpose of these leaflets to be achieved.

Theoretical Framework

The present study adopts the reading fluency theory as theoretical guide for the present study. Even though the concept of fluency has been discussed in different studies, the theoretical assumptions of reading fluency were proposed by Harris and Hodges (1985). The work of Harris and Hodges (1985) was improved by Stecker, Roser, and Martinez (1998, p. 306) especially regarding the graphonic skills that are required for effective fluency in reading. The present study however, adopts the theoretical development of Pikulsi and Chard (2005) who explored fluency as surface and deep level theoretical construct. As such, their theory provides a deeper understanding how reading fluency at its deep level could influence reading comprehension. Since readability studies focus on using reading difficulties to predict level of comprehension of a reader of a text, the present study found the theoretical assumptions of Pikulsi and Chard (2005) useful in connecting the dots between reading difficulty and comprehension of patient information leaflets.

Fluency is regarded as a bridge to reading comprehension when children are developing their decoding skills (Pikulski & Chard, 2005). According to Harris and Hodges (1985, p85), fluency is “freedom from word identification problems that might hinder comprehension”. This definition of fluency has enlarged it to cover comprehension. It is therefore on this notion of fluency that pioneers of fluency theory such as Samuel (2002), Stecker, Roser, and Martinez (1998), based their postulations.

According to Stecker, Roser, and Martinez (1998, p. 306), "fluency has been shown to have a 'reciprocal relationship' with comprehension, with each fostering the other". The real goal of reading fluency is to help people read a text with ease so that they can concentrate on understanding what was read. Therefore, reading fluency refers to efficient, effective word recognition skills that permits a reader to construct the meaning of a text. Elish-Piper (2010) broadens the concept of fluency to encompass accuracy, speed, expression and comprehension. He argues that fluency is the bridge between being able to read or decode words and to comprehend or understand what is read. Pikulsi and Chard (2005) identified two constructs of fluency, namely**,** surface construct and deep construct. The ability to read fast is regarded as the surface construct of fluency while the ability to understand what is read is c considered as the deep construct of fluency.

A surface construct of fluency builds on an oral prosody of oral reading while a deep construct views fluency far more broadly as part of a developmental process of building decoding skills that will form a bridge to reading comprehension and that will have a reciprocal, causal relationship with reading comprehension. Fluency builds on a foundation of oral language skills, phonemic awareness, familiarity with letter forms, and efficient decoding skills.

In 1995, Linnea Ehri developed a theory with stages illustrating how word reading develops for people. Ehri's theory of Stages of Reading Development and Fluency is one elegant theory on fluency. According to Ehri (1995), there are four stages of reading development and fluency which are Pre-Alphabetic Stage, Partial Alphabetic Stage, Fully Alphabetic Stage and Skilled Reading Stage. At the Pre-Alphabetic Stage, readers lack understanding of

alphabetic principle which is letters and their sounds and hence have difficulty pronouncing except by doing association of letters based on their visual components such as Monkey, the 'y' tail represents the monkey's tail. This is problematic if there is error in the visual association such as 'my'. In the Partial Alphabetic Stage, readers learn the letters and their sounds but their knowledge of sounds are limited hence they can find it difficult to pronounce unfamiliar words. Fully Alphabetic Stage is where readers have the ability to use pronunciation and hence can pronounce unfamiliar words based on the sound combinations. At this stage readers cannot be said to be fluent readers. The Skilled Reading Stage is where readers develop the skill of knowing words by sight. At this stage, readers can read fast and can be said to be fluent readers. The implication this have on the study is that the consumers of PILs interviewed have varied educational background hence they can be said to have different stages of reading ability as Ehri posits. It was noted that most readers were not at the Skilled Reading Stage so any material which is not composed readable will not appeal to them at their different reading ability level. When readers have difficulty identifying words in a text, all their energy will be channeled to identifying those words instead of focusing on understanding the text (Elish-Piper ,2010).

Ehri (1998) also identified building graphophonic foundations for fluency. These are letter familiarity, phonemic awareness and knowledge of graphemes typically represent phonemes in words. Ehri's theory made the decoding process as dependent on readers ability to develop their reading fluency. One aspect of Ehri's postulation that is of great importance to readability studies is the addition of language skills to graphophonic skills as a

requirement for success in fluency of reading comprehension among readers. Ehri's (1998) 'theory requires a foundation in language skills so that readers are familiar with the syntax or grammatical function of the words and phrases they are reading and with their meanings. According to Ehri (1998), one of the greatest challenges facing educators is developing the oral language and vocabulary skills of children, particularly those who are learning English as a second language or those who spent their preschool years in language-restricted environment. She further asserts that highly frequently used words such as *the, of, at* among others help readers develop vocabulary skills.

The relevance of fluency theory to this study is therefore clear as on one hand it brings to bare the influence fluency has on comprehension as a key issue in this study and on the other hand it helps to place the varied reading ability of readers interviewed for this study in context per her stages of reading ability. A readable text is a text that is composed with readers in mind. The author of the text tries to make use of familiar words and phrases as well as plain language, so as to enhance readers' comprehension. Ehri's (1995) fluency theory is therefore apt as the theoretical framework for this study. The theory is to guide how the researcher's argument of lexical density and grammatical complexity can be possible causes of readability problems of health information leaflet. Also, because the theory acts as a bridge between the readability of a text and the comprehension of the same text to readers, it makes it suitable for the present study since the study has readability and comprehensibility as key variables in the study.

Chapter Summary

This chapter reported and critiqued extant related literature to the topic under study. It also looked at the conceptual framework in which this work is situated and the linguistic categories that were measured, as well as the theoretical framework guiding this study. Some keywords which emerged from the study were given detailed explanation for further understanding of the topic of study.

CHAPTER THREE

METHODOLOGY

Introduction

This chapter presents the methodology of the study. It begins with a description of the research design and the justification for using such a design. It is followed by a descriptive review of the Patient Information Leaflets (PILs). Thereafter, the sampling technique is laid out, followed by a discussion of the readability testing and the statistical data analysis procedures.

Research Design

The mixed method approach was adopted for the study. The mixed method approach to research is defined as the class of research where a researcher combines qualitative and quantitative research techniques, methods, approaches, concepts or languages into a single study (Johnson and Onwuegbuzie, 2014). Thus, the method fuses both qualitative and quantitative approaches either in equal ratio or with the use of one higher than the other. It involves both numerical data as well as test data so that finally the research will constitute both qualitative and quantitative information.

Quantitative approach to Creswell (2009) is one in which a researcher basically uses questions, measurements and observations and the test of theories to employ strategies of inquiry like surveys, experiments to collect data that are statistical in nature. Creswell again explains that the qualitative approach is one in which a researcher most often than not makes knowledge claims based on individual experiences on a phenomenon. It uses strategies like phenomenology, case study among others to collect open ended data on

emerging themes. It also involves collecting data simultaneously or sequentially to facilitate the research problem.

The researcher is of the view that collecting diverse data will provide a better result for the research problem. The use of the mixed method approach is to help broaden understanding of the results of this research. This research is quantitative in that, it determined the readability levels of the PILs for Over-The-Counter (OTC) drugs. Readability analysis generates numerical data such as mean, median, standard deviation, percentages which are quantitative in nature. It is qualitative because of the interview that was conducted with the consumers of these OTC drugs to ascertain from them whether they read the PILs and if they do, whether they understand what they read. The qualitative research aided in getting a clear and better insight into what the researcher sought to achieve. It also built on the quantitative research to bring to bear the researcher's point of view. Again, Criterion-based sampling was used to select the blocks of text from each leaflet for the readability analysis. Criterion-based sampling or judgmental sampling, is a non-probability process in which cases sampled are selected on the basis of the researcher's typicality and judgment on predetermined criteria (Tavakoli, 2012). This is because the researcher had in mind some parts of the PILs which contain much information that needed to be addressed.

Study Area

The study area is Kumasi. It is the regional capital of Ashanti Region. It has many suburbs but the researcher chose 10 out of the lot because she wanted a size that she could work with.

The 10 suburbs are Krofrom, Ashtown, Bantama, Abrepo Junction, Suame, Magazine Maakro, Tafo, Edwenase, Tanoso, and Tech. These suburbs are native speakers of Asante Twi speaking. Even though the literacy level of the communities is not specifically indicated in literature, the UNESCO (2016) report rated Ashanti region to have 60% literacy rate, and 40% illiteracy rate. This implies that the selected communities could be rated 60% and below in terms of literacy level. These communities belong to the Akan ethnic group, one of the largest ethnic groups in Ghana. Therefore, I chose and visited one OTC shop and one pharmacy from each suburb to collect PILs and interview consumers of these OTC drugs.

Population, Sampling and Sample Size

The target population was 100 PILs of OTC drugs approved by the Food and Drugs Authority (FDA) on the Kumasi market for 7 common illnesses. A list of these drugs was procured from the FDA website. Using convenience sampling, the researcher chose the sample size of 68 PILs. Convenience sampling is a type non-probability sampling where members of the target population that meets certain criteria such as easy accessibility, geographical proximity, availability at a given time or the willingness to participate are used for a study (Ilker et al..2016). It is also the consumers of these OTC drugs who were willing to participate in the study that were interviewed. Twenty (20) consumers who came to the shops to make a purchase were interviewed for the study. These consumers consisted of ten (10) males and ten (10) females with varied ages and literacy levels. Their age ranged from 18 to 50 years while their literacy level ranged from SHS to Master's Degree.

Over the collection period, a total of 100 leaflets were collected for seven (7) common illnesses; common cold (flu or catarrh), cough, body pains, diarrhoea, heartburns, sleeplessness and constipation. However, after sorting, it was found that some of the leaflets were the same, hence I conveniently sampled 68 leaflets to be used for the study.

Data Collection Instrument

The leaflets which represent one of the data for the study were collected personally from the outlets of OTC sales. The interviews were conducted with an interview guide designed by the researcher and approved by her supervisors (see Appendix A on pages 149-165). An interview guide was necessary because it aided in the uniformity in the questions asked the consumers.

Data Collection Procedure

An introductory letter from the Head, Department of English, University of Cape Coast, was taken to the Ghana Pharmacy Council (GPC), Kumasi, on the 5th of September, 2018, to get information pertaining to the data for the study. It was there that she got to know that Food and Drugs Authority (FDA) regulates drugs in the country so her first point of call should be there. Through the GPC, the researcher gained accessed to the FDA. Copies of the drug list were downloaded from the FDA website online for her after she explained what her research was about. The pharmacist, however, emphasized that, in Ghana, attention is given to drug labels than the leaflets which prompted the researcher that there was actually a problem. It was made known to her that there were two avenues where OTC drugs were sold; pharmacies and OTC shops.

At the GPC on the 13th of September, 2018, she was introduced to the Chairman of the OTC Drugs Sellers Association on phone and fortunately for her, there was an on-going meeting with the sellers at the Kumasi Cultural Centre so she had to rush there. The names and numbers of the operators who manage the shops and their locations were given to the researcher. The data collection started from that point. After all leaflets were collected and all interviews recorded, the GPC and FDA were appreciated for their support.

General Structure of PILs and Language Use

Seven groups of PILs were tested for reading difficulty. The documents were grouped according to the ailments or conditions for which their respective medicines were indicated. The medicines fell under these types: appetite stimulants, cold and flu medicines, cough preparations, dewormers, gastrointestinal reflux relievers, haematinics, and pain medication.

The leaflets came in a variety of font styles and sizes, document lengths, font colours, and quality of paper. For each document, the publishers had organised the information into specific rhetorical sections or moves, with appropriate headings. The leaflets varied in the number of these sections they contained. While some had mostly dosage instructions, warning, ingredients used in the drug; other leaflets included the manufacturers details, the other languages aside English and many other aspects.

Text Selection

Blocks of text were selected from each document for readability analysis. The text selection was criterion-based. Criterion-based sampling, also known as judgmental sampling, is a non-probability process in which cases sampled are selected on the basis of the researcher's typicality and his/her

judgment on predetermined criteria (Tavakoli, 2012). Although non-probability sampling has the likelihood of inefficacy to generalize the findings to the population, when the attention of the researcher is to process reasoning, the sample procedure is overshadowed when the results are being interpreted (Hayes,2005).

A primary criterion for selecting text was based on the findings of Raynor et al. (2007) that the parts of patient information leaflets that were most likely to be read were, in that order, side effects, administration, and indication. A three-decade old study had shown that the items on a packet leaflet most likely to be recalled by patients were directions for use and side effects or adverse reactions (Morris, Mazis, and Gordon, 1977). The side effects, administration, and indication sections respectively provide information on possible adverse reactions to the medicine, how and when to take the medicine, and what conditions or ailments the medicine is intended for. In keeping with the finding of Raynor et al. (2007), the researcher selected the following sections for inclusion in sampled texts: indications, contra-indications, adverse reactions, warnings and special precautions, overdosage and treatment, dosage, and pregnancy and lactation. Where available, texts from sections such as special populations were also included in the readability analysis. Based on the researcher's subjective judgment, the researcher excluded sections such as pharmacological actions and pharmacokinetics from the analyses. These routinely contained many technical jargons and appeared to have been written for the benefit of health professionals and not patients.

In cognisance of the fact that bulleted lists, tables, equations and headings were not among the materials used to develop the formulae (Schriver, 2015), the researcher cleaned the sampled texts to remove headings, and to replace contractions, abbreviations, elisions, and initialisms with their full names, “etc.” was replaced with “and so on”; “%” was replaced with “percent”; and mg” was replaced with “milligram(s)”.

For the sake of uniformity, the researcher selected the same parts of the PILs for syntactic complexity analysis as it was done for the readability and lexical density analyses. However, in pre-processing text samples for analysis, the researcher was guided by Dowell, Graesser and Cai (2016). Accordingly, the researcher adopted the following guidelines:

If there was not a good reason to delete any part of the sampled text, it was left in. The principle behind this was to present texts for analysis that were as close as possible to what the authors intended. Unlike in the case for readability analyses, I found no work that recommended or even suggested that punctuations, bulleted points, etc. could throw off Coh-Metrix measures. Therefore, they were left in the texts.

Consistency in the treatment of selected texts were ensured. This means that for any modification(s) that were made in any one text, the same modification(s) were made in all the other texts.

Data Processing and Analysis

Each document was scanned into a jpeg file at a high dot-per-inch setting using a hand-held SkyPix TSN410 Handyscan scanner. The scanned documents were individually converted to editable text by means of ABBYY screenshot reader, an optical character recognition (OCR) software.

Each final sample was analysed for readability using the online calculator at https://www.readabilityformulas.com. While the calculator returned readability scores from eight different indexes, only scores for SMOG and Flesch-Kincaid were recorded. Other data recorded were: word count of sampled text, average number of words per sentence, average number of syllables per word, and percentage of multisyllabic words (3 syllables). It must be noted that per readability analysis, the average score of a leaflet should be at the 8th grade level which is equivalent to 2nd year in Junior High School in Ghana to be considered readable. Scores higher than that is unreadable whereas those below that is considered easy-to-read (Bravos, 2010; Bradley et al.,1994; Gyasi, 2013)

The sampled texts were tested for Lexical Density using the online calculator found at https://www.online-utility.org/text/analyzer.jsp. This calculator was chosen because it is easily accessible online. The data were recorded in the same MS Excel worksheet as those from the readability tests. This application made it easier to process all the selected information leaflets to return scores that were relevant to the researcher's study.

Also, the syntactic complexity of the texts was assessed using Coh-Metrix 3.0. Coh-Metrix is a leading theoretically grounded, computational linguistics analysis facility that analyses texts on multiple levels of language and discourse (McNamara, Graesser, McCarthy and Cai, 2014). Coh-Metrix 3.0 measures 108 linguistic features.

Coh-Metrix' syntactic complexity measure was used to measure complexity of the PILs. This approach is not out of line with that used in Martiniello's (2009) study of the linguistic complexity of math tests for English

Language learners. Syntactic complexity was approached from the second definition of 'complexity' distilled from the literature by Pallotti (2015, p. 2). This definition is concerned with "processing costs" or difficulties that are "associated with linguistic structures". This approach justifies the use of the syntactic complexity measure of the Coh-Metrix facility, because the indices that make up the measure are deemed to be directly or indirectly indicative of the processing load or difficulty that a piece of writing presents to a reader (Dowell, Graesser, & Cai, 2016; McNamara et al.., 2014).

The seven individual indices by which Coh-Metrix measures syntactic complexity are:

Left embeddedness (SYNLE), that is, the number of words before the main verb in a sentence. Coh-Metrix measures the number of words before a main verb in each sentence, and then calculates a mean across the sample text.

Number of modifiers per noun phrase (SYNNP). Coh-Metrix counts the number of words before the main verb in each sentence, and then calculates the mean across the sample text.

1. Minimal Edit Distance (SYNMEDpos), for parts of speech.
2. Minimal Edit Distance (SYNMEDwrd), for all words.
3. Minimal Edit Distance (SYNMEDlem), for lemmas.
4. Sentence Syntax Similarity (SYNSTRUTa), for adjacent sentences.
5. Sentence Syntax Similarity (SYNSTRUTt), for all combinations,
6. across paragraphs.

Each of the indices above is a theoretically and conceptually valid way to measure syntactic complexity (McNamara et al.., 2014). However, in this work, only the first two indices, that is, left embeddedness (abbreviated as

SYNNLE) and mean number of modifiers per noun phrase (abbreviated as SYNNP) were employed. These should be sufficient indication of text complexity and therefore difficulty based on the notion that "the syntax in text tends to be easier to process when there are shorter sentences, few words before the main verb of the main clause, and few words per noun-phrase" (McNamara et al.., 2014, p. 70). According to Graesser, McNamara, Louwerse, and Cai (2004), difficult syntax often involves densed structures, ungrammatical forms, ambiguity, and the use of embedded constituents. These attributes make up the processing and comprehension of complex syntax (Perfetti, Landi, & Oakhill, 2005).

The syntactic complexity scores reported in this study were interpreted according to normative scores published in the Appendix B of the book "Automated evaluation of text and discourse with Coh-Metrix" (McNamara et al.., 2014).

McNamara et al. (2014) used large corpus of text from Touchstone Applied Science Associates (TASA) Inc. to create the norms. The corpus used by TASA was made up of one hundred and nineteen thousand, six hundred and twenty-seven (119, 627) paragraphs from thirty-seven thousand, six hundred and fifty-one (37,651) samples. The norms are based on three largest domains represented in TASA, namely: language arts, social studies and science texts.

McNamara et al.., (2014) randomly chose 100 passages from each of the three genres and each of 13 grade levels, for a total of 3,900 passages. Grade level in the TASA corpus is indexed by the Degrees of Reading Power (DRP;Koslin et al.., 1987), which is a readability measure that includes word- and sentence-level characteristics. As can be observed in the table, DRP is

highly correlated with the Flesch Reading Ease and Flesch-Kincaid Grade Level measures of readability. To simplify the data analysis and presentation, DRP levels were translated to their corresponding grade-level estimates and then collapsed according to the grade bands used within the Common Core State Standards: grades K to 1, 2 to 3, 4 to 5, 6 to 8, 9 to 10, and 11 and higher. Each grade level within each genre was represented by 100 passages. Because the Common Core grade bands include different numbers of grade levels per band (e.g., 2–3 includes two grades, 6–8 includes three grades), there are different number of passages represented for each grade band. (McNamara et al.., 2014, p. 253).

Apart from descriptive indices, the norms published in the Appendix B of the aforementioned book provide normative values that can be used to compare other texts in the corresponding genre. Because PILs are published in the medical field, they fall under the science genre. Therefore, the syntactic complexity scores for these PILs were rightly compared to the norms in the science genre in order to arrive at conclusions on their suitable grade levels.

IBM SPSS® Statistics version 20 was used to conduct both descriptive and inferential statistical analyses of the data. First, the data organised in the MS Excel worksheet were copied and pasted in a pre-coded worksheet in SPSS. Afterwards, a simple descriptive statistic was conducted in order to organize and summarize the characteristics of the sampled texts (Tavakoli, 2012) in terms of their readability scores, their sentence and word characteristics, their lexical density scores, and their grammatical complexity scores. The information generated included maximum values, minimum values, means, and standard deviations. This information was presented in tables in the results chapter. Also,

in order to make a choice between parametric and non-parametric inferential statistics tests, the Shapiro-Wilk test of normality was conducted. Parametric tests of significance require that the distribution of the sample scores be normal or near normal. This requirement is especially important where, as in this work, the researcher has to work with small sample sizes (Tavakoli, 2012). The Shapiro-Wilk test was chosen because it is suitable for sample sizes less than 2000 (maths-statistics-tutor.com, 2010).

Another requirement of parametric tests is the symmetry of the distributions, or the homogeneity of variance, among the various groups under study. Levene's test of homogeneity of variance was conducted. Lastly, a parametric Analysis of Variance procedure was conducted to test the statistical significance of differences, if any, among the readability, lexical density, and syntactic complexity scores of the PILs. The use of Coh-Metrix was informed by the fact that it is the only known computational tool that provides detailed description of how sentence features and lexical features affect complexity of a text. The use of parametric tools such as t-test was to aid in describing the difference of the readability scores in quantitative terms.

The researcher interviewed 20 consumers. The use of the 20 interviews was informed by Creswell (2014)'s recommendation which suggests interview participants should be within 25 and below because the large data could be generated from it. The interviews conducted and recorded were transcribed by the researcher. The outcome was however compared with the scores of the quantitative data.

Ethical Consideration

Confidentiality was of essence to the institutions the researcher visited to gather information which enabled her to collect data. The FDA as they relayed information and answered some questions had an assurance from the researcher that it would be used for academic purposes and nothing else, even with an introductory letter in hand. They categorically stated that the researcher will be solely held responsible if any of the information being relayed was misused. At the GPC, a book was handed to the researcher to study the ACT that governs the production of the PILs and was said to be confidential so it could not be taken away or any part of it photocopied. The researcher was made to glance through it and write anything useful and hand it back to the manager.

Consumers of these OTC drugs that were included in the study were assured of anonymity as some did not want their identity revealed or face shown anywhere. They were assured of that as the researcher did not take any name or pictures during the recording.

Difficulties Encountered and Surmounted

This section of the study outlines some difficulties encountered while collecting and analysing the data for the study and how they were surmounted. Assistance were sought from a statistician to enable the researcher to validate the answers she got from the calculations made for the statistical data generated from the readability, lexical density and syntactic complexity analyses. At some point in the analyses, the researcher got a little bit confused and had to clear some doubts from an expert. He was briefed on the kind of work it was and was made to work on some of the analyses the researcher had calculated and gotten the answers right to see if he was really good at what he did before his help was

accepted. Since the thesis is a public document and would reach a wider readership, the researcher could not afford to take chances with any miscalculation which would render all her effort invalid.

Also, at the FDA, the researcher had a very tough time trying to see the regional manager even with the introductory letter. She was made to wait for hours and then asked to go and come back another day because the regional manager was busy and a whole lot of excuses. She had to go back to see the GPC Manager who put a call through to the manager at the FDA who scheduled a day for her to come before she was granted audience. Things however went on smoothly from there.

Again, even though the researcher met the operators of one of the categories of the OTC sales point at a meeting and was introduced to them by their chairman to offer any assistance to her when she visits their shops, some operators refused to give their numbers out and surprisingly, others gave wrong numbers. She had to call the chairman again to get the correct contacts of the operators or substitute some with others who were willing to help. On the visits, some shops were virtually empty and she could not gather any leaflet or conduct interviews. At other shops because of their location, patronage was poor so there were no consumers as at the time of the visit. At the shops where patronage was good, the researcher took advantage and collected enough leaflets and conducted a good number of interviews especially at the pharmacies to replace the others.

Lastly, because the interviews were conducted in the English Language, consumers especially the women refused to participate and those who were willing to, agreed after so much persuasion. This made the researcher spend

longer time at the shops. The key holder also served as a motivator for this challenge. She had to explain to them that she was not around to mark grammar or correct any mistakes as they speak but to gather ideas in whatever they say.

Chapter Summary

This chapter discussed the study area and research design used for this study and the reasons behind the choices. It also discussed the sample and sampling technique adopted as well as the data collection and analysis procedures. The next chapter, four (4), presents an in-depth insight into how the data collected for the study were analysed.

CHAPTER FOUR

RESULTS AND DISCUSSION

Introduction

This study assessed the readability and comprehensibility of PILs for seven groups of over-the-counter drugs sold in the Kumasi metropolis. The study employed two traditional readability formulas to check readability of the PILs: SMOG and Flesch-Kincaid Grade Level Score. The lexical densities of the text were also assessed. Two indices of grammatical complexity were used to assess the comprehensibility of the package leaflets; this assessment was done using the Coh-Metrix 3.0 tool. The various data collected were and entered into SPSS Version 20 for descriptive and inferential statistical analyses. The results and discussion are presented in this chapter.

Readability of the PILs of the seven groups of OTC medicines

Table 1 presents a quantitative description of the readability and lexical density of PILs for appetite stimulants.

Table 1: Description of PILs for Appetite Stimulants

	Measure		Minimum	Maximum	Mean	Std. Deviation
			Statistic	Statistic	Statistic	Statistic
Appetite stimulants	word count	11	87	517	291.00	118.695
	sentence count	11	8	27	16.91	5.186
	SMOG score	11	9.1	14.6	12.336	1.5977
	Flesch-Kincaid Score	11	10.8	17.9	14.218	1.9818
	number of words per sentence	11	8	25	16.82	4.916
	percentage of multisyllabic words (3 and above)	11	23.0	37.0	28.273	4.1974

The Mean SMOG score for the appetite stimulant PILs was 12.336 (SD=1.5977).

This means that, according to the SMOG formula, it would take approximately 12 years of formal schooling to proficiently read and understand these PILs. While some of these PILs may be readable to patients with 9 years of schooling (Minimum= 9.1), some of them were so difficult that it will take up to 15 years of schooling for readers to be able to read and understand them (maximum= 14.6). Generally, then, the PILs accompanying the appetite stimulants included in this study are difficult to read according to the SMOG formula.

On the Flesch-Kincaid Grade Level scale, a mean score of 14.218 (SD= 1.9818) indicates that the texts of the appetite stimulant PILs were generally written for readers with 14th-Grade reading and comprehension aptitude. The fourteenth grade is equivalent to a second-year student in a tertiary school, thus college or university.

The low readability of the PILs for appetite stimulants was confirmed by the readability consensus returned by the calculator. Data analysed showed that the most frequently occurring consensus for PILs in this group was “Grade 14; very difficult to read; 21 to 22 years old; college level”.

The PILs for cold and flu medicines were found to be just as hard to read. This information is presented in Table 2 below.

Table 2: Description of PILs for Cold and Flu Medicines

	Measure	N	Minimum	Maximum	Mean	Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Statistic
Cold and flu medicines	word count	7	114	512	317.57	165.868
	sentence count	7	10	28	19.57	7.871
	SMOG score	7	9.1	14.0	11.343	1.6811
	Flesch-Kincaid Score	7	11.2	16.4	13.057	2.2493
	number of words per sentence	7	10	19	15.57	3.101
	percentage of multisyllabic words (3 and above)	7	19.0	32.0	25.143	5.1130

The cold and flu medicine information leaflets scored a mean of 11.343 (SD = 1.6811) on the SMOG scale, while they scored a mean of 13.057 (SD = 2.2493). The respective standard deviations show that both readability scores had just about similar variation from their means. The mean SMOG score indicates that the PILs for the flu and cold medicines were generally written for readers with about 11 years of formal schooling. The Flesch-Kincaid score

placed the PILs at the reading level of patients with 13 years of schooling. The consensus of both formulae is that the texts were difficult to read for the less educated person.

The readability levels of PILs for cough preparations were found to approximately to those of cold and flu medicines. Table 3 below presents a quantitative summary of the description of the package leaflets for cough preparations.

According to the readability consensus, the PILs for cold and flu medicines were mostly meant for Grade 12; they were "difficult to read" and suited for those with the reading abilities of formally schooled 17- to 18-year-olds. A readability score of 60 and below which is equivalent to 9th grade and below is considered as easy to read.

Table 3: Description of PILs for Cough Preparations

	Measure	N	Minimum	Maximum	Mean	Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Statistic
Cough preparations	word count	9	127	517	227.44	114.901
	sentence count	9	10	32	16.56	6.729
	SMOG score	9	9.7	13.9	11.067	1.4958
	Flesch-Kincaid Score	9	10.1	16.1	12.778	2.0278
	number of words per sentence	9	12	16	13.67	1.500
	percentage of multisyllabic words (3 and above)	9	18.0	36.0	27.444	6.3070

According to Table 3, the cough medicine package leaflets scored 11.067 (SD= 1.4958) on the SMOG scale. This means that on that scale, the texts are suited to the reading abilities of patients with 11 years of formal schooling. On the Flesch-Kincaid scale, the leaflets scored a mean of 12.778 (SD= 2.0278). This score approximates to 13 years of schooling, thereby indicating that the texts were written at a level suitable for patients with, at least, 13 years of schooling. The scores from both formulae suggest that the texts in the package leaflets of cough medicines used in this study are generally above the reading and comprehension ability of less educated person. The less educated person could be regarded as a person below the standard reading level as opined in readability studies (DuBay, 2007). The standard readability score is 60 reading meaning which means at least 9th grade, thus in Ghanaian educational system, a third-year student in the junior high school. This is believed to be the time where a student could read any public document with less difficulty.

Per the readability consensus, most of the PILs in this group were written at the 11th Grade level; they were suitable for 10th to 11th Graders or 15 to 17-year-old readers.

It is interesting to note that some dewormer PILs may have been written at suitable readability levels (see Table 4 below).

Table 4: Description of PILs for Dewormers

Measure	N	Minimum	Maximum	Mean	Std. Deviation
	Statistic	Statistic	Statistic	Statistic	Statistic
word count	9	268	748	433.11	179.309
sentence count	9	14	56*	25.00	13.528
SMOG score	9	7.9	14.9	12.311	2.0763
Flesch-Kincaid Score	9	7.7	16.6	13.689	2.7374
number of words per sentence	9	13	21	18.00	2.784
percentage of multisyllabic words (3 and above)	9	14.0	32.0	25.333	5.4083

On the basis of Minimum scores on the SMOG scale (Minimum= 7.9) and on the Flesch-Kincaid scale (Minimum= 7.7), there is indication that some PILs for dewormers were written at appropriate readability levels, that is Grade 8 (see Table 4). Nevertheless, the mean score on the SMOG index (Mean= 12.311, SD= 2.0763) shows that these PILs were generally written at the 12th Grade level, with some PILs being written at a level as high as the 15th Grade. The mean score on the Flesch-Kincaid formula placed this group of PILs at a mean grade level of 14 (Mean= 13.689, SD= 2.7374), with some PILs in the group scoring as high as 16.6. The conclusion is that the package leaflets for the dewormers were generally difficult to read because the standard readability scores is at 9th grade or 60 reading level (DuBay, 2007; Heydari & Zammani, 2012).

The consensus for the dewormer PILs had a bi-modal distribution. The two most frequently occurring consensuses among this group were that the package leaflets were "very difficult to read", and required the skills of college level to college graduate readers to read and understand them. Table 5 is a quantitative description of package leaflets for gastrointestinal reflux relievers.

Table 5: Description of PILs for Gastrointestinal Reflux Medicines

	Measure	N	Minimum	Maximum	Mean	Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Statistic
Gastrointestinal reflux medicines	word count	8	201	376	288.63	58.056
	sentence count	8	12	22	18.25	3.454
	SMOG score	8	8.8	13.6	12.175	1.7044
	Flesch-Kincaid Score	8	10.8	16.5	14.188	1.9881
	number of words per sentence	8	9	19	16.00	3.295
	percentage of multisyllabic words (3 and above)	8	21.0	33.0	28.000	4.2762

From Table 5 above, it is seen that the PILs for gastrointestinal reflux medicines scored a mean of 12.175 (SD= 1.7044) on the SMOG index, while they scored a mean of 14.188 (SD= 1.9881) on the Flesch-Kincaid index. Respectively, the texts are written at the 12th and 14th Grades on the indices.

This makes them generally difficult to read for the average person. In fact, the most occurring readability consensus for the leaflets from gastrointestinal reflux medicines was "Grade 15; very difficult to read; college graduate".

Table 6 presents descriptive statistics for those package leaflets taken from Haematinics, or as they are colloquially known, 'blood tonic'.

Table 6: Description of PILs for Haematinics

	Measure	N	Minimum	Maximum	Mean	Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Statistic
Haematinics	word count	7	96	702	349.29	215.312
	sentence count	7	7	45	23.57	13.477
	SMOG score	7	10.8	12.7	11.771	0.6499
	Flesch-Kincaid Score	7	11.5	15.7	13.500	1.4048
	number of words per sentence	7	12	17	14.43	1.718
	percentage of multisyllabic words (3 and above)	7	24.0	40.0	29.143	5.5506

As can be seen in Table 6 above, the SMOG index placed the mean readability of the leaflets from Haematinic medicines at a Grade Level of approximately 12 (Mean= 11.771, SD= 0.6499). Meanwhile, the Flesch-Kincaid Grade Level index showed that the texts from this group of leaflets were written at the between Grades 13 and 14 (Mean= 13.500, SD= 1.4048).

These scores mean that the patient information leaflets from the haematinics were found difficult to read. This conclusion is in agreement with the modal readability consensus for package leaflets from the haematinics: "Grade 13; very difficult to read; 18 – 19 years old; college entry level".

Moreover, the respective standard deviations from both readability indices appear to be lower than those for other groups of leaflets, thereby suggesting that there was lower variation in reading difficulty levels among the seven package leaflets from haematinic medicines. The meaning of this is that even the easiest to read leaflets in this group were closer to the average difficulty level of the group than was the case in the other groups of PILs. In this regard, the pain medication PILs had the second highest variability in their readability scores. This is seen in Table 7 below.

In Table 7 below, a quantitative description of the PILs for pain medication is presented.

Table 7: Description of PILs for Pain Medication

	Measure	N	Minimum	Maximum	Mean	Std. Deviation
		Statistic	Statistic	Statistic	Statistic	Statistic
Pain medication	word count	17	129	982	406.35	223.556
	sentence count	17	11	49	23.47	10.548
	SMOG score	17	7.4	15.6	12.194	2.0714
	Flesch-Kincaid Score	17	8.0	19.3	14.312	2.6351
	number of words per sentence	17	11	22	16.94	3.381
	percentage of multisyllabic words (3 and above)	17	10.0	36.0	27.000	6.0104

As the Table above shows, it will take a patient with 12th Grade reading abilities to proficiently read and understand the pain medication information leaflets, according to the SMOG index (Mean= 12.194, SD= 2.0714). The Flesch-Kincaid Grade Level index placed the texts from the pain medication PILs at the 14th Grade reading level (Mean= 14.312, SD= 2.6351). These scores indicate that the PILs in this group would present the average patient with reading and comprehension challenges. However, with relatively wide variation in readability scores (as indicated by the relatively high standard deviations), some PILs in the group are shown to have been written at Grades 7 to 8; this means that those PILs were more accessible to the average reader in terms of ease of reading and understanding. In spite of this, the readability consensus for this group of PILs was mostly "Grade 14; very difficult to read; 21-22 years old; college level".

The usually recommended grade level for general-purpose written materials is the 8th Grade (Cutts, 2013). It appears that almost all 68 PILs assessed in this study were written above the recommended grade levels that would make the materials accessible to most patients. In fact, according to a frequency analysis of the readability consensuses, only two times did it occur that the consensus was "Grade 8; standard/average; 12-14 years old" (see Table 8 below).

Table 8: Readability Consensus Distribution for all 68 PILs

Consensus Grade Level	Difficulty	Frequency
Grade 8	Standard/average	2
Grade 10	Difficult to read	2
Grade 11	Difficult to read	9
Grade 12	Difficult to read	11
Grade 13	difficult to read (college entry level)	9
Grade 14	Very difficult to read (college level)	14
Grade 15	Very difficult to read (college graduate)	8
Grade 16	Very difficult to read (college graduate)	9
Grade 17	Very difficult to impossible to read (college graduate)	3
Grade 19	Impossible to comprehend (college graduate)	1
Total		68

From Table 8, it can be seen that the single most occurring difficulty level among all the package leaflets tested was Grade 14 (very difficult to read; college level). From the table, it appears that the difficulty levels of the package leaflets are clustered around the college or university level. This means that, most of the PILs require at least university entry-level education to be able to read and understand them. This presents a challenge to most patients who would like to read their medicine package inserts and be well-informed about their medication.

Health communication is the art and technique of informing, influencing and motivating individuals, etc., about important health issues (Healthy People, 2010). Such communication, being an interactive or transactional phenomenon, requires that participants in the activity come to a mutual understanding (Ratzan, 1994). In order words, the participants in a communicative encounter must understand the symbols used and the meaning assigned to those symbols in order to construct meaning. The package inserts studied are modes by which pharmaceutical companies endeavor to reach consumers of their medicines. Since these medicines are of the over-the-counter variety, there is little to no chance of having a health professional thoroughly discuss all pertinent information regarding any of the medicines with patients. In fact, the whole point of printed health education materials is to augment health-care professional's verbal information to patients (Smith et al., 1998). These PILs are supposed to be in handy because the prescriber will not always be around to give instructions or remind consumers of what was said about a medication. Meanwhile, written communication lacks the richness (Daft & Lengel, 1983) that distinctions of tone and facial expressions afford verbal communication (Richards, 2017). Written communication therefore has a greater susceptibility to misunderstanding. It is therefore up to the manufacturer to ensure that the information provided on the leaflets is accessible to the consumer. But, PILs as channels of communication can be affected by noise (Shannon & Weaver, 1948). Noise affects the message fidelity or accuracy with which a receiver receives the exact message intended by the sender (Dominick, 2005).

In the context of this study, the most important barrier to communication between senders and receivers is semantic noise (Shannon & Weaver, 1948). Semantic noise can be the result of wrong constructions, wordiness, or grammatical complexity. PILs with too many words per sentence, or complicated language use, may hinder the communicative transaction between the sender and receiver; the receiver may fail to understand the message as the sender intended it. In fact, this understanding of communication is the basis of readability as a concept. The basic assumption in readability is that easy to read texts are more comprehensible and therefore more useful to target audiences than difficult to read texts. This means that easy to read medicine information leaflets are expected to be easier to comprehend and therefore more useful to consumers of the medicines.

Against this backdrop, it is problematic to find that the PILs tested in this study were mostly difficult to read and therefore beyond the expected reading and comprehension ability of a less educated person. The fact that most of the PILs fell in the 'difficult-to-read' and 'very difficult-to-read' categories means that the PILs are inaccessible to the consumer, at least, according to the SMOG and Flesch-Kincaid Grade Level indices. This is indeed a troubling situation. After all, even individuals with higher reading levels have been found to prefer information that is written at lower levels as it is easier to comprehend and takes less time to read (Wilson, 2008). Indeed, the difficulty levels of the PILs defies its purpose of informing and influencing patients (Healthy People, 2010) about their health issues. The low readability of the written materials cannot be expected to help consumers come to the correct understanding intended by the pharmaceutical companies who published the leaflets (Ratzan,

1994). The difficult levels at which the PILs are written are a source of semantic noise. The semantic noise potentially undermines what according to Smith et al., (1998) is the purpose of those education materials, which is to augment health-care professional's verbal information to patients. The potential implication of these lapses in communication is that patients may not fully benefit from information regarding their medications that could have been useful. To illustrate, package leaflets tend to enhance patients' contentment with treatments and to increase their awareness of potential adverse reactions to medicines (Gibbs, Waters, & George, 1989; Ridout, Waters, & George, 1986; Morris, Mazis, & Gordon, 1977). Moreover, Morris and Halperin (1979) posit that PILs improve compliance with prescriptions. Unfortunately, it seems that the average consumer of most of the PILs tested in this study would not find these benefits because the language used in the materials are beyond his/her ability, according to the readability indices.

Comparison of Readability of the PILs of the Seven Groups of OTC Medicines

Effort was made to test to see if the mean readability scores for the various groups as determined by the SMOG and Flesch-Kincaid formulas differed from each other statistically. This was done by means of the inferential statistical procedure known as Analysis of Variance (ANOVA).

In order to determine the proper ANOVA procedure to use in this test, it was imperative to make sure that the data fulfilled certain assumptions or otherwise. These assumptions included a normality of distribution of the data sets, and a homogeneity of variance among the means. The normality of distribution assumption was tested by means of the Shapiro-Wilk statistical

procedure. At 0.05 significance or alpha level, the data sets were found to be normally distributed (see Table in Appendix A). Levene's statistical test was used to assess the homogeneity of variance among the mean readability scores. At the 0.05 alpha level, the population variances of the PILs groups were found to be equal (see Table in Appendix A). Results from these preliminary tests indicated that the data sets met the assumptions required to conduct a parametric Analysis of Variance of the mean readability scores. Table 9 presents the results of the ANOVA test.

Table 9: Analysis of Variance of Readability Scores

		Sum of Squares	Df	Mean Square	F	Sig.
SMOG score	Between Groups	14.060	6	2.343	0.767	0.599
	Within Groups	186.390	61	3.056		
	Total	200.450	67			
Flesch-Kincaid Score	Between Groups	21.568	6	3.595	0.700	0.650
	Within Groups	313.084	61	5.133		
	Total	334.652	67			
percentage of multisyllabic words (3 and above)	Between Groups	106.396	6	17.733	0.609	0.722
	Within Groups	1776.118	61	29.117		
	Total	1882.515	67			

At the $p<0.05$ level, there were no significant differences in the readability scores among the seven groups of PILs as measured by the SMOG index [$F (6, 61) = 0.767$, $p= 0.599$] (see Table 9 above). At the $p<0.05$ level, there were no significant differences in the readability scores among the seven groups of PILs as measured by the Flesch-Kincaid Grade Level index [F (6, 61)

= 0.700, p= 0.650]. These results mean that, statistically speaking, all the 68 package leaflets were generally written at about the same difficulty level. Since the readability scores did not differ significantly from each other, it is likely that in the real world an average reader will have approximately as much difficulty reading any of the package inserts.

Certainly, the poor readability of the medicine information leaflets as determined by the SMOG and Flesch-Kincaid indices is a cause for concern. The poor readability of the texts may even discourage patients from engaging with the reading materials to begin with (DuBay, 2004). However, readability formulas have their shortcomings. For example, it is argued that they only measure surface level characteristics of texts. For this reason, other concepts and methods of assessing the accessibility of texts are also in use. The next sub-section discusses the lexical density of the PILs tested in this study. It must be borne in mind that the sample texts used in the lexical density analyses were treated the same as were used in the readability formula analyses.

Lexical Density of the PILs of the Seven Groups of OTC Medicines

Table 10 below presents a quantitative description of the lexical densities of the seven groups of PILs tested in this study. In this study, Ure's redefinition of lexical density was employed. According to the definition, lexical density is a ratio of lexical items to grammatical items (Ure & Ellis, 1977) expressed as a percentage. This means that the lexical density values in Table 9 are percentages of words in sampled texts that have lexical or meaning-bearing value.

Table 10: Quantitative Description of Lexical Density of PILs

	N	Minimum	Maximum	Mean	Std. Deviation
	Statistic	Statistic	Statistic	Statistic	Statistic
Appetite Stimulants	11	50.87	72.78	59.8809	7.17752
Cold and Flu Medicines	7	46.29	84.21	61.0314	12.59833
Cough Preparations	9	45.65	76.14	64.9522	8.92367
Dewormers	9	37.97	62.69	51.9467	7.52005
Gastrointestinal Reflux Relievers	7	50.80	63.34	56.6771	4.70945
Haematinics	7	45.25	71.90	57.9500	10.02754
Pain Medication	17	40.61	69.83	56.6565	9.94186

As seen from Table 10 above, the appetite stimulant package inserts scored a mean lexical density of 59.8809 (SD= 7.17752). The highest mean lexical density score was recorded for the PILs that accompanied over-the-counter cough medicines (Mean= 64.9522, SD= 8.92367). At 51.9467 (SD= 7.52005), the PILs accompanying the dewormers scored the lowest mean lexical density. Perhaps this can be explained by the fact some PILs in the dewormer group scored as low as 37.97 of lexical density. Meanwhile, the cold and flu medicines information leaflets recorded the widest variations in their lexical density scores with a standard deviation of 12.59833 for a mean of 61.0314.

Because lexical items are the information components of a sentence, a text with higher lexical density has more information, and therefore carries more meaning, than one with lower lexical density (Arua, 1993; Johansson, 2008).

The concept of lexical density is related to the notion that the greater the information load of a text, the greater that text's demand on working memory, and therefore, the more difficult that text is to understand and recall. On the other hand, the lower the lexical item proportion of the text, the lower the lexical density, the lower the text's demand on working memory, and the easier the text is to understand and recall (Arua, 1993; Ramadhan, Santihastuti, & Wahjuningsih, 2017). Spoken text has lower lexical density relative to written text (Ure, 1971). This suggests that written text is generally more difficult to process and recall than spoken text.

According to a categorization by Sholichatun (2011), there are three levels of lexical density for written texts: high (60 - 70%), medium (50-60%), and low (40-50%). Guillén Galve (1998) found that while lexical density of everyday written text might average 40%, scientific writing might have lexical densities as high as 55-75%. Against these considerations, the PILs tested generally have medium to high lexical densities. In fact, the 'Maximum' statistic shows that in every group of PILs there were those with very high lexical densities, with some in the cold and flu medicine group going as high as over 80%. According to the mean percentages recorded in Table 9, the PILs for the appetite stimulants, the cold and flu medicines, and the cough preparations have high lexical densities mostly. This means that they generally will offer the greatest processing load to working memory among the PILs tested. The implication is that they will be generally difficult to understand and recall. PILs in the other groups should present medium challenges to the person who is less educated.

Generally, though, it appears that all texts tested in this study could present the person with less education with significant cognitive load as they try to process the information offered on the package inserts. This finding seems to support the results from the readability formulas that indicated that the PILs were generally above the reading and comprehension abilities of the average patient. The generally high lexical densities could be construed as semantic noise. This is because the generally high cognitive loads they require for processing could potentially defeat the communicative transaction between the pharmaceutical providers (senders) and the majority of readers (receivers). Perhaps the pharmaceutical companies have generally failed to encode their information in forms that are considerate of many in their target audience. It should be noted that even individuals with higher reading levels have been found to prefer information that is written at lower levels as it is easier to comprehend and takes less time to read (Wilson, 2008). Therefore, encoding package insert information at an appropriate lexical density (more orality) should not present advanced readers with much cognitive difficulty. However, encoding medicine leaflet information at inappropriate lexical densities (in this case too little orality) could be disadvantageous to someone with less education.

Syntactic Complexity of the PILs of the Seven Groups of OTC Medicines

Syntactic complexity is a measure of how complex or dense the grammar used in a piece of text is. Measuring grammatical complexity involves examining the set of strings in a grammatical structure. In this study, grammatical complexity was approached from one of the definitions of 'complexity' distilled from the literature by Pallotti (2015, p. 2); this definition is concerned with "processing costs" or difficulties that are "associated with

linguistic structures". The syntactic complexity measure (of the Coh-Metrix facility) that was used in this study is considered to be directly or indirectly related to the processing difficulty a text presents to a reader (Dowell et al.., 2016; McNamara et al.., 2014). In this work, the indices of syntactic complexity measured were *left embeddedness (the number of words before the main verb in a sentence)* (denoted for brevity as SYNNLE), and *number of modifiers per noun phrase* (denoted for brevity as SYNNP). These are sufficient indicators of text complexity and therefore difficulty because "[t]he syntax in text tends to be easier to process when there are shorter sentences, few words before the main verb of the main clause, and few words per noun-phrase" (McNamara et al.., 2014, p. 70).

The syntactic complexity scores reported are interpreted according to normative scores (hereafter sometimes referred to as 'norms') published in the Appendix B of the book "Automated evaluation of text and discourse with Coh-Metrix" (McNamara et al.., 2014). Apart from descriptive indices, the norms published in the Appendix B of the aforementioned book provide normative values that can be used to compare other texts in the corresponding genre. Because PILs are published in the field of medical field, they fall under the science genre. Therefore, the syntactic complexity scores for these PILs were rightly compared to the norms in the science genre in order to arrive at conclusions on their suitable grade levels. Tables 12 to 18 present the summarized syntactic complexity scores of the various groups of PILs.

Table 11: Quantitative Description of the Syntactic Complexity of Appetite Stimulant PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	11	0.565	4.667	2.199	1.398
number of modifiers per noun phrase	11	0.745	1.087	0.900	0.105

As Table 11 shows, the mean SYNNLE for the appetite stimulants PILs was 2.199 (SD= 1.398). This score maps unto approximately Grades 1 to 3 on the norms table. The SYNNP score (Mean= 0.900, SD= 0.105), however, placed the texts at approximately Grades 6 to 9. It appears that the two indices vary widely on the grade levels for which the appetite stimulant PILs were suitable. Generally, though, it appears that SYNNP placed the texts closer to the readability levels indicated by the SMOG and Flesch-Kincaid indices.

The scores mean that the texts in the appetite stimulant PILs generally did not have many words before main verbs in their sentences. This should present readers with lower processing challenges. However, this could be negated by the relatively high number of modifiers per noun phrase. Still, at Grades 6 to 9, the texts should be suitable for the average formally educated adult.

Table 12: Quantitative Description of Syntactic Complexity of Cold and Flu Medicine PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	7	0.909	3.655	2.032	0.920
number of modifiers per noun phrase	7	0.717	1.109	0.964	0.133

SYNNLE for the package leaflets from cold and flu medicines was 2.032 (SD= 0.920) (see Table 12). This placed the texts at Grades 1 to 2 on the norms table. SYNNP was 0.964 (SD= 0.133), placing the texts at Grades 10 to 11. Again, there appears to be a wide variation between the two indices concerning text's grade-level placement. The relatively low SNNLE should make the texts easier to process for the average adult reader. However, the relatively high SYNNP places the text about a grade or two above the 8th-Grade recommended reading difficulty levels (Cutts, 2013).

Table 13: Quantitative Description of Syntactic Complexity of Cough Preparation PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	9	0.605	2.733	1.743	0.786
number of modifiers per noun phrase	9	0.667	1.426	0.876	0.248

Table 13 shows that the mean SYNNLE for the cough preparation packet inserts was 1.743 (SD= 0.786). This suggests that the text should be easy for most readers to process, the text being placed at the pre-school to Grade 1 level. SYNNP (Mean= 0.876, SD= 0.248), on the other hand, suggests that the texts from these package inserts are similar to typical science texts for Grades 5 to 8 on average.

The mean lexical density of the cough preparation leaflets (see Table 10) showed that these PILs were highly informative or descriptive. They would therefore require high cognitive processing for understanding and recall. However, such cognitive load challenges may be tempered by the relatively low average number of words before main verbs and appropriate number of modifiers per noun phrase.

Table 14: Quantitative Description of Syntactic Complexity of Dewormer PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	9	1.212	6.529	3.490	1.771
number of modifiers per noun phrase	9	0.867	1.104	0.992	0.070

Dewormers PILs scored the lowest mean lexical density (see Table 10). This means that, among the groups of package leaflets studied, they generally offered the least challenge to cognitive processing. Still, the readability indices suggested that they were very difficult to read. According to the norms table, however, the dewormer PILs were, on average, similar to Grades 5 to 6 science

texts in terms of the mean number of words before main verbs (Mean= 3.490, SD= 1.771) (see Table 14). If it is assumed that the average reader has the cognitive processing capacity of an 8th Grader, then the texts from the dewormers should present easy processing costs to the average reader. In terms of SYNNP (Mean= 0.992, SD= 0.070), the dewormer texts were generally placed at Grade 11 and above. This may too high for an average reader to process comfortably.

Table 15: Quantitative Description of Syntactic Complexity of Gastrointestinal Reflux Reliever PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	8	1.097	4.571	2.618	1.128
number of modifiers per noun phrase	8	0.807	1.022	0.917	0.065

As can be seen in Table 15, SYNNLE for the packet inserts from the GIT reflux reliever medicines was 2.618 (SD= 1.128). On the norms table, this placed the texts at Grades 2 to 3. This means that those PILs should present about as much cognitive load as science texts for Grades 2 to 3. SYNNP, however, placed the texts between Grades 8 and 9 (Mean= 0.917, SD= 0.065), or just within the abilities of the average reader according to readability recommendations (Cutts, 2013). The GIT reflux reliever PILs should therefore be easy to process by the average reader. In contrast, the readability formulas suggested that these texts were very difficult to read and suited for university

level readers, while the mean lexical density indicated that they should present medium processing difficulties.

Table 16: Quantitative Description of Syntactic Complexity of Haematinics PILs

	N	Minimum	Maximum	Mean	Std. Deviation
left embeddedness; words before main verb	7	1.520	3.591	2.871	0.725
number of modifiers per noun phrase	7	0.695	1.149	0.910	0.157

Per the norms table, the haematinic PILs have the left embeddedness (SYNNLE) typical of Grades 3 to 4 science texts (Mean= 2.871, SD= 0.725) (see Table 16). However, the norms suggest that the haematinics PILs generally have number of modifiers per noun phrase (SYNNP) that is typical of 8th to 9th Grade science texts. In either case, the syntactic complexity of the texts generally should be easy to process by the average reader, that is, if it assumed that the average reader has the aptitude of an 8th-Grader.

In terms of lexical density, the haematinics PILs generally scored high enough to be typical of academic/scientific writing (see Table 10). The readability consensus concerning this group of PILs was that they were very difficult to read. Nevertheless, the syntactic complexity indices appear to show that, structure-wise, these PILs are suited to cognitive facilities of basic school level readers.

Table 17: Quantitative Description of Syntactic Complexity of Pain Medicine PILs

	N	Minimum	Maximum	Mean	Std. Deviation
Left embeddedness; words before main verb	16	0.600	4.731	2.497	1.391
Number of modifiers per noun phrase	16	0.798	1.298	1.067	0.139

Table 17 shows that on average, pain medicine PILs had 2.497 words before a main verb in typical sentences. That is about three words before a main verb in typical sentence. The standard deviation of 1.391 suggests that sentences may have deviated from the typical words-before-main-verb count by one word or so. Referring to the Coh-Metrix norms table, the mean figure placed the pain medicine PILs at the level of Grade 1 at least, and Grade 2 at most. However, the *Maximum* statistic suggests that some of the PILs in this group had syntactic complexity typical of science texts for 9th to 10th Grade. On the other hand, SYNNP placed the texts of the PILs at Grade 11 and beyond (Mean= 1.067, SD= 0.139).

The pain medication PILs were on average suitable for Grade 14 (university level) according to the readability indices. Concerning lexical density, they were found to be quite dense (see Table 10) and therefore would generally present medium to high processing loads to the average reader. The SYNNP score seems to agree with the processing load suggested by the lexical

density score. However, these difficulties are not further enhanced by a large average number of words before main verb.

It appears that, in terms of syntactic complexity, the texts of the PILs were generally not within the cognitive processing abilities of basic school readers. This would suggest that in terms of structure, the PILs (or more specifically, the portions of the PILs tested) generally would not present high cognitive costs to readers. Table 18 presents a comparison of the syntactic complexity scores for the seven groups of PILs tested.

Table 18: Comparison of Syntactic Complexity of Seven Groups of PILs

		Sum of Squares	Df	Mean Square	F	Sig.
SYNNLE	Between Groups	17.578	6	2.930	1.836	0.107
	Within Groups	95.730	60	1.595		
	Total	113.308	66			
SYNNP	Between Groups	0.327	6	0.055	2.697	0.022
	Within Groups	1.214	60	0.020		
	Total	1.542	66			

At the $p < 0.05$ level, there were no statistically significant differences between seven groups of PILs in terms of the mean number of words before main verb in a sentence [$F(6, 60) = 1.836$, $p = 0.107$] (see Table 19). However, there was a statistically significant difference between some groups of PILs at the $p<0.05$ level where number of modifiers per noun phrase was concerned; [$F(6, 60) = 2.697$, $p = 0.022$].

The result from the readability and Coh-Metrix indices indicated that patients of the PILs will face some difficulties when they are using PILs for relevant information.

Analysis of Transcribed Interview

As part of the purpose of this study, I conducted a one-on-one interview with twenty (20) consumers of OTC drugs who visited the avenues I visited to collect the leaflets to ascertain from them whether they read PILs, and if they do, whether they understand or not and their reason for not reading, if they do not. The participants consisted of *10* males and *10* females with the age range of 18 to 50 years. They are also of varied education background; *5* Senior High School (SHS) students, *1* Diploma Nurse, *1* Nursing Trainee, *2* Teacher Trainees, *1* HND holder, *6* First Degree holders *and 4* Second Degree holders.

Table 19: Description of Interview Participants

Participant	Level of education	Gender
1	Senior High School	Male
2	Diploma	Male
3	Senior High School	Male
4	Second-Degree	Female
5	College of Education	Male
6	First-Degree	Female
7	First-Degree	Female
8	Nurses' Training College	Male
9	Senior High School	Female
10	HND	Female
11	Senior High School	Female
12	Second-Degree	Male
13	Second-Degree	Female
14	College of Education	Female
15	First-Degree	Male
16	First-Degree	Female
17	First-Degree	Male
18	Senior High School	Female
19	Second-Degree	Male
20	First-Degree	Male

There are three main questions that participants were asked in the interview. First, participants were asked:

1. Have you ever read patient information leaflets?
2. How will you describe the language of the patient information leaflets?
3. Kindly explain if there are challenges you have encountered in your reading of the patient information leaflets?

Two of the participants (8 and 19); nursing trainee and a second-degree holder said they read the PILs and understand them but found them too lengthy hence their reason for not reading all the information on them.

Five others (3, 6,9,14 and 18); Three SHS students, a teacher trainee and first-degree holder cited they read the PILs but do not understand everything they read due to the numerous medical jargons and terminologies. Participant three had this to say:

"Yes. But I found it difficult to pronounce some of the words so I didn't understand all."

Another four participants (7,12,13 and 19) disclosed that they read the PILs and does not encounter any difficulty understanding them. Thus, they fully comprehend everything they read from the PILs. One of them (Participant 12) even stated that he had a medical reference material that he refers to, to get more information on every drug he buys.

"Yes, I did. I also have a document prepared by the Ghana Pharmacy Association with a lot of information on diseases and drugs that can fight them so I do read it for more information about a drug I buy."

When asked why he understands everything including the medical terms and jargons, he had this to say,

"Yes, I do understand whatever I read. I have a science background so most often I have a better understanding of what I read from the leaflet."

It is imperative to note that the four participants who fully understood what they read from the PILs are degree holders. Three of them are second degree holders while the remaining one is a first-degree holder. One will not be far from right if it is asserted that their level of education contributed to their ability to comprehend the information on the PILs.

Also, three participants (1,10 and 17); an SHS student, a polytechnic student and a first-degree holder cited time constraints as their reason for not reading the PILs. Participant 1 had this to say when asked why he doesn't read the PILs:

"No, I don't have time to read so I don't read it."

Another three participants (4,5 and 11) a first-degree holder, a teacher trainee and an SHS student stated various reasons for their lack of readership. Participant 4 had no reason for reading. He just did not read the PILs, participant five cited verbosity while participant 11 cited difficult words as their reason for not reading the PILs.

Three other participants (2,15 and 16) a health worker and second first degree holders asserted their conversance with the drugs they buy as their reason for not reading the PILs. They claim to *" know the drugs already"* hence their stance. But participant 15 was quick to add that it is the drugs he has been using that he does not read its leaflet but when he buys a drug he has not used before, he reads the PIL to get himself informed.

One participant (20), a first-degree holder was the only interviewee who relied solely on the counsel of the shop operator on the drugs he buys. His lack of readership stems from the fact that the person who mans the shop he makes

purchases from is trustworthy. Whatever he says on the drug is what he believes so he does not see the need to read the PILs. This is quite alarming because OTC drugs can be dispensed by anybody, not necessarily a health professional. If someone can put his life on the words of a non-professional instead of reading to find out himself then there is actually a problem that needs attention.

From the interviews, the researcher deduced that, comprehension of PILs depended largely on one's level of education. This is because the people who expressed interest in reading the PILs and those that understood most of what was read are all people with higher education background. The average grade level for the comprehension of PILs as per readability analysis is the 8th grade level which is equivalent to the second year in Junior High School in Ghana. The lowest grade level that the researcher interviewed for the study was grade 10 which is equivalent to the Senior High School level. The five participants who were interviewed for that grade level had three of them saying they did not understand what was read with another one saying he stopped reading the PILs because the words were difficult for him to comprehend and the last one stating time constraints as his reason for not reading. If a 10th grader is finding what an 8th grader should be understanding difficult to comprehend, then there is no need arguing over the comprehension level of that material. The words in the PILs posed difficulty to the readers because they are not simple enough to be understood. The technical words in addition to the lengthy nature of some of the sentences make the reading of PILs complex for readers.

In the light of this, the researcher argues that the readability and Coh-Metrix scores were valid in that readers who had not acquired the required level of education (college level) found the PILs very difficult to read and understand

and with some containing too many words. Their main reasons for this was the difficult terms used in the PILs. Which implies that the prediction of the lexical density and grammatical complexity scores were reflecting the users experience with the PILs.

Manual Analysis of the Patient Information Leaflets for Linguistic Complexity and Lexical Density

The manual analysis of the leaflets revealed evidence that confirms the assertion of the participants in the interview that the words of the leaflets are not familiar. Also, the polysyllabic nature of the words as well as the syntactic structures which are usually simple sentences with lengthy compound objects making the sentences relatively longer and, therefore, contributing to higher readability scores.

Flurest

In the analysis of Flurest, which is a drug for treatment of cold or influenza, the researcher found an interesting opening in the leaflet. The researcher discovered that the writer indicated at the opening that the patients should read the leaflet for important information. They wrote:

"*Please read this leaflet carefully before you take this medicine as it contains important information. If you have any questions or are not sure if this product is suitable, ask your pharmacist. Keep this leaflet as you may want to read again."* (Excerpt Flurest Leaflet)

From this, it is succinct that the writer is in the known that leaflets are important documents containing relevant information for patients. Also, the writer acknowledged the patients may have challenges understanding the

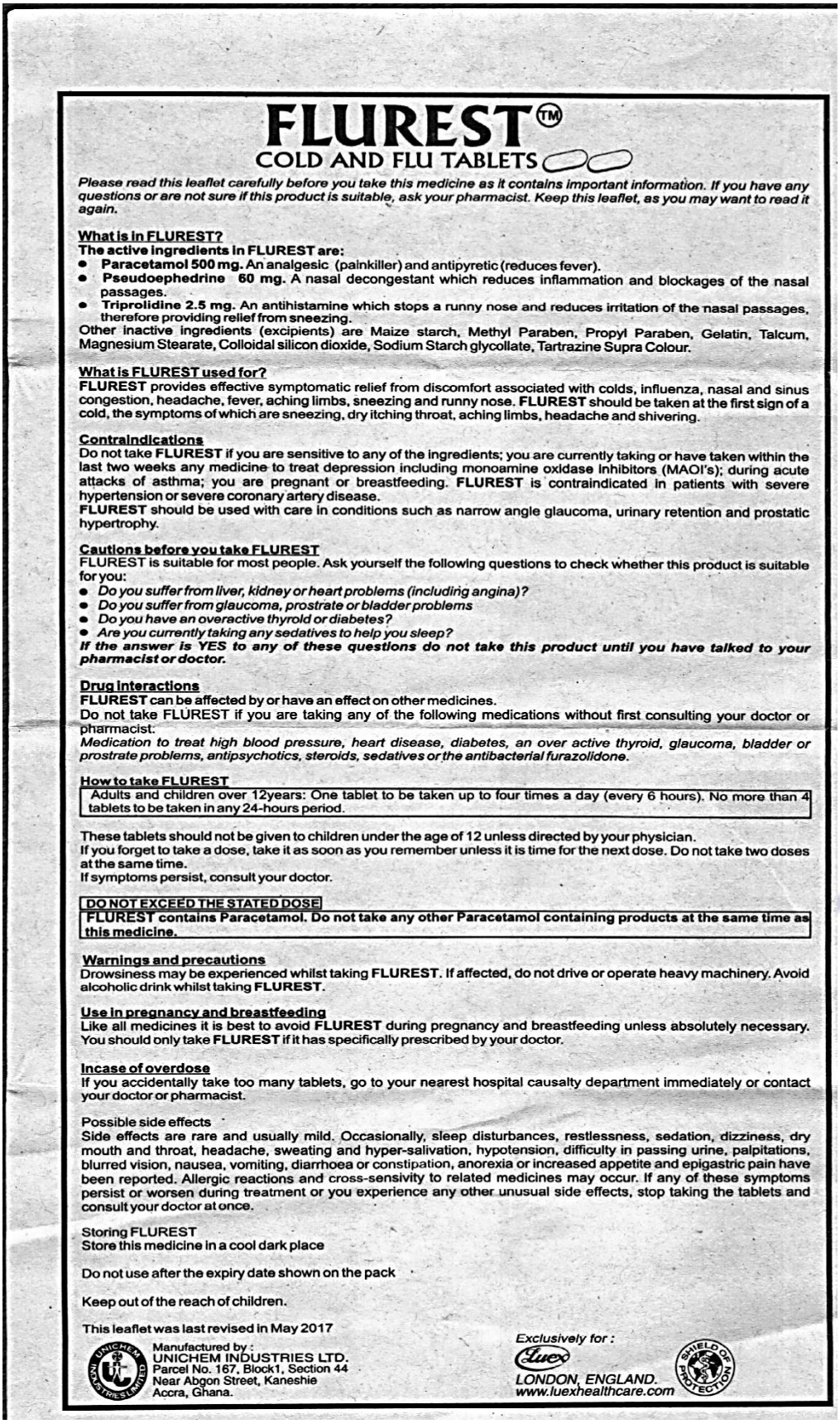
content and, in such cases, they contact the pharmacist or revisit the leaflet for further reading.

The Flurest leaflet presented a readable content because the writer used plain language with explanation for technical words that may not be understandable to readers. For instance, the following structures indicate the writer's approach to complex words regarding the composition of the drug.

1. Paracetamol- an analgesic *(painkiller)* and antipyretic (*reduces fever*)
2. Pseudoephedine – A nasal decongestant which reduces inflammation and blockages of the nasal passage.

In these structures, the writer used parenthetical information to break down the complex technical words to the understanding of the readers by using simple words like *painkiller* in place of *analgesic* and replaced *antipyretic* with *reduces fever.*

Moreover, the writer adopted other varied sentence types such as interrogative sentences, simple sentences and compound sentences with simple words to appeal to all the readers. For instance, the writer used, '*what is Flurest used for?*' to introduce what is the drug is used to treat. Apart from words such as *monoamine, oxidase, inhibitors* which were not explained, the rest of the words were very simple. Out of the 200 words used in the leaflet, 100 words were grammatical while the remaining were content thereby, making the leaflet understandable. This is because as said earlier in Chapter 2, Ure (1971) considered any text which contains more grammatical words than lexical words to be an easy to read text.



FLUREST™

COLD AND FLU TABLETS

Please read this leaflet carefully before you take this medicine as it contains important information. If you have any questions or are not sure if this product is suitable, ask your pharmacist. Keep this leaflet, as you may want to read it again.

What is in FLUREST?
The active ingredients in FLUREST are:
- **Paracetamol 500 mg.** An analgesic (painkiller) and antipyretic (reduces fever).
- **Pseudoephedrine 60 mg.** A nasal decongestant which reduces inflammation and blockages of the nasal passages.
- **Triprolidine 2.5 mg.** An antihistamine which stops a runny nose and reduces irritation of the nasal passages, therefore providing relief from sneezing.

Other inactive ingredients (excipients) are Maize starch, Methyl Paraben, Propyl Paraben, Gelatin, Talcum, Magnesium Stearate, Colloidal silicon dioxide, Sodium Starch glycollate, Tartrazine Supra Colour.

What is FLUREST used for?
FLUREST provides effective symptomatic relief from discomfort associated with colds, influenza, nasal and sinus congestion, headache, fever, aching limbs, sneezing and runny nose. **FLUREST** should be taken at the first sign of a cold, the symptoms of which are sneezing, dry itching throat, aching limbs, headache and shivering.

Contraindications
Do not take **FLUREST** if you are sensitive to any of the ingredients; you are currently taking or have taken within the last two weeks any medicine to treat depression including monoamine oxidase inhibitors (MAOI's); during acute attacks of asthma; you are pregnant or breastfeeding. **FLUREST** is contraindicated in patients with severe hypertension or severe coronary artery disease.
FLUREST should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

Cautions before you take FLUREST
FLUREST is suitable for most people. Ask yourself the following questions to check whether this product is suitable for you:
- *Do you suffer from liver, kidney or heart problems (including angina)?*
- *Do you suffer from glaucoma, prostrate or bladder problems*
- *Do you have an overactive thyrold or diabetes?*
- *Are you currently taking any sedatives to help you sleep?*

If the answer is YES to any of these questions do not take this product until you have talked to your pharmacist or doctor.

Drug interactions
FLUREST can be affected by or have an effect on other medicines.
Do not take FLUREST if you are taking any of the following medications without first consulting your doctor or pharmacist:
Medication to treat high blood pressure, heart disease, diabetes, an over active thyroid, glaucoma, bladder or prostrate problems, antipsychotics, steroids, sedatives or the antibacterial furazolidone.

How to take FLUREST
Adults and children over 12years: One tablet to be taken up to four times a day (every 6 hours). No more than 4 tablets to be taken in any 24-hours period.

These tablets should not be given to children under the age of 12 unless directed by your physician.
If you forget to take a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time.
If symptoms persist, consult your doctor.

DO NOT EXCEED THE STATED DOSE
FLUREST contains Paracetamol. Do not take any other Paracetamol containing products at the same time as this medicine.

Warnings and precautions
Drowsiness may be experienced whilst taking **FLUREST**. If affected, do not drive or operate heavy machinery. Avoid alcoholic drink whilst taking **FLUREST**.

Use in pregnancy and breastfeeding
Like all medicines it is best to avoid **FLUREST** during pregnancy and breastfeeding unless absolutely necessary. You should only take **FLUREST** if it has specifically prescribed by your doctor.

Incase of overdose
If you accidentally take too many tablets, go to your nearest hospital causalty department immediately or contact your doctor or pharmacist.

Possible side effects
Side effects are rare and usually mild. Occasionally, sleep disturbances, restlessness, sedation, dizziness, dry mouth and throat, headache, sweating and hyper-salivation, hypotension, difficulty in passing urine, palpitations, blurred vision, nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite and epigastric pain have been reported. Allergic reactions and cross-sensivity to related medicines may occur. If any of these symptoms persist or worsen during treatment or you experience any other unusual side effects, stop taking the tablets and consult your doctor at once.

Storing FLUREST
Store this medicine in a cool dark place

Do not use after the expiry date shown on the pack

Keep out of the reach of children.

This leaflet was last revised in May 2017

Manufactured by :
UNICHEM INDUSTRIES LTD.
Parcel No. 167, Block1, Section 44
Near Abgon Street, Kaneshie
Accra, Ghana.

Exclusively for :
LONDON, ENGLAND.
www.luexhealthcare.com

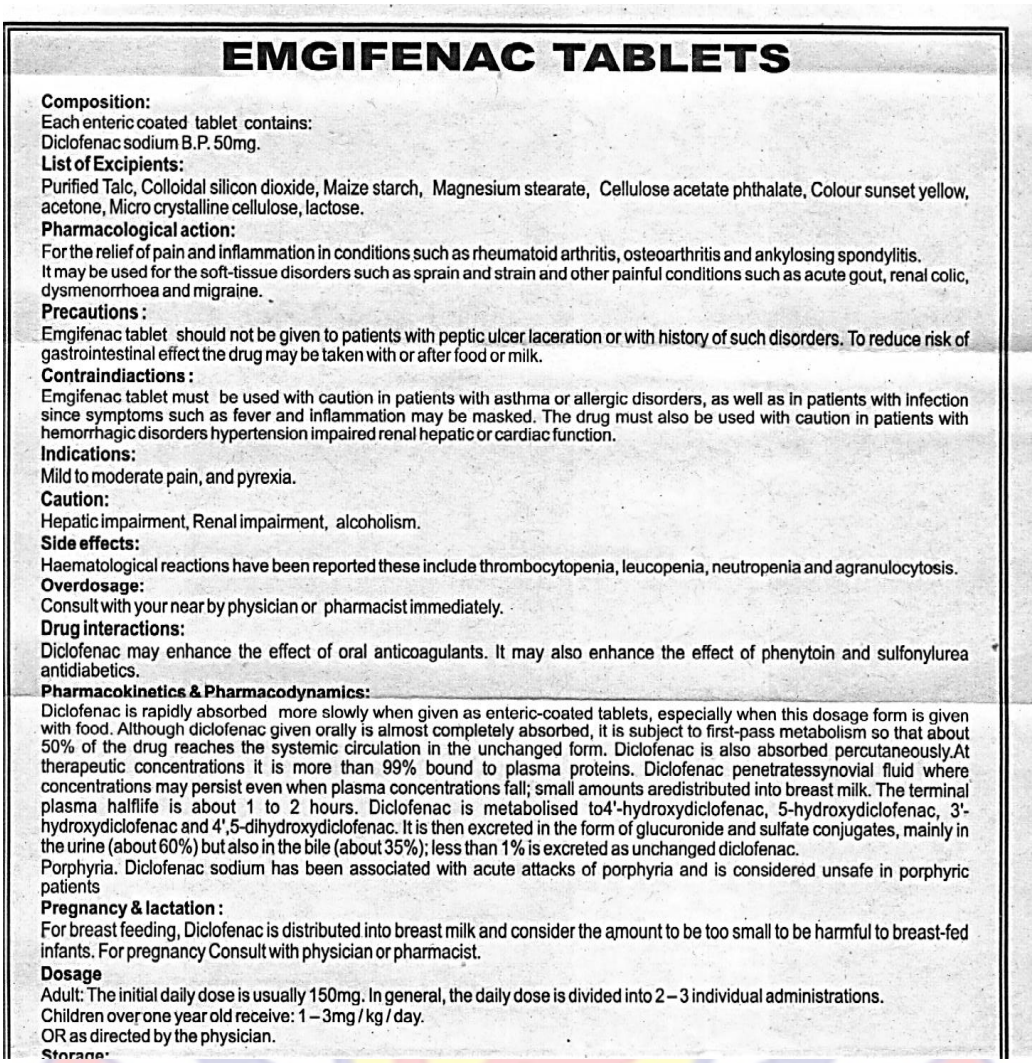
Figure 3: PIL of Flurest Drug

Emginefac

Emginefac is a painkiller medicine that was analysed to ascertain its syntactic complexity. From the analysis, it was found that the writer used polysyllabic words without explaining their meaning to readers. For instance, technical words such as *didofenac, cellulose, hemorrhagic, diclofenac* were not explained in simple terms for the readers' understanding. Also, sentence structures were relatively long making it difficult for readers to grasp the content easily. To exemplify,

"*Although diclofenac given orally is almost completely absorbed, it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form."*

This sentence could have been separated into two simple sentences with one dealing with the absorption of the drug and the other one dealing with the circulation of the drug. Adding the two together makes the sentence a complex sentence and thereby, reducing its readability. Out of 500 words, 300 words were lexical words meaning the lexical density will be high, making the leaflet difficult for the readers to read and understand. Below is the leaflet's image.



EMGIFENAC TABLETS

Composition:
Each enteric coated tablet contains:
Diclofenac sodium B.P. 50mg.
List of Excipients:
Purified Talc, Colloidal silicon dioxide, Maize starch, Magnesium stearate, Cellulose acetate phthalate, Colour sunset yellow, acetone, Micro crystalline cellulose, lactose.
Pharmacological action:
For the relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.
It may be used for the soft-tissue disorders such as sprain and strain and other painful conditions such as acute gout, renal colic, dysmenorrhoea and migraine.
Precautions:
Emgifenac tablet should not be given to patients with peptic ulcer laceration or with history of such disorders. To reduce risk of gastrointestinal effect the drug may be taken with or after food or milk.
Contraindiactions:
Emgifenac tablet must be used with caution in patients with asthma or allergic disorders, as well as in patients with infection since symptoms such as fever and inflammation may be masked. The drug must also be used with caution in patients with hemorrhagic disorders hypertension impaired renal hepatic or cardiac function.
Indications:
Mild to moderate pain, and pyrexia.
Caution:
Hepatic impairment, Renal impairment, alcoholism.
Side effects:
Haematological reactions have been reported these include thrombocytopenia, leucopenia, neutropenia and agranulocytosis.
Overdosage:
Consult with your near by physician or pharmacist immediately.
Drug interactions:
Diclofenac may enhance the effect of oral anticoagulants. It may also enhance the effect of phenytoin and sulfonylurea antidiabetics.
Pharmacokinetics & Pharmacodynamics:
Diclofenac is rapidly absorbed more slowly when given as enteric-coated tablets, especially when this dosage form is given with food. Although diclofenac given orally is almost completely absorbed, it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form. Diclofenac is also absorbed percutaneously.At therapeutic concentrations it is more than 99% bound to plasma proteins. Diclofenac penetratessynovial fluid where concentrations may persist even when plasma concentrations fall; small amounts aredistributed into breast milk. The terminal plasma halflife is about 1 to 2 hours. Diclofenac is metabolised to4'-hydroxydiclofenac, 5-hydroxydiclofenac, 3'-hydroxydiclofenac and 4',5-dihydroxydiclofenac. It is then excreted in the form of glucuronide and sulfate conjugates, mainly in the urine (about 60%) but also in the bile (about 35%); less than 1% is excreted as unchanged diclofenac.
Porphyria. Diclofenac sodium has been associated with acute attacks of porphyria and is considered unsafe in porphyric patients
Pregnancy & lactation:
For breast feeding, Diclofenac is distributed into breast milk and consider the amount to be too small to be harmful to breast-fed infants. For pregnancy Consult with physician or pharmacist.
Dosage
Adult: The initial daily dose is usually 150mg. In general, the daily dose is divided into 2 – 3 individual administrations.
Children over one year old receive: 1 – 3mg / kg / day.
OR as directed by the physician.
Storage:

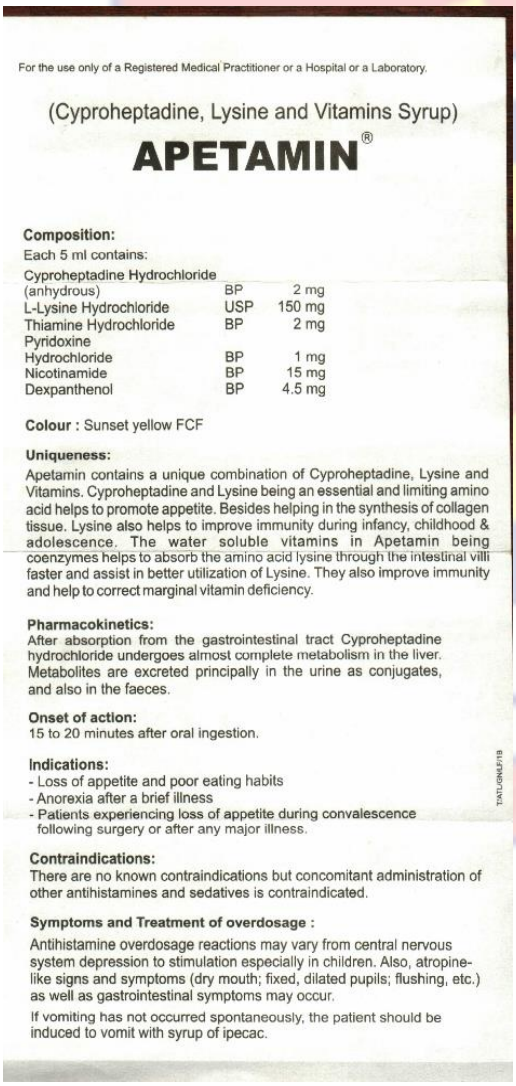
Figure 4: Emgifenac PIL

Apetamin

Apetamin is a haematinic popularly known as blood tonic. In the analysis of the leaflet the researcher found that the technical words were used to indicate the composition of the medicine without any explanation. The leaflet has words such as *hydrochloride, pyridoxine, dexpanthenol, pharmacoknetics, cyproheptadine* among others which appeared technical to readers with no science background. These words could have been used with simple definitions of what they meant so that the reader could understand the content. The sentences were also simple complex ones with relatively high length that could affect the readability of the leaflet. For instance, one of the sentences is:

"Cyproheptadine and lysine being an essential and lomoting amino acid helps to promote appetite. Besides helping in the synthesis of collagen tissue". (Excerpt from Apetamin PIL)

In this sentence, the writer separated the two sentences making the second sentence a fragment because it depends on the first one. This will make the meaning of the sentence incomplete for readers. Out of the 200 words in the leaflet, 130 words were content or lexical words while the remaining 70 words were grammatical. This means that the level of lexical density of the leaflet will be high making it difficult to read according to Ure's lexical density measure.



For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

(Cyproheptadine, Lysine and Vitamins Syrup)

APETAMIN®

Composition:
Each 5 ml contains:

Cyproheptadine Hydrochloride (anhydrous)	BP	2 mg
L-Lysine Hydrochloride	USP	150 mg
Thiamine Hydrochloride	BP	2 mg
Pyridoxine Hydrochloride	BP	1 mg
Nicotinamide	BP	15 mg
Dexpanthenol	BP	4.5 mg

Colour : Sunset yellow FCF

Uniqueness:
Apetamin contains a unique combination of Cyproheptadine, Lysine and Vitamins. Cyproheptadine and Lysine being an essential and limiting amino acid helps to promote appetite. Besides helping in the synthesis of collagen tissue. Lysine also helps to improve immunity during infancy, childhood & adolescence. The water soluble vitamins in Apetamin being coenzymes helps to absorb the amino acid lysine through the intestinal villi faster and assist in better utilization of Lysine. They also improve immunity and help to correct marginal vitamin deficiency.

Pharmacokinetics:
After absorption from the gastrointestinal tract Cyproheptadine hydrochloride undergoes almost complete metabolism in the liver. Metabolites are excreted principally in the urine as conjugates, and also in the faeces.

Onset of action:
15 to 20 minutes after oral ingestion.

Indications:
- Loss of appetite and poor eating habits
- Anorexia after a brief illness
- Patients experiencing loss of appetite during convalescence following surgery or after any major illness.

Contraindications:
There are no known contraindications but concomitant administration of other antihistamines and sedatives is contraindicated.

Symptoms and Treatment of overdosage :
Antihistamine overdosage reactions may vary from central nervous system depression to stimulation especially in children. Also, atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing, etc.) as well as gastrointestinal symptoms may occur.

If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac.

Figure 5: Excerpt from Apetamin PIL

Based on the Shannon and Weaver communication model, the researcher could make sense of the result in that the major thing that hinder effective communication between PILs writers (manufacturers) and the target readers (patients) is semantic noise. The consumers did not complain about the materials' font and other mechanical variables, rather majority cited wordiness while others cited lengthiness as the causes of their lack of understanding of the PILs. It therefore implies that, for manufacturers to increase message fidelity of their PILs, there is the need to reconsider the wording and technical terms using composing PILs so that consumers can find them useful for their information needs when they are using drugs. This is much relevant in the Ghanaian setting in the sense that all the interviewees were consumers of OTC drugs which are purchase without prescription and therefore do not necessarily need an expert to dispense them. This means that their major source of reliable information concerning the drug in order to avoid catastrophic occurrence is the PILs of those drugs. If the PILs are therefore not readable nor lexically and grammatically friendly, the possibility of recording the same casualties that prompted the addition of PILs will be inevitable. Manufacturers of drugs should, therefore, pay keen attention to the readability of their PILs in order to ensure effective health communication with patients of common ailments studied in this research.

Chapter Summary

This chapter saw an analysis of the data collected for the study. The analysis from the readability and Coh-Metrix indices indicated that patients of the PILs will face some difficulties when they are using PILs for relevant information. Concerning lexical density, they were also found to be quite dense

and would therefore generally present medium to high processing loads to the person with low education background. Even though some of the PILs did not have any complex grammatical structures, a good number of them were however difficult to comprehend. The outcome of the interview showed that readers encountered some level of difficulty comprehending the PILs.

CHAPTER FIVE

SUMMARY, FINDINGS AND RECOMMENDATIONS

Summary of the Study

Health communication is vital in health care delivery. Effective health communication is important in mitigating diagnostic challenges, side effects of drugs and overdose of drugs by patients. The use of Patient Information Leaflets (PILs) in over-the-counter drugs sales help users of drugs to know what the drugs contain, the directions of use, the precautions, and the side effects of the drugs. As an information tool, PILs will be relevant to patients if the message in the leaflets is understandable to the patients (users). Readability of PILs is one indicator of the level at which readers will succeed in understanding the leaflets. Readability of PILs in previous studies have revealed that PILs are written at the difficult to read level. Gyasi (2013) discovered that common malaria drugs leaflets in Ghana are difficult to read. Likewise, William et al. (2013) and Wilson (2008) discovered that PILs are difficult to read for an average reader in the western world. The current study was therefore of the view that the communication between manufacturers and patients through PILs could be improved through the production of readable PILs.

Even though studies have found PILs too difficult to read, there are limited studies on how over- the-counter (OTC) drugs leaflets' readability scores affect readers understanding of the leaflets. To fill this gap, the researcher sampled 68 PILs of seven common illnesses in Ghana and run a readability analysis of the selected leaflets using Flesch Kincaid grade level and SMOG readability formulae. The syntactic complexity and lexical density of the leaflets were determined through the Coh-Metrix index which measures syntactic

density and lexical density. Using Shannon and Weaver's Communication Model, the researcher analyzed the results of the study and came out with these findings.

Findings of the Study

The lexical density and syntactic complexity of the selected leaflets ranged from medium to high which means that the person with low education will find it difficult to read and understand the message in the leaflets. Also, there was no statistical difference across the leaflets of the seven common illnesses measured in the current study in that the scores revealed that on the average the lexical density and syntactic complexity were high and readers required advanced knowledge in order for them to understand the leaflets.

Additionally, the readability indexes scores revealed that on the average a reader requires at least 14 years of formal education which is equivalent to university level in order to find the leaflets understandable.

Again, the researcher discovered majority of the participants read the leaflets for information on dosage, side effects and precautions. The readers however acknowledged complex terminologies as a challenge to their understanding of the message in the leaflets.

Recommendations

On the basis of the findings above, the researcher suggests these recommendations to manufacturers, practitioners and researchers. First, the researcher recommends that writers of the PILs could adopt plain language in order to reduce the lexical density and syntactic complexity embedded in the PILs. This will reduce the reading difficult and make the PILs readable to vast majority of users of PILs. This can be achieved through the use of a Plain

Language Thesaurus compiled by the Centre for Disease Control and Prevention's National Centre for Health Marketing (Vanderbilt Health.com). It is a health communication tool which is easily and readily available online that manufacturers of PILs can always refer to, to substitute, if not define, medical terms or jargons with lay man's language for easy comprehension. To exemplify, below are some of the medical terms or jargons; phrases and words, and their plain language meaning as found in the Plain Language Thesaurus.

On an empty stomach- do not eat or drink

Adverse health effect- bad side effect

Central Nervous System- brain and spinal cord

Cerebrovascular disease- stroke

Drowsy- sleepy

Dyspepsia- indigestion or heartburn

Etiology- the cause of

Benign- cancer

Biota- plants and animals

Mutagen- cause

If such a tool is handy, healthcare providers would not have to worry too much about communicating in plain language with their readers. Additionally, the researcher recommends that writers of PILs should take advantage of the online readability formulae or Microsoft readability package as tools to predict the reading level of their leaflets for possible revision before circulation of the leaflets to users or patients. When they are done writing their PILs, all they need do is to feed the content into a tried and tested readability formula online to help predict the grade level of the content. If the level is higher than what an ordinary

citizen with a not too good educational background can contain, it can be revised there and then before publication.

Also, the researcher recommends a survey study on the patients' readership of PILs and the possible reasons and challenges they encounter. Such a study will help to discover the usefulness of the PILs to patients and the urgency for writers of PILs to consider readability as a tool to achieving effective health communication with their users. Establishing the usefulness of the PILs to users will go a long way to curb certain occurrences that could result from not reading the PILs especially the contra-indications since most of the participants of the interview were not much interested in knowing what was there. Again, it will make users take full control of their health by making informed decisions from what they read and not rely on what is said by a vendor, who is sometimes not a health professional.

The researcher recommends further researches that will examine large health documents' readability and comprehensibility such as brochures, booklets and many other health documents. Also, a study can be conducted on the readability and comprehensibility of the other categories of drugs dispense in Ghana, that is, Prescription Only Medications (POMs) and Pharmacy Only (PO). In a country where there is not much work on readability of health-related materials, it is prudent for much studies to be conducted for more voices to be heard to sound an alarm where necessary for a good impact to be made.

The researcher suggest that other researchers could look at educational level as variable. This will provide insights as to how educational levels of readers affect the reading ease level of patient information leaflets.

Implications/Contributions of the Study

The present study has contributed to scholarship on readability and healthcare communication by analyzing the reading difficulty of patient information leaflets of seven common ailments in Ghana from a readability formula, manual and consumers perspectives. The previous study in Ghana only examined PILs of malaria, but the present study added others such as dewormer, cough, cold, gastrointestinal diseases and others. This has added more information to appreciating the complexity of health communication document especially PILs of common ailments.

The present study has contributed to scholarship by blending objective readability formula scores analysis with the manual and consumers views at the same time. This provides a more robust data for triangulating the scores of readability formula in readers' comprehension of the PILs.

The implication of the present study is that composers/writers of PILs should revise the language of the PILs according to plain language recommendations so that the PILs could effectively communicate the desired message to the audience/patients.

Limitations of the Study

The illnesses dealt with were only seven. This is because some illnesses were symptoms of others and not sicknesses on their own hence, they were ruled out. The sample may not be a representation of all PILs because there are a whole lot of PILs in the market.

The researcher had difficulty collecting the required number of leaflets that were initially proposed in the study because the available leaflets were not up to the intended number. This is because the shops she visited for the two avenues

of OTC sales point sold almost the same drugs from the same manufacturing company. In a country where there are limited companies that manufacture drugs, the same company tend to produce different drugs for the same illness. This makes the content of the leaflet almost the same with the exception of the ingredients used. For instance, a company like PokuPharma in Kumasi produces *Pocumol* and *PocuPain* which are both painkillers, because they are from the same company, the content of the leaflets were the same with the exception of the composition which only defers with just 1 component. In such an instance, only 1 leaflet was taken to avoid reduplication and to boost the validity of the readability results. This accounted for the researcher's inability to meet the 100 leaflets target she initially expected.

The study is limited to the analysis of the linguistic categories; lexical density and syntactic complexity which is embedded in the readability analysis of the text of the PILs that were sampled; hence, other analysis such as paper size and type, font size and type, use of symbols, pictorial analysis and bi-lingualism were not considered in this study.

Conclusions

There is a call for the use of plain language to address the needs of limited literacy. Even though plain language does not necessarily aid individuals with limited reading ability to read and understand what is written, it is still the best way to reach out to the masses since written documents are meant for people who can read. Materials that are difficult to read will not be read at all. To ensure understandability of health information by targeted users, health professionals must know how to reach them. Writing clearly is a critical step that helps to achieve this goal.

PILs are relevant information tools for patients, however, their readability is hindering the effective communication between the writers and the patients. The lexical density and syntactic complexity should be revised to make the leaflets understandable for diverse readers. PILs should therefore be written at a level not higher than the 8th grade level which is equivalent to the 2nd year in Junior High School in Ghana.

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APPENDICES

APPENDIX A

INTERVIEW GUIDE

1. Have you bought a drug without prescription before?
2. What is your level of education?
3. What drug did you buy?
4. When you bought the drug did you see any leaflet in it?
5. Did you read it? If yes then question 6 follows. If no then why?
6. Did you understand what you read?

COMMUNICATION EXCHANGES

1.

Interviewer: Hello, good afternoon Sir.

Interviewee: Good afternoon madam.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay go on.

Interviewer: Please what is your level of education?

Interviewee: Senior High School.

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes, many times.

Interviewer: Please what drug did you buy?

Interviewee: Paracetamol.

Interviewer: When you bought it, did you see any leaflet in it?

Interviewee: Yes, sometimes.

Interviewer: Did you read it?

Interviewee: No. I don't have time to read so I don't read it.

Interviewer: Okay, thank you.

Interviewee: Thank you too.

2.

Interviewer: Sir, good evening

Interviewee: Hello good evening

Interviewer: Please can I ask you some few questions?

Interviewee: ok.

Interviewer: Please what is your level of education?

Interviewee: Diploma

Interviewer: Have you bought a drug without prescription before?

Interviewee: Yes, please

Interviewer: Please did you see a leaflet in the package?

Interviewee: Yes, I did

Interviewer: Did you read it?

Interviewee: No, please

Interviewer: Why?

Interviewee: I'm a health worker and I knew the information about the drug that's why I didn't read it.

Interviewer: Ok, thank you

Interviewee: You're welcome.

3.

Interviewer: Hello Sir

Interviewee: Hello

Interviewer: Good evening

Interviewee: Good evening.

Interviewer: Please can I ask you some questions?

Interviewee: Okay.

Interviewer: Please what is your level of education?

Interviewee: Senior High School graduate

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: What drug did you buy?

Interviewee: Malaria drugs

Interviewer: Did you see a leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: Yes. But I found it difficult to pronounce some of the words so I didn't understand all.

Interviewer: Okay, thank you.

4.

Interviewer: Hello madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions?

Interviewee: Yes, you can.

Interviewer: Please what is your level of education?

Interviewee: Degree

Interviewer: First or second?

Interviewee: Second

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes

Interviewer: Please what drug did you buy?

Interviewee: Haemoglobin

Interviewer: Please when you bought it, did you see the leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: No

Interviewee: Why didn't you read it?

Interviewee: It's nothing. Please I don't have any reason.

Interviewer: Okay, thank you.

Interviewee: You're welcome.

5.

Interviewer: Hello, good afternoon Sir

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay.

Interviewer: Please what is your level of education?

Interviewee: I am a student.

Interviewer: At where?

Interviewee: The College of Education

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: Quick Action (Painkiller)

Interviewer: When you bought the drug, did you see a leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: No

Interviewer: Why?

Interviewee: The printed material was too long so I didn't read.

Interviewer: Really. Thank you.

6.

Interviewer: Hello madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay.

Interviewer: Please what is your level of education?

Interviewee: First Degree

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes

Interviewer: Please what drug did you buy?

Interviewee: I bought some painkillers

Interviewer: Please when you bought the drug, did you see any leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: Yes, I read it. The most important part that I read was the indications, the side effects and the rest. So as soon as I buy drugs, I just open that part and read it

before I take the drug.

Interviewer: Please when you read do you understand what you read?

Interviewee: Sometimes I don't understand the various terminologies in the indication, but I just want to see whether it's good for pregnancy and what will happen if I take it. Example, stomach upset, nausea, vomiting, etc. That's why I read those leaflets.

Interviewer: Oka y, thank you very much.

Interviewee: You're welcome.

7.

Interviewer: Hello madam, good morning

Interviewee: Please can I ask you some few questions so you answer for me?

Interviewee: Okay

Interviewer: Please what is your level of education?

Interviewee: Degree

Interviewer: First or second?

Interviewee: First

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes

Interviewer: What drug did you buy, please?

Interviewee: A sachet of Paracetamol

Interviewer: Please when you bought it did it come with any leaflet?

Interviewee: Yes

Interviewer: Please did you read it?

Interviewee: Sometimes. I read it when I want to know more about the drug before I take it;

when to take it, the time to take it, and the side effects.

Interviewer: When you read it did you understand what was written on it?

Interviewee: Yes. I understand it.

Interviewer: Okay, thank you very much.

8.

Interviewer: Hello sir, good afternoon.

Interviewee: Good afternoon madam.

Interviewer: Please can I ask you some questions?

Interviewee: Okay I'm listening.

Interviewer: Please what is your level of education?

Interviewee: I'm at the Nurses' Training College

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes, I have.

Interviewer: Please what drug did you buy?

Interviewee: I have bought many but let's say paracetamol.

Interviewer: When you bought it, did you see any leaflet in it?

Interviewee: Yes, sometimes.

Interviewer: Have you been reading it?

Interviewee: Yes.

Interviewer: Did you understand what you read?

Interviewee: Yes, I did. Just that it was plenty so I didn't read all.

Interviewer: Okay, thank you very much.

Interviewee: You're welcome.

9.

Interviewer: Hello, good afternoon lady.

Interviewee: Good afternoon madam.

Interviewer: Please can I speak with you before you leave?

Interviewee: Okay go on.

Interviewer: Please what is your level of education?

Interviewee: Senior High School.

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes, many times.

Interviewer: Please what drug have you been buying you buy?

Interviewee: Amoxicillin, paracetamol and others.

Interviewer: When you bought it, did you see any leaflet in it?

Interviewee: Yes, sometimes.

Interviewer: Do you read it?

Interviewee: Not always.

Interviewer: When you read, do you understand?

Interviewee: I don't understand because of the difficult terminologies.

Interviewer: Okay, thank you.

Interviewee: Thank you too.

10.

Interviewer: Madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay.

Interviewer: Please what is your level of education?

Interviewee: Tertiary

Interviewer: Please which of them?

Interviewee: HND

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: Cipro

Interviewer: Please when you bought it, did you see any leaflet in it?

Interviewee: Yes

Interviewer: Please did you read it?

Interviewee: No, I didn't read it.

Interviewer: Please why didn't you read it?

Interviewee: I didn't get the time to read it.

Interviewer: Please can I ask why?

Interviewee: Awww it's nothing. It's nothing.

Interviewer: Okay, thank you.

Interviewee: You're welcome.

11.

Interviewer: Hello, good afternoon dear.

Interviewee: Good afternoon.

Interviewer: Please may I speak to you for a moment before you leave?

Interviewee: Yes.

Interviewer: What is your level of education?

Interviewee: Senior High School

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: Paracetamol

Interviewer: When you bought it, did you see a leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: No

Interviewer: Why didn't you read it?

Interviewee: The words were difficult for me to understand.

Interviewer: Okay, thank you.

Interviewee: You're welcome.

12.

Interviewer: Hello, good morning Sir

Interviewee: Morning.

Interviewer: Please can I ask you some few questions?

Interviewee: Yes, you can. I am ready for you.

Interviewer: What is your level of education?

Interviewee: Second degree

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes severally.

Interviewer: What drug did you buy?

Interviewee: Paracetamol with B.co, Folic acid, Antimalarial among others.

Interviewer: Please did you see a leaflet in the pack?

Interviewee: Yes, mostly.

Interviewer: Did you read it?

Interviewee: Yes, I did. I also have a document prepared by the Ghana Pharmacist Association with a lot of information on diseases and drugs that can fight them so I do read it for more information about a drug I buy.

Interviewer: When you read it did you understand what has been written.

Interviewee: Yes, I do understand whatever I read. I have a science background so most often I have a better understanding of what I read on the leaflet.

Interviewer: Okay thank you very much.

Interviewee: You are welcome.

13.

Interviewer: Hello Madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some questions?

Interviewee: Yes, please you may.

Interviewer: What is your level of education?

Interviewee: Degree

Interviewer: First or second

Interviewee: Second but does it matter?

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes, I have.

Interviewer: Please what drug did you buy?

Interviewee: I bought painkiller for body pains, blood tonic, some medicines for my kids.

Interviewer: Please did you see any leaflet in it?

Interviewee: Yes, I did

Interviewer: Did you read it?

Interviewee: Yes, I did.

Interviewer: Did you understand everything you read?

Interviewee: Yes, I did. I understood it.

Interviewer: Okay, thank you very much.

14.

Interviewer: Hello Madam, good morning.

Interviewee: Good morning.

Interviewer: Please can I have a minute of your time to ask you some few questions?

Interviewee: You may go on.

Interviewer: Please what is your level of education?

Interviewee: Tertiary

Interviewer: Please which of them?

Interviewee: College of Education

Interviewer: Ok. Have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: I have bought so many of them but I think the common one is paracetamol.

Interviewer: Please when you bought it, did you see a leaflet in it?

Interviewee: Yes, I did

Interviewer: Did you read it?

Interviewee: Yes. I love to read the leaflets because sometimes I want to see the effects of the drug.

Interviewer: Please when you read it did you understand what you read?

Interviewee: I understood some and there were some I didn't understand.

Interviewer: Okay, thank you very much.

Interviewee: You're welcome.

15.

Interviewer: Hello sir, good morning.

Interviewee: Good morning.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay go ahead.

Interviewer: Please what is your level of education?

Interviewee: University graduate

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes, I always do.

Interviewer: Please what drug did you buy?

Interviewee: I have bought many drugs but commonly painkillers.

Interviewer: When you buy drugs, do you see a leaflet in it?

Interviewee: Yes, always.

Interviewer: Do you read it?

Interviewee: No

Interviewer: Why?

Interviewee: For the painkillers, I don't usually read because I already know how they work. But when I buy other drugs, I read them.

Interviewer: Okay, thank you very much.

Interviewee: You're welcome.

16.

Interviewer: Hello madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions so you answer for me?

Interviewee: Okay.

Interviewer: Please what is your level of education?

Interviewee: First Degree

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes

Interviewer: Please what drug did you buy?

Interviewee: Dewormer and antimalarial.

Interviewer: Please when you bought it, did you see any leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: Not actually

Interviewer: Please why didn't you read it?

Interviewee: Because I already know how the drug works since I'm a health worker. I know everything about the drug I buy so there is no need reading about it

Interviewer: Okay, thank you.

Interviewee: You're welcome.

17.

Interviewer: Hello, Sir good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can you spare a few minutes of your time to answer some questions for me?

Interviewee: Go ahead.

Interviewer: What is your level of education?

Interviewee: First Degree

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: Pain killer, cough syrup, antimalarial.

Interviewer: Oh, okay. Please when you bought the drug did you see a leaflet in it?

Interviewee: Yes, I did.

Interviewer: Did you read it?

Interviewee: No

Interviewer: Why didn't you read it?

Interviewee: I didn't have the time to read it.

Interviewer: Really? Okay. Thanks very much.

Interviewee: You are welcome.

18.

Interviewer: Hello madam, good afternoon.

Interviewee: Good afternoon.

Interviewer: Please can I ask you some few questions?

Interviewee: Okay.

Interviewer: What is your level of education?

Interviewee: Senior High School

Interviewer: Please which of them?

Interviewee: Nursing Training

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: I bought Flucloxacillin and others.

Interviewer: When you bought it, did you see any leaflet in it?

Interviewee: Yes

Interviewer: Did you read it?

Interviewee: Yes, I did

Interviewer: Please when you read it did you understand what you read?

Interviewee: Not really.

Interviewer: Why?

Interviewee: Some of the words were not understandable. I found it difficult to understand. They were big words. That's why.

Interviewer: Okay, thank you.

Interviewee: You're welcome.

19.

Interviewer: Hello Sir. Good afternoon.

Interviewee: Good afternoon dear.

Interviewer: Please can I ask you some few questions?

Interviewee: Yes. Feel free.

Interviewer: What is your level of education?

Interviewee: I have an MBA

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: Coatem, dewormer, blood tonics.

Interviewer: Okay. Please when you bought the drugs did you see a leaflet in it?

Interviewee: Yes.

Interviewer: Did you read it?

Interviewee: Yes, but it's plenty and lengthy.

Interviewer: Did you understand what you read?

Interviewee: Yes. I understood almost everything. I think it's just a few that I didn't quite grasp them well, but on the average, I understood everything.

Interviewer: Okay thank you very much.

Interviewee: You are welcome.

20.

Interviewer: Good afternoon Sir

Interviewee: Good afternoon.

Interviewer: Please can I ask you some questions?

Interviewee: You may go ahead.

Interviewer: What is your level of education?

Interviewee: Degree

Interviewer: Please first or second degree?

Interviewee: First

Interviewer: Please have you bought a drug without prescription before?

Interviewee: Yes.

Interviewer: Please what drug did you buy?

Interviewee: I buy painkillers like paracetamol, Ibuprofen and others.

Interviewer: Do you see any leaflet in the drugs you buy?

Interviewee: Yes, sometimes.

Interviewer: Do you read it?

Interviewee: No

Interviewer: Please why?

Interviewee: I know the guy at the shop and I trust him so whatever drug he recommends for me, I know it's good so I don't see the need to still read the leaflet.

Interviewer: Okay thanks a lot for your time.

Interviewee: You are welcome.

APPENDIX B

SAMPLES OF PATIENT INFORMATION LEAFLETS

RONADOL®

Diclofenac Sodium & Paracetamol Tablets

COMPOSITION :
Each uncoated tablet contains :
Diclofenac Sodium BP 50 mg
Paracetamol BP 500 mg

EXCIPIENTS : Maize Starch, Di calcium Phosphate, Sunset Yellow, Gelatin, Sodium Methylparaben, Sodium Propylparaben, Magnesium Stearate, Talcum, Colloidal Silicon Dioxide, Sodium Starch Glycolate.

PHARMACOLOGY : Diclofenac sodium has potent anti-inflammatory, analgesic and antipyretic actions. The mechanism of actions is inhibition of the enzyme, cyclo-oxygenase in the pathway of prostaglandin (PG) synthesis. PGs are known to be associated with inflammation. Its ability to inhibit prostaglandin synthesis is involved in its anti-inflammatory activity, as well as contributes to its efficacy in relieving pain related to inflammation and primary dysmenorrhea. With regard to its analgesic effect, Diclofenac Sodium is not a narcotic analgesic.

Paracetamol has analgesic and anti-pyretic properties due to its ability to inhibit prostaglandin synthesis. Paracetamol produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulating center.

PHARMACOKINETIC PROPERTIES :

For Diclofenac Sodium : Diclofenac Sodium is quickly absorbed after oral administration. Peak plasma levels, which are 2028.9 ± 1020.0 mg/ml, are achieved within approximately 0.63 ± 0.57 hours of dosing with 50mg of diclofenac Sodium. Diclofenac is about 99.7percent bound to human serum proteins. About half the biological active component, are metabolized in liver by first pass effect. About 60 percent of a 50mg dose is excreted via the urine as metabolites, 1percent or less of a 50 mg dose is excreted as the original active component, the rest is excreted via bile.

For Paracetamol : It is rapidly and practically completely absorbed from the gastro-intestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is about 2 hours after therapeutic doses. It is distributed into most body tissues.

It crosses the placenta and is present in breast milk.

INDICATIONS : RONADOL is indicated in the treatment of painful rheumatic disorders such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout. Acute musculoskeletal disorders and soft tissue inflammation such as periarthritis, sprains, strains, tenosynovitis, bursitis, pain in fractures and dislocation. Relief of pain and inflammation associated with orthopaedic, dental, gynaecological and other minor surgical procedures.

DOSAGE AND ADMINISTRATION : Adults : 1 tablet 2-3 times daily.
Children : 1/4 to 1/2 tablet 2-3 times daily or as directed by the Physician.

CONTRAINDICATIONS : Hypersensitivity to the components of the formulation, peptic ulcers or GI bleeding.

SIDE EFFECTS : Redness of the rectal mucous membranes, Allergic reactions, Exanthema, urticaria, Liver damage, Increase in creatinine, abdominal pain, constipation, diarrhoea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers and vomiting, Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus, Fever, infection, sepsis, congestive heart failure, hypertension, tachycardia, syncope, dry mouth, esophagitis, gastric/peptic ulcers, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice, ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia, anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, vertigo, asthma, dyspnea, alopecia, photosensitivity, sweating increased, blurred vision, cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, renal failure.

Pregnancy

Teratogenic Effects

Pregnancy Category C : There are no adequate and well-controlled studies in pregnant women. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided.

Nursing Mothers : Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from diclofenac sodium and paracetamol tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use : Safety and effectiveness in pediatric patients have not been established.

DRUG INTERACTIONS :

Aspirin : concomitant administration can result in lower plasma concentration, peak plasma levels, and AUC values.

Digoxin, Methotrexate, Cyclosporin : Diclofenac Sodium may affect renal prostaglandins and increase the toxicity of certain drugs. Ingestion of Diclofenac Sodium may increase serum concentrations of digoxin and methotrexate and increase cyclosporine nephrotoxicity.

Lithium : Diclofenac Sodium decreases lithium renal clearance and increase to insulin or oral hypoglycemic agents.

Diuretics : Diclofenac Sodium can inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels.

Cholestyramine : Reduces absorption of Paracetamol.

Activated charcoal : Administered immediately reduces absorption of Paracetamol.

Domperidone & metoclopramide : Enhance absorption of Paracetamol

Alcohol : Chronic excessive ingestion of alcohol potentiates hepatotoxicity of Paracetamol.

Zidovudine : Effects of zidovudine may be decreased.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :
Symptoms of overdosage include nausea and vomiting. Liver damage which may be fatal may only appear after a few days. Kidney failure has been described following acute intoxication.

In the event of an overdose, consult your doctor immediately or take the patient to the nearest hospital at once.

Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre. Special measures such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to the high protein binding and extensive metabolism. Activated charcoal may be considered in case of a potentially toxic overdose, and gastric decontamination (e.g. vomiting, gastric lavage) in case of a potentially life-threatening overdose.

CAUTION : Overdosage of Paracetamol may be injurious to liver.

STORAGE : Store in a dry place below 30°C. Protect from light, heat and moisture. Keep medicines out of reach and sight of children.

PRESENTATION : 1 x 10 Tablets, 6 x 1 x 10 Tablets.

SHELF LIFE : 36 Months

DATE OF PUBLICATION : January 2018

DATE OF REVIEW : Every three years

FDB Reg. No. : FDB/SD.153-3121

213/P-AB/R2

Manufactured by :
RONAK EXIM PVT. LTD.
Gendigate, Baroda-1
(Guj) INDIA

Marketed & Distributed by :
Nissi Pharma Ltd.
Accra, Ghana

METHIONINE, CHOLINE& VITAMINS LIQUID

NEUTROSEC®

COMPOSITION :

Each 15 ml. contains :

DL-Methionine	USP XXI	100 mg
Choline Dihydrogen Citrate	NF XII	100 mg
Riboflavin (as Riboflavin Sodium Phosphate)	B.P.	3 mg
Thiamine Hydrochloride	B.P.	3 mg
Pyridoxine Hydrochloride	B.P.	1.5 mg
Nicotinamide	B.P.	22.5 mg
Dexpanthenol	B.P.	4.5 mg
Biotin	USP	0.1 mg
Folic Acid	B.P.	0.5 mg
Cyanocobalamin	B.P.	3 mcg
Alpha Tocopheryl Acetate	B.P.	7.5 I.U.

Colour used : Caramel

UNIQUENESS:

Neutrosec is a unique combination of liver protectives such as Methionine (responsible for the integrity of liver cells) and choline, these together in combination protects the liver from fatty infiltration by detoxifying certain endogenous and exogenous poisons.

Neutrosec also provides other multivitamins which play a key role in the metabolic activities of the liver.

Properties :

Methionine

Methionine is an essential amino acid that contains sulphur. Methionine is a non-polar molecule, meaning not water-soluble. This aliphatic linear chain is made up of mostly carbon, while also containing a single sulphur atom. A principle source of sulphur, which the body needs to replenish daily and it must be kept in balance with other amino acids, or nutritional imbalances could occur. Functions as an antioxidant (free radical deactivator) and neutralizes toxins by a process of conversion of Methionine into Glutathione, a master antioxidant, through S-adenosine Methionine and Cystathione. Methionine also helps to regenerate bile flow through its conversion into Taurine, which gets conjugated into bile salts and bile acid.

Choline

Choline is an essential nutrient, a B-vitamin. It can be manufactured in the body (from the amino acid Methionine), although there is some debate whether it can be made in sufficient amounts for optimal health. Folic acid and vitamin B12 are also needed to process choline. Choline plays a role in liver function and cardiovascular health. Choline is an important constituent of cell membranes, so choline has functions in virtually every bodily system. Choline participates in lipid (fat) transport in the body and may reduce accumulation of fat in the liver and also helps for the regeneration of plasma membrane.

Pharmacokinetics :
Methionine along with Choline and vitamins present in Neutrosec helps in regeneration of plasma membrane, liver cell regeneration and increased bile flow into intestine. Methionine, choline, Folic acid and vitamin B12 in particular helps to remove excess fat from the liver. The detoxifying property of Neutrosec is on its account of the conversion of Methionine into Glutathione.

Indications :
As a supportive therapy in,
1. Acute and chronic hepatitis
2. Alcoholic hepatitis
3. Fatty liver
4. Drug induced hepatitis
5. As an adjuvant to hepatotoxic drugs

CONTRA-INDICATIONS:
Hypersensitivity to any of the ingredients. Pantothenol is contra-indicated in haemophiliacs and in patients with ileus due to mechanical obstruction.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Vitamin B6: Reduces the effects of levodopa.

DOSAGE:
15ml (1 tablespoonful) two times a day or as directed by the physician.

SAFETY:
Neutrosec is generally considered to be quite safe in all age groups and is well tolerated.

PACKING:
Amber bottle of 110ml & 200ml in an individual carton.

STORAGE:
Store below 30°C

"KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN"

T/NTL/SELF/1B

Made in India by:
TIL HEALTHCARE PVT LTD
100, Sri city SEZ, Irugulam Post,
Andhra Pradesh - 517 588. India.

Nugel

Antacid Antiflatulent Combination

Composition:
Nugel Suspension / Tablets
Each 15 ml / chewable tablet contains

Alginic Acid	BP	200 mg
Magnesium Hydroxide	BP	250 mg
Dried Aluminium Hydroxide	BP	250 mg
Magnesium Trisilicate	BP	250 mg
Dimethicone (Activated)	BP	125 mg

EXCIPIENTS
Nugel Suspension: Sorbitol Solution 70%, Propylene Glycol, Methyl Paraben, Propyl Paraben, Sodium Saccharin, CMC Sodium, Sodium Citrate, Guar Gum, Flavour, Colour

Nugel Tablets: Sugar, Starch, Aerosil, Magnesium Stearate, Aspartame, Flavour, Colour

ACTIONS AND PHARMACOLOGY : NUGEL is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with NUGEL and this makes it especially suitable when long term therapy is necessary.
Simethicone either alone or with antacid mixture acts as an antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from the stomach or down from the colon. Antacid Simethicone combination may also be useful for the relief of hiccup in palliative care.

Alginic Acid is combined with antacids to encourage adherence of the mixture to the mucosa. Alginate as mucosal protectant is useful in reflux oesophagitis. As the ingredients used in this drug are well established, tolerated and accepted all over the world and hence test confirming its physiological availability pharmacological effects studies are not conducted.

PHARMACOKINETICS : The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

INDICATIONS : NUGEL acts as an antacid in dyspepsia and is used for the symptomatic relief of gastritis, hyperacidity associated with peptic ulceration.

DOSAGE & ADMINISTRATION : One tablespoon full (15ml) or One tablet twice daily for adults, One teaspoon full (5ml) for children or as directed by the physician

SIDE EFFECTS: Some patients may experience dizziness, faintness or drowsiness. Sensitivity reactions including skin eruptions (dermatitis, urticaria), pruritus, glossitis, have been reported. Magnesium-containing antacids may cause diarrhoea. Aluminium-containing antacids may cause constipation.

CAUTIONS : The use of magnesium-containing antacids in patients with mild to moderate renal impairment should be carefully monitored due to a possible increased danger of hypermagnesaemia. In patients with chronic renal failure, hyperaluminaemia may occur. Encephalopathy and dementia may occur in patients with poor renal function or patients on dialysis, due to an increase in plasma concentration of aluminium. Hypophosphataemia may occur with prolonged administration or large doses of aluminium-containing antacids (except aluminium phosphate) especially in patients with an inadequate dietary intake of phosphorus. Laboratory Tests Serum phosphate levels should be monitored at monthly or bi-monthly intervals in patients on maintenance haemodialysis who are receiving chronic antacid therapy.

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only

Haematinic Liquid

Zincofer

Liquid

For Therapeutic Use

COMPOSITION:

Each 15 ml contains:

Ferric Ammonium Citrate	USP	225 mg
Nicotinamide	BP	50 mg
Pyridoxine Hydrochloride	BP	1.5 mg
Cyanocobalamin	BP	7.5 mcg
Zinc Sulfate Heptahydrate	BP	44.4 mg

in a flavoured base

ACTIONS: Zincofer is an orange flavoured palatable haematinic liquid. It provides 50mg of elemental iron and 10 mg of elemental zinc per tablespoonful. It corrects loss of appetite during pregnancy. **Zincofer** corrects commonly occurring anaemias.

INDICATIONS: Zincofer is indicated in treatment of iron deficiency and iron deficiency anaemia prevention of iron deficiency before, during and after pregnancy, during the second and third trimester of pregnancy for prophylaxis against Iron deficiency and megaloblastic anaemia.

WARNING AND PRECAUTIONS: Iron overdose may be fatal. Some post-gastrectomy patients show poor absorption of Iron. Care is needed when treating iron deficiency anaemia in patients with treated or controlled peptic ulceration. Caution should be exercised when administering Folic acid to patients who may have folate dependent tumours. Since anaemia due to combined Iron and Vitamin B12 or folate deficiencies may be microcytic in type, patients with microcytic anaemia resistant to therapy with iron alone should be screened for Vitamin B12 or folate deficiency.

SIDE EFFECTS: Gastro-intestinal disorders have been reported including gastro-intestinal discomfort, anorexia, nausea, vomiting, constipation, diarrhoea. Darkening of the stools may occur. Rarely allergic reactions may occur.

PREGNANCY AND LACTATION: Since **Zincofer** is haematinic, safely given during pregnancy and lactation. Administration of **Zincofer** during the first trimester of pregnancy may be undesirable. It is not known how much iron from **Zincofer** is passed into mother's milk. The development of anaemia despite prophylaxis with **Zincofer** calls for investigation.

DRUG-DRUG INTERACTION: Concurrent administration of antacids may reduce absorption of Iron. Iron reduces the absorption of penicillamine. Iron compounds impair the bioavailability of fluoroquinolones, levodopa, carbidopa, thyroxine and bisphosphonates. Absorption of both Iron and antibiotic may be reduced if **Zincofer** is given with tetracycline. Absorption of both Iron and Zinc are reduced if taken concomitantly. Oral chloramphenicol delays plasma iron clearance, incorporation of Iron into red blood cells and interferes with erythropoiesis. Some inhibition of Iron absorption may occur if it is taken with cholestyramine, trientine, tea, eggs or milk. Administration of oral Iron may increase blood pressure in patients receiving methyldopa. Coffee may be a factor in reducing Iron bioavailability. Neomycin may alter the absorption of Iron.

CONTRAINDICATION: Zincofer is contraindicated in patients with known hypersensitivity to any of the ingredients in the formulation, Vitamin B12 deficiency, paroxysmal nocturnal haemoglobinuria, haemosiderosis, haemochromatosis, active peptic ulcer, repeated blood transfusion, regional enteritis and ulcerative colitis. **Zincofer** must not be used in the treatment of anaemias other than those due to iron deficiency.

DOSAGE: 2 - 5 years: 5 ml, 5 - 12 years: 10 ml, Adult above 12 years: 15 - 30 ml. All twice a day after meals or as directed by the Physician. The recommended duration is 3 to 6 months.

OVERDOSAGE: Signs and symptoms of severe iron poisoning consist largely of abdominal pain, diarrhoea or vomiting brown or bloody stomach contents of particular concern are pallor or cyanosis, lassitude, drowsiness, hyperventilation due to acidosis and cardiovascular collapse. If any of the above symptoms appear due to very high dose then, deferoxamine should be administered.

LIST OF EXCIPIENTS: Sucrose, Sodium Benzoate, Disodium Edetate, Sorbitol, Glycerol, Propylene Glycol, Citric Acid, Orange Flavour.

COLOUR: Sunset Yellow

CAUTION: Keep out of reach of children.

PRESENTATION: 200 ml amber bottle with a measuring cup in an attractive carton.

STORAGE CONDITION: Store below 25°C in a dry place. Protect from light.

DATE OF PUBLICATIONS/REVIEW: May 2012

apex

Manufactured by:
apex laboratories private limited
Tamil Nadu, INDIA.

GNAZFLLLB069E

DRUG INTERACTIONS : The rate and/or extent of absorption of many medicines may be increased or decreased. Therefore, medication should not be taken within one to two hours of NUGEL. An incomplete list of substances for which the above statement has been shown to apply includes: tetracycline, iron salts, isoniazid, ethambutol, some anti-muscarinic drugs, benzodiazepines, phenothiazines ranitidine, indomethacin, phenytoin, nitrofurantoin, Vitamin A, fluoride and phosphate. An increase in the plasma level of quinidine and possible toxicity may result in alkalisation of the urine occurs following antacid therapy.

CONTRAINDICATIONS: Do not use this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline. This medicine should not be given to any patient who has demonstrated a sensitivity to it. The use of aluminium- or magnesium-containing antacids is contra-indicated in patients with symptoms of appendicitis, since these medicines may increase the danger of perforation or rupture due to their constipating or laxative effects. The use of aluminium-containing antacids (except those containing aluminium phosphate) is contra-indicated in patients with hypophosphataemia due to the phosphate binding properties of aluminium salts. The use of magnesium-containing antacids is contra-indicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesaemia. Pregnant and lactating women can take it after consulting the Physician

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Antacids may interfere with drugs by Increasing the gastric pH altering disintegration, dissolution, solubility, ionization and gastric emptying time.

Absorbing or binding drugs to their surface resulting in decreased bioavailability such as tetracycline

Increasing urinary pH affecting the rate of drug elimination.

Urinary excretion of certain drugs may also be affected.

Antacids reduce the absorption of ACE Inhibitors Beta blockers

Antacids containing Magnesium saltmay increase absorption of Sulphonylureas and there by increases the hypoglycemic effect

OVERDOSE : Treatment is symptomatic and supportive.

STORAGE CONDITION : Store in a cool dry place, protected from light.

WARNING & PRECAUTIONS : No clinical data on exposed pregnancies are available. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women. Adequate diagnostic studies are recommended. The possibility of gastrointestinal carcinoma should be considered in patients with protracted or recurrent indigestion.

SHELF LIFE : Nugel Tablet & Suspension should be administered within 30 months from the date of manufacture.

PRESENTATION : NUGEL Suspension - 200 ml / 100ml bottle & 15ml x 15 Sachets in a carton.
NUGEL Tablet - 10 tablets in a blister and 3 such blisters in a Box

Manufactured in India by :
Sai Mirra Innopharm Pvt. Ltd.
Chennai.

INNUG5 Indus