



National Return and Disposal of Unwanted Medicines Project Audit 2016

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November 2016

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Acronyms

| | |
|--------------|--|
| ABS | Australian Bureau of Statistics |
| ACT | Australian Capital Territory |
| AMT | Australian Medicines Terminology |
| API | Australian Pharmaceutical Industries |
| ATC | Anatomical Therapeutic Chemical classification system |
| AUD | Australian Dollars |
| AUST L | Listed medicine on the Australian Register of Therapeutic Goods |
| DAA | Dose Administration Aid |
| DUMP | Disposal of Unwanted Medicines Properly (Campaign delivered in New Zealand) |
| EPA | Environment Protection Authority |
| FIFO | Fly-in-fly-out (employing people in remote areas by flying in temporarily to site) |
| GUHREC | Griffith University Human Research Ethics Committee |
| NatRUM | National Return and Disposal of Unwanted Medicines |
| NPS | National Prescribing Service |
| NSW | New South Wales |
| NT | Northern Territory |
| NZ | New Zealand |
| OH&S | Occupational Health and Safety |
| PBS | Pharmaceutical Benefits Scheme |
| QLD | Queensland |
| RPBS | Repatriation Pharmaceutical Benefits Scheme |
| RUM | Return of Unwanted Medicines |
| SA | South Australia |
| SNOMED CT-AU | Systematised Nomenclature of Medicine – Clinical Terms (Australian Edition) |
| SOP | Standard Operating Procedure |
| UK | United Kingdom |
| USA | United States of America |
| WA | Western Australia |

Definitions

AUST-R and AUST-L medicines

The Australian Register of Therapeutic Goods categorises medicines as registered medicines (AUST-R) or listed medicines (AUST-L) according to quality, safety and efficacy. Registered medicines are higher risk and have been evaluated for quality, safety and efficacy; product information for these medicines is approved by the Therapeutic Goods Administration. <https://www.tga.gov.au/registered-and-listed-medicines>. Limited therapeutic claims can be made about listed medicines and these medicines contain pre-approved, low risk ingredients.

Complementary/alternative medicine

Any vitamin, mineral, herbal, aromatherapy or homeopathic product.

Medicine item

Prescription medicine, over-the-counter medicine, and/or complementary/alternative medicine returned in a RUM bin. The item may consist of more than one pack with the same expiry date (i.e paracetamol 500mg tablets 3x100 tablet packs all expiring on 21st June 2016 are defined as one item).

Over-the-counter medicine

Medicines available for purchase without a prescription from a pharmacy, supermarket or online.

Sharps

Any used or unused syringes, injection devices and blades.

Unwanted medicine

Any used (opened), unused (unopened), but no longer needed or expired medicine.

Waste

For an item to be considered as 'PBS Waste' it is required to be listed on the PBS, be unopened, have been dispensed under the categories 'General', 'Concession' or 'Safety-Net', not be a sample pack, and not be packaging only.

Acknowledgements

Griffith University would like to thank the Department of Health and the National Return and Disposal of Unwanted Medicines Limited for funding this Project.

The authors acknowledge the contributions of Susie Head, Scott Burnell and Kerrin Henderson (Griffith University Health and Safety Advisors), Peter Cohen (Quality Manager, Incineration Facility), Greg Harrison (Depot Supervisor, Incineration Facility), David Cuff (Manager, Incineration Facility), the data collection assistants and members of the Advisory Panel for their guidance and support. We also acknowledge the contribution of Research Now® for their support with the timely delivery of the online general population survey.

We thank Dr Sara McMillan for assistance with the interviews and qualitative analysis, Dr Helen Stapleton for proofreading all versions of the report, and Professor Lynne Emmerton for the peer-review of the report.

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This report was produced with the financial assistance of the Australian Government Department of Health and the National Return and Disposal of Unwanted Medicines Limited. The financial assistance provided must not be taken as endorsement of the contents of this report.

Key findings

A two-stage approach with mixed methods was used to explore the current use of the National Return and Disposal of Unwanted Medicines (NatRUM) scheme and general public awareness and attitudes towards the storage and disposal of unwanted medicines. In total, representative samples of 423 Return of Unwanted Medicines (RUM) bins from all Australian states/territories and 4302 adults from the Australian general population (including a sub-sample of 166 interview participants who were higher medication users) were included in the research.

1. Medicines returned to community pharmacies were disposed of in RUM bins appropriately and safely. 2016 audit results are similar in terms of the most frequently dispensed PBS medicines in 2015. Generally, small amounts of inappropriate items and materials were found in bins; however the pharmacy protocol for disposing of sharps and capped pre-filled syringes, in particular, should be more explicit. Targeted random checks of bins for inappropriate items may be more efficient than large national bin audits.

2. The majority of medicines in RUM bins were not high cost PBS items. The estimation of PBS waste (all dispensed and unopened medicines, irrespective of expiry date) collected via the NatRUM scheme in Australia for one year is \$11,629,231 AUD. The term 'PBS waste' should be used with caution as estimates of waste differ substantially under different assumptions. Defining waste to include opened packets (meaning there could be valid clinical reasons for discontinuation) has far reaching implications with regard to existing supply arrangements.

3. The Australian population generally did not know how to dispose of unwanted medicines safely and appropriately, and were largely unaware of the NatRUM scheme. Increasing awareness of the scheme and the safe and appropriate disposal of unwanted medicines requires a campaign that targets the general population, particularly those who use, or care for people using multiple medicines.

4. Less than half of healthcare workers asked patients if they had unwanted medicines in the home and if they did most commonly they recommended disposing of these with the household rubbish and/or taking to the dump. All members of the healthcare team should receive targeted information about the free national disposal scheme available at community pharmacies, to ensure that multiple healthcare workers opportunistically ask patients about unwanted medicines on a regular basis.

5. People reported large proportions of medicines in their homes that were unwanted, expired or used infrequently, potentially exposing vulnerable household members to risk of harm. Information campaigns are needed to increase awareness of these risks and encourage people to clean out their medicine cabinets regularly and return unwanted or expired medicines to the pharmacy to minimise medicine accumulation.

6. Variable perception of risk related to storage, therapeutic use, expiry and appropriate disposal of medicines has implications for quality use of medicines Increased insight into variability in consumer perceptions of risk, medicines related behaviour and disposal practices is needed to inform targeted education of all stakeholders in quality use of medicines including healthcare workers, health consumers and carers.

Overall, this research provided evidence that the national RUM scheme continues to provide the public with a safe and appropriate method to dispose of unwanted medicines but that people are largely unaware of the scheme. Once informed, people were positive about using the scheme and education is needed to increase awareness, encourage people to regularly clean out their medicines and promote appropriate medicines disposal.

Executive summary

Medicines that are out-of-date (expired), used (open-packs) and unused (unopened) but no longer required, are considered to be 'unwanted medicines' and require safe and appropriate disposal. Old and unwanted medications can become toxic once out-of-date, are potentially dangerous to children through accidental ingestion, and can become a point of confusion for the elderly (1). In addition, disposal of medication down the sink or toilet, or in the general household rubbish, can lead to poor environmental consequences (1-5). In Australia the National Return and Disposal of Unwanted Medicines (NatRUM) scheme has been operating for 18 years. This scheme provides for people to return unwanted medicines to community pharmacies free-of-charge for disposal by high temperature incineration.

This cross-sectional research project aimed to provide a comprehensive understanding about the current use of the NatRUM scheme and further insight into public and healthcare workers awareness and attitudes towards the storage and disposal of unwanted medicines. In addition, this report aimed to contribute to the development of recommendations for raising awareness about the safe disposal of unwanted medicines, and of the NatRUM scheme.

Research design

A literature review was undertaken to identify how other countries and jurisdictions addressed unwanted medicines disposal in their communities and to ascertain the significance of any environment effects of the incorrect disposal of medicines. The research consisted of two stages, and was conducted from June to October 2016. The first stage involved an audit of a sample of returned medicines containers from all Australian states and territories. The second stage involved a two-step general population audit that consisted of a survey to assess awareness of the NatRUM scheme, and the risks associated with the improper disposal of unwanted medicines and accumulation of medicines, and structured interviews with higher medication uses to identify perceptions and behaviours surrounding the disposal of unwanted medicines.

Stage One: Return of unwanted medicines bin audit

The Return of Unwanted Medicines (RUM) bin audit aimed to collect data on the type and amount of medicines returned and to identify the proportion of total waste that was subsidised by the Pharmaceutical Benefits Scheme (PBS). The audit consisted of the following steps:

1. *Sample size and bin selection:* identification of the statistically significant number of RUM bins included in audit and processes to ensure random selection of bins.
2. *Data collection and training:* development of a purpose-built database for data collection and training tools for data collectors, which included data collection protocols, quality assurance procedures and Occupational Health and Safety Standard Operating Procedures.
3. *Bin audit:* RUM bin audits were conducted at three incineration sites (n=373 target sample size).
4. *Data analysis:* descriptive data analyses of the types and amounts of medicines returned and, using a number of assumptions, extrapolation to estimate the value of waste subsidised by the PBS.

Stage Two: General population audit

i) General population survey

The aim of the 2016 General Population survey was to audit awareness amongst a representative sample of the general population regarding appropriate practices for the disposal of unwanted medicines and of the NatRUM scheme, and to identify what people currently do with their unwanted medicines.

1. *Participants:* an experienced panel data company (Research Now®) was contracted to administer the survey and address sample size selection with oversight from the research team (n=4300 target sample size).

2. *Survey development*: the development of a purpose-driven, 10-minute survey which would provide valuable outcome information and which could be delivered online in a user-friendly manner.
3. *Data analysis*: descriptive data analysis of the survey responses to identify unwanted medicines disposal practices and assess awareness of the NatRUM scheme amongst the general population and healthcare workers.

ii) **Structured interviews with higher medication users**

Interviews with a sub-population of higher medication users aimed to ascertain the quantity and nature of unwanted or 'when required' medicines stored in the home that may require disposal, and to explore consumer perceptions related to key areas from the survey, such as disposal practices.

1. *Participants*: survey respondents who took five or more medicines (including complementary, alternative and/or over-the-counter medicines) self-selected into the interview sample at the end of the survey (n≈215 target sample size).
2. *Interview development*: the development of a structured interview guide informed by earlier studies, the survey and stakeholders, and was administered as a 15-minute telephone interview.
3. *Data analysis*: descriptive data analysis of data related to medicines and disposal practices and thematic analysis of responses to open-ended questions seeking participants' views on medicines storage and disposal.

Key findings and recommendations

In total, representative samples of 423 RUM bins from all Australian states/territories and 4302 adults from the Australian general population (including a sub-sample of 166 interview participants who were higher medication users) were included in the research.

Stage One: Return of unwanted medicines bin audit

- Inappropriate waste items (e.g. general rubbish, sharps and Schedule 8 medicines) were found infrequently suggesting that large national audits such as this one, and that conducted in 2013, are not needed. Resources may be better used with more frequent, targeted, random monitoring for items such as sharps and Schedule 8 medicines, protocol updates and reminders for pharmacy staff, and evaluation of the impact of campaigns and protocol updates. The low level of inappropriate items highlights the value of the service provided by community pharmacists in promoting medicine safety through appropriate disposal.
- Of the 26,114 items (excluding DAAs), 15,572 (59.6%) were matched with PBS data and coded as a PBS item. Of the remaining 10,542 unmatched items, the majority (39.9%) were classified as 'International', 'Unscheduled', 'Unknown schedule' or 'Complementary' (and/or alternative) medicines; 36.2% were Schedule 4 and Schedule 8 items; 6.4% were Schedule 3 and 17.5% were Schedule 2 items.
- Our audit estimate of PBS waste in Australia for one-year (using a strict definition i.e. dispensed and unopened, irrespective of expiry date) was a total of \$11,629,231 AUD. This figure is higher than the 2013 RUM audit estimate, which was based on a restricted sample of 31 medicines and used different methodology.
- The top 20 medicines most frequently found in RUM bins were relatively low cost items. In terms of 'PBS waste', using our strict definition, products containing levodopa + carbidopa provide the biggest contribution to the overall estimate using medicinal product terms. Ten of the 20 most commonly discarded PBS items were also on the list of the 20 most commonly dispensed PBS medicines for 2015-2016. This is a similar finding to the 2013 audit and suggests that the content of the RUM bins broadly reflects the most commonly dispensed PBS items in Australia.

- A total of 9,381 of the 26,114 items (35.9%) were expired as of 30th June 2016. The highest proportion of medicines were dispensed in 2016 (37.9%), followed by 2015 (27.3%), 2014 (12.9%), 2013 (8.3%), 2012 (4.1%) and 2011 (2.2%).
- Dispensing labels were found on 7,220 of the 26,114 items (27.6%) and 'Concession' (44.4%) labels were most common, followed by 'Private' (18.2%), 'Safety-Net' (16.1%), 'General' (5.9%), 'Hospital' (3.2%) and Doctors Bag (1.0%). The dispensing category was unclear or unknown in 11.2% of items.
- It is important to remember that the NatRUM scheme is only one method of unwanted medicines disposal used by the Australian population and that these results must be viewed together with Stage Two findings.

Stage Two: General population audit

i) General population survey

- Around 60% of the general population respondents had unwanted medicines in their home and their main reason for keeping them was *'in case they needed them again'*. The primary concern for people who had unwanted medicines at home was that unsafe storage could lead to unintended poisoning (e.g. children).
- Members of the general population were generally unaware of the NatRUM scheme, most commonly disposed of their unwanted medicines with household garbage and only a quarter had returned medicines to the pharmacy. A grassroots campaign, primarily to educate people who take multiple medicines, should be implemented to raise awareness of the scheme and safe disposal of unwanted medicines.
- Over 80% of respondents had not heard of the NatRUM scheme with awareness highest amongst older respondents, yet 92% of people said they would use it after learning about the scheme.
- Around half of the healthcare worker respondents had not asked their patients about unwanted medicines stored at home and the most common advice was that these should be disposed of in the household rubbish and/or taken to the dump (69.2%). All healthcare workers, but in particular pharmacy staff, should be asking patients about unwanted medicines in the home and providing information about the NatRUM scheme. Training and information resources for pharmacy staff and healthcare workers should be available.
- A television campaign was ranked as the most effective way to promote awareness of the safe disposal of unwanted medicines. A potential role for pharmacy staff to increase awareness about safe medicines disposal also emerged particularly when consumers were picking up prescription medicines. A sticker on the packet or information directly from the staff was considered most effective.

ii) Interviews with higher medication users

- A total of 1424 currently unused or 'when required' medicines were reported across 166 homes and about half of these were expired or expiring within six months. Some participants were unaware that medicines did expire or reported being confident using medicines beyond their expiry date, particularly topical and complementary medicines.
- Interview participants were often unaware of the magnitude of medicines in their home; the use of multiple storage locations within the home to support adherence may be a contributory factor.
- There was limited evidence of medicines accumulation for chronic conditions although participants admitted to collecting medicines 'just in case', for overseas travel or episodic illnesses. Evidence of collection of 'just in case' antibiotics was particularly concerning;
- Key risks associated with storing medicines in the home were related to safety mainly in the context of reduced efficacy and unintentional poisoning.
- Variable risk assessments were used to make decisions about continuing to store unused medicines in the home, use beyond expiry, and disposal of such medicines, suggesting that misconceptions exist.
- Multiple disposal practices were applied, sometimes within one household, according to different medicine schedules and formulations, highlighting the need for further education in this area.

- Interview participants discussed returning medicines to the pharmacy at a greater frequency than survey respondents, perhaps reflecting an educational effect of the survey, which should be extended further.
- Trust in pharmacies to safely dispose of medicines was tempered by participants' perceptions about inappropriate disposal methods and possible reuse and resale of medicines, particularly overseas.
- National and pharmacy based campaigns could address misconceptions, increase awareness of the free medicines disposal service provided by pharmacies via the NatRUM scheme, and encourage a regular clean outs of medicines.

Strengths and limitations

The size and representative nature of the audit and population samples, and the combined qualitative and quantitative approaches, are research strengths. The use of the Australian Medicines Terminology as the basis of the RUM bin audit database ensured consistency in the medicines terms used. Possible limitations included the large number of data collectors involved in the audit, assumptions made to estimate PBS wastage, the use of survey participants registered to participate in research with internet access, participant self-selection into the interviews from the survey, and difficulties contacting people by telephone. In addition, not all of the PBS data was fully reconciled with the Australian Medicines Terminology meaning manual matching was undertaken for the small subset of medicines that could not be automated. Strategies to minimise these issues included: standard operating procedures, protocols, training and quality checking throughout audit process; and conducting interviews at a range of times including evenings and weekends. Ongoing discussions with the Advisory Panel ensured the validity and reliability of the findings.

Conclusion

The research provides evidence that greater knowledge is needed by all stakeholders in quality use of medicines particularly in relation to appropriate disposal practices for unwanted medicines stored at home. It is encouraging that medicines were being disposed of in RUM bins appropriately and safely, that trends for returned medicines remained similar over time and that wastage of medicines was limited. However, evidence from the survey and interviews supports our finding that the majority of the population were unaware of the NatRUM scheme but were willing to use it once informed. Healthcare workers did not always ask people about unwanted medicines or recommend appropriate disposal practices. Evidence of large volumes of medicines in homes that are expired, used or unused but no longer needed, potentially expose all household members to a range of risks currently not recognised by the general public.

Many opportunities have been revealed for national and grassroots campaigns targeting all stakeholders in quality use of medicines. These strategies will ideally be aligned with existing quality use of medicines campaigns and encourage people to regularly check and clean out their medicines, limit inappropriate medicines use or accumulation, and promote appropriate medicines disposal.

1 Introduction

The National Return and Disposal of Unwanted Medicines Limited of Australia engaged Griffith University to undertake cross-sectional research to assess the current use and public awareness of the National Return of Unwanted Medicines (NatRUM) scheme and further insight into public and healthcare workers awareness and attitudes towards the storage and disposal of unwanted medicines. The findings will contribute to the development of recommendations for raising public and health professional awareness about the safe disposal of unwanted medicines and of the NatRUM scheme. This research was funded by the Australian Government Department of Health and National Return and Disposal of Unwanted Medicines Limited. This is the final report for the project entitled: ***National Return and Disposal of Unwanted Medicines Project Audit, 2016.***

National Return of Unwanted Medicines Scheme

Medicines that are out-of-date (expired), used (opened) and unused (unopened) but no longer required are considered to be 'unwanted medicines' and require safe and appropriate disposal. The NatRUM scheme, which has been operating for 18 years, is a national program that provides for unwanted medicines to be collected by community pharmacies from consumers (1). Medicines that are returned to community pharmacies are disposed of by high temperature incineration, which is the Environment Protection Authority (EPA) approved method of disposal (1).

The National Return and Disposal of Unwanted Medicines Limited, a national not-for-profit company which is registered specifically for this purpose, receives funding from the Commonwealth Government to manage the safe disposal of medications (1). The NatRUM scheme operates through community pharmacies, where unwanted medications are collected at no cost to consumers. Pharmaceutical wholesalers deliver and collect the Return of Unwanted Medicines (RUM) bins at a reduced cost (1).

Common reasons cited for the return of unwanted medicines include safety and efficacy issues, death, change in therapy, and resolution of a health condition (6-9). The safe and appropriate disposal of unwanted medicines is a quality use of medicines issue (1). Old and unwanted medicines can become toxic once out-of-date, are potentially dangerous to children through accidental ingestion, and can become a point of confusion for the elderly taking multiple items (1). In addition, disposal of medication down the sink or toilet, or in the general household rubbish, can lead to poor environmental consequences (1-5). It is also possible that people hoard medicines for future use, which raises safety and efficacy concerns (7).

In the 2015/2016 financial year 705,079 kg of medicines were returned via the NatRUM scheme, an increase of 7.7% compared with the previous year (1). However, despite the availability of the national scheme, in 2012 alone, more than one million households were estimated to have discarded unwanted medicines, drugs or ointments with their usual garbage (10).

It is clear that understanding the quantity and nature of medicines returned via the NatRUM scheme, and inappropriate disposal and/or accumulation practices, has important implications for health and environmental outcomes and related expenditure. A 2005 Victorian study and a 2013 audit of the NatRUM scheme provided evidence to support the significant value of, and need for, this national scheme and insight into public awareness of, and attitudes towards, the disposal of unwanted medicines (6, 11). However, as funding of this initiative will be reviewed in June 2018, there is a need for a more contemporary and comprehensive understanding of public attitudes towards the safe disposal of unwanted medicines and further need to increase public and health professional awareness about the scheme.

1.1 Project purpose and outline

This research provides a contemporary and comprehensive assessment of the use and value of the NatRUM scheme and further insight into public and health professional awareness and attitudes towards the disposal of unwanted medicines. It involved an audit of a sample of returned medicines containers from all Australian states and territories and a general population awareness audit of the NatRUM scheme assessing the risks of unwanted medicines disposal and of accumulating medicines.

The overall aims of this project were to:

- 1) Conduct an audit of returned medicines from an Australian-wide representative sample of RUM bins; and
- 2) Assess consumer awareness of the NatRUM scheme.

In achieving these aims, this project intends to provide National Return and Disposal of Unwanted Medicines Limited with:

- further evidence that the current NatRUM scheme activities are consistent with the program objectives and the National Medicines Policy;
- an extrapolation of the value of wastage to the Pharmaceutical Benefits Scheme (PBS) and information for consideration and use in the broader post market monitoring program of medicine use; and
- further information to develop the NatRUM scheme particularly regarding both consumer awareness and pharmacy participation.

In order to meet these aims, the specific objectives of the research were to:

- collect quantitative data on the return and disposal of unwanted medicines using a statistically valid sample of returned RUM bins from all states and territories in Australia including type of medicines discarded, whether medicines were used (opened) and the amount of medication returned;
- extrapolate the value of wastage to the PBS;
- audit awareness amongst the general population of appropriate practices for disposal of unwanted medicines and the risks of accumulating medicines; and
- collect data on the quantity of unwanted or expired medicines in the households of a subset of the general population with higher medication burden.

A review of the literature, including grey literature, was performed in May 2016 to identify how other countries and jurisdictions address unused and unwanted medicines in their communities, and to ascertain the significance of any environmental effects of incorrect disposal of unwanted medications.

The research itself involved two stages, commenced in June 2016 and was conducted over six months. Ethical approval for this project was obtained from the Griffith University Human Research Ethics Committee (2016/449/GUHREC). An Advisory Panel for the study comprising representatives from the Department of Health and the NatRUM Board of Directors was established to provide oversight and guidance to the research team at a strategic level.

In **Stage One** we conducted an audit of returned medicines bins at the three national incineration sites. Documentation included the source (state or territory, based on wholesaler data) of the bin, container weight and percentage filled, and all items returned in the bin including dose administration aids (DAA). All containers of discarded medication (e.g. boxes of tablets, bottles of liquid, metered dose inhalers, tubes of cream) were inspected for the quantity of medicine remaining – unit doses (tablets, capsules, nebulas, suppositories,

ampoules, etc.) were individually counted, the amount remaining in bottles of liquids and aerosols was estimated and creams/ointments were weighed. Loose tablets and capsules (i.e. not in bottles or blister packs) were excluded. The volumes of complementary and/or alternative medicines returned were estimated. From this information, comparisons were made with the 2013 NatRUM audit and, using a number of assumptions (tested in the uncertainty analyses), an extrapolated value of wastage to the PBS was estimated (11).

In **Stage Two**, a two-step general population audit was conducted. Step one explored general population awareness of the NatRUM scheme and identified what people currently do with their unwanted medicines using a household e-mail survey. The survey included people who had never used the NatRUM scheme. Those who identified as healthcare workers were asked additional questions about whether, and how, they promoted the NatRUM scheme or disposal of unwanted medicines to their patients and/or customers. From this information comparisons were made with the Australian Bureau of Statistics (ABS) Waste Management, Transport and Motor Vehicle Usage Surveys, which estimated the number of households who disposed of 'medicines, drugs or ointments' and the main method of disposal (10, 12).

In step two, a sample of survey respondents who took five or more medicines (including complementary, alternative and/or over-the-counter medicines) participated in a telephone interview about the medicines they had in their home, including those that were out-of-date or unused. Interviews also provided an opportunity for the pharmacist researcher to provide information to participants about discarding medicines via their local pharmacy.

2 Literature Review

A narrative literature review (including grey literature) was conducted to identify research on the return of unwanted medicines in other countries and jurisdictions. The aim was to find Australian and international studies which detailed:

- a) medicine return programs;
- b) audits of unwanted medicines; and
- c) awareness surrounding issues relating to the disposal of unwanted medications, including any potential environmental impacts.

Results

a) Australian studies

Two previous reviews of the NatRUM Program were identified: (i) a 2005 Victorian study conducted by Brushin; and (ii) an audit (and an associated publication) of the Program which was conducted by Monash University in 2013 (6, 11). A third study by Guirguis (2010) identified medications collected by outreach pharmacists who performed medication reviews for elderly patients of St Vincent's Hospital, Melbourne (13).

The aims of the 2005 Victorian study were to identify consumer practices related to the return of unwanted medicines, the social and demographic influences of those who returned medicines, and which medicines were being returned and why (6). Consumers returning medications to 100 community pharmacies in Melbourne, Victoria were interviewed and the medications returned were documented. In 2005, 66.2% of consumers returning medication to a community pharmacy had done so previously, with 64% of respondents having learned about the NatRUM scheme from a pharmacist. The most commonly returned medications, by therapeutic class (according to their therapeutic index classification), were those used for the cardiovascular system (19.8%), nervous system (19.5%) and alimentary tract and metabolism (14.6%). The most commonly returned medicines, by generic name, were glyceryl trinitrate (2.2%), prednisolone (1.8%), salbutamol (1.8%), paracetamol (1.7%) and warfarin (1.7%). The reasons for medicine return were: passed expiry (30.9%), death (26.4%) and change of medication (8.5%) (6).

In 2013, Bergen and colleagues from Monash University conducted an audit of the NatRUM scheme to identify the quantity and type of unwanted medications returned, to compare these results with PBS data to estimate the annual cost of unwanted medicines annually, and to determine the extent of adherence by community pharmacists to NatRUM protocols (11, 14). A total of 686 RUM bins from all states (excluding Western Australia) were audited, with the majority of returned medicines belonging to the following therapeutic classes: cardiovascular system (17.9%), nervous system (17.5%) and alimentary tract and metabolism (15.7%). Of the returned medicines, 43.7% had not expired. The five most commonly discarded PBS medications were salbutamol, insulin, frusemide, prednisolone and glyceryl trinitrate. The total government cost for the 31 most frequently discarded medicines was estimated to be approximately \$2.05 million (11, 14).

Outreach medication review pharmacists from St Vincent's Hospital in Melbourne, Victoria collected medicines that were expired or no longer required by patients over a two month period in 2008 and estimated the cost to the PBS (13). Forty patients, who were older than 65 years and had chronic medical conditions, returned 293 items in total, with most items belonging to the cardiovascular therapeutic group (26.6%) and analgesics/anti-inflammatories (21.2%). Based on the average PBS price of a medication, it was estimated that the value of expired or unwanted medications collected per patient per year would average \$1,308 (13).

The ABS Waste Management, Transport and Motor Vehicle Usage Survey questions were also identified (10, 12). These survey questions, administered every three years from 2000 to 2012 as a supplement to the monthly Labour Force Surveys (containing 121 questions), estimated the proportion of households in each state/territory who had disposed of 12 potentially hazardous waste items (e.g. garden/pool chemicals, paints, fluorescent lights, household appliances) in the previous 12 months and the main method of disposal. One of these potentially hazardous waste items was '*medicines, drugs or ointments*': 26% of households in 2012 reported disposing of these items; 55% with the usual household garbage, 34% taken to a business or shop (e.g. pharmacy or chemist) and 14% poured these down the drain or toilet (10).

b) International return of unwanted medicine programs and audits

Our review of the literature found that although a number of countries have a medicines return policy and municipal collection schemes, public awareness of schemes is generally low. Countries including Spain, United Kingdom (UK), Ireland, Qatar, New Zealand (NZ) and the United States of America (USA) had assessed the effectiveness of their unwanted medicines return programs (2, 8, 15-20). All studies found that although people agreed that the appropriate disposal of medicines was an important issue, the majority of respondents were not aware of the medicines return scheme available in their own country and most currently disposed of their unwanted medications with the household garbage or via the sewerage system (flushing down the toilet or washing down the sink). In fact, in the USA people were advised that if a community-based medicine take-back program was not available, disposal of some medications (e.g. opioids and benzodiazepines) via the sewerage system was perceived as the easiest method to protect humans and pets from unwanted medications that might otherwise accumulate in the household or be recovered from the garbage bin (2, 21).

A number of overseas studies included audits of returned medications. A 2007 audit of the Disposal of Unwanted Medicines Properly (DUMP) campaign in a district of Auckland, NZ assessed the types of medicines returned to pharmacies and the reasons why consumers had old and unwanted medications in their homes (19). The most common medications returned, by therapeutic group, were alimentary tract and metabolism (22.5%), cardiovascular system (20.4%) and nervous system (18.4%). The most commonly returned items were glyceryl trinitrate sprays, lactulose liquid, psyllium hydrophilic mucilloid powder and paracetamol tablets. Reasons for having unused medications in the house included 'don't know where to dispose them' (34%), it was a 'waste of money to throw away' (25%) and that the 'medicine might be useful for some other purpose' (23%) (19).

A study of medicines returned to community pharmacies or general practitioner surgeries in Birmingham, UK in 2002 found that 50.0% of returns were due to the doctor stopping or changing the medication, 13.2% to excess supplies or a clear out, and 10.5% to patient death (18). The most common classes of returned medications were cardiovascular system (28.5%), central nervous system (18.8%) and respiratory system (14.7%) (18). A second study in the same locality conducted in 2003, found that the most commonly returned classes of medication were cardiovascular (26.6%) and central nervous system (23.5%) (22). In this later study the majority of medications were returned following patient death (22).

A study of returned medications to 118 community pharmacies in Barcelona, Spain found that the most commonly returned medications were for the alimentary tract and metabolism (18.3%), nervous system (18.2%) and cardiovascular system (11.7%) (15). The most common reasons for medication return were because they were out-of-date (28.2%), no longer required (24.9%), or patient death (20.8%) (15).

c) Environmental issues

There is also literature on the environmental impact of the disposal of medications in general waste or into the sewerage system, especially the growing concern about pharmaceuticals in wastewater (3-5, 23, 24). A wide range of pharmaceuticals have been found in fresh and marine waters (5). Although some effects on aquatic life are known, for example the feminisation of some fish due to exposure to 17 α -ethinyl oestradiol, other effects such as the risk of drug resistance due to the creation of antibiotic resistant strains of pathogens, and the impact of pharmaceuticals in drinking water supplies, remain unknown (4, 5). Medicines disposed of via household waste or the sink/toilet enter the waterways in an unmodified form, having avoided metabolism in the body, and might therefore contribute disproportionately to environmental contamination (5).

Preliminary studies suggest that improved general public awareness about environmental issues and appropriate disposal practices for unwanted medications would impact on the method of disposal chosen (4, 5).

3 Stage One:

Return of unwanted medicines bin audit

This stage aimed to audit an Australia-wide representative sample of RUM bins, collecting data on the type of medicines discarded, whether medicines were used and the amount returned. The specific objectives included identifying:

- the quantity and types of medicines returned to pharmacies throughout Australia; and
- the proportion of the total waste that was PBS-subsidised, and where possible, the dispensed category of the returned medicines (i.e. concession, general, Safety-Net, etc.).

Method

Sample size and bin selection

National data (excluding Western Australia) provided by NatRUM Limited showed that over the last three years (2013-2015) an average of 10,000 to 12,000 RUM bins per month were collected for incineration. Western Australian data (provided by Medical Solutions) reported that, on average, 960 RUM bins per month were collected for incineration. For the purpose of calculating the minimum sample size for a statistically valid sample of RUM bins in this present study, 12,000 bins per month was used in the Raosoft® sample size calculator (<http://www.raosoft.com/samplesize.html>); a minimum of 373 bins needed to be sampled (assuming 5% margin of error and 95% confidence level).

Table 3.1 outlines the number of RUM bins calculated for each state or territory to ensure an Australian-wide representative sample of 373. It was estimated that an additional 10% (37 bins) would require inspection due to exclusion criteria (e.g. greater than 50% of bin containing loose tablets/capsules).

Table 3.1: Selection of RUM bins for audit*

| State/territory | Average number of pallet collections per month | Average number of bin collections per month | Percentage of bins (%) | Number of bins for audit |
|--|--|---|------------------------|--------------------------|
| Australian Capital Territory | 2 | 96 | 0.8 | 3 |
| New South Wales | 79 | 3,792 | 30.4 | 113 |
| Northern Territory | 2 | 96 | 0.8 | 3 |
| Queensland | 48 | 2,304 | 18.5 | 69 |
| South Australia | 37 | 1,776 | 14.2 | 53 |
| Tasmania | 4 | 192 | 1.5 | 6 |
| Victoria | 68 | 3,264 | 26.2 | 97 |
| Western Australia (including Christmas Island) | 20 | 960 | 7.7 | 29 |
| TOTAL | 260 | 12,480 | 100 | 373 |

RUM = Return of Unwanted Medicines

* Pallet collections by State (first six months of 2015/2016): national data (excluding Western Australia) were provided by NatRUM Limited. Data for Western Australia were provided by Medical Solutions.

Incineration contractors were requested to randomly select and set aside one bin from every ten from each sequential pallet arriving from all states or territories in the month prior to the audit until the total (plus 10%) for that site was achieved. Only one pallet of RUM bins was available for both Tasmania and Christmas Island; therefore, in both cases the project Data Collection Manager took a random selection onsite of the required number of bins (plus 10%) from the pallet.

Data collection and training

A purpose-built database was developed in Microsoft Access®. We used Australian Medicines Terminology (AMT) - a subset of the SNOMED CT-AU clinical terminology, supported by the Australian Digital Health Agency (<http://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/clinical-terminology>).

This national terminology unambiguously identifies branded and generic medicines commonly used in Australia. It included a list of most prescription and over-the-counter medications and complementary products sold in Australian pharmacies, allowing generic and/or trade names to be easily searched and data such as form, strength and original quantity to be easily selected. For items that were not available in this list, manual entry of the name of the product, form, strength and original pack quantity was required. The database and data collection process was piloted with three RUM bins at the Brisbane incineration site and a number of modifications were implemented. Appendix 1 presents example screenshots of the Access® database (within the Data Collection Protocol), which was loaded onto laptop computers for data entry in real time at each incineration site.

Audit training tools, including the data collection protocol and quality assurance procedure (Appendix 1), and Occupational Health and Safety (OH&S) Standard Operating Procedure (SOP) (Appendix 2), were developed prior to commencing the audit, in consultation with incineration plant managers, personnel from Griffith University OH&S and NatRUM Limited.

At each of the three incineration sites project data collectors, who were higher degree research students, pharmacy and/or medical science graduates, worked in pairs to conduct the audit under the supervision of the project Data Collector Manager, who was a registered pharmacist. An additional data collector was employed for each site to act in a quality control role and to provide cover for breaks and/or absences such as unexpected illness.

Data collectors were trained on each site to safely audit a RUM bin and to enter data into the Access® database. They were familiarised with the specific auditing equipment including protective clothing (gloves, safety glasses, dust masks, coveralls), and tools (tongs, tweezers, scales). Auditors were then provided with a demonstration of how to safely open and assess the contents of a RUM bin. Training also emphasised the importance of the confidential nature of bin contents including any pharmacy, prescriber and patient information on medicine waste. A representative from Griffith University OH&S was present for this training.

Bin audit

The audit of RUM bins was conducted at three incineration sites, one in Victoria (by eight pairs of data collectors for six days), one in Queensland (by five pairs of data collectors for three days) and one in Western Australia (by two pairs of data collectors for three days). The difference in duration and staffing numbers reflects the capacity of the site to accommodate the data collection process and the number of bins collected at each site for incineration. For example, the Queensland site is responsible for incinerating bins only from that state, Western Australia for that state and bins from Christmas Island, and Victoria for bins from all remaining states and territories.

Each RUM bin was visually inspected prior to opening to record the source of the bin (state/territory and wholesaler returning the bin), container weight and bin identification number (assigned by the project Data Collection Manager on Day 1 of each site visit). On opening, the proportion of the bin that was filled was documented (i.e. less than 50%, 50-75% and 75-100%), as well as whether DAAs or inappropriate items (such as sharps, liquid cytotoxics, biological or general waste) were present. RUM bins were excluded from the audit if they:

- were less than 50% full; or
- contained a high proportion of general waste; or
- contained more than 50% loose tablets (not in an identifiable bottle/packet or blister/strip); or
- contained unsafe items such as broken glass, biological waste, unknown liquid or powder waste.

The Data Collection Protocol (Appendix 1) outlines the process followed for all discarded medicines. In summary, for those medicines in their original packaging, or that were easily identifiable (e.g. boxes/bottles/blisters of tablets, bottles of liquid, metered dose inhalers, tubes of cream etc.), the generic name, trade name, schedule (Schedule 2, 3, 4, 8 or unscheduled), strength, dose form and expiry date were recorded. All medicines were inspected for the quantity remaining: unit doses (tablets, capsules, nebulas, suppositories, ampoules, etc.) were individually counted; the amount remaining in bottles of liquid was estimated (0-25%, 25-50%, 50-75% or 75-100% full); creams/ointments were weighed if they had been opened; and the amount remaining in aerosols was recorded from the indicator or was estimated by placing the device/canister in water to determine whether they were full (quickly sank), used (slowly sank) or empty (floated). Loose tablets and capsules (those not in bottles or blister packs) and products that were unidentifiable (e.g. from another country or not in original packaging) were excluded. The remaining volumes of complementary and/or alternative medicines returned were estimated rather than counted (0-25%, 26-50%, 51-75% or 76-100% full).

When dispensing labels were present on a product, the year of dispensing and, when possible, the PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) category (i.e. concession, Safety Net concession, general, doctor's bag or private) was recorded. If the item was identified as a sample pack this was also recorded.

If DAAs were present, the type (e.g. dosette, blister or sachet pack) was recorded and proportion remaining was estimated (e.g. 0%-25%, 26%-50%, 51%-75%, and 76%-100% full).

When an item was identified as a Schedule 8 medicine, this was recorded specifically in the database. This included when there was evidence of destruction of the medicine (i.e. cut and empty foil strip or an empty bottle) before it was returned in the bin.

If any sharps were present, which included any used or unused needles and syringes, lancets, and blades (25, 26), this was recorded in the database.

A number of quality assurance processes were built into the audit to ensure safety and adherence to legislation, audit protocols and data entry processes. The Data Collection Manager and senior members of the research team were on site for the first day of data collection in all sites to observe adherence to audit protocols and data entry conventions, and to answer any process questions. The Data Collection Manager was on each site for the entire data collection period and (working with the quality-control data collector) re-inspected and checked the data entered for the first RUM bin and a second, randomly selected, bin audited by each pair of data collectors. Random bins were chosen each day by the Data Collection Manager to continually check the accuracy of data

collection. An OH&S officer from Griffith University was also present on the first day of data collection in Queensland and Victoria to ensure compliance with the audit procedures and related safety and legal requirements. The Western Australia site had restricted space capacity for personnel and for this reason the research team leader remained on site for two days rather than an additional OH&S officer.

Data collectors were advised to immediately raise any issues regarding the consistency or reliability of entered data. Any such issues were immediately shared with all data collectors and, if necessary, the quality assurance procedures and protocols were updated.

Data analysis

For data collection purposes, we used the *trade product pack terms*, allowing data entry personnel to search and select on branded or generic names of products, for example:

- Panadeine Caplet® (codeine phosphate hemihydrate 8 mg + paracetamol 500 mg) tablet: film-coated, 12 tablets.

Use of the AMT allowed linkage between trade product pack terms with other formal definitions such as the *medicinal product pack term*:

- paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 12 tablets;

and the *medicinal product term*:

- paracetamol + codeine.

Following data collection the trade product pack terms were matched with both the medicinal product pack and medicinal product terms (using the SNOMED CT-AU v1.7 Common Release). AMT is also compatible with PBS data and hence the PBS dataset (October 2016 version) was merged, along with the Anatomical Therapeutic Chemical (ATC) classification system number, into the bin audit database. This allowed PBS items to be matched with a price (Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack).

Some discrepancies during the matching process occurred. AMT identification numbers have not yet been fully reconciled with the PBS dataset, meaning a subset of possible matches were not automatic. Further, the time discrepancy between data collection and data analysis meant that a new AMT version was released in the interim. This resulted in a small number of items that were not automatically matched with their AMT terms. Automated matching was not possible for any manually entered items (where no trade product pack listing was found at data entry). Overall, this meant that manual matching was required in some instances and was undertaken for all Schedule 8 and the majority of Schedule 4 items. Where matching issues may affect results, this is noted.

Following data matching, audit data were cleaned in preparation for visualisation and descriptive data analyses. Using a number of assumptions an extrapolated value of 'wastage' to the PBS was estimated. This estimate is sensitive to the definition of waste, such as whether only unopened packs were counted, whether products were expired at the time of counting (but not necessarily at the time of disposal), and if a dispensing label was visible. These assumptions are tested and presented alongside the main results.

Results

In total 452 bins were sampled and inspected for the audit (Table 3.2). Twenty-nine bins (6.4%) were excluded by the Data Collection Manager at the point of inspection: four bins were less than 50% full; seven contained items other than medicines that made up more than 50% of the bin contents; five bins contained loose

tablets/capsules that made up more than 50% of the bin contents; nine bins were deemed unsafe to audit; and four bins were from an incorrect state/territory at the incineration site. The proportion of bins we excluded is considerably lower than the proportion in the 2013 audit (12.5%; n=98/784). The primary reason for exclusion in 2013 was that 62 bins (7.9%) contained more than 50% of loose tablets, capsules or blister strips (11). In comparison only five bins (1.1%) were excluded for this reason in the 2016 audit because of different inclusion criteria for blister strips i.e. all tablets and capsules contained in blister or foils strips were recorded as part of the audit data collection.

Table 3.2: Total RUM bins audited

| State/territory | Number of bins to be sampled | Number of bins opened | Number of bins excluded | Number of bins audited |
|------------------------------|------------------------------|-----------------------|-------------------------|------------------------|
| Australian Capital Territory | 3 | 4 | Nil | 4 |
| New South Wales | 113 | 127 | 7 | 120 |
| Northern Territory | 3 | 4 | Nil | 4 |
| Queensland | 69 | 87 | 8 | 79* |
| South Australia | 53 | 61 | 1 | 60 |
| Tasmania | 6 | 11 | 1 | 10 |
| Victoria | 97 | 116 | 7 | 109 |
| Western Australia | 29 | 42 | 5 | 37^ |
| TOTAL | 373 | 452 | 29 | 423 |

RUM = Return of Unwanted Medicines

** Including 10 bins from Far North Queensland*

^ Including 5 bins from Christmas Island.

A total of 87 bins were inspected at the Queensland site, including 10 bins from far North Queensland. Eight bins were excluded: two were less than 50% full; two bins contained general waste that made up more than 50% of bin contents; two were from an incorrect state; and two contained loose tablets/capsules that made up more than 50% of the bin contents. In Western Australia 42 bins were inspected, including five from Christmas Island. Five bins were excluded: one was less than 50% full; two contained more than 50% loose tables/capsules; one contained general waste that made up more than 50% of bin contents; and one contained unsafe contents (liquid spill). A total of 324 bins were inspected at the Victorian site from Australian Capital Territory, New South Wales, Northern Territory, South Australia, Tasmania and Victoria. Of these bins, 16 were excluded: one contained more than 50% loose tables/capsules; one was less than 50% full; four contained general waste that made up more than 50% of bin contents; eight contained unsafe contents (smashed glass, loose unknown powder, liquid spill); and two were from an incorrect state.

Weight of bins

The total weight for the waste contents of the 423 bins audited (not including the plastic bin that weighed 1kg) was 1,766 kg (1.8 tonnes). This corresponds to 0.32% of the total weight of RUM bin waste (reported by the National Return and Disposal of Unwanted Medicines Limited) that was collected for incineration between July 2015 and June 2016 (544,234 kg; 544 tonnes of nett waste collected for incineration in 160,845 bins over the 12-month period (1)).

The average net weight of the 423 bins audited was 4.2 kg per bin (39 bins weighed > 6 kg; 381 bins weighed 2-6 kg; 3 bins weighed < 2 kg). Most of the bins audited (n=408/423; 96.5%) were recorded with a content volume of 75% to 100% (considered full), and only 3.5% of bins (n=15/423) had a content volume of 50% to 75% (considered three-quarters full). These bin weight and volumes are consistent with the 2013 RUM bin audit which reported an average net bin weight of 4.2 kg per bin and 93.7% were 75% to 100% full (11).

Bin contents

A total of 30,422 medicine items (see page 5 for definition) were disposed of in the sample of 423 bins included in the audit. Table 3.3 presents a summary of these items, which excludes empty packaging for which no corresponding product was found. A total of 1,426 instances of empty packaging were recorded.

The 26,114 items (excluding DAAs) were recorded in 20,881 separate observations. An observation could be recorded in one of two ways. Either, unopened packs of medicines with the same expiry date and dispensing details could be recorded as multiple items of the same product; or, for opened items, the amount remaining was recorded. For tablets, capsules and other 'single' units, this count was recorded. For example, for an observation of 'paracetamol 500 mg tablets, 100 pack size' a total count of 200 tablets, from multiple packs with the same expiry and dispensing details, was possible. In such an instance, a count of '1 item' was assigned as it was often unclear if these loose units belonged to the same original 'pack' or multiple packs. 200 loose tablets were recorded as a separate variable. Thus, we believe our figures are conservative.

Of the 26,114 items (excluding DAAs), 15,572 (59.6%) were matched with PBS data and coded as a PBS item. Of the remaining 10,542 unmatched items, the majority (39.9%) were classified as 'International', 'Unscheduled', 'Unknown schedule' or 'Complementary' (and/or alternative) medicines; 36.2% were Schedule 4 and Schedule 8 items; 6.4% were Schedule 3 and 17.5% were Schedule 2 items.

There were eight bins that contained veterinary medicines (n=81 items). These items were not included in the summary of bin contents in Table 3.3; however, Appendix 3 provides detailed information.

Table 3.3: Summary of RUM bin contents (n=423 bins)

| Item category | Number of items*^ | Proportion of total items (%) |
|--|-------------------|-------------------------------|
| Prescription only medicines (Schedule 4) | 16,632 | 54.6 |
| Pharmacist only medicines (Schedule 3) | 1,337 | 4.4 |
| Pharmacy only medicines (Schedule 2) | 2,892 | 9.5 |
| Controlled medicines (Schedule 8) | 413 | 1.4 |
| Complementary listed medicines (Aust L) | 1,194 | 3.9 |
| Unscheduled medicines | 3,361 | 11.0 |
| International medicines | 188 | 0.6 |
| Unknown schedule medicines | 97 | 0.3 |
| Dose Administration Aids | 4,308 | 14.2 |
| TOTAL | 30,422 | 100 |

RUM = Return of Unwanted Medicines;

* A count of '1' was given to any observation at data entry where a pack was broken. The count of loose or partial packs may therefore have exceeded '1' pack, but this is reported separately in results, e.g. paracetamol 500mg tablets, 100 pack size where a record of 120 tablets were recorded in one observation would receive a count of '1'. Five unopened packs would receive a count of '5';

^ Empty items i.e. packaging without product were excluded.

Labelling

Dispensing labels were found on 7,220 of the 26,114 items (27.6%). In terms of dispensing category, the highest proportion was 'Concession' (44.4%), followed by 'Private' (18.2%), 'Safety-Net' (16.1%), 'General' (5.9%), 'Hospital' (3.2%) and Doctors Bag (1.0%). The dispensing category was unclear or unknown in 11.2% of items.

In terms of the year dispensed, the highest proportion was for 2016 (37.9%), followed by 2015 (27.3%), 2014 (12.9%), 2013 (8.3%), 2012 (4.1%) and 2011 (2.2%). Labels from 2010 or earlier accounted for 4.7% and the year dispensed was unclear for 2.7% of dispensing labels.

The 2013 RUM audit reported that a dispensing label was attached to the packaging on 50.3% of all discarded medicines (11), which is considerably higher than the 27.6% identified in this 2016 audit. However, in contrast to our audit method of recording and counting all loose strips of medicines contained in the bins, the 2013 audit excluded medicines that were not packaged in either the original packaging or the pharmacy dispensed pack (i.e. all loose strips of medicines were excluded except for Schedule 8 medicines).

Expired medicines

A total of 9,381 of the 26,114 items (35.9%) were expired as of 30th June 2016. This expiry date was used in the research as it was the beginning of the audit data collection and bins had been collected from pharmacies and delivered to the incineration sites for destruction by this date. The expiry date could not be determined for 1,133 of the 26,114 items (4.3%). The proportion of expired items decreased with earlier 'cut-off' dates: 6,045 of the 26,114 items (23.1%) were expired as of 30th June 2015; 3,436 of the 26,114 items (13.1%) were expired as of 30th June 2014; and 428 of the 26,114 (1.6%) items were expired as of the 30th June 2006.

The proportion of expired items which are reported for each medicine appearing in the highest frequency tables (Tables 3.4 – 3.10), used a cut-off date of 30th June 2016.

Just over half of the medicines (51.4%) were reported to be expired in the 2013 audit (11), which is higher than the 35.9% identified in this 2016 audit. However, a similar proportion of items did not have an expiry date that could be determined (4.8% 2013: 4.3% 2016). As previously explained, this could be due to our inclusion of all loose strips of medicines, however the reasons why medicines were disposed of (i.e. expired, used or unused but no longer needed) was beyond the scope of this stage of the research.

Dose administration aids (DAAs)

A total of 4,308 DAAs were identified in three packaging systems: 2,528 blister/bubble packs (e.g. MedicoPak, Webster-Pak®); 1,733 sachet systems (e.g. APHS medication sachets, MPS packettes); and 47 compartmentalised plastic boxes (e.g. Dosette®).

Overall 39.7% of DAAs were considered full (76-100% remaining), 22.1% were considered partly full (26-75% remaining), and 38.2% were considered empty (0-25% remaining). Appendix 7 provides details of how data collectors assessed remaining bin contents.

Inappropriate items

Liquid cytotoxic agents, Schedule 8 items (without evidence of destruction in some states and without exception in others states) and sharps are all classified under the RUM scheme as 'inappropriate'; that is, they should not be disposed of in RUM bins (25).

Liquid cytotoxic agents

No liquid cytotoxic agents were identified in the bin audit. Appendix 4 lists all the cytotoxic medicines that were found (n=50 items in 49 bins).

Schedule 8 medicines

A total of 413 Schedule 8 items were identified from the total of 26,114 items (1.6%). This did not include any Schedule 8 medicines that may have been present in DAAs or any empty packaging disposed in the bins. The items containing Schedule 8 medicines were located in 114 of the 423 audited bins (27.0%). Most of the Schedule 8 medicine items were opened or partly used; 40.9% (n=169/413) were unopened packs.

More than 40% of all the Schedule 8 medicines had expired as at 30th June 2016 (n=185/413; 44.8%) irrespective of whether they were opened or unopened. Appendix 5 provides more detail about Schedule 8 items.

Sharps

There were 46 bins (10.8%) that contained sharps items (any used or unused needles, syringes, lancets and blades). These items also included 12 plastic containers specifically designed for sharps waste that had been disposed in RUM bins. Appendix 6 provides detailed information.

This finding is consistent with the 2013 audit where 12.1% of bins were reported to contain sharps. Of note, the 2013 audit did not include prefilled capped syringes (such as vaccines, insulin) in the sharps count, which suggests that less sharps items overall were disposed of in bins audited in 2016.

General waste

Seven bins were excluded from the audit process because they contained 50% of waste other than medicine items i.e. rubbish (Table 3.2). We also recorded the existence of small amounts of general rubbish in the RUM bins, such as patient medication records, plastic cannulas, hair treatments, baby formula, band aids, food, plastic bags etc.

Highest frequency items

Results of the most frequently reported items are presented in a number of ways including: by medicinal product term (Table 3.4); by medicinal product pack term (Table 3.5); combination products (Table 3.6); and sample packs (Table 3.7).

All of the highest frequency items were scheduled medicines; the majority were Schedule 4 items that appear on the PBS.

Table 3.4: Top 20 items by medicinal product term

| Rank | Medicine | Total* | Unopened (%) | Loose tabs/caps [^] | Expired [#] (%) | PBS price/pack [†] |
|------|-----------------------|--------|--------------|------------------------------|--------------------------|-----------------------------|
| 1 | Paracetamol | 705 | 30.5 | 12,558 | 54.6 | \$ 2.50 |
| 2 | Salbutamol | 415 | 54.9 | Nil | 62.7 | \$ 3.46 |
| 3 | Aspirin | 322 | 43.2 | 8,454 | 59.6 | \$ 1.69 |
| 4 | Glyceryl trinitrate | 261 | 52.1 | 757 | 69.0 | \$ 12.10 |
| 5 | Metoclopramide | 251 | 39.4 | 1,641 | 46.6 | \$ 3.00 |
| 6 | Paracetamol + codeine | 249 | 28.1 | 1,783 | 56.6 | \$ 0.93 |
| 7 | Cephalexin | 207 | 18.4 | 1,523 | 46.9 | \$ 1.45 |
| 8 | Doxycycline | 195 | 30.3 | 1,896 | 68.2 | \$ 2.20 |
| 9 | Frusemide | 195 | 21.5 | 6,979 | 22.6 | \$ 1.32 |
| 10 | Simvastatin | 191 | 75.4 | 735 | 80.6 | \$ 2.79 |
| 11 | Ibuprofen | 190 | 34.2 | 1,528 | 70.5 | \$ 2.13 |
| 12 | Atorvastatin | 188 | 30.3 | 1,911 | 41.0 | \$ 3.06 |
| 13 | Pantoprazole | 175 | 20.6 | 1,518 | 27.4 | \$ 3.59 |
| 14 | Warfarin | 169 | 42.6 | 2,499 | 36.7 | \$ 5.08 |
| 15 | Perindopril | 169 | 46.2 | 1,377 | 15.4 | \$ 2.94 |
| 16 | Tramadol | 169 | 28.4 | 1,205 | 43.2 | \$ 2.30 |
| 17 | Diclofenac | 160 | 31.3 | 2,033 | 83.8 | \$ 3.30 |
| 18 | Oxycodone | 158 | 37.3 | 1,044 | 54.4 | \$ 5.42 |
| 19 | Metformin | 156 | 21.2 | 5,036 | 37.2 | \$ 3.38 |
| 20 | Prochlorperazine | 155 | 31.0 | 1,325 | 67.1 | \$ 1.65 |

caps = capsules; PBS = Pharmaceutical Benefits Scheme; tabs = tablets

** Items plus multiple packs (each item of an unopened medicine is counted as '1', items containing multiple unopened packs are counted as the number of packs).*

[^] Loose tabs/caps included strips of tablets and/or capsules that no longer had an original package or tablets or capsules that were loose in a dispensed labelled bottle or original bottle.

[#] Expired as of 30/06/2016.

[†] Weighted average Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack across included items, Oct 2016.

Table 3.5: Top 20 items by medicinal product pack term

| Rank | Medicine pack | Total* | Unopened (%) | Loose tabs/caps^ | Expired# (%) | PBS price† |
|------|---|--------|--------------|------------------|--------------|------------|
| 1 | Paracetamol 500 mg tablet, 100 | 261 | 23.0 | 6,385 | 55.6 | \$ 1.53 |
| 2 | Salbutamol 100 microgram/actuation pressurised inhalation, 200 actuations | 241 | 55.2 | Nil | 69.3 | \$ 2.99 |
| 3 | Paracetamol 665 mg modified release tablet, 96 | 230 | 34.3 | 5,154 | 40.4 | \$ 3.47 |
| 4 | Glyceryl trinitrate 400 microgram/actuation oral spray, 200 actuations | 168 | 50.0 | Nil | 76.8 | \$ 11.09 |
| 5 | Cephalexin 500 mg capsule, 20 | 167 | 13.8 | 1,337 | 47.9 | \$ 1.49 |
| 6 | Aspirin 100 mg tablet, 112 | 153 | 12.4 | 6,523 | 32.7 | \$ 1.17 |
| 7 | Oseltamivir 75 mg capsule, 10 | 138 | 98.6 | 17 | 100 | NA |
| 8 | Insulin glargine 100 units/mL injection, 5 x 3 mL cartridges | 119 | 63.9 | Nil | 23.5 | \$ 72.15 |
| 9 | Pantoprazole 40 mg enteric tablet, 30 | 117 | 18.8 | 1,185 | 20.5 | \$ 2.83 |
| 10 | Fruzemide 40 mg tablet, 100 | 116 | 18.8 | 4,711 | 11.2 | \$ 1.14 |
| 11 | Simvastatin 80 mg tablet, 30 | 116 | 97.4 | 40 | 99.1 | \$ 4.27 |
| 12 | Oxycodone hydrochloride 5 mg tablet, 20 | 113 | 37.2 | 693 | 57.5 | \$ 2.16 |
| 13 | Paracetamol 500 mg + codeine phosphate 30 mg tablet, 20 | 112 | 25.0 | 792 | 71.4 | \$ 0.76 |
| 14 | Metoclopramide hydrochloride 10 mg tablet, 25 | 112 | 42.0 | 986 | 49.1 | \$ 1.07 |
| 15 | Prochlorperazine maleate 5 mg tablet, 25 | 110 | 25.5 | 1,161 | 74.5 | \$ 1.03 |
| 16 | Metoprolol tartrate 50 mg tablet, 100 | 101 | 19.8 | 3,428 | 32.7 | \$ 3.32 |
| 17 | Aspirin 100 mg enteric tablet, 28 | 99 | 93.9 | 109 | 97.0 | NA |
| 18 | Temazepam 10 mg tablet, 25 | 96 | 24.0 | 970 | 61.5 | \$ 0.78 |
| 19 | Amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 | 94 | 27.7 | 358 | 43.6 | \$ 2.64 |
| 20 | Metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules | 91 | 38.5 | Nil | 42.9 | \$ 5.31 |

caps = capsules; NA= PBS price not available; PBS = Pharmaceutical Benefits Scheme; tabs = tablets;

** Items plus multiple packs (each item of an unopened medicine is counted as '1', items containing multiple unopened packs are counted as the number of packs).*

^ Loose tabs/caps included strips of tablets and/or capsules that no longer had an original package or tablets or capsules that were loose in a dispensed labelled bottle or original bottle.

Expired as of 30/06/2016.

† Weighted average Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack across included items, Oct 2016.

Table 3.6: Top 20 combination items by medicinal product terms

| Rank | Combination medicine | Total* | Unopened (%) | Loose tabs/caps^ | Expired* (%) | PBS price † |
|------|--|--------|--------------|------------------|--------------|-------------|
| 1 | Paracetamol + codeine | 249 | 28.1 | 1783 | 56.6 | \$ 0.93 |
| 2 | Amoxycillin + clavulanic acid | 141 | 34.0 | 440 | 42.6 | \$ 3.09 |
| 3 | Olmesartan + amlodipine | 136 | 89.7 | 208 | 94.1 | \$ 17.52 |
| 4 | Macrogol-3350 + sodium chloride + bicarbonate + potassium chloride | 109 | 32.1 | Nil | 32.1 | \$ 7.04 |
| 5 | Budesonide + eformoterol | 106 | 67.0 | Nil | 61.3 | \$ 36.22 |
| 6 | Paracetamol + codeine + phenylephrine + chlorpheniramine | 99 | 48.5 | 475 | 91.9 | NA |
| 7 | Levonorgestrel + ethinylloestradiol | 93 | 80.6 | 923 | 77.4 | \$ 7.41 |
| 8 | Docusate + sennoside | 82 | 19.5 | 2780 | 53.7 | \$ 5.43 |
| 9 | Fluticasone + salmeterol | 79 | 35.4 | Nil | 43.0 | \$ 50.84 |
| 10 | Olmesartan + amlodipine + hydrochlorothiazide | 68 | 89.7 | 127 | 95.6 | \$ 14.05 |
| 11 | Polyethylene glycol-400 + propylene glycol | 64 | 37.5 | Nil | 31.3 | \$ 3.45 |
| 12 | Paracetamol + codeine + phenylephrine | 61 | 83.6 | 85 | 96.7 | NA |
| 13 | Sitagliptin + metformin | 54 | 83.3 | 265 | 79.6 | \$ 44.08 |
| 14 | Fluticasone + vilanterol | 53 | 98.1 | Nil | 92.5 | NA |
| 15 | Insulin aspart + insulin aspart protamine | 51 | 64.7 | Nil | 23.5 | \$ 42.38 |
| 16 | Triamcinolone + neomycin + gramicidin + nystatin | 42 | 66.7 | Nil | 57.1 | \$ 1.50 |
| 17 | Trimethoprim + sulfamethoxazole | 42 | 45.2 | 119 | 21.4 | \$ 2.55 |
| 18 | Aluminium hydroxide dried + magnesium hydroxide + simethicone | 42 | 33.3 | 179 | 83.3 | \$ 16.37 |
| 19 | Amlodipine + atorvastatin | 40 | 75.0 | 146 | 65.0 | \$ 4.23 |
| 20 | Dextran-70 + hypromellose | 40 | 50.0 | Nil | 12.5 | \$ 6.71 |

caps = capsules; NA= PBS price not available; PBS = Pharmaceutical Benefits Scheme; tabs = tablets;

** Items plus multiple packs (each item of an unopened medicine is counted as '1', items containing multiple unopened packs are counted as the number of packs).*

^ Loose tabs/caps included strips of tablets and/or capsules that no longer had an original package or tablets or capsules that were loose in a dispensed labelled bottle or original bottle.

Expired as of 30/06/2016.

† Weighted average Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack across included items, Oct 2016.

Table 3.7: Top 20 sample pack items by medicinal product term

| Rank | Sample product | Total* | Unopened (%) | Loose tabs/caps^ | Expired* (%) |
|------|---|--------|--------------|------------------|--------------|
| 1 | Olmesartan + amlodipine | 43 | 97.7 | 10 | 88.4 |
| 2 | Nomegestrol + oestradiol | 28 | 100.0 | Nil | 100.0 |
| 3 | Sitagliptin + metformin | 22 | 95.5 | 28 | 81.8 |
| 4 | Olmesartan + amlodipine + hydrochlorothiazide | 19 | 100.0 | Nil | 100.0 |
| 5 | Fluticasone + vilanterol | 19 | 100.0 | Nil | 100.0 |
| 6 | Amlodipine + valsartan | 16 | 100.0 | Nil | 100.0 |
| 7 | Ezetimibe + simvastatin | 16 | 100.0 | Nil | 100.0 |
| 8 | Vildagliptin + metformin hydrochloride | 16 | 93.8 | 8 | 93.8 |
| 9 | Sitagliptin | 14 | 92.9 | 7 | 92.9 |
| 10 | Solifenacin | 12 | 91.7 | 9 | 58.3 |
| 11 | Apixaban | 11 | 100.0 | Nil | 100.0 |
| 12 | Levonorgestrel + ethinyloestradiol | 11 | 100.0 | Nil | 100.0 |
| 13 | Dapagliflozin | 11 | 90.9 | 14 | 100.0 |
| 14 | Olanzapine | 10 | 90.0 | 7 | 100.0 |
| 15 | Celecoxib | 9 | 66.7 | 21 | 100.0 |
| 16 | Telmisartan + amlodipine | 9 | 100.0 | Nil | 100.0 |
| 17 | Empagliflozin | 9 | 88.9 | 10 | Nil |
| 18 | Desvenlafaxine | 9 | 100.0 | Nil | 66.7 |
| 19 | Indacaterol | 8 | 100.0 | Nil | 100.0 |
| 20 | Indacaterol + glycopyrronium | 8 | 100.0 | Nil | 100.0 |

caps = capsules; tabs = tablets

** Items plus multiple packs (each item of an unopened medicine is counted as '1', items containing multiple unopened packs are counted as the number of packs).*

^ Loose tabs/caps included strips of tablets and/or capsules that no longer had an original package or tablets or capsules that were loose in a dispensed labelled bottle or original bottle.

Expired as of 30/06/2016.

Comparison with PBS data

For comparison, the top 20 PBS medicines found in the 2016 bin audit are listed in Table 3.8 alongside the top 20 PBS medicines (2015) by prescription counts (27). There are similarities across the 2015-2016 lists, with ten items appearing in both (bolded in Table 3.8), although the absolute rank did not match. A comparison of the results from the 2013 NatRUM audit with 2012 PBS data is presented in Appendix 7 (11). In 2012-2013 only six items were common to both groups.

Table 3.8: Top 20 PBS medicines in 2016 audit compared with 2015 PBS data

| Rank* | 2016 NatRUM audit | 2015 top 20 medicines by PBS/RPBS prescription counts (27) |
|-------|--------------------------------------|--|
| 1 | Paracetamol | Atorvastatin |
| 2 | Salbutamol | Rosuvastatin |
| 3 | Glyceryl trinitrate | Esomeprazole |
| 4 | Cephalexin | Paracetamol |
| 5 | Metoclopramide | Pantoprazole |
| 6 | Doxycycline | Perindopril |
| 7 | Frusemide | Amoxycillin |
| 8 | Simvastatin | Cephalexin |
| 9 | Atorvastatin | Metformin |
| 10 | Aspirin | Amoxycillin + clavulanic acid |
| 11 | Warfarin | Irbesartan |
| 12 | Tramadol | Paracetamol + codeine |
| 13 | Oxycodone | Salbutamol |
| 14 | Pregabalin | Atenolol |
| 15 | Pantoprazole | Sertraline |
| 16 | Amoxycillin | Oxycodone |
| 17 | Metformin | Simvastatin |
| 18 | Prednisolone | Escitalopram |
| 19 | Valproate | Ramipril |
| 20 | Amoxycillin + clavulanic acid | Telmisartan |

NatRUM= National Return and Disposal of Unwanted Medicines; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

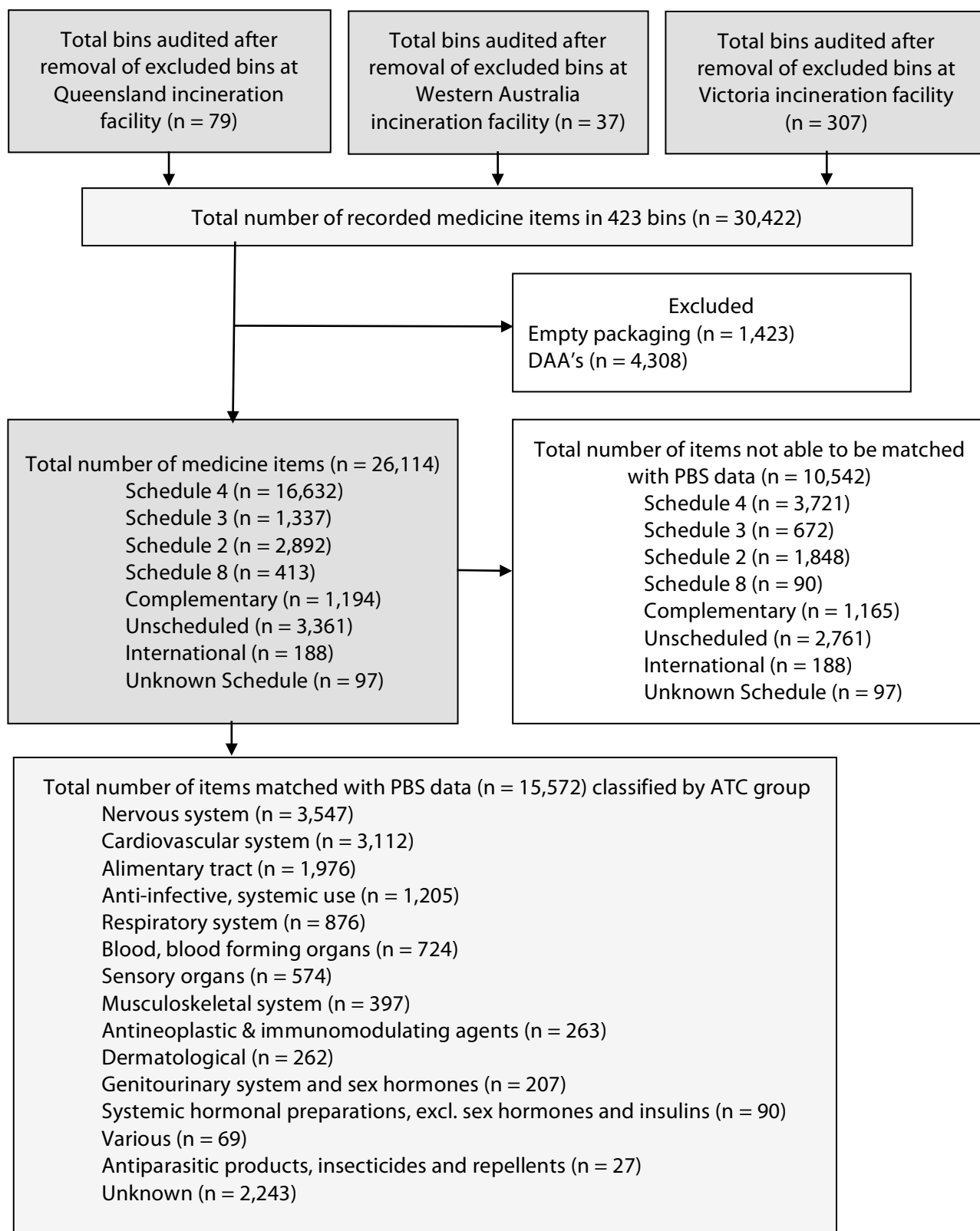
* Item 1 is the most common.

NOTE: items occurring in both lists are **bolded**.

A summary of the PBS items by ATC classification can be found in Appendix 8. The most commonly returned medicines, by therapeutic class, were those used for the nervous system (22.8%), cardiovascular system (20.0%), and alimentary tract and metabolism (12.7%). Our findings correlate with the 2013 audit (11) and the 2005 Victorian study (6), which both identified similar proportions of these top three therapeutic classes, however the order in both studies was different to ours: cardiovascular system was most common, followed by nervous system and alimentary tract and metabolism.

Figure 3.1 presents an overview of the PBS items identified during the bin audit.

Figure 3.1: Overview of PBS items identified in RUM bins audited



RUM = Return of Unwanted Medicines; DAA = Dose Administration Aid; ATC = Anatomical Therapeutic Chemical; PBS = Pharmaceutical Benefits Scheme.

PBS waste

We used a strict definition of 'PBS waste' items being those that are listed on the PBS, were unopened, had a dispensing label determining a PBS category of 'general', 'concession', or 'safety-net', and were not a sample pack. The top 20 items by price are listed by medicinal product term (Table 3.9) and medicinal product pack term (Table 3.10). Note that we did not consider expiry date in this analysis as it could not be determined if products were expired when they were disposed of rather than audited, but we test this assumption below (Table 3.11).

Table 3.9: Top 20 PBS 'waste' items, by price (medicinal product terms)*

| Rank | Medicine | Total | Cost to PBS# | Expired^ (%) |
|------|---|-------|--------------|--------------|
| 1 | Levodopa + carbidopa anhydrous | 3 | \$2,914.28 | 66.7 |
| 2 | Insulin glargine | 40 | \$2,886.00 | 22.5 |
| 3 | Abacavir + lamivudine + zidovudine | 2 | \$1,226.90 | 100 |
| 4 | Adrenaline | 17 | \$1,221.23 | 94.1 |
| 5 | Enoxaparin sodium | 22 | \$1,182.08 | 18.2 |
| 6 | Insulin aspart | 27 | \$1,144.26 | 59.3 |
| 7 | Follitropin alfa | 3 | \$ 982.44 | Nil |
| 8 | Human menopausal gonadotrophin | 2 | \$ 796.77 | Nil |
| 9 | Etanercept | 1 | \$ 774.25 | 100 |
| 10 | Follitropin beta | 5 | \$ 712.50 | Nil |
| 11 | Tiotropium | 13 | \$ 584.35 | 30.8 |
| 12 | Pregabalin | 17 | \$ 577.64 | 17.6 |
| 13 | Insulin aspart + insulin aspart protamine | 12 | \$ 508.56 | 25.0 |
| 14 | Budesonide + eformoterol | 13 | \$ 480.82 | 46.2 |
| 15 | Fluticasone + salmeterol | 9 | \$ 457.56 | 22.2 |
| 16 | Zoledronic acid | 1 | \$ 437.77 | Nil |
| 17 | Glyceryl trinitrate | 31 | \$ 359.90 | 58.1 |
| 18 | Risperidone | 9 | \$ 325.78 | 77.8 |
| 19 | Risedronate | 8 | \$ 314.48 | 87.5 |
| 20 | Insulin glulisine | 7 | \$ 296.66 | Nil |

PBS = Pharmaceutical Benefits Scheme

* For an item to be included as PBS 'waste' it was required to be unopened, be listed on the PBS, have been dispensed as General, Concession or Safety-Net, not be a sample pack and not be packaging only.

^ Expired as of 30/06/2016.

#Total cost using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack, Oct 2016 (i.e. number of packs multiplied by cost per pack).

Table 3.10: Top 20 PBS 'waste' items, by price (medicinal product pack term)*

| Rank | Medicine pack | Total | PBS price/pack# | Expired [^] (%) |
|------|--|-------|-----------------|--------------------------|
| 1 | Insulin glargine 100 units/mL injection, 5 x 3 mL cartridges | 40 | \$2,886.00 | 22.5 |
| 2 | Levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL | 2 | \$2,884.00 | 100 |
| 3 | Abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60 | 2 | \$1,226.90 | 100 |
| 4 | Adrenaline 300 microgram/0.3 mL injection, 1 dose | 15 | \$1,199.85 | 93.3 |
| 5 | Insulin aspart 100 units/mL injection, 5 x 3 mL cartridges | 27 | \$1,144.26 | 59.3 |
| 6 | Follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge | 3 | \$ 982.44 | Nil |
| 7 | Etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack | 1 | \$ 774.25 | 100 |
| 8 | Follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge | 5 | \$ 712.50 | Nil |
| 9 | Tiotropium 18 microgram powder for inhalation, 30 capsules | 12 | \$ 539.40 | 33.3 |
| 10 | Human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack | 1 | \$ 531.18 | Nil |
| 11 | Insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes | 12 | \$ 508.56 | 25.0 |
| 12 | Zoledronic acid 5 mg/100 mL injection, 100 mL vial | 1 | \$ 437.77 | Nil |
| 13 | Enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes | 6 | \$ 353.04 | Nil |
| 14 | Pregabalin 75 mg capsule, 56 | 10 | \$ 352.00 | 30.0 |
| 15 | Enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes | 5 | \$ 338.50 | Nil |
| 16 | Enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes | 8 | \$ 329.12 | 50.0 |
| 17 | Risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack | 2 | \$ 306.00 | 100 |
| 18 | Insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges | 7 | \$ 296.66 | Nil |
| 19 | Glycopyrronium 50 microgram powder for inhalation, 30 capsules | 6 | \$ 283.92 | 100 |
| 20 | Insulin detemir 100 units/mL injection, 5 x 3 mL cartridges | 4 | \$ 273.80 | 100 |

PBS = Pharmaceutical Benefits Scheme

* For an item to be included as PBS 'waste' it was required to be unopened, be listed on the PBS, have been dispensed as General, Concession or Safety-Net, not be a sample pack and not be packaging only.

[^] Expired as of 30/06/2016.

#Total cost using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack, Oct 2016 (i.e. number of packs multiplied by cost per pack).

Waste cost using different assumptions

To estimate the total 'PBS waste' per year for Australia we first estimated the total price for our sample using different assumptions (Table 3.11). October 2016 PBS prices (using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack) were used for all PBS matched items in the sample (60% of the 26,114 items). We then determined that our sample represented approximately 0.26% of the total RUM waste for the country (423 audited bins/160,845 bins collected nationally = 0.26%)¹. Sample prices were estimated using different assumptions and then extrapolated across the country. Using the most restricted definition of waste, the total for Australia per year is \$6,326,538 increasing to \$26,960,385 per year for the least restrictive definition. This calculation assumes that the sample audited was sufficiently representative of the yearly RUM collection to be generalisable to yearly totals.

Table 3.11: Cost of PBS waste using different assumptions

| Assumption | Number of packs included | Total price for sample*# | Extrapolated Total AUD (2016) |
|---|--------------------------|--------------------------|-------------------------------|
| Dispensed, unopened, not expired | 970 | \$16,449 | \$6,326,538 |
| Dispensed, unopened, expired & not expired | 1,572 | \$30,236 | \$11,629,231 |
| Dispensed, opened & unopened, & not expired | 2,949 | \$44,141 | \$16,977,308 |
| Dispensed, opened & unopened, expired & not expired | 4,384 | \$70,097 | \$26,960,385 |

AUD = Australian dollar; PBS = Pharmaceutical Benefits Scheme; RUM = Return of Unwanted Medicine;

* The estimated sample proportion used was 0.26%, based on 423 RUM bins audited from the total 160,845 number of RUM bins collected nationally for incineration from July 2015 to June 2016. An alternative is to use 0.31% based on a total weight of 2,189 kg of RUM bins audited from the total of 705,079kg collected nationally for incineration from July 2015 to June 2016. Use of the later proportion results in lower estimates of PBS waste.

#Total cost using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack, Oct 2016 (i.e. number of packs multiplied by cost per pack).

The 2013 RUM audit also estimated 'PBS waste' for one year using slightly different methodology, taking the ten most frequently recorded medicines within each ATC classification (a total of 31 medicines) and extrapolating use for 12 months. Here, we included all items in the database matched with a PBS record which met our inclusion criteria (various assumptions detailed in Table 3.11). Instead of applying a standard proportion of audited waste to extrapolate national yearly usage from audit results as we have done here, proportions in 2013 were calculated for each included medicine compared to yearly PBS dispensing statistics for that item. Further, it must be noted that the 2013 audit assumed that all items were defined as "a full pack of the item". Therefore, an important difference between the 2013 and 2016 estimates of 'waste' is that data were not collected for loose blister/foil strips and post-audit analyses could not distinguish between full and partially full packs (it was assumed that all packs were full). Also, in 2013 a medicine was considered dispensed if it was a 'prescription only' medicine (excluding sample packs) and/or contained a dispensing label. In 2016, we only considered medicines to be dispensed if they had a dispensing label attached.

Due to these methodological differences, we have made a direct comparison with the 2013 'PBS waste' estimate with caution. The 2013 audit estimated AUD (2012) \$2.055 million in 'PBS waste' for the top 10 medicines in each of five ATC classes (31 items in total). We believe the most comparable figure from Table 3.11

¹ Using the total weight of bins this proportion is slightly higher (2,189 kg audited/705,079 kg collected nationally = 0.31%).

to the methodology used in 2013 is that for the assumptions of 'dispensed, unopened, not expired' packs, which results in a waste estimate of AUD (2016) \$6,326,538. We believe our higher estimate to be mostly due to the inclusion of all eligible PBS items in the database rather than the 31 most frequently discarded medicines only.

Our preferred definition of 'PBS waste' is all 'dispensed and unopened items (irrespective of expiry date)', which results in an estimate of \$11,629,231. As it is unknown if items audited in RUM bins were expired at the time of disposal, we think this definition is more appropriate than classifying items as expired at an arbitrary point in time. We also define an item as 'waste' only if it is unopened. If a medicine had been opened and at least one dose taken, then the medicine may have been discontinued for valid reasons such as adverse events or poor efficacy. Unless a major change to the maximum quantities dispensed is considered, it is difficult to think how to avoid generating fewer unwanted products in such circumstances.

Whilst the estimates presented in Table 3.11 above are significantly higher than the single 'waste' estimate from the 2013 audit, we believe this can be explained by methodological differences. As such, the 2013 audit figure of AUD (2012) \$2.055 million represents a plausible estimate of a restricted sample (31 PBS listed medicines) which is best compared to our AUD (2016) \$6.326 million estimate for 'dispensed, unopened and not expired' items using the whole sample. By varying the definition of 'waste' in Table 3.11, we show that the extrapolated figures are sensitive to the definition used and are significantly higher when less restrictive definitions of waste are applied.

Further, it must be noted that previous evidence suggests that only a proportion of unwanted medicines are discarded in RUM bins and that other means of disposal are more common, such as disposal in the household rubbish or sewerage system. This is explored further in Stage Two.

Another important limitation is that consumer co-payments have not been considered in this analysis, which would offset the true cost to the PBS and lower the estimate of 'waste'.

Summary

Key findings for Stage One

- Although inappropriate items were found in the bins (including sharps, Schedule 8s, and rubbish), as a proportion of the total waste these items were infrequent;
- The top 20 most frequently reported items in RUM bins using medicinal product terms are relatively low cost items;
- This is true also for the top 20 most frequently reported items using medicinal product pack terms, with the exception of insulin glargine;
- Comparing the top 20 PBS items by frequency found in the RUM bins with the PBS statistics on dispensed medicines (2015), there is considerable overlap with ten medicines appearing in both lists. This is a similar finding to the 2013 audit and suggests that the content of the RUM bins broadly reflects the most commonly dispensed PBS items in Australia. It also suggests that PBS listed medicines, rather than non-PBS (e.g. over-the-counter, complementary, alternative and/or unscheduled products), comprise a larger proportion of bin contents;
- Large volumes of high-cost PBS-listed items were not found. In terms of 'PBS waste', using our strict definition, products containing levodopa + carbidopa provides the biggest contribution to the overall estimate using medicinal product terms. Insulin glargine was the next biggest contributor and the highest contributor using medicinal product pack terms;
- Depending on the definition of 'PBS waste' used, the estimate for Australia for one year ranges from \$6,326,538 to \$26,960,385 (using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack, Oct 2016). When we use our preferred definition of 'PBS waste' that is, 'dispensed and unopened (irrespective of expiry date)', the estimate is \$11,629,231. This figure is higher than the previous estimate from the 2013 RUM audit of AUD (2012) \$2.055 million AUD, which was based on a restricted sample of 31 medicines from the audit. We argue that if a pack has been opened and at least one dose used then it is too strong an assumption to classify that item as 'waste' given there are a range of reasons why that medicine may have been discontinued;
- It is important to remember that using RUM bins to dispose of unwanted medicines is only one method used by people; these audit results cannot be assumed to be representative of the totality of methods used to dispose of medicines in Australia. This important issue is explored in Stage Two.

Insights for the National Return and Disposal of Unwanted Medicines Limited and the Department of Health

- The existence of inappropriate items in RUM bins, although comprising a small proportion of total contents, highlights the need for ongoing education for pharmacists and pharmacy staff;
- The contents of the RUM bins, in terms of the highest frequency items, suggest that results are broadly reflective of comparable PBS dispensing statistics, a similar finding to the first (2013) audit. For this reason, more frequent and targeted audit activities for the RUM project may be justified given the expense and complexity of a full national audit;
- Large volumes of high-cost PBS-listed items were not found, giving some reassurance that costly, subsidised medicines are not readily discarded by consumers using RUM bins. This finding does not exclude the possibility that such items are disposed of by less appropriate means or are being kept at home.

4 Stage Two:

General population audit

The second stage of the research involved a two-step general population audit to identify i) general population awareness of the NatRUM Program, and ii) behaviours surrounding the disposal (or retention) of unwanted medicines among people with a high medication burden. The specific objectives of this stage were to:

- a) audit awareness amongst the general population of appropriate practices for disposal of unwanted medicines; and
- b) collect data on the quantity of unwanted medicines and storage and disposal practices in the households of a subset of the general population who experience higher medication burden.

4.1 General population survey

The General Population survey was a 10-minute online questionnaire that explored awareness of the NatRUM program and aimed to identify what, if anything, people currently do with their unwanted medicines. The population surveyed was a representative sample of the Australian population, aged over 18 years.

Method

Participants

The 2016 General Population survey was conducted with an existing panel of adult individuals who represented the Australian adult population. An experienced panel data company (Research Now®) was contracted to undertake the data collection.

The most recent ABS Waste Management, Transport, and Motor Vehicle Usage Survey was conducted in March 2012 and included data from 12,870 households. (10) This survey, administered as part of the regular monthly Labour Force Survey, estimated the proportion of households who had disposed of 'medicines, drugs or ointments' in the previous 12 months and the main method of disposal, using a multi-stage area sampling method (10). A sample size of 4300 was proposed for the 2016 General Population survey to enable comparison with ABS Waste Management, Transport, and Motor Vehicle Usage Survey.

Table 4.1 provides the population distributions required to achieve a national representative sample of 4300 (based on gender, age and geographical location from the 2011 census data (28)).

Development of the general population survey

The 2016 survey was developed by referencing the 2012 ABS Survey which included household waste questions, the 2014-2015 ABS National Health Survey and other relevant literature, and through input from Advisory Panel members (6, 10, 19, 29).

The wording and response options for each question were assessed by the researchers for applicability, need and whether the response would provide valuable and necessary outcome information. Questions that were taken from the 2012 ABS Waste Management Survey were included in our survey with minimal changes to allow for the accurate comparison of results (10). The General Population survey was piloted (in hardcopy) with seven people from the general population and two Advisory Panel members; this resulted in minor amendments to the wording and question order.

The final survey (Appendix 10) included questions relating to whether people currently had any unwanted (used, unused or expired) medicines in their homes, the type of medicines retained (i.e. prescription, over-the-

counter, complementary and/or alternative) and whether they had previously disposed of such medicines. If participants had disposed of unwanted medicines, they were asked how they had disposed of them and why. Knowledge of the NatRUM scheme was explored and information regarding the national scheme was provided to those who were unaware of the program. Respondents were then asked to rank six statements in order of importance relating to concerns regarding safety of medicines disposal and to rank eight potential methods of increasing public awareness of safe medicine disposal in order of effectiveness. Respondents were also asked to self-identify as healthcare workers. This population was asked additional questions related to if, and how, they promoted the safe disposal of unwanted medicines to their patients. Respondents were then asked some general demographic questions.

In addition, and to build on evidence collected in the 2005 Victorian study (6), a sub-sample of respondents who took five or more medications (including complementary, alternative and/or over-the-counter medicines) were recruited for additional data collection via a telephone interview (Section 4.2).

Once the survey questions were finalised, Research Now® worked to develop a user-friendly interface which could be easily completed on-line, including on mobile devices such as tablets and phones. For questions with more than six multiple-choice response options, the option list was randomised. The online survey was then soft-launched with 48 members of the general population to test the response algorithms. The 2016 General Population Survey commenced on 30th August and was closed on 5th October after 4302 completions (i.e. full complement of respondents). Research Now® provided weekly update reports on the number and distribution of participants. The median time for completing the survey was 6.44 minutes (interquartile range: 4.97 minutes to 8.78 minutes).

Data analysis

A quantitative data analysis was performed on the data obtained from our 2016 General Population Survey using Microsoft Office Excel® 2007 and Stata® v.13. The primary statistical analyses were intended to be descriptive in nature. Therefore responses to 2016 General Population Survey questions were coded and entered into an Excel® database. General descriptive analysis of frequencies was performed, with all survey questions analysed in terms of the total response distributions.

Results

In total, 4,302 Australian adults over the age of 18 years completed the 2016 General Population Survey. Table 4.1 outlines the participant characteristics and provides comparisons with the national population distributions (28).

The national distributions for gender, state/territory and age were met, except for the 18-24 age group, which recruited a slightly lower number of participants (9% of survey sample versus 12% of national population). This was not unexpected given the medication focus of the survey and consequently, the targets for 25-34 age groups were increased. Overall, three-quarters of the survey population were born in Australia, 10% in the UK or NZ and 14% in other countries including China, India, Philippines, Malaysia, Italy and Germany. The majority of participants (94%) spoke English at home. The mean age of the survey population was 46.4 years and more than half had a post-secondary education qualification, were living with their partner, and working full-time or part-time, or were self-employed.

Table 4.1: 2016 General Population Survey participant characteristics

| | Australian representative sample (28) | 2016 General Population Survey sample |
|--------------------------------|---------------------------------------|---------------------------------------|
| | n (%) | n (%) |
| TOTAL (N) | 4,300 | 4,302 |
| Gender | | |
| Female | 2,193 (51.0) | 2,203 (51.2) |
| Male | 2,107 (49.0) | 2,099 (48.8) |
| Age range (years) | | |
| 18-24 | 516 (12.0) | 399 (9.3) |
| 25-34 | 774 (18.0) | 848 (19.7) |
| 35-44 | 817 (19.0) | 826 (19.2) |
| 45-54 | 774 (18.0) | 785 (18.2) |
| 55-64 | 645 (15.0) | 660 (15.3) |
| 65-99 | 774 (18.0) | 784 (18.2) |
| Mean (SD) | NA | 46.4 years (16.2) |
| State or territory | | |
| Australian Capital Territory | 86 (2.0) | 89 (2.1) |
| New South Wales | 1,376 (32.0) | 1,383 (32.1) |
| Northern Territory | 43 (1.0) | 51 (1.2) |
| Queensland | 860 (20.0) | 868 (20.2) |
| South Australia | 301 (7.0) | 306 (7.1) |
| Tasmania | 86 (2.0) | 91 (2.1) |
| Victoria | 1,075 (25.0) | 1,081 (25.1) |
| Western Australia | 430 (10.0) | 433 (10.1) |
| Rural or urban | | |
| Rural | NU | 1,008 (23.4) |
| Urban | NU | 3,294 (76.6) |
| Country of birth | | |
| Australia | NU | 3,264 (75.9) |
| United Kingdom | NU | 296 (6.9) |
| New Zealand | NU | 132 (3.1) |
| Other* | NU | 610 (14.2) |
| Language spoken at home | | |
| English | NU | 4,026 (93.6) |
| Other | NU | 276 (6.4) |
| Living arrangements | | |
| With spouse | NU | 1,745 (40.6) |
| With partner | NU | 615 (14.3) |
| With family members | NU | 1,044 (24.3) |
| In a share house | NU | 201 (4.7) |

| | | |
|---|----|--------------|
| Alone | NU | 683 (15.9) |
| Other | NU | 14 (0.3) |
| Highest educational qualification | | |
| Year 9, 10 or below | NU | 522 (12.1) |
| Year 11 or 12 | NU | 823 (19.1) |
| Cert/diploma/advanced diploma | NU | 1,355 (31.5) |
| Bachelor degree | NU | 1,035 (24.1) |
| Postgraduate (diploma/, Masters, PhD) | NU | 567 (13.2) |
| Employment status | | |
| Retired or pensioner | NU | 980 (22.8) |
| Working part time or casual | NU | 784 (18.2) |
| Working full time | NU | 1,587 (36.9) |
| Unemployed | NU | 348 (8.1) |
| Student | NU | 187 (4.3) |
| Self-employed | NU | 236 (5.5) |
| Other [^] | NU | 180 (4.2) |
| Occupation | | |
| Manager | NU | 574 (12.7) |
| Professional | NU | 1,014 (23.6) |
| Technical or trades | NU | 302 (7.0) |
| Community or personal service | NU | 152 (3.5) |
| Clerical or administrative | NU | 597 (13.9) |
| Sales | NU | 279 (6.5) |
| Machine operator or driver | NU | 103 (2.4) |
| Labourer | NU | 191 (4.4) |
| Homemaker | NU | 572 (13.3) |
| Other [#] | NU | 518 (12.0) |
| Approximate yearly income, household | | |
| \$0 - \$50,000 | NU | 1,147 (26.7) |
| \$50,000 - \$100,000 | NU | 1,292 (30.0) |
| \$100,000 - \$150,000 | NU | 736 (17.1) |
| More than \$150,000 | NU | 486 (11.3) |
| Prefer not to say | NU | NU |

NA = not available; NU = not used in sample target for survey representation; SD = standard deviation

* Other Country of Birth responses were collated into: Asia, n=295; Europe, n=160; North America, n=39; Africa, n=30; Oceania, n=13;

South America, n=12; and Middle East, n=12.

[^] Other Employment status responses included: Homemaker, n=119; Disabled/On disability pension, n=31; Carer, n=18; and Other, n=12.

[#] Other Occupation responses included: Retired, n=184; Not working/Disabled, n=57; Student, n=47; and Other, n=230.

Unwanted medicines at home

Of the 4,302 survey respondents, 60.2% (n=2,592) stated that they currently had unwanted medicines (any used, unused [but no longer needed] or expired medicines) in their home, 31.6% (n=1,358) stated that they had no unwanted medicines at home, and 8.2% (n=352) did not know.

Those who had unwanted medicines in their home were asked further questions about the types of medicines they kept (Table 4.2). The majority of unwanted medicines were *used* medicines (i.e. open packs) irrespective of whether they were prescription, unscheduled, complementary or alternative medicines. Approximately 30% of prescription and unscheduled medicines were unused (but no longer needed) medicines, and up to 40% were expired. Complementary and/or alternative medicines had a similar pattern of response, albeit with more people reporting they did not know the details of these medicines.

A number of respondents (n=150) stated that they had 'other' types of unwanted medicines in the home. Fifteen (10.0%) did not know what type of medicines these were, 52 respondents (34.7%) had misclassified these medicines (i.e. they should have been reported in the prescription, unscheduled or complementary/alternative categories) and 51 (34.0%) stated they did not have any unwanted medicines in the house. Thirty-two (21.3%) gave 'other' answers unrelated to the question; this group included veterinary medicines (n=2), illicit substances (n=2), dandelion tea (n=1) and sample medicines (n=1).

Table 4.2: Types of unwanted medicines people had in their homes* (N=4,302)

| | Respondents with medicines n (%) |
|--|-------------------------------------|
| Prescription medicines | N = 2,469 |
| Used (open pack) | 1,907 (77.2) |
| Unused (unopened pack) | 694 (28.1) |
| Expired | 961 (38.9) |
| Don't know | 118 (4.8) |
| Non-prescription medicines (bought from a pharmacy, supermarket or online) | N = 2,369 |
| Used (open pack) | 1,657 (69.9) |
| Unused (unopened pack) | 712 (30.1) |
| Expired | 803 (33.9) |
| Don't know | 184 (7.8) |
| Complementary or alternative medicines (vitamin, mineral, herbal, aromatherapy or homeopathic products) | N = 2,145 |
| Used (open pack) | 1,213 (56.6) |
| Unused (unopened pack) | 440 (20.5) |
| Expired | 559 (26.1) |
| Don't know | 480 (22.4) |

* Respondents could select more than one answer in each category of medication.

In response to why they had kept these medicines, the primary reason given by respondents was *just in case they needed them again* (n=1,937/2,592; 74.7%). This was followed by *it was a waste of money to dispose of them* (n=823/2,592; 31.8%), *did not know how to dispose of them* (n=468/2,592; 18.1%), and *to give them to family or friends if they needed them* (n=241/2,592; 9.3%). Other reasons reported by 11.4% of respondents included: *forgotten about them/hadn't gotten around to disposing of them*; *planning on returning them to a pharmacy in the future*; *keeping them as a reminder for what had worked in the past*; and *did not believe in expiry dates*.

Of those respondents who had unwanted medicines in the house, 28.0% (n=726/2,592) stated that these included prescription medications that they had stopped taking without discussing with a doctor.

Disposal practices of unwanted medicines

All 2016 respondents (n=4,302) were asked if, and how, their household had disposed of any medicines, drugs or ointments in the previous 12 months. Table 4.3 presents the proportion of households that had disposed of any medicines in the previous 12 months. This is compared with data from the ABS Waste Management, Transport and Motor Vehicle Usage Surveys (2000 to 2012) (10, 12, 30-33).

Table 4.3: Households that have disposed of medicines in previous 12 months

| Year n | General Population Survey n (%) | ABS Waste Management Surveys | | | | |
|------------------------------|--|------------------------------|----------------|-----------------|-----------------|-----------------|
| | 2016 4,302 | 2012 12,870* | 2009 9,362* | % of households | | |
| | | | | 2006 14,603* | 2003 18,500* | 2000 15,500* |
| TOTAL | 2,521 (58.6) | 26.2 | 32.3 | 29.8 | 35.2 | 38.1 |
| Australian Capital Territory | 56 (62.9) | 29.9 | 38.0 | 34.3 | 40.9 | 36.8 |
| New South Wales | 795 (57.5) | 24.9 | 29.5 | 28.2 | 34.6 | 36.7 |
| Northern Territory | 31 (60.8) | 30.6 | 34.2 | 30.7 | 33.6 | 45.1 |
| Queensland | 526 (60.6) | 26.1 | 36.3 | 32.0 | 37.1 | 40.6 |
| South Australia | 168 (54.9) | 26.6 | 34.5 | 28.5 | 33.2 | 33.8 |
| Tasmania | 52 (57.1) | 29.9 | 30.4 | 31.7 | 33.0 | 36.9 |
| Victoria | 633 (58.6) | 27.1 | 31.4 | 28.8 | 34.0 | 40.1 |
| Western Australia | 260 (60.0) | 26.0 | 33.4 | 33.2 | 37.7 | 37.0 |

ABS = Australian Bureau of Statistics;

*N = number of households from which survey information was collected.

Overall more than double the proportion of respondents in the 2016 sample reported disposing of medicines in the last year than in the most recent ABS Waste Management, Transport and Motor Vehicle Survey (2012), and this was the same across each of the eight states and territories. The large increase between 2012 and 2016 could be attributed to the fact that our 2016 survey focussed solely on the disposal of medicines, whereas the ABS Surveys considered the disposal of a range of 12 types of household waste of which medicines was only one item. However, it is important to note that the 2012 ABS Survey reported the lowest national average of medicines disposal over the 12-year period that the surveys were conducted (10, 12).

Methods of disposal

Table 4.4 shows that the majority of respondents in our survey (65.0%) disposed of their unwanted medicines with the usual household garbage (either recycled or non-recycled); followed by poured down the drain or toilet (23.3%); and taken to a business or shop (e.g. pharmacy or chemist) (22.6%). The last two ABS Waste Management Surveys (10, 12), reported higher rates of returning unwanted medicines to a pharmacy or chemist (34.3% in 2012 and 31.0% in 2009) and lower rates of disposal in the household garbage or drainage/sewerage system. This suggests a reduced current population awareness of the NatRUM scheme or perhaps less concern a more cavalier attitudes towards appropriate methods of disposal.

Table 4.4: How people disposed of unwanted medicines*

| | 2016 General Population Survey n (%) | 2012 ABS Survey % | 2009 ABS Survey % |
|--|---|---------------------------|--------------------------|
| TOTAL (N) | 2,521 | 12,870[^] | 9,362[^] |
| Collected from house with the usual garbage (recycled/non-recycled)# | 1,635 (64.9) | 55.1 | 58.5 |
| Took it to the dump/waste transfer centre † | 201 (8.0) | 1.1 | 1.0 |
| Took it to a business or shop (e.g. pharmacy or chemist) | 568 (22.6) | 34.3 | 31.0 |
| Took to a central collection point other than dump/waste transfer centre | 56 (2.2) | NA | NA |
| Poured down the drain or toilet | 585 (23.3) | 13.6 | 14.0 |
| Burnt or incinerated | 80 (3.2) | NA | NA |
| Buried | 30 (1.2) | } | Nil |
| Gave away | 86 (3.4) | | |
| Sold | 23 (0.9) | | |
| Other [§] | 26 (1.0) | 0.8 | 0.4 |

ABS = Australian Bureau of Statistics; NA = not asked

* Respondents could select more than one answer

[^] Number of households from which survey information was collected

2016 General Population Survey included recycled n=211 (8.4%) and non-recycled n=1424 (56.5%); 2012 ABS Survey included recycled 52.3% and non-recycled 2.8%; and 2009 ABS Survey included recycled 54.8% and non-recycled 3.7%.

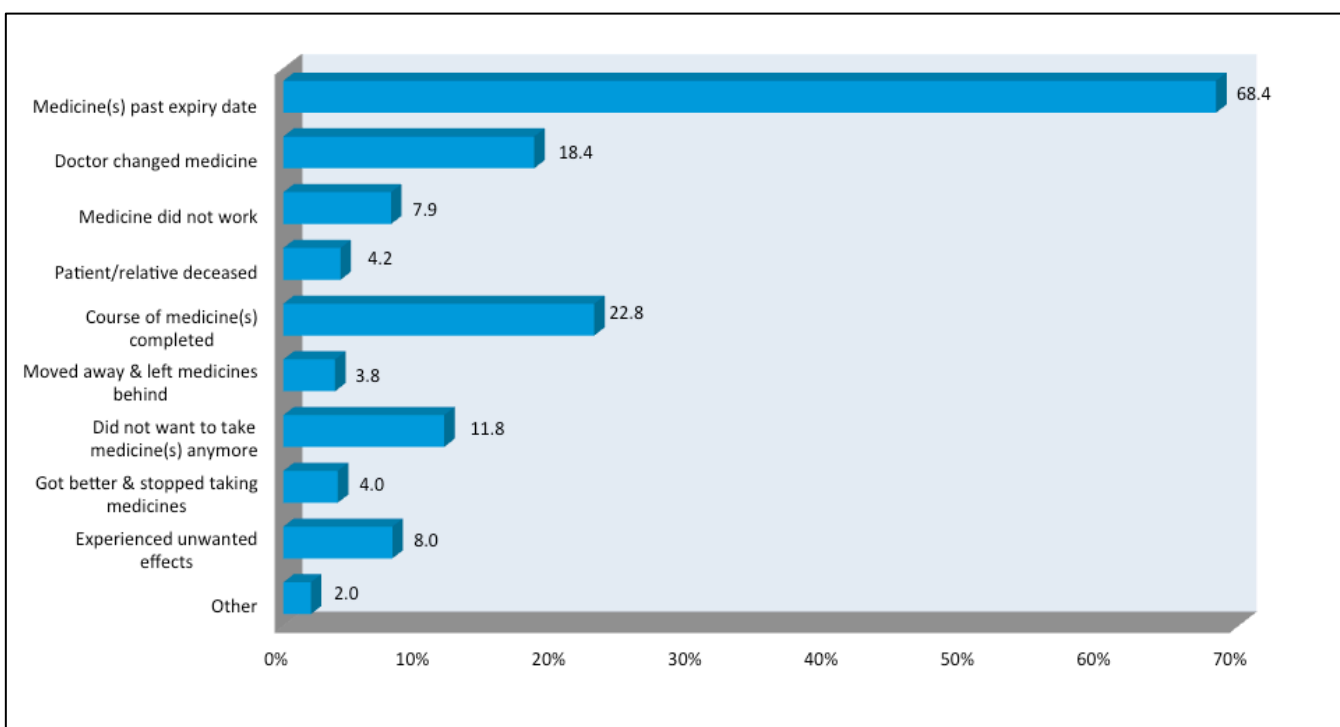
† 2016 General Population Survey included general area at dump/waste transfer station=136 (5.4%) and special area n=65 (3%)

[§] Other responses included: Took to doctor, n=12; hospital, n=2; or vet, n=3; disposed in insulin sharps container, n=3; and other, n=6.

Reasons for disposal

The majority of respondents disposed of unwanted medicines because they had expired (n=1,724/2,521; 68.4%). Other common reasons for disposal were that the *person(s) got better and stopped taking the medicines* (n=643/2,521); the *recommended course of medicine(s) was completed* (n=576/2,521) and the *doctor changed the medicine* (n=465/2,521). The top four reasons for returning medicines to community pharmacies in the Victorian study were: medicine passed expiry, patient death, doctor changed/replaced medicine, and consumer experienced unwanted effects (6).

Figure 4.1: Reasons for disposal of medicine(s)*



*Respondents could select more than one answer.

Awareness of the National Return of Unwanted Medicines (NatRUM) scheme

Only 17.6% (n=759/4,302) of survey respondents had heard of the national scheme for returning medicines to a pharmacy for safe disposal (Table 4.5). Those aged under 54 years were less likely to have heard of the scheme, with awareness increasing in those aged over 55 years.

Table 4.5: Awareness of the NatRUM scheme among the general population

| | Age group (years) | | | | | | TOTAL N=4,302 |
|---|---|----------------|----------------|----------------|----------------|----------------|------------------|
| | 18-24 N=399 | 25-34 N=848 | 35-44 N=826 | 45-54 N=785 | 55-64 N=660 | 65-99 N=784 | |
| | Have you heard of the NatRUM program? n (%) | | | | | | |
| No | 337 (84.5) | 720 (84.9) | 729 (88.3) | 665 (85.1) | 522 (79.1) | 570 (72.7) | 3,543 (82.4) |
| After learning about the program, would you now use it? n (%) | | | | | | | |
| Yes | 309 (91.7) | 654 (90.8) | 648 (88.9) | 610 (91.7) | 486 (93.1) | 541 (94.9) | 3,248 (91.7) |

NatRUM = National Return of Unwanted Medicines.

Respondents who were not aware of the NatRUM program (n=3,543) were provided with the following information and a link to the website (www.returnmed.com.au):

The National Return and Disposal of Unwanted Medicines (RUM) project is funded by the Commonwealth Government allowing for all Australians to dispose of any unwanted medicines by taking them to their local community pharmacy. This is a free service.

Although 91.7% of respondents who did not previously know about the scheme stated they would now use it, 8.3% (n=297/3,543) indicated that they would not. The most common reasons for not wanting to use the

NatRUM scheme are presented in Table 4.6. Interestingly three respondents appeared confused by the term 'community pharmacy' stating that they did not know what this was.

Table 4.6: Reasons for not wanting to use the NatRUM scheme

| | Number of respondents n (%) |
|--|--------------------------------|
| TOTAL (N) | 297 |
| Too much hassle/waste of time/too difficult to access | 168 (56.6) |
| Not applicable (want to keep medicines or don't have any unused medications) | 54 (18.2) |
| Don't know about/understand the scheme | 14 (4.7) |
| Privacy concerns/concerns the pharmacy would re-use the medication | 14 (4.7) |
| Would use the scheme if there was a cash incentive/partial refund | 9 (3.0) |
| Other | 34 (11.4) |

NatRUM = National Return and Disposal of Unwanted Medicines.

Healthcare staff promotion of the safe disposal of medicines

All respondents were asked whether they had worked in healthcare in the previous five years; 446 people identified they had (10.4%), with 341 (76.5%) working in healthcare roles that included patient contact. Table 4.7 summarises these healthcare roles; the 'other, without patient contact' category were predominantly service, IT and technical positions.

Of the 341 respondents who had worked in healthcare in a role with patient contact, approximately half (n=156/341, 45.7%) stated that they asked their patients and/or consumers whether they had unwanted medicines in the home. In terms of giving advice regarding the disposal of unwanted medicines, healthcare workers most commonly advised that these should be disposed with the usual household garbage and/or taken to the dump (n=108/156; 69.2%), and returning them to a pharmacy or chemist (n=82/156; 52.6%) (Table 4.8).

Of those healthcare workers who had asked their patients/consumers whether they had unwanted medicines in the home, 65.4% (n=102/156) stated they had told them about the NatRUM scheme. The main reason offered by healthcare workers who had not asked was because they themselves were unaware of the existence of the national scheme (n=44/54; 81.5%). Of the healthcare workers who had not asked about unwanted medicines 75.9% stated they would in the future now that they were aware of the national scheme.

Table 4.7: Respondents who had worked in healthcare in previous five years

| | Male n (%) | Female n (%) | All participants n (%) |
|---------------------------------|---------------|-----------------|---------------------------|
| TOTAL (N) | 131 | 315 | 446 |
| Nurse | 11 (8.4) | 67 (21.3) | 78 (17.5) |
| Aged-care worker | 10 (7.6) | 28 (8.9) | 38 (8.5) |
| Social worker/welfare worker | 7 (5.3) | 13 (4.1) | 20 (4.5) |
| Medical receptionist | Nil | 19 (6.0) | 19 (4.3) |
| Specialist doctor | 9 (6.9) | 6 (1.9) | 15 (3.4) |
| Disability worker | 4 (3.1) | 11 (3.5) | 15 (3.4) |
| General practitioner | 5 (3.8) | 6 (1.9) | 11 (2.5) |
| Dietician/nutritionist | 4 (3.1) | 7 (2.2) | 11 (2.5) |
| Dentist/dental assistant | 3 (2.3) | 11 (3.5) | 14 (3.1) |
| Physiotherapist/hydrotherapist | 5 (3.8) | 5 (1.6) | 10 (2.2) |
| Pharmacist/pharmacy assistant | 7 (5.3) | 9 (2.9) | 16 (3.6) |
| Other, with patient contact* | 28 (21.4) | 66 (20.9) | 94 (21.1) |
| Other, without patient contact^ | 38 (29.0) | 67 (21.3) | 105 (23.5) |

* Other, with patient contact responses included roles such as podiatrist, occupational therapist, psychologist & speech pathologist;

^ Other, without patient contact responses included roles such as administration/clerical, information technology & food services.

Table 4.8: Healthcare workers advice for disposal of unwanted medicines*

| | Respondents n (%) |
|--|----------------------|
| TOTAL (N) | 156 |
| Throw out with the usual household garbage (recycled/non-recycled)^ | 73 (46.8) |
| Take it to the dump/waste transfer centre# | 35 (22.4) |
| Take it to a business or shop (e.g. pharmacy or chemist) | 82 (52.6) |
| Take to a central collection point other than dump/waste transfer centre | 6 (3.8) |
| Pour it down the drain or toilet | 8 (5.1) |
| Burn or incinerate it | 3 (1.9) |
| Bury | 3 (1.9) |
| Give away | 3 (1.9) |
| Sell | Nil |
| Other † | 13 (8.3) |

* Respondents could select more than one answer

^ 2016 General Population Survey included recycled, n=23 (15%) and non-recycled, n=50 (32%).

2016 General Population Survey included general area, n=18 (12%) and special area, n=17 (11%).

† Other responses included: return to doctor, n=7, or hospital, n=2.

Participant concerns about unwanted medicines and the promotion of safe medicine disposal

Survey respondents were asked two ranking questions: the first related to their awareness and concerns about storing and disposing of unwanted medicines; the second addressed how the safe disposal of unwanted medicines could be best promoted in the community. For both questions the order of response statements was randomised. Participants were asked to rank the statements in order of most important/effective to least important/effective.

Table 4.9: Concerns about unwanted medicines and promotion of safe disposal

| Statement | Rank (1-6) |
|--|-------------------|
| Unsafe storage of medicines can lead to unintended poisoning (e.g. children, vulnerable people) | 1=Most important |
| Sharing medicines with friends or family is unsafe | 2 |
| Unsafe disposal of medicines can have a negative impact on the environment and affect plants and animals | 3 |
| It is free to bring unwanted medicines back to the pharmacy | 4 |
| Unsafe disposal can lead to medicines in the drinking water | 5 |
| The government pays to safely dispose of medicines | 6=Least important |
| Statement | Rank (1-8) |
| Television | 1=Most effective |
| Sticker on prescription medicines | 2 |
| Information from your doctor | 3 |
| Information from people in the pharmacy | 4 |
| Social media | 5 |
| Radio | 6 |
| Poster at your doctor's office and/or pharmacy | 7 |
| Newspaper | 8=Least effective |

Participants ranked their two top statements about safety issues as follows: i) storage at home and risks of unintended ingestion, and ii) sharing medicines with friends or family is unsafe. Their two recommendations regarding the most effective way to promote safe disposal of unwanted medicines was firstly via a television campaign, and secondly via a sticker placed on packs of prescription medicines.

Summary

Key findings for Stage Two: i) General population survey

- Around 60% of General Population Survey respondents reported that they had unwanted medicines in their homes;
- The primary reason for respondents keeping unwanted medicines was *in case they needed them again*, but 20% did not know how to dispose of these medicines safely;
- Disposing of unwanted medicines in the usual household rubbish collected at the kerbside was the most common disposal method reported by respondents and only a quarter had returned medicines to a pharmacy previously;
- Over 80% had not heard of the National Return and Disposal of Unwanted Medicines scheme: awareness was highest amongst older respondents;
- After learning about the national scheme, 92% of people said they would use it;
- The primary concern for people who had unwanted medicines at home was that unsafe storage could lead to unintended poisoning (e.g. children);
- Less than 50% of healthcare workers asked consumers about unwanted medicines they kept at home. Most advised these medicines should be disposed with the household garbage and/or taken to the dump (69%);
- A television campaign was ranked as the most effective way to promote awareness of the safe disposal of unwanted medicines; and
- A potential role for pharmacy staff emerged for increasing awareness about safe medicines disposal particularly when consumers were picking up prescription medicines. A sticker on the packet or information directly from the staff was considered most effective.

Insights for National Return and Disposal of Unwanted Medicines Limited and the Department of Health

- A national public campaign to:
 - Increase awareness of the risks of unsafe disposal including quality use of medicine and wider environmental impacts;
 - Increase awareness of the free service for returning unwanted medicines to a community pharmacy;
- A pharmacy campaign:
 - Using simple low-cost strategies, for example
 - A reminder sticker placed on prescription medicines;
 - An information card placed in the bag when medicines are picked up/purchased;
 - A poster in pharmacies linked to specific national public campaigns e.g. diabetes week, mental health week, NPS campaigns;
 - Small, low cost initiatives are likely to have significant impact.
- For the health profession relevant training is needed to:
 - Increase awareness and knowledge about the safe disposal of medicines;
 - Change the behaviour of individuals with respect to their role in safe disposal practices;
 - Promote a whole-of-healthcare team approach.

4.2 Structured interviews with higher medication users

In step two, a sub-sample of the General Population Survey respondents who took five or more medicines (including complementary, alternative and/or over-the-counter medicines) participated in a 15-minute telephone interview about the unwanted or 'when required' medicines they had at home. The structured interviews aimed to build on survey findings by exploring the quantity and nature of unwanted or 'when required' medicines that may require disposal, and to explore participants' perceptions related to disposal practices.

Method

Participants

We proposed to interview around 5% of the original General Population Survey sample (i.e. 215 participants). Participants self-selected into the interview sample when they indicated they took five or more medicines in a screening question in the survey and then provided their contact details. Data collection was ceased once 166 interviews were completed as no new information was offered, i.e. data saturation had been reached.

Data collection

Data collection tools used in the 2005 Victorian study (6), the NZ DUMP project (19) and input from the Advisory Panel informed the development of interview questions. An interview guide was developed to ascertain the quantity and nature of unwanted or 'when required' (e.g. analgesics) medicines currently stored in the home and to explore key areas related to medicines storage, use and disposal, and perceived associated risks. Participant views on these topics were explored in more depth to build on findings from the survey through contextual information. The telephone interview was piloted with six people from the general population who were taking five or more medicines and minor amendments were made.

An interview protocol was developed to ensure interviewer consistency. The protocol included text to be read prior to commencing each interview, including background information on the research, statements to obtain verbal confirmation that participants understood the nature of the research, and verbal consent to record the interview (recordings were destroyed following transcription and quality checks). Interviews were conducted by three pharmacist researchers, two with experience in telephone interviews and qualitative research, the other a senior practising community pharmacist. One pharmacist researcher, the primary interviewer, conducted 128 interviews in total and the other two pharmacists completed the remaining 38 interviews. Initially, the primary interviewer conducted 37 interviews with one of the other pharmacist researchers for the purpose of training and quality assurance. Additional quality assurance processes included twice daily debriefs whilst interviews were occurring, transcript and data entry checks.

Interviewers asked participants to collect and list, or name, all the medicines in the house, and identify which were regularly used, which were unwanted (expired or no longer required), and which were 'when required' medicines. Where possible, and when permitted, participants provided information for the household, including for other household members. In some cases they provided information for themselves only. Details of all the unwanted and 'when required' medicines including drug name, formulation, amount remaining and expiry date were collected by the interviewer. As interviews were conducted during September and October 2016, the 31st October 2016 was used to determine whether medicines were expired. Participants were also asked who used the medicines and how they would dispose of them. Additionally, they were asked how far in advance they filled repeat prescriptions for regularly used medicines and if they would be prepared to pay for the safe disposal of unwanted or expired medicines.

If time permitted and the participant agreed, they were asked their views on what they thought happened to medicines that were returned to pharmacies, if they had any concerns or issues with returning medicines and the perceived risks of keeping unwanted medicines at home. Lastly, demographic information was collected.

The interview also provided an opportunity for the pharmacist researcher to provide information about discarding medicines via the local pharmacy.

Data analysis

Data related to medicines in the home were entered into a purpose-built Microsoft Access database and descriptive analyses were conducted. The interviews were transcribed and thematic analysis was conducted of the qualitative responses to open-ended questions by the two pharmacist researchers with experience in qualitative research using NVivo 11®. Italicised participant quotes are presented verbatim throughout the text to provide narrative examples of the findings presented below.

Results

Of the 4,302 survey participants 608 self-identified as higher medication users (i.e. took five or more medicines), and provided contact details to participate in a telephone interview (14.1%); 166 completed the interview (3.9% of total survey participants). People were excluded when they could not be reached by telephone, incorrect contact details had been provided or they declined to participate.

Telephone interviews ranged from eight to 81 minutes in duration depending on how many medicines were stored in the home (mean=19.5 minutes). Table 4.10 outlines participant characteristics and provides comparisons with the General Population survey sample and the 2005 Victorian study (6).

Interview participant characteristics were similar to the 2016 survey sample as a whole with respect to gender, state/territory location, employment status and educational qualification (Table 4.10). However, interview participants were generally older. This was not unexpected for participants taking a greater number of medicines; in a study of 602 health consumers with chronic health conditions, 82% surveyed were older than 40 years (34). The 2005 Victorian study reported similar age-related characteristics to our 2016 interview sample: in both samples only 8% were younger than 35 years. However, 61% were ≥55 years in this 2016 sample and 74% were ≥50 years in the 2005 sample (6).

The majority (80.7%) of interview participants resided in households of between two and five people (mean=2), with twelve participants reporting that they lived with children aged less than 12 years old. Participants on average reported using seven medicines regularly (including complementary and alternative medicines); and 36 was the maximum number reported.

Table 4.10: 2016 Interview participant characteristics

| | 2016 Interview sample | 2016 General Population Survey sample | 2005 Victorian sample (6) | |
|------------------------------|--------------------------|---|------------------------------|------------|
| | n (%) | n (%) | n (%) | |
| TOTAL (N) | 166 | 4,302 | 605 | |
| Gender | | | | |
| Female | 85 (51.2) | 2,203 (51.2) | 369 (61.0) | |
| Male | 81 (48.8) | 2,099 (48.8) | 200 (33.1) | |
| Age range (years)* | | | | |
| 18-24 | 5 (3.0) | 399 (9.3) | | |
| 25-34 | 8 (4.8) | 848 (19.7) | 18-34 | 46 (7.6) |
| 35-44 | 14 (8.4) | 826 (19.2) | 35-49 | 101 (16.7) |
| 45-54 | 33 (19.9) | 785 (18.2) | 50-64 | 151 (25.0) |
| 55-64 | 45 (27.1) | 660 (15.3) | 65-79 | 221 (36.5) |
| 65-99 | 57 (34.3) | 784 (18.2) | 80 + | 70 (11.6) |
| Mean (SD) | NA | 46.4 years (16.2) | NA | |
| State or territory* | | | | |
| Australian Capital Territory | 4 (2.4) | 89 (2.1) | NA | |
| New South Wales | 49 (29.5) | 1,383 (32.1) | NA | |
| Northern Territory | 2 (1.2) | 51 (1.2) | NA | |
| Queensland | 38 (22.9) | 868 (20.2) | NA | |
| South Australia | 10 (6.0) | 306 (7.1) | NA | |
| Tasmania | 3 (1.8) | 91 (2.1) | NA | |
| Victoria | 42 (25.3) | 1,081 (25.1) | 605 (100) | |
| Western Australia | 15 (9.0) | 433 (10.1) | NA | |
| Rural or urban* | | | | |
| Rural | 48 (28.9) | 1,008 (23.4) | NA | |
| Urban | 112 (67.5) | 3,294 (76.6) | NA | |
| Language spoken at home* | | | | |
| English | 158 (95.2) | 4,026 (93.6) | 514 (85.0) | |
| Other^ | 3 (1.8) | 276 (6.4) | NA | |
| Living arrangements* | | | | |
| With spouse | 67 (40.4) | 1,745 (40.6) | NA | |
| With partner | 12 (7.2) | 615 (14.3) | NA | |
| With family members | 45 (27.1) | 1,044 (24.3) | NA | |
| In a share house | 8 (4.8) | 201 (4.7) | NA | |

| | | | |
|---------------------------------------|------------|--------------|------------|
| Alone | 29 (17.5) | 683 (15.9) | NA |
| Other# | 2 (1.2) | 14 (0.3) | NA |
| Highest educational qualification* | | | |
| Year 9, 10 or below | 23 (13.9) | 522 (12.1) | 36 (6.0) |
| Year 11 or 12 | 31 (18.7) | 823 (19.1) | 279 (46.1) |
| Cert/diploma/advanced diploma | 54 (32.5) | 1,355 (31.5) | 146 (24.1) |
| Bachelor degree | 34 (20.5) | 10,35 (24.1) | 114 (18.9) |
| Postgraduate (diploma/, Masters, PhD) | 18 (10.8) | 567 (13.2) | NA |
| Employment status | | | |
| Retired or pensioner | 64 (38.6) | 980 (22.8) | NA |
| Working part time or casual | 24 (14.5) | 784 (18.2) | NA |
| Working full time | 27 (16.3) | 1,587 (36.9) | NA |
| Unemployed | 10 (6.0) | 348 (8.1) | NA |
| Student | 3 (1.8) | 187 (4.3) | NA |
| Self-employed | 9 (5.4) | 236 (5.5) | NA |
| Other † | 23 (13.89) | 180 (4.2) | NA |

NA = not available; SD = standard deviation.

* Missing data – not all respondents provided this information.

^ Other language responses included: Chinese, Pilipino and Italian

Other living arrangements included: living with full-time carer and living as a carer with a care recipient.

† Other Employment status responses included: homemaker, n=5; disabled/on disability pension, n=11; voluntary work, n=2; and on workers compensation, n=1.

Medicines stored in the home

Interview participants described a total of 1424 unwanted and/or 'when required' medicines that were stored at home. The kitchen was the most common storage location, followed by the bedroom and the bathroom. Storage locations within the kitchen included in and above the refrigerator, pantry, above the microwave, in high cupboards and above the stove. Other locations included the laundry, dining table, lounge room, study, safe or locked box (for Schedule 4 and Schedule 8 medicines), linen cupboard and under the television. Use of DAAs was reported in some interviews, which were packed by the individual (e.g. dosette box) or by the pharmacy (e.g. Webster Pak®).

Locations such as above the stove or on a table have implications for appropriate storage, temperature and ease of access by children (and pets). Participants were not asked to define how they understood the term 'appropriate storage', nor were they specifically asked why they used the stated locations, although a minority referred to appropriate storage temperatures or strategies used to restrict access by children or pets.

More than half of the participants described storing all medicine-related items in one place and the remainder described using multiple storage locations. Use of multiple locations reflected storage requirements (e.g. insulin), segregating medicines storage for individuals in the household, intended use for medicine (e.g. vitamins in the kitchen), extra supplies of medicine, differentiation between regular and 'when required' medicines (e.g. analgesics), and strategies to assist participants to remember to take their medication:

"The ones that I'm taking daily I keep on my dining room table then I remember to take them every morning, and the others are kept either in my bathroom cupboard or in my bedroom cupboard, depending on which I use the most." (P 139)

"Okay, so creams it would be in the bedroom, or the bathroom....frequently used ones I tend to keep in the bathroom, other ones I keep in my bedroom. Other tablet medicines I keep, the ones I use I keep in my bedroom and the ones that are intermittent like Panadol or whatever I keep in a locked cupboard in the laundry." (P 2252)

Some participants did not offer a rationale for multiple storage locations and this could potentially lead to the duplication of medicines in the home. Participants openly discussed having more than one box/pack of certain medicines (e.g. paracetamol and ibuprofen), either because they were used regularly or multiple people in the same household used them:

"...Well, there are 3 packets [paracetamol] there because I buy this in bulk...this is an item that everyone uses in the house and I buy 3 or 4 boxes at a time..." (P 711)

One participant stated that they kept multiple bottles of chloramphenicol eye drops at home for eye infections associated with work. Another reported having five bottles of Redipred® (prednisolone) at home, but did not explain why, or show concern about the quantity. Some participants queried the amount of medicine they were given on prescription, viewing it as wasteful:

"...But when I got the cream [skin corticosteroid], I got like three tubes. Which I don't understand why they do that. Because in life, you don't need that much medication." (P 1106)

"Yeah, that's a brand new box (Nurofen® 200mg). I got 2 boxes actually...What happens is you go to a dentist and get something done they give you this prescription and that's what you come home with. You don't use them." (P 1893)

Unwanted and 'when required' medicines in the home

Initially 45.2% of interview participants (n=75/166) stated that they currently had medicines in the house that they were no longer using. However, as the interview progressed, participants often found additional unwanted medicines that they had been unaware of until undertaking the listing/naming process for the research, and some expressed concern about the quantity of medicines they found. For others, the interview appeared to provide an opportunity to assess and clean out their medicines:

"I've got Betnovate® cream and that's expired March 2015. This is cleaning out my cupboard nicely...So whatever we got that for we haven't had to use it again by the looks of it...Got a cream called Elocon®. Just looking at the expiry date on that one - the 10th, 2012. See here I thought I was so good. I'd thrown all my other stuff out and I'm finding all these ones." (P 548)

Participants were asked to report any medicines that they used on a 'when required/as needed' basis in order to identify any medicines that they had not initially considered unwanted, but which were expired. The majority of unwanted medicines (85.2%; n=1213/1424) were *used* medicines (i.e. opened packets) with 70.4% (n=1002/1424) for use by the participant themselves and a third by family members (33.1%, n=472/1424). There were also 43 examples of veterinary medicines identified.

A range of reasons were provided as to why stored medicines were no longer used. These included prescriber medicine changes (e.g. to therapeutic agent, strength or dose), the medicine was no longer required, for example, when lifestyle modification had improved a health condition (Box 4.1). Some participants discussed their decision not to use strong pain medicines because of side effects, or to use them only when really needed.

Others kept certain medicines on hand in case of a flare-up in their condition. Frustration emerged when changes to medicine(s) resulted in out-of-pocket expenses, potentially creating financial burden, which is associated with people electing to delay, or not collect, prescription medicines (35). When similar medicines are available in the home it could encourage use of these without prescriber knowledge.

Box 4.1: Participant quotes about reasons why medicines were no longer used

"He [doctor] increased the, I was going to say voltage. He increased the dosage [antipsychotic]. I had new prescriptions with increased amounts. So these just got left in my bedside table." (P 542)

"...I was prescribed it because my blood pressure increased after birth so I was just kind of on it short term and now the doctor said my blood pressure's under control." (P 92A)

"Yes I ceased it [gout medication] because I didn't think it was making any difference to my life; I was sick of taking tablets." (P 457)

"... I've learnt now what to avoid food wise and also how to manage my skin's daily routine a lot better. I just use a non-soap body wash and lots of moisturiser. So I haven't had to use the cortisone cream for quite a long time." (P 464)

"...I had a shoulder operation and they gave me a packet of Endone® [opioid analgesic] from the hospital when I left. I only have taken two of them and I didn't like the way they made me feel sick in the stomach and that sort of thing. So I've got them sitting here but nobody's taking those at the moment...." (P548)

"...I try and manage it [condition] with other means starting with music and starting with lighter pain killers. Sometimes I can't manage it and then I go back to the heavier painkillers. The doctor has said take them when you really need to, otherwise try and manage without." (P 711)

"...They said stop taking this one and start taking this one. I thought, "I've just had that script filled, and now I have to go buy one that costs me \$53." (P 1696)

Expiry dates of unwanted or 'when required' medicines stored in the home

Expiry dates were provided for 1117 of the 1424 medicine items stored in participants' homes (78.4%). Expiry dates spanned 30 years from December 1991 to May 2021: 37.0% (n=413/1117) expired as of the 31st October 2016; 12.8% (n=143/1117) expired within the next six months; and 50.2% (n=561/1117) between the 1st May 2017 and 31st May 2021.

Higher proportions of expired, or almost expired, medicines were observed for unscheduled or complementary and alternative medicines (58.8%, n=177/301) than scheduled medicines (44.7%, n=317/709) (Table 4.11).

Table 4.11: Unwanted or when required medicines stored in the home

| Medicines stored at home with an expiry date classified by medicines schedule | |
|--|------------|
| | n (%) |
| TOTAL unwanted or when required medicines with an expiry date | 1,117* |
| Prescription medicines (Schedule 4) | N=300 |
| Expired (as at 31 st October 2016) | 111 (37.0) |
| Expires in the next six months (1 st November 2016 to 31 st May 2017) | 41 (13.7) |
| Expires after six months (after 1 st June 2017) | 148 (49.3) |
| Prescription medicines (Schedule 8) | N=19 |
| Expired (as at 31 st October 2016) | 7 (36.8) |
| Expires in the next six months (1 st November 2016 to 31 st May 2017) | 4 (21.1) |
| Expires after six months (after 1 st June 2017) | 8 (42.1) |
| Non-prescription medicines (Pharmacy medicines (Schedule 2) and Pharmacist only medicines (Schedule 3)) | N=390 |
| Expired (as at 31 st October 2016) | 118 (30.3) |
| Expires in the next six months (1 st November 2016 to 31 st May 2017) | 38 (9.7) |
| Expires after six months (after 1 st June 2017) | 234 (60.0) |
| Unscheduled medicines (medicines available from outside of pharmacies e.g. supermarkets) | N=210 |
| Expired (as at 31 st October 2016) | 87 (41.4) |
| Expires in the next six months (1 st November 2016 to 31 st May 2017) | 29 (13.8) |
| Expires after six months (after 1 st June 2017) | 94 (44.8) |
| Complementary or alternative medicines (vitamin, mineral, herbal, aromatherapy or homeopathic products) | N=91 |
| Expired (as at 31 st October 2016) | 47 (51.6) |
| Expires in the next six months (1 st November 2016 to 31 st May 2017) | 14 (15.4) |
| Expires after six months (after 1 st June 2017) | 30 (33.0) |

* Includes 107 items that were classified as: international medicines (n=13), unknown (n=21) or the information was missing (n=73).

For many participants the expiry date was difficult to find or read:

“Expiry... Hang on a second. You know what, it's like it's printed into the thing [analgesics], and even with a magnifying glass I can't read it.” (P 1758)

In some cases dispensing labels had hidden the expiry date, underscoring the need for good labelling practice. Expiry dates were sometimes obscured, e.g. when the crimp of topical products was rolled up, or they were missing, e.g. when primary packaging had been discarded. One participant assumed that medicines were within date if recently dispensed, which may not account for short-dated stock:

“Now I was looking for that [expiry] and I can't actually find it, but I know I got it earlier this year so it ought to be all right. I've looked on the container and I just can't see any expiry date on it.” (P 2182)

Some participants were surprised to find expired medicines in their home, or were unaware that medicines do expire. This has implications for consumer education about medicines use beyond expiry:

"It's a full tube [Celestone M®] so... Yeah, in fact I don't use that very often so I wouldn't call that a regular, but it's a full tube I haven't opened this one.... Expires 12 '08. Hold on, can that be right? That wouldn't be right, 2008....Expires 12... maybe it is 2008, I actually don't use it very much." (P 2252)

"...see the Duralax®. I'm trying to look what's on it. Yeah, 2009. Do they go out of date, really?" (P 2183)

Use of expired medicines

Examples of expired medicines currently in use included paracetamol, paracetamol + codeine, pseudoephedrine, chloramphenicol eye preparations, and topical corticosteroids, first aid and cold sore agents. Medicine expiry was generally associated with reduced efficacy rather than safety, and factors influencing use included time since expiry, formulation and type of medicine. Accepted timeframes ranged from 'just' expired (i.e. recently), to a year, or longer in a few cases. Greater use of expired topical, rather than systemic medicines reflected lower perceived risk:

"Well I suppose I'd weigh up how out of date it was. If it was just a couple of years I might decide it's going to be okay particularly with the creams and so on. And even tablets, ..., I think I'm taking my own risk with those, if it's not terribly out of date I wouldn't worry too much. I just use them." (P 2252)

One participant explained their rationale for continued use of items such as Retrieve® and Ovestin® Vaginal Cream *"...I've stopped using it, basically, but I've still got the tube because you don't throw these things out."* (P 2280).

Others were unaware of, or tended to ignore, recommended timeframes to discard medicines once opened:

"...It just says discard 28 days after opening so that'd be the end of this month but in saying that the expiry date is fifth month 2018. I would probably hang onto it [Nystatin® drops]." (P605)

"... Chloromycetin® is an antibacterial eye cream that I've used and I've still got that in case I get a similar infection in my eye that I can use it still, so I haven't thrown that out." (P1240)

Vitamins were viewed as less likely to 'go off' than herbal products and comparisons between medicine expiry dates and 'best before' dates on food were offered:

"If it was just one day you wouldn't worry about it but it says expires, it doesn't say use by....The same as food products. It says best before, that doesn't mean that it's no good after that date." (P 714)

One participant justified that he would be more concerned about prescription medicines associated with higher health risks, such as a DVT:

"With the Panadeine® and the Sudafed® I would normally take them and not worry about the expiry date... The Clexane® slightly different. With the Clexane® if I was doing a trip home [long-haul flight] I would go visit my doctor and make sure that the Clexane® was a valid in stock prescription and I would actually bring the out of date ones back to the chemist at that stage." (P 58)

Medicine collection and accumulation

To ascertain whether the amount of medicine stored at home was due to accumulation, rather than planned medicines management, participants were asked when they collected regular prescription medicine(s) and whether they ever obtained medicines 'just in case.' The majority (90%, n=117/130) reported obtaining regular prescription medicines when due, or up to seven days prior to needing them. Influential factors included living

or working out of town; being prompted by medicine adherence tools; financial circumstances; and convenience during pharmacy visits for another purpose (Table 4.12).

Multiple participants used the repeat prescription date to determine when they were 'allowed' to pick up their next supply and ensure that they did not run out; adequate supplies equated to obtaining one or more packets as a back-up. Stock-piling of prescription medicines was not prevalent in the interview sample and this is supported by the fact that the majority of expired medicines were available without prescription.

Table 4.12: Factors influencing medication collection and stock-piling practices

| Factors | Participant quotes |
|---|---|
| Ensuring adequate supply | |
| Having back-up supply | <i>"Just in case I'm sick or I have to do something and I can't get there, I don't want to run out. I always have a spare packet there..."</i> (P 1925) |
| Geographical location | |
| Living rurally or out of town | <i>"I usually get two months' supply because being so far out of town I don't want to do a trip just to go and get medication. So I usually try and keep about three weeks in advance just in case."</i> (P 605) |
| Working out of town (e.g. FIFO workers) | <i>"Well that depends on whether I'm home on leave or not or whether I'm working away. So – because normally some of these things here are only 30 days tablets and I'm normally away for 35 days so I've got to get double doses...and if I'm home on leave I will not worry about it, I'll just pick them up as when it comes close to needing them again."</i> (P 209) |
| Use of tools to promote adherence | |
| Insufficient medicines to fill dosette box | <i>"You know those pill boxes and you do 7 days? ... When I know I'm not going to have the next 7 days, I go down and get the script filled."</i> (P 812) |
| Reminder from MedAdvisor® app www.medadvisor.com.au | <i>"... Because my scripts are all at the pharmacy and they send me a text message to remind me that the end of the month is coming and do I need replacement and then I just text them back yes."</i> (P 1524) |
| Other reasons | |
| Financial factors | <i>"....I monitor how many pills I've got left in my medicine box and basically it's a combination of how much money I've got in my bank account and how many pills I've got left in my box and I work out my little budget to see how many of my scripts I can afford to fill like everybody else I suppose."</i> (P58) |

Obtaining medicines 'just in case'

When participants were asked if they had ever obtained prescription medicines 'just in case' they needed them, the majority were adamant that this was not routine practice. When this did occur, it was mostly due to people wanting to be prepared for impending overseas travel. Participants also reported obtaining prescription and non-prescription medicines to have on-hand for immediate treatment of episodic conditions such as acute migraine, colds and flu (Table 4.13).

Some participants described obtaining 'just-in-case' antibiotics as a repeat prescription for future use or by retaining part of a prescribed, but not completed, antibiotic course. Examples included broader spectrum antibiotics and more specific agents for malaria prophylaxis, treatment of urinary tract infections, eye infections and prostatitis. For some participants keeping antibiotics was an 'insurance policy' against future infections; there was no mention of potential risk of harm, incorrect self-diagnosis or antimicrobial resistance. Acknowledgement of risks to eye health from chloramphenicol eye drops six months after opening was limited to: "[I] probably should throw it out" (P 224).

Table 4.13: Factors influencing collection of 'just in case' medicines

| Factors | Participant quotes |
|--------------------------------------|--|
| Impending overseas travel | <i>"I think when we've gone overseas; we've had some stuff that was just in case, like Gastro-Stop, and things like that." (P 1659)</i> |
| Episodic illness(es) | <i>"Mainly the Imigran®, I don't like to run out of those, they treat migraines. I don't like to run out of any of them." (P 169)</i> |
| Risk of recurrent infections | <i>"Then there's norfloxacin...I haven't disposed of it because I had acute prostate episodes and that was prescribed to me, that helps. I kept it just in case it happens again. Like I said, it's kind of a security blanket. I've had so many problems. I don't go anywhere without having at least something that might address immediate emergencies." (P 1711)</i> |
| Repeat courses of antibiotics | <i>"...The chemist basically issued a repeat and the first dose in one go because I wasn't too well at the time so it saves you coming back, there's your repeat, but I never used the repeat so that box [amoxycillin] is full. The expiry is 12/15..." (P 711)</i> |
| Saving antibiotics | <i>"...I'll take the first course completely, and then I might only take 2/3 of the rest of the second course and not complete it, and that means I might have a few spare. The way I see it, if I get something that looks pretty bad, like a bacterial infection in the throat or whatever, I don't have to go racing to the doctor in the middle of the night if I've got a couple on hand, if you know what I mean?" (P1240)</i> |

A few participants cited specific reasons for not obtaining medicines 'just in case', including a perception that they took enough regular medicines already, not wanting to use antibiotics unwisely and the ability to purchase medicines overseas:

"Because I'm on these nine medications that's the most medication I've ever been on in my life and it's a lot of medication to be taking every day so I try my best not to take any further medication." (P 58)

"No not antibiotics no ... I wouldn't take them just in case, no they're no good taking them just in case." (P 302)

"I generally don't take medicines [overseas] with me because I know like in Vietnam which is probably the only country I travel to now with my partner I know we can get everything we need there, like antibiotics and antihistamines and so forth." (P 2252)

Disposal of medicines

There were mixed responses when participants were asked how they would dispose of their medicines if the doctor changed them or they became expired. Participants described disposing of medicines in a variety of ways, such as in the rubbish bin, down the toilet, composting, or returning it to the pharmacy or another health professional or clinic (Tablet 4.14).

The two most common disposal methods '*return medicines to the pharmacy for disposal*' and '*dispose with the household garbage (recycled/non-recycled)*' were reported at similar rates. Comparatively, almost three times as many survey respondents had discarded medicines in the household garbage than returned them to the pharmacy in the preceding 12 months. About 23% of survey respondents had poured medicines down the drain or in the toilet and a similar proportion had returned medicines to the pharmacy. These proportions diverged for the Interviews with almost half of the participants stating they would return medicines to the pharmacy and 10% would pour them down the drain or toilet. These findings may reflect particular characteristics of this sub-population of higher medicine users or could be indicative of an educational effect from the survey, which was acknowledged by a minority of participants:

"Well now that I've heard about taking them back to the chemist I would suppose I would do that." (P 169)

"Well, up until a couple months ago I think I just tossed them in the bin, because I've never been told before that I actually have to hand them in at the pharmacy..." (P 2895)

Regardless, there were participants who remained unaware of how to dispose of medicines:

"That's a good question. I don't. I don't know. If it's a bottle, like if it was the Irish Moss, I'd probably just put it in the bin. Tablets, I don't know. I sit here in the kitchen talking to you with four boxes. I don't know how to get rid of them at all." (P 542)

A small number of participants stated they were unlikely to discard medicines due to frequent prescribing changes, to limit wastage, to keep for future use or because they are often forgotten and left at "*the bottom of the cupboard*" (P 975). When medicine dosage strengths were increased, instead of disposing of the medicine, doctors advised consumers to take double the dose to avoid medicine wastage. A disposal strategy adopted by less than 10% of participants was to return medicines to health professionals, primarily doctors, on the assumption that doctors reused medicines e.g. as samples, or to give to people who cannot afford them, or send them overseas (Box 4.3). Participants suggested alternative locations for the return of unwanted medicines including hospitals, health clinics and veterinary clinics. A few participants described risk minimisation strategies as part of their disposal method, for example, carefully wrapping medicines before discarding or dissolving in hot water before putting down the drain.

Table 4.14: Disposal practices for unwanted or expired medicines stored at home

| Method of disposing of unwanted or expired medicines (N=166)* | n (%) |
|--|-----------|
| Return to the pharmacy for disposal | 75 (45.2) |
| Dispose with the usual household garbage (recycled/non-recycled) | 70 (40.2) |
| Poured down the drain or toilet | 17 (10.2) |
| Keep medicine for future use | 9 (5.4) |
| Have not thought about how to dispose of their medicines | 6 (3.6) |
| Give to a family member or friend | 2 (1.2) |
| Other methods of medicines disposal^ | 17 (10.2) |

* Participants could describe more than one disposal practice.

^ Other methods of disposal included: return to other health professionals (e.g. doctors, veterinarians), never throw out medicines because medicines are used until finished even if changed, it is a waste of money or they are just never discarded, return to another central location (e.g. local council), incinerate medicines, return to clinic or health centre for reuse and place in the compost (vitamins).

It is important to note that survey respondents were asked how they had disposed of unwanted medicines in the previous twelve months and interview participants were asked how they would dispose of a medicine if it became expired or was no longer needed.

Thirty-six interview participants described using various combinations of the disposal practices listed in Table 4.14. The most common combination was disposal in the rubbish and returning medicines to the pharmacy (n=18). Factors influencing the combination chosen included medicine schedule, formulation, quantity remaining, convenience and possibly other (undisclosed) factors. Participants discussed being more likely to return prescription tablets to the pharmacy while discarding ointments, liquids, unscheduled or complementary and alternative medicines in the rubbish or the drain. Examples of unscheduled medicines that would be discarded included antacids, lozenges and cough mixtures. In a few interviews, participants applied risk assessment strategies across different prescription medicines to help them decide which to return to the pharmacy and which to discard. Rationales offered for decisions included risks of side effects, toxicity, perceived efficacy and potential for medicine diversion. Participants' individual perceptions of risk appeared to inform disposal practices and this was highlighted by the use of multiple disposal practices.

Box 4.2: Examples of multiple disposal practices used in combination and rationales

"Prescription ones we take down to the chemist. The other ones we obviously hoist in the rubbish bin." (P 270)

"Well, anything that's like medicines as such, and they're all medicines I know that, but like the medicines that if somebody could go into my bin and get hold of and take and make themselves sick or kill themselves on, I'll take to the chemist... But if it's something like cream that I'm sure nobody's going to eat a tube of cream, yeah, I'd just throw it out." (P 598)

"If I thought it was addictive or could be used by druggies or used to make other things that they're doing nowadays definitely take it to the pharmacy." (P 605)

"If it's liquid, I throw it down the toilet. If they are other pills, I throw them in the garbage. I wrap them up in a plastic bag and throw them in the garbage." (P 2001)

"The Panamax®, yes [would return to the pharmacy]. The Strepsils® I would probably just throw in my rubbish because I'm sure what's in them." (P 333)

"When they go out of date, if I've got a two or three loose sort of thing, just a handful, I throw them in the bin. If I have like a half a packet or a packet, I take it to the chemist." (P 1655)

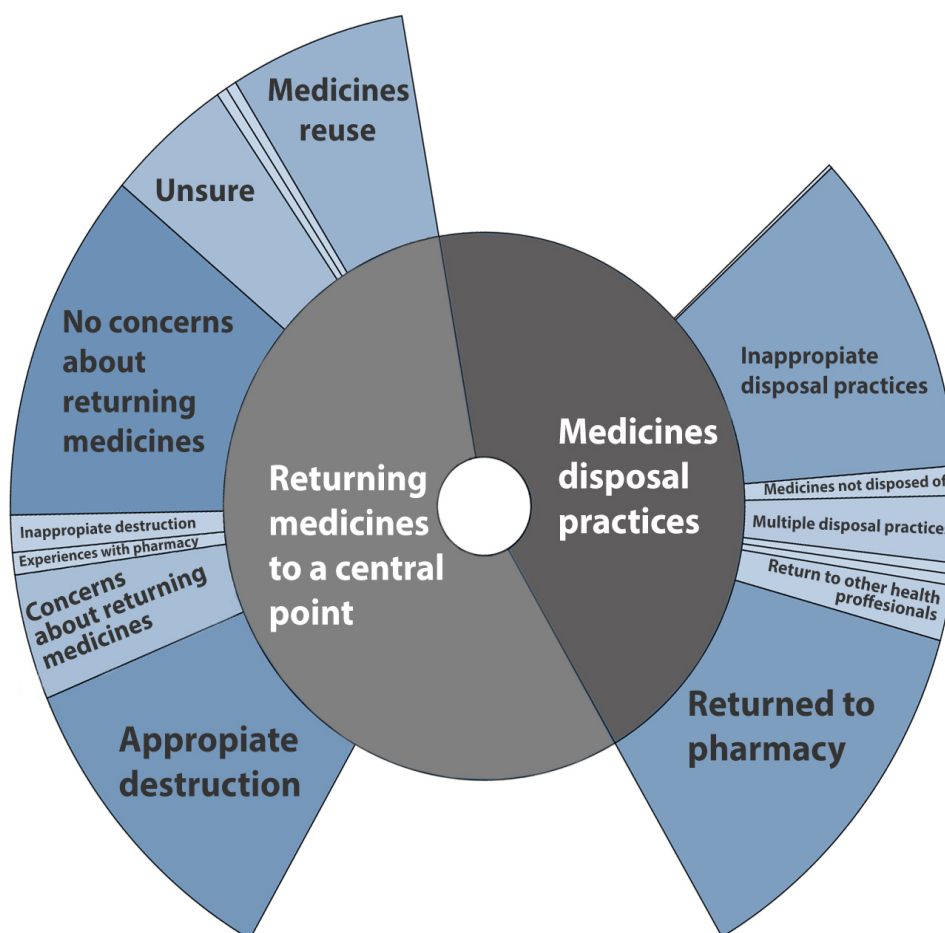
Views on medicines disposal and what happens to returned medicines

Figure 4.1 provides a visual overview of the key topics discussed by participants when asked to describe their medicine disposal practices, and their views on what happens when medicines are returned to a central point such as a pharmacy. The figure is a 'sunburst hierarchy chart' produced in the qualitative software analysis program NVivo11® to visualise prominent themes in the data and potentially identify areas requiring further investigation. Larger sections in the figure reflect more commonly expressed views. This means that researchers identified these topics or themes more frequently in interview transcripts, for example, participants more frequently discussed returning medicines to the pharmacy than returning them to another health professional and this is reflected as different sized sections in Figure 4.1. The figure is not a pie chart and the format is atypical to allow comparative visualisation of two key over-arching topics of *medicine disposal practices* and *views on what happens to medicines returned to a central point* and prominent sub-themes or topics within these.

When asked how they disposed of medicines participants reported returning medicines to the pharmacy was a common disposal practice and various motivating factors appeared to guide participants' decisions, including a desire to minimise risk of harm, be environmentally responsible, and prevent inappropriate access to medicines (Table 4.15). The majority of participants trusted pharmacists (or other health professionals) to appropriately dispose of, or destroy, medicines:

"I guess I'm not particularly concerned if I return them to a chemist. What they do with them, I'm sure they do whatever needs to be done, the right thing." (P 2168)

Figure 4.1: Views on medicines disposal and what happens to returned medicines



| Figure label* | Explanation |
|---|---|
| Returning medicines to a central point | Participant reports of what they thought happened when medicines were returned to a central point (e.g. pharmacy) and whether they had any concerns about returning medicines |
| Medicines reuse | Reference to medicine being recycled for reuse by others |
| Unsure | Participant was unaware or unsure of what happens to returns |
| No concerns about returning medicines | Participant reported no concerns about returning medicines |
| Inappropriate destruction | Reported assumptions of inappropriate disposal of medicines. |
| Experiences with pharmacy | Examples of previous experiences returning medicines. |
| Concerns about returning medicines | Concerns expressed about returning medicines (e.g. privacy) |
| Appropriate destruction | Reported assumptions of appropriate disposal of medicines |
| Medicines disposal practices | Participant descriptions of how they dispose of medicines when they are no longer needed |
| Inappropriate disposal practices | Reports of inappropriate disposal practices (e.g. in rubbish) |
| Medicines not disposed of | Participants keep medicines, sometimes in case of future need |
| Multiple disposal practices | Multiple methods to dispose of medicines (e.g. rubbish and drain or pharmacy and rubbish) |
| Return to other health professionals | Medicines returned to health professionals (e.g. doctor) |
| Returned to pharmacy | Participants return medicines to pharmacies |

* There were a few topics discussed infrequently that are shown in the figure without a label. For 'Returning Medicines to a central point' these included: reference to other professionals (e.g. returning to a vet); and other miscellaneous comments. 'Medicines disposal practice' included: disposal of unwanted medicines following an HMR; no thoughts about disposing medicines; and reference to cessation rationale.

Participants generally assumed there was a “*proper process*” (P 1381) for disposal yet most were unaware of what this was and sometimes sought clarification in the interview. Perceived methods included the pharmacy crushing, incinerating, or discarding medicines with medical waste, collection by medical waste specialists, or sending medicines to an incineration facility. However, a minority of participants expressed ambivalence or indeed, a suspicion about inappropriate disposal in the pharmacy, and about a third discussed the potential for reuse of medicines to reduce wastage, e.g. for people who cannot afford them or sending them to developing countries (Box 4.3). Less than a quarter of participants expressed concern over returning medicines to the pharmacy; concerns related to privacy, safety with the potential reuse of medicines, the inconvenience of having to go to the pharmacy, risk of pharmacy break-ins and thieves having access, and medicines wastage.

A small number of participants reported negative experiences when pharmacists had refused to accept unwanted medicine returns although occurrences appeared to be largely historical. Regardless, this highlights the need for further promotion of the RUM project, and information about what happens when medicines are returned to the pharmacy for disposal.

Table 4.15: Returning medicines to the pharmacy

| Topics discussed | Participant quotes |
|---|---|
| Minimise risk of harm | <p><i>"We've got Lantus SoloSTAR® and we've got NovoRapid®. Both of those I would not bin. They'd definitely go back to the chemist because they've got needles attached."</i> (P 605)</p> <p><i>"Years ago I made a mistake of throwing some [medication] down the toilet, before we knew how it affected the waterways and that sort of thing. I'm going back 30 years. I found my son, my two year old, in there and I didn't know whether he'd actually taken one of the tablets or not. So I never, ever throw any down the toilet ever again."</i> (P548)</p> |
| Environmentally responsible | <p><i>"Got to get rid of this, but I want to do it safely and I know other people tell me that they flush it down the sink, but I just say that just goes out into the ocean."</i> (P 2788)</p> |
| Prevent inappropriate access | <p><i>"I wouldn't really have any concerns, I'd rather they're [medicines] all going there and not being left in bins where other people can get their hands on and misuse them. Like children get hold of them or people take them to try and get high or whatever."</i> (P 332)</p> |
| Trust in pharmacy or other health professionals | <p><i>"If it was a pharmacy, no [concerns], but if it was anywhere else that wasn't a pharmacy, I probably wouldn't do it."</i> (P 975)</p> |
| Inappropriate disposal by pharmacy | <p><i>"[The pharmacy] probably do the same thing I did, just throw them in the bin."</i> (P 3698)</p> <p><i>"[The pharmacy] probably flush it down the toilet or give it back to the manufacturer. They might be able to make a claim on it..."</i> (P2465)</p> |
| Privacy and ethical concerns | <p><i>"I presume they're just destroyed now unless they recycle them."</i> (P2025)</p> <p><i>"I wouldn't want it going to anywhere else, you know, who could see what I was taking, type of scenario."</i> (P 1667)</p> <p><i>"I'd be concerned, well I wouldn't think that ethically that they would reuse expired medicines but it is a bit of a concern to, yeah, to know exactly what does happen to them."</i> (P 1940)</p> <p><i>"I guess, a while ago, I would've said I'd have privacy concerns. Or being judged on what sort of medications, people are looking at you and judging you based on what you're handing in. But these days I'm a lot more relaxed about it."</i> (P 494)</p> |

Box 4.3: Reusing medicines – what is safe and ethical practice?

Potential reuse of medicines was discussed in relation to recycling or resale of medicines, to reduce wastage, provide greater access to medicines for people who cannot afford them, or to send to developing countries. Some participants expressed ambivalence over the reuse of medicines, occasionally qualifying this according to whether medicines were current, whereas others did not consider expiry date important:

"I don't know. I would never even give it a second thought. I would assume that anything in date, they would donate to people and the out of date, they'd dispose of how they saw fit." (P 2214)

I think some medicines would be appropriate [to send overseas], I don't think they are useless completely when they're past their use by date. Others maybe not, I'd rather they be disposed of. (P 945)

"...I would hope that he [the pharmacist] wouldn't on sell them. I don't know. If he's going to on sell them he should give me a refund. No I would expect that they would dispose of them in a careful manner and responsibly." (P 464)

There was a perception amongst a few participants that their medicines were sent overseas and for some this was seen as a means to reduce wastage. An analogy with donating prescription glasses was offered:

"I know there's a scheme where if you've got old spectacles that you don't use anymore, you can take them back to your specs place and they pass them on and they're able to be used in other countries and programs and things like that. It would [be] wonderful if there was something like that. That they could be used for people who can't afford to buy them..." (P 1524)

Many participants had no concerns with recycling medication in this manner; in fact, that this was seen as helpful as medicines *"in Australia aren't dodgy, you know they're for real"* (P 812), compared to manufacturing processes overseas.

Other participants questioned the ethics of such practices. While such actions no doubt came from good intentions, it raised concerns about valuing our health system over others less fortunate:

"...I think everyone should really be entitled to the best medicine available." (P 1887)

"...My thinking is well, why do they get our cast-offs [medical goods]... They probably deserve just as good as we have....We shouldn't just necessarily throw our rubbish at them. We should sort of fund proper supplies...but I suppose on the other hand it's better to have something rather than nothing..." (P 2252)

One participant explained that you could not tell how a medication had been stored, and therefore, if the medicine was still effective. Other ideas included re-packaging returned medicine for animals, GPs re-issuing returned medicine as samples for other patients, or taking unwanted medication overseas to *"either donate it or sell it to pharmacies over there."* (P 2252). One participant discussed that if medication was going to be re-used, they might as well just keep it.

Risks of storing unwanted medicines in the home

Potential for harm and safety risks were the main concerns raised in interviews, with some reference to environmental concerns. These included decreased efficacy and under treatment, taking medicine prescribed for someone else, sharing medicines, inappropriate self-prescribing or treatment, and side effects from expired medicines (Table 4.16). Unintentional poisoning in children, pets or the elderly, through confusion or use of multiple generic brands, was a particular concern. There was disquiet over the negative health impact if inappropriate medicines were taken in an emergency, or at the wrong dose. A minority highlighted risks of

misuse, or a perception that unused medicine could be sold or trigger break-ins. These concerns underscore the importance of storing medicines safely.

Table 4.16: Risks of storing unwanted medicines in the home

| Topics discussed | Participant quotes |
|--------------------------------|--|
| Loss of efficacy | <p><i>"I guess primarily if it was really out of date it wouldn't be as effective for the purpose it was intended for so it might create issues. Especially if you take something in an emergency and it doesn't do what it's supposed to."</i> (P 945)</p> <p><i>"Number one they won't work. Number two they can change and be not very good for you. It's just – I just don't see the point of keeping anything past the time. They're the best before for a reason..."</i> (P 1423)</p> |
| Unintentional poisoning | <p><i>"There are obviously several [risks] and we touched on it before. If they're not properly stored in the house, children could easily pick them up and eat them. You might be more tempted to share. I've got this, I'm sure, they worked for me I'm sure they'll work for you. You might hand them out to other people, your friends, relatives, family, whatever. Having them lying around at home probably means they'll eventually expire and may not be working as well if you took them say a year or two down the line."</i> (P 2268)</p> <p><i>"Look, it just depends on how careful people are. I mean, particularly if there are young children around then I would be concerned. You've got to keep the stuff secure, either out of height or sight of little people, I mean kids..."</i> (P 139A)</p> |
| Generic medicines | <p><i>"The patient themselves can get confused, particularly when you've got all these generic medicine brands at eye level today and be taking two of one thing! So, it's a bit of a hazard, I think, to have unused medicines and unwanted medicines in the home."</i> (P 65)</p> |
| Self-medication | <p><i>"People may be inclined to, later on down the track, self-medicate without proper advice."</i> (P 1596)</p> |
| Medicines misuse | <p><i>"Well a lot of people have children in their home and teenagers especially will experiment with just about anything. I think if you've got drugs in your home then your kids are going to regardless - they're not interested in dates. They're going to play around with different medication."</i> (P 605)</p> <p><i>"...I also know that a lot of break and enters and all that are happening for people looking for medications..."</i> (P 931)</p> <p><i>"Or you've got someone in the family who is addicted to drugs who might go looking just to try what you have there. That's probably it."</i> (P 2535)</p> |

Opinions on payment for disposal of medicines

When asked whether they would be willing to pay for the safe disposal of their medicines, 82 of the 141 participants who responded (58.2%) were unwilling to pay for such a service, 24.1% agreed that they would pay (n=34/141) and the remaining 25 participants were ambivalent about payment. Participants who were unwilling to pay did perceive value in a disposal of medicines service yet would generally use alternative methods of disposal (e.g. in the rubbish or toilet) and largely considered these methods equally safe:

"No definitely not....Why would I because you can, most of them you can dispose quite safely either down the toilet or you know, down the sink." (P 2177)

"Why would somebody want to pay when it's easier just to throw everything in a bin?" (P 1381)

There was a sense that payment for medicines was sufficient and that disposal should not incur additional costs:

"No. My reasoning for that is I think pharmaceutical companies should be responsible enough to pay for their own... Clean up their own messes. We pay enough. Especially when you weigh it off to the fact that I can flush it down the toilet for free." (P 945)

One participant considered that they were providing a service returning the medicines and expected reciprocity. A few participants would seek out an *"alternative service that maybe does dispose of them safely without charge"* (P1454), or return to clinics for reuse. Others saw it as the responsibility of the government or pharmaceutical companies acting in the interests of public safety, equating it to similar services such as needle exchange:

"I would have thought that it [payment for safe disposal of medicines]... would be something that in public safety that the, either it's controlled by the government or the pharmacy companies." (P 2000)

About a quarter of participants were willing to pay for the safe disposal of medicines but for many this was contingent on a reasonable charge, convenience, and assurances about safe and appropriate disposal. Even participants who were willing to pay expressed concerns that a charge would encourage accumulation of medicines or discourage medicines returns:

"People would tend to store them and only take them down to the pharmacy when they had to and give, perhaps, half a dozen or more in all at once so there was only the one charge hopefully." (P 65)

When asked how payment for disposal of medicines should work, suggestions included by item, by quantity/weight (e.g. a bag of medicines) and as a *"twenty cent surcharge on every prescription"* (P 1433). One participant was only willing to pay if medicines were in date and would be sent to a developing country for reuse. Another felt that the charge should be linked to the amount of medicines returned to encourage sensible use of medicines:

"I think it should go by the quantity that you return because if you're sensible enough, you should time it, that you don't have things that run out of date...If you're returning a lot you should pay more, if you're only returning a little bit, you pay a little bit. Might make people more aware of timing it when they buy stuff and use stuff." (P 1925)

Key findings for Stage Two: ii) Interviews with higher medication users

- A total of 1424 currently unwanted or 'when required' medicines were stored in various locations in the home; examples of inappropriate storage were voiced with respect to temperature or potential access by children or pets;
- Multiple storage locations were used to support/improve medication adherence, although this perhaps inadvertently also contributed to duplication of medicines, including unwanted medicines;
- Key risks associated with storing medicines in the home were related to safety mainly in the context of reduced efficacy and unintentional poisoning;
- About half of medicines were expired or almost expired; some participants were unaware that medicines actually expired, others were happy to use them past expiry, particularly topical, complementary, and/or alternative medicines;
- Variable perceptions of risks associated with use of expired medicines highlights a need for education;
- There was limited evidence of medicines accumulation for chronic conditions although participants admitted to collecting medicines 'just in case', primarily for overseas travel or episodic illnesses. Evidence of collection of 'just in case' antibiotics was particularly concerning;
- The likelihood of returning medicines to the pharmacy appeared to be higher with interview participants which may reflect an educational effect of the survey that could be extended;
- Multiple disposal practices were applied across different medicines schedules and formulations, suggesting variation in perceived risks;
- Variable risk assessments were used to make decisions about storing medicines, using them beyond expiry and applying multiple disposal practices; and
- Significant trust in pharmacists to safely dispose of medicines was tempered by ambivalence over whether this actually occurs and a perception that medicines maybe recycled or sent overseas for reuse.

Insights for National Return and Disposal of Unwanted Medicines Limited and the Department of Health

- A national public campaign that will:
 - Increase awareness of risks related to medicines storage, use of expired medicines and disposal practices, including quality use of medicines and wider environmental impacts;
 - Address misconceptions related to risks in these areas; and
 - Increase awareness of the free national service for returning unwanted medicines to a community pharmacy;
- A pharmacy campaign that will:
 - Train staff to communicate key messages related to unwanted medicines and safe disposal ;
 - Use simple low-cost strategies
 - A reminder sticker placed on prescription medicines;
 - An information card placed in the bag when medicines are picked up / purchased;
 - A poster in pharmacy linked to specific national public campaigns e.g. Be Medicines Wise week, Antibiotic Awareness Week; and
 - Prescription repeat folders printed with key messages.
- A national health promotion campaign to encourage people to clean out unwanted or expired medicines from the home:
 - A one-off or annual campaign that aligns with existing quality use of medicines campaigns such as those run by the National Prescribing Service; and
 - Local pharmacy health promotions to encourage return of unwanted or expired medicines; and
 - Further research to explore the significance in variation of perceived risks, consumer risk assessments used, behaviour related to storage of medicines, using expired medicines and disposal practices.

5 Key Findings and Recommendations

This section provides the:

- a) Key findings regarding firstly the quantity and types of unwanted medicines currently being returned to Australian community pharmacies for disposal, and secondly general public storage and disposal practices of unwanted medicines in the 12 months prior to the survey, awareness of the NatRUM scheme, and public perspectives about safety and risks of unwanted medicines storage and disposal, and the potential for campaigns to improve awareness and safety; and
- b) Key recommendations regarding the role that the Department of Health and National Return and Disposal of Medicines Limited can play in improving awareness of safe medicines storage and unwanted medicines disposal, and education and resources for community pharmacy staff and other healthcare practitioners.

The findings of this research should be widely disseminated to professional and consumer organisations, pharmacists and support staff to promote awareness of the NatRUM scheme and the role of community pharmacy in appropriate disposal of unwanted medicines.

1. Medicines returned to community pharmacies were disposed of in RUM bins appropriately and safely. Audit results from 2016 are similar in terms of the most frequently dispensed PBS medicines in 2015.

Liquid cytotoxic agents, Schedule 8 items (without evidence of destruction in some States and without exception in others States) and sharps are all classified under the RUM scheme as 'inappropriate', that is, they should not be disposed of in RUM bins. Overall, there was limited evidence of inappropriate items/materials in audited bins. There were no liquid cytotoxic agents (Appendix 4); a total of 413 Schedule 8 items were identified from the total of 26,114 items (1.6%) (Appendix 5); around 11% of RUM bins contained sharps (Appendix 6), seven bins were excluded from audit because they contained more than 50% of their contents as general rubbish, but apart from these bins, only small amounts of general rubbish found.

The content of RUM bins, in terms of the most frequently reported medicines, are very similar to the last audit and have similarities with the most frequently dispensed PBS medicines (Table 3.8). These findings suggest that PBS listed medicines, rather than over-the-counter, complementary or alternative and/or unscheduled products comprise a larger proportion of bin contents. This is supported by data from the interviews that inappropriate disposal methods were more frequently used for over-the-counter, complementary, alternative and/or unscheduled products (Box 4.2). The most common medicines are also consistent with the 2005 Victorian study of medicines taken to a community pharmacy for disposal (6).

The similarity in audit results over a three-year period suggests that there is not necessarily a need for frequent national audits of the size and complexity of this audit, and the one undertaken in 2013. Rather, more frequent and targeted monitoring may be more efficient and provide more real-time feedback about the impact of campaigns and protocol updates. The low level of inappropriate medicines or items in the RUM bins highlights the value of the service provided by community pharmacists in promoting medicine safety through appropriate disposal.

Recommendations

1a. The existence of inappropriate items in RUM bins requires monitoring but this could be done more efficiently and economically than periodic large national audits. Targeted random checks of bins for

inappropriate items (i.e. Schedule 8 medicines and sharps) may be justified to improve compliance with collection protocols and evaluate the impact of protocol updates.

1b. The definition of 'sharps' and the acceptability of disposing of pre-filled capped syringes in RUM bins in particular should be more explicitly specified in the RUM pharmacy collection protocol. This information should then be communicated effectively to pharmacists.

1c. Ongoing information and training for pharmacy staff is recommended to maintain vigilance. For example, placement of a sticker on the top of RUM bins reminding pharmacy staff not to dispose of inappropriate items in RUM bins.

2. The majority of medicines in RUM bins were not high cost PBS items. The estimation of PBS waste (all dispensed and unopened medicines, irrespective of expiry date) collected via the NatRUM scheme in Australia for one year is \$11,629,231 AUD.

In terms of the highest 'cost' items, using PBS prices, there were no instances of high cost items being disposed of frequently (Table 3.9; Table 3.10). We have estimated the total cost of PBS waste returned in RUM bins in Australia over a one-year period using four definitions of 'PBS waste' to range between \$6,326,538 to \$26,960,385 (using Manufacturer's 'Ex-Manufacturer Price' for a manufacturer's pack, Oct 2016) (Table 3.11), depending on the definition of 'waste' used. When we use our preferred definition, that is, 'dispensed and unopened, irrespective of expiry date', the estimate is \$11,629,231 AUD. This figure is higher than the previous estimate AUD (2012) of \$2.055 million from the 2013 RUM audit, which was based on a restricted sample of 31 medicines from the audit and a different methodology (11).

Recommendations

2a. The term 'PBS waste' should be used with caution. Using the methodology described here, estimates of waste differ substantially under different assumptions. Defining waste to include opened packets (where there could be valid clinical reasons for discontinuation) has far-reaching implications with regard to existing supply arrangements.

2b. Whilst consideration could be given to decreasing pack sizes for high cost medicines, or for consumers who are initiating or changing treatment, this needs to be balanced with minimal impact on financial burden of treatment for people with serious and complex chronic conditions.

3. The Australian population generally did not know how to dispose of unwanted medicines safely and appropriately and were largely unaware of the national RUM scheme.

Almost 60% of the Australians we surveyed had disposed of some unwanted medicines in the last year, which was more than double the proportion of respondents in the most recent ABS Waste Management, Transport and Motor Vehicle Survey (Table 4.3). However, only about one in five respondents had taken these unwanted medicines to a community pharmacy for safe disposal (pg. 41, Table 4.4), which was lower than the rates reported in the ABS Surveys (Table 4.4) and the interviews (Table 4.14). Most commonly respondents disposed of their unwanted medicines with the usual household garbage and/or took it to the dump or poured it down the drain or toilet (Table 4.4). Similar disposal practices were described in the interviews and many considered these improper disposal practices particularly appropriate for over-the-counter, unscheduled, complementary and alternative medicines (Box 4.2). In addition, although most survey respondents had no previous knowledge about the NatRUM program (Table 4.5), when provided with information more than 90% reported that they

would now use the national scheme for medicines disposal, a position which was reconfirmed in the interviews (Table 4.14).

Recommendations

3a. A national television campaign, which primarily targets viewing times of people who use multiple medicines, should be conducted to increase general awareness of the NatRUM scheme. Such a campaign could be conducted in conjunction with the National Prescribing Service's *Be Medicinewise Week* or The Pharmacy Guild of Australia's *Ask Your Pharmacist* consumer campaign. Any awareness campaign should include key messages that address consumer concerns about returning medicines to pharmacies, such as privacy and concerns related to the reuse and wastage of medicines.

3b. Community pharmacies should run a grassroots campaign. This could be a simple strategy that consisted of pharmacists placing a sticker on all dispensed medicines for one month in every six, reminding people to return their unwanted medicines to the pharmacy. Prescription repeat folders used in the campaign months should contain a similar message. We acknowledge that individual pharmacies or pharmacy groups may have conducted grassroots campaigns in the past and identification and evaluation of these could inform future campaigns. Our survey provides current evidence of low consumer awareness of the service that needs to be addressed.

3c. An annual one month health promotion campaign should be considered to encourage people to clean out unwanted or expired medicines from their homes and return them to the pharmacy. This could be run in conjunction with the television and/or sticker campaigns, creating efficiencies through an annual planning process.

4. Less than half of healthcare workers asked patients if they had unwanted medicines in the home and if they did most commonly they recommended disposing of these with the household rubbish and/or taking to the dump.

Only 8% of the survey respondents were healthcare workers (including hospital staff) who had patient contact, however, less than half of these respondents regularly asked their patients whether they had unwanted medicines in the home (Table 4.7). When they did check with their patients, the most commonly recommended method of disposal was with the usual household garbage and/or take to the dump (69.2%); followed by return to a pharmacy or chemist (52.6%) (Table 4.8).

Recommendations

4a. General education is recommended for all healthcare workers and those in training programs to raise awareness of safe and appropriate disposal practices for unwanted medicines, and of the NatRUM scheme. The aim of this education should be to promote a whole-of-health-team approach, to ensure that multiple healthcare workers opportunistically ask people about unwanted medicines on a regular basis.

4b. Targeted education should be provided to specific healthcare workers and teams whose patients might use multiple medicines, such as palliative care, mental health, chronic pain and aged care.

4c. Targeted education about the NatRUM scheme could be provided to support staff in medical practices (i.e. medical receptionists and practice nurses), pharmacies (i.e. pharmacy assistants and technicians) and aged care facilities (i.e. enrolled nurses and carers).

5. People reported large proportions of medicines in their homes that were unwanted, expired or used infrequently, potentially exposing vulnerable household members to risk of harm.

Sixty percent of survey respondents reported having unwanted medicines across different medicines schedules in their home and 1424 unwanted, expired or 'when required' medicines were currently stored in the 166 homes of the interview participants (Table 4.2; Box 4.1; Table 4.11). Factors influencing medicines accumulation included prescriber changes, medicines were no longer required, and ensuring adequate supplies for future use and convenience (Box 4.1; Table 4.12). It became apparent through the interviews that participants were often unaware of the volume of unwanted medicines in the household. About half of these medicines were expired or expiring within six months (Table 4.11) and whilst participants recognised the risks of having unwanted medicines in the home for vulnerable household members (Table 4.9; Table 4.16) some were confident about retaining and using medicines beyond expiry. Expired medicines was the most common reason for disposal in the survey (Figure 4.1) and recognition of the presence of unwanted medicines in the home during the interview prompted some people to clean out their medicines. Interview participants stated that they would return medicines to the pharmacy (Table 4.14) with greater frequency than survey respondents (Table 4.4) possibly reflecting an educational impact of the survey and highlighting the need for further education.

Recommendations

5a. Educational strategies should be trialled to ascertain those with the highest impact on encouraging people to clean out their medicine cabinets and return unwanted or expired medicines to the pharmacy. These strategies will be informed by the findings from the general population survey and the interviews. Examples of strategies include aligning with existing quality use of medicine campaigns such as the National Prescribing Service's *Be Medicinewise* Week or the Pharmacy Guild of Australia's *Ask Your Pharmacist* consumer campaign.

5b. A one-off, or annual one month, health promotion campaign should be considered to encourage people to clean out unwanted or expired medicines from their cupboards and return them to the pharmacy. The campaign should include key safety messages related to risk on unintentional poisoning and appropriate disposal practices.

5c. Community pharmacies should run a grassroots campaign reminding people to return their unwanted medicines every six months. Pharmacy staff should be trained to deliver key messages related to unwanted medicines and safe disposal. Simple low-cost strategies should be used such as printed repeat folders containing similar messages, reminder stickers on prescription medicines and information cards placed in the bag when medicines are picked up / purchased.

5d. Medication management services such as MedsChecks® and Home Medicines Reviews should specifically address whether people have unwanted or expired medicines in the home. Research could explore the impact of these services on the quantity and nature of unwanted, unused or expired medicines in the home.

6. Variable perception of risk related to storage, therapeutic use, expiry and appropriate disposal of medicines has implications for quality use of medicines.

The significant numbers of unwanted medicines that were stored in homes, highlighted in Key Finding 5, may introduce risks that are not necessarily recognised by participants. Although the risks for vulnerable household members were generally recognised, there was less emphasis on other important risks, for example sharing or

reusing medicines (Table 4.9; Box 4.3; Table 4.16). Different perceptions of risk related to retaining medicines for future use and/or use beyond expiry emerged, with limited understanding of more high risk situations such as using eye preparations beyond the recommended expiry once opened. The perception of lower risks associated with non-prescription or complementary and alternative medicines emerged through greater confidence in using these medicines beyond their expiry and more frequent use of inappropriate disposal practices for these medicines (Table 3.3; Table 3.8; Box 4.2). It is unclear what influences variability in risk perceptions and associated consumer behaviour. Concerns related to returning medicines to the pharmacy such as assumptions about inappropriate disposal practices within pharmacies, or recycling medicines for reuse, could be influential (Table 4.6; Table 4.15; Box 4.3).

Recommendations

6a. Expiry dates need to be highly visible and easy to read to reinforce the importance of applying them to medicines use.

6b. Targeted education for healthcare workers could promote reinforcement of the importance of expiry dates in higher risk situations (e.g. chloramphenicol eye drops, insulin, specific formulations; reconstituted antibiotic liquids; and tetracyclines).

6c. Additional education is needed to address misperceptions of risk related to retaining unused medicines, therapeutic use of stored or expired medicines and appropriate disposal practices, particularly for non-prescription medicines, topical products, liquids, complementary and/or alternative medicines. Such education could encourage a more informed risk assessment by consumers. Existing structures such as the NPS website and communication strategies should be utilised to promote increased awareness of appropriate storage, therapeutic use and application of expiry dates and disposal practices. These should target all stakeholders in quality use of medicines including health workers, health consumers and carers. For example, case studies for GPs and pharmacists could be designed to highlight consumer misperceptions and promote grassroots education. Stakeholders such as the consumer health forum and carer organisations should be consulted as part of this process.

6d. Additional insight is needed into the variance in consumer perceptions of risk and risk assessment rationales and strategies. Further research could ascertain public perceptions and inform future health promotion campaigns related to both the disposal of medicines and quality use of medicines.

5.1 Strengths and limitations

Strengths of this research included the audit of a statistically representative sample of returned medicines Australia-wide via the NatRUM scheme, the size and representation of the Australian adult population samples surveyed and interviewed, and the combination of qualitative and quantitative methods. This national audit of returned medicines was informed by a previous audit. Our 2016 method firstly increased representation by including medicines returned via the RUM bins from all states and territories and, secondly, collected more detailed data to enable greater precision in calculation and extrapolation of potential wastage of medicines when comparing to PBS dispensing and cost data. There were both strengths and limitations with using the Australian Medicines Terminology as the basis of the bin audit database. Using this terminology ensured consistency in the medicines terms used; however, PBS data has not yet been fully reconciled with these terms meaning that the matching of PBS data was incomplete. Manual matching was undertaken for the small subset of medicines for which matching could not be automated. Further, a small proportion of items had to be manually entered, making data cleaning and analysis of this subset more difficult and time consuming.

The research also investigated the disposal practices of consumers with unwanted medicines stored at home through a large General Population Survey. This provided a more holistic view on unwanted medicines disposal in the community, supplementing audit data about those medicines already returned to a community pharmacy for disposal. Additionally, structured interviews were conducted with a sub-population of higher medication users to explore medicines disposal practices in greater depth and investigate medicines storage in their homes in order to identify whether accumulation is an issue and if so, to explore influencing factors.

The 2016 national audit data collection process involved 33 individuals (15 pairs of data collectors and three additional people, one at each site to work with the Data Collection Manager), which was a practical solution to manage the size and geographical needs of the audit, however it introduced challenges for standardisation. Consequently, we introduced a number of strategies to minimise this issue which included: standard operating procedures; data collection protocols and training; real-time data entry directly into a database with limited free-text options; oversight and scrutiny by the Data Collection Manager at all sites; and quality checking of medicines audit processes and data entry for all data collectors. The General Population Survey was delivered by an experienced panel research company and was restricted to people registered with the company and with internet access. This may have introduced a degree of selection bias. Similarly, interview participants self-selected into the interview process from the survey and not all potential participants could be contacted during the times that interviews were conducted. Strategies introduced to minimise selection bias included conducting interviews at a range of times including evenings and weekends and screening participants purposively. It was not always possible for participants in multiple occupancy households to provide information for the entire household, potentially resulting in under-reporting of the overall volume of unwanted medicines in that particular home.

5.2 Conclusion

This research combined a national audit of returned medicines with a General Population Survey and structured interviews to provide a more holistic view of current medicines storage and disposal practices, and to identify areas for information campaigns and education on quality use of medicines. The research provides evidence at a number of levels that greater knowledge is needed by all stakeholders in quality use of medicines, particularly in relation to appropriate disposal practices for unwanted medicines stored at home. It is encouraging that medicines are being disposed of in RUM bins in community pharmacies appropriately and safely, that trends for returned medicines remained similar over time and that wastage of medicines was limited. However, evidence from the survey and interviews supports the finding that the majority of the population were unaware of the NatRUM scheme but were willing to use it once informed, reflecting a need for consumer information and reminder campaigns. Healthcare workers did not always ask their patients about unwanted medicines in the home or recommend appropriate disposal practices, further highlighting the need for targeted information and training. Evidence of large proportions of medicines in homes that are expired, used or unused but no longer needed, potentially exposed all household members to a range of risks which were currently not recognised by participants. Research findings provide initial insight into the variable risk perceptions, risk assessment and medicines use and disposal behaviour amongst consumers, with implications for quality use of medicines and risk of harm.

We need national and grassroots information campaigns that target all stakeholders in quality use of medicines including healthcare workers and members of the general population, and particularly for those who use, or care for people who use, multiple medicines. Education should be informed by previous campaigns in pharmacies and promote a whole-of-health-team approach, so as to ensure that multiple healthcare workers opportunistically ask people about unwanted medicines on a regular basis, for example healthcare workers in aged care, and pharmacists conducting Home Medicines Reviews. To ensure the effectiveness of such campaigns it is important that they are informed by input from stakeholders such as consumer and carer organisations, and align with existing quality use of medicine campaigns. These strategies will ideally encourage people to regularly check and clean out their medicines, limit inappropriate medicines use and/or accumulation, and promote appropriate medicines disposal.

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Appendices

Data Collection Protocol

NatRUM project 2016

Staff Confidentiality Agreement

“Confidential Information” means all information, data, know-how or experience relating to the personal data of the medicines labels including names, addresses, etc. or pharmacy label information in all forms including documents, databases, records, drawings, oral disclosures.

DATA COLLECTORS CONFIDENTIAL OBLIGATIONS

1. The Data collector agrees not to make any use whatsoever of the Confidential Information;
2. Not to reveal any confidential information to any person except for the Data Collection Manager;
3. To keep all information strictly confidential;
4. To take such steps as are reasonable to preserve the confidentiality of the information;
5. Not to make copies or duplicates of confidential information except to the extent that it is reasonably necessary to carry out the Employer’s duties.

SITE SAFETY RULES

Each site has a set of Site Safety Rules which will be communicated to you when you enter a site. You must follow the site safety rules at all times. Common site safety rules include:



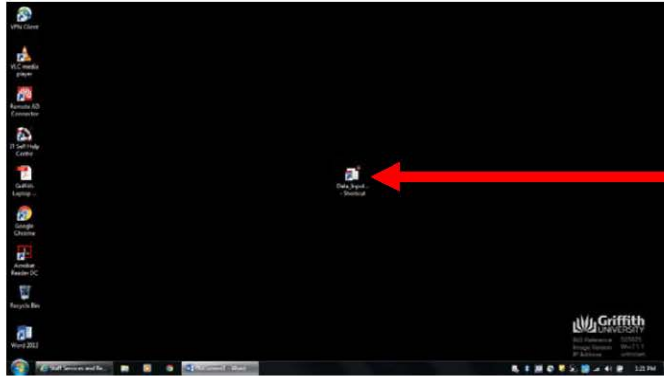
- Obey all site safety signs
- PPE must be worn in relevant areas
- Appropriate clothing and footwear must be worn
- Smoking is only permitted in designated areas
- Horseplay and skylarking are prohibited
- Animals are prohibited on site
- Only use mobile phones in selected areas on site
- Passengers are not allowed in trucks, plant or equipment without the approval of the Site Manager
- Scavenging from any waste stream and retaining it for personal use or benefit is not permitted
- All injuries, incidents and plant defects must be reported immediately
- Restricted access areas are prohibited unless with the Site Manager's approval.

LOGIN: .\natrum

Password: HSVnatrum2016

OPEN ACCESS DATA BASE:

1) Open Access Data Base:



2) First, we will introduce the BIN information: Add New Bin



Each bin lid will be photographed prior to opening

2) Type Bin ID and Data associated with it:

New Bin

Enter New Bin Details

Bin ID:

Date Entered:

Counted By:

Recorded By:

Checked By:

State Of Origin:

Label Location:

Weight Of Bin:
*Including Bin

Volume Of Contents:

☐ Bin contents make-up less than 50% of the bin volume

☐ Greater than 50% of the bin contents are NOT medicines/therapeutic goods/sharps

☐ Greater than 50% of the bin contents are loose tablets

☐ Bin contents appear noxious or unsafe for assessment (e.g. biological material)

Inappropriate Items?

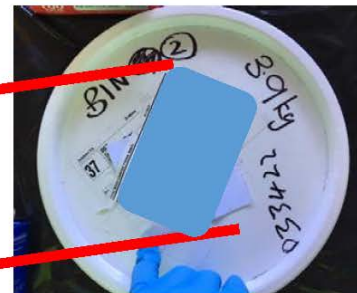
☐ None

☐ Sharps* ☐ Biological Waste

☐ S8 Medicines ☐ General Waste

☐ Other ☐ Cytotoxic

Other Details:



3) When is the bin **Excluded**?

New Bin

Enter New Bin Details

Bin ID:

Date Entered:

Counted By:

Recorded By:

Checked By:

State Of Origin:

Label Location:

Weight Of Bin:
*Including bin

Volume Of Contents:

☐ Bin contents make-up less than 50% of the bin volume

☐ Greater than 50% of the bin contents are NOT medicines/therapeutic goods/sharps

☐ Greater than 50% of the bin contents are loose tablets

☐ Bin contents appear noxious or unsafe for assessment (e.g. biological material)

Bin Excluded ☒

Inappropriate Items?

☐ None

☐ Sharps* ☐ Biological Waste

☐ S8 Medicines ☐ General Waste

☐ Other ☐ Cytotoxic

Other Details:

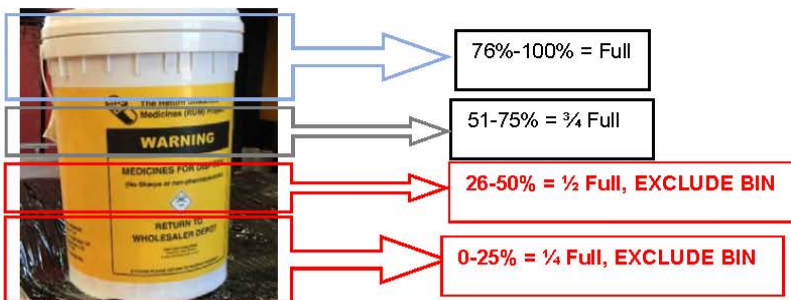
4) Examples of bins to be excluded



Greater than 50% bin contents are loose tablets



Bin contents make up less than 50% of bin volume



5) Inappropriate Items?

New Bin

Enter New Bin Details

Bin ID:

Date Entered:

Counted By:

Recorded By:

Checked By:

State Of Origin:

Label Location:

Weight Of Bin:

Volume Of Contents:

Inappropriate Items?

☒ None

☐ Sharps* ☐ Biological Waste

☐ S8 Medicines ☐ General Waste

☐ Other ☐ Cytotoxic

Other Details:

☐ Bin contents make-up less than 50% of the bin volume

☐ Greater than 50% of the bin contents are NOT medicines/therapeutic goods/sharps

☐ Greater than 50% of the bin contents are loose tablets

☐ Bin contents appear noxious or unsafe for assessment (e.g. biological material)

☐ Bin Excluded

**TYPE AS MUCH
INFORMATION AS
POSSIBLE AND
PHOTOGRAPH**

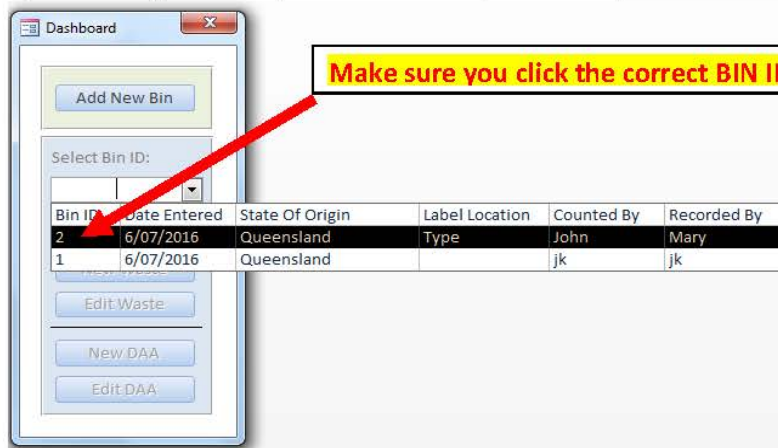


Example: cytotoxic medicines,
sharps, S8 medicines, tea towel,
empty coffee cups etc.

Type items full details and
photograph

6) Select Save + Close

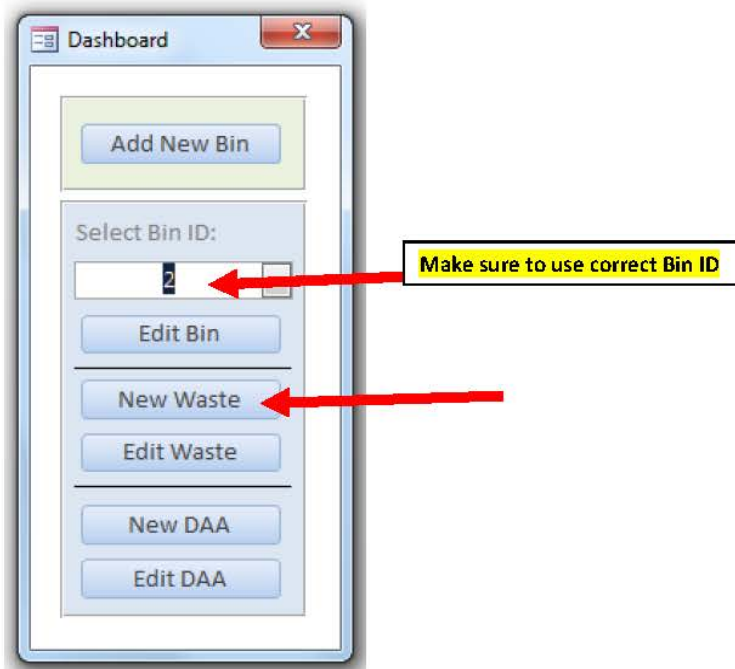
7) Next to begin data entry for the Waste items, make sure to select the correct BIN ID number:



Make sure you click the correct BIN ID!

| Bin ID | Date Entered | State Of Origin | Label Location | Counted By | Recorded By |
|--------|--------------|-----------------|----------------|------------|-------------|
| 2 | 6/07/2016 | Queensland | Type | John | Mary |
| 1 | 6/07/2016 | Queensland | | jk | jk |

8) Once the correct Bin ID is selected, start data entry for New Waste:



Make sure to use correct Bin ID

New Waste

- 9) **Medication Details:** Type the first 3 letters of the item, then **CHOOSE** from dropdown list:

Enter New Waste Details Bin ID: 2

Medication Details: **Elocon 0.1% lotion, 30 mL**

Medication not in list? ☐ Elocon 0.1% cream, 15 g

Sample Pack? ☐ Elocon 0.1% cream, 45 g

Manual Description: Elocon 0.1% cream, 50 g

Is the packed opened? ☐ Elocon 0.1% lotion, 30 mL

If unopened, how many packets? Elocon 0.1% ointment, 15 g

* with same expiry date Elocon 0.1% ointment, 45 g

Schedule: Elocon 0.1% ointment, 50 g

Packaging Included? ☐ Elocon Alcohol Free 0.1% cream, 15 g

Expiry Date: Elocon Alcohol Free 0.1% cream, 5 g

Dispensing Label? ☐ Elocon Alcohol Free 0.1% cream, 50 g

Year Dispensed: Eloflex (2480) 10 cm x 3.5 m bandage: high stretch, 1

Dispense Category: Elova 100 microgram/0.5 mL injection: solution, 0.5 mL syringe

If S8, evidence of destruction? ☐ Elova 150 microgram/0.5 mL injection: solution, 0.5 mL syringe

Elovax One Dose 500 mg tablet: film-coated, 3

Eloxatin 100 mg/20 mL injection: concentrated, 20 mL vial

Eloxatin 200 mg/40 mL injection: concentrated, 40 mL vial

Cancel Save + Close

- 10) **Medication not in the list?** CLICK 'Medication not in the list' and TYPE in 'Manual Description'

Enter New Waste Details Bin ID: 2

Medication not in list? ☒

Sample Pack? ☐

Manual Description: Name: Form: Strength: Amount:

Is the packed opened? ☒

If unopened, how many packets?

* with same expiry date

Schedule: Unknown

Packaging Included? ☒

Expiry Date: 6/07/2010

Dispensing Label? ☐

Year Dispensed:

Dispense Category:

If S8, evidence of destruction? ☐

Quantity Box

Number remaining?

E.g. For tablets, capsules, ampoules, rebules etc.

If liquid, what is its estimated volume? 50

If creams/gels, what is its weight?

If inhalers, what is its weight?

Cancel Save + Close

11) Sample Pack? Click if YES

The screenshot shows a software window titled "New Waste Details" with a subtitle "Enter New Waste Details". At the top right, there is a "Bin ID:" dropdown menu set to "2". Below this is a "Medication Details:" dropdown menu. Underneath, there is a checkbox labeled "Medication Details?" which is checked. The "Sample Pack?" checkbox is circled in red and is currently unchecked. Below the checkboxes, there are four input fields: "Name:" containing "acetone", "Form:" containing "liquid", "Strength:" which is empty, and "Amount:" containing "100ml". A large text area for "Manual Description:" is located below these fields. At the bottom right of the window are two buttons: "Cancel" and "Save + Close".

12) When the medication item is in the list, enter required information as described :

-Open packs are: open box, loose blisters, open eye drops, open bottles of capsules or tablets,

IF ANY DOUBT ASK THE DATA COLLECTION MANAGER

The screenshot shows the 'Edit Waste Details' form. At the top, there's a 'Bin ID' dropdown set to '77'. Below it, the 'Medication Details' section has a dropdown menu showing 'Norspan 5 microgram/hour patch\, 2'. There are checkboxes for 'Medication not in list?' and 'Sample Pack?'. Below these are input fields for 'Name:', 'Form:', 'Strength:', and 'Amount:'. A red box highlights the 'Is the packed opened?' checkbox, which is checked. A red arrow points from this box to the 'Quantity Box' section. In the 'Quantity Box', there's a 'Number remaining?' field with the value '0'. A red box with the text 'Please enter 0 (zero) if the container is empty' has an arrow pointing to this field. Below 'Number remaining?' are three more input fields: 'If liquid, what is its estimated volume?', 'If creams/gels, what is its weight?', and 'If inhalers, what is its weight?'. At the bottom right is a 'Close' button. The footer shows 'Record: 55 of 86' and a 'Filtered' status.

Bin ID: 77

Medication Details: Norspan 5 microgram/hour patch\, 2

Medication not in list? ☐

Sample Pack? ☐

Manual Description: Name: Form: Strength: Amount:

Is the packed opened? ☒

Quantity Box

Number remaining? 0

If liquid, what is its estimated volume?

If creams/gels, what is its weight?

If inhalers, what is its weight?

Close

Record: 55 of 86 Filtered Search

For Open Packs:



stock photo

Count number of tablets



Expiry date

Loose blisters with the same expiry date, can be counted as an item.

PLEASE ASK DATA COLLECTION MANAGER



Opened creams or gel tubes: Please weigh with provided scales, type in weight.



Opened bottles of capsules or tablets: Please count with counters provided

For Liquids: Opened when seal is broken



ESTIMATE PERCENT REMAINING –
DO NOT TYPE % SYMBOL

76% TO 100% FULL → TYPE 100

50% TO 75% → TYPE 75

25% TO 50% → TYPE 50

0% TO 25% → TYPE 25

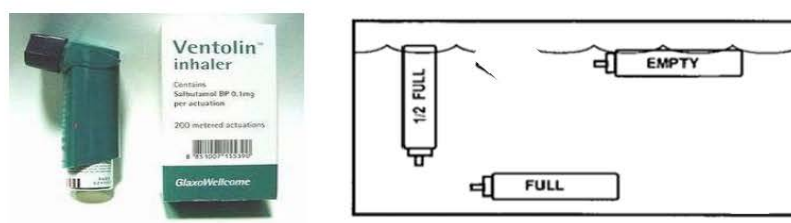
EMPTY → TYPE 0

For Inhalers, there are two types:

1) WITH DOSAGE INDICATION



2) NO DOSAGE INDICATION



FOR INHALERS 1) WITH DOSAGE INDICATION, [Type number of doses left]

FOR INHALERS 2) NO DOSAGE INDICATION, [See below]:

0.9 IF INHALER SINKS IN WATER (full but opened)

0.5 IF INHALER FLOATS DOWN

0.1 IF INHALER FLOATS ON TOP OF WATER

For

Bricanyl Turbohalers do not drop in water.

White window used [type 0.5];

Red window [type 0.1]



Used: TYPE 0.5



Empty: TYPE 0.1

IF ANY DOUBT PLEASE ASK THE DATA COLLECTION MANAGER

This is counted as a complete unit – the plastic is still surrounding the inhaler



- 13) When item is sealed (unopened) e.g. sealed boxes, bottles, eye drops, creams, gels, inhalers
[WITH SAME EXPIRY TYPE QUANTITY OF ITEMS]

****When you find multiple sealed items with different expiry dates, they have to be entered as separate items****

IF ANY DOUBT ASK THE DATA COLLECTION MANAGER



**5 boxes with
the same
expiry date**

New Waste Details

Enter New Waste Details

Bin ID: 2

Medication Details: Aspirin (Bayer) 300 mg tablet: uncoated\, 100

If unopened, how many packets?

* with same expiry date

Cancel Save + Close

14) Choose from dropdown list for all medication items that are NOT Schedules 2,3,4,8 medicines:

Complementary listed medicines (Aust L): includes vitamins, fish oil, homeopathy items, herbs

We are not counting the content (e.g. tablets, capsules) remaining in the container items, just giving them a proportion statistic eg 0,25 ,50 ,75 or 100

Unscheduled items: includes items available from supermarkets including baby milk, osmelax, elastoplast spray, unsued bandages, Rennie antacid, Spiriva handihaler, diagnostic test strips, amongst others.



International items: can be from an assortment of schedules, - PLEASE ASK THE DATA COLLECTOR MANAGER.

Unknown items: include schedule 1, 5, 6, 7 and 9 (e.g. glacial acetic acid = poison)

IF ANY DOUBT ASK THE DATA COLLECTION MANAGER

15) Expiry date: [Enter if this information is legible] [Type 01/01/1901 if not legible]

The screenshot shows the 'Edit Waste Details' form. The 'Expiry Date' field is highlighted with a red circle. Below it, a red box contains the instruction: 1) [Type 01/01/1901 if not legible]. The form includes fields for Medication Details, Manual Description (Reducta), Form (Chewing Gum), Strength, Amount (30), and a Schedule dropdown set to 'Unscheduled'. The 'Expiry Date' is currently set to 29/10/2015.

16) Dispensing Label: Tick if you can see a dispensing label, and complete year dispensed if visible, otherwise select unclear.

The screenshot shows the 'Edit Waste Details' form. The 'Dispensing Label?' section is highlighted with a red box. It includes a checkbox for 'Dispensing Label?' which is checked. Below it is a 'Year Dispensed' dropdown menu. A list of years from 2010 to 2016 is shown, with '2015' selected. The 'Dispense Category' is set to '2015'. The 'If S8, evidence of destruction' field is empty. The 'Delete' button is visible. The 'Record' bar at the bottom shows '1 of 44'.

- 17) Dispensed Category:** Review dispensing category table to select from dropdown list.
Check with DATA COLLECTION MANAGER if any doubts.

Edit Waste Details

Bin ID: 90

Medication Details:

Medication not in list? ☒

Sample Pack? ☐

Name: Reducta Form: Chewing Gum Strength: Amount: 30

Manual Description: Reducta Chewing Gum 30

Dispensing Label? ☒

Year Dispensed:

Dispense Category:

If S8, evidence of destruction:

General
Hospital
Concession
Safety-net
Private
Doctors Bag
Unclear or unknown from label

Delete Close

Record: 1 of 44

BRAND NAME

ACTIVE INGREDIENT

30 SUPERSTAT TABLETS 10mg
[Simvastatin]

Take ONE tablet at night.
Avoid eating grapefruit or drinking grapefruit juice.

Mr A. Contos

Dr D Thorpe
20/10/2011

KEEP OUT OF REACH OF CHILDREN

Full cost
XXX.XXX

THE COST OF MEDICINE WILL DETERMINE THE DISPENSING CATEGORY

DOWNTOWN PHARMACY
64 Brisbane St, Perth WA 7000 Tel: 08 9555 8200

Dispensing Category Table

| YEAR | General Price paid | Concessional Price paid | Hospital | Safety - net | Doctor Bag | |
|-----------|--------------------|-------------------------|----------|--------------|------------|---|
| 1/01/2000 | \$20.60 | \$3.30 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/07/2000 | \$20.60 | \$3.30 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2001 | \$21.90 | \$3.50 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2002 | \$22.40 | \$3.60 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2003 | \$23.10 | \$3.70 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2004 | \$23.70 | \$3.80 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2005 | \$28.60 | \$4.60 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2006 | \$29.50 | \$4.70 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2007 | \$30.70 | \$4.90 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2008 | \$31.30 | \$5.00 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2009 | \$32.90 | \$5.30 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2010 | \$33.30 | \$5.40 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2011 | \$34.20 | \$5.60 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2012 | \$35.40 | \$5.80 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2013 | \$36.10 | \$5.90 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2014 | \$36.90 | \$6.00 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2015 | \$37.70 | \$6.10 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |
| 1/01/2016 | \$38.30 | \$6.20 | ? | \$0.00 | No price | Patient name the same doctors prescribed name |

IF ANY DOUBT ASK THE DATA COLLECTION MANAGER

18) For any S8 items, tick if any evidence of destruction? Click if the containers are empty.

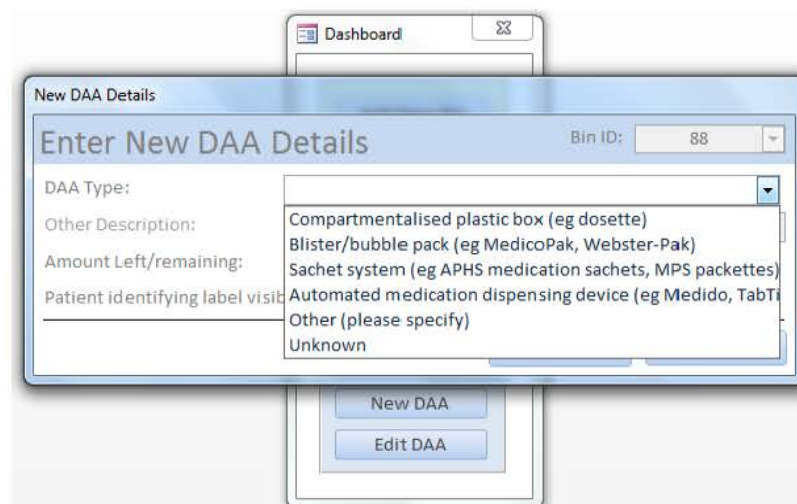
19) Save + Close

The screenshot shows a web-based form titled 'New Waste Details'. The main heading is 'Enter New Waste Details'. There is a 'Bin ID' dropdown set to '2'. The 'Medication Details' section has a dropdown menu showing 'Ranitidine (Chemists' Own) 150 mg tablet: film-coated, 28'. Below this are checkboxes for 'Medication not in list?' and 'Sample Pack?'. The 'Manual Description' section has fields for Name, Form, Strength, and Amount. There is a checkbox for 'Is the packed opened?' which is checked. Below that is a field for 'If unopened, how many packets?' with a note '- with same expiry date'. The 'Schedules' dropdown is set to 'PHARMACY MEDICINE (S2)'. The 'Packaging included?' checkbox is checked. The 'Expiry Date' is set to '13/04/2016'. The 'Dispensing Label?' checkbox is checked. The 'Year Dispensed' is set to '2013'. The 'Dispense Category' is set to 'Concession'. At the bottom, there is a checkbox for 'If S8, evidence of destruction?'. The 'Quantity Box' section has a 'Number remaining?' field set to '22' and three empty fields for 'If liquid, what is its estimated volume?', 'If creams/gels, what is its weight?', and 'If inhalers, what is its weight?'. At the bottom right, there are 'Cancel' and 'Save + Close' buttons. The 'Save + Close' button is circled in red.

20) FOR DAA (Dose Administration Aids): **Check bin number is the correct one** then select New DAA



21) Choose DAA Type from dropdown list:



22) Amount Left / remaining: Please see Table below.

| Days complete/week | amount left/remaining |
|-----------------------|-----------------------|
| 0 | 0% - 25% |
| 1 | |
| 2 | 25% - 50% |
| 3 | |
| 4 | 50% - 75% |
| 5 | |
| 6 | 75% - 100% |
| 7 | |

Example of Blister / bubble packs:



NOTE:

**THIS DAA IS FULL (CLICK 75% - 100%) EVEN THOUGH
EMPTY BLISTERS ARE VISIBLE IN FIRST AND THIRD ROW**



NOTE:

**THIS DAA is 3/4 FULL (Select 50% -
75%)**

Example of Sachet Roll system (AHPS / MPS packettes)

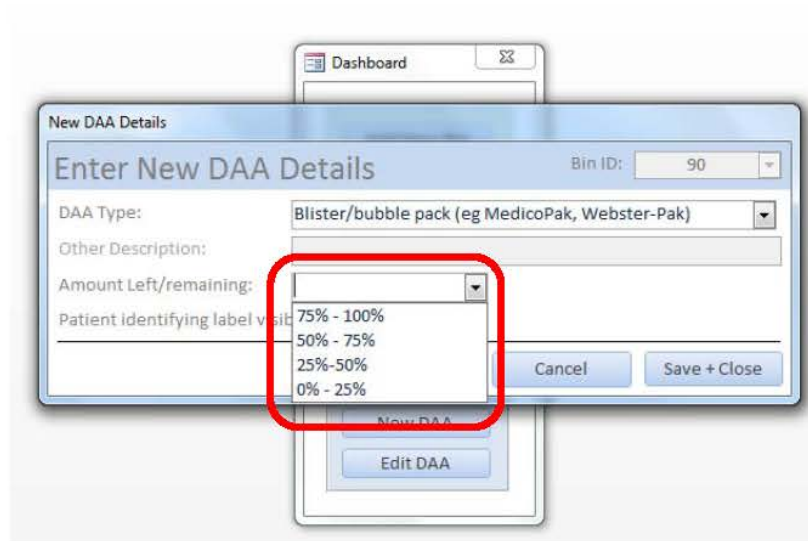


****Please ask for assistance from the Data Collection Manager****

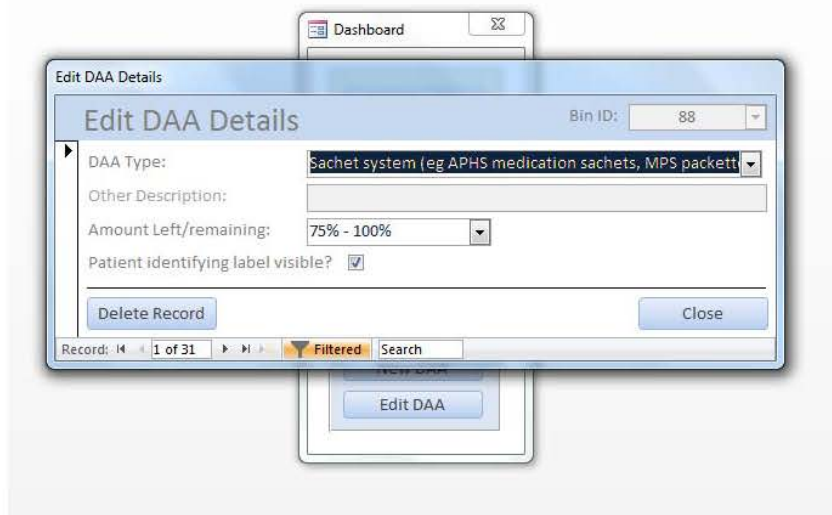
ONE DAA is 7 consecutive days (one week)

-Carefully count the number of days and refer to table below to choose option in dropdown menu

| Days complete/week | amount left/remaining |
|--------------------|-----------------------|
| 0 | 0% - 25% |
| 1 | |
| 2 | 25% - 50% |
| 3 | |
| 4 | 50% - 75% |
| 5 | |
| 6 | 75% - 100% |
| 7 | |



23) Click if Patient identifying label visible and **CLOSE**



24) Do not count any loose tablets/capsules or liquids, etc, in unidentifiable containers



25) AT THE END OF THE DAY, ALL LAPTOPS MUST BE BACKED UP.

The list of cytotoxic drugs was obtained from the Workplace Health and Safety Queensland (Guide for handling cytotoxic drugs and related waste, PN10522 Version 3 Last updated July 2016).

Appendix 2 - Commonly used cytotoxic drugs

This list contains cytotoxic drugs currently used however this listing is not exhaustive.

| Drug | Trade names |
|------------------------|----------------------------------|
| Altretamine | Hexalen |
| Amsacrine | Amsidyl |
| L-Asparaginase | See Colaspase |
| Bleomycin | Blenoxane, Blenamax |
| Busulfan | Myleran |
| Capecitabine | Xeloda |
| Carboplatin | Paraplatin, CBDCA |
| Carmustine | Bicnu |
| Chlorambucil | Leukeran |
| Cisplatin | Cisplatin |
| Cladribine | Leustatin, Litak |
| Colaspase | Leunase |
| Cyclophosphamide | Cycloblastin, Endovan |
| Cytarabine | Ara-C, Cytosar |
| Dacarbazine | DTIC |
| Dactinomycin | Cosmegen |
| Daunorubicin | Daunorubicin |
| Daunorubicin liposomal | Dauno Xome |
| Docetaxel | Taxotere |
| Doxorubicin | Adriamycin |
| Doxorubicin liposomal | Caelyx |
| Epirubicin | Pharmorubicin |
| Etoposide Phosphate | Etopophos |
| Etoposide | Etoposide, Vepesid |
| Fluorouracil | Efudix, 5FU |
| Fludarabine | Fludara |
| Fotemustine | Muphoran |
| Ganciclovir | Cymevene |
| Gemcitabine | Gemzar |
| Hydroxyurea | Hydrea |
| Idarubicin | Zavedos |
| Ifosfamide | Holoxan |
| Irinotecan | Camptosar, CPT-11 |
| Lomustine | Cee Nu |
| Melphalan | Alkeran |
| Mercaptopurine | Puri-nethol |
| Methotrexate | Ledertrexate, Methoblastin, MTX |
| Mitozantrone | Novantrone, Onkotrone |
| Mitomycin-C | Mutamycin |
| Nimustine | Nimustine |
| Oxaliplatin | Eloxatin |
| Paclitaxel | Anzatax, Paclitaxel Ebewe, Taxol |
| Pemetrexed | Alimta |
| Procarbazine | Natulan |
| Raltitrexed | Tomudex |
| Temozolomide | Temodal |
| Teniposide | Vumon |

PN10522 Version 3 Last updated July 2015 – Guide for handling cytotoxic drugs and related waste

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| | |
|-------------|-----------|
| Thioguanine | Lanvis |
| Thiotepa | Thiotepa |
| Topotecan | Hycamtin |
| Vinblastine | Velbe |
| Vincristine | Oncovin |
| Vindesine | Eldisine |
| Vinorelbine | Navelbine |

List of Schedule 8 was obtained from the Poison Standard July 2016 from the Australian Government, Department of Health
(<https://www.legislation.gov.au/Details/F2016L01071/Download>)

| PART 4 – THE SCHEDULES SCHEDULE 8 (Substances marked # are listed in Appendix D.) | |
|---|---|
| DIHYDROCODEINE | except when included in Schedule 2, 3 or 4. |
| DIHYDROMORPHINE | |
| DIPHENOXYLATE | except when included in Schedule 3 or 4. |
| DIPIANONE | |
| # DRONABINOL (delta-9-tetrahydrocannabinol) | when prepared and packed for therapeutic use. |
| DROTEBANOL | |
| ETHYLAMFETAMINE | |
| ETHYLMORPHINE | except when included in Schedule 2 or 4. |
| FENTANYL | |
| # FLUNITRAZEPAM | |
| HYDROCODONE | |
| HYDROMORPHINOL | |
| HYDROMORPHONE | |
| KETAMINE | |
| LEVAMFETAMINE | |
| LEVOMETHAMFETAMINE | |
| LEVOMORAMIDE | |
| LEVORPHANOL | (excluding its stereoisomers). |
| LISDEXAMFETAMINE | |
| METHADONE | |
| METHYLAMFETAMINE | |
| METHYLDIHYDROMORPHINE | |
| METHYLPHENIDATE | |
| 1-METHYL-4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID (Pethidine intermediate C) | |
| MORPHINE | |
| MORPHINE METHOBROMIDE | |
| MORPHINE-N-OXIDE | |
| Poisons Standard July 2016 227 | |
| Authorised Version F2016L01071 registered 24/06/2016 | |

PART 4 – THE SCHEDULES
SCHEDULE 8
(Substances marked # are listed in Appendix D.)

NABILONE.

NABIXIMOLS (botanical extract of Cannabis sativa which includes the following cannabinoids: tetrahydrocannabinol, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acid, tetrahydrocannabivarinol, and cannabidivarinol, where tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content) in a buccal spray for human therapeutic use.

NORCODEINE.

NORMETHADONE.

OPIUM except the alkaloids noscapine in Schedule 2 and papaverine when included in Schedule 2 or 4.

OXYCODONE.

OXYMORPHONE.

PENTAZOCINE.

PENTOBARBITAL except when included in Schedule 4.

PETHIDINE.

PHENDIMETRAZINE.

PHENMETRAZINE.

PHENOPERIDINE.

4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER (Pethidine intermediate B).

PHOLCODINE except when included in Schedule 2 or 4.

PIRITRAMIDE.

PROPIRAM.

QUINALBARBITONE.

RACEMORAMIDE.

REMIFENTANIL.

SECBUTOBARBITONE.

SODIUM OXYBATE for human therapeutic use.

SUFENTANIL.

TAPENTADOL.

THEBACON.

Poisons Standard July 2016

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Authorised Version F2016L01071 registered 24/06/2016

PART 4 – THE SCHEDULES
SCHEDULE 8
(Substances marked # are listed in Appendix D.)

THEBAINE.

TILIDINE.

Poisons Standard July 2016

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Authorised Version F2016L01071 registered 24/06/2016

Appendix 2

Occupational Health & Safety SOP for Bin Audit



STANDARD OPERATING PROCEDURE

GRIFFITH HEALTH – NatRUM Project 2016

AUDIT DATA COLLECTION PROCESS

PROJECT OVERVIEW

Participants will analyse Return of Unwanted Medicine (RUM) bin contents to evaluate the quantity and type of medicines returned to pharmacies throughout Australia. Three incineration sites across Australia will be participating in this audit.

Data will be collected using laptops. Hard copy (paper) will only be available for data collection in a situation where laptop computers do not work.

PURPOSE

These procedures are designed to protect the safety of audit participants, meet legal requirements and maximise the amount and consistency of collected data.

SCOPE

The procedures documented within this SOP are transferable across all sites. Any site process anomalies will be discussed with the Project Manager and safety personnel prior to the audit at each site commencing and updated instructions passed onto audit participants through on-site training.

KEY STAKEHOLDERS and CONTACT DETAILS

| | | |
|--|--|--|
| Principle Investigator: Professor Amanda Wheeler a.wheeler@griffith.edu.au 07 338 21068 Mobile number | Project Manager (operations): Dr Alejandra Gallardo-Godoy a.gallardo-godoy@griffith.edu.au 07 338 21310 Mobile number | Data Collection Manager: Joye Kerr, B. Pharm. joye.kerr@griffith.edu.au 07 338 21310 Mobile number |
| Investigators: | | |
| Dr Fiona Kelly f.kelly@griffith.edu.au 07 5552 9743 Mobile number | Dr Jean Spinks j.spinks@griffith.edu.au 07 3735 9101 Mobile number | Emilie Bettington e.bettington@griffith.edu.au 07 3735 9123 Mobile number |
| Health & Safety Support: | | |
| Susie Head s.head@griffith.edu.au 07 5678 8148 Mobile number | Scott Burnell s.burnell@griffith.edu.au 07 5552 8680 Mobile number | Kerrin Henderson kerrin.henderson@griffith.edu.au 07 3735 3663 Mobile number |

RUM BINS TO BE COUNTED:

2016 minimum bins to be selected = 373 to achieve statistical validation

| State or Territory | Approximate number of RUM bins to be audited (to meet minimum sample size n=373) |
|--------------------|---|
| ACT | 3 |
| NSW | 113 |
| NT | 3 |
| QLD | 69 |
| SA | 53 |
| TAS | 6 |
| VIC | 97 |
| WA | 29 |
| TOTAL | 373 |

Aim to count 1.5 bins / hour.

SITE SCHEDULES

| Location | Company | Dates | Days to count and collect data | Project people / site |
|-----------|---------|---|--------------------------------|-----------------------|
| Brisbane | te | | | |
| Perth | | | | Up to 6 |
| Melbourne | te | August 15 th to 26 th | Up to 10 days | Up to 18 |

GENERAL REQUIREMENTS

| MATERIALS / NOTES | | |
|--|---|-----------------------------------|
| Protective clothing | Tongs – 40cm long | Kitchen scales to weigh medicines |
| • Gloves – Nitrile – long cuff – md, lg, x-lg | Tongs – 24cm long | Batteries for scales - AAA |
| • Safety glasses | Laptops and chargers | Dustpans and brushes |
| • Dust masks | Data collection forms – hardcopy | Paper towel |
| • Disposal lab coats | 240L Garbage bags | Calculators |
| • Closed toed shoes (participants own) | Sharps containers – 2lt | Hire tables and chairs |
| Bin opener | Garden gloves | Large flat head screw drivers |
| Standing knives | Viraclean disinfectant: spray equipment and hand cleaning | |
| Disposal bin to place used items in – e.g. gloves, paper towel etc | Scales to weigh bins | Scales calibration date |
| Tape for zoning – striped (e.g. red/white) to indicate hazard zone | Pens, pencils, note pads, permanent marker pen | |

SPECIFIC EQUIPMENT REQUIREMENTS:

Include all major equipment needed, with details on calibration, standards and routine maintenance required. Also include any photographs or sketches which may help define apparatus setups.

Laptops

Charges to be tested and tagged before going to incineration sites

Charged overnight – data collection manager to do this

Electrical equipment:

Multi-outlet power boards and extension leads to be tested and tagged in accordance with the Queensland Electrical Safety Regulations within the last twelve (12) months.

- The multi-outlet power board has an in-built load limiting switch with a maximum rating of 10A
- All the power points on the multi-outlet power board are individually switched
- The multi-outlet power board has been tested and tagged

Scales –

Calibration

Extra batteries

CHEMICAL REQUIREMENTS:

Ensure that correct disposal facilities are available, labelled and users are made aware of these procedures.

| CHEMICAL NAME | CAS NUMBER. | HAZARDOUS CLASSIFICATION | LOCATION OF STORAGE | BOTTLE SIZE (mL) |
|---|-------------|--------------------------|---------------------|------------------|
| Viraclean – hospital grade disinfectant | | | | |

RUM BIN DETAILS

Bin measure:

- Full – 76%-100%
- $\frac{3}{4}$ - 51-75%: Guide – top of black warning sign on bin
- $\frac{1}{2}$ - 26-50%: Guide – pharmaceutical wording on bin
- $\frac{1}{4}$ - 25%: Guide – depot wording on bin

Bin weight empty = 1kg

PROCEDURE

Prior to coming on site:

Data Collectors:

Confirm:

- Site Details and Parking
 - Brisbane:
 - Melbourne:
 - Perth
- Work day schedule:
 - **Start:** 8am
 - **Morning tea:** 9.30am – 9.40am [Wash hands with Viraclean]
 - **Lunch:** 12:00pm – 12:30pm [Wash hands with Viraclean]
 - **Afternoon tea:** 2.30pm – 2.40pm [Wash hands with Viraclean]
 - **Finish:** 4pm [Wash hands with Viraclean]
- Pay rates
- Primary contact: Data Collection Manager
 - Joye Mobile number

What to wear:

- **Comfortable casual clothing that is easy to move in**
- **It is winter – warm clothing recommended as we will be working outdoors.**
- **Covered footwear – sandshoes, boots**
- **Long hair to be tied back**

What to bring:

- Food and drinks – morning tea, lunch and afternoon tea, water. There are no shops nearby to purchase items.

What to read / review:

- Work Procedure – so you are aware of what to expect.
- Risk assessment: Data Collection Process for the National Return and Disposal of Unwanted Medicines (NatRUM) 2016

Arriving on site:

- Sign in at front desk
- Display your visitor card
- Wear hi-vis vest

Data collector's attendance and induction process to be recorded each day on 'Daily Working Log' sheet.

NatRUM Project Team:

- Meet with site personnel on the day prior to data collection start if possible
- Arrive 1hr earlier than data collectors to set up the counting site
 - Sign in
- Setup tables, zone areas with tape (red, yellow, counted, unusable, resting / first aid)
 - Table
 - Chair
 - Computer – extension leads, power boards
 - Garbage bag to cover table
 - Gloves - box
 - Safety glasses x 2
 - Masks x 2
 - Sharps container
 - Tongs x 4
 - Scale x 1



- Post A3 procedure signs – signs to be laminated so they can be sprayed down (disinfected)
- Provide ice and water bottles for participants.
- Number bins (lids and bases)
- Weigh bins and write weight on the lids with permanent marker pen

General welcome – Introductions - Induction

- Data Collection Manager and other members of team
 - Name tags to be put on
- Company representatives

Local site induction provided by company representative/s

- On site expectations – rules, safety, compliance
- Lunchroom
- Toilets

Work day schedule:

- **Start:** 8am
- **Morning tea:** 9.30am – 9.40am *[Wash hands with Viraclean]*
- **Lunch:** 12:00pm – 12:30pm *[Wash hands with Viraclean]*
- **Afternoon tea:** 2.30pm – 2.40pm *[Wash hands with Viraclean]*
- **Finish:** 4pm *[Wash hands with Viraclean]*

Overview:

- Review process to follow and risk assessment information
 - Review safety precautions and requirements
 - Review Risk Assessment
 - Safety officer or data collection manager ensure they are appropriately dressed
 - Comfortable casual clothing that is easy to move in
 - Covered footwear – sandshoes, boots
 - Long hair to be tied back
- Practical show and tell – collection site setup, data collection procedures using an actual RUM bin
- Laptop use will be demonstrated – Appendix 3 (Data Collection Protocol)
- Competency assessed and signed off – Appendix 2
- Commence data collection process

Proceed to RUM bin demonstration.

DATA COLLECTION PROCESS

Safety:

- Put on lab coats with hi-vis vest on outside so you are still identified as an approved site visitor
- Put on gloves

Step 1: Collect a bin

- Move bin around – if you hear a sloshy liquid noise seek advice from the Data Collection Manager whether to open the bin or discard this bin as not suitable due to possible biological fluids within.

Step 2: Record data on origin of the bin (i.e. enter bin location from bin if known)

Step 3: Weigh the bin prior to opening (this may have already been done – check lid of bin for weight)

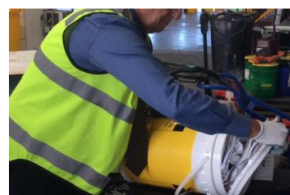


Safety:

- Wear dust mask to minimize exposure to aerosols.

Step 4: To open bin (two person job – 1 to open, 1 to hold the bin)

- Garden gloves may assist to open the bin. *Garden gloves will protect your hands and offer friction to prevent the bin from slipping.*
- Lay the bin down in its side with the lid face away from you. Cut any tape with a standing knife or screwdriver.
- Pry lid of the bin off using large flat head screwdriver. Move around the circumference of the bin lid to loosen and uncap the lid. This can be very difficult and strength is required. *Position the screwdriver so that it is pointing away from the body and away from hands to avoid an accident.*
- or
- Use bin opener
- Once the lid can be removed use the palm of your hand to pry the lid off by pushing up under the lid and away from yourself. Do not use your fingers.



NB:

- Do not pour contents out yet.

Step 5: Bin content assessment and data collection

5.1: Initial visual assessment of contents and approximate volume of container occupied by contents.

The volume of the container occupied by contents will be measured.

Volume measurements:

- Full = 76%-100%
- $\frac{3}{4}$ = 51-75%: Bin guide – top of black warning sign on bin
- $\frac{1}{2}$ = 26-50%: Bin guide – pharmaceutical wording on bin
- $\frac{1}{4}$ = 25%: Bin guide – depot wording on bin



Signs of hazardous materials such as biohazard waste will exclude that bin from further examination. In such cases the bin will be immediately resealed and securely stored prior to incineration.

Safety:

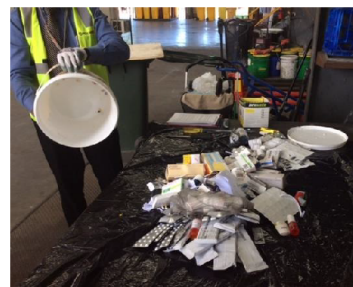
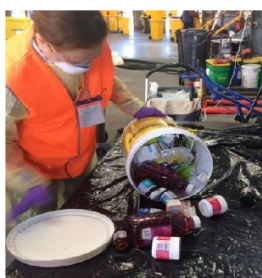
- DO NOT USE HANDS - Tongs must be used until you have fully inspected the contents of the bin for safety.
- Be aware of sharps and needles which may be within the bins.



5.2: Transfer the contents of each NatRUM bin onto the black plastic mat so that the contents are distributed over a larger area and are more easily observed.

Take Note - DO NOT USE HANDS - Sharps:

- Unidentified syringes (needles capped or uncapped) will be discarded into sharps containers, NOT COUNTED.
- Identifiable syringes (needles uncapped) will be discarded into sharps containers, NOT COUNTED.
- Identifiable syringes/flex pens WILL BE COUNTED before disposed in sharps container.



If plastic bags containing medicines are within the bins use tongs to tip the bags up to get the contents within out. Do not use your hands.

5.3 Second visual inspection

After the contents of the bin have been tipped onto the table a second visual examination of the contents will be performed to determine suitability for further assessment.

The contents of a particular bin will be excluded from further assessment if:

- The majority of the contents are not medicines/sharps/therapeutic goods;
OR
- The contents appears noxious, contains biological material or is otherwise clearly unsafe for assessment;
OR
- The contents have a high proportion of material (>~50%) that will not be counted (e.g. loose tablets/capsules).



The reason for exclusion will be documented. The supervising pharmacists will make this assessment to ensure safety and consistency. The contents of bins deemed unsuitable for further assessment will be returned to the original container, resealed and placed in a separate, secure section of the facility for incineration.

Safety:

- At no stage will hands be placed directly into the original NatRUM bin or used to directly handle any of the non-auditable contents.

NB:

Sharps:

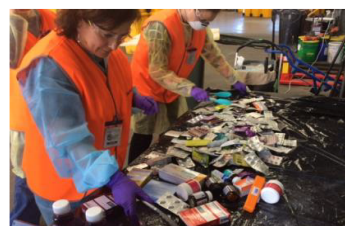
- A presence of sharps items will be recorded.
- Uncapped syringes will be discarded into sharps containers.

Using tongs: both data collectors will sort the bin contents into TWO sections on the table:

- Left hand side = non-auditable material that will not be counted and will be disposed back into the bin. Place items back into bin using tongs or dustpan.
- Right hand side = auditable material that will be counted/weighed.

Remove medicines from their original box - use a screwdriver to open medicine boxes as there may be sharps within.

All medicines must be easily observed. i.e. nothing hidden beneath another box.



Safety:

- Dust mask can be removed once medicines to be counted have been placed in the audit zone.

5.4: Inside the audit zone, gloved hands are permitted to handle the contents.

Record data details.

- Count liquids first
- Weigh creams

5.5: In the event that an item is identified during auditing that is outside the scope of the project, the supervising pharmacists will be notified and decides upon the appropriate course of action; if deemed necessary the audit will be suspended until the project manager has been notified. These steps ensure that the likelihood of exposure to any hazardous material by either the study personnel or other parties is minimized so far as is practicable.



Step 6: End of counting process

Following counting, the bin contents will be transferred back into the original NatRUM bin, sealed and stored securely in preparation for incineration.

Computer data will be saved after each bin is complete and at the end of each day the Data Collection Manager will save the core data to a USB.

Grab another bin and start again!

Rotate jobs – if you entered data into the computer last time swap to identifying the bin contents this time.

LEAVING THE SITE / END OF EACH DAY:

All NatRUM participants must:

- Return all project material to central collection area (laptops, safety gear)

- Throw used gloves, garbage bags and paper towel into the waste bins.
- Spray and wipe table with Viraclean.
- Remove your visitor card – paper slip to be handed to the company staff, plastic id sleeve to be placed back in sleeve box
- Return hi-vis vest
- Sign out at front desk
- Wash hands with Viraclean

SAFETY PRECAUTIONS AND REQUIREMENTS:

Persons participating in community research activities may be exposed to a variety of hazards (e.g. faulty equipment, damaged cables, complacency, water spills), resulting in musculoskeletal injury, electrocution, skin penetrating injury or others depending on the activities being performed. All treatment or a security response must be in a timely manner.

General control measures include:

1. Major event organisation planning, hazard identification, risk assessment and control measures required are determined and recorded.
2. Coordinators seek advice from Griffith Health and Safety specialists to minimise risks and assist in ensuring a safe environment for set-up, conducting and packing down activities.
3. Adequate work space.
4. Appropriate Biological, chemical and sharps disposal containers and procedures in practice.
5. Safe work procedures / protocols.
6. Correct use of manual handling techniques and safe lifting practices used. Online manual tasks training completed.
7. All tasks Risk Assessed.
8. Equipment maintained and tested and tagged. Use lifts, not stairs for moving equipment.

"Hands Free Policy" – use the tongs provided. It is so easy to become comfortable. Comfort leads to complacency and if you can't see it the subliminal thinking says nothing is there! Put your safety first.

- Sharps / Needlestick injury SOP


GSAFE incident report – hardcopies available.

Refer to completed Risk Assessment: Data Collection Process for the National Return and Disposal of Unwanted Medicines (NatRUM) 2016 (copies for everyone) – Appendix 4

A copy of the University's General and Products Liability Protection insurance is available.

REFERENCES

- AS/NZS 2243.3:2010
- SUSMP

| | | | |
|------------------------------|--|------------------------------------|-----------------------------------|
| Author: Susie Head | Approved by:  | Approval Date: 30.6.2016 | Review Date: 31.12.2016 |
|------------------------------|--|------------------------------------|-----------------------------------|

Appendix 1: SITE LOCATION & PARKING DETAILS

Appendix 2: DAILY WORKING LOG

Location (please circle)

- Brisbane
- Melbourne
- Perth

Day: _____

Date: _____

| Name | Contact Number | Induction Completed | Start time | Finish time | Confirmed by: |
|------|----------------|---------------------|------------|-------------|---------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Appendix 3: DATA COLLECTION PROTOCOL

Appendix 4:



| | | | | |
|---|--|-------------|--|-----------------------------|
| Risk Assessment Name: | Data Collection Process for the National Return and Disposal of Unwanted Medicines (NatRUM) 2016 | | | |
| Describe Task/Issue you are undertaking: Participants will analyse Return of Unwanted Medicine (RUM) bin contents to evaluate the quantity and type of medicines returned to pharmacists throughout Australia. | | | | |
| Who is the Risk Approver? | Professor Amanda Wheeler | | | |
| Date of Risk Assessment: | 30 June 2016 | | | |
| Who is the Risk Owner? | School of Human Services and Social Work | | | |
| Who are the members of the Assessment Team? | Susie Head, Scott Burnell, Kerrin Henderson, Peter Cohen (AceWaste Brisbane), Alejandra Gallardo-Godoy, Joye Kerr. | | | |
| RISK RATING (if all control measures as outlined below are adhered to:) | Work Area | Opening Bin | Decanting and Separating Contents from Bin | Recording Auditable Results |
| | Low | Medium | Medium | Low |

Rating your Risk

| Likelihood/Consequences | Insignificant No injuries* | Minor First Aid treatment* | Moderate Medical treatment* | Major Serious or extensive injuries* | Catastrophic Death or large number of serious injuries* |
|-------------------------|-------------------------------|-------------------------------|--------------------------------|---|--|
| Almost Certain | Low | Medium | High | High | Extreme |
| Likely | Low | Medium | Medium | High | High |
| Possible | Low | Low | Medium | Medium | High |
| Unlikely | Low | Low | Low | Medium | Medium |
| Rare | Low | Low | Low | Low | Medium |

Appendix 3

Veterinary Items

Geographical distribution of bins

| State/Territory | Number of RUM bins (N=423) | | |
|------------------------------|----------------------------|--------------|--------------|
| | Number of bins | Total items* | Unopened (%) |
| Australian Capital Territory | 1 | 3 | Nil |
| New South Wales | 1 | 31 | 100 |
| Northern Territory | Nil | Nil | Nil |
| Queensland | Nil | Nil | Nil |
| South Australia | Nil | Nil | Nil |
| Tasmania | Nil | Nil | Nil |
| Victoria | 3 | 3 | 100 |
| Western Australia | 3 | 44 | 36.4 |
| TOTAL | 8 (1.9%) | 81 | 50 |

RUM = Return of Unwanted Medicines

* The total = 1 for any observation detailing loose/opened products, regardless of the amount recorded PLUS the number of unopened packets.

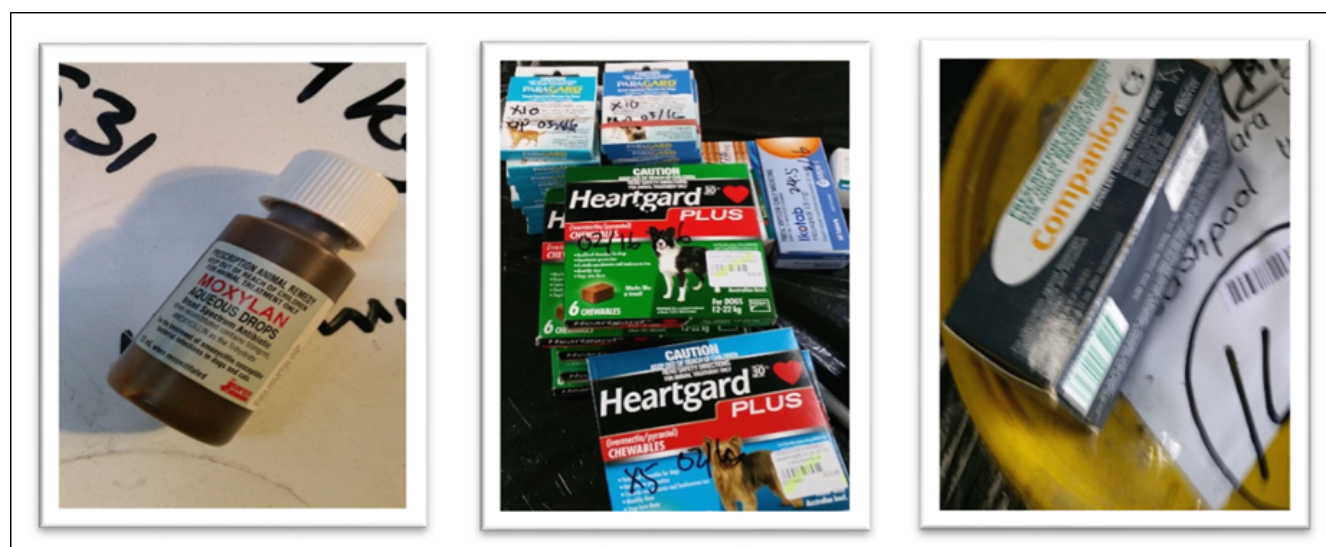
Item contents

| Veterinary item | Total* | Unopened | Amount remaining |
|--|--------|----------|------------------|
| Acetylpromazine (ACP) | 3 | 1 | |
| Tablet 10mg | 2 | 1 | 11 tablets |
| Injection 2mg/ml | 1 | Nil | ~ 50 mL |
| Benzazepril | 1 | Nil | |
| Tablet 2.5mg | 1 | Nil | 53 tablets |
| Antibiotics | 8 | Nil | |
| Amoxycillin + clavulanic acid | 2 | Nil | 4 tablets |
| Doxycycline | 1 | Nil | 5 tablets |
| Penicillin | 1 | Nil | ~ 100 mL |
| Framixin eye and ear ointment (5g) | 1 | Nil | used |
| Topical powder antibiotic | 3 | Nil | 45 g |
| Flea and worm control | 40 | 35 | |
| Advantage Flea treatment | 4 | 3 | ~ 320 mL |
| Exelpet Intestinal All-wormer for Dogs | 2 | Nil | 2 tablets |
| Heartgard Plus | 11 | 11 | 66 tablets |

| | | | |
|---------------------------------|-----------|-----------|------------|
| Paragard Wormer for Dogs | 20 | 20 | 80 tablets |
| Purina Total Care Flea Control | 1 | Nil | ~250 mL |
| Drontal Allwormer | 1 | Nil | 1 tablet |
| Revolution for Dogs Selamectin | 1 | 1 | 6 mL |
| Animal supplements | 2 | 1 | |
| Food supplement for dogs | 1 | 1 | 150 g |
| Vitamin B Complex | 1 | Nil | ~ 50 mL |
| Various animal medicines | 27 | 13 | |
| Ivermectin | 1 | 2 | ~ 37.4 g |
| Meloxicam | 1 | 6 | 60 mL |
| Torsemide | 1 | 1 | 50 mL |
| Azaperone | 1 | Nil | ~ 20 mL |
| Buscopan | 1 | Nil | ~ 100 mL |
| Dexamethasone | 1 | Nil | ~ 25 mL |
| Isoxsuprine | 1 | Nil | ~ 50 mL |
| Lignocaine | 1 | Nil | ~ 100 mL |
| Xylazine | 1 | Nil | ~ 12 mL |
| Dermeusal | 1 | Nil | ~ 100 mL |
| Megestrol | 1 | Nil | 20 tablets |
| Diethylstilboestrol | 1 | Nil | 61 tablets |
| Bunamidine | 1 | Nil | 11 tablets |
| Praziquantel | 1 | Nil | 14 tablets |
| Cythioate | 1 | Nil | 95 tablets |
| Trimazine | 1 | Nil | 65 tablets |
| Rapigel | 1 | 1 | 250 g |
| Hormone implant | 1 | 2 | 2 units |
| Vaccine | 2 | 1 | 13 doses |
| TOTAL | 81 | 50 | |

* The total = 1 for any observation detailing loose/opened products, regardless of the amount recorded PLUS the number of unopened packets.

Photographic examples of veterinary items



Appendix 4

Schedule 4 Cytotoxic Medicines

| Cytotoxic medicine | Total* | Unopened (%) | Loose tabs/caps^ | Expired# (%) | PBS price |
|--|--------|--------------|------------------|--------------|-----------|
| Busulfan 2 mg tablet, 100 | 1 | Nil | 1 | 100 | \$ 71.82 |
| Capecitabine 150 mg tablet, 60 | 2 | 50.0 | 4 | 50.0 | \$ 20.89 |
| Capecitabine 500 mg tablet, 120 | 16 | 18.8 | 457 | 43.8 | \$ 129.51 |
| Chlorambucil 2 mg tablet, 25 | 3 | 100 | Nil | Nil | \$ 29.59 |
| Fludarabine phosphate 10 mg tablet, 20 | 1 | Nil | 2 | Nil | \$ 831.94 |
| Fluorouracil 5% cream, 20 g | 14 | 35.7 | Nil | 21.4 | \$ 50.40 |
| Hydroxyurea 500 mg capsule, 100 | 3 | 33.3 | 93 | 66.7 | \$ 56.26 |
| Mercaptopurine 50 mg tablet, 25 | 4 | 50.0 | 24 | 50.0 | \$ 53.53 |
| Methotrexate 10 mg tablet, 15 | 3 | 33.3 | 15 | Nil | \$ 11.25 |
| Methotrexate 10 mg tablet, 50 | 5 | Nil | 139 | 20.0 | \$ 37.50 |
| Methotrexate 2.5 mg tablet, 30 | 4 | Nil | 90 | 50.0 | \$ 5.42 |
| Temozolomide 100 mg capsule, 5 | 1 | Nil | 5 | 100 | \$ 155.13 |
| Temozolomide 140 mg capsule, 5 | 2 | Nil | 6 | Nil | \$ 213.94 |
| Temozolomide 20 mg capsule, 5 | 4 | 100 | Nil | Nil | \$ 36.21 |
| Temozolomide 250 mg capsule, 5 | 1 | Nil | 2 | Nil | \$ 368.58 |
| Thioguanine 40 mg tablet, 25 | 6 | 83.3 | 19 | Nil | \$ 193.01 |
| Vinorelbine 30 mg capsule, 1 | 3 | 100 | Nil | 100 | \$ 108.80 |

PBS = Pharmaceutical Benefits Scheme

* The total = 1 for any observation detailing loose/opened products, regardless of the amount recorded PLUS the number of unopened packets;

^ Loose tabs/caps = included strips of tablets and/or capsules that no longer had an original package or tablets or capsules that were loose in a dispensed labelled bottle or original bottle;

Expired as of 30/06/2016.

Photographic examples of cytotoxic items



Appendix 5

Schedule 8 Items

| State/Territory | Number of RUM bins (N=423) | | | |
|--------------------------------|----------------------------|--------------|------------|------------|
| | Number of bins | Total items* | Unopened % | Expired^ % |
| Australian Capital Territory | 2 | 2 | Nil | 50.0 |
| New South Wales | 39 | 110 | 30.0 | 37.3 |
| Northern Territory | 1 | 1 | Nil | Nil |
| Queensland [#] | 7 | 105 | 45.7 | 55.2 |
| South Australia | 11 | 31 | 51.6 | 16.1 |
| Tasmania | 1 | 4 | 100.0 | Nil |
| Victoria | 47 | 153 | 43.1 | 51.6 |
| Western Australia [†] | 6 | 7 | 28.6 | 14.3 |
| TOTAL | 114 (28.4%) | 413 | 169 | 185 |

* Items plus multiple packs (each item of an unopened medicine is counted as '1', items containing multiple unopened packs are counted as the number of packs;

^ Expired as of 30/06/2016

Included 10 bins from Far North Queensland;

† Included 5 bins from Christmas Island.

The total PBS waste cost of dispensed, unopened, not expired Schedule 8 medicine items was \$815.02.

Appendix 6

Bins Containing Sharps

Geographical distribution of bins

| State/Territory | Number of bins audited | RUM bins containing sharps |
|------------------------------|------------------------|----------------------------|
| Australian Capital Territory | 4 | Nil |
| New South Wales | 120 | 13 (10.8%) |
| Northern Territory | 4 | Nil |
| Queensland* | 79 | 11 (13.9%) |
| South Australia | 60 | 4 (6.7%) |
| Tasmania | 10 | 1 (10%) |
| Victoria | 109 | 9 (8.3%) |
| Western Australia^ | 37 | 8 (21.6%) |
| TOTAL | 423 | 46 (10.9%) |

RUM = Return of Unwanted Medicines;

** Included 10 bins from Far North Queensland;*

^ Included 5 bins from Christmas Island.

Photographic examples of sharps



Appendix 7

Top 20 Medicines from 2013 Audit and 2012 PBS Dispensing Data

| Rank* | 2013 NatRUM audit | 2012 top 20 medicines by PBS/RPBS prescription counts |
|-------|------------------------------|---|
| 1 | Salbutamol | Atorvastatin |
| 2 | Insulin | Paracetamol |
| 3 | Frusemide | Rosuvastatin |
| 4 | Prednisolone | Esomeprazole |
| 5 | Glyceryl trinitrate | Atenolol |
| 6 | Telmisartan + amlodipine | Pantoprazole |
| 7 | Fluticasone + salmeterol | Salbutamol |
| 8 | Paracetamol | Cephalexin |
| 9 | Metoclopramide | Clopidogrel |
| 10 | Warfarin | Rabeprazole |
| 11 | Influenza vaccine | Tiotropium |
| 12 | Perindopril | Simvastatin |
| 13 | Metoprolol | Temazepam |
| 14 | Paracetamol + codeine | Amoxicillin + clavulanic acid |
| 15 | Atorvastatin | Irbesartan + Hydrochlorothiazide |
| 16 | Amoxicillin | Diazepam |
| 17 | Betamethasone | Latanoprost |
| 18 | Oxycodone | Amoxicillin |
| 19 | Cephalexin | Paracetamol + codeine |
| 20 | Ipratropium | Irbesartan |

NatRUM= National Return and Disposal of Unwanted Medicines; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

* Item 1 is the most common.

NOTE: items occurring in both lists are **bolded**.

Appendix 8

PBS Items by ATC Classification

| ATC classification | Total items* | % |
|---|---------------|--------------|
| Nervous system | 3,547 | 22.8 |
| Cardiovascular system | 3,112 | 20.0 |
| Alimentary tract and metabolism | 1,976 | 12.7 |
| Anti-infective for systemic use | 1,205 | 7.7 |
| Respiratory system | 876 | 5.6 |
| Blood and blood forming organs | 724 | 4.6 |
| Sensory organs | 574 | 3.7 |
| Musculoskeletal system | 397 | 2.5 |
| Antineoplastic and immunomodulating agents | 263 | 1.7 |
| Dermatological | 262 | 1.7 |
| Genitourinary system and sex hormones | 207 | 1.3 |
| Systemic hormonal preparations, excl. sex hormones and insulins | 90 | 0.6 |
| Various | 69 | 0.4 |
| Antiparasitic products, insecticides and repellents | 27 | 0.2 |
| Unknown | 2243 | 14.4 |
| TOTAL | 15,572 | 100.0 |

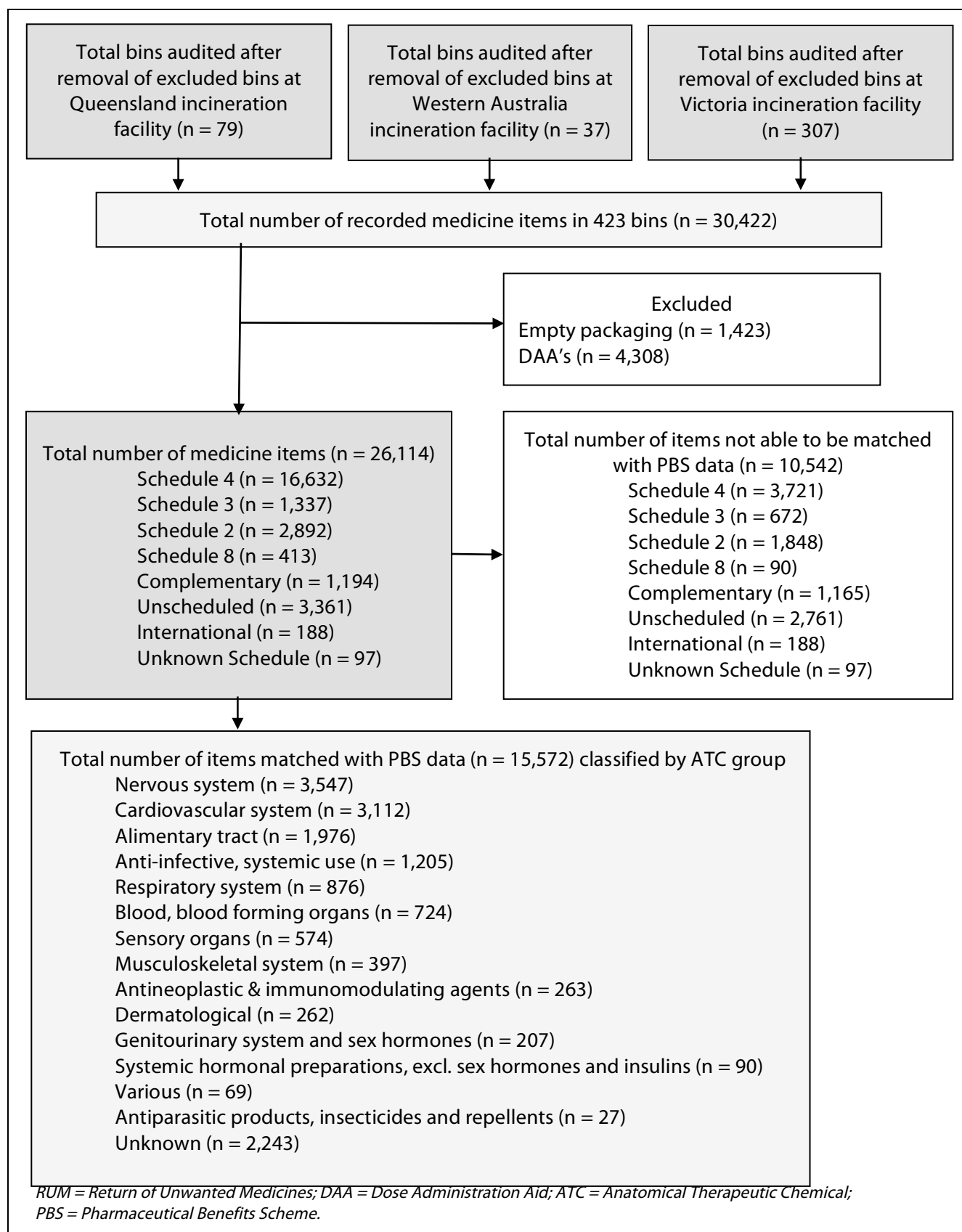
ATC = Anatomical Therapeutic Chemical; PBS = Pharmaceutical Benefits Scheme

* The total = 1 for any observation detailing loose/opened products, regardless of the amount recorded PLUS the number of unopened packets;

Note: ATC classifications were only available to be merged with PBS data as ATC classifications have not yet been added to SNOMED-CT AU. A complete match with PBS data was not achieved. Where this occurred, the item was classified as 'Unknown'.

Appendix 9

Overview of PBS Items Identified in RUM Bins Audited



Appendix 10

General Population Awareness Online Survey

Thank you for participating in this survey. Participation is totally voluntary and you will remain anonymous. This survey is about unwanted medicines and forms part of a study being conducted by Griffith University. The aim of the study is to gain information about how Australians dispose of their unwanted or out-of-date medicines. Information you give will help form the basis of recommendations about how to promote the safe disposal of unwanted medicines. This project is funded by the Australian Government Department of Health. **The research team** is led by Professor Amanda Wheeler, and includes Dr Jean Spinks, Dr Fiona Kelly, and Ms Emilie Bettington (Griffith University).

Please read the following information before starting the survey:

Unwanted medicines are any used (open-packs), unused (unopened but no longer needed) or expired medicines.

The definition of medicine includes:

- A prescription medicine (one that needs a doctor's prescription that you would then get from the pharmacy or chemist).
- Over the counter medicines that can be bought without a prescription (e.g. cold and flu medicines; pain medicines; tinea creams)
- Complementary/alternative medicines – this includes vitamins, minerals, herbal preparations, aromatherapy and homoeopathic products

Medicines can come in different forms such as tablets, capsules, liquids, aerosols and creams.

This study has Griffith Human Research Ethics Committee approval (GU ref No: 2016/449). Griffith University conducts research in accordance with the National Statement of Ethical Conduct in Human Research. If you have any concerns or complaints about the ethical conduct of this research project you should contact the Manager, Research Ethics on (07) 3735 4375 or research- ethics@griffith.edu.au

For more information on the study on the study please click [here](#).

If you have any further questions, or would like to request a summary of the results, please contact the research team on +61 (0)7 3382 1241 or at a.wheeler@griffith.edu.au.

This survey should not take more than 10 minutes to complete.

Q1. Do you currently have any unwanted, unused (but no longer needed), used (open-packs) or expired medicines in your house?

- ☐ Yes
- ☐ No [Go to Q5]
- ☐ I don't know [Go to Q5]

Q2. Do your unwanted medicines include? (Please tick that apply)

- Prescription medicines (requires a doctor's prescription to be dispensed)
 - ☐ Used (open-pack)
 - ☐ Unused (unopened)
 - ☐ Expired

Unwanted medicines are any used (open-packs), unused (unopened but no longer needed) or expired medicines.

Definition of Medicine:

- A prescription medicine needs a doctor's prescription.
- Over the counter medicine can be bought without a prescription (e.g. cold and flu medicines; pain medicines; tinea creams)
- Complementary/alternative medicines include vitamin, mineral, herbal, aromatherapy and homoeopathic products

Medicines can come in different forms such as tablets, capsules, liquids, aerosols (puffers), eye/ear drops, suppositories and injections.

all

- Don't know
- Medicines bought without prescription from a pharmacy, supermarket or online;
 - Used (open-pack)
 - Unused (unopened)
 - Expired
 - Don't know
- Complementary/alternative medicines including vitamin, mineral, herbal, aromatherapy and homoeopathic products;
 - Used (open-pack)
 - Unused (unopened)
 - Expired
 - Don't know
- Other, Please describe: _____

Q3. Why have you kept these medicines? (Please tick all that apply)

- Just in case I needed them again;
- To give them to a family / friend when they need them;
- I did not know how to dispose of them;
- It seems like a waste of money to dispose of them;
- Other, please describe: _____

Q4. Among the prescription medicines are there any that you have stopped without talking to your doctor?

- Yes
- No
- I don't know

Q5. In the last 12 months [has your household / have you] disposed of any medicines, drugs or ointments?

- Yes
- No [Go to Q8]
- I don't know [Go to Q8]

Q6. What are all the ways [your household / you] disposed of these items in the last 12 months? (Please tick all that apply) [Randomised list order]

- Collected from house with the usual (non-recycled) garbage;
- Collected from house as part of municipal kerbside recycling;
- Took it to a general area at the dump / waste transfer station;
- Took it to a special area at the dump / waste transfer station;
- Took it to a business or shop (e.g. pharmacy or chemist);
- Took to a central collection point other than dump / waste transfer station;
- Poured down the drain or toilet;
- Burnt or incinerated;
- Buried;
- Gave away;
- Sold;
- Other; Please specify: _____

Q7. Why did you dispose of these medicines? (Please tick all that apply) [Randomised list order]

- The medicines were past their expiry dates;
- The doctor changed the medicine;

- The medicine did not work;
- The person(s) these medicines belonged to died;
- The recommended course of medicine(s) was completed;
- The person(s) these medicines belonged to, moved out and left medicines behind;
- The person(s) these medicines belonged to, didn't want to take them anymore;
- The person got better and stopped taking the medicines;
- The person experienced unwanted effects;
- The person can no longer afford the medicine;
- Other reasons; Please explain:_____

Q8. Please rank these statements in order of importance from 1 to 6 where 1 is the most important and 6 is the least important.

- 🍏 Unsafe storage of medicines can lead to unintended poisoning (e.g. children, vulnerable people).
- 🍏 Unsafe disposal of medicines can end up in the environment and affect plants and animals.
- 🍏 Unsafe disposal of medicines can end up in drinking water.
- 🍏 Sharing medicines with friends or family is unsafe.
- 🍏 The government pays to safely dispose of medicines.
- 🍏 It is free to bring unwanted medicines back to the pharmacy.

Q9. Please rank these ways of letting people know about safe medicines disposal from 1 to 8 where 1 is the best way and 8 is the worst way.

- 🍏 Television
- 🍏 Radio
- 🍏 Newspaper
- 🍏 Information from your doctor
- 🍏 Social media
- 🍏 Information from people in the pharmacy
- 🍏 Sticker on prescription medicines
- 🍏 Poster at your doctor's office / pharmacy

Q10. Have you **heard of** the Return of Unwanted Medicines (RUM) project where you can take medicines of any type to any pharmacy for safe disposal?

- Yes [Go to Q12]
- No [Show Textbox]

Textbox 1: The National Return and Disposal of Unwanted Medicines (RUM) project is funded by the Commonwealth Government allowing for all Australians to dispose of any unwanted medicines by taking them to their local community pharmacy. This is a free service. Visit www.returnmed.com.au

Q11. After reading what the Return of Unwanted Medicines (RUM) project is, would you use RUM, ie. Would you return your unwanted medicines to your community pharmacy for free?

- Yes
- No; Why not?:_____

Your demographic information:

Q12. Gender [Dropdown]

- Male
- Female
- Transgender

Q13. Age [type number]

Q14. State/Territory [Dropdown]

- South Australia
- Tasmania
- New South Wales
- Victoria
- Western Australia
- Queensland
- Australian Capital Territory
- Northern Territory

Q15. State: [Dropdown]

- Rural
- Urban

Q16. Country of birth [Dropdown list of countries, starting with Australia first]

Q17. Main language spoken at home [Dropdown most common languages in Australia first]

Q18. Living arrangements: [Randomised list order]

- With spouse:
 - How many members in household [_____]
- With partner:
 - How many members in household [_____]
- With family member:
 - How many members in household [_____]
- In a share house:
 - How many members in household [_____]
- Alone
- In a managed care facility
- Other; Please specify _____

Q19. Highest educational qualification: [Randomised list order]

- High school year 9 or 10 or below
- High school year 11 or 12
- Certificate, diploma or advanced diploma
- Bachelor degree
- Postgraduate degree (post-graduate diploma, Masters, PhD)

Q20. Employment status: [Randomised list order]

- Retired or pensioner
- Working part time or casual
- Working full time
- Unemployed
- Student
- Self-employed
- Other; Please specify _____

Q21. Main area of occupation: [Randomised list order]

- Manager

- Professional
- Technical or trades worker
- Community or personal service worker
- Clerical or administrative worker
- Sales worker
- Machine operator or driver
- Labourer
- Homemaker
- Other; Please specify _____

Q22. Current approximate household income (before tax):

- \$0-\$50,000
- \$50-\$100,000
- \$100-\$150,000
- more than \$150,000
- Prefer not to say

Q23. Have you worked in healthcare in the last 5 years?

- Yes
- No [Go to Q29]
- I don't know [Go to Q29]

Q24. What is your primary occupation: [Randomised list order]

- Nurse;
- GP
- Specialist doctor
- Pharmacist;
- Acupuncturist;
- Aged-care worker;
- Chinese Medicine Doctor;
- Chiropodist/podiatrist;
- Chiropractor;
- Dentist;
- Dietician/nutritionist;
- Disability worker;
- Indigenous health worker;
- Naturopath;
- Occupational therapist;
- Optometrist/optician;
- Osteopath;
- Physiotherapist/hydrotherapist;
- Psychologist;
- Social worker/ welfare worker;
- Speech pathologist;
- Other; Please specify: _____

Q25. Do you ever ask your patients (or clients) whether they have unwanted medicines at home?

- Yes
- No; Why not?: _____ [Go to Q28]

Q26. How do you advise your patients (or clients) that they can dispose of unwanted medicines?
(Please tick all that apply) [Randomised list order]

- Throw out with the usual (non-recycled) garbage;
- Throw out as part of municipal kerbside recycling;
- Take to a general area at the dump / waste transfer station;
- Take to a special area at the dump / waste transfer station;
- Take to a business or shop (e.g. pharmacy or chemist);
- Take to a central collection point other than dump / waste transfer station;
- Pour down the drain or toilet;
- Burn or incinerate;
- Bury;
- Give away;
- Sell;
- Other; Please specify:_____

Q27. Have you ever told your patients (clients) about the Return of Unwanted Medicines Program?

- Yes
- No; Why not?:_____

Q28. After completing this survey, would you now promote the Return of Unwanted Medicines Program to your patients (clients)?

- Yes
- No; Why not?:_____

Q29. Do you personally take any medicines at the moment (prescription, over the counter, complimentary/alternative)

- Yes
- No [Thank you for participating in our survey]

Q30. How many medicines do you take?

- Type number:_____

If number is ≥ 5 ask about participation in phone interview