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Disposal Practices for Unwanted Medicines from Households in Johannesburg

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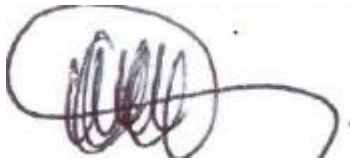
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DECLARATION

I declare that this thesis that I now submit for assessment on the programme of study leading to the award of Master of Science in Pharmacy Administration and Policy Regulation has not been submitted as an exercise for a degree at this or any other university. It is entirely my own work and has not been taken from the work of others; save to the extent that such work has been cited and acknowledged within the text of my work.

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Signed:

A handwritten signature in dark ink, consisting of several loops and a long horizontal stroke extending to the right.

Dated: 31 March 2016



ABSTRACT

AUTHOR: Mashiane, M.M.

TITLE: Disposal practices of unwanted medicine from households in Johannesburg

AIM: The primary objective of this research was to establish the disposal practices for unwanted medicines from households in Johannesburg.

METHODS: A mixed research method was used where quantitative research facilitated qualitative research. Three questionnaires were drafted and distributed by email to respondents in the Johannesburg area. One questionnaire was for households. The second questionnaire was targeted at pharmacists who work in community pharmacies. The third questionnaire was aimed at South African Pharmacy Council (SAPC) registered Responsible Pharmacists for community pharmacies.

In order to reduce bias the household questionnaire was also distributed as hard copies to access respondents in lower Living Standards Measures. Data analysis was done by using the Survey Monkey data analysis package.

RESULTS: Garbage disposal is the most favoured method of disposal of unwanted medicines from households (52%, n = 102) followed by down the sink or in the toilet (34%, n = 66).

CONCLUSION: There is a willingness among household respondents to support a return to pharmacy program which is matched by the pharmacists' willingness to play a central role in such a program.

Key Words: Disposal of pharmaceuticals, Unwanted medicines, Unused medicines, Environmental risk of pharmaceuticals

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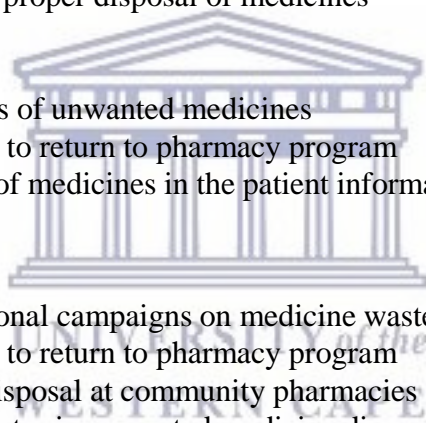
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LIST OF ABBREVIATIONS

LSM	Living Standards Measure (a Southern African population segmentation tool that divides the population according to their living standards)
NEMWA	National Environmental Management Waste Act
OTC	Over The Counter
SAPC	South African Pharmacy Council
SOP	Standard Operating Procedure



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CHAPTER 1 – INTRODUCTION

1.1. Background of the problem

Chapter 2: Bill of Rights of the Constitution, clause 24 states that “everyone has the right to an environment that is not harmful to their health and wellbeing”. It is against this backdrop that the Department of Environmental Affairs legislated the National Environmental Management: Waste Act (NEMWA), (Act 59 of 2008) as amended.

In line with the requirements of NEMWA, Regulation 27 of the Medicines and Related Substances Control Act, (Act 101 of 1965) as amended, states that no medicine or scheduled substance may be disposed of in the municipal sewerage system and their destruction must be conducted in such a manner as to prevent retrieval of the medicine or scheduled substance.

In March 2012 the South African Pharmacy Council (SAPC) published the minimum standards for the destruction and disposal of medicines and scheduled substances as an additional standard to the rules relating to Good Pharmacy Practice in terms of Section 35A(b)(ii) of the Pharmacy Act (Act 53 of 1974) as amended.

1.2. Statement of the problem

Abahussain et al (2006) assert that guidelines exist for corporations and governments on the proper disposal of healthcare waste, however information available to the public is often limited and sometimes contradictory. They recommend a ‘reverse distribution network’ as a solution for safe disposal of unused medicine from homes.

1.3. Purpose of the study

The South African Medicines Control Council’s guideline for the compilation of a Patient Information Leaflet of a medicine has mandatory statements informing the patient not to dispose of medicines in sewerage systems. Patients are advised to return unused medicines to the pharmacy. The study aims to determine the various means of disposal of unwanted medicines, and identify factors influencing the means of disposal of unwanted medicines. This information is necessary input in drafting guidelines for the role of the pharmacist in the proper disposal of unwanted medicines.

The survey by Tong et al (2011b) highlighted the need to raise awareness with community

pharmacists on the proper disposal of unwanted or expired medicines. Therefore, the present research was also aimed at aggregating the opinions of the community pharmacists on the role they foresee the pharmacist playing in the proper disposal of unwanted medicines from households.

1.4. Research question

The present research sought to determine the disposal practices of unwanted medicines from households in Johannesburg. Further to that the study sought to determine why households ended up with unwanted medicines.

1.5. Significance of the study

The South African Sunday Times newspaper published an article by Govender on the 27th of September 2015 with the headline ‘Cocktail of drug waste lurks in SA’s tap water’. The article highlighted the extent of water contamination due to pharmaceutical waste in South Africa. According to one academic interviewed in the article ‘Pharmaceuticals in the environment and the impact on health is a new focus with opportunities for senior postgraduate research’. The study intends to create an awareness among households of the proper disposal of unwanted medicines in order to reduce the negative impact on the environment.

1.6. Scope of the study

The current study sought to determine the disposal practices of unwanted medicines by households and community pharmacies in the Johannesburg area. This was done through the use of semi-structured questionnaires that were distributed via email and printed questionnaires [in order to include those who do not have email and possibly access people in lower Living Standards Measures (LSM’s)] to households.

CHAPTER 2 – LITERATURE REVIEW

2.1 Introduction

Human excretion of pharmaceutical compounds either through urine, faeces or the skin during bathing is inevitable. However, the improper disposal of unwanted medicines from households can be managed and controlled. In order to address the improper disposal of unwanted medicines, it is also important to understand the factors that lead to accumulation of unwanted medicines in households.

According to Lindberg et al (2008) poor patient compliance is one of the reasons for the accumulation of expired or unwanted medicines in households. Ekedahl (2006) argues that over prescribing by doctors may be a contributory factor. Over dispensing by Pharmacists may also contribute to accumulation of unwanted medicines in the household as reported by Ruhoy and Daughton (2008).

Wood et al. (2015) and Schoeman et al. (2015) confirmed the occurrence of anti-retrovirals in South African surface water and wastewater treatment works respectively. These studies prove conclusively that the South African environment is also under threat of pollution from pharmaceuticals.

The present study aims to raise awareness in South Africa of the need for proper disposal of unwanted medicines for the sake of conservation of our environment. A pilot study conducted in South Africa by Amod et al (2008) on a random sample of 200 adults, found that 62.5% of the respondents threw unwanted medicine in the bin, 17% flushed it down the toilet, 6.5% poured it down the sink and 2% buried it in the garden. Only 2.5% of respondents returned medicines to the pharmacy for disposal.

Amod et al. (2008) and Kotchen et al. (2009) reported that the number of people returning medicines to the pharmacy for disposal was lower than other disposal methods at 2.5% and 6% respectively. The majority of people still discard unwanted medicines in the garbage and sewerage systems, as highlighted by Amod et al. (2008) and Bound and Voulvoulis (2005) despite the mandatory statements in patient information leaflets advising patients to return unwanted medicines to the pharmacy and advising against discarding unwanted medicines in municipal sewerage systems.

2.2. Main Body

2.2.1. Summary of studies

The key words ‘disposal of pharmaceuticals’, ‘unwanted medicines’, ‘unused medicines’ and ‘environmental risk of pharmaceuticals’ were used to search peer reviewed literature in Pubmed®, Medline® and Google Scholar®. Forty studies in total were identified most of which made a link between environmental toxicity and pharmaceutical waste disposal.

Mackridge and Marriott (2007) was the only study identified in the literature review to recommend the re-use of medicines returned to pharmacies in the U.K. and developing countries as they considered most of them to still be in good condition. This is not a favoured option in our opinion as there is no guarantee that the medicine has been subjected to safe storage conditions that did not compromise its safety and efficacy.

Studies were narrowed down to those investigating patient or public behaviours, attitudes and perceptions regarding the disposal of medicines. Seven studies were identified that fit the criteria, the details of which are summarized in Table 1.

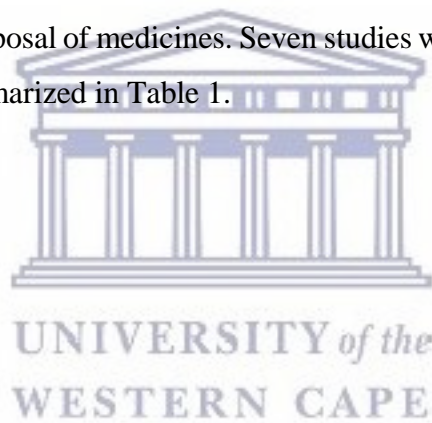


Table 1. Studies found in the peer-reviewed literature that are relevant to the current thesis

Year of study	Author(s)	Place	Objective(s) of the study	Materials and methods	Conclusion(s) of the study
2005	Bound and Voulvoulis	England	<p>1. Identify and assess the significance of the different pathways of pharmaceuticals from the household to the environment.</p> <p>2. Demonstrate the possible importance of household disposal of unused medicines as a pathway into the aquatic environment.</p>	Interview, closed ended questions with the interviewer specifying possible answers.	<p>1. Disposal pathway of unused medicines from households is a cause for concern and should figure more prominently in the investigations into the presence of pharmaceuticals in the aquatic environment.</p> <p>2. Minimising the disposal pathway could be more effective and less costly than extensive WWTW modifications or other remediation steps.</p>
2006	Abahussain et al.	Kuwait	Measure the attitude and practice of patients with regard to safe disposal of unwanted medicines.	Questionnaire.	There is a need for an appropriate method of disposal for unwanted medicines. Guidelines on safe disposal of unwanted medicines are required and an organized method of collecting unused medicine needs to be introduced.
2006	Seehusen and Edwards	United States	Identify patients' disposal habits and explore patients' beliefs about disposal methods.	Computerised anonymous questionnaire.	There is a role for patient education on the proper disposal of unused and expired medications. Future research should focus on how to most effectively educate patients on proper disposal techniques.

Table 1 (continued). Studies found in the peer-reviewed literature that are relevant to the current thesis

Year of study	Author(s)	Place	Objectives of the study	Materials and methods	Conclusion of the study
2008	Amod et al.	South Africa	Investigate medicine storage and disposal by the public.	Random anonymous self-administered questionnaire.	While the general public has knowledge on the proper storage of medicines, knowledge with regard to disposal of medicines is inadequate and needs to be addressed
2009	Kotchen et al.	United States	Assess willingness of the public to pay to establish a pharmaceutical disposal program.	Random telephone survey.	There is willingness to pay for a surcharge on prescriptions to support a pharmaceutical disposal program and respondents are likely to participate in a disposal program if one were set up.
2011	Auta et al.	Nigeria	Determine the common classes of unused medicines in households and medication disposal practices.	Interview using a pre-tested questionnaire.	There is a need for public education on appropriate disposal of medicines. Government should encourage a reverse distribution network in which community members are encouraged to return unwanted medicines to pharmacies which then arrange for approved agents to collect and destroy them.
2012	Kusturica et al.	Serbia	Investigate the storage and disposal habits of medications amongst the population and to gain insight into the attitudes and knowledge of the population about the proper disposal of medications.	Random questionnaire administered by a trained interviewer.	Public services, including government and health sectors, need to be more proactive about educating people on how to store and dispose medications, as well as finding a way for implementation of the law on medications wastage destruction.

2.2.2. Discussion

In the literature review, Bound and Voulvoulis (2005), Abahussain et al. (2006), Seehusen and Edwards (2006), Amod et al. (2008), Auta et al. (2011) and Kusturica et al. (2012) were aimed at understanding public perceptions regarding the proper disposal of unwanted medicines (see Table 1). Kotchen et al. (2009) measured the willingness of the public to pay for an unwanted medicine proper disposal program. Abahussain et al. (2006), Seehusen and Edwards (2006), Amod et al. (2008), Auta et al. (2011) and Kusturica et al. (2012) favoured the use of questionnaires to engage the participants. This is in line with the methodology used for the present research.

2.2.3. Results

The disposal practices identified in the seven studies are summarized in Table 2 below. Throwing unwanted medicines in the garbage seemed to be the most favoured method of disposal in all the studies except one (Seehusen and Edwards 2006) where that option was not measured in the questionnaire. Bound and Voulvoulis (2005) and Seehusen and Edwards (2006) reported the highest number of returns to the pharmacy at 21.8% and 22.9% respectively. Seehusen and Edwards (2006) raised a concern about some state laws preventing pharmacies from accepting returned controlled substances as a hurdle to effective utilisation of return to pharmacy disposal programs. The same study also determined that prior education on proper disposal of medicines contributed to the public returning medicines to a pharmacy or healthcare provider.

Table 2. Disposal practices of unwanted medicines as reported in the relevant literature

Year of study and author	Toilet or sink	Garbage	Return to pharmacy	Other (stated)	Sample size (n)
2005 Bound and Voulvoulis	11.5%	63.2%	21.8%	3.5% waste sites	392
2006 Abahussain et al	11.2%	76.5%	11.9%	8.5% give to friend	300
2006 Seehusen and Edwards	89%	-	22.9%	14% returned to healthcare provider	301
2008 Amod et al.	23.5%	62.5%	2.5%	2.5% bury in the garden	200
2009 Kotchen et al.	28%	45%	6%	5% hazardous waste centre	1005
2011 Auta et al.	-	100%	-	-	427
2012 Kusturica et al.	8.7% urban 6.4% rural	85.6% urban 74.5% rural	-	-	108 urban 100 rural

Kusturica et al. (2012) reported that even though the public was aware of the detrimental effects of disposal of unwanted medicine in the sewerage systems and garbage, this was still practiced. This highlighted the need for a program for the proper disposal of unwanted medicines in Serbia. Although the awareness was there, there were no facilities available to support the proper disposal of unwanted medicines by the public.

Return to pharmacy rates are still very low despite certain countries like the United Kingdom and South Africa actively advising the public to return unwanted medicines to the pharmacy in the patient information leaflet that is included in the packaging. This shows a need for consumer education. This was confirmed by Auta et al. (2011) who observed that basic education on the appropriate disposal of medicines is lacking in Nigeria.

2.3. Conclusion

As awareness increases on the link between improper medicine disposal and environmental pollution, the literature highlights the need for public education. Kuspis and Krenzelok (1996) report that in the 1990's pharmacists in the United States advised patients to dispose of unwanted medicines in the sink, toilet or garbage. More recently, Jones et al (2005) have highlighted the threat of pharmaceuticals to drinking water. Thus there is a need for re-education of not only the public but the healthcare professionals as well to a certain extent. Hence the present study aims to engage the pharmacists as well in its methodology.

The studies summarized in Table 1 and Table 2 are aligned in their conclusions in that there is a need for patient education regarding the proper disposal of medicines. Bound and Vouvolis (2005) assert that disposal of medicines from households should be highlighted and investigated more prominently as a contributory factor in the environmental pollution by unwanted medicines. The need for guidelines and policies on the proper disposal of unwanted medicines is also raised as an area that needs attention. This was further confirmed by Tong et al. (2011a) after studying medicine disposal practices in several countries where they concluded that there is a need for formalised protocol for the disposal of unused medicines by patients.

The present research is in line with current global trends which indicate the need to study disposal practices of unwanted medicines from households, the reasons for accumulation of unwanted medicines and the possibility of establishing formalised reverse distribution take back programs for unwanted medicines at community pharmacies.



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CHAPTER 3: METHODOLOGY

3.1 Materials

A mixed research method was employed where quantitative research facilitated qualitative research. The addition of a quantitative aspect to the qualitative research method will allow the results to be generalized to a greater sample size. Three Survey Monkey questionnaires were drafted and distributed by email to respondents. One questionnaire was for households in Johannesburg (see Appendix A), the second one was targeted at community pharmacists in Gauteng (see Appendix B) the third questionnaire was for SAPC Registered Responsible Pharmacists in Community Pharmacies in Gauteng (see Appendix C).

Since the study questionnaire was in an electronic format, informed consent was sort from all prospective respondents in the form of an email containing the Participant Information Leaflet and Invitation Letter (see Appendix D). The electronic link to the questionnaire was only emailed to participants who responded affirmatively to the initial email. Thus each prospective respondent received two emails, one with the Participant Information Leaflet and Invitation Letter and the other with the survey. Ten invitations were sent out for each questionnaire to pilot and test the questionnaires.

200 invitations of the household questionnaire were sent out by email. In order to reduce bias in the respondents to the household questionnaire being only accessed by people with email, 200 questionnaires were also distributed as hard copies so that the distribution of respondents was across different Living Standards Measures.

The Community Pharmacist questionnaire and the SAPC Registered Responsible Pharmacist questionnaire were sent out by email. The surveys were kept open for a period of two weeks. Two reminders were sent out during the two weeks.

The objective of the household questionnaire was to find out the reasons why people ended up with unwanted medicines in their households and how these are disposed of. The questionnaire also sought to assess the respondents' opinions to the use of a return to pharmacy program for unwanted medicines.

The community pharmacist questionnaire was aimed at assessing whether the pharmacist ever received any formal advice on the proper disposal of medicines, if there was a need for a return unwanted medicine disposal program and who should manage such a program.

The responsible pharmacist questionnaire asked about the presence of standard operating procedures for the disposal of medicines in the pharmacy, costs involved in disposal of unwanted medicines and if the pharmacist should be subsidized for the disposal of unwanted medicines returned by the public. Both pharmacist questionnaires enquired about the disposal methods used in the pharmacy for unwanted medicines according to dosage form.

3.2 Sample size

The sample sizes were estimated using the Raosoft sample size calculator. The total population of households in Johannesburg is 1,434,856 according to the South African National Census of 2011. If a confidence level of 95% is assumed and the margin of error is accepted as 5%, a sample size of 385 is recommended for the household questionnaire assuming a response distribution of 50%. 402 household questionnaires were distributed.

The SAPC register of community pharmacies in Gauteng was used to access the Community Pharmacists and SAPC Registered Responsible Pharmacists.

The number of Gauteng community pharmacists on the SAPC register is 1881 according to the SAPC Statistics as at 01 March 2016. If a confidence level of 90% is assumed and the margin of error is accepted as 5%, a sample size of 237 is recommended for the community pharmacist questionnaire assuming a response distribution of 50%. 1772 community pharmacist questionnaires were distributed by email.

The number of community pharmacies in Gauteng Province is 1097 according to the SAPC statistics as at 01 March 2016. Each community pharmacy has one SAPC registered Responsible Pharmacist. If a confidence level of 90% is assumed and the margin of error is

accepted as 5%, a sample size of 218 is recommended for the responsible pharmacist questionnaire assuming a response distribution of 50%. 886 Responsible Pharmacist questionnaires were distributed by email.

3.3. Data analysis

Analysis of the responses to the questionnaire was done using the Survey Monkey data analysis package. Simple descriptive statistics of key themes of the questionnaire data was done, and graphs and tables used in the narrative analysis of the findings in chapter 4.

3.4 Ethical considerations

The current research did not pose possible risk to the health of the participants. However, the ethical issues related to the invasion of privacy and confidentiality need to be taken into consideration. The Participants received with the link to the questionnaire a “Participant information leaflet and invitation letter” (Appendix D). This made it clear to the prospective respondents that the survey was voluntary. The information leaflet also explained to the respondents that the responses were web based and collated automatically without the researcher having access to the individual responses.

The first question on all three surveys required the respondents to confirm that they have read the “Participant information leaflet and invitation letter”. A “no” response to question 1, prompted the respondent with a message “Please read the Participant Information Leaflet and Invitation Letter before completing the survey”.

CHAPTER 4 – FINDINGS

4.1 Introduction

4.1.1 Household Questionnaire

The electronic invitations were 202 in total. The hardcopy questionnaires distributed were 200. The sum total of household questionnaires distributed was 402. Out of the electronic invitations only 7 invitations bounced due to incorrect email addresses. No one opted out of the electronic household questionnaire. If the bounced invitations are excluded, the actual number of invitations is 395. The total number of responses was 202 which represented 51% of the actual number of invitations. Majority of the respondents (94%, n = 188) confirmed that they had read the Participant Information Leaflet and Invitation Letter. The remaining 13 (6%, n = 13) respondents did not read the Participant Information Leaflet and Invitation Letter and one respondent skipped question 1.

4.1.2 Community Pharmacist Questionnaire

The total invitations sent out were 1772, 78 bounced due to incorrect email addresses and 58 opted out of the survey. The total number of responses received was 161. If the bounced invitations and those that opted out are excluded from the initial invitation amount, the actual number of invitations is 1641. The response total of 161 represented 9.8% of the actual number of invitations. Out of the 161 respondents, 78% (n = 124) read the Participant Information Leaflet and Invitation Letter and 22% (n = 34) did not read it. Three respondents skipped the question.

4.1.3 Responsible Pharmacist Questionnaire

The total invitations sent out were 886, 30 bounced due to incorrect email addresses and 23 opted out of the survey. The total number of responses was 71. If the bounced invitations and those that opted out are excluded from the initial invitation amount, the actual number of invitations is 833. The response total of 71, represented 8.5% of the actual number of invitations. Out of the 71 respondents, 85% (n = 58) read the Participant Information Leaflet and Invitation Letter and 15% (n = 10) did not read it. Three respondents skipped the question.

4.2 Findings

4.2.1 Household questionnaire findings

The unwanted medicines in the households were reported to be a mixture of Over-The-Counter (OTC) and prescription medicines by 47% (n = 94) of respondents. Of the remaining respondents, 37% (n = 73) had mainly OTC medicines as unwanted medicines in their homes and 18% (n= 35) had mainly prescription medicines. Pain killers (60%, n = 120), cold & flu medicines (68.5%, n = 137) and anti-allergy medicines (33.5%, n = 67) were predominant in the households of the respondents as shown in Figure 1 below.

Among the “other” unwanted medicines, vitamins were mentioned by 5% of respondents followed by steroids and anti-inflammatories which were both mentioned by 2% of respondents. The other medicines mentioned by 0.5% of the respondents each were probiotics, complementary & alternative medicines and hormone replacement therapy. It is important to note that for the question ‘the unwanted medicines in my house are?’ the respondents could choose more than one option. Figure 1 below represents the responses to this question.

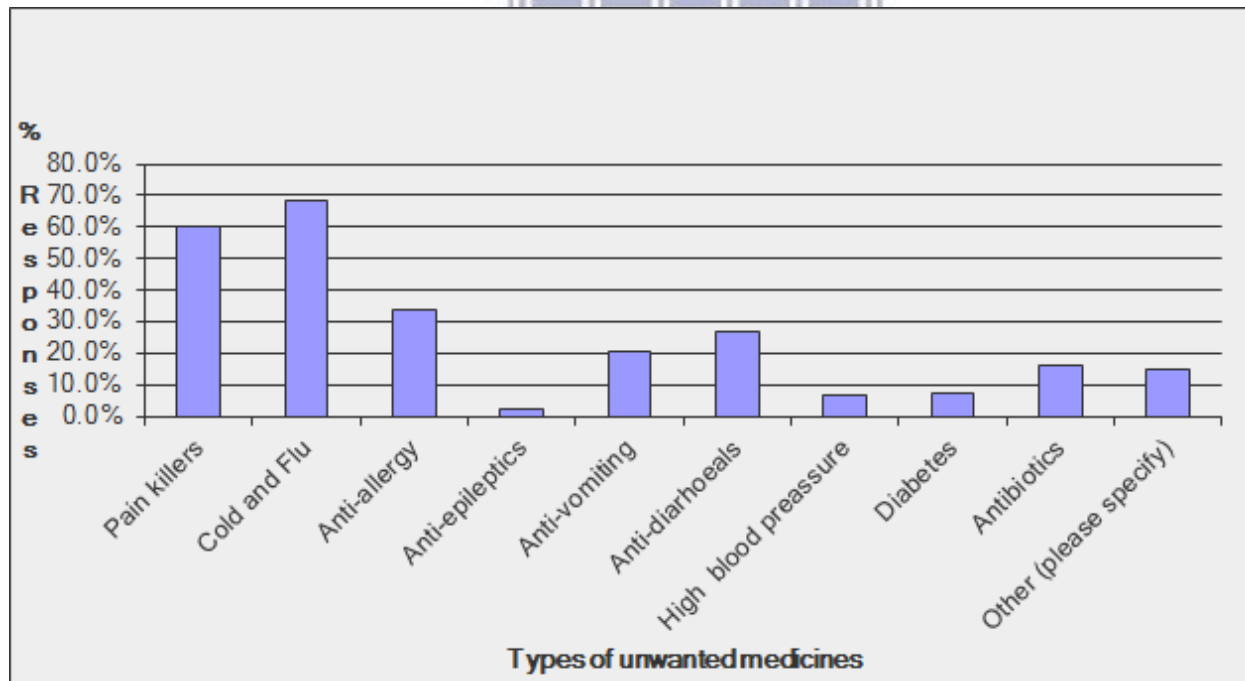


Figure 1. The types of unwanted medicines in the households

The predominant reason for unwanted medicines in the household was that they were expired as reported by 58% (n = 115) of respondents. This was followed by 51% (n = 100) of respondents who had unwanted medicines because they felt better. Table 3 below shows the reasons why households have unwanted medicines. Five respondents skipped the question.

Table 3. Reasons for unwanted medicines in households

Reason for unwanted medicines	Responses	number (n=)
Expired	58.38%	115
The full course was not finished	25.89%	51
Stopped taking the medicine because of side effects	14.21%	28
Stopped taking the medicine because I felt better	50.76%	100
Doctor prescribed too much medicine	10.66%	21
Pharmacist gave me too much medicine	3.05%	6
Medicine was changed by doctor	11.17%	22

The majority of households throw away their unwanted medicines. Table 4 outlines the fate of unwanted medicines in the households. One respondent made a comment “n/a” when requested to specify what they do with unwanted medicines.

Table 4. The fate of unwanted medicines in households

What do you do with unwanted medicines in your house?	Responses	number (n)
Throw it away	76.24%	154
Keep it	15.84%	32
Give it away	1.98%	4
Other – take to pharmacy	4.95%	10
Other – take to clinic	0.50%	1
Total		201

The primary objective of the current research was to find out the disposal practices of unwanted medicines in households in Johannesburg. Table 5 below shows the specific disposal practices with the most common disposal method being in the rubbish bin or trash followed by down the sink or in the toilet (51.78%, n = 102 and 33.50%, n = 66 respectively). Five respondents skipped the question.

Table 5. Household disposal practices of unwanted or unused medicines

Disposal practice	Responses	number (n)
Trash/Rubbish bin	51.78%	102
Bury in the garden	0.51%	1
Down the sink/toilet	33.5%	66
Burn in the backyard	1.02%	2
Return to pharmacy	13.20%	26
Total		197

When asked if they were aware that the patient information leaflet enclosed in the medicine packaging advises on the proper disposal of medicines, 59% (n = 118) of the respondents reported that they were not aware, as opposed to 41% (n = 83) who indicated that they were aware (Figure 2).

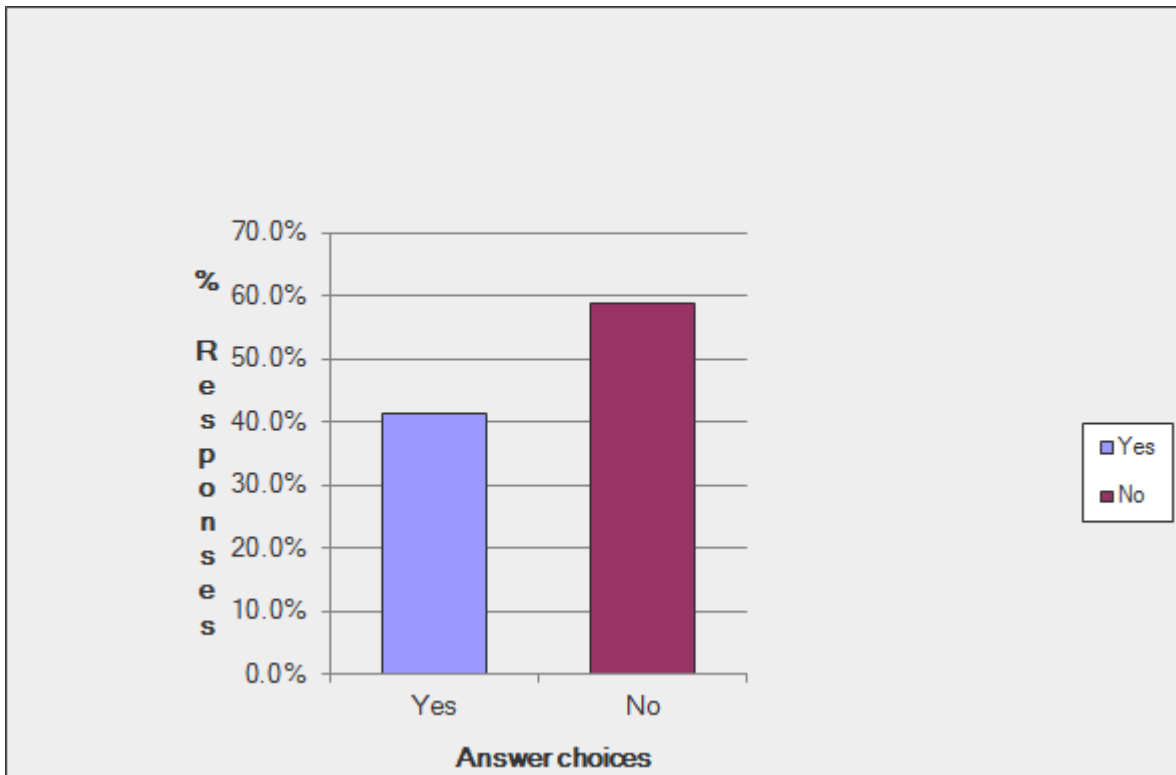


Figure 2. Awareness that the advice on proper medicine disposal is enclosed in the patient information leaflet

Most of the respondents (72%, n = 144) had never received advice on the proper disposal of unwanted or unused medicines from a pharmacist or other health care professional. Only 28% of respondents reported that they had received advice on the proper disposal of unwanted or unused medicines. The majority of respondents (78%, n = 157) indicated that they did not know whether their local community pharmacy accepted unused or unwanted medicines from the public, whereas 12% (n = 24) indicated that their local community pharmacy did accept unused or unwanted medicines from the public. The remaining 10% (n = 21) responded that their local community pharmacy did not accept unused or unwanted medicines from the public (Figure 3).

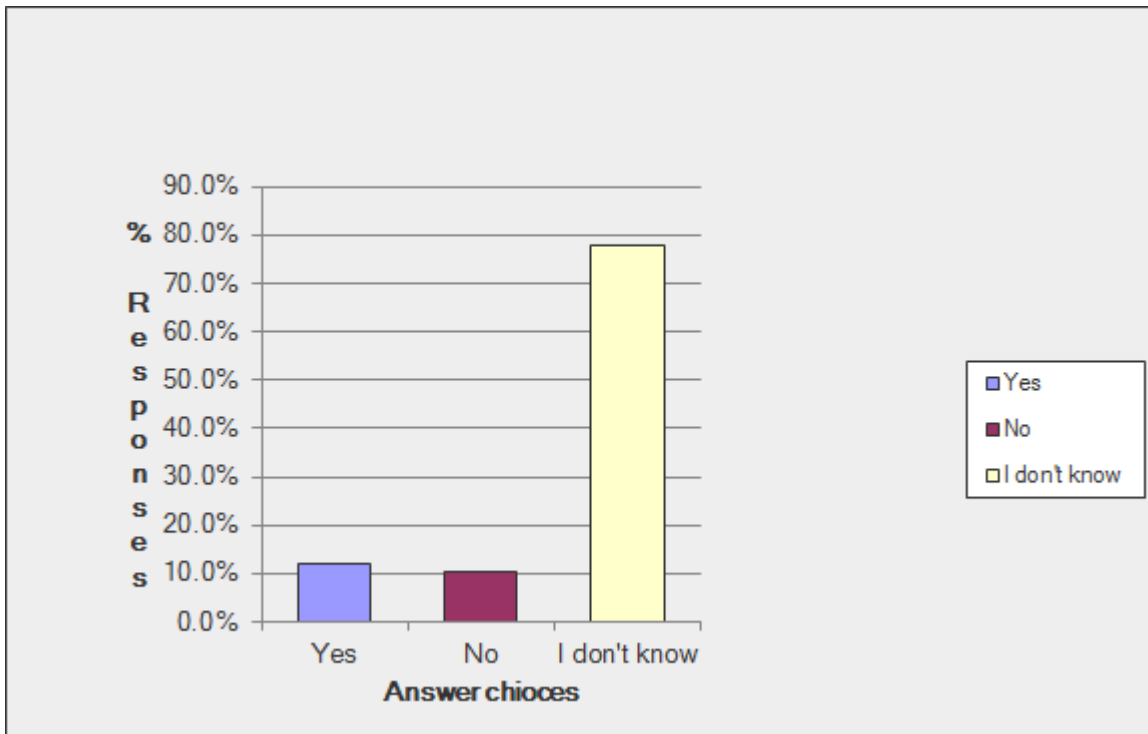


Figure 3. Local community pharmacy acceptance of unused or unwanted medicines returned by the public

The respondents showed a willingness to support an unwanted or unused medicine disposal program at their local community pharmacy with 79% (n = 158) indicating that they would use such a service as opposed to 21% (n = 43) who would not use it (Figure 4).

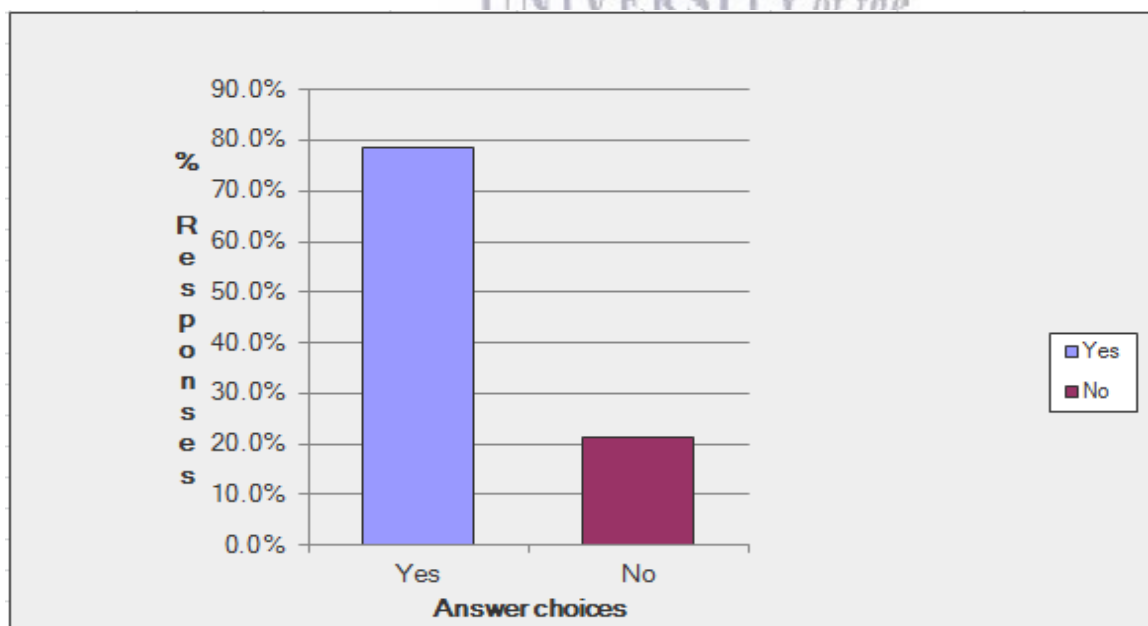


Figure 4. Willingness to use an unwanted or unused medicine disposal program at the local community pharmacy

4.2.2 Community Pharmacist questionnaire findings

Most of the respondents (92.45%, n = 147) indicated that they have been formally advised on the proper disposal of unwanted medicines as opposed to 7.55% (n = 12) who were not formally advised. Two respondents skipped the question. Figure 4 shows the various avenues they were advised through.

The other avenues include self-taught and an SAPC inspection.

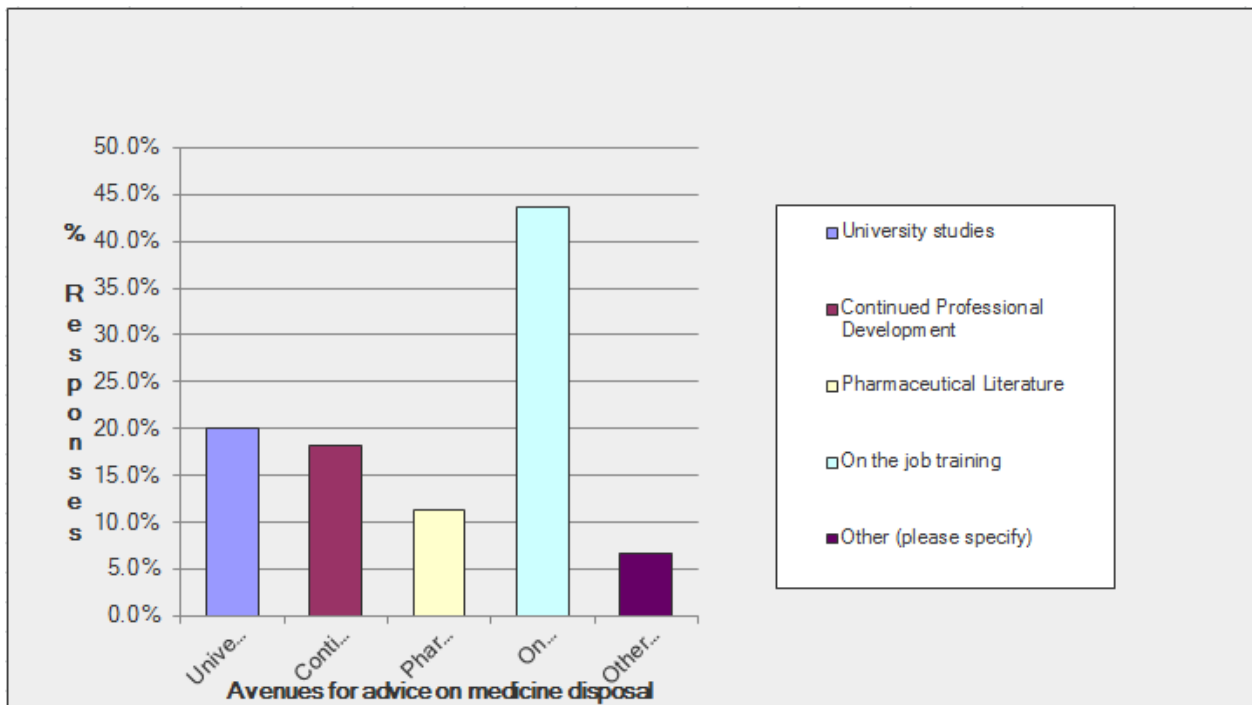


Figure 5. Where Community Pharmacists have been advised about the proper disposal of medicines

Majority of the respondents (98%, n = 158) agreed that Pharmacists as custodians of medicines should raise the awareness of the public on the proper disposal of medicines. When asked whether the patient information leaflet has mandatory text advising the patient of the proper disposal of unwanted medicines, 76% (n = 152) responded false and only 24% (n = 37) responded correctly by choosing the true option (Figure 6). Nine respondents skipped the question.

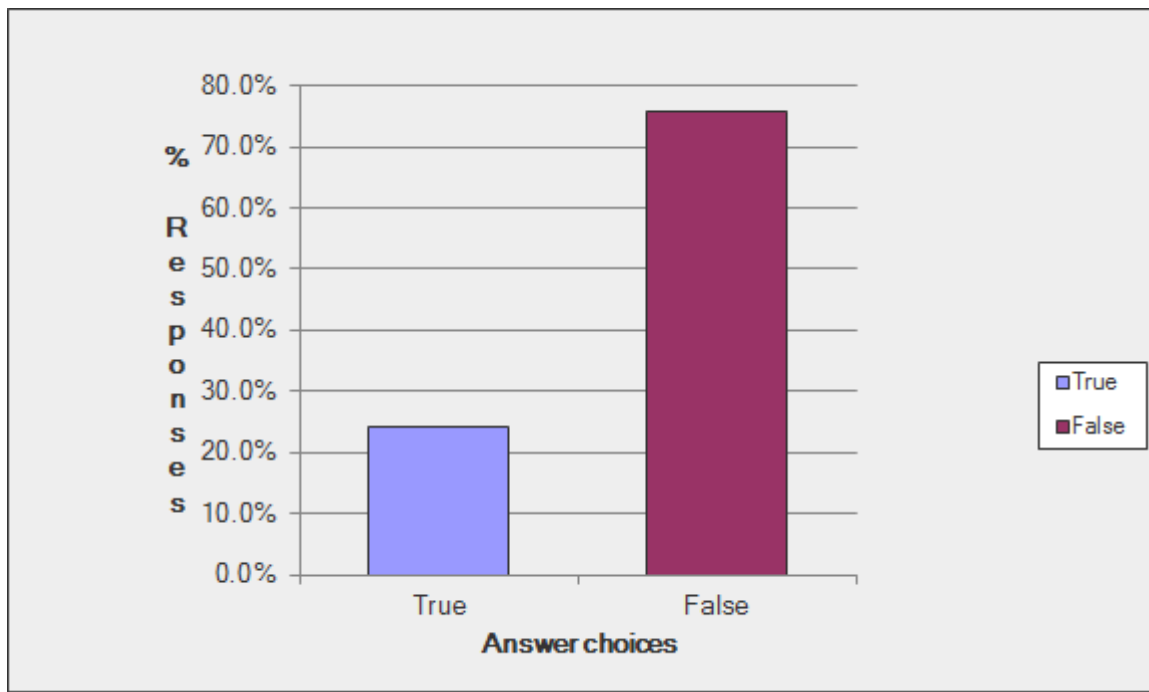


Figure 6. Presence of mandatory text on the proper disposal of unwanted medicines in the patient information leaflet

The majority of respondents (77%, n = 120) indicated that their community pharmacy offers an unwanted medicine disposal programme for the public whereas 23% (n = 35) did not offer such a programme at their community pharmacy. When asked if there is a need for a formalised, state managed ‘returned medicine disposal program’ at pharmacies, 81% (n = 159) agreed that such a programme was a necessity. On the other hand, 19% (n = 30) did not see the need for a state managed ‘returned medicine disposal program’ at pharmacies. The department of health was the favoured choice by 56% (n = 70) of the respondents to oversee such a state managed ‘returned medicine disposal program’ rather than the SAPC which was considered an option by 44% (n = 56) of the respondents. Thirty five respondents skipped the question.

Most of the community pharmacies (98%, n = 142) dispose of unwanted medicines, irrespective of dosage form, through waste management companies. However one response of solid dosage forms being dissolved in a bucket of water was received. It was not clear what happens to the water once the solid dosage forms have dissolved. There was also one response that creams were being disposed of in the bin. For liquid dosage forms three respondents reported they are thrown down the drain. When asked if they actively advise patients about the proper disposal of unwanted medicines 80% (n = 126) of the community pharmacists responded yes (Figure 7).

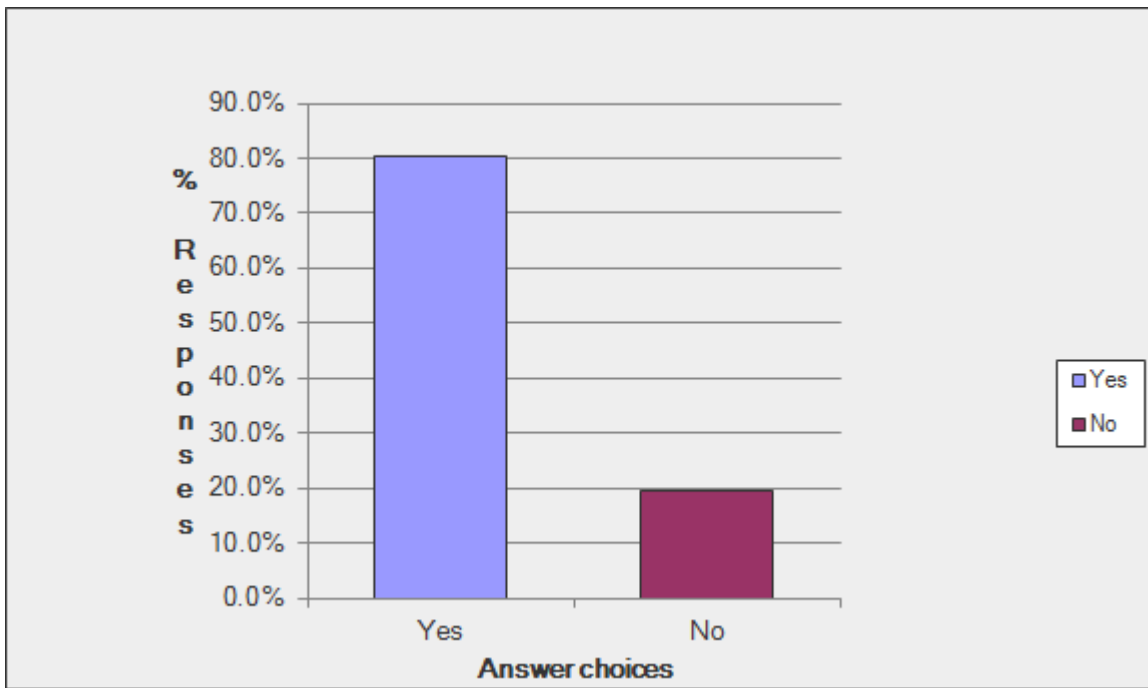


Figure 7. Community Pharmacists who actively advised patients about the proper disposal of medicines

4.2.3 Responsible Pharmacist questionnaire findings

Regarding the availability of Standard Operation Procedure (SOP) on the disposal of unwanted medicines in the pharmacy, 96% (n = 68) of respondents confirmed that an SOP was available, 3 respondents skipped the question. All the respondents reported that disposal of unwanted medicines was through a contracted waste management company. This was confirmed by 94% (n = 69) of respondents saying that their community pharmacies are contracted to a waste management company that disposes of medicines. Majority 88% of the respondents (88%, n = 61) indicated that their pharmacy accepts returned unwanted medicines from the public for proper disposal as opposed to 12% (n = 8) who did not accept returned medicines from the public (Figure 8).

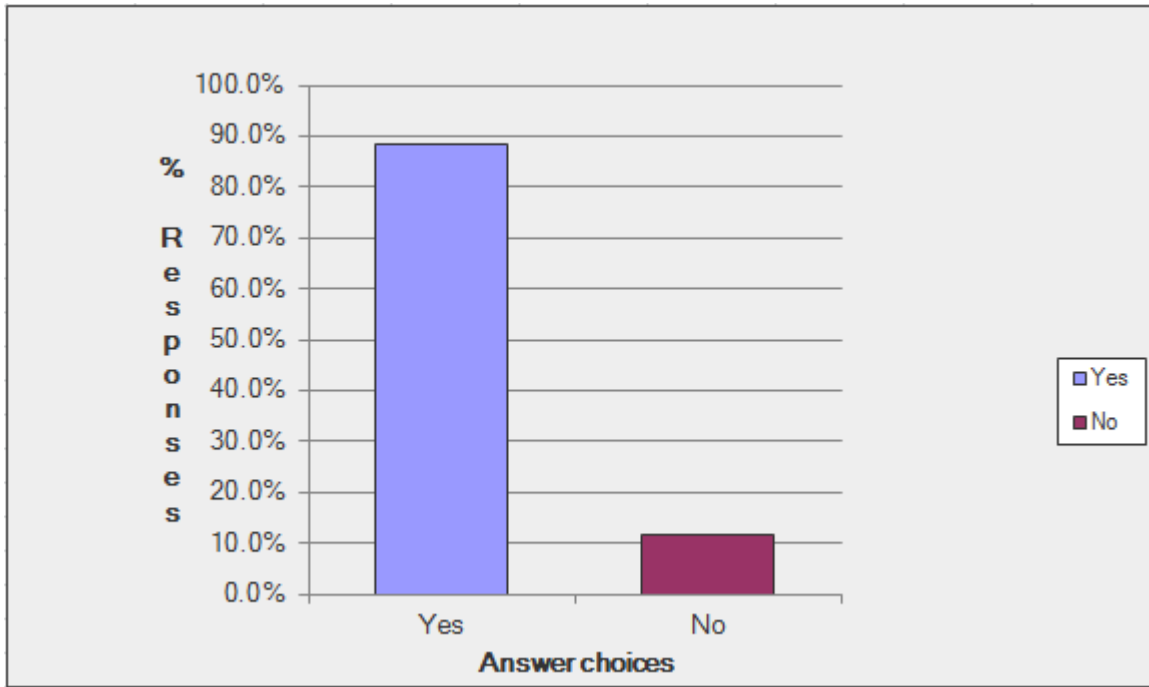


Figure 8. Community Pharmacy accepts returned unwanted or unused medicines from the public

When asked if it is mandatory to include advice on the proper disposal of medicines in a patient information leaflet, 53% (n = 37) of respondents answered correctly by choosing the yes option and 47% (n = 33) responded that it was not mandatory (Figure 9).

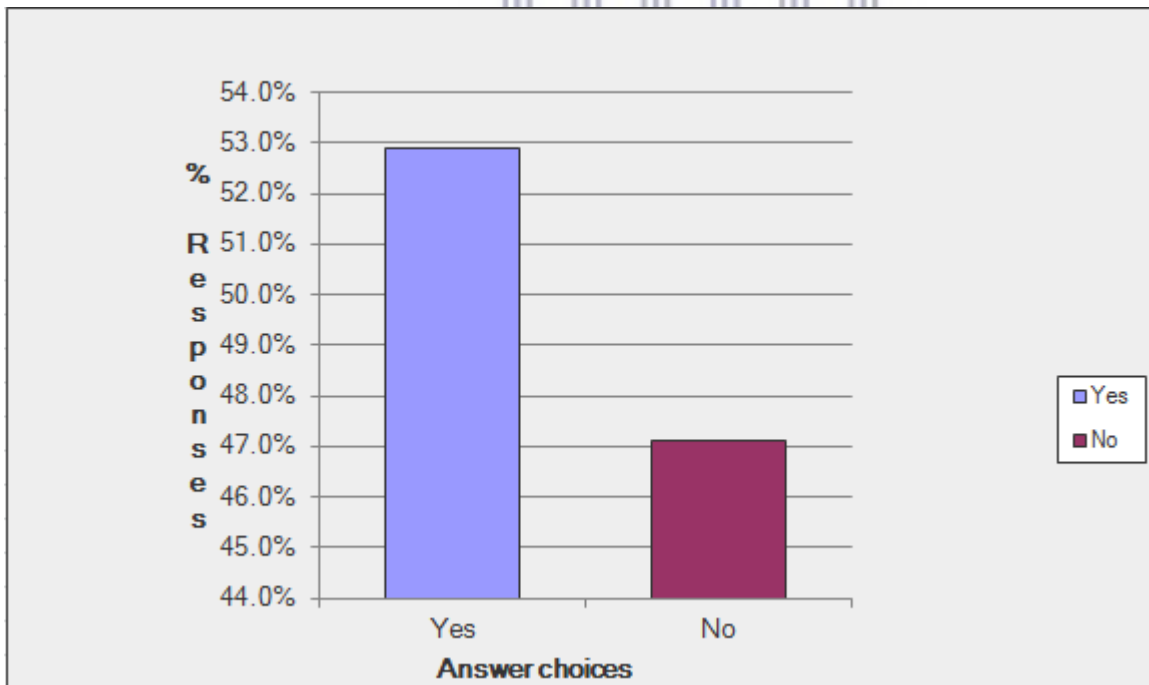


Figure 9. Text on the proper disposal of medicines is mandatory in the patient information leaflet

The majority of respondents (67%, n = 47) agreed that there is a need for a State managed “Returned Medicines Disposal Program” in pharmacies. The average monthly cost of disposing of unwanted medicines at each community pharmacy varied widely among the respondents ranging from R30.00 to R10, 000.00. Furthermore, 27% (n = 19) of the respondents did not know the average monthly costs of disposal of unwanted medicines at the community pharmacy.

According to 83% (n = 58) of the respondents, bearing the cost of disposing of medicines returned by the public to the pharmacy is part of the role of a pharmacist as the custodian of medicines. Furthermore, 87% (n = 61) believed that the pharmacist should be subsidised on the cost of disposal of unwanted medicines returned by the public to the pharmacy.



CHAPTER 5 - DISCUSSION

5.1 Household questionnaire

5.1.1. Disposal Practices

Table 6 below lists the disposal practices of unwanted medicines as reported in the reviewed literature compared with the findings of the present study. Garbage disposal remains the most favoured disposal method for the disposal of unwanted medicines from households. This was confirmed in the reviewed literature and present study.

Table 6. Disposal practices of unwanted medicines as reported in the relevant literature and the present study

Year of study and author	Toilet or sink	Garbage	Return to pharmacy	Other (stated)	Sample size (n)
2005 Bound and Voulvoulis	11.5%	63.2%	21.8%	3.5% waste sites	392
2006 Abahussain et al	11.2%	76.5%	11.9%	8.5% give to friend	300
2006 Seehusen and Edwards	89%	-	22.9%	14% returned to healthcare provider	301
2008 Amod et al.	23.5%	62.5%	2.5%	2.5% bury in the garden	200
2009 Kotchen et al.	28%	45%	6%	5% hazardous waste centre	1005
2011 Auta et al.	-	100%	-	-	427
2012 Kusturica et al.	8.7% urban 6.4% rural	85.6% urban 74.5% rural	-	-	108 urban 100 rural
2016 Present study	33.5%	51.57%	13.2%	1.02% burn in the backyard 0.51% bury in the garden	197

The present study results can be compared with Amod et al. (2008) which was the only study in the reviewed literature that was conducted in South Africa. The present study was also conducted in South Africa although in a different city. Amod et al. (2008) was conducted in eThekweni. A comparison of the two studies shows a reduction in the use of garbage as a disposal method for unwanted medicines, from 62.5% in Amod et al. (2008) to 51.57% in the present study. There was an increase in the use of the toilet or sink from 23.5% as reported by Amod et al. (2008) to 33.5% as reported in the present study. On the other hand there is a substantial increase in the return to pharmacy disposal method from 2.5% in Amod et al. (2008) to 13.2% in the present study.

The patient information leaflet was implemented in 2004 in South Africa with mandatory texts advising patients to return unwanted medicines to the pharmacy. The reported increase in the return to pharmacy could be an indicator of the positive impact of the mandatory text in the patient information leaflet. However, the reported increase in the disposal through the toilet and sink suggests that there is still a need for public education on the need to return unwanted medicines to the pharmacy for proper disposal.

The disposal of unwanted medicine via the toilet or sink reported in the present study is the second highest in the reviewed literature after the rate reported by Seehusen and Edwards (2006). This confirms that the presence of pharmaceuticals in water is a concern in South Africa as reported by Wood et al. (2015) and Schoeman et al. (2015).

5.1.2 Reasons for unwanted medicines

Table 3 lists the reasons for unwanted medicines as reported in the present study. The top three reasons were that the medicine had expired (58%, n = 115), the patient stopped taking the medicine because they felt better (51%, n = 100) and that the full course was not finished (26%, n = 51). These results suggest a certain level of patient non-compliance. However, when we consider that pain killers, cold & flu medicines and anti-allergy medicines were reported as the most common types of unwanted medicines in the households (see Figure 3) it is possible that the unwanted medicines in households are mainly for self-limiting conditions which do not require the full course to be finished.

This raises the question of promotion of medicines to the public. In South Africa some pain killers, cold & flu medicines and anti-allergy medicines are OTC medicines which can be promoted directly to the public. Ruhoy and Daughton (2008) cited promotion of medicines as one aspect that contributes to the accumulation of unwanted medicines. The link between promotional practices and accumulation of unwanted medicines in households warrants further investigation.

Doctor prescribing habits also come under the spotlight as 10.66% (n = 21) of respondents indicated that the reason for unwanted medicines in their household was that the doctor prescribed too much medicine. Additionally, 11.17% (n = 22) reported that they had unwanted medicines in their household because the doctor changed the medicine. According to Ruhoy and

Daughton (2008) over-prescribing is a reason why end users have unwanted medicines; they further attribute this to the influential promotional campaigns from the pharmaceutical industry. It was interesting to note that the pharmacist dispensing too much medicine being the reason for unwanted medicines in the household was reported by very few respondents (3.05%, n = 6).

5.1.3 Willingness to use a return to pharmacy program

Abahussain et al (2006), Kotchen et al. (2009) and Auta et al. (2011) in the reviewed literature recommended a 'return to pharmacy medicine program' at community pharmacies as a way to enhance proper disposal of unwanted medicines from households. Thus the household questionnaire of the present study sought to assess the willingness of respondents to use an unwanted medicine disposal program at their local pharmacy.

The majority of respondents were willing to use an unwanted medicine disposal program at their local community pharmacy (79%, n = 158) whereas 22% (n = 43) responded that they would not use such a program. A further analysis of the 22% sample of respondents unwilling to use an unwanted medicine disposal program at their local pharmacy indicated that the majority of these respondents (n = 34) were from the questionnaires that were distributed as hard copies to households. The total number of responses from the hard copies were 81, thus the 34 respondents that were unwilling to use a return to pharmacy program at their local community pharmacy represented 42% of the sample size.



Three of the respondents that were unwilling to use an unwanted medicine disposal program at their local community pharmacy volunteered reasons. One reason mentioned was that the healthcare professional will change the expiry date and sell the medicine back to the public. The other reason was that they were unsure of the safety of the disposal methods the pharmacy uses. The final reason cited was that they did not know what the pharmacy will do with the returned medicines.

These reasons highlighted the need for public education on the roles and responsibilities of pharmacists as custodians of medicines. Tai et al (2016) reported that pharmacists demonstrated a positive intention to provide education to the public about proper medicine disposal. This is further

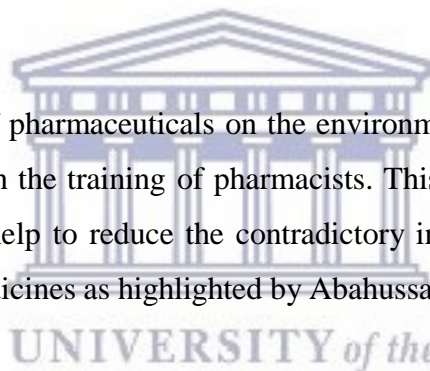
confirmed by the respondents in the present study where 100% (n = 158) of respondents to the community pharmacist questionnaire indicated that the pharmacist as a custodian of medicines should raise the awareness of the public on the proper disposal of medicines. Currently there seems to be a disconnect where the public does not seem to understand the role and responsibilities of the pharmacists as custodians of medicines and the role they can play in the proper disposal of unwanted medicine.

5.2 Pharmacist questionnaire

5.2.1 Pharmacist awareness regarding proper disposal of unwanted medicines

The present research findings show that pharmacist awareness of the proper disposal of medicines was obtained mainly through other avenues as opposed to university studies. This was mainly through on the job training (44%, n = 65). The pharmacist on the other hand considers it their responsibility as custodians of medicines to advise the public on the proper disposal of unwanted medicines (100%, n = 158).

Thus it is critical that the impact of pharmaceuticals on the environment, their fate and disposal are formalised as part of the modules in the training of pharmacists. This will ensure that the subject is given the priority it deserves and help to reduce the contradictory information disseminated to the public on the proper disposal of medicines as highlighted by Abahussain et al. (2006)



5.2.2 Disposal practices for unwanted medicines at community pharmacies

The respondents to both pharmacist questionnaires showed that community pharmacies employ waste management companies to ensure the proper disposal of medicines. This was further confirmed by the responsible pharmacists where 94% (n = 65) of respondents indicated that the community pharmacy was contracted to a waste management company. Whereas 6% (n = 4) responded that the community pharmacy was not contracted to a waste management company. Two respondents skipped the question.

This data confirms that community pharmacies can be entrusted with the responsibility of disposing of medicines from households in the proper manner. Abahussain et al. (2006), Kotchen et al. (2009), Auta et al. (2011) and Tong et al. (2011a) recommended the return to pharmacy of unwanted medicines from households as a solution to ensure proper unwanted medicine disposal.

5.2.3 Attitudes towards a return to pharmacy medicine program

Glassmeyer et al. (2009) observed that approximately 30 countries have some form of national, state or local drug collection system and pharmacies played a central role in the process even though the approaches used for collection were varied among the countries. The majority of respondents to the community pharmacist and responsible pharmacist questionnaires indicated that their pharmacies accepted returned medicines from the public for proper disposal (77%, n = 120 and 88%, n = 61 respectively).

Most of the household questionnaire respondents (78%, n = 157) did not know whether their local community pharmacy accepted unwanted medicines returned by the public for disposal. The remaining 10% (n = 21) responded that their local pharmacy did not accept returned unwanted medicines and 12% (n = 24) indicated that their local community pharmacy accepted returned unwanted medicines from the public.

The results of the present study suggest that the pharmacist is willing and available to offer the public the service of disposal of unwanted medicines. However, the public does not seem to be aware that such a service exists at their local pharmacy. The SAPC and community pharmacists need to highlight the availability of this service to the public.

The findings of the present research further highlight the need for pharmacists to educate the public on the proper disposal of medicines. The majority of household questionnaire respondents (72%, n = 144) indicated that they have never received advice on the proper disposal of unwanted medicines from a pharmacist or other healthcare professional. This however does not seem to correlate with the findings of the community pharmacist questionnaire where 80% (n = 126) of respondents indicated that they have actively advised patients on the proper disposal of unwanted medicines.

Finally, a question that was common in all three questionnaires related to the patient information leaflet which is included in the medicine packaging. The household questionnaire respondents were asked whether they were aware that the patient information leaflet gave advice on the proper disposal of medicines. The majority of household respondents (59%, n = 116) indicated that they did not know that the patient information leaflet had this advisory text as opposed to 41% (n = 83) who responded that they knew about this advisory text.

Both pharmacist questionnaires asked respondents whether the patient information leaflet had mandatory text advising patients on the proper disposal of unwanted or unused medicine. The pharmacist respondents showed a similar pattern to the household respondents where the majority of respondents (66%, n = 148) indicated that the patient information leaflet did not contain mandatory text advising patients on the proper disposal of unwanted medicines. The remaining 74 respondents (44%) responded correctly that the patient information leaflet contains mandatory text advising the patients on the proper disposal of unwanted medicines.

The mandatory text in the South African patient information leaflet advises the patient to return unwanted medicines to the pharmacy for proper disposal. The present research indicates that the majority of both pharmacists and the public are unaware of this mandatory text. This further highlights the need for education of both the pharmacists and public on the various aspects pertaining to the subject of proper disposal of unwanted medicines. Seehusen and Edwards (2006), Amod et. al. (2008), Auta et al. (2011) and Kusturica et al. (2012) all concluded that public education on the proper disposal of medicines needed to be addressed. Roig and Touraud (2010, p.284) assert that postgraduate studies and technical schools should be able to inform students about medicines, their rational use, environmental fate and impact.

5.3 Limitations

When the pilot questionnaires were sent out for testing, the researcher omitted to send out the Participant Information Leaflet and Invitation Letter. The researcher was more focused on testing the content of the questionnaires. Thus it only became apparent when sending out the actual invitations to the respondents that it is not possible to attach the Participant Information Leaflet

and Invitation Letter to the survey link directly from Survey Monkey. In order to overcome this hurdle, the researcher sent out two separate emails to prospective respondents. One email, with the Participant Information Leaflet and Invitation Letter as an attachment and the other with the actual survey directly from Survey Monkey.

This led to most of the respondents that responded after the two reminders were sent out not reading the Participant Information Leaflet and Invitation Letter. In an overall sample size of 434 respondents to all the questionnaires, 85% (n = 370) read the Participant Information Leaflet and Invitation Letter, 13% (n = 57) did not read it. The remaining 2% (n = 7) skipped the question.

In the responses to the household questionnaire, it was noted that 5 respondents skipped question 4 (The reason for unused/unwanted medicines in my house is?) and question 6 (How do you dispose of unused/unwanted medicines OR if you decided to dispose of the unwanted medicines in your house, which method will you use?). The reason for skipping the questions could be that these respondents did not have unwanted medicines in their households. This highlighted a limitation of the household questionnaire, which did not first ask respondents whether or not they had unwanted or unused medicines in their households. The household questionnaire in its design, assumed that everyone had unwanted or unused medicines in their household.

In the responsible pharmacist questionnaire there was a request for the average monthly cost of the disposal of unwanted medicines for the community pharmacy. The responses ranged from R30/month to R10, 000.00/month. There seems to have been either a reluctance to answer this question or the respondents did not know the figure. Thus the results for this particular question should be conservatively approached.

CHAPTER 6 – CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions on findings

6.1.1 Household disposal practices of unwanted medicines

Garbage disposal is the most favoured method of disposal of unwanted medicines from households (52%, n = 102) followed by down the sink or in the toilet (34%, n = 66). Return to pharmacy rates showed an improvement (13%, n = 26) when compared with Amod et al. (2008) the only other study reviewed that was conducted in South Africa (2.5%, n = 5). This could suggest a positive outcome of inclusion of mandatory text in the patient information leaflet advising patients to return unwanted medicines to the pharmacy which was implemented in 2004 in South Africa.

6.1.2 Return to pharmacy program

There is a willingness for households (79%, n = 158) to use a return to pharmacy program at their local pharmacy to dispose of unwanted medicines. Pharmacists also indicated a willingness to support such a program as most of the community pharmacists (77%, n = 120) indicated that their pharmacies accepted returned unwanted medicines from the public for proper disposal.

6.1.3 The pharmacist's role in the proper disposal of medicines

Pharmacists are willing to play a positive role in raising public awareness on the proper disposal of medicines. Most of the community pharmacist questionnaire respondents (100%, n = 158) agreed that the pharmacist as a custodian of medicines should raise the awareness of the public on the proper disposal of medicines. Furthermore, 83% (n = 58) of respondents to the responsible pharmacist questionnaire believe that the cost of disposing of medicines returned by the public to the pharmacy is part of the role of a pharmacist as a custodian of medicines.

6.2 Summary of contributions

6.2.1 Household disposal practices of unwanted medicines

The current research contributed to the further understanding of disposal practices of unwanted medicines from households in South Africa. This knowledge is critical to the resolution of the problem of the presence of pharmaceuticals in the South African environment as reported by Wood et al. (2015) and Schoeman et al. (2015).

6.2.2 Perceptions of lower LSM's to return to pharmacy program

During data capturing of the responses to the household hard copy questionnaires distributed to factory workers it was noted that a relatively high number of these respondents indicated that they would not support a return to pharmacy medicine program at their local pharmacy. Out of the total respondents (n = 43) that indicated that they would not use a return to pharmacy programme, 34 (79%) were from the hard copy questionnaires distributed to factory workers. This raises questions about the possible existence of perceptions to return to pharmacy programs that are unique to members of the public in lower LSMs.

6.2.3 Mandatory text on disposal of medicines in the patient information leaflet

The findings of the present research show that the majority of both pharmacists (59%, n = 116) and the public (66%, n = 148) are not aware of the existence of the mandatory text advising patients to return medicines to the pharmacy. This indicates that more needs to be done beyond just placing the information in the patient information leaflet. This further supports the need for holistic education for both the pharmacist and public on the various aspects that pertain to the proper disposal of unwanted medicines.

6.2.4 Doctor prescribing habits

The household responses indicated a possible link between doctor prescribing habits and the accumulation of unwanted medicines in households. A similar link was observed by Tong et al. (2011a), Ruhoy and Daughton (2008) and Daughton and Ruhoy (2010, p. 87) where prescribing habits were found to have an impact on the accumulation of pharmaceuticals in households or the environment. The household questionnaire respondents indicated that some of the reasons for

unwanted medicines in their households were because the doctor prescribed too much medicine (10.66%, n =21) and the doctor had changed the medicine (11.17%, n = 21).

6.3 Future research

6.3.1 Impact of medicine promotional campaigns on medicine waste

They types of unwanted medicines in households were mainly pain killers (60%, n = 120), cold & flu (69%, n = 137) and anti-allergy medicines (34%, n =67). These medicines fall mainly into the OTC category which is characterised by aggressive promotional campaigns. The relationship between promotional campaigns for medicines and the accumulation of unwanted medicines in households warrants further research.

6.3.2 Perceptions of lower LSM's to return to pharmacy program

Seehusen and Edwards (2006) believe that patient education is critical to the success of return to pharmacy programs. This requires public buy-in and support. Therefore, it is important to further investigate the reasons why people in lower LSM have showed an unwillingness to support a return to pharmacy program at their local community pharmacy.

6.3.3 Cost of returned medicine disposal at community pharmacies

Most of the respondents in the responsible pharmacist questionnaire (87%, n = 61) indicated that the pharmacist should be subsidised on the cost of disposal of medicines returned by the public to the pharmacy. In order to determine a subsidy mechanism, a further investigation of the actual cost of the disposal of medicines returned by the public for proper disposal at community pharmacies is advisable.

6.3.4 Role of pharmaceutical industry in unwanted medicine disposal

In a survey of unused and expired medicine take back schemes in the European Union and Norway, Taylor and Poulmaire (2008) observed that out of the twenty eight nations surveyed, in six countries the pharmaceutical industry covered the whole cost of managing the take back scheme.

This confirms that the pharmaceutical industry as a stakeholder in the health and welfare of the public, can play a critical role in resolving the problem of disposal of unwanted medicines from

households. An investigation of the opinions of the pharmaceutical industry in South Africa on the role they foresee themselves playing in this challenge is warranted.

6.3.5 Impact of doctor prescribing habits on medicine waste

Daughton and Ruhoy (2010, p. 87) explored the link between healthcare practices and the environment and concluded that inefficiencies in medical prescribing and dispensing impacted directly on the environment. Thus researchers in South Africa would do well to explore the link between healthcare practices and medical waste in seeking a solution to the problem of disposal of unwanted medicines from households.

6.4 Recommendations

6.4.1 Education

Extensive education on the proper disposal of medicines is critical for the public. Learnings from the European Union where medicine take back schemes have been legislated since 2004 indicate that the success of such programs depend on high levels of public awareness and education on environmental impact of the disposal of unused medicines according to Kampa et al. (2010). Thus we recommend the implementation of a focused, measurable and consistent public awareness campaign on the environmental impact of medicines and the need for their proper disposal.

Roig and Touraud (2010, p.283) believe that “education and awareness on pharmaceuticals in the environment have to be integrated in medical and pharmaceutical education”. The present research indicated that most pharmacists learnt about the proper disposal of medicines through on the job training (44%, n = 65) and continued professional development (18%, n = 27). Only 20% (n = 30) of respondents learnt through university studies (see figure 5). The inclusion of the topic of medicine disposal and impact on the environment needs to be included in the pharmaceutical and medical curricula.

6.4.2 Return unwanted medicine to pharmacy program

Glassmeyer et al. (2009) suggest that despite insufficient information to measure the extent of the impact of disposal of medicines on the environment, it is easier to control the disposal of unwanted medicines as a source of pharmaceutical environmental pollution. The legislation of a

medicine return to pharmacy program is a viable solution to managing the impact of pharmaceutical waste on the environment.

6.4.3 National lead agency for the disposal of unwanted medicines

Daughton (2010) observed that in the United States the topic of medicine disposal had received attention from various stakeholders. This had led to government agencies in various states and cities devoting time, energy and money to proper disposal of unwanted medicines initiatives. However this resulted in duplicated efforts and in some cases contradictions. South Africa can take these learnings and rather implement a national lead agency to spearhead, oversee and coordinate the efforts related to the broad subject of proper disposal of unwanted medicines.



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School of
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Fax +27 21 9591588

This voluntary survey has 10 questions and should take no more than 15 minutes.

1. I have read and understood the Participant Information Leaflet and Invitation Letter

Yes

No

2. The unwanted or unused medicines that are in my house are

mainly Over-The-Counter (OTC) medicines

mainly prescription medicines

a mixture of OTC and prescription medicines

3. The unwanted/unused medicines in my house are for (you may choose more than one option)

Painkillers

Cold and Flu

Anti-allergy

Anti-epileptics

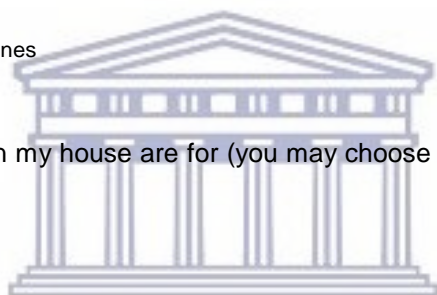
Anti-vomiting

Anti-diarhoeals

High blood pressure Diabetes

Antibiotics

Other (please specify)



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4. The reason for unused/unwanted medicines in my house is (you may choose more than one option)

- Expired
- The full course was not finished
- stopped taking the medicine because of side effects
- stopped taking the medicine because I felt better
- Doctor prescribed too much medicine
- Pharmacist gave me too much medicine
- Medicine was changed by Doctor

Other (please specify)

5. What do you do with unwanted/unused medicines in your house?

- Throw away
- Keep it
- Give it away
- Other (please specify)



6. How do you dispose of unused/unwanted medicines OR if you decided to dispose of the unwanted medicines in your house, which method will you most likely use?

- Trash/ Rubbish bin
- Bury in the garden
- Down the sink/ toilet
- Burn in the backyard
- Return to the pharmacy

Other (please specify)

7. Are you aware that the Patient Information Leaflet enclosed in the medicine packaging advises on the proper disposal of medicines?

- Yes
- No

8. Have you ever received advice on the proper disposal of unwanted/unused medicines from a Pharmacist or other Health Care Professional?

Yes

No

9. Does your local Community Pharmacy accept unused/unwanted medicines returned by the public that needs to be disposed of?

Yes

No

I don't know

10. If your local Pharmacy started an unwanted/unused medicine disposal program, will you use it?

Yes

No



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APPENDIX B



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Please respond to this voluntary survey if you work part time or full time as a Community Pharmacist. This survey contains 10 questions and should take no more than 15 minutes to complete.

1. I have read and understood the Participant Information Leaflet and Invitation Letter.

- Yes
 No

2. Have you been formally advised on the proper disposal of unwanted/unused medicines?

- Yes
 No

3. If Yes, you were advised through

- University studies
 Continued Professional Development
 Pharmaceutical Literature
 On the job training
 Other (please specify)



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4. Do you believe that Pharmacists as custodians of medicines should raise the awareness of the public on the proper disposal of medicines?

- Yes
 No

5. The Patient Information Leaflet has mandatory text advising patients on the proper disposal of unwanted/unused medicines.

- True
 False

6. Does the Community Pharmacy you work at offer a return unwanted/ unused medicine disposal programme for the public?

- Yes
 No

7. Do you believe that there is a need for a formalised, State managed 'Returned Medicine Disposal Program' at Pharmacies?

Yes

No

8. If Yes, who should oversee such a program?

The South African Pharmacy Council

The Department of Health

Other (please specify)

9. How do you dispose of unwanted medicines in the Community Pharmacy where you work?

Solid dosage forms e.g.
tablets & capsules

Semi-solid dosage forms
e.g. creams & ointments

Liquid dosage forms e.g.
syrups & suspensions

10. Have you actively advised patients about the proper disposal of unwanted/unused medicines?

Yes

No





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Please respond to this voluntary Survey if you are the SAPC Registered Responsible Pharmacist

1. I have read and understood the Participant Information Leaflet and Invitation Letter.

- Yes
 No

2. The Pharmacy has a Standard Operating Procedure for the disposal of unwanted/unused medicines.

- Yes
 No

3. The Pharmacy staff has been trained on the proper disposal of medicines.

- Yes
 No



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4. How do you dispose of unwanted/unused medicines in the Pharmacy?

Solid dosage forms e.g.
tablets and capsules

Semi solid dosage forms
e.g. ointments and creams

Liquid dosage forms e.g.
syrups and suspensions

5. The Pharmacy accepts returned unused/unwanted medicines from the public for proper disposal.

- Yes
 No

6. It is mandatory to include advice on the proper disposal of medicines in a patient information leaflet that is included in medicine packaging.

- Yes
 No

7. The Pharmacy is contracted to a waste management company that disposes of medicines.

Yes

No

8. Do you believe there is a need for a State managed "Returned Medicine Disposal Program" in Pharmacies?

Yes

No

9. The average monthly cost of disposing of unwanted medicines is

10. The cost of disposing of medicines returned by the public to the Pharmacy is part of the role of a Pharmacist as a Custodian of medicines.

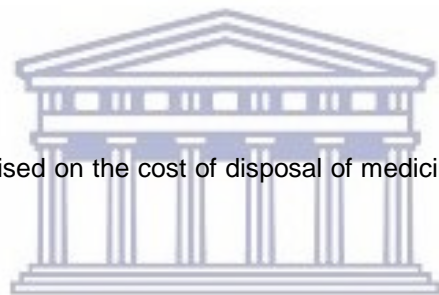
Yes

No

11. The Pharmacist should be subsidised on the cost of disposal of medicines returned by the public to the Pharmacy.

Yes

No



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APPENDIX D

Participant Information Leaflet and Invitation

Letter Protocol Title:

DISPOSAL PRACTICES OF UNWANTED MEDICINES FROM
HOUSEHOLDS IN JOHANNESBURG

Principal Investigator's Name: MATHABO MASHIANE

Principal Investigator's Title: MISS

Telephone No. of Principal Investigator: +2782 379 0771

You are being invited to take part in an email survey. Before you decide whether or not you wish to take part, you should read the information provided below carefully.

You are not obliged to take part in this study, participation is voluntary.

WHY IS THIS STUDY BEING DONE?

This study is being done to understand how and where people throw away their unwanted medicines and the reasons why households end up with unwanted medicines. Unwanted medicines pose a health risk as they can be mistakenly taken by children leading to poisoning accidents. They also place a burden on the health budgets of households. Improper disposal of unwanted medicines can be harmful to the environment. The study aims to raise awareness on the proper disposal of medicines by creating a partnership between the public and pharmacists.

WHO IS ORGANISING AND FUNDING THIS STUDY?

The research is being conducted for the purposes of attaining a Master of Science in Pharmacy Administration and Policy Regulation qualification through the University of the Western Cape in partnership with Hibernia College. The study is funded by the researcher.

HOW WILL IT BE CARRIED OUT?

The study involves three email surveys on Survey Monkey. One will be sent to members of the public and two to pharmacists. You will receive only one survey depending on whether you are a member of the public or a pharmacist. The feedback collated from the surveys will be analysed and submitted in the final thesis.

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

Your information will be kept confidential as all responses are collated in Survey Monkey. The researcher will not see individual responses so your feedback will be anonymous.

CONFIDENTIALITY ISSUES

The data collected from the study will be anonymous. It will be treated confidentially and only used in pursuance of the qualification as stated above and shared with the academic personnel at the University of the Western Cape (and Hibernia College).

If you decide to participate, click on the link in the email and it will direct you to a questionnaire on Survey Monkey. Please note that your responses will be web based and thus anonymous.

By participating in the survey, I confirm that I understand the objectives of the study and give consent for my anonymous feedback to be used as outlined in the participant information leaflet and invitation letter.

IF YOU REQUIRE FURTHER INFORMATION

For additional information now or any future time please contact:

Name: **Mathabo Mashiane**

Email: **mathabo.mashiane@yahoo.com** Phone No: **+2782 379 0771**



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DEPARTMENT OF RESEARCH DEVELOPMENT

09 February 2016

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Dr K Obikeze (School of Pharmacy)

Research Project: Disposal practices of unwanted medicines from households in Johannesburg.

Registration no: 15/7/233

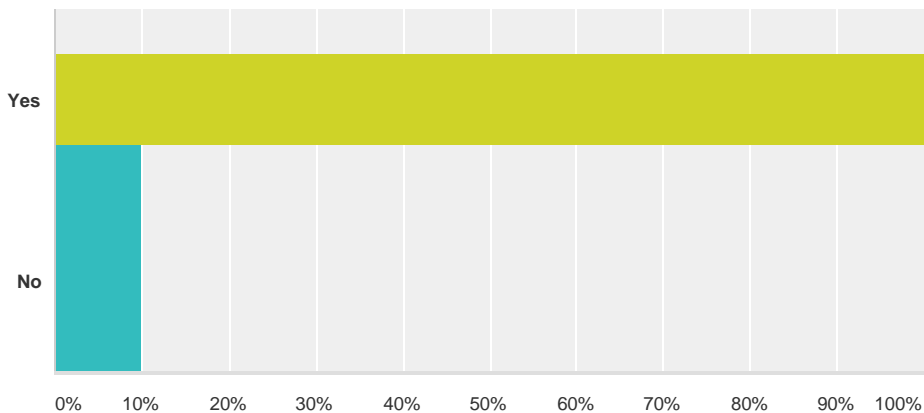
Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

*Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape*

Q1 I have read and understood the Participant Information Leaflet and Invitation Letter

Answered: 201 Skipped: 1

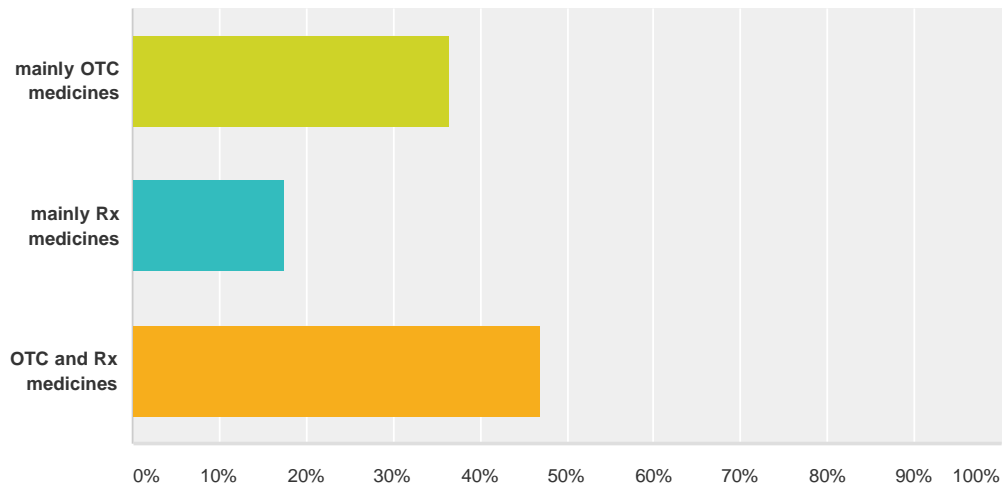


Answer Choices	Responses
Yes	93.53% 188
No	6.47% 13
Total Respondents: 201	



Q2 The unwanted or unused medicines that are in my house are

Answered: 200 Skipped: 2

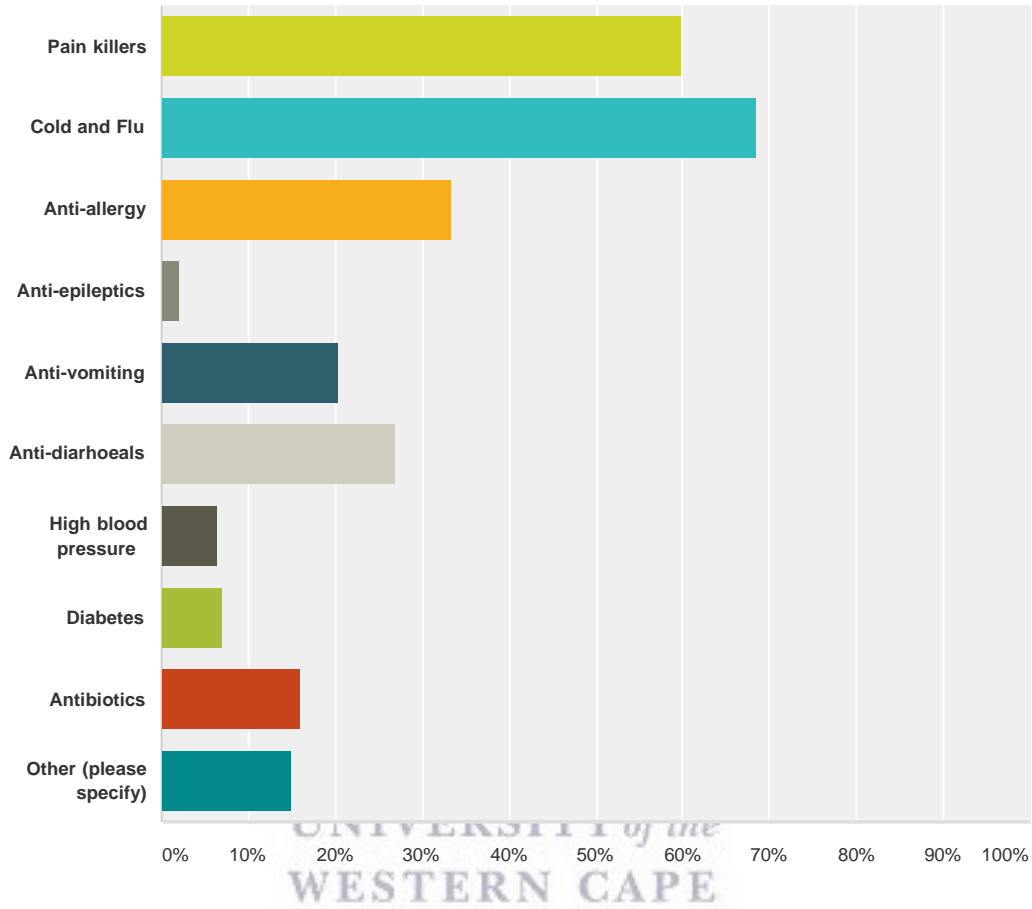


Answer Choices	Responses
mainly OTC medicines	36.50% 73
mainly Rx medicines	17.50% 35
OTC and Rx medicines	47.00% 94
Total Respondents: 200	

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Q3 The unwanted/unused medicines in my house are for (you may choose more than one option)

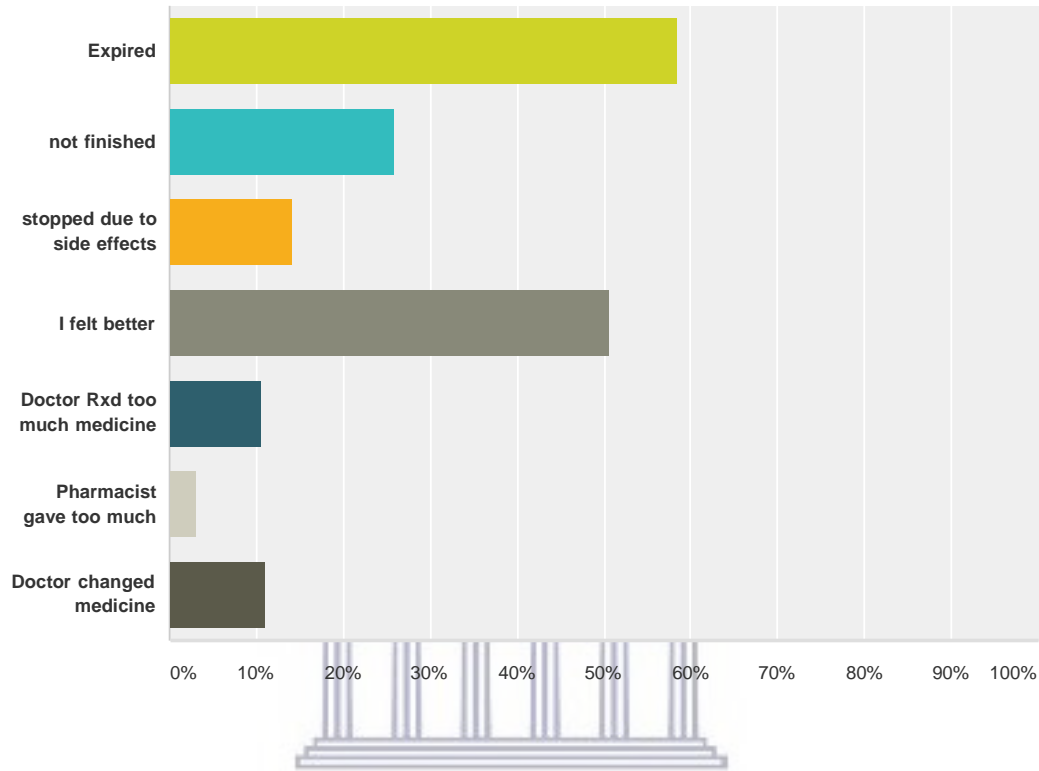
Answered: 200 Skipped: 2



Answer Choices	Responses	Count
Pain killers	60.00%	120
Cold and Flu	68.50%	137
Anti-allergy	33.50%	67
Anti-epileptics	2.00%	4
Anti-vomiting	20.50%	41
Anti-diarhoeals	27.00%	54
High blood pressure	6.50%	13
Diabetes	7.00%	14
Antibiotics	16.00%	32
Other (please specify)	15.00%	30
Total Respondents: 200		

Q4 The reason for unused/unwanted medicines in my house is (you may choose more than one option)

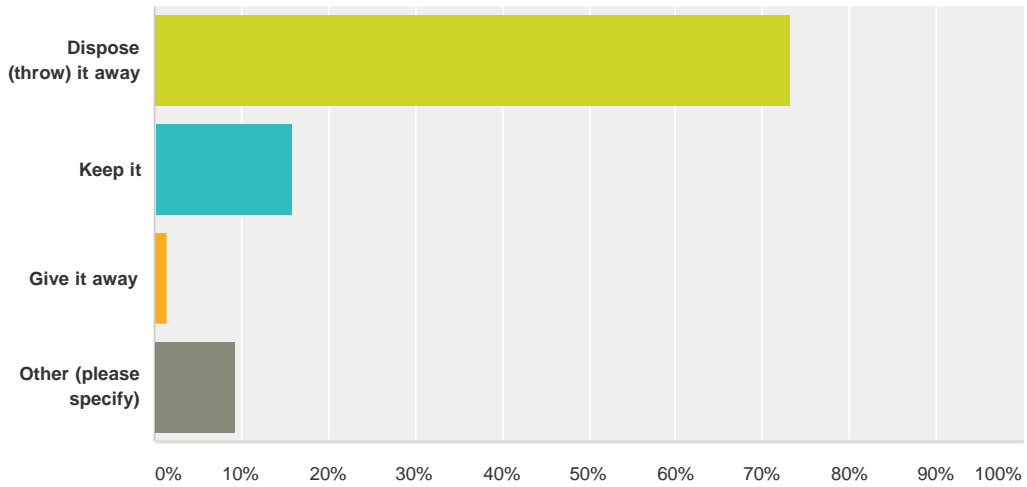
Answered: 197 Skipped: 5



Answer Choices	Responses
Expired	58.38% 115
not finished	25.89% 51
stopped due to side effects	14.21% 28
I felt better	50.76% 100
Doctor Rxd too much medicine	10.66% 21
Pharmacist gave too much	3.05% 6
Doctor changed medicine	11.17% 22
Total Respondents: 197	

Q5 What do you do with unwanted/unused medicines in your house?

Answered: 202 Skipped: 0

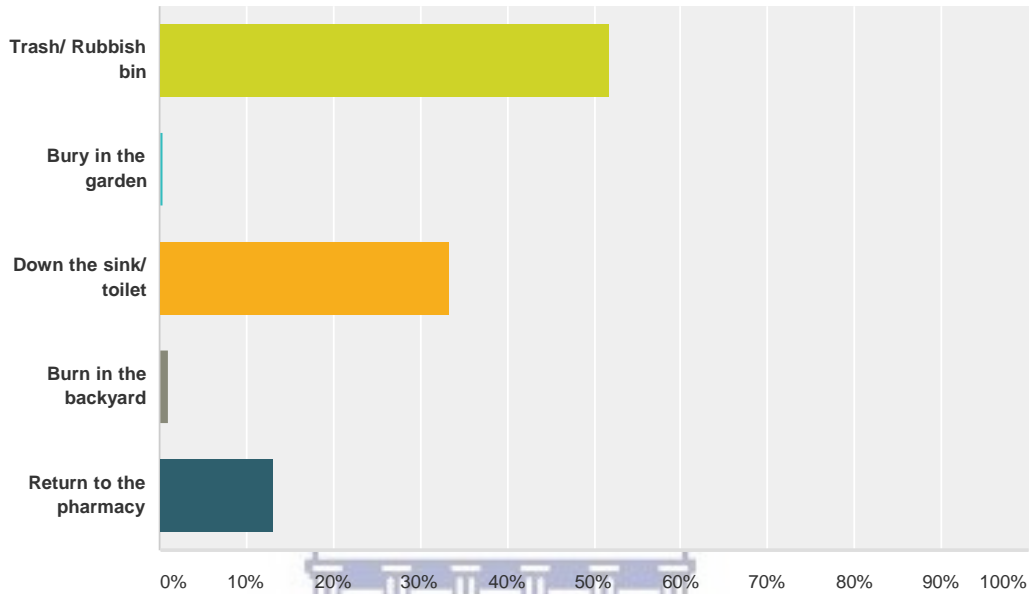


Answer Choices	Responses	Count
Dispose (throw) it away	73.27%	148
Keep it	15.84%	32
Give it away	1.49%	3
Other (please specify)	9.41%	19
Total		202



Q6 How do you dispose of unused/unwanted medicines OR if you decided to dispose of the unwanted medicines in your house, which method will you most likely use?

Answered: 197 Skipped: 5

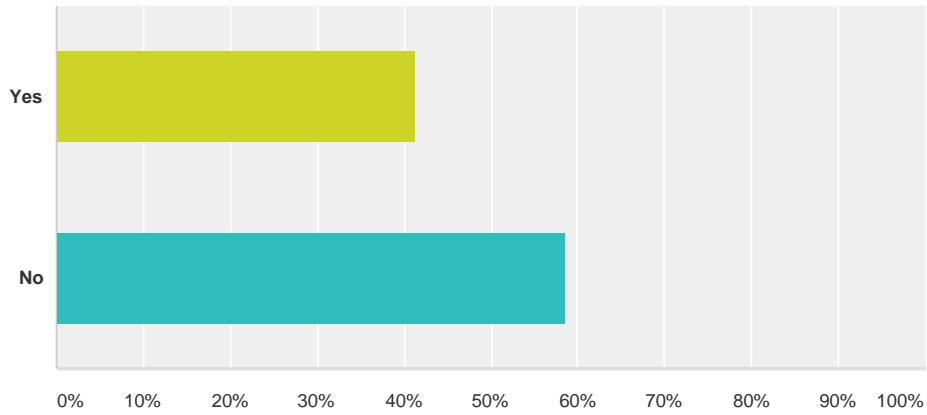


Answer Choices	Responses
Trash/ Rubbish bin	51.78% 102
Bury in the garden	0.51% 1
Down the sink/ toilet	33.50% 66
Burn in the backyard	1.02% 2
Return to the pharmacy	13.20% 26
Total	197

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Q7 Are you aware that the Patient Information Leaflet enclosed in the medicine packaging advises on the proper disposal of medicines?

Answered: 201 Skipped: 1

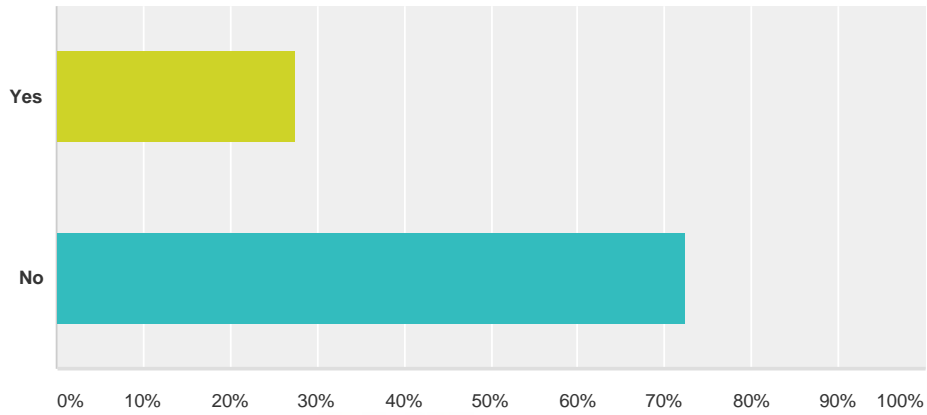


Answer Choices	Responses
Yes	41.29% 83
No	58.71% 118
Total	201



Q8 Have you ever received advise on the proper disposal of unwanted/unused medicines from a Pharmacist or other Health Care Professional?

Answered: 199 Skipped: 3

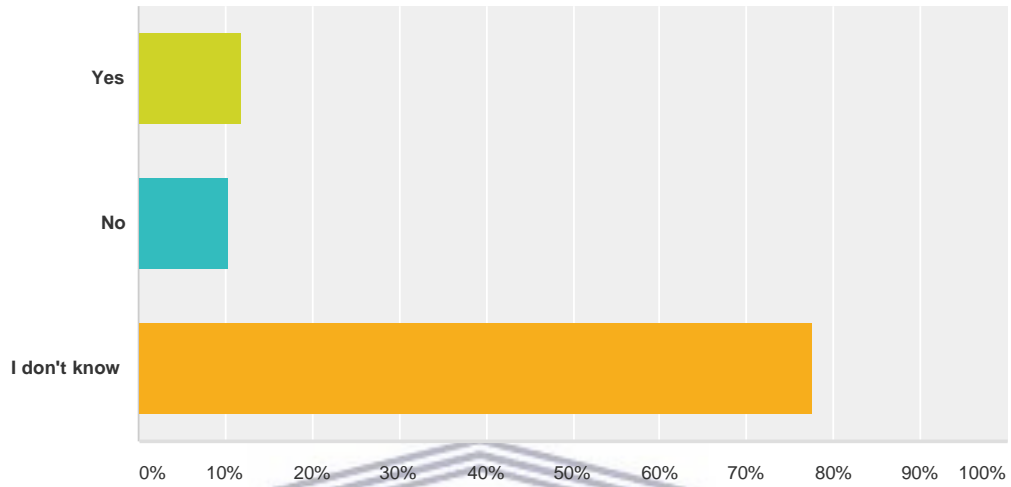


Answer Choices	Responses
Yes	27.64% 55
No	72.36% 144
Total	199

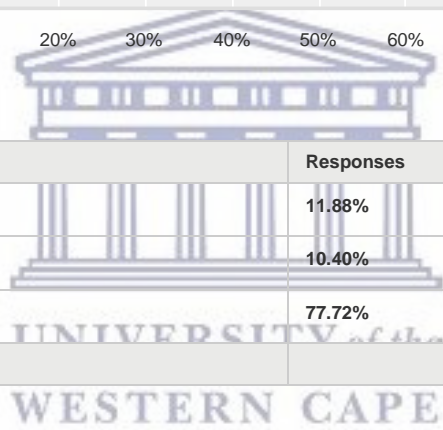


Q9 Does your local Community Pharmacy accept unused/unwanted medicines returned by the public that needs to be disposed of?

Answered: 202 Skipped: 0

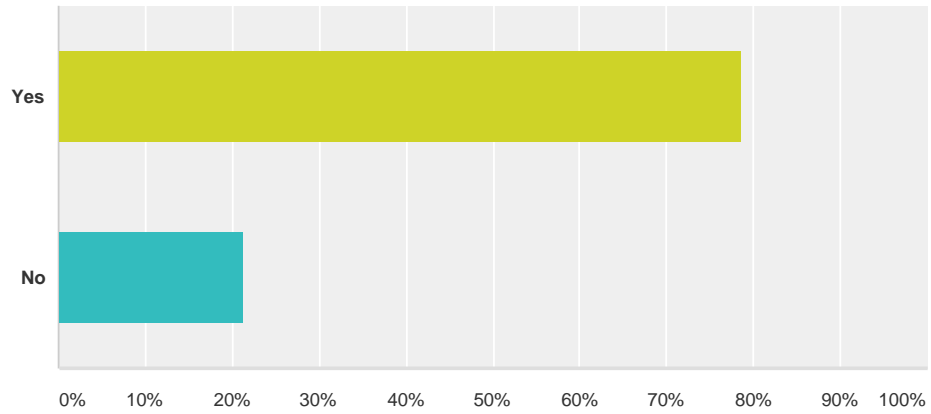


Answer Choices	Responses
Yes	11.88% 24
No	10.40% 21
I don't know	77.72% 157
Total	202

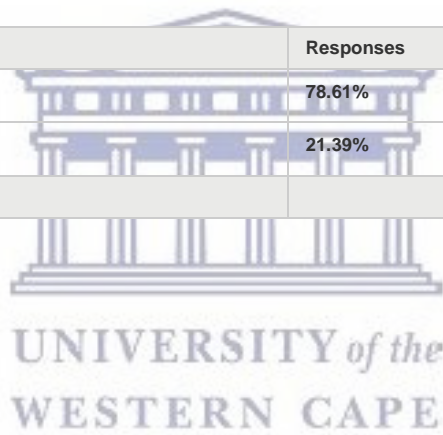


Q10 If your local Pharmacy started an unwanted/unused medicine disposal program, will you use it?

Answered: 201 Skipped: 1

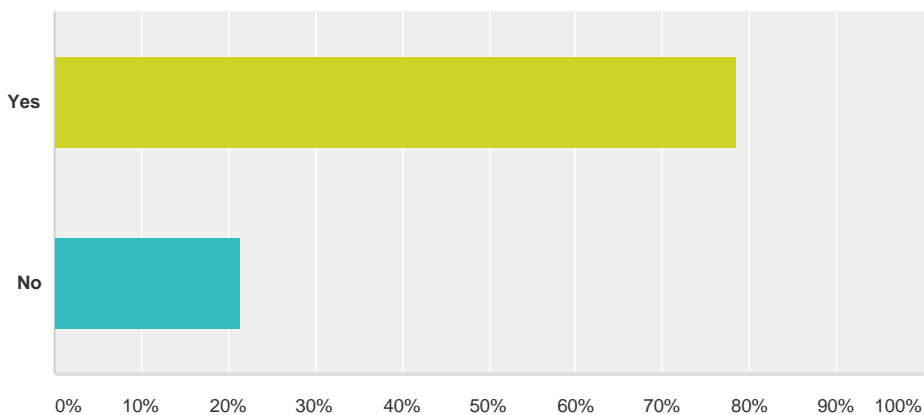


Answer Choices	Responses	Count
Yes	78.61%	158
No	21.39%	43
Total		201

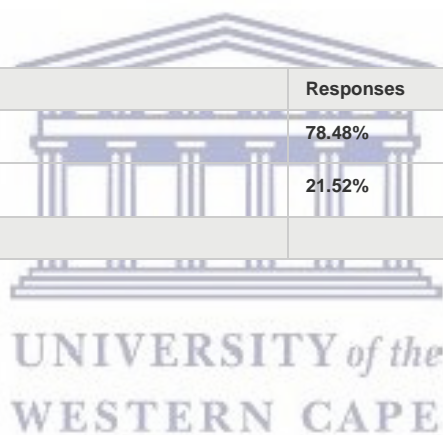


***Q1 I have read and understood the
 Participant Information Leaflet and Invitation
 Letter.***

Answered: 158 Skipped: 3

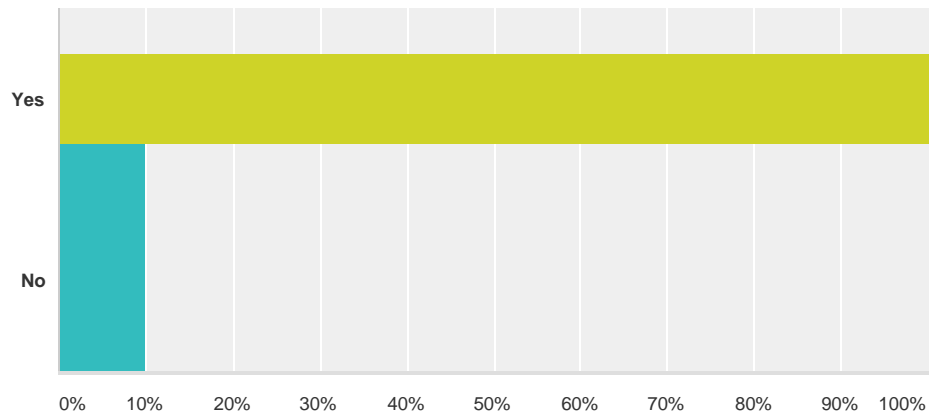


Answer Choices	Responses	Count
Yes	78.48%	124
No	21.52%	34
Total		158

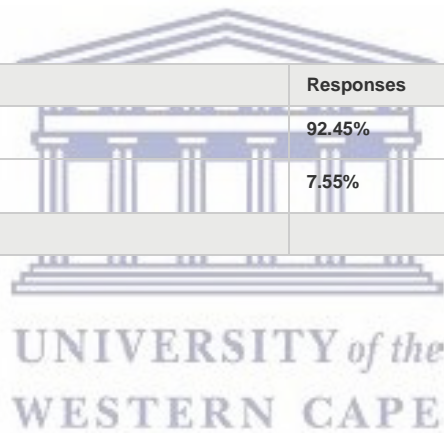


Q2 Have you been formally advised on the proper disposal of unwanted/unused medicines?

Answered: 159 Skipped: 2

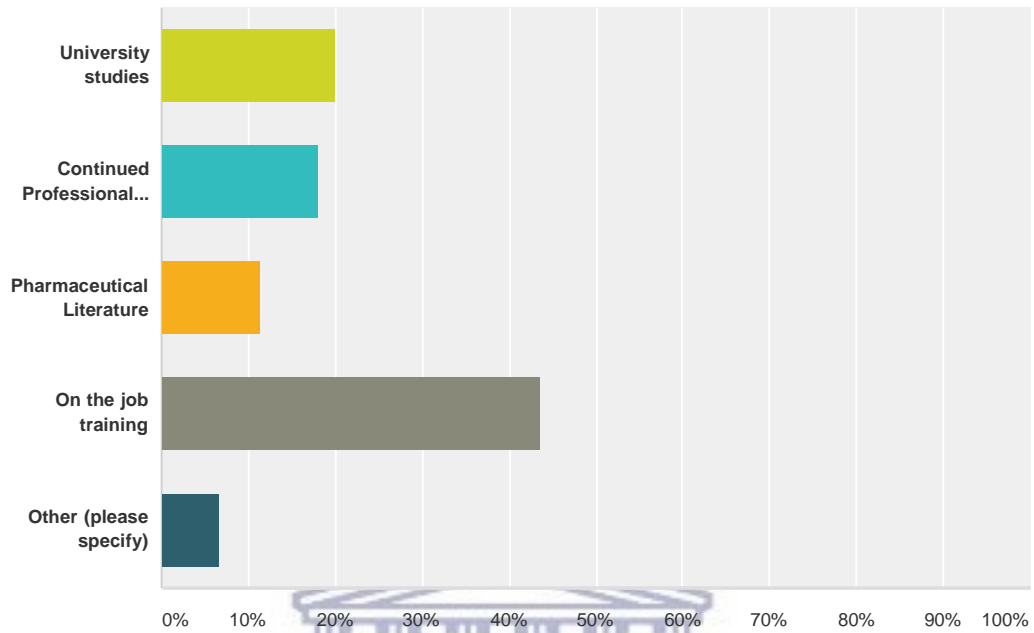


Answer Choices	Responses
Yes	92.45% 147
No	7.55% 12
Total	159



Q3 If Yes, you were advised through

Answered: 149 Skipped: 12

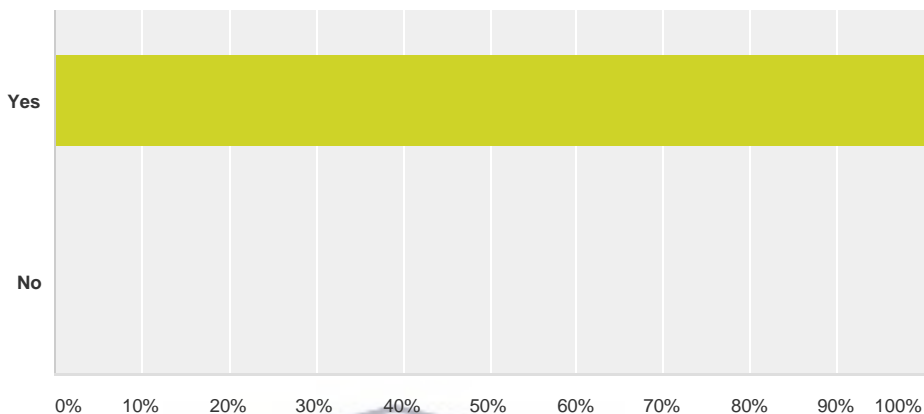


Answer Choices	Responses
University studies	20.13% 30
Continued Professional Development	18.12% 27
Pharmaceutical Literature	11.41% 17
On the job training	43.62% 65
Other (please specify)	6.71% 10
Total	149



Q4 Do you believe that Pharmacists as custodians of medicines should raise the awareness of the public on the proper disposal of medicines?

Answered: 158 Skipped: 3

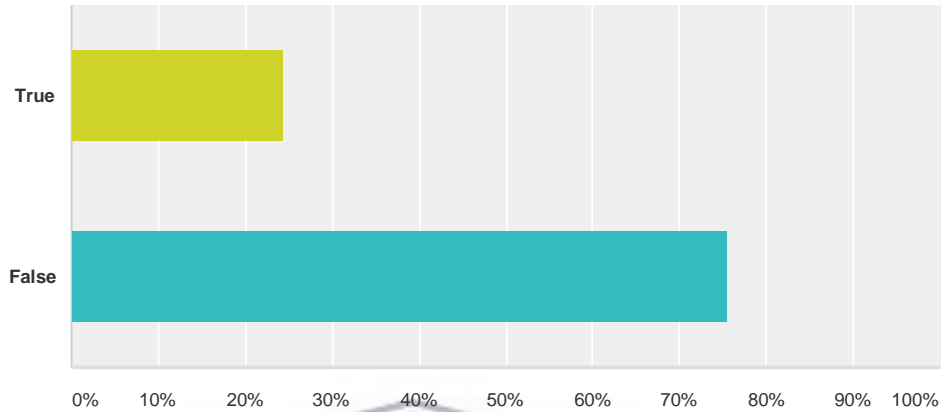


Answer Choices	Responses
Yes	100.00% 158
No	0.00% 0
Total	158



Q5 The Patient Information Leaflet has mandatory text advising patients on the proper disposal of unwanted/unused medicines.

Answered: 152 Skipped: 9

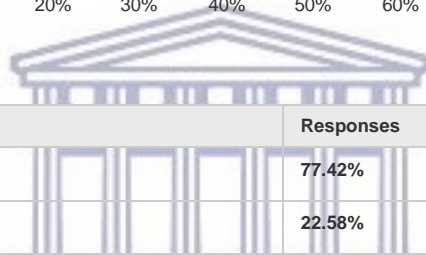
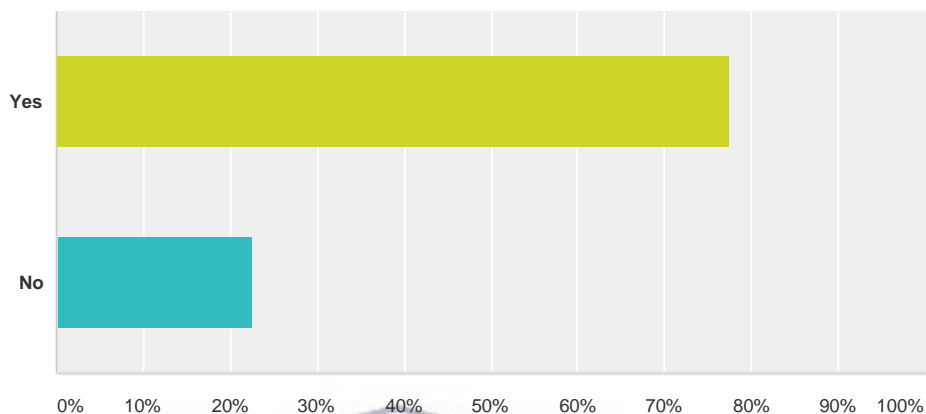


Answer Choices	Responses
True	24.34% 37
False	75.66% 115
Total	152

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Q6 Does the Community Pharmacy you work at offer a return unwanted/ unused medicine disposal programme for the public?

Answered: 155 Skipped: 6

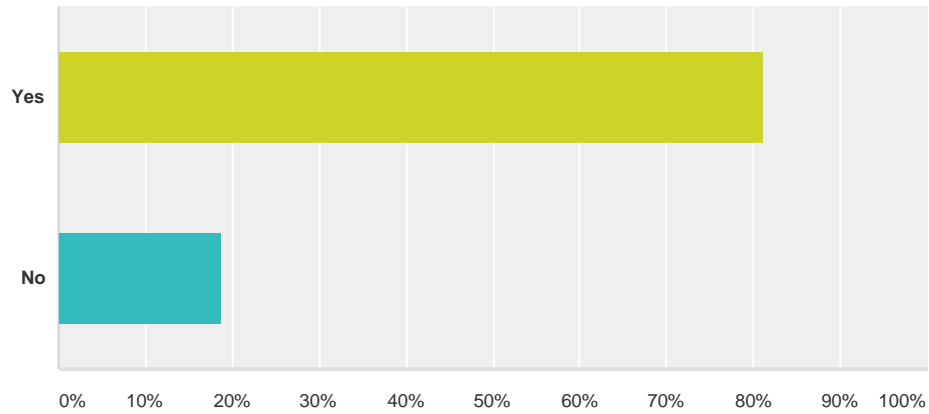


Answer Choices	Responses
Yes	77.42% 120
No	22.58% 35
Total	155

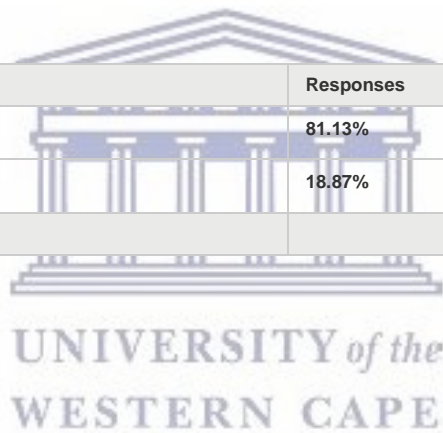
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Q7 Do you believe that there is a need for a formalised, State managed 'Returned Medicine Disposal Program' at Pharmacies?

Answered: 159 Skipped: 2

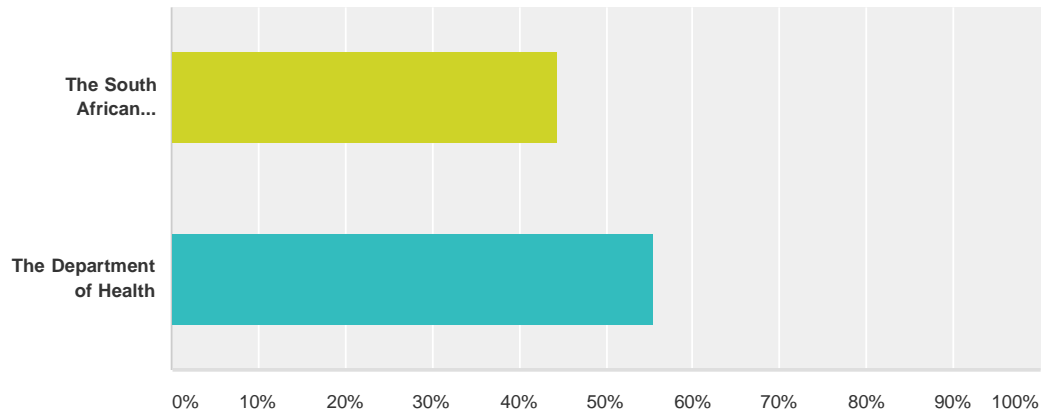


Answer Choices	Responses
Yes	81.13% 129
No	18.87% 30
Total	159



Q8 If Yes, who should oversee such a program?

Answered: 126 Skipped: 35



Answer Choices	Responses
The South African Pharmacy Council	44.44% 56
The Department of Health	55.56% 70
Total	126



Q9 How do you dispose of unwanted medicines in the Community Pharmacy where you work?

Answered: 145 Skipped: 16

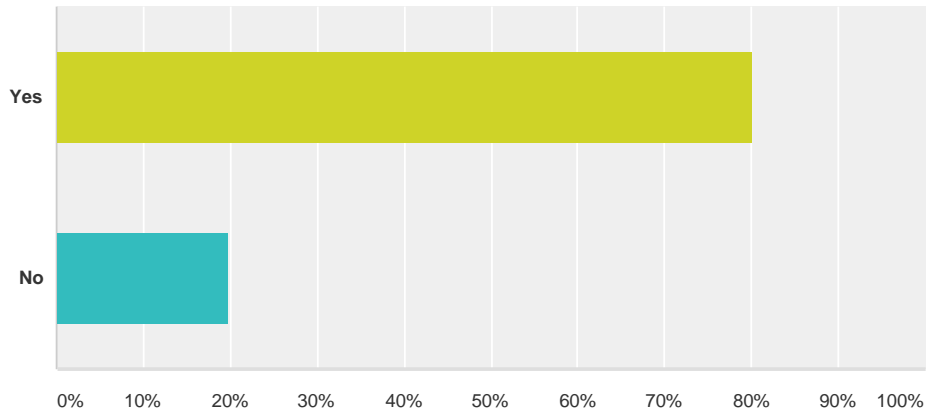
Answer Choices	Responses
Solid dosage forms e.g. tablets & capsules	100.00% 145
Semi-solid dosage forms e.g. creams & ointments	98.62% 143
Liquid dosage forms e.g. syrups & suspensions	97.93% 142



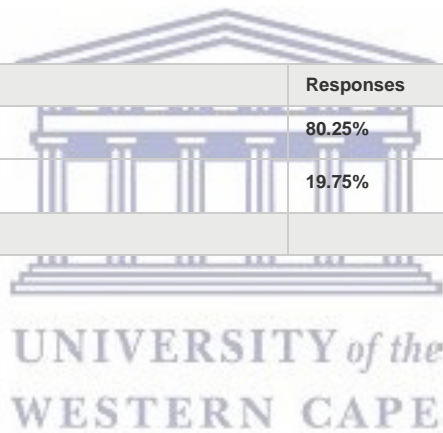
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Q10 Have you actively advised patients about the proper disposal of unwanted/unused medicines?

Answered: 157 Skipped: 4

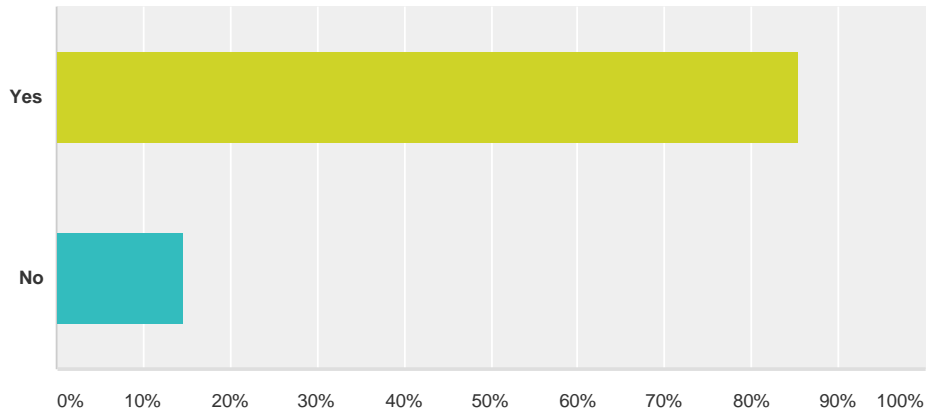


Answer Choices	Responses
Yes	80.25% 126
No	19.75% 31
Total	157

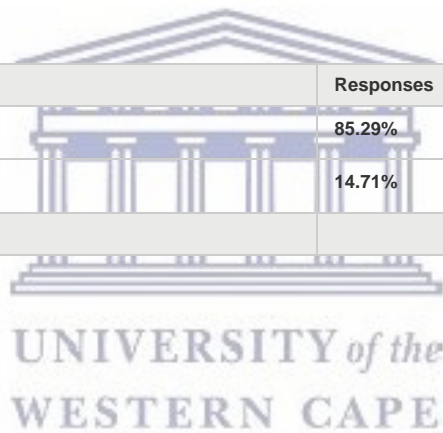


***Q1 I have read and understood the
 Participant Information Leaflet and Invitation
 Letter.***

Answered: 68 Skipped: 3

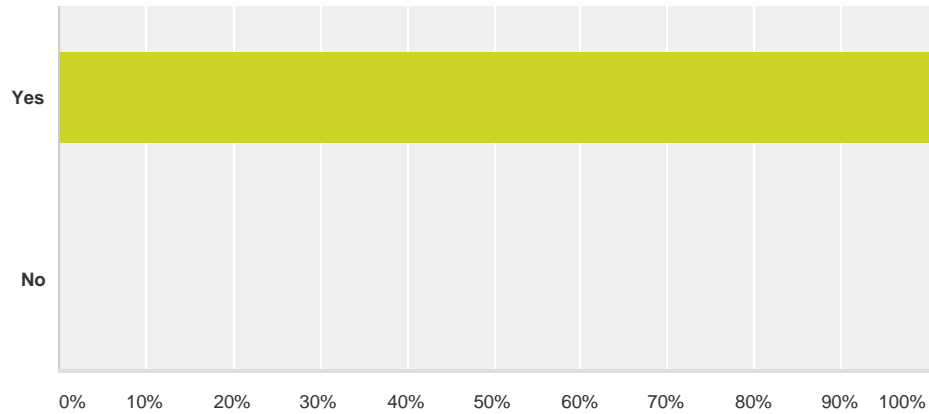


Answer Choices	Responses
Yes	85.29% 58
No	14.71% 10
Total	68

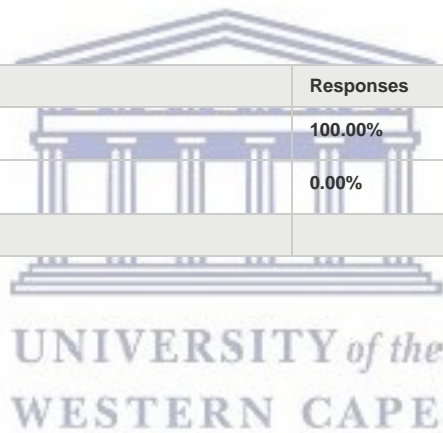


Q2 The Pharmacy has a Standard Operating Procedure for the disposal of unwanted/unused medicines.

Answered: 68 Skipped: 3



Answer Choices	Responses
Yes	100.00% 68
No	0.00% 0
Total	68



***Q3 How do you dispose of
unwanted/unused medicines in the
Pharmacy?***

Answered: 67 Skipped: 4

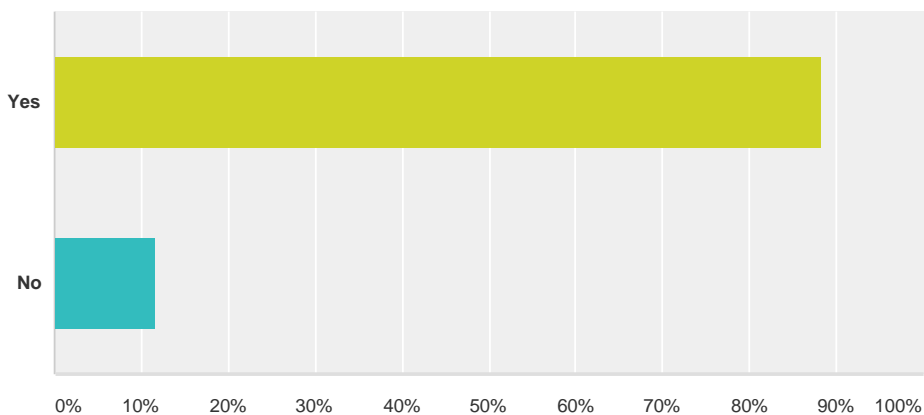
Answer Choices	Responses
Solid dosage forms e.g. tablets and capsules	100.00% 67
Semi solid dosage forms e.g. ointments and creams	97.01% 65
Liquid dosage forms e.g. syrups and suspensions	95.52% 64



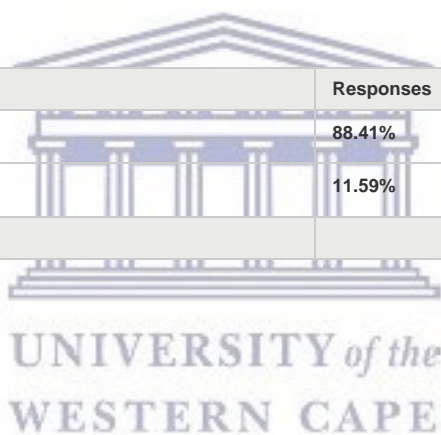
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Q4 The Pharmacy accepts returned unused/unwanted medicines from the public for proper disposal.

Answered: 69 Skipped: 2

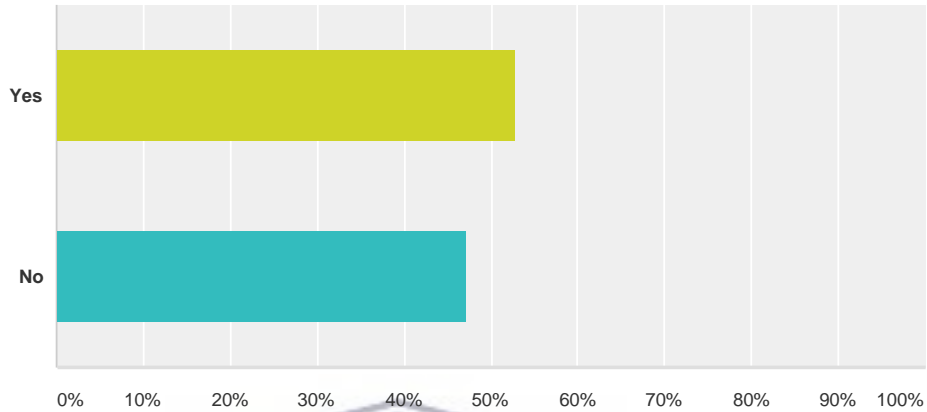


Answer Choices	Responses
Yes	88.41% 61
No	11.59% 8
Total	69



Q5 It is mandatory to include advice on the proper disposal of medicines in a patient information leaflet that is included in medicine packaging.

Answered: 70 Skipped: 1



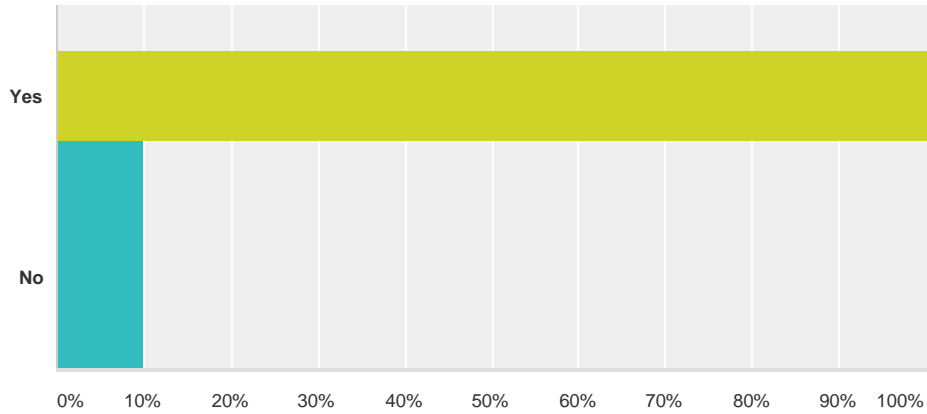
Answer Choices	Responses
Yes	52.86% 37
No	47.14% 33
Total	70



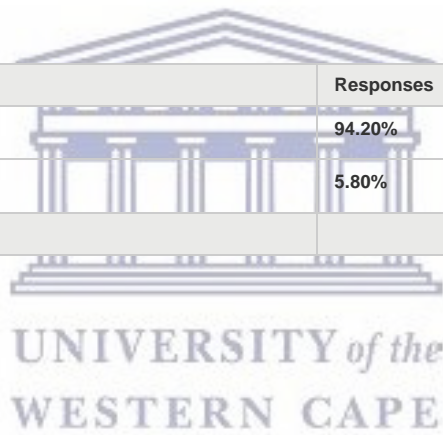
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Q6 The Pharmacy is contracted to a waste management company that disposes of medicines.

Answered: 69 Skipped: 2

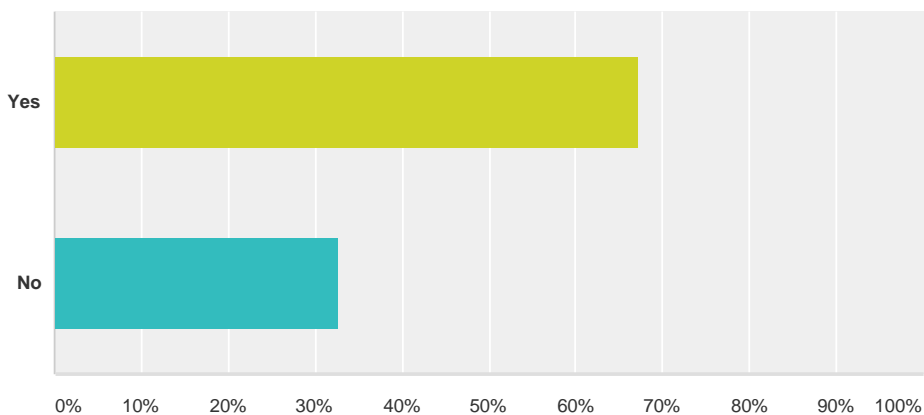


Answer Choices	Responses
Yes	94.20% 65
No	5.80% 4
Total	69

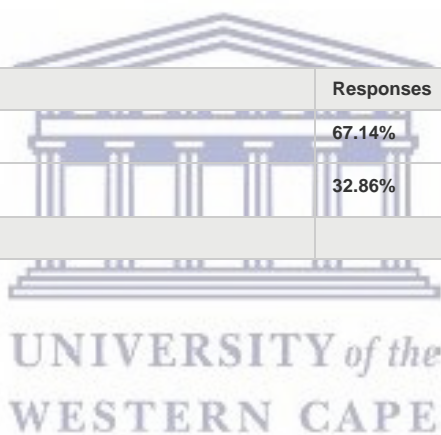


Q7 Do you believe there is a need for a State managed "Returned Medicine Disposal Program" in Pharmacies?

Answered: 70 Skipped: 1



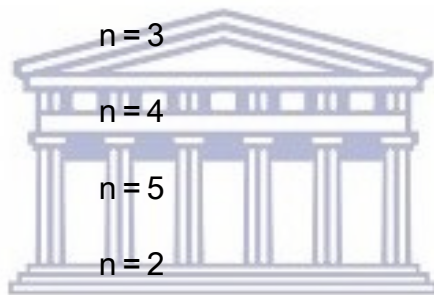
Answer Choices	Responses
Yes	67.14% 47
No	32.86% 23
Total	70



Q8 The average monthly cost of disposing of unwanted medicines is

Answered: 64 Skipped: 7

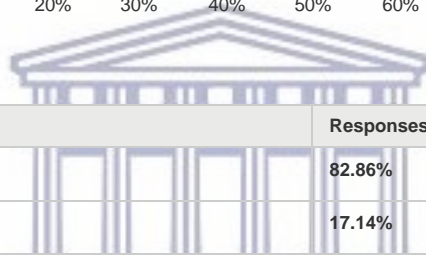
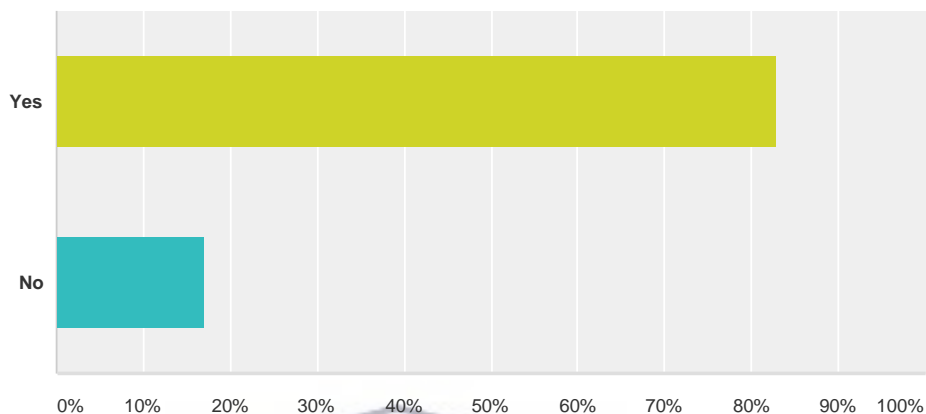
I don't know	n = 19
R1200/month	n = 1
R1000/month	n = 5
R350-R450/month	n = 3
R200/month	n = 1
R500/month	n = 5
R2000/month	n = 3
R5000/month	n = 4
R3000/month	n = 5
R10 000/month	n = 2
R30/month	n = 1
R80/month	n = 1
R800/month	n = 1
R250/month	n = 2
R400/month	n = 2
R900/month	n = 1
R300/month	n = 2
R1500/month	n = 6



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Q9 The cost of disposing of medicines returned by the public to the Pharmacy is part of the role of a Pharmacist as a Custodian of medicines.

Answered: 70 Skipped: 1

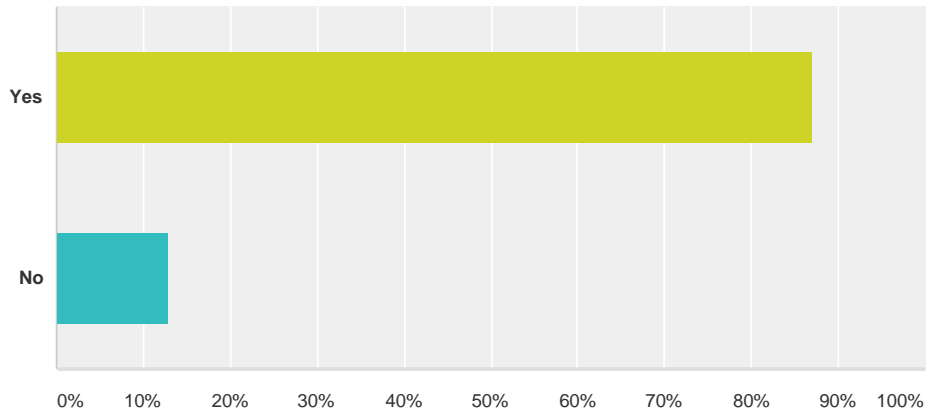


Answer Choices	Responses
Yes	82.86% 58
No	17.14% 12
Total	70

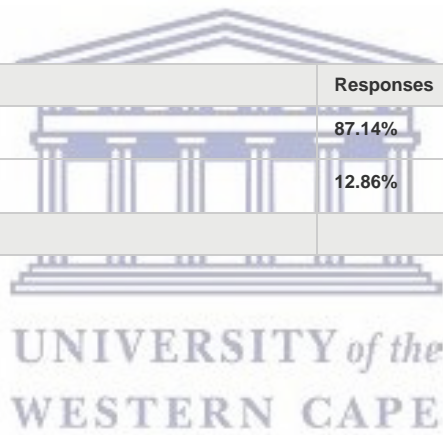
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Q10 The Pharmacist should be subsidised on the cost of disposal of medicines returned by the public to the Pharmacy.

Answered: 70 Skipped: 1



Answer Choices	Responses
Yes	87.14% 61
No	12.86% 9
Total	70





**University of the Western
Cape**
in partnership with
Hibernia College, Ireland



**MASTER OF SCIENCE IN PHARMACY ADMINISTRATION AND
PHARMACY POLICY SPECIALISING IN REGULATORY SCIENCES**

RESEARCH PROPOSAL

Name: MATHABO M. MASHIANE

Student Number: MRS101301

Student Cohort: OCT 2013

Research Title: Disposal Practices for Unwanted Medicines from
Households in Johannesburg

Word Count (excl. title page &
bibliography): 1,775

Submission Date: 12 October 2015

I agree that I have researched and written the work submitted in this research proposal, and that the work submitted is my own. Any information and opinions drawn from other sources are attributed by means of a reference to that source.

X

DISPOSAL PRACTICES FOR UNWANTED MEDICINES FROM HOUSEHOLDS IN JOHANNESBURG

INTRODUCTION

According to Bound et al (2006) pharmaceutical residues were first detected in the environment around 1975. These have led to toxicological effects where feminisation of fish occurred after exposure to levels as low as 1 ng l⁻¹ of the synthetic hormone 17 α -ethinyl estradiol when the hormone was released in waste water treatment works (WWTW). This has led healthcare stakeholders to be vigilant about the disposal of unwanted pharmaceuticals. Tong et al (2011a) concluded that there is confusion on the proper disposal practices for medicines in most countries due to lack of adequate guidelines for the proper disposal of unwanted medicines.

In South Africa the Medicines and Related Substances Control Act and Good Pharmacy Practice rules state that medicines must be disposed of in an irretrievable manner and not into municipal sewerage systems. The Medicines Control Council's guideline for the compilation of a Patient Information Leaflet for the registration of a medicine has mandatory statements informing the patient not to dispose of medicines in sewerage systems and they are advised to return unused medicines to the pharmacy.

The primary objective of this research is to establish the actual disposal practices for unwanted medicines from households in Johannesburg in order to offer possible solutions in drafting guidelines for the role of the pharmacist in the proper disposal of unwanted medicines.

Tong et al (2011b) conducted a survey of community pharmacists in New Zealand with the objective of finding out their disposal practices for unused or expired medicines. Out of the 265 community pharmacists surveyed, 80.4% and 61.1% responded that they disposed of solid and semi-solid dosage forms respectively via professional waste management contractors. Of concern was the feedback that 44.7% of the respondents disposed of liquids dosage forms predominantly down the pharmacy sink. Furthermore, 58.2% of the respondents disposed of Class B controlled medicines down the pharmacy sink as well.

The survey by Tong et al (2011b) highlighted the need to raise awareness with community pharmacists on the proper disposal of unwanted or expired medicines. Therefore the present study will conduct a survey of community pharmacists as well. The community pharmacist is an important partner in the efforts for educating the public about the proper disposal of unwanted medicines from households. Annually, the first week of September is celebrated as Pharmacy Week. During this week, the South African Pharmacy Council (SAPC) invests in media campaigns urging the public to return unwanted medicines to their pharmacy for proper disposal. This has raised awareness but there still needs to be more efforts done in this area as not all pharmacies are committed to the return to pharmacy for disposal concept. There is a need to lobby pharmacies and get their buy in and commitment.

METHODOLOGY

Materials

A mixed research method will be used where quantitative research will facilitate qualitative research. Three questionnaires will be drafted and randomly distributed by email to respondents in the Johannesburg area. One questionnaire will be for households (see Appendix A). The second questionnaire will be targeted at pharmacists who work in community pharmacies (see Appendix B). The third questionnaire will be aimed at SAPC registered Responsible Pharmacists for community pharmacies (see Appendix C). The email with the link to the questionnaire will be accompanied by the Participant Information Leaflet and Invitation Letter (see Appendix D) as an attachment.

The objective of the household questionnaire is to find out if people have unwanted medicines in their homes, the reasons why they ended up with unwanted medicines and how these are disposed of. In order to reduce bias in the respondents to the household questionnaire being only accessed by people with email, 200 questionnaires will be distributed to factory workers as hard copies so that the distribution of respondents is across different Living Standard Measures (LSMs). The hard copies will be accompanied by the Participant Information Leaflet and Invitation Letter.

The pharmacist questionnaire targeted at pharmacists who work in community pharmacies (see Appendix B) aims to establish if these pharmacists have received any advice on the proper disposal of medicines and if they convey such advice to patients when they dispense medicines. The questionnaire also assesses whether the pharmacists feel that the community pharmacies should be involved in “return-to-pharmacy” programs and who should oversee such a program.

The community pharmacy Responsible Pharmacist questionnaire (see Appendix C) aims to determine if the pharmacies have standard operating procedures for the proper disposal of unwanted medicines, the average monthly cost of waste management at a community pharmacy and who should bear such a cost. Both pharmacist questionnaires will seek to understand the disposal practices of unwanted medicines at community pharmacies.

Sample size

The sample sizes were estimated using the Raosoft sample calculator. The total population of households in Johannesburg is 1,434,856 according to the South African National Census of 2011. If a confidence level of 95% is assumed and the margin of error is accepted as 5%, a sample size of 385 is recommended assuming a response distribution of 50%. 500 household questionnaires will be distributed to make allowance for non-respondents.

According to the SAPC Statistics, the number of Pharmacists in Gauteng is 4830. The SAPC statistics for community service pharmacist lists 1125 community pharmacists. It was decided to rather use the total number of pharmacists in Gauteng in order to make the sample more representative. This is justified by the fact that most pharmacists even though they are employed full time in other fields of pharmacy, they “moonlight” by doing locums in community pharmacies. If a confidence level of 90% is assumed and the margin of error is accepted as 5%, a sample size of 257 is recommended assuming a response distribution of 50%. 200 pharmacist questionnaires will be distributed to community pharmacists. 100 pharmacist questionnaires will be distributed to community pharmacy responsible pharmacists. The data analysis will be done using the Statistical Package for the Social Sciences (SPSS).

ETHICAL CONSIDERATIONS

When considering the ethical issues associated with research, four principles need to be taken into consideration. According to Bryma and Bell (2007, p.126) these are whether there is harm to participants, lack of informed consent, invasion of privacy and whether deception is involved. These principles are explained below in relation to the present project proposal.

Harm to participants

The possibility of harm to participants through this research is minimal. The study will not involve medication administration to participants. There will be no collection of human tissues or blood. The study involves the collection of data in relation to the medicines used in households and how unwanted medicines accumulate and how they are disposed of. The harm that can occur to participants may be emotional in case their feedback to the questionnaire is made public. This is addressed by making the feedback anonymous where no respondent personal data is collected.

Lack of informed consent

Doyal (1997) outlines exceptions where informed consent is not required. One of them is where, for practical reasons it is difficult to receive informed consent. As already outlined, the study poses minimal risk to participants and their data will be anonymous. The surveys will be sent out by email as links to Survey Monkey with the participant information leaflet and invitation letter (see Appendix D) attached to the email explicitly stating that the survey is voluntary. Expecting respondents to sign and return an informed consent form for this type of research is not practical and might reduce the response rates. When weighing up the risk posed to the participants and for practical reasons, it is proposed that a waiver for informed consent be granted.

Invasion of privacy

Requesting participants to divulge information about their behaviours in relation to unwanted medicines in their households is an invasion of their privacy. It is for this reason that the participant information leaflet and invitation letter states clearly that participation is voluntary. As the participants respond to the questionnaire, there may be certain questions they are not comfortable in responding to. Should the participant wish to withdraw, they have the option not to submit the completed survey.

Deception

In certain cases to maintain the authenticity of results, it may be necessary for a researcher not to divulge the full details of their research methods. This is especially valid for observational studies where it is necessary to observe participants in a natural setting. The concept of deception does not apply in this study. The aims and outcomes of the study are outlined in the participant information leaflet and invitation letter. By participating in the study, the participants are fully aware of where and how their information will be used.

The main ethical principle that is relevant to this project proposal is that of invasion of privacy. The participant information leaflet and invitation letter will outline the aims of the study to prospective respondents and hopefully allay any concerns in relation to invasion of privacy.

Furthermore it is not necessary to seek written informed consent from the participants because the questionnaire does not ask for identifying information about the participants like age, name or gender. The results of the survey will be reported in the aggregate and not by the individual and responding to the survey will not make respondents vulnerable in any way.

CONCLUSION

As the awareness increases on the link between improper medicine disposal and environmental pollution the literature highlights the need for public education. Kuspis and Krenzelok (1996) report that in the 1990's pharmacists in the United States advised patients to dispose of unwanted medicines in the sink, toilet or garbage. More recently, Jones et al (2005) have highlighted the threat of pharmaceuticals to drinking water. Thus there is a need for re-education of not only the public but the healthcare professionals as well to a certain extent. Hence the present study aims to engage the pharmacists as well in its methodology.

Bound and Vouvoulis (2005) assert that disposal of medicines from households should be highlighted and investigated more prominently as a contributory factor in the environmental pollution by unwanted medicines. The need for guidelines and policies on the proper disposal of unwanted medicines is also raised as an area that needs attention. This was further confirmed by Tong et al. (2011a) after studying medicine disposal practices in several countries where they concluded that there is a need for formalised protocol for the disposal of unused medicines by patients.

The present project proposal is in line with current global trends which indicate the need to study disposal practices of unwanted medicines from households, the reasons for accumulation of unwanted medicines and the possibility of establishing formalised reverse distribution take back programs for unwanted medicines at community pharmacies.

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