PREVALENCE OF OVER THE COUNTER (OTC) MEDICINE USE AND THE POTENTIAL OF DRUG-DRUG INTERACTIONS WITH CONCOMITANT PRESCRIPTION MEDICINE USE AT AN OLD AGE HOME IN JOHANNESBURG

A research report submitted by

Sandile Olivia Dube

(1318148)

in partial fulfilment of the requirements for the degree of

Master of Science in Medicine (Pharmaceutical Affairs)

to the

Faculty of Health Sciences

at the

University of the Witwatersrand

Supervisor: Dr Neelaveni Padayachee

Johannesburg, August 18, 2021

DECLARATION

I Sandile Olivia Dube (1318148), declare that this research report is my own, unaided work. It is being submitted for the Degree of Master in Science in Medicine (Pharmaceutical Affairs) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____

(Signature of candidate)

_____18th____day of _____August____2021_____at____Gallo Manor, Johannesburg___

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

I am appreciative of the continued support from the following people who encouraged me towards the successful completion of my research report:

- Supervisor: Dr Neelaveni Padayachee
- My children: Tadiwa and Hakeem
- Cousin sister and brother: Lumbi and Zwelithini

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

DEFINITIONS

Reported drug-drug interactions

The drug-drug interactions that were generated by the interaction checker between prescription medicines and over the counter medicines.

Alternative medicines

Medicines that are classified as either complementary medicines or herbal medicines and are not considered conventional medicines.

Inappropriate prescribing

Prescribing medication that is outside the confines of being considered medically acceptable.

Underutilization of medications

When prescription medicines are intentionally not used for the treatment or prevention of disease conditions that they were prescribed for by the doctor/physician.

Chronic medication

Medication obtained at the pharmacy by means of a prescription from the doctor.

Drug-drug interaction

When 2 or more medicines' concomitant use affects the efficacy, safety and metabolism of either one or all the medicines involved in the interaction.

ABSTRACT

Background: The prevalence of the use of OTC medicines in the elderly in South Africa is understudied. The elderly are known to use OTC medicines in combination with their chronic medicines. To prevent drug-drug interactions and adverse drug reactions, understanding the commonly used OTC medicines amongst the elderly will assist in preventing complications and reducing healthcare costs for these patients.

Objectives: To describe utilization patterns of OTC medicines, perceptions and the potential of drug-drug interactions from OTC medicine use amongst the elderly at an old age home.

Method: The study was a cross-sectional, quantitative study. One hundred and six questionnaires were completed by study participants, between the ages of ≥65 to ≤85. The study was conducted at Summerfield Park Methodist Home, in Johannesburg between December 2019 – August 2020. A questionnaire was used as the data collection tool. Data were analyzed using Microsoft® Excel.

Results: Eighty six and a half percent (95% CI, 83.7% - 90.0%) of the study participants used at least one OTC medicine. Severe drug-drug interactions made up 15.5% of those reported. Forty five percent of the study participants responded that they use OTC medicines at the first sign of illness.

Conclusion: The prevalence of use of OTC medicines was high and there is a general lack of knowledge of their safety and efficacy. The potential for drug-drug interactions between OTC and prescription medicines exists and healthcare providers need to have practice good history taking.

INTRODUCTION

1.1 Introduction

This chapter gives an overview of over the counter (OTC) medicines. Furthermore, it provides the background information to the rationale for conducting this study.

1.2 Background and rationale for the study

The use of over the counter (OTC)/non-prescription medicines in geriatrics in South Africa is understudied.[1] Prevalence of use of OTC medicines in high-income countries has been increasing over the years.[1] It is important that low-middle income countries understand the use of these types of medicines in their populations to create intervention systems to ensure the safe use of OTC medicines.[1]

The role of pharmacotherapy in the elderly as with any other age is to cure, be palliative and improve the health-related quality of life (HRQOL).[2] Improved physical, social and physiological functioning are the pillars of HRQOL.[2] Medicine related problems usually hinder achieving these benefits of pharmacotherapy and concerns arise on usage levels and potential of drug-drug interactions of prescription medicines with OTC medicines when used concomitantly.[2]

Studies conducted in other countries reveal a high use of OTC medicines in their older populations and an escalated risk of potential drug-drug interactions.[2,3] Non-optimized medicine use results in avoidable financial expenditure due to increased hospitalization and further treatment to manage older adults who have experienced undesirable events due to drug-drug interactions.[2,3]

An understanding of any misconceptions or lack of knowledge about the use, safety, efficacy and toxicity of OTC medicines by the elderly is important to be able to intervene appropriately. Inappropriate use may be linked to a lack of information on how to use the medicines and the consequences associated with the misuse of OTC medicines.[3]

1.3 Research Question

The study was conducted to answer the following research questions; What are the utilization patterns of OTC medicines by the elderly and what are their perceptions towards OTC medicines. And are there potential drug-drug interactions between OTC medicines and prescription medicines used by the elderly. This study will be beneficial in giving more insight into OTC usage levels, perceptions associated with OTC medicines and potential drug-drug interactions amongst older adults in South Africa.

1.4 Aim

The study aims to discover the utilization patterns of OTC medicines and the potential drug-drug interactions amongst elderly patients at an old age home.

1.5 Objectives

1. To describe the utilization patterns of OTC medicines in the elderly population at an old age home.
2. To describe perceptions on the use of OTC medicines in the elderly population at an old age home.
3. To identify potential drug-drug interactions between prescription medicines with OTC medicines.

1.6 Conclusion

This chapter provided insight into the rationale for the study and an overview of OTC medicines. The chapter covered the current data available on use of OTC medicines in older adults and the aims and objectives of the study.

LITERATURE REVIEW

2.1 Introduction

This chapter provides insight into the literature on OTC medicines including what they are, why they are used and the benefits and risks of their use in the geriatric population. It gives an overview of OTC medicines, their benefits, and potential disadvantages in varying scenarios. It also gives details on drug-drug interactions and how patient perceptions affect the use of OTC medicines.

2.2 What are OTC medicines and their role in pharmacotherapy?

Over the counter medicines are medications sold without a prescription from a doctor or other authorized prescriber (nurses and pharmacists) and includes traditional and herbal medicines.[4] With a market share of 31%, the OTC medicine sector in South Africa was valued at 10.2 billion rands in 2015.[5]

Over the counter medicines are important in the treatment of minor ailments which include pain, allergies, cough and cold conditions.[6] Minor ailments are defined as illnesses that are of limited severity which can be self-limiting or can be easily self-diagnosed by the general population and self-treated through the use of OTC medicines.[6,7,8]

2.3 Regulation of OTC medicines in South Africa

In South Africa, medicines are regulated by the South African Health Products Regulatory Authority (SAHPRA). SAHPRA is an entity of the National Department of Health and it regulates all health products in South Africa to ensure safe, effective and quality medicines and medical devices are registered and used in South Africa.[9] The sale and supply of medicines are governed by Section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended).[9]

Medicines in SA are grouped in schedules, i.e., Schedule 0 to Schedule 8 according to risk profiles of the active pharmaceutical ingredient at a specific quantity and dosage form.[9] Schedules are a grading system set by the regulating body to control the sale and supply of medicinal products.

With control increasing as the schedule number rises, i.e., Schedule 0 medicines are those that can be sold in general sales outlets such as supermarkets, for example, paracetamol in a 24 pack.[9]

Schedule 0 are those considered by the regulator as largely safe for use without the need for regular monitoring and where counselling and advice regarding the use of the medicinal product are not essential such as with paracetamol.[9]

In South Africa, OTC medicines consist of Schedule 0, Schedule 1 and Schedule 2. Schedule 1 (S1) (e.g., ibuprofen) and Schedule 2 (S2) (e.g., chlorpheniramine) medicines are mainly sold by pharmacists, pharmacist interns or pharmacist assistants under the direct supervision of a pharmacist without the need for a prescription. Other healthcare professionals such as medical practitioners or dentists can also compound and dispense S1 and S2 medicines if they are a holder of a license as stipulated in section 22C of the Medicines and Related Substances Act No.101 of 1965.[9]

The sale of S2 medicines is more stringently controlled as compared to the other OTC medicines. Although S2 medicines do not require a prescription, they require verification by the pharmacist as appropriate for the ailment that the patient desires to treat. The regulator recognizes S2 medicines as largely safe for use however they require advice, counselling and monitoring to be conducted by the pharmacist or other healthcare professionals. A permanent record of the sale of the S2 medicine should be made with all the necessary information such as patient name, patient identifier (ID, birth date), product specifications.[9]

2.4 OTC medicines and their role in self medication

The World Health Organization (WHO) stresses the need for patients using OTC medicines to be well taught on their use.[4] OTC medicine use is a form of self-medication (SM)[5]. The use of SM has been in existence for many years, as an alternative for physician-initiated pharmacotherapy.[10] The practice of using medicines without obtaining medical information from a healthcare professional is defined as self-medication and is based on self-knowledge and/ or advice from other lay people.[10,11,12]

Concerns arise if the OTC medicines are used safely and in the correct doses.[10] Self-medication has several advantages to the healthcare system; these include increased access to medicines to a greater number of people and fewer patients visiting doctors for minor ailments.[13] In almost half of the illnesses that occur it has been found that most people will use OTC medicines as their first response especially when the illness is not considered serious.[4,14,15] SM use has been found to be more prominent in the elderly and a study in Spain found that 34% of study participants had more than 3 boxes of the same medication in their medicine cabinet.[16] The table below summarizes the benefits and risks of self-medication.

Table 1: Benefits and Risks of Self Medication

Benefits	Easy accessibility[17] Affordable (when compared to the process involved in acquiring prescription medicines) [17] Health care providers (pharmacists, doctors) can focus on more serious ailments[17]
Risks/Disadvantages	Inappropriate use (due to lack of knowledge on how to use or abuse) [17] Inaccurate medicine selection (mismatch between ailment and medication) [17] Drug-drug interactions with existing prescription medicines that the patient is taking for a chronic condition[18] Duplication of active pharmaceutical ingredients (purchase of different named medicines which have the same medicinal product) [18] Under-reporting to healthcare providers can lead to misdiagnosis or over medication if adverse reactions are caused by self medication[17] Serious illnesses can be masked or delayed using OTC medicines.[28]

Many prescription medicines have in the past few decades become available as OTC medicines, making more medicines available to treat various ailments without the need of seeing an authorized prescriber.[4] Changes in control of medication has in most countries including South Africa been based on clear guidelines and demonstrated safety to ensure that only medicines that have been proved to be safe for SM are available to the public.[3] Utilization of the clinical skills of pharmacists has also been a positive outcome for the use of SM where they assist patients by assessing patients' needs and provide patient education which empowers older patients when making future section of OTC medicines.[19]

2.5 Pharmacotherapy considerations in the Elderly

The study population was a cohort of older adults between 65-85 years old, this age group consisted of individuals who are generally still active, with independent lives. Advancement in age is accompanied by deterioration of physiologic functions, which have been found to decrease by up to 30% as compared to younger adults.[2,20] Older adults may be more sensitive to the effects of medicines as the ability to metabolize medicines deteriorates with age.[2]

Pharmacotherapy in the elderly should take into consideration the gradual decline in physiological functions, because they may be more vulnerable to adverse reactions or drug toxicity due to altered pharmacodynamics and pharmacokinetics.[2,20] Renal and hepatic function are more variable with the elderly, and this requires that medicines used by this age group are individualized to prevent the occurrence of adverse effects.[21]

Renal function can decrease by more than 35% in the elderly without any underlying renal disease.[3] With age also comes the increase in the number of pathologies and inevitably a higher number of medicines used to manage multiple comorbidities that may affect the elderly, increasing the risk of the occurrence of adverse drug-drug interactions.[3] However, response to medication is highly individualized, age-related changes can be minimal especially in the "healthy old". Other factors that may influence the effects of medicines are nutritional problems, simultaneous diseases and compliance.[22]

2.5.1 Adverse events/reactions and Polypharmacy

Adverse events are undesirable reactions to medicines that are unanticipated and occur at normal doses that are within the therapeutic window for treatment, diagnosis and palliative care in humans.[23] The risk of adverse events occurring increases with each additional medication that is included in a patients' regimen.[23] Gray SL., et al. reported that 10-35% of adverse events reported are from community-dwelling geriatrics.[2]

The use of multiple medicines to manage a patient's pathologic conditions is known as polypharmacy. [2,24] Polypharmacy has traditionally been defined as the use of more than 5 medicines concomitantly.[2,25] This definition allows for relatively easy implementation of strategies to eliminate polypharmacy as it would involve reducing the number of medicines prescribed to the patient however, it does not fully take into account why the patient was prescribed those medicines by the physician, given that the definition is more arbitrary than clinical.[2,25]

Polypharmacy has more recently been defined as the use of more medicines than is clinically required.[2] The latter definition is preferable as it measures the appropriateness of each medicine prescribed to a patient and requires the clinician or pharmacist to fully assess and review the patient's medication list and identify areas of concern.[22]

The evaluation would include any other medications that the patient uses for self-medication. The use of unnecessary medications in older adults has been identified in studies to be between 55-59%, therefore, once the healthcare team that manages the patient clinically have a full picture of the medications that the patient is taking it allows for better evaluation and implementation of strategies to minimize polypharmacy and achieve clinical goals.[2,26]

The incidence of adverse events has been found to be twice as high in the elderly, than in other age groups.[23] In a study in 2011, 36% of older adults in a community-dwelling were categorized as being on polypharmacy.[44] This reflects that polypharmacy is concerning in the elderly and clinical evaluations of the appropriateness of medicines would help improve and lead to better clinical outcomes and reduce the risk of adverse reactions that may occur if the patient is being exposed to more than the necessary number of medications.[2,25]

Undesirable events such as geriatric syndromes (falls, cognitive impairment), hospitalizations can be minimized through the implementation of control mechanisms (clinical assessments and reviews) to reduce polypharmacy and educate the elderly about self-medication.[25]

2.5.2 Drug-drug Interactions

A drug-drug interaction occurs when a medicine affects the pharmacokinetic and/or pharmacodynamic properties of another medicine, which may result in undesirable effects on the patient taking the medicines.[27,28]

A study by Qato, D.M., et al (2008), found that half of all possible drug-drug interactions involved non-prescription medicines.[3] There is also the risk that people purchasing OTC medicines are not able to use them correctly which can lead to undesirable events.[27,28] The World Health Organization (WHO) stresses the need for patients using OTC medicines to be well taught on their use.[4]

Older adults must be encouraged to communicate with their doctors on OTC medicines they are using to reduce the risk of drug-drug interactions.[18,26] Inappropriate use of OTC medicines comes with several risks such as drug intoxication, drug-drug interactions, adverse drug reactions and consequently elevated healthcare costs to manage patients who get hospitalized due to inappropriate medicine use.[18]

O'mahony, D., and Gallagher, P. F., (2008) found that most older adults were not taking the correct doses of their OTC medicines.[29] This is influenced by several factors, such as instances where patients will either overdose or use OTC medicines for a prolonged period of time if they perceive the targeted ailment is not improving.[26,29,30] Lam A. and Bradley G. (2006) found that some older adults were using OTC medicines with the same active ingredients at the same time and this raises the risk of overdose.[31]

2.6 Patient perceptions and OTC medicine use

Perception of health status has been found in several studies as a contributor to the use of OTC medicines. Wu. S., et al found that self-rated health status can serve as a global measure of health

status as it is comparable to objective health status. [32] Self rated health status is influenced by the individual's desire to achieve their health goals and can be used as a tool to assess their OTC medicine use patterns. [33,34] Therefore, in this study we will investigate the relationship between self-rated health status and the use of OTC medicines.

2.7 Conclusion

Goh, L.Y., et al (2009) have found that the use of OTC medicines in older adults is an understudied area globally.[35] Current available research on the use of OTC medicines in elderly people are mainly in the European and North American regions, there is very limited or no study information on the same topic in the African region, specifically in South Africa. OTC medicines are usually the medicine of choice for the treatment of self-limiting illnesses as they are more economical without the need to pay consultation fees for a prescription.[30] With this in mind, and an increasing population of elderly people it is important to monitor the use of OTC medicines by the elderly in South Africa.[31]

The elderly population in South Africa has grown to approximately 4 million elderly people over 60 years of age.[36] It is estimated that by 2030, 7 million elderly people will make up the population.[36] This study, therefore, aims to discover the utilization patterns of OTC medicines and the potential drug-drug interactions amongst elderly patients at an old age home in Johannesburg. The goal of this study is to better understand the knowledge and perceptions the elderly have on OTC medicines. The results obtained will contribute to building a knowledge base of the prevalence of OTC medicines used amongst the elderly and assist the identifying knowledge gaps if any amongst the elderly and interventions can be developed from these findings.

METHODOLOGY

3.1 Introduction

This chapter describes the methodology of the study, providing the study design, setting, population and sampling details. It gives details into the selection criteria, followed by the pilot study that was conducted to validate the questionnaire and details on ethics approval. It also covers the data collection tool which was the questionnaire. It concludes by providing details of the data analysis and the tools used in processing the data collected.

3.2 Study design

This cross-sectional, quantitative study was conducted between December 2019 – August 2020. Data regarding participant demographics (age, gender, level of education), general health status, names of prescription medicines and OTC medicines, and perceptions on the use of OTC medicines were collected.

3.3 Study setting, population and sampling

The study population included the residents of an old age home in Johannesburg, Summerfield Park Methodist Home (SPOAH) aged between 65-85 years old. This site was selected due to the accessibility of the site to the investigator**.** Additionally, it was the only site that accepted the invitation to participate in the study.

The facility accommodates elderly residents of varying ages with 260 elderly people. Residents aged between ≥ 65 years of age and ≤ 85 years old from SPOAH were recruited to participate in the study through communication via the SPOAH administration office.

Inclusion Criteria

1. Individuals ≥ 65 years of age and ≤ 85 years old.
2. Individuals who reside at the Summerfield Park Methodist Home.
3. Individuals currently on prescription medication.

Exclusion Criteria

1. Employees at the old age home.
2. Non-residence of the old age home.
3. Individuals not on prescription medicine.

3.4 Pilot Study

A pilot study was carried out with a sample size of 10 experts from the Faculty of Health Sciences. This assisted in measuring the reliability, validity and robustness of the questionnaire. It also allowed the testing of statistical processes. Amendments to the questionnaire were made taking into account the responses from the experts who reviewed it. They recommended making some questions more clear, given the age of the participants and ensuring the questionnaire was as concise as possible. Data from the pilot study was not used in the study analysis.

3.5 Ethics

Ethics clearance number: M180659

The Human Research Ethics Committee (medical) granted ethics approval. The consent form was read out to the prospective participants of the study (pre-COVID) pandemic and was available on the digitized form (during the COVID lockdown period). Participation was voluntary.

Participants were made aware that they have the right to withdraw at any stage of the study and this was mentioned during the informed consent process. Participants' personal information will be kept confidential and anonymous. Once the study is completed, the research outcomes will be made available to the old age home management and residents if required.

3.6 Questionnaire

The questions that made up the questionnaire were derived from similar studies on the use of OTC medicines by elderly people and took an average of 15-20 minutes to complete[37] (**Appendix 1)**. The questionnaire was divided into 4 main sections namely; demographics, chronic/prescription medicines, OTC medicines and perceptions.

Data variables collected included;

1. Participants' demographics (Age, Gender)[35,37,38]

2. Level of education[37]
3. Participants' perception of their state of health[37]
4. Types of prescription medicine used[37]
5. OTC medicines used by participants[37]
6. The types of conditions they are treating[37]
7. Participants' perception of OTC medicines[19]

3.7 Interaction checker

Essential Medical Guidance (EMG) is a clinical and medical information platform that provides medical/clinical information to healthcare professionals and is freely accessible. EMGuidance interaction checker was used to confirm potential drug-drug interactions between prescription medicines and OTC medicines that the participants were concomitantly taking on an individual basis. The EMGuidance interaction checker categorises drug-drug interactions into 3 levels i.e minor, moderate and serious, with increasing severity of the drug-drug interaction respectively.

The medicines were checked for interactions using the identifiable brand names, this provided information on the potential influence of excipients in the formulation. The EMGuidance interaction checker database is based on medicines used in South Africa and therefore was the preferred choice.

For each patient who used prescription medicines in combination with OTC medicines, the medicine names were loaded in the interaction checker and the report for each combination was assessed.

3.8 Data Analysis - Excel

The data collected was analyzed using Microsoft Excel. The data was arranged into tables based on the four categories of the questionnaire. Thereafter, pivot tables were used to group the data and analyze it based on the objectives of the study.

Prevalence was calculated to obtain a percentage value of the prevalence and at the 95% CI. The p-value for checking if there are no differences in the use of OTC medicines between males and

females was also calculated using the T-test distribution. The frequency of use of chronic medicines and OTC medicines, illnesses reported by participants in the questionnaire were analyzed and presented in graphs, tables and figures.

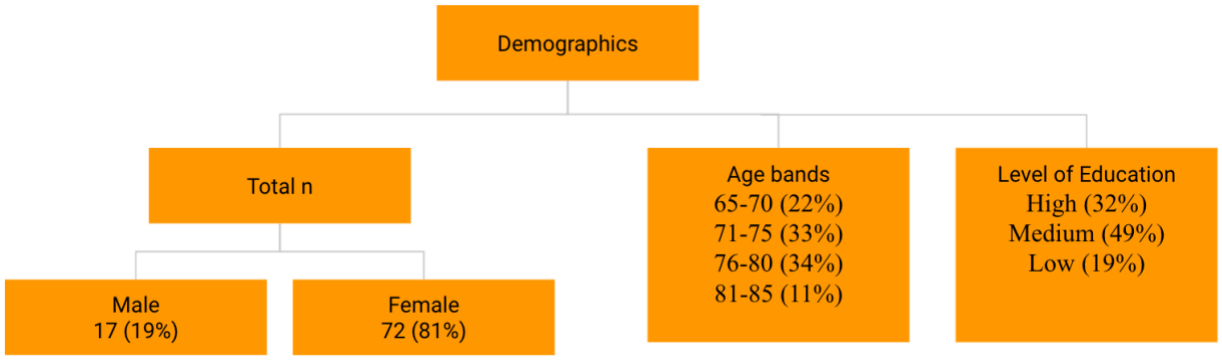
RESULTS

4.1 Introduction

The results chapter includes information that was gathered from the questionnaires completed by the participants. A total of 106 questionnaires were completed of the 200 distributed to enrolled participants, which translated to an unweighted response rate of 51.4%. Eighty nine questionnaires met the study inclusion criteria and were analyzed using excel.

4.2 Demographics

Figure 1: Demographics

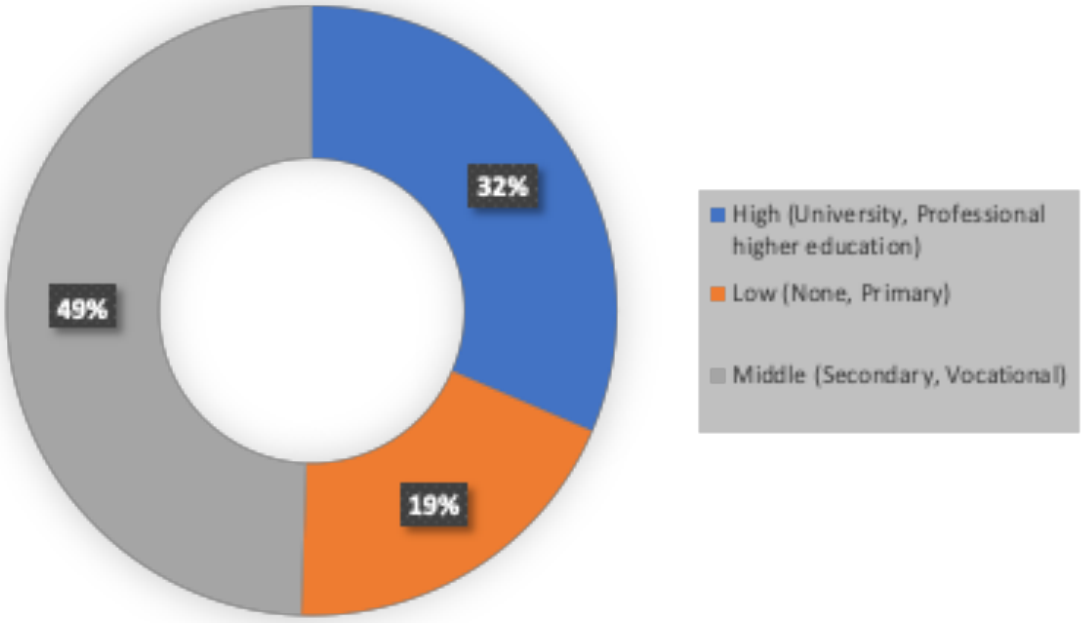


Eight one percent, (n=72) of the participants were female while 19% (n=17) were male. **Figure 1** reports on the age representation of the cohort, with the largest proportion of participants being in the 76-80 (34%) and 71-75 (33%) age band.

4.3 Level of Education

Figure 2 shows 49% (44) of the participants responded that they had middle-level education (secondary, vocational), 31% (28) high-level education (university, professional higher education) and 19% (17) low-level education (none, primary).

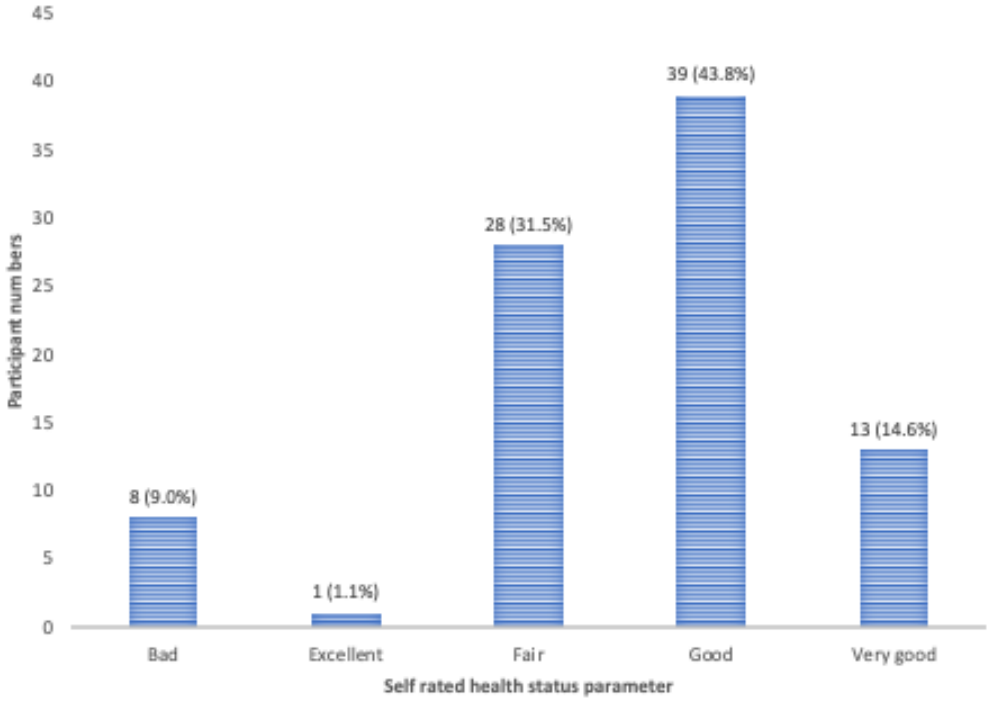
Figure 2: Participants' level of education



4.4 Self rated health status

Participants rated their general health status as being one of the following; Excellent (1%, 1), Very good (15%, 13), Good (44%, 39), Fair (31%, 28), Bad (9%, 8). Shown in **Figure 3.**

Figure 3: Participant's Self Rated Health Status



4.5 Chronic medicine use

The number of chronic medicines used by the elderly ranged between the use of 1 (5, 5.6% of respondents) to 13 (1, 1.1% of respondents) see **Table 2**. The use of 3 chronic medications in the chronic medicine regimen was the highest amongst the participants (27, 30.3%). The median was calculated to be 3. The mean usage was calculated as 3.8 chronic medicines.

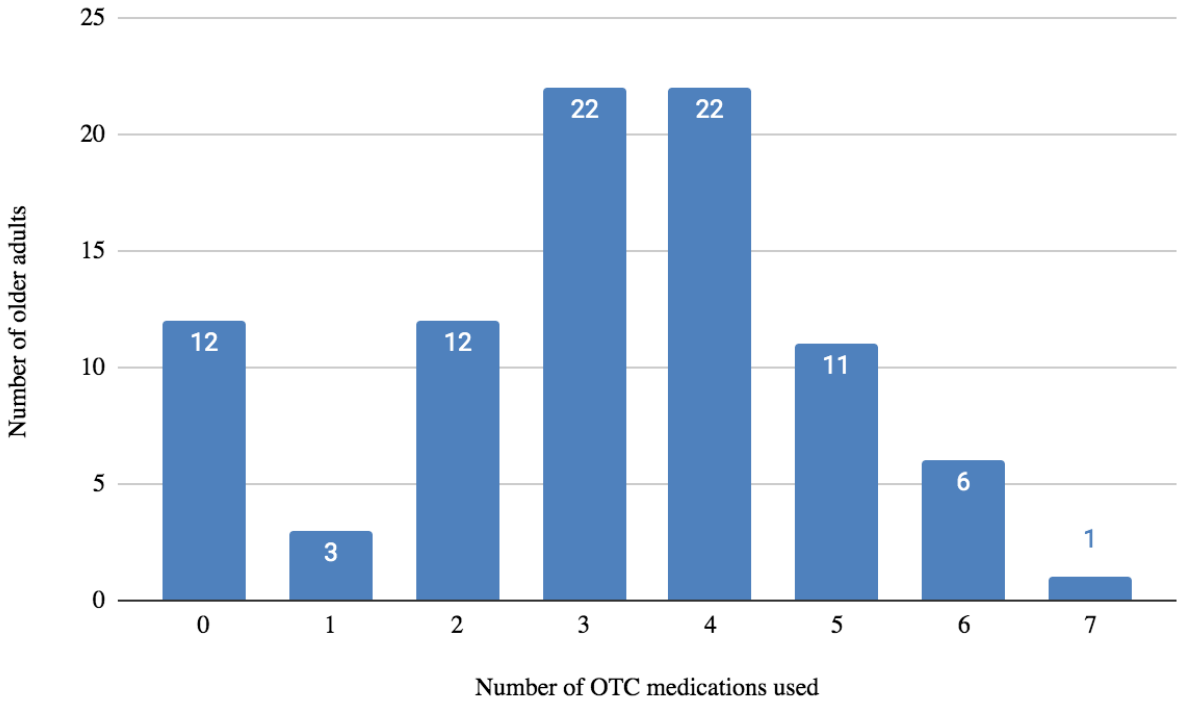
Table 2: Chronic Medicines in treatment regimen vs number of older adults

Chronic medications in treatment regimen	Number of older adults taking this number of chronic medicines
1	**5**
2	**16**
3	**27**
4	**15**
5	**14**
6	**5**
7	**2**
8	**4**
9	**0**
10	**0**
11	**0**
12	**0**
13	**1**
Median	**4**

4.6 OTC medicine use

The number of OTC medicines used by the elderly ranged from zero (13.5%) to use of seven (1.1%) **Figure 4**. The range was calculated as 7 (7 (max) - 0 (min)). Most participants used between three (22%) and four (24.7%) OTC medicines and the mean usage was calculated to be 3.1.

Figure 4: Number of older adults vs. Number of OTC medications taken by participants



4.7 Prevalence of use of medicines

4.7.1 Use in study participants

Just over four-fifths of the population, 86.5% (95% CI, 83,7% - 90.0%) responded that they use at least one OTC medicine and 13.5% (95% CI, 10.7%-17.0%) did not use any OTC medicines. Approximately 69.7% (95% CI, 66.9% - 73.2%) used 3 or more OTC medicines and 20.2% (95% CI, 17.4% - 23,7%) of the participants used 5 or more OTC medicines. Concomitant use of OTC medicines and prescription medicines was at 82.0% of the study participants. All the participants in the study used at least one prescription medicine.

4.7.2 Gender-based

Men where the highest users of OTC medicines with 88.2% (95%CI, 85.5% - 91.7%) using at least one OTC medicines, 70.6% (95%CI, 67.8% - 74.1%) using at least three OTC medicines and 23.5% (95%CI, 20.8% - 27.0%) using at least five OTC medicines.

In female participants, 86.1% (95%CI, 83.3% - 89.6%) used at least one OTC medicine, 69.4% (95%CI, 66.7% - 72.9%) used at least three OTC medicines and 19.4% (95%CI, 16.7% - 22.9%) using at least five OTC medicines. A p-value of $p < 0.001$ was obtained showing a statistically significant difference in the prevalence of use between older men and women.

4.7.3 Age band based

The highest prevalence of use was in the 81-85 aged participants with 100% (95%CI 97.2% - 103.5%) using at least one OTC medicine, although this group made up 11.2% of the study participants, see **Table 3** below. The age band with the second-highest use of OTC medicines was the 76-80 age band with 86.6% (95% CI, 83.4% - 90.2%) using at least one OTC medicine. The age band that had the least prevalence of use of OTC medicines was the 71-75 aged participants, with 82.3% (95% CI, 80.0% - 86.3%).

Table 3: Age bands vs Participant numbers for each category of OTC medicines used.

	Number of OTC medicines used (0-7)							
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Age Band	**Participant numbers for each category of OTC medicines used**							
65-70 N=20 (22.5%)	3	-	3	6	5	1	2	-
71-75 N=29 (32.6%)	5	-	2	6	8	6	2	-
76-80 N=30 (33.7%)	4	2	6	7	7	2	1	1
81-85 N=10 (11.2%)	-	1	1	3	2	2	1	-

4.7.4 Self rated health status and use of OTC medicines

Table 4 shows the relationship between the participant's description of their health status and the average number of OTC medicines that they use. Interesting to note was low self-rated health status was correlated with higher average usage of OTC medicines and the rating of excellent had no reported use of OTC medicine.

Table 4: Relationship between self rated health status and average number of OTC medicines used

Self Rated Health Status	Average number of OTC medicines used
Bad	**3.6**
Fair	**3.5**
Good	**3.0**
Very Good	**3.1**
Excellent	**0**

4.7.5 Level of Education and use of OTC medicines

The highest prevalence of OTC medicines use in relation to the participant's level of education was in the group "Middle (Secondary, Vocational)" with 90.9% (95% CI, 88.1% - 94.4%) using at least one OTC medicine. For "Low (None, Primary)" and "High (University, Professional higher education)" use of at least one OTC medicine was 88.2% (95% CI, 85.5% - 91.7%) and 78.5% (95% CI 75.8% - 82.1%) respectively.

The "Low (None, Primary)" group had the highest use for at least three OTC medicines (76.4%; 95% CI, 73.7% - 80.0%) used and at least five OTC medicines (23.5%; 95% CI 20.8% - 27.0%) used. See **Table 5** below for full details.

Table 5: Relationship between the level of education and the use of OTC medicines

Level of Education	Number of OTC Medicines being used		
	At least one	At least three	At least 5
Low (None, Primary)	88.2% (95% CI, 85.5% - 91.7%)	76.4% (95% CI, 73.7% - 80.0%)	23.5% (95% CI 20.8% - 27.0%)
Middle (Secondary, Vocational)	90.9% (95% CI, 88.1% - 94.4%)	70.0% (95% CI, 67.2% - 73.5%)	18.2% (95% CI, 15.4% - 21.7%)
High (University, Professional higher education)	78.5% (95% CI 75.8% - 82.1%)	75% (95% CI, 72.2% - 78.5%)	21.4% (95% CI, 18.7% - 24.9%)

4.8 Selection of medicines

The self-selection of medication was the highest-ranking response at 62,4% (58) of the participants. **Table 6** provides the breakdown of the responses. Participants were able to select more than one answer to this question. Of the 6 participants who have a caregiver select medication for them, it was either a spouse (2), sibling (3) or friend (1) selecting the medication for them.

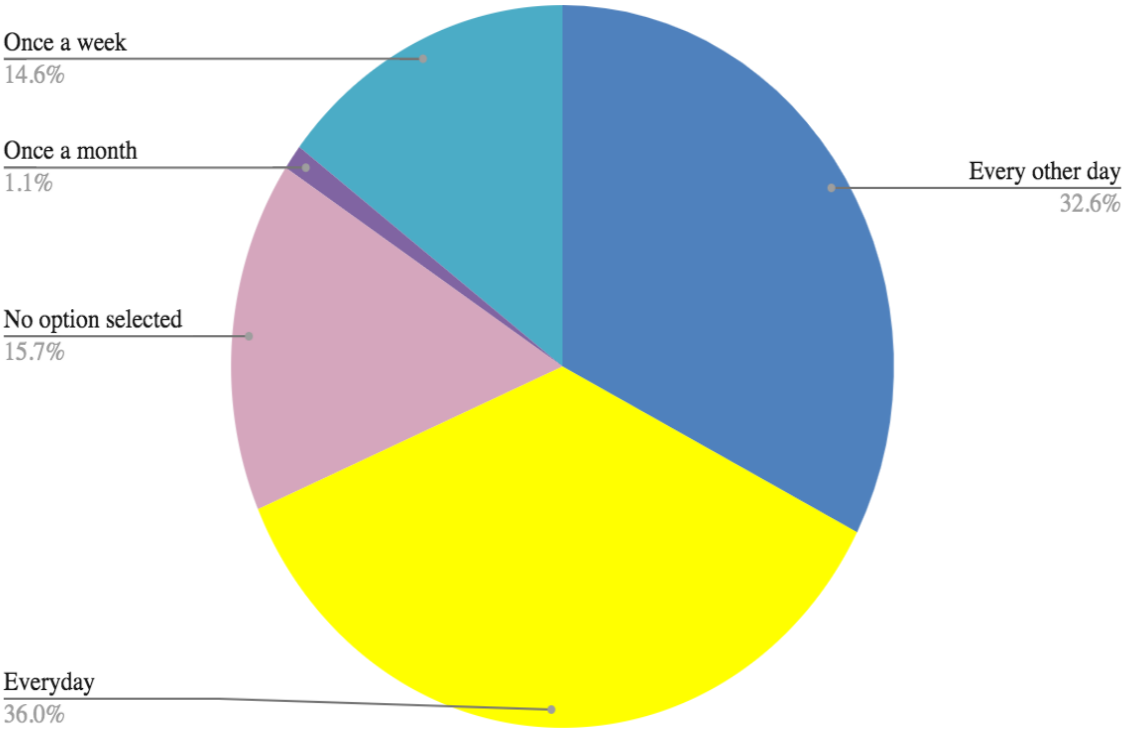
Table 6: Who selects the OTC medicines that you use?

Response	Number of study participants
A caregiver, family member or friend selects the medicines for me	6 (6,5%)
I select my own medicines	58 (62,4%)
The pharmacist	29 (31,2%)

4.9 Frequency of OTC medicine use

The majority of the population (36%) used OTC medicines daily see **Figure 5**.

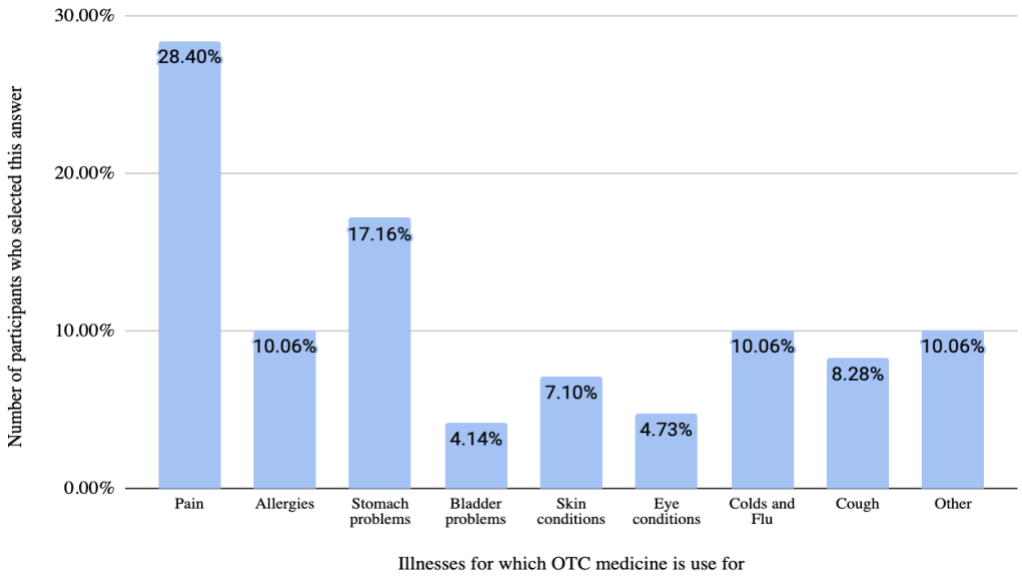
Figure 5: Frequency of the usage of OTC medicines



4.10 Illness that trigger use of OTC medicines

Although pain was the biggest trigger, stomach related illnesses represented (17.6%) of reported illness, **Figure 6**.

Figure 6: Conditions/Illnesses that triggered the use of an OTC medicine



4.11 Perceptions

Participants' patterns of use, safety, and OTC medication efficacy and toxicity were investigated, shown in **Table 7**. The answers that the participants could choose from were “Agree, Disagree, Unsure, Strongly Agree and Strongly Disagree”. A highlight was that over half of the study participants were aware that OTC medicines can have serious side effects.

Table 7: Participants responses to perception statements

	Response				
Perception Statement	Strongly Agree	Agree	Unsure	Disagree	Strongly disagree
At the first sign of illness I will reach out for an OTC medicine	7 (7.8%)	40 (45%)	8 (9%)	28 (31.5%)	6 (6.7%)
I only use OTC medicines when the illness is severe	11 (12.4%)	44 (49.4%)	4 (4.5%)	24 (26.9%)	6 (6.7%)
OTC medicines are absolutely safe	8 (9%)	30 (33.7%)	28 (31.5%)	21 (23.6%)	2 (2.3%)
OTC medicines can have serious side effects	7 (7.9%)	45 (50.6%)	25 (28.1%)	12 (13,5%)	0 (0%)
Incorrect use of OTC medicines can have serious medical consequences as those of prescription medicines	12 (13,5%)	38 (42.7%)	26 (29.2%)	9 (10.1%)	12 (13,5%)
OTC medicines sometimes mask serious health problems	12 (13,5%)	31 (34.8%)	35 (39.3%)	11 (12.4%)	0 (0%)
Continuous use of some OTC medicines can cause them to lose effectiveness	11 (12.4%)	46 (51.7%)	28 (31.5%)	4 (4.5%)	0 (0%)
Some OTC medicines may cause dependency or addiction if taken for a long time	17 (19.1%)	38 (42.7%)	26 (29.2%)	8 (9%)	0 (0%)

4.12 Drug-drug Interactions

The potential for drug-drug interactions was assessed using the EMGuidance interaction checker. Minor drug-drug interactions were the highest recorded at 219 (53.9%) of the interactions reported by the interaction checker. Severe drug-drug interactions made up 64 (15.5%) of the reported drug-drug interactions, with moderate drug-drug interactions at 127 (30.5%).

4.12.1 Drug-drug interactions in relation to the number of OTC medicines used

All reported interactions

The highest number of reported drug-drug interactions was for participants taking 3 and 4 OTC medicines concomitantly with their prescription medicines at 111 (26.8%) and 131 (31.6%) respectively. See **Table 8** below for the reported drug-drug interactions as per severity and number of OTC medicines used by participants.

Table 8: Reported severity of drug-drug interactions (between OTC medicines and chronic medicines) in relation to the number of OTC medicines used by participants

Number of OTC medicines used	Minor Interactions	Moderate Interactions	Severe Interactions	Total Interactions per number of OTC medicines used
0	0	0	0	0
1	6	3	0	9 (2.2%)
2	21	18	7	46 (11.1%)
3	48	35	28	111(26.8%)
4	88	29	14	131 (31.6%)
5	25	22	10	57 (13.8%)
6	29	17	3	49 (11.8%)
7	6	3	2	11 (2.7%)
Total Interactions	223 (53.9%)	127 (30.7%)	64 (15.5%)	**414**

Minor drug-drug interactions

Minor drug-drug interactions made up the highest proportion of the reported drug-drug interactions at 53.9% and interestingly participants taking 4 OTC medicines with their prescription medicines had the highest number of the reported drug-drug interactions (88).

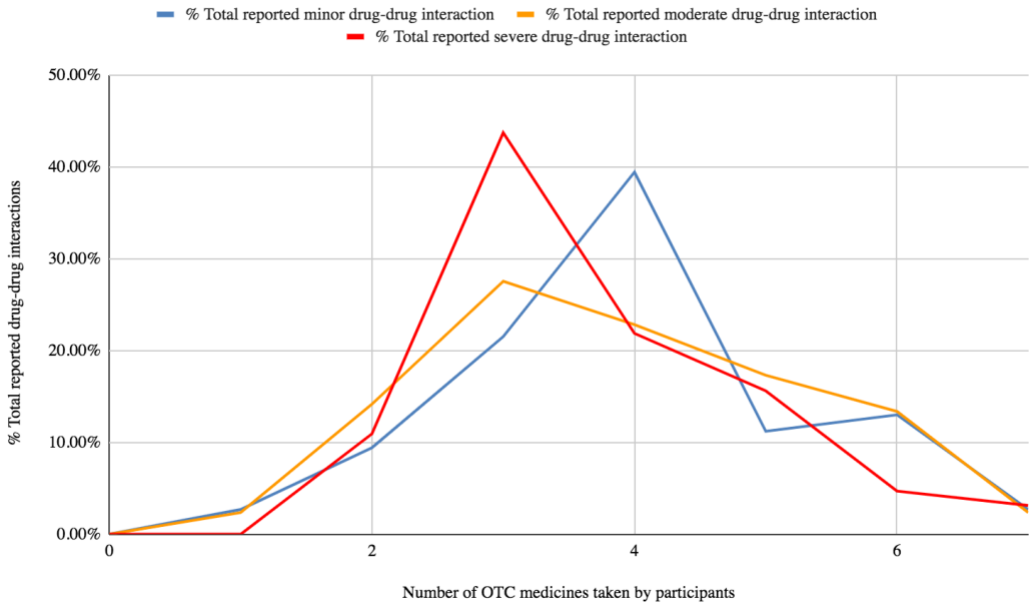
Moderate drug-drug interactions

The highest number of reported moderate drug-drug interactions were for participants taking 3 and 4 OTC medicines concomitantly with their prescription medicines at 35 and 29 respectively.

Severe drug-drug interactions

Severe drug-drug interactions made up 64 (15.5%) of all the reported drug-drug interactions Interestingly, no severe drug-drug interactions were reported for participants taking one OTC medicine concomitantly with their prescription medicine. **Figure 7** shows the reported drug-drug interactions as per severity to give a visual illustration of drug-drug interactions. Of note is that over 40% of the severe drug-drug interactions occurred for 3 OTC medicines concomitantly with prescription medicines.

Figure 7: Reported drug-drug interactions as per severity, and in relation to the number of OTC medicines used



4.12.2 Other drug-drug interactions

Table 9: Herbal and complementary medicine

Thirty eight point two percent of the study population used alternative medicines. The most used alternative medicines being for joint pain relief (14.6%).

Formulation	Percentage of participants taking formulation
Gingko Biloba	3.4%
St John's wort	4.5%
Joint pain remedies	14.6%
Immune boosting remedies	5.6%
Herbal cough mixture	1.1%
Menopause remedies	1.1%
Eye remedies	2.3%
Diabetes remedies	1.1%
Other	10.1%

DISCUSSION

5.1 Introduction

This chapter goes into the interpretation of the results, their connection to current literature and provides details on the insights and learnings that we have obtained from them.

5.2 Overview

The use of OTC medicine is widespread worldwide. Due to their accessibility, they are considered as medicines that are safe, effective and have adequate information for personal use by the patient or individual without much or any assistance from the pharmacist.[23]

When used appropriately and with consideration of the chronic medicines that the patient is on, there are usually no problems.[23] However, healthcare providers are usually unaware of the OTC medicines that patients are on and patients are not always in a position that they are aware of the potential of drug-drug interactions between medicines leading to undesirable medication outcomes.[23] This is because of challenges of availability of doctors for regular patient enquiries and patients reluctance due to the cost involved in having time with a doctor.[21,23]

The information available on OTC medicine use by older adults in South Africa is limited. The prevalence of use of OTC medicine in other medium- to high-income countries has been reported to be high or common in the elderly. [3,23] Qato D.M et al., reported a prevalence of use of at least one OTC medication in the elderly population in the USA to be at 42.2%.[3]

Older adults are the largest consumers of prescription medicines, due to factors such as age-related diseases, lifestyle diseases and increased comorbidities, therefore the use of OTC medicines adds another layer of treatment that is not always known by the patient's doctor or pharmacist.[3] Qato D.M., et., al found that, of the 4% identified drug-drug interactions identified in the medicine regimens of their study participants and 50% of these were related to concomitant intake of non-prescription medications.[3] This puts the elderly patients at risk of undesirable adverse effects from medicine use.[3]

This study achieved 3 research outcomes; determining the prevalence of use of OTC medicines; determining the potential of drug-drug interactions between the prescription medicine and the OTC medicines that the participants were taking concomitantly and obtaining insights into the elderly participants' perceptions of OTC medicines.

5.3 Medicine Use

All the participants enrolled in the study used at least one chronic prescription medication. Based on the average use (3.8 chronic medicines per participant and 3.1 OTC medicines per participant) of medicines that the study participants used, it can be concluded that polypharmacy is of concern as the combined value is over the 5 medicines taken concomitantly as defined in the traditional polypharmacy definition.[2,39]

Polypharmacy is modernly now defined as the use of medicines that are not clinically relevant/indicated for the patients' ailments and this requires that the patients' medication is reviewed for appropriateness and safety.[2,39] Duplication of medications was observed in this study where older adults received chronic pain medications but were also taking OTC medications in the same medicine class. An example, a participant would be on diclofenac as prescribed by their doctor whilst they are also taking an OTC medicine such as ibuprofen which is also used pain in the management of pain. Both medicines are non-steroidal anti-inflammatory drugs (NSAIDs).

This can exacerbate gastrointestinal side effects of these medications. It goes back to improving communication between the patient and the doctor to ensure better patient management.[22] Pharmacist are well positioned to identify the risk of duplication of medications through adequate medication history taking and ensuring proper procedures are followed when dispensing OTC medicines, such as looking into the patient's profile to check chronic medications and any continuous use of OTC medicines.[25,39]

Polypharmacy occurs frequently and is illustrated in this study and others and it warrants more research into medicine use in the elderly.[40] The assessment of older adults' medications is essential to ensure each medication that the patient is taking is appropriate and necessary for the patient.

CHAPTER 5 – DISCUSSION

Polypharmacy is often linked to increased risk of adverse events and inevitably affects older adults' quality of life.[2]

Drug-drug interactions are of common occurrence in the elderly, and healthcare providers need to limit or prevent medicine associated complications and ensure pharmacotherapy goals are realized.[2] Identifying the appropriateness of each medication that the older adults are taking is important to eliminate any duplications of medicines and to remove any unnecessary medication whether it is a prescription or OTC medication.[2]

Pharmacists can mitigate the occurrence of undesirable events from medicine use through proper record keeping and communicating with elderly patients.[2,25] Older adults should be encouraged to use one provider for prescription/medical services and one pharmacy group for medication needs as much as possible. This is to ensure that all the patient's medication history is on one system and medication interactions can be more easily identified.[25]

When it comes to older adults, the use of the main dispensing pathway is encouraged. It allows for the medication to be recorded on the patient profile and creates a permanent and traceable record. This helps the pharmacist have a comprehensive patient history they can refer to in evaluating treatment strategies employed previously and at present and facilitates pharmacists to detect any medication problems, advise the patient appropriately and offer more suitable treatment alternatives.[2]

Although such strategies can be employed, patient challenges such as patient underreporting (due to beliefs or cognitive impairment), vision and hearing impairment can hinder the process. OTC medicines may also be selected by caregivers and this can compromise the medication history taking processes. Pharmacists should encourage patients to keep records of their medications either in diaries or images of their medications to ensure informed decision making by the healthcare provider.[2]

5.4 Prevalence of use of OTC medicines

In our study 86.5% of the older adults used at least one OTC medicine. In a study by Qato D.M et al., (2008), OTC medicines use prevalence was reported to be 42% amongst older adults.[3] Hanlon J.T., et al., (2001), reported that after assessing major studies of community based older adults over 65 years old, use of non-prescription medicines ranged between 31-96%.[21]

On average the study participants used 3 OTC medicines alongside their prescription medicines. This is higher than studies that have been conducted on larger cohorts of older adults aged 65 years and older. A study in the USA found that on average older adults use 1.8 OTC medicines everyday.[21] High use of OTC medicines in low- to middle-income countries could also be associated with OTC medicines being a more affordable option as compared with consultations with doctors/physicians.

5.4.1 Gender usage

In our study female participants (81% of the study population) were more than male participants (19% of the study population). The difference in usage of OTC based on gender was noted. The prevalence of use was higher in the male group (88.2%) than the females (86.1%) for use of at least one OTC medicine. Qato D.M et al. found that the prevalence of use of OTC medicines was similar in men and women.[3] A p-value of $p < 0.001$ was obtained showing a statistically significant difference in the prevalence of use between older men and women. However other studies in high-income countries have shown an increased prevalence of use in women than in men. Hanlon J.t., et al., found that the use of OTC medicines was higher in women.[21]

5.4.2 Age usage

In a study by Hanlon J.t., et al., (2001), the use of OTC medicines was found to decrease with age within the elderly population.[21] In our study the highest prevalence of use was in the 81-85 aged participants with 100% (95%CI 97.2% - 103.5%) using at least one OTC medicine, although this group made up 11.2% of the study participants. The use of OTC medicines in this African setting study showed a difference from the available studies that have been performed in North America and European countries where the trend is less use of OTC medicines with increasing age.[21] In this

study the prevalence of use of OTC medicines increased with age as seen in the results. Several socioeconomic factors can be responsible for the results observed here.

An understanding of geriatric patients' financial circumstances is an essential part of achieving treatment goals. Currently, in South Africa, there is no active national health insurance that would make healthcare services more accessible as in high-income countries where such strategies have been implemented.[22] Older adults in South Africa, rely mostly on personal savings, retirement incomes, or for a few, salaries if they are still employed. However, these incomes are usually limited for the majority and their ability to spend on healthcare services is limited.[22]

The high cost of some prescription medicines may be a deterrent to adherence to these medications and patients may stretch the use of a month's quantity to cover longer periods through skipping doses or breaking doses and may opt to use OTC medications to manage symptoms due to uncontrolled disease.[22] Current systems in the South African health system do not allow for efficient monitoring of patient adherence.[7,22]

An example of this is doctors are not always aware if the patient took all six medication refills (one monthly refill as prescriptions are usually valid for six months) as per the prescription given to the patient. When patients are considered as managed on a treatment they receive a prescription from their doctor that is valid for a maximum of six months and they will take this to their preferred pharmacy to obtain the medication on a monthly basis until they require a new prescription at the end of the period.[22]

The advantage of this system is the patient has the independence to select the pharmacy (except in the few instances where there is a dispensing doctor) they collect their medication either because it is closer to their residence or they consider it an affordable pharmacy. Another benefit of this system is the patient would only need to visit the doctor twice a year if no complications were experienced saving the patient on doctor visits.[22]

However, the main challenge of this process is that the doctor does not interact with the patient for half a year and in most cases will not be aware of the patient's use of OTC medications during this

period. Any undesirable effects that may occur may be associated with the prescription medication when the patient's condition is reviewed by their doctor and lead to a possible switch to another prescription medication when the cause of the adverse event was the use of an OTC medicine.[22]

Physicians/doctors are rarely aware if the elderly patients went to collect or received their full six months' worth of medication when they re-visit the doctor for a repeat prescription and have to rely on the patient's feedback. Having systems that are integrated would allow better delivery of healthcare services, identify underutilization of medications, and allow healthcare providers to be less reliant on patient's feedback as they may forget or withhold information to their peril.[22]

Therefore, an understanding of the patient's financial capabilities regarding available funding for healthcare is essential when planning the patient's treatment goal. Use of older prescription medicines that have generics on the market is a strategy to minimize cost and encourage adherence.[21,22]

5.4.3 Self rated health status and use of OTC medicines

A rating system was used for the older adults to give a score of their health status as they perceived it to be. Bailis D.S. et al., found that self-rated health status is often controlled by the individual's endeavours to achieve health-related goals.[33]

The rating system was made up of 5 possible options; Bad, Fair, Good, Very good and Excellent. Most of the participants (43.8%) rated their health status as good. However, the participant group with the "Good" rating had the least prevalence of the use of at least one OTC medicine, see supplementary material Table 1B **(Appendix 2)**. The assumption would be that participants who considered themselves to have a good general health status are more satisfied with their state of health and have fewer requirements for use of multiple OTC medicines. 8 out of the 39 participants with a "good" rating did not use any OTC medicines. One participant rated their health status as "Excellent" and they used no OTC medicines, see supplementary material Table 1A **(Appendix 2)**.

The highest prevalence of use of at least one OTC medicine was in the participant group that rated their state of health as "Bad". All participants who were in this group used at least one OTC medicine and this group had one participant who used 7 OTC medicines concomitantly, which is the highest for this study. It is worthwhile assessing these results as an actual or perceived poor health status results in a high probability of OTC medicine use which also increases the risk of drug-drug interactions with the patient's prescription medicines as well as drug-drug interactions amongst the OTC medicines.

The participant group that rated themselves as having a "Fair" general health status had the second-highest prevalence of use of at least one OTC medicine (96.4%). This leads to the deduction that the more negative the health rating is the higher the use of OTC medicines amongst the participants.

Due to the limited research content on this topic, it is difficult to make any substantial conclusions from this data, however, more research and work into understanding the use of OTC medicines in the elderly will give more insights. A study investigating the relationship between meeting patient's information requirements and their general health status found that when the patient's medical information needs were met this was associated with positive outcomes such as improved general health status ratings.[34]

This can be applied in this setting, informed patients are in a better position to select OTC medicines more appropriately and use them rationally, therefore pharmacists should ensure they provide adequate information when dispensing OTC medicines to elderly patients to improve health-related goals for the patients.[34]

5.4.4 Level of education and use of OTC medicines

The relationship between the level of education and the use of OTC medicines was investigated. The results showed the highest prevalence of use of at least one OTC medicine was in the participant group that had a "Middle" level of education (90.9%), followed by those with a "Low" level of education (88.2%) and the lowest prevalence of use of at least one OTC medicine used was in the participant group that had "High" level of education (78.5%).

When looking into the use of higher quantities of OTC medicines per participant in each of the 3 categories, participants with a high level of education were consecutively the second highest after those with a low level of education, for the prevalence of use of at least 3 OTC medicines (75.0%) and 5 OTC medicines (21.4%) concomitantly.

The assumption is the level of education has an impact on decision making when selecting OTC medicines. From the study results, the prevalence of OTC medicine use was highest in the participant group that had a low level of education. Therefore, older adults that did not attain higher education levels may be more likely to use OTC medicines due to factors such as socioeconomic status as it may be more affordable to use self-medication than go to a doctor.

A study in Ghana investigated the utilization of health services by older adults and found that age, health insurance and education independently resulted in the utilization of different healthcare options.[41] Health beliefs may also play a role resulting in higher use of OTC medicines and alternative medicines.[2]

Conversely, although the participant group with the older adults who have a high level of education had a low prevalence of use of at least one OTC medicine this changed for use of at least 3 and 5 OTC medicines where this group ranked as the second highest as mentioned above. This can be also interpreted with the ability to utilize health services by this participant group as they have more disposable income.

A high level of education was associated with better career opportunities during the working years of this participant group, therefore, they are more likely to have healthier pension funds and be on medical insurance/aid. Therefore, OTC medicines are easily accessible because they can easily purchase them for self-medication purposes. There was noticeably high use of complementary medicines to boost energy levels, multivitamins and omega fish oils.

5.5 Selection of OTC medicines

Sixty two percent of the responses to the question, "Who selects the OTC medicines that you use?" were "I select my own medicines" and 31.2% of the responses stated that a pharmacist assisted in the selection of the OTC medicines. Although a third of the respondents do consult a pharmacist from time to time when they select OTC medicines it is important that there are more patient pharmacist interactions to ensure the optimal and safe use of OTC medicines.

Older adults use OTC medicines to treat most minor ailments as these are an economic alternative to consulting a doctor. It is important that as older adults utilize this treatment choice that they use the medicines safely and that there is the participation of healthcare providers such as pharmacists in the selection of the medications.

Only 6.5% of the responses were from those participants who had a friend or family member select their OTC medications. This shows that participants are still actively involved in going to the pharmacy to collect their medications and interactions with pharmacists and supporting staff is possible.

5.6 Frequency of OTC medicines use

The use of OTC medicines is essential for the management of self-limiting conditions, it would be expected that use is infrequent, and only when intended for short periods. In our study, 43% of the participants responded to using OTC medicines everyday which was the highest of all the other responses. 39% of the participants responded that they use OTC medicines every other day, 17% once weekly and 1% only once a month. Gilson, A., et al., reported that estimates suggest that approximately 33% of older adults use OTC medicines on a regular basis.[42]

The frequency of use of OTC medicines was high in the study population. It must be asked whether OTC medicines are being used as substitutes for prescription medicines as they are more cost-effective medicines. It is important for doctors and pharmacists to identify patient strategies such as this that are used by older adults to cope with the cost of prescription medicines and/or services relating to obtaining prescription medicines and employ interventions that can help patients.[43]

A study that investigated how to improve the safe use of OTC medicines in the elderly found that introducing a "Senior Section" in the pharmacy improved pharmacist and patient interaction allowing for improved medication safety and convenience. Such interventions should be considered to assist in minimizing undesirable medication-related adverse events and to promote public health.[42]

5.7 Illness that triggers the use of OTC medicines

The older adults' used OTC medicines for the treatment of mostly pain-related ailments with 28% of participants using analgesics to alleviate pain. These results are consistent with those of related studies which have found analgesic medicines are the most commonly used OTC medicines.[19,44]

Use of pain medications most commonly nonsteroidal anti-inflammatory drugs should be done so with caution as these medications increase the risk of gastrointestinal, cardiovascular and renal adverse reactions.[45] There is limited information to be able to determine if older adults in South Africa utilize pharmacists or read the patient information leaflets inserted in medicine packaging or containers to be able to determine if medicines are used safely.

A Canadian study found that 91% of the population claim to read medicine labels before using the medicine for the first time.[45] However, they also found that amongst the 5% that did not follow the medicine instructions provided by the manufacturer 31 % administered a dose greater than that stipulated. Such non-compliance is triggered by perceptions of lack of efficacy of the medicinal product and in some cases if the severity of symptoms is high.[45] It is therefore necessary that OTC medicine use by the elderly in South Africa is better understood to be able to employ adequate interventions.

Stomach problems affected 17.2% of the study participants and this was the second-highest reason for use of OTC medicines in the study population. Other noteworthy uses of OTC medicines in the elderly were for allergies, colds and flu and other conditions (supplementary uses) which accounted for 10.6% each of the reported illnesses that the older adults are using the OTC medicines for.

Therefore, the importance of interventions directed at the elderly cannot be overemphasized, pharmacist-patient interactions are encouraged and for pharmaceutical companies to develop innovative ways to educate patients on medicine use catering for the aged as well to ensure the safe use of OTC medicines in this population group.

5.8 Patient perceptions

Patient perceptions on OTC medicines were measured using 3 categories of questions/statements namely use patterns, safety and toxicity, and knowledge to gain a better understanding of patient's perceptions and knowledge.

5.8.1 Use patterns

The participant responses are given in **Table 7** in the results section. OTC medicines are convenient and are more easily accessible to older adults as they do not require a prescription. 45% of the study participants responded that they use an OTC medicine at the first sign of illness which was the highest score for this statement. The use of OTC medicines is meant for acute illnesses to make the duration of illness short and manageable.[1,2]

There is no major opposition to the use of OTC medicines at the onset of an illness if it is used rationally for the correct illness. Frequent use of OTC medicines is concerning as it may be due to unaddressed medication problems such as poorly controlled chronic conditions requiring revision of chronic prescription medicines.[1] Frequent use of OTC medicines also increases the risk of drug-drug interactions and may be associated with medication abuse and pharmacist should check patient medication histories when dispensing to older adults.[1]

Fourty nine point nine percent responded that they agree with the statement "I only use OTC medicines when the illness is severe". With this statement, there is no absolutely correct answer and it is more to understand the use patterns of the study participants. Conservative use can also be detrimental if the elderly do not seek help to treat acute illness within a reasonable time as minor ailments can become more severe.

5.8.2 Safety and Toxicity

Participants' knowledge of OTC medicine safety was investigated with 4 safety statements (see **Table 7)**. Although 33% of participants responded that they agree with the statement "OTC medicines are absolutely safe", 31.5% were unsure and 23.6% disagreed with the statement. The clinically correct response to this question is to disagree with this statement.

Although OTC medicines are generally safe, they can have undesirable effects if used inappropriately and for conditions that they are not indicated for.[16] It is important therefore that older adults are educated on the safety and risks that are associated with OTC medicines and encouraged to discuss the use of these medicines with their pharmacists and doctors.

5.8.3 Knowledge

The responses to the statements "OTC medicines can have serious side effects" and "Incorrect use of OTC medicines can have serious medical consequences as those of prescription medicines" showed that some knowledge exists on the consequences of inappropriate use of OTC medicines. 50.6% and 42.7% of the participants agree with the statements respectively.

However, one study found that patients will usually overestimate the risk of the adverse reaction occurring from an OTC medicine and a balanced approach is required when educating the public about OTC medicines.[20] Although OTC medicines can be associated with adverse events these are generally experienced because of misuse.[20]

Approximately 39% of the participants were unsure if OTC medicines mask serious health problems. This is an indicator that older adults require more information regarding OTC medicines. Serious chronic conditions can be temporarily masked by OTC medication, leading to late diagnosis and poor prognosis.[1]

Almost 52% of the participants agreed with the statement "Continuous use of some OTC medicines can cause them to lose effectiveness" and 31.5% were unsure. OTC medicines that may lose their effectiveness during continual use are commonly those of addictive potential.[28] It is therefore essential the dispensing of OTC medicines of addictive potential is regulated.[6]

Currently, in South Africa, OTC medicines with active ingredients that may have an addictive potential are in the Schedule 2 grouping, which requires the pharmacist to record patient identifiers such as name, address and ID number so that the pharmacy can keep a record of how often the patient collects this medication.[6,9] However, the current challenges of systems that are not integrated limit the effectiveness of this regulation as a patient can obtain medication from different pharmacies before being identified as a potential abuser.

It is encouraging that 42.7% of the older adults in the study agree with the statement that "Some OTC medicines may cause dependency or addiction if taken for a long time". Abuse of OTC medicine is when they are used for non-medical reasons to obtain a "high" or some type of mood alteration or use for an indication that the medication is not registered for.[28] Patient education on rational OTC medicine use is required.

5.9 Drug-drug interactions

When prescription medicines are used with OTC medicines there is an increased risk of drug-drug interactions as OTC medicines are mostly self-selected by patients who may not always know if it interacts with their chronic medication.[1]

There were 15.5% drug-drug interactions between prescription and OTC medicines that were reported as severe by the interaction checker. This shows the need for implementing strategies to ensure better record keeping of OTC medicine use by the elderly. The use of OTC analgesics concomitantly with prescription anticoagulants, and antiplatelet agents results in increased risks of bleeding.[2,27]

Not every drug-drug interaction will be a reason to discontinue the medicine.[3] Many prescription medicines are used concomitantly with known drug-drug interactions however because these have been evaluated by healthcare providers, clinical judgment has been applied when considering the interaction.[3,7]

For example, some medicines have minor interactions that do not significantly affect the efficacy of the interacting agent and therefore can be used concomitantly. With others, medicine dose

adjustment can be done to accommodate the effects of the interacting medicines to maintain the same level of efficacy and safety. [20,28]

Usage of complementary and herbal medicines was calculated to be used by 38.2% of the study participants. Although not the focus of the study use of alternative medicines was noted. Ginkgo Biloba was used by 3,4% of participants and St John's Wort by 4.5% of participants.[31] Ginkgo Biloba has the potential to interact with antiplatelet agents such as aspirin and anticoagulant medications and should be avoided in patients that are taking these medications.[31] In patients taking antidepressants such as monoamine oxidase inhibitors and serotonin reuptake inhibitors, and in patients with psychiatric disorders St John's Wort has to be avoided due to its potential to induce the P-glycoprotein transporter and the cytochrome P450 isoforms.[2,31]

Therefore, within the confines of healthcare provider-initiated medicines and care, drug-drug interactions are monitored. The concern arises with the use of OTC medicines as these are not always under the watchful eye of healthcare providers meaning drug-drug interactions can occur and cause problems in older adults as clinical reasoning to adjust doses appropriately/ or switch medications will not be used.[2,20,28]

Less efficient renal and hepatic function makes older adults are more vulnerable to the effects of medicines as clearance and metabolism of these medications is affected by the reduced capacity of these systems.[3,30] They also have reduced water content and altered body fat content which all make older adults more vulnerable to adverse reactions.[25] Therefore, good communication between older adults and healthcare providers is encouraged to limit any adverse events due to drug-drug interactions that can manifest in several ways such as poor control of chronic conditions because an OTC medicine that the patient is taking increases the metabolism of prescription medicine that the patient is taking making it inefficient in controlling the condition.[25]

LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

6.1 Limitations

Some limitations of this study have been identified. Firstly, it is the first time such a study is being conducted in South Africa, therefore, there is limited information on OTC medicine use in the elderly population in South Africa. Secondly, the study is focused on elderly people who are of a certain socioeconomic status, i.e., those who afford to stay at an old age home and thus may not be giving a clear picture of the OTC medicine use of the majority of the elderly in South Africa.

This study was focused on the use of OTC medicines in participants taking prescription medicines however, the data obtained from the study revealed that the participants also take other forms of non-prescription medicine namely complementary medicine and herbal medicines. Complementary medicines are defined by the WHO as "*A broad set of health practices that are not part of the country's conventional or traditional medicines*" and herbal medicines as "*Herbal preparations, herbs or herbal materials that contain the part of plants as the active ingredient*".[47]

In future studies evaluating the potential of drug-drug interactions between alternative medicines and prescription medicines would be important to assess if there are no major drug-drug interactions.[31] The study of the use of complementary and herbal medicines in the elderly also brings focus to this population group so that the appropriate health interventions can be taken.

6.2 Recommendations and Conclusion

To ensure that pharmacotherapy is optimized, in elderly patients it is important that patients and the health care providers collaborate on treatment goals. The patient should have an adequate understanding of the role of each of their prescription medicines and how to appropriately take these medicines. It is also of importance that patients are made aware of OTC medicines that can possibly interact with their chronic medicines and cause undesirable effects. Assessment of the goals of treatment is important to reduce the risks of drug-drug interactions and monitor drug efficacy.[2]

CHAPTER 6 – LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

Drug-drug interactions have been a major concern for decades in the treatment of geriatric patients, given that they are more likely to use several medications to manage morbidities.[22] Ensuring that patients can easily communicate health problems to their physician and pharmacists is essential so that healthcare providers can assist the patient in the decision-making process when it comes to OTC medication selection and on whether any additional medication is required as some conditions may be associated with the use of an existing medication in the patient's medication regimen.[22]

Healthcare providers must be encouraged to always check and be alert for potentially interacting medications on a patient's regimen and encourage the patient to communicate details of other medications they are taking.[22] Inappropriate medication prescribing must be avoided for both prescription and OTC medicines to reduce the potential of drug-drug interactions and undesirable effects.[2,22]

Monitoring the efficacy of the patient's chronic medicines is essential. Inadequately controlled disease conditions can lead the elderly patient to seek other treatments such as OTC medicines or alternative medicines to supplement the prescription medicines leading to polypharmacy and undesirable effects. [2,3]

Knowledge of the use of OTC medicines must be actively driven by healthcare providers to ensure the safe use of these medicines by older adults and other population groups.[1] This study revealed that knowledge on the safety of OTC medicine use is lacking and interventions such as pharmacists providing both oral and written information about OTC medicines use to older adults is important.

REFERENCES

1. Major, C., & Vincze, Z. (2010). Consumer habits and interests regarding non-prescription medications in Hungary. Family Practice, 27(3), 333-338.
2. Hajjar E.R., & Hersh L.R., & Gray S.L. (2020). Prescribing in the older adult. DiPiro J.T., & Yee G.C., & Posey L, & Haines S.T., & Nolin T.D., & Ellingrod V(Eds.), Pharmacotherapy: A Pathophysiologic Approach, 11e. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/
3. Qato, D. M., Alexander, G. C., Conti, R. M., Johnson, M., Schumm, P., & Lindau, S. T. (2008). Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. Jama, 300(24), 2867-2878.
4. WHO. Self Medication. (2014). Sudan Journal of Rational Use of Medicine. Available from Jafari, F., Khatony, A., & Rahmani, E. (2015). Prevalence of self-medication among the elderly in Kermanshah-Iran. Global Journal of Health Science, 7(2), 360.
5. Healthcare and Life Sciences Review. Pharma Boardroom. South Africa. (April 2016). https://pharmaboardroom.com/country_reports/south-africa-pharma-report/
6. Lowe, N. K., & Ryan-Wenger, N. M. (1999). Over-the-counter medications and self-care. Nurse Practitioner, 24(12), 34.
7. Myers, B., Siegfried, N., & Parry, C. D. (2003). Over-the-counter and prescription medicine misuse in Cape Town-findings from specialist treatment centres. South African Medical Journal, 93(5), 367-370.
8. Ayele, A. A., Mekuria, A. B., Tegegn, H. G., Gebresillassie, B. M., Mekonnen, A. B., & Erku, D. A. (2018). Management of minor ailments in a community pharmacy setting: findings from simulated visits and qualitative study in Gondar town, Ethiopia. PLOS One, 13(1), e0190583.
9. Medicines and Related Substances Act 101 of 1965. http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf
10. Sherazi., B. A., Mahmood, K. T., Amin., F., Zaka., M., Riaz., M., & Javed., A. (2012). Prevalence and measure of self-medication: A review.
11. Montastruc, J. L., Bagheri, H., Geraud, T., & Lapeyre-Mestre, M. (1997). Pharmacovigilance of self-medication. Therapie, 52(2), 105-110.
12. Hughes, C. M., McElnay, J. C., & Fleming, G. F. (2001). Benefits and risks of self-medication. Drug safety, 24(14), 1027-1037.

REFERENCES

13. Aljinović-Vučić, V., Trkulja, V., & Lacković, Z. (2005). Content of home pharmacies and self-medication practices in households of pharmacy and medical students in Zagreb, Croatia: findings in 2001 with a reference to 1977. Croatian Medical Journal, 46(1).
14. Bush, P. J., & Rabin, D. L. (1976). Who's using nonprescribed medicines?. Medical Care, 1014-1023.
15. Tam V.H. (2016). Application of pharmacokinetics to clinical situations. Shargel L, & Yu A.C.(Eds.), Applied Biopharmaceutics & Pharmacokinetics, 7e. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/content.aspx?bookid=1592&sectionid=100674798
16. Vacas, E. R., Castell., I. D., S.nchez, M. G., Pujol, A. A., Pallar.s, M. C., & Balagu., M. C. (2009). Self-medication and the elderly. The reality of the home medicine cabinet. Primary Healthcare, 41(5), 269-274.
17. Chouhan, K. I. R. A. N. B. I. R., & Prasad, S. B. (2016). Self-medication and their consequences: a challenge to health professional. Asian J Pharm Clin Res, 9(2), 314-317.
18. Important Drug Interactions & Their Mechanisms. In: Katzung BG, Kruidering-Hall M, Trevor AJ. eds. Katzung & Trevor's Pharmacology: Examination & Board Review, 12e New York, NY: McGraw-Hill; http://accesspharmacy.mhmedical.com/content.aspx?bookid=2465&sectionid=197947178.
19. Wazaify, M., Shields, E., Hughes, C. M., & McElnay, J. C. (2005). Societal perspectives on over-the-counter (OTC) medicines. Family Practice, 22(2), 170-176.
20. Berry, D., Raynor, T., Knapp, P., & Bersellini, E. (2004). Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. Patient Education and Counseling, 53(2), 129-134.
21. Hanlon, J. T., Fillenbaum, G. G., Ruby, C. M., Gray, S., & Bohannon, A. (2001). Epidemiology of over-the-counter drug use in community dwelling elderly. Drugs & Ageing, 18(2), 123-131.
22. Katzung B.G. (2017). Special aspects of geriatric pharmacology. Katzung B.G.(Ed.), Basic & Clinical Pharmacology, 14e. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/content.aspx?bookid=2249&sectionid=175225509
23. Olesen, C., Harbig, P., Barat, I., & Damsgaard, E. M. (2014). between the use of 'over-the-counter' medicines and adherence in elderly patients on multiple medications. International Journal of Clinical Pharmacy, 36(1), 92-97.
24. Coons JS, Johnson M, Chandler MHH. Sources of self-treatment information and use of home remedies and over-the-counter medications among older adults. J Geriatr Drug Ther 1992; 7: 71–82

25. South African Health Products Regulatory Authority (SAHPRA); https://www.sahpra.org.za/; Accessed 21 October 2020.
26. Special populations (children and elderly). Rollins D.E., & Blumenthal D.K.(Eds.), (2016). Workbook and Casebook for Goodman and Gilman's The Pharmacological Basis of Therapeutics. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/content.aspx?bookid=1697&sectionid=111004548
27. Roden D.M. (2018). Principles of clinical pharmacology. Jameson J, & Fauci A.S., & Kasper D.L., & Hauser S.L., & Longo D.L., & Loscalzo J(Eds.), Harrison's Principles of Internal Medicine, 20e. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/content.aspx?bookid=2129&sectionid=179924708
28. Bond, C., & Hannaford, P. (2003). Issues related to monitoring the safety of over-the-counter (OTC) medicines. Drug Safety, 26(15), 1065-1074.
29. O' Mahony, D., & Gallagher, P. F. (2008). Inappropriate prescribing in the older population: need for new criteria. Age and Ageing, 37(2), 138-141.
30. Brabers, A. E. M., Van Dijk, L., Bouvy, M. L., & De Jong, J. D. (2013). Where to buy OTC medications? A cross-sectional survey investigating consumers' confidence in over-the-counter (OTC) skills and their attitudes towards the availability of OTC painkillers. BMJ Open, 3(9), e003455.
31. Lam, A., & Bradley, G. (2006). Use of self-prescribed nonprescription medications and dietary supplements among assisted living facility residents. Journal of the American Pharmacists Association, 46(5), 574-581.
32. Wu, S., Wang, R., Zhao, Y., Ma, X., Wu, M., Yan, X., & He, J. (2013). The relationship between self-rated health and objective health status: a population-based study. BMC Public Health, 13(1), 320.
33. Bailis, D. S., Segall, A., & Chipperfield, J. G. (2003). Two views of self-rated general health status. Social Science & Medicine, 56(2), 203-217.
34. Larson, C. O., Nelson, E. C., Gustafson, D., & Batalden, P. B. (1996). The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. International Journal for Quality in Health Care, 8(5), 447-456.
35. Goh, L. Y., Vitry, A. I., Semple, S. J., Esterman, A., & Luszcz, M. A. (2009). Self-medication with over-the-counter drugs and complementary medications in South Australia's elderly population. BMC Complementary and Alternative Medicine, 9(1), 42.
36. Lehohla, P. (2011). Census 2011: Profile of older persons in South Africa. Statistics South Africa. https://www. google. co. za/url.

37. Stoehr, G. P., Ganguli, M., Seaberg, E. C., Echemen, D. A., & Belle, S. (1997). Over-the-Counter Medication Use in an Older Rural Community: The Mo VIES Project. Journal of the American Geriatrics Society, 45(2), 158-165.
38. DeSalvo, K. B., Bloser, N., Reynolds, K., He, J., & Muntner, P. (2006). Mortality prediction with a single general self-rated health question: A meta-analysis. Journal of General Internal Medicine, 21(3), 267-275.
39. Amoako, E. P., Richardson-Campbell, L., & Kennedy-Malone, L. (2003). Self-medication with over-the-counter drugs among elderly adults. Journal of Gerontological Nursing, 29(8), 10-15.
40. Linjakumpu, T., Hartikainen, S., Klaukka, T., Veijola, J., Kivelä, S. L., & Isoaho, R. (2002). Use of medications and polypharmacy are increasing among the elderly. Journal of Clinical Epidemiology, 55(8), 809-817.
41. Gyasi, R. M., & Phillips, D. R. (2020). Demography, socioeconomic status and health services utilisation among older Ghanaians: implications for health policy. Ageing International, 45(1), 50-71.
42. Gilson, A. M., Xiong, K. Z., Stone, J. A., Jacobson, N., & Chui, M. A. (2020). A pharmacy-based intervention to improve safe over-the-counter medication use in older adults. Research in Social and Administrative Pharmacy.
43. Sanyal, C., Ingram, E. L., Sketris, I. S., Peltekian, K. M., & Kirkland, S. (2011). Coping strategies used by patients infected with hepatitis C virus who are facing medication costs. The Canadian Journal of Hospital Pharmacy, 64(2), 131.
44. Simonson, W. (2013). Implications of over-the-counter proton pump inhibitors for patient counseling by pharmacists. American Journal of Therapeutics, 20(6), 676-684.
45. Stosic, R., Dunagan, F., Palmer, H., Fowler, T., & Adams, I. (2011). Responsible self-medication: perceived risks and benefits of over-the-counter analgesic use. International Journal of Pharmacy Practice, 19(4), 236-245.
46. Taylor, J. (2017). Over-the-counter medicines and diabetes care. Canadian Journal of Diabetes, 41(6), 551-557.
47. World Health Organisation: Health topics: Traditional, complementary and integrative medicine: Overview: Accessed online on 22 September 2020: https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1
48. Dietary supplements & herbal medications. Katzung B.G., & Kruidering-Hall M, & Trevor A.J.(Eds.), (2019). Katzung & Trevor's Pharmacology: Examination & Board Review, 12e. McGraw-Hill. https://0-accesspharmacy-mhmedical-com.innopac.wits.ac.za/content.aspx?bookid=2465&sectionid=197947087

APPENDICES
Appendix 1: Research Questionnaire

1. Demographics

Please fill in the appropriate box with an **X**

Sex

Female ☐

Male ☐

Other ☐

Age

65 – 70 ☐

71 – 75 ☐

76 – 80 ☐

>80 ☐

Level of education[1]

Low (None, Primary) ☐

Middle (Secondary, Vocational) ☐

High (University, Professional higher education) ☐

How would you describe your general health?[1,4,5]

Bad ☐ Fair ☐ Good ☐ Very Good ☐

Excellent ☐

2. Chronic/Prescription Medicines

What medicines have you taken in the last two months for your chronic disease(s) Please fill in the table below?

Prescription Medication List		
1.	2.	3.
4.	5.	6.
7.	8.	9.
10.	11.	12.
13.	14.	15.
16.	17.	18.
19.	20.	21.

3. Over The Counter (OTC) medicines[2]

An OTC (over the counter) medicines or non-prescription medicines are those medicines that you can buy at a pharmacy or chemist without the need for a prescription. These also include those medicine which you can purchase at a supermarket and petrol filling stations. Examples of OTC medicines include painkillers, cough mixtures and allergy medicines.

Do you use OTC medicines?

Yes ☐

No ☐

Who selects the OTC medicines that you use? (you may select more than one option)

☐ The Pharmacist

☐ I select my own medicines

☐ A caregiver, family member or friend selects the medicines for me

Please specify relationship……..

How often do you use OTC medicines?

Frequency	Tick the option which best describes your use of OTC medicine
Everyday	
Every other day	
Once a week	
Once a month	

Which illnesses do you usually use OTC medicine for? Tick the appropriate option(s);

Pain		**Skin conditions**	
Allergies		**Eye conditions**	
Stomach problems		**Colds and Flu**	
Bladder problems		**Cough**	

If other please specify;

……..

……..

In the table below please list the OTC medicines you have used in the last 2 months.

OTC Medication List		
1.	2.	3.
4.	5.	6.

7.	8.	9.
10.	11.	12.
13.	14.	15.
16.	17.	18.
19.	20.	21.

If you do not remember the name of medicine, please specify for which condition(s) below:

……..

……...

4. Perceptions

For the following statements circle the most appropriate response

At the first sign of illness I will reach out for an OTC medicine.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

I only use OTC medicines when the illness is severe.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

OTC medicines are absolutely safe.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

OTC medicines can have serious side effects.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

Incorrect use of OTC medicines can have serious medical consequences similar to those of prescription medicines.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

f). OTC medicines sometimes mask serious health problems.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

The continuous use of some OTC medicines can cause them to lose effectiveness.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

Some OTC medicines may cause dependency or addiction if taken for a long time.[3]

Strongly Agree Agree Unsure Disagree Strongly Disagree

References

1. Stoehr, G. P., Ganguli, M., Seaberg, E. C., Echemen, D. A., & Belle, S. (1997). Over-the-Counter Medication Use in an Older Rural Community: The Mo VIES Project. *Journal of the American Geriatrics Society*, *45*(2), 158-165.
2. Qato, D. M., Alexander, G. C., Conti, R. M., Johnson, M., Schumm, P., & Lindau, S. T. (2008). Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *Jama*, *300*(24), 2867-2878.
3. Wazaify, M., Shields, E., Hughes, C. M., & McElnay, J. C. (2005). Societal perspectives on over-the-counter (OTC) medicines. *Family practice*, *22*(2), 170-176.
4. Goh, L. Y., Vitry, A. I., Semple, S. J., Esterman, A., & Luszcz, M. A. (2009). Self-medication with over-the-counter drugs and complementary medications in South Australia's elderly population. *BMC Complementary and Alternative Medicine*, *9*(1), 42.
5. DeSalvo, K. B., Bloser, N., Reynolds, K., He, J., & Muntner, P. (2006). Mortality prediction with a single general self-rated health question: A meta-analysis. *Journal of general internal medicine*, *21*(3), 267-275.

Please Note: Due to the Covid-19 pandemic the form was translated to also have an electronic version (consisting of consent form, information sheet and the research questionnaire) to comply with lockdown rules. This digital form was which was approved by the ethics committee.

Link: **Digital Questionnaire available at:** https://form.jotform.com/201002454646041

Appendix 2: Supplementary Sheet

Table 1A: Health Rating Vs Number of OTC medicines that the participants' are currently taking

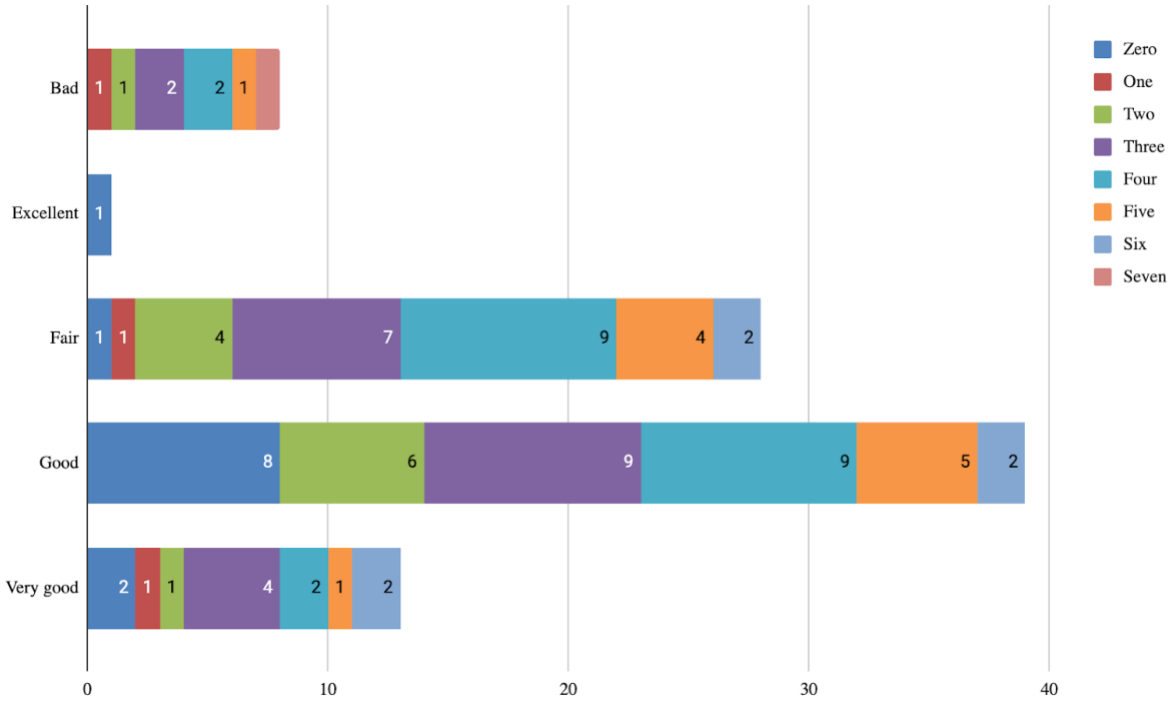
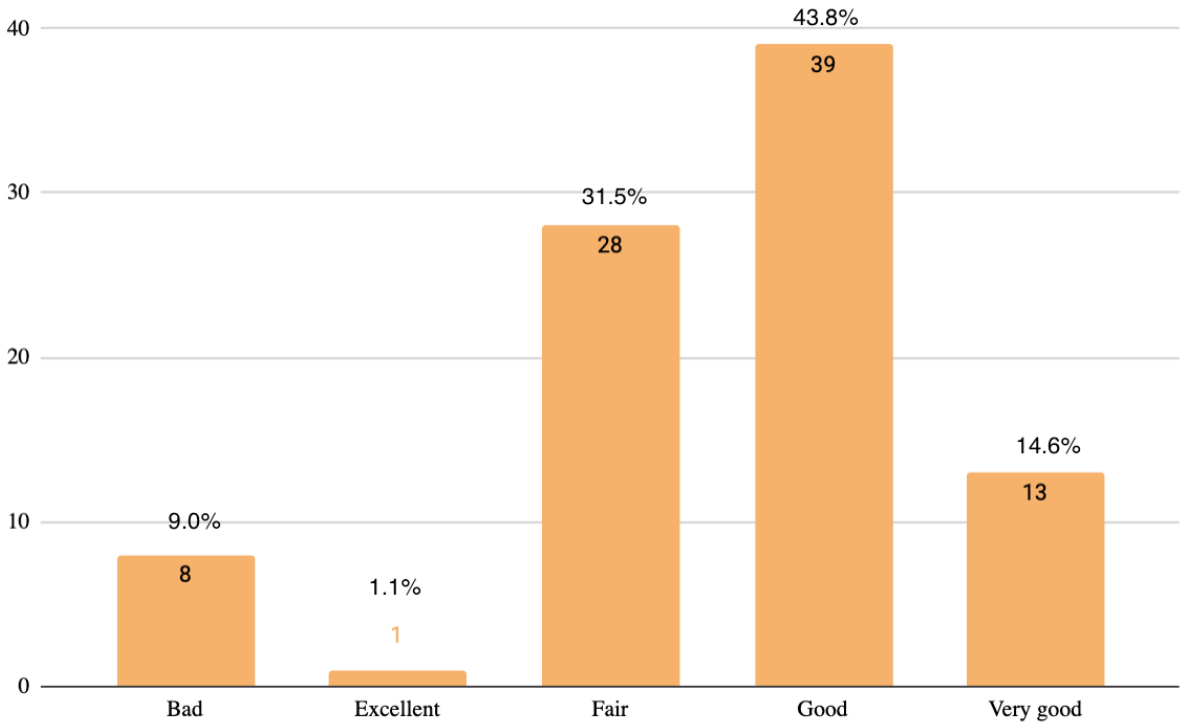


Table 1B: Participant's Health Rating per Category



Appendix 3: Study Information Sheet

STUDY INFORMATION DOCUMENT

Study title: Prevalence of over the counter (OTC) medicine use and the potential of drug-drug interactions with concomitant prescription medicine use at an old age home in Johannesburg

Good day

I, Sandile Olivia Dube am doing research on prevalence of over the counter (OTC) medicine use and the potential of drug-drug interactions with concomitant prescription medicine use at an old age home in Johannesburg. Research is a process used in seeking new knowledge. In this study we want to get insight into the prevalence of use OTC medicine medicines by older adults and if there are potential drug-drug interactions between the prescription medicines and OTC medicines that they use. The study is for research purposes only.

We are inviting you to take part in a research study.

The study will involve taking part in completing a questionnaire. The questionnaire will be take approximately 20 minutes to complete.

You will not receive any direct benefits from participation in this study, and there are no disadvantages or penalties for not participating in the study.

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits. You may discontinue participation at any time without penalty, or loss of benefits. There is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless you, as the participant specially consent for retention of the data.

Personal information will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and her supervisor, in the case wherein the PI is a postgraduate student. The only exceptions - and all of them are rare - would normally be:

1. Personal information may be disclosed if required by law.
2. The Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint, or for a compliance audit

3. The South African Health Products Regulatory Authority (SAHPRA), which is the successor body to the South African Medicines Control Council (SAMCC), might conceivably require access to personal data, if conducting an investigation into a drug trial.

If results are published, this may, exceptionally, lead to cohort, or more rarely, individual identification. All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly. Anonymity will be up-held.
The outcomes of the study will be available to you once the study is completed

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.

Date: February 2020

Yours Sincerely

Sandile Olivia Dube

Researcher: Sandile Olivia Dube
Email: 1318148@students.wits.ac.za
Cell: 078 762 5859

Supervisor: Neelaveni Padayachee
Email: neelaveni.padayachee@wits.ac.za
Tel: 011 717 2269

Appendix 4: Consent Form

CONSENT FORM

Project Title: Prevalence of over the counter (OTC) medicine use and the potential of drug-drug interactions with concomitant prescription medicine use at an old age home in Johannesburg

1. I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
2. I was given time to read it, or had it read to me, in the language I best understand;
3. I was given time to ask any questions I wanted to and found any answers given to me to be reasonable and satisfactory;
4. I believe I fully understand why the study is being conducted and what the intended outcomes will be;
5. I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time;
6. I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained
7. I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study I am free to speak to any of these contacts.

Sandile Olivia Dube, Principal Investigator, telephone no. 078 762 5859, or by e-mail at 1318148@students.wits.ac.za,
Neelaveni Padayachee, Supervisor, on telephone no. 011 717 2269, or by e-mail at neelaveni.padayachee@wits.ac.za

Professor CB Penny, Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand, on telephone no. 011 717 2301, or by e-mail at Clement.Penny@wits.ac.za.
Ms. Z Ndlovu or Mr Rhulani Mkansi, Committee Secretariat, telephone nos.: 011 717 2700 or 1234, or by e-mail at: Zanele.Ndlovu@wits.ac.za or Rhulani.Mkansi@wits.ac.za

Name of Participant: _____
Date: _____
Place: _____
Signature or mark _____

Witnessed by:
Name of Witness: _____
Signature: _____
Date: _____

Appendix 5: Ethics Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research & Post Graduate Affairs)

TO: Ms SO Dube
School of Therapeutic Sciences
Department of Pharmacy and Pharmacology
Medical School
University

E-mail: 1318148@students.wits.ac.zq

CC: Supervisor: Ms N Padayachee <Neelaveni.Padayachee@wits.ac.za>
and <HREC-Medical.ResearchOffice@wits.ac.za>

FROM: Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 03/10/2019

REF: *R14/49*

PROTOCOL NO: **M180659** *(This is your ethics application study reference number. Please quote this reference number in all correspondence relating to this study)*

PROJECT TITLE: *Prevalence of over-the-counter (OTC) medicine use and the potential of drug-drug interactions with concomitant chronic medicine use at an old age home in Johannesburg*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to the Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Ms SO Dube

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M180659

NAME: (Principal Investigator)	Ms SO Dube
DEPARTMENT:	School of Therapeutic Sciences Department of Pharmacy and Pharmacology Medical School University
PROJECT TITLE:	Prevalence of over-the-counter (OTC) medicine use and the potential of drug-drug interactions with concomitant chronic medicine use at an old age home in Johannesburg
DATE CONSIDERED:	29/06/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Ms N Padayachee
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	03/10/2019

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore reports and re-certification will be due early in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

03/11/2019
Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

23/06/2020

Ms SO Dube
School of Therapeutic Sciences
Department of Pharmacy and Pharmacology
Medical School
University

Sent by e-mail to: 1318148@students.wits.ac.za

Dear Ms Dube

Re: **Protocol Ref No: M180659**
Protocol Title: *Prevalence of over-the-counter (OTC) medicine use and the potential of drug-drug interactions with concomitant chronic medicine use at an old age home in Johannesburg*
Principal Investigator: Ms SO Dube

Thank you for your e-mail of 09/06/2020.

I confirm that we have noted and approved your intention to survey your study participants online, rather than in person.

Thank you for keeping us informed.

Yours Sincerely

I. Burns

.....

Mr I Burns
For the Human Research Ethics Committee (Medical)

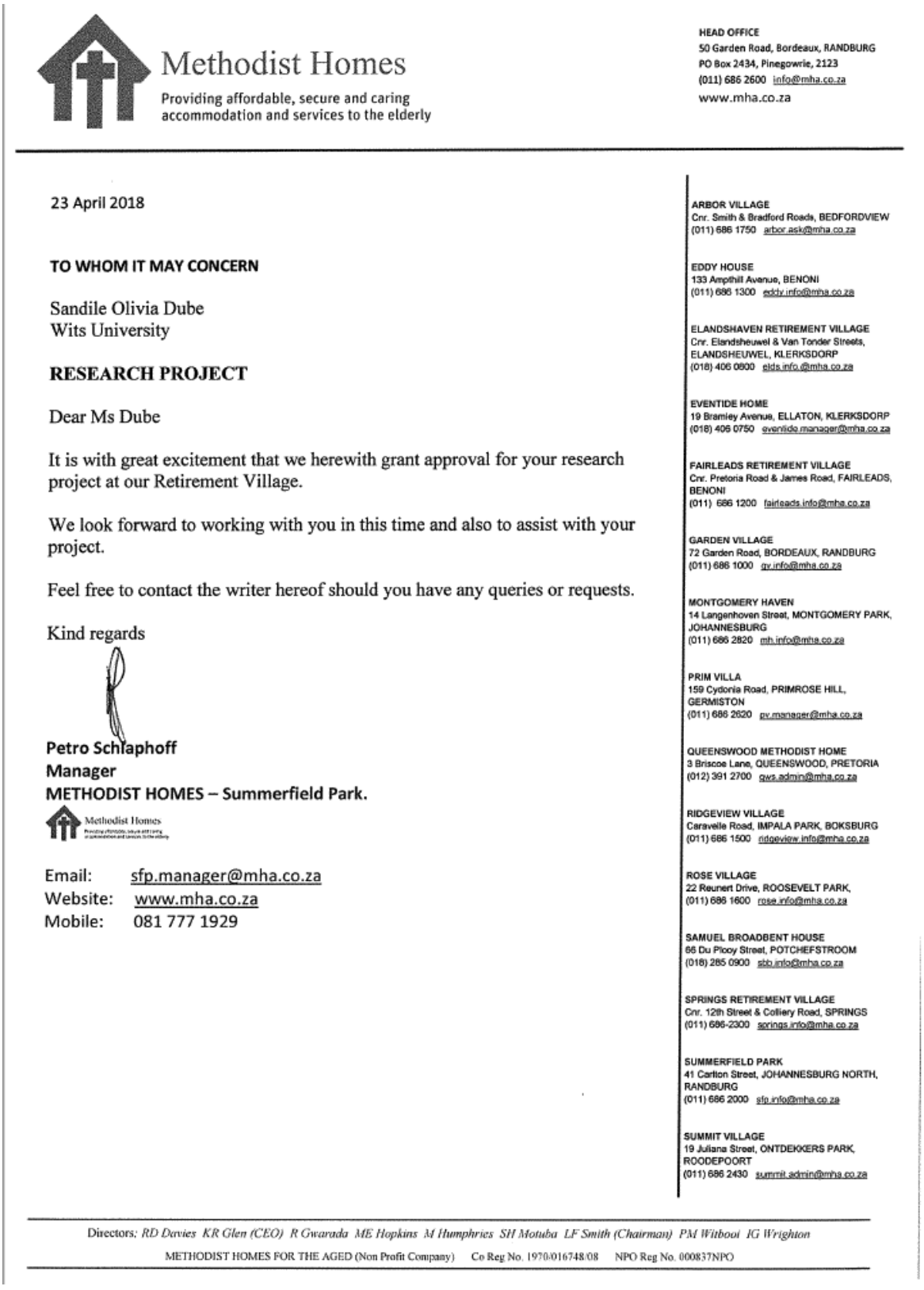
CB Penny

.....

Dr CB Penny, Chairperson, Human Research Ethics Committee (Medical)

cc Ms N Padayachee

Appendix 6: Permission to access research site



Methodist Homes

Providing affordable, secure and caring accommodation and services to the elderly

HEAD OFFICE
50 Garden Road, Bordeaux, RANDBURG
PO Box 2434, Pinegowrie, 2123
(011) 686 2600 info@mha.co.za
www.mha.co.za

23 April 2018

TO WHOM IT MAY CONCERN

Sandile Olivia Dube
Wits University

RESEARCH PROJECT

Dear Ms Dube

It is with great excitement that we herewith grant approval for your research project at our Retirement Village.

We look forward to working with you in this time and also to assist with your project.

Feel free to contact the writer hereof should you have any queries or requests.

Kind regards

Petro Schlaphoff
Manager
METHODIST HOMES – Summerfield Park.

Methodist Homes

Email: sfp.manager@mha.co.za
Website: www.mha.co.za
Mobile: 081 777 1929

ARBOR VILLAGE
Cnr. Smith & Bradford Roads, BEDFORDVIEW
(011) 686 1750 arbor.ask@mha.co.za

EDDY HOUSE
133 Ampthill Avenue, BENONI
(011) 686 1300 eddy.info@mha.co.za

ELANDSHAVEN RETIREMENT VILLAGE
Cnr. Elandsheuwel & Van Tonder Streets,
ELANDSHEUWEL, KLERKSDORP
(018) 406 0800 elds.info@mha.co.za

EVENTIDE HOME
19 Bramley Avenue, ELLATON, KLERKSDORP
(018) 406 0750 eventide.manager@mha.co.za

FAIRLEADS RETIREMENT VILLAGE
Cnr. Pretoria Road & James Road, FAIRLEADS,
BENONI
(011) 686 1200 fairleads.info@mha.co.za

GARDEN VILLAGE
72 Garden Road, BORDEAUX, RANDBURG
(011) 686 1000 gv.info@mha.co.za

MONTGOMERY HAVEN
14 Langenhoven Street, MONTGOMERY PARK,
JOHANNESBURG
(011) 686 2820 mh.info@mha.co.za

PRIM VILLA
159 Cydonia Road, PRIMROSE HILL,
GERMISTON
(011) 686 2620 pv.manager@mha.co.za

QUEENSWOOD METHODIST HOME
3 Briscoe Lane, QUEENSWOOD, PRETORIA
(012) 391 2700 qws.admin@mha.co.za

RIDGEVIEW VILLAGE
Caravelle Road, IMPALA PARK, BOKSBURG
(011) 686 1500 ridgeview.info@mha.co.za

ROSE VILLAGE
22 Reunert Drive, ROOSEVELT PARK,
(011) 686 1600 rose.info@mha.co.za

SAMUEL BROADBENT HOUSE
66 Du Plooy Street, POTCHEFSTROOM
(018) 285 0900 sbb.info@mha.co.za

SPRINGS RETIREMENT VILLAGE
Cnr. 12th Street & Colliery Road, SPRINGS
(011) 686-2300 springs.info@mha.co.za

SUMMERFIELD PARK
41 Carlton Street, JOHANNESBURG NORTH,
RANDBURG
(011) 686 2000 sfp.info@mha.co.za

SUMMIT VILLAGE
19 Juliana Street, ONTDEKKERS PARK,
ROODEPOORT
(011) 686 2430 summit.admin@mha.co.za

Appendix 7: Turnitin Report

Research Report SO Dube 2021-1.docx

ORIGINALITY REPORT

8%	6%	3%	4%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to Trinity College Dublin Student Paper	1%
2	hdl.handle.net Internet Source	<1%
3	Submitted to University of Witwatersrand Student Paper	<1%
4	repository.up.ac.za Internet Source	<1%
5	academic.oup.com Internet Source	<1%
6	www.sahpra.org.za Internet Source	<1%
7	Submitted to Universiti Teknologi MARA Student Paper	<1%
8	ulspace.ul.ac.za Internet Source	<1%
9	carersqld.asn.au Internet Source	<1%

10	Submitted to Federation University Student Paper	<1 %
11	Rothenberg, Richard, Christine Stauber, Scott Weaver, Dajun Dai, Amit Prasad, and Megumi Kano. "Urban health indicators and indices—current status", BMC Public Health, 2015. Publication	<1 %
12	Submitted to Birzeit University Main Library Student Paper	<1 %
13	wiredspace.wits.ac.za Internet Source	<1 %
14	Submitted to North West University Student Paper	<1 %
15	erepository.uonbi.ac.ke:8080 Internet Source	<1 %
16	www.um.edu.mt Internet Source	<1 %
17	"Proceedings: 2nd Joint Meeting ESCP-ACCP Optimizing Outcomes in Pharmacotherapy: Paris, France 28-30 April 2004", Pharmacy World & Science, 2004 Publication	<1 %
18	Submitted to Swinburne University of Technology Student Paper	<1 %

19	Submitted to UNIVERSITY OF LUSAKA Student Paper	<1 %
20	Submitted to Cranfield University Student Paper	<1 %
21	Submitted to Griffth University Student Paper	<1 %
22	Submitted to Middlesex University Student Paper	<1 %
23	"The Epidemiology of Aging", Springer Science and Business Media LLC, 2012 Publication	<1 %
24	Submitted to Tennessee State University Student Paper	<1 %
25	Submitted to University of Sheffield Student Paper	<1 %
26	epubs.surrey.ac.uk Internet Source	<1 %
27	tees.openrepository.com Internet Source	<1 %
28	Submitted to Leeds Beckett University Student Paper	<1 %
29	ir.uitm.edu.my Internet Source	<1 %
30	uir.unisa.ac.za	

	Internet Source	<1 %
31	erepository.uonbi.ac.ke Internet Source	<1 %
32	A. Lu. "Regular health care use by lesbians: a path analysis of predictive factors", Family Practice, 07/11/2006 Publication	<1 %
33	Hirsch, Patricia, Mathieu Declerck, and Iring Koch. "Exploring the functional locus of language switching: Evidence from a PRP paradigm", Acta Psychologica, 2015. Publication	<1 %
34	Matthäus Vigl, Eva Niggemeyer, Alfred Hager, Gerda Schwedler, Siegfried Kropf, Ulrike Bauer. "The importance of socio-demographic factors for the quality of life of adults with congenital heart disease", Quality of Life Research, 2010 Publication	<1 %
35	Submitted to Segi University College Student Paper	<1 %
36	bmcpublichealth.biomedcentral.com Internet Source	<1 %
37	core.ac.uk Internet Source	<1 %

38	democracy.hyndburnbc.gov.uk Internet Source	<1 %
39	lib.dr.iastate.edu Internet Source	<1 %
40	oro.open.ac.uk Internet Source	<1 %
41	Anna-Ursula Happel, Ravesh Singh, Nireshni Mitchev, Koleka Mlisana, Heather B. Jaspan, Shaun L. Barnabas, Jo-Ann S. Passmore. "Results from the first South African Health Products Regulatory Authority-approved randomised trial evaluating supplementation of standard antibiotic therapy with a commercially available probiotic in South African women with bacterial vaginosis", Cold Spring Harbor Laboratory, 2020 Publication	<1 %
42	Carmen C. Franz, Sabin Egger, Christa Born, Alexandra E. Rätz Bravo, Stephan Krähenbühl. "Potential drug-drug interactions and adverse drug reactions in patients with liver cirrhosis", European Journal of Clinical Pharmacology, 2011 Publication	<1 %
43	F. Benazzi. "Anticholinergic Toxic Syndrome with Venlafaxine-Desipramine Combination", Pharmacopsychiatry, 2007	<1 %

	Publication	
44	Submitted to Institute of Technology, Sligo Student Paper	<1 %
45	Knights, Kathleen, and Arduino Mangoni. "Drug and Nutrient Interactions in Masters Athletes", Nutrition and Performance in Masters Athletes, 2014. Publication	<1 %
46	Maria Ruiz. "Risks of Self-Medication Practices", Current Drug Safety, 2010 Publication	<1 %
47	Mayyada Wazaify. "Societal perspectives on the role of community pharmacists and over-the-counter drugs in Jordan", Pharmacy World & Science, 12/2008 Publication	<1 %
48	Pagan, J.A.. "Self-medication and health insurance coverage in Mexico", Health policy, 200601 Publication	<1 %
49	Roschelle Heuberger. "Polypharmacy and Food–Drug Interactions Among Older Persons: A Review", Journal of Nutrition in Gerontology and Geriatrics, 2012 Publication	<1 %
50	biblio.ugent.be Internet Source	<1 %

51	centaur.reading.ac.uk Internet Source	<1 %
52	e-space.mmu.ac.uk Internet Source	<1 %
53	etheses.bham.ac.uk Internet Source	<1 %
54	mafiadoc.com Internet Source	<1 %
55	onlinelibrary.wiley.com Internet Source	<1 %
56	orwh.od.nih.gov Internet Source	<1 %
57	pdf.usaid.gov Internet Source	<1 %
58	ulir.ul.ie Internet Source	<1 %
59	www.whb.ie Internet Source	<1 %
60	Carmel M. Hughes. "Benefits and Risks of Self Medication", Drug Safety, 2001 Publication	<1 %
61	usir.salford.ac.uk Internet Source	<1 %

62	Espino, D. V., O. V. Bazaldua, R. F. Palmer, C. P. Mouton, M. L. Parchman, T. P. Miles, and K. Markides. "Suboptimal Medication Use and Mortality in an Older Adult Community-Based Cohort: Results From the Hispanic EPESE Study", The Journals of Gerontology Series A Biological Sciences and Medical Sciences, 2006. Publication	<1 %
63	Lynn Yeen Goh, Agnes I Vitry, Susan J Semple, Adrian Esterman, Mary A Luszcz. "Self-medication with over-the-counter drugs and complementary medications in South Australia's elderly population", BMC Complementary and Alternative Medicine, 2009 Publication	<1 %
64	Natasa Gisev. "Psychiatric Drug Use Among Patients of a Community Mental Health Service", Disease Management & Health Outcomes, 2006 Publication	<1 %
65	eprints.mdx.ac.uk Internet Source	<1 %